1	UNITED STATES DISTRICT COURT	
2	DISTRICT OF NEVADA BEFORE THE HONORABLE MIRANDA DU, DISTRICT JUDGE	
3		000
4	AMARIN PHARMA, INC., and AMARIN PHARMACEUTICALS	:
5	IRELAND LIMITED,	: : No. 2:16-cv-02525-MMD-NJK
6	Plaintiffs,	
7	-vs-	:
8	HIKMA PHARMACEUTICALS USA	
9	INC., et al.,	: Volume 7 :
10	Defendants.	: :
11		
12	TRANSCR	RIPT OF BENCH TRIAL
13	APPEARANCES:	
14	FOR THE PLAINTIFFS:	MEAGAN P. KEANE, CHRISTOPHER N. SIPES, MICHAEL KENNEDY, JEFFREY
15		ELIKAN, JOSEPH KENNEDY, ELAINA M. WHITT, BARBARA KURYS, HAN PARK,
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19	FOR DEFENDANT HIKMA:	CHARLES B. KLEIN and CLAIRE A. FUNDAKOWSKI,
20		Attorneys at Law Washington, D.C.
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22	Reported by:	Kathyrn M. French, CCR #392, RPR
23		Official Reporter U.S. District Court
24		Reno, Nevada
25	(Appearances continue on r	next page.)

1	RENO, NEVADA, TUESDAY, JANUARY 28, 2020, 8:30 A.M.
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3	THE COURT: Good morning. Please be seated.
4	MR. ELIKAN: Your Honor, good morning.
5	THE COURT: Good morning. Are you ready?
6	MR. ELIKAN: May I proceed?
7	THE COURT: Yes. Thank you.
8	PETER PAUL TOTH, M.D., recalled as a witness on behalf of the plaintiffs, previously sworn, testified further as follows:
LO	DIRECT EXAMINATION RESUMED
11	BY MR. ELIKAN:
12	${\mathbb Q}$ Yesterday we were discussing the JELIS trial when we
13	broke. I want to turn now to PX 272, the publication by
L 4	Dr. Bhatt the REDUCE-IT study we looked at before.
15	MR. ELIKAN: Can we have Figure 4 on page 10.
16	BY MR. ELIKAN:
17	Q How do these results compare to the JELIS results?
18	A Well, what we see here, counsel, are across-the-board
19	significant reductions in all of the cardiovascular endpoints
20	evaluated, whereas within JELIS, the primary composite
21	endpoint.
22	And the endpoint unstable angina, only those two are
23	reduced.
24	Q And you explained yesterday that unstable angina is the
25	driver of the other endpoint, right?

- 1 A Yes.
- 2 Q And these differences, all of the cardiovascular
- differences, those are all statistically significant?
- 4 A Yes.
- 5 MR. ELIKAN: Can we pull up the second full 6 paragraph in the right-hand column on page 9 and highlight the
- 7 | first sentence.
- 8 BY MR. ELIKAN:

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- 9 Q What does Dr. Bhatt state here about how Vascepa results
  10 stand apart from other results achieved with other drugs?
  - The results of REDUCE-IT stand apart from the negative findings of several contemporary trials of other agents that also lower triglyceride levels, including other omega-3 fatty acids, extended release niacin, fenofibrate, and cholesterol ester transfer protein inhibitors."
  - Q Do you recall that Dr. Heinecke testified that there was not a failure of others to reduce cardiovascular risk with a triglyceride-lowering agent?
- 20 A **Yes.**
- 21 Q Is Dr. Heinecke's position consistent with Dr. Bhatt's 22 observations?
- 23 A No.
- Q Proceeding to the next sentence, does Dr. Bhatt offer a clear explanation for why clinical trials fail to demonstrate

1	a cardiovascular benefit or was it for him still a matter of
2	uncertainty? What did he have to say?
3	A He reflects some uncertainty. He states,
4	Q "It is not known whether the lack of benefit
5	from omega-3 fatty acids in previous trials may be
6	attributable to the low dose or the low ratio of EPA
7	to DHA."
8	Q Still looking at the same paragraph I'm going to ask you
9	about an additional sentence further down the paragraph
10	beginning with "although the dose."
11	What does Bhatt have to say here about how the dose
12	in JELIS compared to the dose in REDUCE-IT?
13	A Dr. Bhatt notes,
14	Q "Although the dose of EPA administered in
15	JELIS (1.8 grams daily) was lower than the
16	EPA-equivalent dose used in REDUCE-IT (4 grams
17	daily), it resulted in a plasma EPA level
18	(170 micrograms per milliliter in a Japanese
19	population) similar to that attained in a previous
20	12-week lipid study in which a total daily dose of 4
21	grams of icosapent ethyl was used in a Western
22	population (183 micrograms per milliliter) and
23	similar to that attained in the current trial."
24	Q So my question was how does the dose in JELIS compare to
25	the dose administered in REDUCE-IT.

- 1 A In terms of attained EPA levels in serum --
- 2 Q Before we get to the serum, what was the dose
- 3 | administered in the two trials?
- 4 A Okay. In REDUCE-IT, it was 4 grams, in JELIS, it was
- 5 | 1.8 grams.
- 6 | Q Now, let's turn to the serum. Maybe you can unpack the
- 7 passage you read. What is this saying about the serum levels?
- 8 A That they were very close, 170 micrograms per milliliter
- 9 of EPA in JELIS, and 183 micrograms per milliliter in the
- 10 MARINE trial, and similar to what was seen in REDUCE-IT.
- 11 Q Do you see a reference to -- citation to references 25
- 12 | and 26?
- 13 | A I do.
- 14 MR. ELIKAN: Let's take a look at those for a
- 15 | second as they're listed at the end the article.
- 16 Can we pull up those references on page 12.
- 17 BY MR. ELIKAN:
- 18 Q Based on the dates of publication, would these references
- 19 have been available to the person of ordinary skill in the art
- 20 in March 2008?
- 21 A They were published in 2011 and 2016, so the answer is
- 22 **no.**
- 23 Q Do you recall that yesterday we looked at the Yokoyama
- 24 article?
- 25 A **Yes**.

1	Q Where it acknowledged that an exclusively Japanese
2	population was studied?
3	A Yes.
4	MR. ELIKAN: I want to turn back to that. Can
5	we go to DX 1553 and page 8, and I want to pull up on the
6	screen the last paragraph of the paper and highlight the
7	second to last sentence.
8	BY MR. ELIKAN:
9	Q What did the author state here about the consequence of
L O	the study population being exclusively Japanese?
11	A Dr. Yokoyama notes that,
12	Q "Because our population was exclusively
13	Japanese, we cannot generalize our results to other
L 4	populations."
15	MR. ELIKAN: And I want to go now to page 7 and
16	highlight the statement at the bottom of the left-hand column
L7	which carries over to the top of the right-hand column.
18	BY MR. ELIKAN:
19	Q What did the author state here about how the average
20	Japanese diet compares to the diet of people in other
21	countries?
22	A "In Japan, death from coronary artery disease
23	is rare, and the average dietary intake of fish is
24	about five times higher than that in other
25	countries."

- 1 O Does fish contain DHA?
- 2 A Yes.
- 3 Q If a person of ordinary skill in the art wanted to
- 4 | formulate an omega-3 for other populations that don't eat as
- 5 | much fish, and believed it was necessary to mimic the
- 6 | composition of omega-3 fatty acids that Japanese people
- 7 consume throughout the day, would that person have included
- 8 substantial amounts of DHA?
- 9 A Yes.
- 10 Q And why is that?
- 11 A Because they would try to mimic -- is a good word -- the
- dietary reconditions of the people in Japan who participated
- 13 in this study.
- 14 The supplement was EPA alone, but because they eat
- 15 | five times as much fish as people in other countries, they're
- 16 still taking in a very substantial amount of DHA daily.
- 17 | Q Have you prepared a slide showing the doses used for
- 18 omega-3 fatty acid cardiovascular outcome trials underway as
- 19 of March 2008?
- 20 A **Yes.**
- 21 MR. ELIKAN: Can we have PDX 6-31.
- 22 BY MR. ELIKAN:
- 23 Q Before we walk through the specifics, are these the same
- trials you discussed earlier, that is, yesterday, the omega-3
- 25 | fatty acid cardiovascular outcome trials underway as of March

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- 2 A Yes, counsel.
- 3 O And are the source materials the same?
- 4 A Yes.
- 5 Q And what were the doses that were being studied as of
- 6 | March 2008?
- 7 A Well, you see five trials used one gram daily, one trial
- 8 used 400 milligrams daily, one used 600 milligrams daily, and
- 9 another used 2.4 grams daily.
- 10 Q Did any of the outcome trials underway as of March 2008
- on omega-3 fatty acids use 4 grams?
- 12 A No.
- 13 MR. ELIKAN: We move for the admission of PDX
- 14 6-31 under Federal Rule of Evidence 1006.
- MR. KLEIN: No objection.
- 16 THE COURT: PDX 6-31 is admitted.
- (Plaintiffs' Exhibit 6-31 received in evidence.)
- 18 BY MR. ELIKAN:
- 19 Q What, if anything, do the doses used in these
- 20 cardiovascular outcome trials suggest about whether it would
- 21 have been obvious to use 4 grams of EPA to lower
- 22 | cardiovascular risk?
- 23 A Well, it suggests that no one believed that 4 grams was
- 24 the magic bullet here. People were using different doses
- 25 | because, as I said, they were feeling their way through the

- 1 dark.
- MR. ELIKAN: Let's go back to PDX 6-32, and
- 3 | skepticism.
- 4 BY MR. ELIKAN:
- 5 Q In your work on this case, did you review materials that
- 6 reflected skepticism about whether or not omega-3 fatty acids
- 7 would provide a cardiovascular benefit?
- 8 A Yes.
- 9 Q Do you recall yesterday we looked at a statement in the
- 10 | Cochrane collaboration, PX 953, that Omega-3s, and I'm
- 11 quoting, "probably are not useful for preventing or treating
- 12 | cardiovascular disease"?
- 13 A **Yes.**
- 14 Q And do you recall looking at a statement in an article by
- 15 Dr. Aung, PX 954, that there is, quote,
- 16 "No support for current recommendations for
- the use of such supplements in people with a history
- of coronary heart disease"?
- 19 A Yes.
- 20 Q Do you consider these examples of skepticism?
- 21 A **Yes.**
- 22 Q Were you, Dr. Toth, as skeptical as some other people
- 23 were?
- 24 A No, I was more optimistic. I was more hopeful. And I
- 25 | was still hoping that the omega-3s would be able to

- 1 demonstrate benefit.
- 2 Q And in being hopeful, do you believe you were in the
- 3 majority or the minority?
- 4 A Oh, I was in the minority.
- 5 Q Are there other materials you have reviewed in this case
- 6 | that reflect skepticism about the potential of omega-3 fatty
- 7 acids to lower cardiovascular risk before REDUCE-IT?
- 8 A Yes.
- 9 O Let's turn to PX 951. And what is this?
- 10 A This is an article by Adam Feuerstein entitled "Amarin
- 11 Fish Oil Capsule Shows Dramatic Benefit For Cardiovascular
- 12 Patients, Potentially Upending Market."
- 13 0 What's the date of the article?
- 14 A September 24th, 2018.
- 15 MR. ELIKAN: Your Honor, we move for admission
- 16 of PX 951.
- MR. KLEIN: No objection.
- 18 BY MR. ELIKAN:
- 19 Q Let's turn to --
- 20 **THE COURT: 951?**
- 21 MR. ELIKAN: Yes, I'm sorry, Your Honor.
- 22 THE COURT: Exhibit 951 is admitted.
- (Plaintiffs' Exhibit 951 received in evidence.)
- 24 BY MR. ELIKAN:
- 25 Q Turning to the sixth paragraph on page 2, what did

- Dr. Ethan Weiss, the cardiologist at UCSF, have to say about the Vascepa study?
  - A "I thought the Vascepa study would be negative, colored by all the prior failed studies, so I'm surprised. I'm willing to eat my shoe on this one. This could be really beneficial to people."
    - Q And in the last paragraph on page 3, what did Dr. Norman Lepor of Cedars-Sinai Medical Center have to say?
- 9 A "I went into this study not convinced that
  10 Vascepa would make a difference, but these results
  11 will definitely change my practice and the way I
  12 treat patients."
- 13 Q Do you consider these examples of skepticism?
- 14 A **Yes.**

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- 15 Q In general, have the REDUCE-IT trial results now been embraced by the medical community?
- 17 A **Yes.**
- 18 Q Do you recall that Dr. Heinecke testified that there was
  19 no relevant skepticism that EPA would reduce cardiovascular
- 20 risk?
- 21 A **Yes.**
- 22 Q And in light of all the materials that you've reviewed,
  23 do you agree with Dr. Heinecke that there was no relevant
  24 skepticism that EPA would reduce cardiovascular risk?
- 25 A No.

- MR. ELIKAN: Let's turn back to PDX 6-33. 1 2 want to turn now to Unexpected Results. 3 BY MR. ELIKAN: You testified earlier that the REDUCE-IT results apply 4 5 equally to a population with severe hypertriglyceridemia 6 because, among other things, we knew from MARINE there would 7 be no substantial rise in LDL-C. 8 Do you recall that testimony? 9 Α Yes. 10 Was there any parallel study that existed in March 2008 11 that would have told the person of ordinary skill in the art 12 that when Epadel is given to a patient population with severe 13 hypertriglyceridemia, there will be no substantial rise in 14 LDL-C? 15 Α No. 16 Do you recall that Dr. Heinecke testified that JELIS 17 reported a 19 percent reduction in cardiovascular risk? 18 Α Yes.
  - Q And accepting that risk reduction at face value, would the person of ordinary skill in the art have expected -- would they have had reason to expect that this risk reduction reported in patients with, I believe you said a mean baseline triglyceride level of 153?
- 24 A **Yes.**

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25 Q -- that it would apply to patients with severe

1	hypertriglyceridemia?
2	A No.
3	Q Triglycerides over 500.
4	A No.
5	Q And why not?
6	A Because a person of ordinary skill in the art as of March
7	2008 would have understood that the response in LDL for
8	patients below 500 on their triglycerides and above 500 were
9	distinctly different.
10	MR. ELIKAN: I'd like to pull up, again, PX 272,
11	the Bhatt publication, and go to page 10 and back to Figure 4.
12	And, Mr. Brooks, can you highlight Fatal Or
13	Nonfatal Stroke.
14	BY MR. ELIKAN:
15	Q What's the risk reduction shown for stroke?
16	A Twenty-eight percent, and it is statistically
17	significant.
18	Q Would this result have been expected after JELIS?
19	A No.
20	MR. ELIKAN: Let's look at JELIS on stroke. Can
21	we have DX 1553, please, and Figure 3 on page 5, and I want
22	to look at the analysis on stroke. It starts at the bottom.
23	And, Mr. Brooks, can you highlight the stroke
24	line.
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- 2 Q What was reported in terms of risk reduction for stroke 3 in the JELIS study?
- A Well, the hazard ratio is 1.02, statistically not
  significant, and you'll notice that the point is virtually
  straddling unity, that vertical bar. So there was no impact
  on stroke in the JELIS trial.
- 8 Q What does it mean that it's a number that's higher than 9 1?
  - A Well, if it's higher than 1, that means there's hazard that it would increase that specific endpoint. But we can't conclude here that stroke went up by 2 percent because it's not statistically significant.
- 14 Q Is a statistically significant reduction in stroke of 15 28 percent an important clinical benefit?
- A Counsel, it is enormously important because it's over and above that observed with statin therapy.
  - And if we think about this, stroke is one of the most dreaded cardiovascular complications of all because it can leave a loved one with the inability to speak, walk, think, it could change their personality.
- Yes, it's of enormous, enormous importance.
- 23 Q Do you consider this difference, 28 percent and zero, one of degree or one of kind?
- 25 A Well, I think it speaks for itself. It's one of kind.

- 1 Q And for patients who don't experience a stroke, who would
- 2 | have without Vascepa, is that a difference in kind or in
- 3 degree?
- 4 A It's a difference in kind.
- 5 Q Let's go back to PX 272 and back to Figure 4. I'm going 6 to look at the cardiovascular death endpoint.
- What did REDUCE-IT report with respect to the effect of Vascepa on cardiovascular death?
- 9 A REDUCE-IT reported a 20 percent relative risk reduction
  10 in cardiovascular death that was statistically significant at
  11 P equal to .03.
- 12 Q Would that result have been expected based on JELIS?
- 13 A No, counsel.
- 14 MR. ELIKAN: I'd like to go back to Yokoyama,
- 15 DX 1553, and page 5, Figure 3, and can we highlight the
- 16 | coronary death entry.
- 17 BY MR. ELIKAN:
- 18 Q What did JELIS report in terms of the risk of
- 19 | cardiovascular death?
- 20 A There was a 6 percent trend for reduction. There's a
- 21 | slight leftward shift, left of unity. But, it didn't even
- come close to statistical significance with a P value of .81.
- 23 Q It looks like this line through which the dot runs is
- 24 very wide. What does that signify?
- 25 A That means there's great uncertainty about how accurate

1 that estimate is.

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- Q Is REDUCE-IT significant reduction in cardiovascular death a difference in kind or in degree compared to JELIS' nonsignificant risk reduction on cardiovascular death?
- A It is a difference in kind. This has never been shown before when using an adjutant therapy over and above a statin.

We've seen numerous trials with adjutant therapies on top of a statin and none of them have been able to demonstrate an incremental reduction in mortality over and above a statin.

This is a profound difference in kind. Death is it, there is no second chance. Reducing death by 20 percent for cardiovascular events over and above a statin is a landmark achievement.

- Q In summary, do you agree with Dr. Heinecke that the cardiovascular benefits shown in REDUCE-IT were expected?
- 17 A No, they were not expected. I think the evidence speaks
  18 for itself.
  - Q And do you agree with him in summary that the results of REDUCE-IT were merely a difference in degree as compared to JELIS rather than one -- than a difference in kind?
- 22 A No, I do not agree with that assessment.
- Q I want to go back to PDX 6-34. Are you ready to discuss praise?
- 25 A Yes, counsel.

- 1 MR. ELIKAN: Can we pull up PDX 6-10 that we
- 2 discussed earlier.
- 3 BY MR. ELIKAN:
- 4 Q In your opinion, are the references listed in PDX 6-10
- 5 | that you testified about yesterday, PX 952, PX 902, and PX
- 6 714, examples of praise for REDUCE-IT?
- 7 | A **Yes.**
- 8 O You testified earlier that the cardiovascular benefits in
- 9 REDUCE-IT were independent of the triglyceride levels of the
- 10 participants and that severely hypertriglyceridemic patients
- 11 enjoy the same benefits. Do you recall that?
- 12 A **Yes.**
- 13 Q So my question to you is do you read the praise in these
- 14 | articles as equally applicable to patients with severe
- 15 hypertriglyceridemia?
- 16 A **Yes**.
- 17 Q Do you recall that Dr. Heinecke testified that there is
- 18 no nexus between the benefits observed in REDUCE-IT and the
- 19 | asserted claims?
- 20 A **Yes.**
- 21 Q Do you agree with him?
- 22 A No.
- 23 | Q Do you recall that Dr. Heinecke first disputed nexus on
- 24 the ground that the asserted claims are directed to a method
- of reducing triglycerides, but that cardiovascular risk

1	reduction in REDUCE-IT was not the result of triglyceride
2	lowering?
3	A Yes.
4	Q So I want to now turn to the Bhatt article again, PX 272
5	at page 10, starting at the bottom of the left-hand column and
6	carrying over to the right-hand column.
7	Does this passage beginning with "these
8	observations," does it rule out the possibility that some of
9	the cardiovascular reduction may be the result of triglyceride
10	lowering?
11	A No.
12	"These observations suggest that at least
13	some of the effect of icosapent ethyl that resulted
14	in a lower risk of ischemic events than that with
15	placebo may be explained by metabolic effects other
16	than the reduction of triglycerides,"
17	but he doesn't rule it out.
18	Q And setting aside whether triglyceride lowering explains
19	any of the cardiovascular benefits observed in REDUCE-IT, will
20	administering the claimed treatment method of 4 grams of high
21	purity EPA result in patients receiving the cardiovascular

there's no nexus between the REDUCE-IT findings and the

Do you recall that Dr. Heinecke also testified that

Yes.

benefits observed in REDUCE-IT?

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- asserted claims because REDUCE-IT did not begin to show a divergent of reduction in cardiovascular events until year one rather than at 12 weeks?
  - A Yes.

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- Q In your opinion, does the fact that there was no statistically significant reduction in cardiovascular events in REDUCE-IT at 12 weeks mean that there is no cardiovascular advantage to a patient who has taken Vascepa for 12 weeks compared to a patient who hasn't?
  - A Well, as a clinician, I have to say you have to start somewhere. You have to initiate treatment if you want to expect benefit downstream.

We know from MARINE that within three months you will most certainly induce biochemical metabolic changes in that patient's lipoprotein physiology that are beneficial, reducing triglycerides, keeping LDL neutral, reducing apo B.

And MARINE also demonstrated that multiple different inflammatory mediators also decrease. These would all be seen as beneficial and all have been tied to cardiovascular benefit.

- Q You said that these benefits were observed at three months. Were they observed at 12 weeks in MARINE?
- 23 A Yes, I'm sorry, 12 weeks.
- 24 Q Does that mean that the patient is getting closer to a 25 point where there will be -- where that patient will be at the

- 1 | point in a study in which there are observable differences?
- 2 A Yes, we know that with any drug it takes time to accrue
- 3 | enough benefit, enough physiologic change or anatomical change
- 4 so that you can reserve reductions in cardiovascular events.
- Do you also need a study to have enough events occur in
- 6 order to see a divergence --
- 7 A Yes.
- 8 0 -- between two arms?
- 9 A You do.
- 10 Q Now, do you recall that Dr. Heinecke testified that the
- 11 patients in REDUCE-IT were on statin therapy while some of the
- 12 asserted claims specify that the medication is administered
- 13 | without concomitant lipid-altering therapy?
- 14 Do you recall that testimony?
- 15 A **Yes.**
- 16 Q I want to ask you some questions about that.
- What's the primary mechanism by which statins lower
- 18 | cardiovascular risk?
- 19 A LDL cholesterol reduction.
- 20 Q Does Vascepa lower cardiovascular risk by lowering LDL-C?
- 21 A No.
- 22 | Q Is it the case, then, that Vascepa and statins lower
- 23 | cardiovascular risk through different mechanisms?
- 24 A Yes, that is the best explanation.
- 25 Q And what, if anything, does that suggest about whether

1	patients taking Vascepa will derive a benefit, even if they're
2	not on statins?
3	A It would strongly suggest that they would derive benefit
4	even if they're not on statins.
5	Q Given that fact, do you agree with Dr. Heinecke that
6	there's no nexus between the REDUCE-IT benefits and the claims
7	that require patients not to be on concurrent statin therapy?
8	A No.
9	${\mathbb Q}$ I want to turn to the remaining asserted claims.
10	Do the reasons you've testified that claim 1 of the
11	'728 patent would not have been obvious apply to the other
12	asserted claims as well?
13	A Yes.
14	Q Some of the asserted claims other than claim 1 of the
15	'728 patent specify that the claimed treatment must effect a
16	reduction in apo B. Have you prepared a slide that identifies
17	the claims that discuss reductions in apo B?
18	A Yes.
19	Q Can we have PDX 6-35.
20	What are the claims and limitations relating to apo
21	B?
22	A Claim 8 of the '677 patent states "to.
23	Effect a reduction in apolipoprotein B compared to
24	placebo control."
25	Claim 5 of the '929 patent states "effective to

1 reduce apolipoprotein B." 2 And claim 14 of the '715 patent states "to effect a 3 statistically significant reduction in apolipoprotein B." 4 You testified yesterday that Lovaza did not reduce apo B in patients with very high triglycerides. In your opinion, 6 would a person of ordinary skill in the art have reasonably 7 expected that administering 4 grams of EPA in March 2008, 8 would reduce apo B in patients with very high triglycerides? 9 No, they have no foundation for that. 10 Do you recall that Dr. Heinecke testified that a person 11 of ordinary skill in the art would have reasonably expected 12 that 4 grams of EPA would reduce apo B in patients with very 13 high triglycerides based on Grimsgaard and Kurabayashi? 14 Α No. 15 I'm sorry, I'm just asking you if you recall. You said 16 no? 17 Α I'm sorry. 18 Let me read --19 THE COURT: It's all right if you don't recall. 2.0 THE WITNESS: No, I do. 21 MR. ELIKAN: If you don't recall --22 THE WITNESS: Please repeat the question. 23 MR. ELIKAN: I will. 24 BY MR. ELIKAN: 25 Do you recall that Dr. Heinecke testified that a person

- of ordinary skill in the art would have reasonably expected
- 2 | that 4 grams EPA would reduce apo B in patients with very high
- 3 | triglycerides based on Grimsgaard, Nozaki, and Kurabayashi?
- 4 A Yes.
- 5 Q Did any of those references report reductions in apo B --
- 6 A **No**.
- 7 Q -- in patients -- hold on, Doctor.
- 8 Did any of those references report mechanism --
- 9 report reductions in apo B in patients with very high
- 10 triglycerides?
- 11 A No.
- 12 Q Would the person of ordinary skill in the art have looked
- 13 to those references in forming an expectation about the effect
- of EPA on apo B in patients with very high triglycerides?
- 15 A No.
- 16 | Q Why not?
- 17 A Because they didn't look at apo B in patients with very
- 18 | high triglycerides.
- 19 Q Did Dr. Heinecke cite a single prior art reference
- 20 reporting that any omega-3 fatty acid formulation reduced apo
- 21 | B in patients with very high triglycerides?
- 22 A No.
- 23 Q Beyond apo B some of the other asserted claims have
- 24 | limitations that do not appear in claim 1 of the '782 patent.
- 25 | I want to go through those now.

Claim 1 the '728 patent claims a dose of about 4 grams of EPA a day, whereas claims 4 and 17 of the '560 patent cover a daily dose of about 3.6 to 4 grams per day.

Do you have a different opinion or different reasoning about the nonobviousness of those claims that have a slightly different dose limitation or do you believe that the same opinion and reasoning applies with equal force to those claims?

- A I believe the latter.
- Q And turning to concurrent lipid altering therapy.

Whereas claim 1 of the '782 patent specifies that the EPA is administered without concurrent lipid altering therapy, other claims are silent on whether the subject receives concurrent lipid altering therapy.

Do you have a different opinion or different reasoning about the nonobviousness of those claims that are silent on whether the subject is on concurrent lipid altering therapy, or do you believe the same opinion and reasoning applies with equal force to those claims?

- A I believe the latter.
- Q Some of the claims use different language than claim 1 of the '782 patent to describe the effects of administering Vascepa on LDL-C levels. I want to walk through that now.
  - MR. ELIKAN: Can we have PDX 6-36.

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- Q And can you walk us through the claims and limitations.
- A These are variations on LDL-C limitation in claims other than claim 1 of the '728 patent.

Claim 1 of the '677 patent states "without substantially increasing LDL-C compared to placebo control."

Claim 14 of the '715 patent states "without effecting a statistically significant increase of [LDL-C] in the subject."

Claims 4 and 17 of the '560 patent state "without increasing LDL-C by more than 5 percent in the subject," and "without increasing LDL-C in the subject compared to placebo control."

And claim 1 of the '652 patent stating "without substantially increasing LDL-C compared to baseline."

- Q And as to those claims, do you have a different opinion or different reasoning about their nonobviousness, or do you believe the same opinion and reasoning applies with equal force to those claims?
- A The latter.
- 21 Q Let's talk about the two asserted claims that don't 22 mention LDL-C, claims 1 and 5 of the '929 patent.
- 23 MR. ELIKAN: Can we pull up PDX 6-37.
- 24 **BY MR. ELIKAN:**
- 25 Q Do you have a different opinion or different reasoning

1	about the nonobviousness of these two claims, claim 1 of the
2	'929 patent and 5 of the '929 patent, or do you believe the
3	same opinion and reasoning applies with equal force to these
4	claims?
5	A The latter.
6	${\mathbb Q}$ In sum, then, what's your opinion on whether any of the
7	asserted claims would have been obvious?
8	A None of them would have been obvious.
9	MR. ELIKAN: Your Honor, can you give me one
10	moment?
11	THE COURT: Yes.
12	MR. ELIKAN: Your Honor, I have no further
13	questions at this time.
14	We have a technical issue. The screens at
15	counsel table, at least on our side, are not working. I don't
16	know whether you're experiencing
17	MR. KLEIN: Ours are okay.
18	MR. ELIKAN: Yours are okay? Ours are not.
19	MR. SIPES: We're hoping when we flip over the
20	screens will come back. That's it.
21	THE COURT: Why don't we see if we can address
22	that issue before cross-examination, maybe, perhaps.
23	THE CLERK: I just flipped it over. Did it
24	change?
25	MR. SIPES: It did change.

1	THE CLERK: Is it coming up on all of the
2	screens?
3	MR. SIPES: Now it is.
4	THE COURT: Okay.
5	MR. ELIKAN: Thank you very much.
6	MR. KLEIN: May I proceed?
7	THE COURT: Yes.
8	MR. KLEIN: Good morning, Dr. Toth.
9	THE WITNESS: Good morning, Mr. Klein. Good to
LO	see you again.
11	MR. KLEIN: You and I met at your deposition,
12	right?
13	THE WITNESS: Yes, we did.
L 4	MR. KLEIN: For the record, I'm Charles Klein.
15	I'll be asking you questions for the defendants.
16	Mr. Gross, can you put on DDX 10.1, please.
L7	CROSS-EXAMINATION
18	BY MR. KLEIN:
19	Q Dr. Toth, were you here for Dr. Heinecke's direct?
20	A I was not present for it, no.
21	Q Okay. Did you read his testimony?
22	A Yes.
23	${\mathbb Q}$ Okay. This I will represent to you that this slide
24	was used during Dr. Heinecke's direct. It was DX 6.75. Have
25	you seen this slide before?

- A I don't believe I've seen the slide. I read the testimony.
- Q Okay. Why don't you take ten seconds, read through the slide to yourself, and let me know when you're done.
  - A (Witness reviews document.)
- 6 Thank you.
- Q Okay. Now, you understand the simple logic -- I know you disagree with it, but you understand the logic of defendants' obviousness theory, right?
- 10 A **Yes.**
- 11 Q Okay. And let's walk through this slide.
- You agree that FDA approved Lovaza as a 4-gram per
  day mixture of EPA and DHA for the claimed method of treating
  patients with triglycerides over 500, correct?
- 15 A But increased LDL-C, yes.
- Q Okay. It's important for you to listen to the question and we'll take it one step at a time. I promise I will get to the LDL-C issue.
- Okay. Let me repeat the question. You agree that

  FDA approved Lovaza as a 4-gram per day mixture of EPA and DHA

  for the claimed method of treating patients with triglycerides

  over 500, right?
- 23 A **Yes.**
- Q Okay. And Lovaza has two active ingredients, EPA and DHA, right?

- A No, it is a mixture of omega-3 acid ethyl esters. There
- 2 | are contaminants. It's not just a mixture of two things.
- 3 Q But the two active ingredients are EPA and DHA in Lovaza,
- 4 correct?
- 5 A No, it's organic acid ethyl esters.
- 6 Q Okay. Now, Doctor, purified EPA and purified DHA were
- 7 | both known in the art as of March 2008, right?
- 8 A Yes.
- 9 Q And a POSA at that time who have understand that both DHA
- 10 and EPA were active components that lowered triglycerides,
- 11 | right?
- 12 A Yes, they would have been active components that lower
- 13 triglycerides.
- 14 Q Okay. And Lovaza reported a side effect of increased
- 15 | LDL-C, correct?
- 16 A **Yes**.
- 17 Q And, in your opinion, the LDL-C increases with Lovaza was
- 18 | an important problem warranting new solutions, right?
- 19 A Yes.
- 20 Q You spent a lot of time on direct talking about that,
- 21 | right?
- 22 A Sure did.
- 23 O And it would have been obvious for a skilled artisan to
- 24 | consider whether it was only one of Lovaza's agreement --
- 25 | ingredients, the DHA or the EPA, for example, that causes the

- 1 | LDL side effect, correct?
- 2 A Not in patients with severe hypertriglyceridemia.
- Q Okay. Now, I want to separate for a moment the question of reasonable expectation of success, okay? Because -- and
- 5 | we'll get to that.

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- But just looking at the Lovaza label, a skilled artisan seeing that there's DHA and EPA in Lovaza, and seeing a side effect, would at least consider whether the side effect could be associated with only DHA or only EPA, correct?
- 10 A They could.
  - Q Okay. And because, after all, if that's true, if the side effects associated with only DHA, for example, pure EPA was known, and it could help those patients reduce triglycerides without the side effect, right?
- 15 A Say that again, counsel?
  - Q Okay. If it turned out -- and we'll get to reasonable expectation of success -- but a skilled artisan looking at the Lovaza label could appreciate that if it turned out that the side effect were attributed solely to DHA, it could -- the skilled artisan would understand that using pure EPA could benefit those patients who received the LDL-C side effect, correct?
- A But a skilled artisan wouldn't want to remove the DHA given the benefits that it also appeared to occur.
- 25 Q Okay. Okay. But a skilled artisan would understand that

- 1 pure EPA was available in the art, and if a patient had LDL-C
- 2 | spikes with Lovaza and it was harmful, a skilled artisan would
- 3 | appreciate that if EPA were LDL neutral, that could benefit
- 4 | the patient, correct?
- 5 A But they had no reason to believe it was LDL neutral.
- 6 Q I get that, and I promise you we will get to that.
- Now, you agree that Mori involved a study with 4 grams pure EPA and 4 grams per DHA, correct?
- 9 A Yes, it did.
- 10 Q And Mori found that LDL-C increased significantly with
- 11 DHA but not with EPA in the studied population, correct?
- 12 A Do I agree with that?
- 13 Q Well, that's what Mori found.
- 14 A Well, okay. Both groups increased.
- 15 THE COURT: I'm sorry, what was the answer?
- 16 THE WITNESS: Both groups increased numerically.
- 17 BY MR. KLEIN:
- 18 Q Okay. But Mori found that the increase of LDL-C with DHA
- 19 was statistically significant and the increase with EPA was
- 20 not, correct?
- 21 A Yes. But there was an imbalance on the baseline
- 22 triglyceride.
- 23 Q And we'll get to that. But that's what Mori reported,
- 24 correct?
- 25 A **Yes**.

1	Q Okay. And in view of Mori, it was at least obvious to
2	use 4 grams of purified EPA in patients with very high
3	triglycerides to try to avoid the LDL-C side effect of Lovaza,
4	correct?
5	A No.
6	Q Okay.
7	A They had no data on very high triglycerides. It was not
8	obvious.
9	${\mathbb Q}$ All right. So this your answer is getting to the
10	issue of reasonable expectation of success, right?
11	A Yes.
12	Q Okay. And if I understand your opinion, you're saying a
13	skilled artisan would not do what I just asked because the
L 4	skilled artisan would not have a reasonable expectation of
15	success for two reasons, first, there's no LDL-C data in the
16	prior art for patients with very high triglycerides, and,
17	second, the skilled artisan would know that LDL-C goes up with
18	fibrates and Lovaza in that patient population; is that fair?
19	A And with niacin, any drug that had been tested to that
20	point led to an increase in LDL cholesterol because of
21	increased conversion of the VLDL to LDL in the patients with
22	very high triglycerides.
23	Q Okay. And we'll come back to that in a moment.

But your opinion with regard to reasonable

expectation of success really falls into two points, the lack

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- of data in the prior art and the references to Lovaza and fibrates and niacin, right?
- 3 A There was remarkable consistency in the response, yes.
- Q Okay. I want to focus on the first point, the lack of LDL-C data.
- Now, on direct you emphasize that there's LDL-C data in the prior art for patients above 500 who were taking pure EPA, right?
- 9 A Yes.
- Okay. And you mention -- you talked about the Friedewald equation, right?
- 12 A Yes, counsel.
- 13 Q And, in your opinion, a skilled artisan could not
  14 reasonably expect pure EPA to have an LDL-C neutral effect in
  15 patients with very high triglycerides because there's no
  16 clinical data on that point, right?
- A And because of the history of the use of other agents, including EPA, DHA, and how patients respond, yes.
- Q Okay. And for now, we'll get to that, but I want to focus on the lack of data first.
- In your opinion, prior art showing a neutral LDL-C
  effect with pure EPA in patients below 500 won't translate
  above 500, right?
- A Well, but we never established that there was neutral effect because we saw that there was inconsistency in the

- 1 results with EPA.
- 2 Q Okay. But, in your opinion, even if a skilled artisan
- 3 | were looking at Mori which said there was no statistically
- 4 | significant increase in LDL-C with pure EPA, your opinion is
- 5 | that finding wouldn't translate above 500 without data,
- 6 correct?
- 7 A Correct.
- 8 Q Okay. And, in your opinion, a skilled artisan could not
- 9 know if 4 grams of pure EPA is LDL neutral until the
- 10 | conclusion of a new clinical trial, correct?
- 11 A Well, that would most certainly be true, yes.
- 12 Q Okay. And even then, you would want to look at median
- 13 data in the clinical trial to assess whether the drug was LDL
- 14 | neutral, right?
- 15 A Yes. You would want as much information as possible.
- 16 Q Okay. And anything short of a clinical study like that,
- in your view, would not provide a reasonable expectation of
- 18 success. Is that your opinion?
- 19 A I'm sorry, counsel, repeat it, please.
- 20 Q Sure. Anything short of a new clinical trial in patients
- 21 | with triglycerides above 500 showing LDL neutrality would be
- 22 insufficient to provide a reasonable expectation that you will
- 23 | achieve that result, right?
- 24 A You would want a well done study to show this, yes.
- 25 Q Okay. And in your view, even if a skilled artisan were

- 1 to start testing 4 grams of pure EPA in patients with very
- 2 | high triglycerides, in your view, there still would not be a
- 3 reasonable expectation of success until the results come out,
- 4 right?
- 5 A That's right.
- 6 And even if a skilled artisan came up with a clinical
- 7 | trial protocol that said we're going to use 4 grams pure EPA
- 8 in patients with triglycerides above 500, and we're hoping
- 9 | that it will be LDL neutral, that would not provide a
- 10 reasonable expectation of success in your view, right?
- 11 A No, because there was no foundation for thinking that it
- 12 | would be neutral.
- Okay. And certainly in your view, if a skilled artisan
- 14 | simply reviewed the prior art and came up with a prediction
- 15 | that LDL-C -- that pure EPA would be LDL-C neutral in patients
- 16 above 500, that would not be reasonable, a reasonable
- 17 | prediction of success in your view, correct?
- 18 A It would not settle the issue.
- 19 Q Okay. And that's why in your view, the MARINE study
- 20 | constituted an unexpected result; is that right?
- 21 A **Yes.**
- 22 Q Okay. And in your view, no skilled artisan could have
- 23 expected that 4 grams of pure EPA would be LDL-C neutral until
- 24 the MARINE study results came out, right?
- 25 A You would need a large enough study that was powered

- 1 | adequately to show neutrality.
- 2 Q Okay. And you know the MARINE study results were not
- 3 known until late 2010?
- 4 A Yes.
- 5 Q And so in your view no one was able to reasonably expect
- 6 the LDL-C neutral effects seen in MARINE until late 2010,
- 7 correct?
- 8 A Not until the study was completed.
- 9 MR. KLEIN: Can we go to DDX 10.119.
- 10 BY MR. KLEIN:
- 11 Q Now, Doctor, on the screen is DX 1500. Do you recognize
- 12 this as the '728 patent?
- 13 A **Yes.**
- 14 Q Okay. Do you understand that Amarin filed its patent
- 15 | applications in February 2009?
- 16 A **Yes**.
- 17 Q Okay. So Amarin applied for patents at least
- one-and-a-half years before the MARINE study results came out,
- 19 | right?
- 20 A **Yes.**
- 21 Q And you've read the patent, right?
- 22 A **Yes.**
- 23 MR. KLEIN: Let's go to DDX 10.120.
- 24 BY MR. KLEIN:
- 25 Q And, by the way, you understand that the patent

1	specifications are identical for all the asserted patents?
2	A Yes.
3	Q Okay. So I'm just going to use the '728 patent as an
4	example. Is that okay?
5	A Yes.
6	$\mathbb Q$ Now, on the screen is DX 1500, pages 14 and 16, and I'm
7	focusing on column 2, lines 55 to 59, and column 5, lines 37
8	to 46.
9	And here you can see the patent says,
10	"In another embodiment, the subject or
11	subject group being treated has a baseline
12	triglyceride level of" and I'm just going to read
13	the highlighting "at least about 500 milligrams
14	per deciliter."
15	And then you can see later on it talks about all
16	kinds of possible effects, and one of them is no increase in
17	LDL-C levels. Do you see that?
18	A Yes.
19	${\mathbb Q}$ Okay. Do you understand that this is all the patent says
20	about using 4 grams pure EPA to treat very high triglycerides
21	with no LDL-C effects?
22	MR. ELIKAN: Objection, Your Honor. This is
23	well outside the scope of the direct. It also relates to the
24	112 issues that have been disposed of during the course of
25	summary judgment practice.

1	MR. KLEIN: Your Honor, this is highly relevant
2	to obviousness, and I'll cite three federal circuit cases that
3	I think Your Honor will find not only very interesting, but we
4	believe could be case dispositive.
5	I'll start with Merck v Teva, 395 F.3d 1364, pin
6	cite 1374, Federal Circuit 2005, reversing a nonobviousness
7	holding.
8	As well as <i>Alcon Research versus Apotex</i> , 687
9	F.3d 1362, pin cite 1369, Federal Circuit 2012.
10	And also Hoffman Le Roche versus Apotex, 748
11	F.3d 1326, pin cite 1331, Federal Circuit 2014.
12	These are all obviousness cases. I would prefer
13	not to discuss the holdings of those cases during my
14	cross-examination, but we will obviously brief this in
15	post-trial briefing and it relates to obviousness.
16	THE COURT: Mr. Elikan?
17	MR. ELIKAN: I have not actually read all of
18	these cases after hearing Mr. Klein's reference them. We're
19	happy to brief the issue. But if the it seems to me like
20	if he's if Mr. Klein believes that that opens the door to
21	this line of questioning, then we ought to be able to review
22	the cases and respond substantively.
23	He hasn't even mentioned what the holdings are.
24	We haven't had a chance to review them. I would suggest that
25	we move on to other things, that will allow us later to look

1	at the cases, and Mr. Klein can raise this issue again.
2	THE COURT: I'm sorry. But your I just want
3	to make sure I understand the objection.
4	The objection is this issue is not has
5	already been resolved on summary judgment.
6	MR. ELIKAN: It appears to be related to 112
7	issues. This isn't even an asserted claim. I have no idea
8	how this relates to anything. I believe it's not one of the
9	asserted claims.
10	MR. KLEIN: This is
11	MR. ELIKAN: What?
12	MR. KLEIN: That's not a claim, that's a
13	specification.
14	MR. ELIKAN: I'm sorry. Do you have a number?
15	Okay. In any event, then it certainly isn't one
16	of the asserted claims, it's just a passage in the
17	specification. It appears to relate to 112 issues.
18	He's mentioned three cases saying it has
19	something to do with obviousness. We haven't looked at the
20	cases, I haven't even heard from Mr. Klein what the holdings
21	are or how the court discussed the issue.
22	So I would suggest we move on, and that will
23	allow us time during the break to look at the three cases if
24	they're provided to us.
25	THE COURT: I'm going to overrule the objection.

1	I'm going to allow the testimony based on the representation
2	that Mr. Klein is moving into the issue of obviousness, and if
3	it turns out that the cases do not support his argument, I'll
4	just ignore the testimony.
5	For now I'm going to continue.
6	Mr. Klein?
7	MR. KLEIN: Thank you.
8	BY MR. KLEIN:
9	Q Dr. Toth, do you understand that the statements we read
10	from the '728 patent specification and similar statements is
11	all the patents have to say about using 4 grams of pure EPA to
12	treat very high triglycerides with no LDL-C effect?
13	A That this is all?
14	Q Yes.
15	A I'm just reading it through.
16	Well, I see it
17	THE COURT: Hang on. To be fair, do you want to
18	look at the entire patent? Because the question is not just
19	what this paragraph says, but you're asking Dr. Toth to
20	represent that this represents the entire patent.
21	MR. KLEIN: Let me ask a different question that
22	I think won't require Dr. Toth to read through the entire
23	patent.
24	BY MR. KLEIN:
25	$\mathbb Q$ Now, Dr. Toth, can we agree if you read the patent from

1 top to bottom you're not going to see any clinical data in the 2 patent? 3 May I see the patent? 4 MR. KLEIN: It should be in your binder. DX 1500. BY MR. KLEIN: 6 And, Doctor, if it's helpful you did answer this question 8 in the deposition. 9 Α This question? If I could play it, it won't be impeachment but it 10 11 will help move things along. 12 THE COURT: Instead of playing it, do you have 13 the transcript and the testimony --14 MR. KLEIN: Yes, the --15 THE COURT: -- you can show that to Dr. Toth. 16 MR. KLEIN: Sure the transcript is page 354, 17 lines 10 through 18. 18 THE COURT: Do you have the transcript? 19 THE WITNESS: What would the number of that be? 20 MR. KLEIN: Page 354. Do you have the 21 deposition? 22 THE WITNESS: Which, PX or DX --23 MR. KLEIN: No. It's not -- it should just be a 24 transcript.

THE WITNESS: That I don't believe I have up

25

1	here.
2	MR. KLEIN: Hold on.
3	I'll be able to give you my copy.
4	May I approach?
5	THE COURT: Yes.
6	MR. KLEIN: And, Dr. Toth, it was 354, lines 10
7	through 18.
8	THE WITNESS: (Witness reviews document.)
9	Okay, counsel.
LO	BY MR. KLEIN:
11	${\mathbb Q}$ Okay. Does that refresh your recollection as to whether
12	there is clinical data in the patent?
13	A Yes.
L 4	Q Okay. And what is your recollection? Was there any
L 5	clinical data in the patent?
16	A No.
17	Q Okay. And would would it surprise you to learn
18	there's no animal data or in vitro data in the patent either?
19	A Not based on what I'm seeing here, no.
20	${\mathbb Q}$ Okay. And so there's literally no support in the patents
21	for the claim that 4 grams pure EPA will be LDL neutral or
22	reduce apo B. Is that your understanding?
23	MR. ELIKAN: Renew the objection. This appears
24	to also be straight about 112, not obviousness. I don't even
25	understand how this can possibly relate to that.

Т	MR. KLEIN: Well, maybe four Honor, I'm
2	representing that it's about obviousness. If you disagree,
3	then 112 is not you told us we couldn't present 112 at
4	trial, so I'm not presenting 112. I'm presenting an
5	obviousness argument relating to a reasonable expectation of
6	success.
7	THE COURT: The objection is overruled.
8	BY MR. KLEIN:
9	Q Okay. Let's go to DX 10.121.
10	Doctor, I will represent to you that on the left is
11	DX 1500, pages 14 and 16, which is the '728 patent
12	specification we were reviewing, and on the right is Table 2
13	from Mori 2000, which is DX 1538, page 4.
14	Now, you understand that the Mori 2000 reference
15	contains more information about LDL neutral effects from 4
16	grams pure EPA than Amarin's own patents, correct?
17	A There is information in Mori and there's apparently no
18	data in the patent.
19	Q Okay. And so to be clear, you're arguing that clinical
20	data is required for a reasonable expectation of success, ever
21	though the patent itself contains no clinical data, correct?
22	A Well, as I said in my deposition, I'm sure they had
23	something, but I don't know what it was.
24	Q Yeah. And that's actually my next question. Under your
25	theory, Amarin had no invention as of 2009 when it filed its

- 1 | patent application, correct?
- 2 A Well, clearly, they were basing their conclusion on
- 3 something.
- 4 Q Now, Doctor, you're here to defend the validity of the
- 5 | patents-in-suit, right?
- 6 A Yes.
- 7 Q And you don't know what the inventors had to support
- 8 their claims in 2009 that using 4 grams pure EPA in patients
- 9 above 500 would, in fact, have LDL neutral effects and reduce
- 10 apo B, correct?
- 11 A I don't have the data in front of me, no.
- 12 | Q Now, let's go back to the second argument you made with
- regard to reasonable expectation of success. That is when you
- 14 looked to Lovaza, fibrates, and niacin. Do you remember that?
- 15 A **Yes.**
- 16 Q Okay. And on direct you testified that a skilled artisan
- would believe that both EPA and DHA raise LDL-C in patients
- with very high triglycerides by looking to those three classes
- 19 of drugs, correct?
- 20 A **Yes.**
- 21 Q All right. And the fact that Lovaza itself has an LDL-C
- 22 | side effect doesn't answer the question of whether that side
- 23 effect could be attributed to solely EPA or solely DHA,
- 24 correct?
- 25 A Yes, that's correct.

1	$\mathbb Q$ Okay. So that's why you rely on niacin and the fibrates,
2	correct?
3	A Well, it's all of a piece.
4	Q Right.
5	Okay. Let's go to DDX 10.3.
6	Now, you understand that Amarin made this same
7	argument to the patent office?
8	A Which same argument?
9	${\mathbb Q}$ The same argument with regard to fibrates.
10	A Please repeat what the argument is.
11	Q Okay. Well, we're actually looking at it. On the screen
12	is DX 1522, page 772, and this is Amarin's June 2011 response
13	to the patent office rejection.
14	And I won't read the whole thing, but I'll just read
15	what is essentially highlighted, which is,
16	"Amarin argued to the patent office that the
17	actual evidence of record indicates that any change
18	in LDL in those subjects is not at all predictive of
19	the impact on LDL in subjects with very high
20	triglycerides."
21	And then if you go to the subparagraphs,
22	"Amarin argued that approved medications for
23	triglyceride lowering in this very high triglyceride
24	patient population, e.g., Lovaza, Trilipix, Lopid, et
25	cetera, all increase LDL-C."

1	And if you go to the second indented
2	paragraph, "Amarin argued that subjects with very
3	high triglycerides clearly respond very differently
4	to triglyceride-lowering therapy compared to subjects
5	with borderline high, high triglyceride levels."
6	Do you understand that Amarin made those types
7	of arguments to the patent office?
8	A Yes.
9	$\ensuremath{\mathbb{Q}}$ Okay. And those are the same arguments that you made in
LO	your direct testimony, correct?
11	A Yes.
12	Q And Trilipix and Lopid are fibrates, right?
13	A Yes, they are.
L 4	Q All right. Let's go to DDX 10.4, and this is DX 1587,
15	page 19.
L 6	And here the examiner responded and said,
L 7	"Triplix" I think that's a typo, it should be Trilipix.
L 8	"which is a fenofibric acid, is
L 9	structurally and biologically very different from
20	EPA-E an omega-3 fatty acid."
21	And you skip a sentence, it says,
22	"On the other hand Epadel is omega-3 fatty
23	acid known to lower triglycerides although the
24	mechanism is not known," and the examiner said, "so
25	one cannot extrapolate the results observed with the

- 1 fibrate Trilipix to omega-3 fatty acids like EPA."
- Were you aware that the examiner rejected
- 3 Amarin's argument that a skilled artisan would extrapolate the
- 4 results observed with a fibrate to omega-3 fatty acids like
- 5 pure EPA?
- 6 A Yes.
- 7 Q Okay. And on direct you extrapolated the results
- 8 observed with the fibrate to purified EPA, correct?
- 9 A Yes.
- 10 Q And so your position is the patent office got this point
- 11 wrong, right?
- 12 A Yes, that's correct, counsel.
- 13 Q And, by the way, on direct you discuss prior art talking
- 14 about how niacin, fibrates, and Lovaza can all increase LDL
- when triglycerides get very high, right?
- 16 A **Yes**.
- 17 Q But you did not cite on direct any prior art comparing
- 18 | the LDL-C effects of niacin or fibrates on the one hand with
- 19 | pure EPA, correct?
- 20 A There wasn't any data to go on.
- 21 Q Let's go to slide DDX 10.5.
- Doctor, you understand that during prosecution, the
- 23 patent office repeatedly rejected the patents as obvious,
- 24 right?
- 25 A **Yes**.

- 1 Q And in the Notice of Allowance the examiner wrote,
- 2 "Based on these references" -- referring to
- 3 prior art -- "it was concluded that it will be
- 4 obvious to treat patients having triglycerides above
- 5 500 milligrams with 96 percent pure ethyl EPA,"
- 6 right?
- 7 | A **Yes.**
- 8 Q And the examiner ultimately issued the patent based on
- 9 those secondary considerations listed on the screen, and, for
- 10 the record, it's DX 1591, pages 5 and 6. Correct?
- 11 A Yes.
- 12 \ Q Now, you understand that the patent office thus found
- 13 | that the prior art would have motivated a skilled artisan to
- 14 use purified EPA in patients with triglycerides above 500,
- 15 right?
- 16 A Counsel, say that again? I'm sorry.
- 17 Q You understand that the patent office found that the
- 18 prior art would have motivated a skilled artisan to use
- 19 | purified EPA in patients above 500, correct?
- 20 A That was one point of contention.
- 21 Q Okay. But that's what the patent office found, right?
- 22 A **Yes.**
- 23 Q Okay. And you understand the patent office found a
- 24 reasonable expectation of success in using EPA to reduce
- 25 | triglyceride levels below 500, right?

- 1 A Yes.
- 2 Q And you're offering testimony today on the point that the
- Patent Office got that wrong, correct?
- 4 A Yes.
- Now, I want to unpack your opinion with regard to
  extrapolating to fibrates and niacin in a little more depth.

Am I correct that, in your opinion, a skilled
artisan would believe that when patients have triglycerides
above 500, the triglyceride level will necessarily increase -the reduction of triglycerides will necessarily increase

LDL-C?

- 12 A Correct.
- Q Okay. And, in your opinion, the higher the baseline triglyceride level, the more likely you're going to see an
- 15 LDL-C increase?
- 16 A **Yes**.
- 17 Q And that -- and you point to Lovaza and fibrates and 18 niacin as an example, right?
- 19 A Yes.
- 20 Q And, in your view, a skilled artisan wouldn't think that
  21 a drug could reduce triglycerides in patients with very high
  22 triglyceride levels without also increasing LDL-C.
- 23 A Based on the prior art, yes.
- Q Okay. And you said on direct something to effect that all drugs approved for severe hypertriglyceridemia have a

- common theme, LDL elevation is proportionate to the magnitude
- 2 of the baseline triglycerides, something like that; is that
- 3 right?
- 4 A Something like that, yes.
- Okay. And that's what I wrote down so hopefully I got it
- 6 right.
- And this is why, in your opinion, Vascepa had unexpected results and satisfied a long-felt need, right?
- 9 A Yes.
- 10 Q Now, this is a critical point supporting your
- 11 nonobviousness opinion, you spent a lot of time on it, right?
- 12 A **Yes.**
- 13 Q Now, Doctor, it was known before 2008 that patients with
- 14 | triglycerides above 500 could take a drug that both reduces
- 15 triglyceride levels and also reduces LDL-C.
- 16 A It was known?
- 17 | Q It was known, right?
- 18 A Prior to --
- 19 O March 2008.
- 20 A Well, the patent that was submitted by Amarin would
- 21 | suggest that they knew something about it, but it was not
- generally known, no.
- 23 Q Okay. Well, Vascepa was not the first FDA-approved
- 24 | treatment shown to reduce triglycerides from above 500 to
- 25 | below 500 without increasing LDL-C, right?

- 1 A No, I'm not aware of that.
- 2 Q Okay. Doctor, are you familiar with LIPITOR?
- 3 A Of course I'm familiar with LIPITOR, counsel.
- 4 Q You've prescribed is thousands of times, right?
- 5 A Yes, probably.
- 6 Q It's probably one the most prescribed drugs of all time,
- 7 right?
- 8 A Yes.
- 9 Q And LIPITOR was available before March 2008?
- 10 A **Yes.**
- 11 Q And a skilled artisan by March 2008 would be very
- 12 | familiar with the LIPITOR label, right?
- 13 A They would.
- 14 Q Now, LIPITOR is primary used for cardiovascular risk
- 15 | reduction, correct?
- 16 A Yes, counsel.
- 17 Q And LIPITOR is not specifically indicated to treat all
- patients with severe hypertriglyceridemia, right?
- 19 A It had no indication to treat severe hypertriglyceridemia
- 20 **at all.**
- 21 Q Okay. But LIPITOR was and actually still is FDA approved
- 22 to reduce triglycerides in some patients who have levels above
- 23 | **500**, right?
- 24 A It is -- okay. So -- may I see the label where it says
- 25 | **that?**

1	MR. KLEIN: Yes, let's go to the label. Let's
2	go to DDX 10.6. And on the screen is DX 3007, page 14.
3	And there's a housekeeping issue here, Your
4	Honor, because the current LIPITOR label is in evidence as
5	DX 1986. DX 3007, which I'm using for impeachment is not
6	in on the exhibit list, but I'd like to use it because it's
7	dated before March 2008 and the relevant language is identical
8	to the LIPITOR exhibit that is in evidence, and so I move to
9	admit DX 3007.
10	THE COURT: So has the LIPITOR label changed?
11	MR. KLEIN: Not the portions I'm going to talk
12	about. But I would like to move into evidence DX 3007 solely
13	because this is the label that's dated before March 2008.
14	THE COURT: Any objection?
15	MR. ELIKAN: Yes, Your Honor. It's not on the
16	exhibit list, and they have another LIPITOR label on the
17	exhibit list.
18	I understand that they may want to use this for
19	impeachment, but I don't understand why it would be added now
20	to the exhibit list based on a representation made in court.
21	The deadline to put in exhibits was in early
22	January, weeks ago. I can understand using it for
23	impeachment. We have no objection to that but don't see why
24	it should be admitted into evidence.
25	MR. KLEIN: Your Honor, the local rules as well

1	as the pretrial order do not require documents to be used for
2	impeachment to be identified on the exhibit list, and it
3	doesn't preclude us from moving them into evidence, which is
4	what I'm doing.
5	And there's obviously no prejudice because the
6	only difference is that this makes it clear it was revised in
7	2007.
8	THE COURT: Well, there is such an exception to
9	the rule that allows for impeachment evidence not to be
10	disclosed before the impeachment, but what I'm understanding
11	is the portion that you're using to impeach is the same as
12	that on the exhibit that's already been admitted.
13	MR. KLEIN: Correct.
14	THE COURT: So, really, you're not using
15	anything new to impeach. You just want to have this label be
16	admitted because it's one that was in existence in 2007 to
17	make the record clear.
18	MR. KLEIN: Exactly.
19	THE COURT: So how can you use the exception to
20	try to get the evidence in when you're not really using it for
21	impeachment?
22	MR. KLEIN: Well, I am
23	THE COURT: Well, in other words, what you need
24	for impeachment is already in the other exhibit.
25	MR. KLEIN: Well, this makes it very clear that

1	what's in the other exhibit was in the LIPITOR label as of
2	March 2008, and Dr. Toth said he wasn't aware of any drug that
3	was approved for patients above 500.
4	So it's being used for impeachment, and the only
5	reason I want it move this label in is to make the record
6	clear that this that the language was in the prior art.
7	THE COURT: Well, I understand why you want the
8	2007 label in, because we're looking at March at this point
9	anyway, the March 2008 as the time period.
10	I'm just pointing out that using the rule that
11	allows for impeachment evidence not to be disclosed prior to
12	the impeachment doesn't seem to fit here because what you
13	the content of what you're using it to impeach is not in this
14	new exhibit.
15	Am I right?
16	MR. KLEIN: Yes, except part of the impeachment
17	is that this was in the prior art.
18	THE COURT: All right. Anymore comment before I
19	give my ruling? Mr. Elikan?
20	MR. ELIKAN: I mean
21	THE COURT: The parties don't dispute that this
22	is in the prior art. There's no dispute that LIPITOR was in
23	existence before 2000 it's been around for a long time.
24	MR. ELIKAN: Your Honor, there should be
25	there is a LIPITOR label that's on the exhibit list. My only

1	issue is moving this into evidence.
2	Simply, we're fine with it being used as
3	impeachment, but it seems that Mr. Klein then ought to be
4	comparing the two labels and showing that whatever he says is
5	in this older label is in the newer label.
6	We don't see how this is not having to disclose
7	impeachment evidence in advance translates to being able to
8	admit impeachment materials.
9	THE COURT: Mr. Klein?
10	MR. KLEIN: The the only issue for
11	impeachment is the date. The content is the same. I can
12	obviously go through this as impeachment and then go through
13	the current label and compare them, ask if they've changed.
14	But I don't think there's going to be a dispute,
15	and it seems like a waste of time when all we're disputing is
16	whether I could put into the evidence something to establish
17	that this was the language before March 2008.
18	THE COURT: All right. If you're not using
19	anything if you're saying that what you're using in this
20	label is the same material that's already in the label that's
21	admitted as 1986, Exhibit 1986?
22	MR. KLEIN: Correct.
23	THE COURT: I'm going to overrule the objection.
24	I'm going to admit DX 3007, the 2007 LIPITOR label, solely for
25	the limited purpose of establishing that the label was in

1 existence in 2007. 2 MR. KLEIN: Okay. Thank you. 3 (Defendants' Exhibit 3007 received in evidence.) BY MR. KLEIN: 4 5 Okay. Now, Doctor, to get back on track, we're looking at DX 3007, page 14. You asked to look at the LIPITOR label. 6 Do you recognize DX 3007 as the LIPITOR label revised as of 8 September 2007? 9 Α Yes, I recognize it. 10 Okay. And it says "LIPITOR is indicated" -- and you go 11 to number two. 12 "...as an adjunct to diet for the treatment 13 of patients with elevated serum triglyceride levels, 14 Frederickson Type IV." 15 Do you see that? 16 Α Yes. 17 And Frederickson Type IV includes some patients with 18 triglycerides above 500, right? 19 Very few. Fredrickson Type IV is typically less than 20 500, typically between 350 and 499, and this was also indicated in the Tricor label. 21 22 MR. KLEIN: Okay. Let's go to DDX 10.7. 2.3 BY MR. KLEIN:

regard to Fredrickson Type IV hypertriglyceridemia, and this

Okay. I added the relevant portion of the label with

24

25

1	section talks about how the response to LIPITOR in 64 patients
2	with isolated hypertriglyceridemia were treated across several
3	clinical trials as shown in a table below, and the median
4	baseline median baseline triglyceride level was 565. Do
5	you see that?
6	A Yes.
7	MR. ELIKAN: Your Honor
8	THE COURT: There's an objection?
9	MR. ELIKAN: Yes. He should at least be
10	provided with the label. I don't think he has that now.
11	If he's being shown other portions of it, he has
12	a different version as I understand it, we certainly don't.
13	MR. KLEIN: No I think you do.
14	MR. ELIKAN: I don't believe so.
15	MR. KLEIN: You should.
16	BY MR. KLEIN:
17	Q Doctor, do you have DX 3007 in your binder?
18	THE COURT: So I admitted DX 3007 solely to show
19	that the label was in existence in 2007 based on your
20	representation, Mr. Klein, that the portion you were asking is
21	the same in both labels.
22	I know that you prepared this already so you're
23	referencing 3007, and I'm allowing you to proceed based on the
24	representation that the materials in both 3007 and 1986 are
25	the same.

- 1 MR. KLEIN: Yes. Right. Yes, Your Honor.
- 2 May Ms. Heydorn approach the witness?
- 3 THE COURT: Yes.
- 4 THE WITNESS: Thank you.
- 5 BY MR. KLEIN:
- 6 | Q Now, Doctor, you can see this is referring to pages 11
- 7 and 14. If you need to look at the document, can you look at
- 8 | the document. But, you can see that the baseline triglyceride
- 9 level on the LIPITOR label for the hypertriglyceridemia
- 10 | section was 565, right?
- 11 A Yes.
- 12 Q And, okay, a patient with triglyceride levels of 565 is
- 13 | obviously above 500?
- 14 A If a patient has a 565, it's over 500.
- 15 Q Okay. And more importantly that patient has severe
- 16 hypertriglyceridemia?
- 17 A Yes, but it doesn't say how many patients here had severe
- 18 hypertriglyceridemia.
- 19 Q Okay. Well, let's go -- look at DDX 10.8.
- 20 A Counsel, which page is that going to be on?
- 21 | Q It's on 11 and 12.
- 22 A **Okay**.
- 23 O And this is Table 4.
- 24 A This is still the LIPITOR label?
- 25 | Q Correct.

- 1 A It says DX 1966.
- 2 MR. KLEIN: Maybe you're on the --
- 3 THE COURT: That's not the correct exhibit.
- 4 MR. KLEIN: It should be DX 3007.
- THE WITNESS: Okay. Page 11, you said?
- 6 MR. KLEIN: Eleven and 12.
- 7 THE WITNESS: I have it.
- 8 MR. KLEIN: Okay. And I'm just going to look at
- 9 | it focus on the table. I'm not sure there's anything else you
- need but you're welcome to look at the exhibit if you want.
- 11 BY MR. KLEIN:
- 12 Q The generic name for LIPITOR is Atorvastatin, right?
- 13 A **Yes.**
- 14 Q Okay. So this Table 4 compares LIPITOR 10 milligrams,
- 15 | 20 milligrams, and 80 milligrams to a placebo, right?
- 16 A **Yes**.
- 17 Q Okay. And according to Table 4 from the 2007 LIPITOR
- 18 | label, and I'll represent to you that this hasn't changed,
- 19 triglyceride levels were reduced 41 percent with 10 milligrams
- 20 of LIPITOR, right?
- 21 A **Yes.**
- 22 Q And LDL-C went down 26.5 percent, right?
- 23 | A **Yes.**
- 24 Q And for 20 milligrams, it was similar, triglycerides went
- 25 | down 39 percent, right?

- 1 A Yes.
- 2 Q And LDL-C went down 30.4 percent, right?
- $3 \mid A \quad Yes.$
- 4 Q And for 80 milligrams, triglycerides went down
- 5 | **52** percent, right?
- 6 A Yes.
- 7 Q And LDL-C went down 40.5 percent.
- 8 A Yes.
- 9 MR. KLEIN: Now, let's go to DDX 10.9.
- 10 BY MR. KLEIN:
- 11 Q Okay. On the left, we've got the portions of the LIPITOR
- 12 label we were looking at, DX 3007, page 12. And on the right
- we have the Lovaza PDR, DX 1535, page 3.
- 14 Do you see that?
- 15 A **Yes.**
- 16 Q And you rely on Table 2 from the Lovaza label to show
- 17 | that LDL-C went up 49.3 percent, right?
- 18 A **Yes.**
- 19 Q Now, the median baseline triglycerides reported in the
- 20 Lovaza PDR were 816, right?
- 21 A **Yes.**
- 22 And in contrast, the median baseline triglyceride level
- 23 | in the LIPITOR label was 565, right?
- 24 A Yes. The distinction I would draw here is that everybody
- in the Lovaza study had triglycerides over 500. We have no

- 1 | idea how many in the LIPITOR study did.
- 2 Q Okay. But we do know the median triglyceride level was
- 3 | above 500, right?
- 4 A I don't find that helpful.
- 5 Q Okay. You don't find median data helpful?
- 6 A Well, I need to know how many patients were above and
- 7 below 500, and what happened above and below 500.
- 8 Q Okay. Now, you testified that the higher the
- 9 triglyceride baseline, the more likely you are to have an
- 10 LDL-C increase, right?
- 11 A Yes.
- 12 Q And a skilled artisan would know that, that's your
- 13 opinion?
- 14 A Hopefully, yes.
- 15 Q So a skilled artisan would expect different LDL-C effects
- 16 | from a drug treating a patient with a baseline triglyceride
- 17 | level of 500, as opposed to a patient with a triglyceride
- 18 | level above 800, correct?
- 19 A Yes.
- 20 Q Okay. And you understand every asserted claim in this
- 21 case covers patients with triglyceride levels of 500 and
- 22 above, right?
- 23 A And above, yes.
- 24 Q Okay. But it includes patients who have a triglyceride
- 25 | level of only 500?

- 1 A Sure. Greater than or equal to 500.
- 2 Q And so you understand that if it were obvious to use
- 3 | 4 grams pure EPA to get and LDL neutral effect in a patient
- 4 | with triglyceride levels of exactly 500, those claim
- 5 | limitations would be obvious, right?
- 6 A No. No, no.
- Based on what?
- 8 Q You understand there's no such thing as "partial
- 9 obviousness" of a claim?
- 10 A **Yes.**
- 11 Q Okay. So if it's obvious to get an LDL neutral effect
- with a patient at 500, you understand the claims are obvious,
- 13 right?
- 14 And if you don't understand, it's a legal question.
- 15 | That's fine, too. I know it's a legal issue.
- 16 A Yeah. I must say I'm not familiar with that.
- 17 Q Okay. But no asserted patent in this case requires
- 18 | triglyceride levels to be above 800, right?
- 19 A No. That's correct.
- 20 MR. KLEIN: Okay. Let's go to DDX 10.118.
- 21 BY MR. KLEIN:
- 22 Q This is PDX 6.7 that you used on direct. Do you remember
- 23 | that?
- 24 A **Yes.**
- 25 Q Okay. And I want to focus on the high triglyceride bar

- 1 | you had there.
- 2 A Yes.
- 3 Q And just to orient everyone, this is for Tricor, right?
- 4 A Yes.
- 5 Q Okay. And this refers to triglycerides of 350 to 499,
- 6 right?
- 7 A Which was defined as Type IV, as Fredrickson's Type IVs,
- 8 yes.
- 9 Q And the mean was -- the mean triglyceride level was 432,
- 10 right?
- 11 A Yes.
- 12 Q And in this group there was no statistically significant
- 13 | increase in LDL-C, correct?
- 14 A Yes.
- 15 Q And triglyceride levels of 499 and 500 are within error
- of the measurement, right?
- 17 A That would be true.
- 18 Q Okay. And, again, the claims here start at 500, right?
- 19 A **Yes**.
- 20 Q **And they --**
- MR. KLEIN: Can you cut out.
- 22 BY MR. KLEIN:
- 23 Q Your very high triglyceride bar has a mean of 726, right?
- 24 A **Yes.**
- 25 Q There's no claim in this case that requires triglycerides

- 1 | above 700, right?
- 2 A Correct.
- MR. KLEIN: All right. Let's move to DDX 10.10.
- 4 BY MR. KLEIN:
- 5 Q And I'm hoping that we can move through these points
- 6 fairly quickly. You recognize DX 1635, page 3, as the Lovaza
- 7 **PDR?**
- 8 A Yes.
- 9 Q And the Lovaza indication is the same method covered by
- 10 the claims to treat adult patients with very high triglyceride
- 11 | levels, right?
- 12 A **Yes.**
- 13 Q And as of March 2008, a skilled artisan would have found
- 14 | it obvious to treat a patient with triglyceride levels above
- 15 | 500 with a 4-gram per day mixture of EPA and DHA according to
- 16 | the Lovaza label, right?
- 17 A Well, defined as omega-3 acid ethyl esters, yes.
- 18 O And the label discusses a clinical trial that lasted --
- 19 there are two clinical trials, but one of them lasted
- 20 | 16 weeks, right?
- 21 A **Yes.**
- 22 Q And so it would have been obvious to a skilled artisan,
- 23 as of March 2008, to treat patients with severe
- 24 hypertriglyceridemia for at least 12 weeks, that they
- 25 | can be treated, right?

- 1 A Yes.
- 2 MR. KLEIN: Let's go to DDX 10.11.
- 3 BY MR. KLEIN:
- 4 Q This is DX 1535 page 3. We're still on the Lovaza PDR.
- 5 And I don't think there's going to be any dispute
- 6 here, but a side effect of Lovaza is LDL-C increase, right?
- 7 | A **Yes.**
- 8 Q And in your opinion, as of March 2008, a skilled artisan
- 9 | would have been motivated to avoid LDL-C increases when
- 10 treating patients with severe hypertriglyceridemia, right?
- 11 A Yes.
- 12 Q And as of March 2008, many patients who took Lovaza were
- also given a statin to address the LDL-C increases, right?
- 14 A **Yes.**
- 15 Q And those patients would have to take two pills, the
- 16 Lovaza and a statin, right?
- 17 A **Yes.**
- 18 Q And as of March 2008, a skilled artisan would have been
- 19 | motivated to develop a single pill that treats severe
- 20 hypertriglyceridemia without LDL-C increases, correct?
- 21 A **Sure**.
- 22 Now, the patent claims require purified EPA, right?
- 23 A **Yes.**
- 24 Q And the prior art taught that both EPA and DHA could be
- 25 purified, correct?

- 1 A Yes.
- 2 Q And you are aware of Epadel before March 2008, right?
- 3 | A **Yes**.
- 4 Q Okay. And Epadel was approved in the 1990s; is that
- 5 right?
- 6 A Yes. In Japan.
- 7 MR. KLEIN: In Japan.
- 8 Let's go to DDX 10.12. This is DX 1528, page 3.
- 9 BY MR. KLEIN:
- 10 Q Do you recognize this as the Epadel PI?
- 11 A Yes, counsel.
- 12 Q Okay. And a skilled artisan would have been aware of
- 13 | Epadel, at a minimum, because of the JELIS trial, right?
- 14 A **Yes.**
- 15 Q Okay. And the JELIS trial was not conducted by Amarin,
- 16 | right?
- 17 A Correct.
- 18 Q And purified EPA, such as Epadel, was given to patients
- 19 before March 2008 to reduce triglyceride levels, right?
- 20 A **Yes.**
- 21 Q And a skilled artisan, as of March 2008, would have found
- 22 | it obvious to use either pure DHA, or pure EPA, to reduce
- 23 | triglyceride levels, right?
- 24 A skilled artisan would have been what?
- 25 Q Would have found it obvious to use either pure EPA or

- 1 pure DHA to reduce triglyceride levels.
- 2 A It had been done. Yes.
- 3 Q Right. And so it would have been obvious to a skilled
- 4 | artisan, as of March 2008, that purified EPA reduces
- 5 triglyceride levels, right?
- 6 A Yes, that was obvious.
- 7 | Q Now, there's nothing in the Epadel label that warns about
- 8 LDL-C increases, correct?
- 9 A No. It's far too nebulous to warn about anything.
- 10 Q Now, multiple studies in the prior art show that EPA
- 11 reduces triglycerides, correct?
- 12 A **Yes.**
- 13 MR. KLEIN: Let's go DDX 10.13.
- 14 BY MR. KLEIN:
- 15 Q All right. And this is DX 1538, which is the Mori
- 16 reference you discussed on direct, right?
- 17 A **Yes.**
- 18 O And the title of Mori is "Purified EPA and DHA Have
- 19 Differential Effects on Serum Lipids and Lipoproteins, LDL
- 20 Particle Size, Glucose, and Insulin in Mildly Hyperlipidemic
- 21 Men," right?
- 22 A **Yes.**
- 23 Q And so Mori was addressing all those things.
- 24 A **Yes.**
- 25 Q I know you talked about some of the portions of the

- 1 | article, but I want to walk through it with you.
- 2 MR. KLEIN: Let's go to DDX 10.14.
- 3 BY MR. KLEIN:
- 4 Q The background says,
- 7 "Regular consumption of n-3 fatty acids of marine origin can improve serum lipids and reduce cardiovascular risk."
- 8 That was known at the time Mori published the 9 2000 reference, right?
- A Well, we -- no. Regular consumption of omega-3 fatty
  acids of MARINE origin can improve serum lipids, yes. But
  reduce cardiovascular risk? No. There was no foundation for
  that.
- MR. KLEIN: All right. Let's go to the next portion, the objective -- I'm sorry, it's 10.15.
- 16 BY MR. KLEIN:
- 17 Q The objective of the Mori study was to determine whether
- 18 EPA and DHA acids have differential effects on serum lipids.
- 19 | That was one the objectives, right?
- 20 A **Yes.**
- 21 MR. KLEIN: Okay. And let's go to DDX 10.16,
- 22 and, for the record, we're still on 1538, page 1.
- 23 **BY MR. KLEIN:**
- 24 Q Now, the design was a double-blind, placebo-controlled trial that used 4 grams purified EPA, 4 grams purified DHA,

- 1 and a placebo, which was olive oil, right?
- 2 A Yes.
- 3 MR. KLEIN: Okay. Let's go to DDX 10.17.
- 4 BY MR. KLEIN:
- 5 Q And the purity of EPA used in Mori was 96 percent, right?
- 6 A Yes.
- 7 Q And that's what's covered by the claims?
- 8 A Yes.
- 9 MR. KLEIN: All right. And let's go to DDX
- 10 **10.18.**
- 11 BY MR. KLEIN:
- 12 Q So one of the purposes of Mori 2000 was to assess whether
- 13 EPA and DHA had different effects on triglycerides, right?
- 14 A **Yes.**
- 15 | Q Now, the article -- I can't remember if this came up in
- 16 direct, but the article uses the term "triacylglycerols."
- 17 A Triacylglycerols. Yes.
- 18 Q That's a synonym for triglycerides, right?
- 19 A One in the same.
- 20 Q Okay. And Mori concluded that triglycerides fell by
- 21 | about 20 percent in the DHA group, and about 18 percent in the
- 22 EPA group, right?
- 23 A **Yes.**
- 24 Q Okay. And about 18 percent is pretty close to
- 25 | **20** percent, right?

- 1 A Yes.
- 2 Q Okay. And so it would have been obvious to a skilled
- 3 artisan, in March 2008, that 4 grams pure EPA could reduce
- 4 | triglycerides by about 20 percent, right?
- 5 A Yeah. 18 percent here. Uh-huh.
- 6 MR. KLEIN: Okay. Let's go to slide DDX 10.19.
- 7 BY MR. KLEIN:
- 8 Q And then in the "Results" section, Mori says, "LDL
- 9 cholesterol...were not affected significantly by EPA," and
- 10 then "DHA increased LDL cholesterol by 8 percent," correct?
- 11 A Yes.
- 12 MR. KLEIN: Okay. The -- let's go to DDX 10.20.
- 13 **BY MR. KLEIN:**
- 14 Q So this has the "Results" section, and then the
- 15 | "Conclusion" followed, right, in the abstract?
- 16 A **Yes**.
- 17 Q And the conclusion was EPA and DHA had differential
- 18 | effects on lipids, right?
- 19 A Yes.
- 20 Q And so Mori isn't saying these differential effects
- 21 between EPA and DHA are due to baseline triglyceride
- 22 differences or sample size, correct?
- 23 A Well, a POSA would have looked at that and would have
- 24 drawn a conclusion on that, yes.
- Q Okay. But that would -- but Mori did not say that,

- 1 | correct?
- 2 A No, he did not.
- Okay. Mori teaches that a skill -- teaches a skilled
- 4 artisan that EPA and DHA have differential effects on LDL-C;
- 5 | namely, DHA increased LDL-C by 8 percent, and it was
- 6 statistically significant, and EPA had no significant effect,
- 7 | correct?
- 8 A Mori doesn't teach that, he states that. But, certainly,
- 9 Rambjør disagrees with that, and multiple other papers
- 10 disagreed with that.
- 11 Q Okay. And we'll talk about Rambjør and the other papers
- 12 later.
- Now -- and you talked about other portions of Mori
- 14 that found other differences between EPA and DHA, correct?
- 15 A Yes, sir.
- 16 Q Okay. And you said that those other differences could
- 17 favor DHA?
- 18 A Yes, we did.
- 19 Q Okay. But, Mori is certainly teaching that EPA and DHA
- 20 | have different effects on the body, right?
- 21 A Have different effects on --
- 22 Q The body.
- 23 | A The body?
- 24 Q **Yes.**
- 25 A Where does he make reference to different effects on the

- 1 body?
- 2 Q Well, Mori is talking about different effects in LDL-C,
- different effects in particle size, different effect -- Mori
- 4 | is saying EPA and DHA have different effects, right?
- 5 A Yes, he is.
- 6 Q Okay. And a skilled artisan would understand from Mori
- 7 that DHA and EPA can work differently.
- 8 A Yeah, they clearly had some different effects. Yes.
- 9 MR. KLEIN: Okay. Let's go to DDX 10.21.
- 10 BY MR. KLEIN:
- 11 Q And I -- we've seen this before, but Mori also says
- 12 elsewhere in the paper, on DDX 1538, page 3, that, "Serum LDL
- cholesterol increased significantly with DHA, but not with
- 14 | EPA," right?
- 15 A **Yes.**
- 16 Q Okay. And so the authors of Mori concluded that there
- 17 | was not a statistically significant increase in LDL-C
- attributed to those patients who were taking purified EPA,
- 19 correct?
- 20 A He does state that.
- 21 Q Okay. And as of March 2008, a skilled artisan could
- reasonably rely on Mori 2000 as teaching that DHA, but not
- 23 EPA, increases LDL-C?
- 24 A But they would both look at a numerical increase.
- 25 Q Okay. A skilled artisan, in March 2008, could reasonably

- 1 look at the LDL-C statements in Mori 2000, and believe that a
- 2 | future study assessing differential results on LDL-C, between
- 3 purified EPA and DHA, would be warranted.
- 4 Do you agree with that?
- 5 A You would want to confirm the results of a small study
- 6 like this. Yes.
- 7 Q Okay. And skilled artisan, in March 2008, would have
- 8 read Mori 2000 as teaching that 96 percent pure EPA was LDL
- 9 neutral, correct?
- 10 A Yeah. I'm not going to agree with that because of the
- caveats we've already discussed, but it -- it still increased.
- 12 Q Okay. Now, Amarin, itself, read Mori, and other prior
- 13 art, as teaching that pure EPA was LDL neutral. Are you aware
- 14 of that?
- 15 A No. But, I don't speak for Amarin.
- 16 MR. KLEIN: Okay. Well, let's take a look at
- 17 DDX 10.22. And this is DX 1829, page 11, and DX 2241. And
- 18 the reason there are two documents is -- well, let me ask.
- 19 BY MR. KLEIN:
- 20 Q Were you here -- you weren't here for Dr. Ketchum's
- 21 testimony, right?
- 22 A No.
- 23 | Q Have you read his testimony?
- 24 A I have not.
- 25 Q Okay. Well, the reason there are two documents is solely

1	to establish the date. The second document is metadata. So
2	I'll represent to you that the date of this Amarin document is
3	March 20, 2008. And you understand that that date is before
4	the alleged conception date of March 25th, 2008?
5	A Yes.
6	Q Okay. And Appendix 4 in this Amarin document is titled,
7	"EPA versus DHA Mori, et al." And you see that Amarin
8	describes the LDL effect of Mori as teaching that serum LDL
9	increases significantly with DHA, but not EPA what we read
10	in the article, right?
11	A Yes.
12	Q And at the bottom,
13	"Amarin concludes that Mori 2000 taught both
L 4	EPA and DHA reduced triglycerides."
15	Do you see that?
16	A Yes.
17	Q And then concluded,
18	"DHA was also associated with and increase in
19	LDL cholesterol," right?
20	A Yes.
21	Q Now, Amarin, in this March 20, 2008 document accurately
22	described the Mori reference, correct?
23	A They're quoting it.
24	MR. KLEIN: Yeah.
25	Okay. Let's go to DDX 10.23. This is another

- 1 Amarin document. It's DX 1862, page 47.
- 2 BY MR. KLEIN:
- 3 Q And I'll represent to you that this is a partnering
- 4 presentation, you can see it, with a company called Arisaph,
- 5 dated August 3rd, 2009.
- 6 Have you seen this document?
- 7 A I have not.
- 8 Q Okay. Well, on this slide, page 47 of the exhibit,
- 9 | there's a slide that's titled "EPA, No LDL Effect."
- 10 Do you see that?
- 11 A Yes.
- 12 Q Okay. And by the date of this reference, August 2009,
- 13 there were no MARINE study results yet, right?
- 14 A Correct.
- 15 Q And below the title is a description of the Mori
- 16 reference, right?
- 17 A **Yes.**
- 18 Q Okay. And so Amarin told its potential partner, Arisaph,
- 19 | that Mori 2000 teaches that 96 percent pure EPA, 4 grams per
- 20 day, has zero percent change in LDL, right?
- 21 A That's what it says.
- 22 Q Okay. And Amarin did not misrepresent Mori to its
- 23 | potential partner Arisaph, correct?
- 24 A I can't -- apparently not.
- 25 Q **Okay**.

- 1 A They -- it's not something they would want to do, no.
- 2 MR. KLEIN: Let's go to DDX 10.24.
- 3 BY MR. KLEIN:
- 4 Q This is another document, DX 1800, page 10. It's another
- 5 one of these Amarin slide decks. And if you can read the
- date, it says March 2010. And by March 2010, Amarin still had
- 7 | no MARINE data, correct?
- 8 A Yes.
- 9 Q Okay. And I'll represent to you that Dr. Ketchum
- 10 testified that this presentation was directed to and investor
- 11 audience. Okay?
- 12 For the record, that's transcript 210, line 20, to
- 13 | 211, line 4. Just to orient you, Dr. Toth.
- 14 Okay. Now, here, Amarin, you can see Amarin is
- 15 distinguishing Lovaza from AMR 101.
- 16 Do you see that?
- 17 A **Yes.**
- 18 Q And you understand AMR 101 is the code name for Vascepa?
- 19 A **Yes.**
- 20 Q And under the Lovaza section for LDL effect, it says,
- 21 "elevates LDL-C."
- Do you see that?
- 23 | A **Yes.**
- 24 Q That's, obviously, not disputed, right?
- 25 | A **Yeah**.

- 1 Q And then under the Vascepa section, you see -- I guess
- 2 | there are two potential indications, but one is above
- 3 | 500 milligrams per deciliter, right?
- 4 A Yes.
- 5 Q And Amarin tells its investors that there's no DHA
- 6 induced elevation.
- Do you see that?
- 8 A Yes.
- 9 Q Okay. And that statement to investors is consistent with
- 10 | what the prior art taught, correct?
- 11 A That's a statement. But, on balance, the prior art noted
- 12 that both EPA and DHA could induce elevations in LDL.
- 13 Q Okay. So is it your testimony that when Amarin made this
- 14 presentation to investors, it was mischaracterizing the prior
- 15 | art?
- 16 A No. I would never say that.
- MR. KLEIN: Okay. And for the record, this is
- 18 DX 1800, page 10, in case I missed that.
- 19 Let's go DDX 10.25.
- 20 BY MR. KLEIN:
- 21 Q Here is another slide in the presentation where Amarin
- 22 | tells investors "multiple studies demonstrate that DHA raises
- 23 **LDL-C."**
- 24 Do you see that?
- 25 | A **I do.**

- 1  $\mathbb{Q}$  And you can tell that the support is all coming from the
- 2 prior art, correct?
- 3 A Yes. The references are all before 2008.
- $4 \mid Q$  Okay. And let's go to the next slide, which is
- 5 DDX 10.26, and this slide says "multiple studies demonstrate
- 6 that EPA is LDL neutral."
- 7 Do you see that?
- 8 A Yes.
- 9 Q And this is Amarin's support for the representation to
- 10 investors that the prior art demonstrated EPA is LDL neutral,
- 11 right?
- 12 A It's data they're showing.
- 13 Q Right.
- In fact, in the six references cited, on -- by the
- 15 way, this is page 13. I may not have said that for the
- 16 record. And the last one was page 12 -- but on this slide,
- page 13, Amarin cited six references, all dated before 2008,
- 18 correct?
- 19 A **Yes.**
- 20 Q And those references include the Mori 2000 reference,
- 21 correct?
- 22 A Not on this page.
- 23 Q It's highlighted.
- 24 A **Mori --**
- 25 On the left.

- 1 A Oh, okay. Yes. Okay.
- 2 Q Okay. And you can see that what Amarin is telling its
- 3 | investors in 2010, is that Mori reported a zero percent change
- 4 | in LDL, right?
- 5 A Zero point zero zero.
- 6 Q And Amarin is also citing Kurabayashi, right?
- 7 | A **Yes.**
- 8 Q And that's one of the references that you understand the
- 9 defendants' are relying on, right?
- 10 A **Yes.**
- 11 Q And for Kurabayashi, Amarin is telling investors that LDL
- 12 | will reduce by 6 percent, right?
- 13 A **Yes.**
- 14 Q Okay. And you're not testifying that Amarin
- 15 mischaracterized the Mori and the Kurabayashi references to
- 16 | its investors, correct?
- 17 A I am not.
- 18 MR. KLEIN: Okay. Let's go to DDX 10.27, and
- 19 | this is DX 1741, pages 1, 7, and 9.
- 20 **BY MR. KLEIN:**
- 21 Q And do you recognize this as the Bays article from 2011?
- 22 A I do.
- 23 And, counsel, I need to pull this article up.
- 24 What's the --
- 25 | Q It's DX 1741.

- 1 A Yes.
- 2 | Q Hopefully, it's in the binder.
- 3 A Excuse me just one second. It's an awful lot of papers.
- 4 1741.
- 5 Okay. I have it, counsel.
- 6 O Okay. Let me know when you're ready.
- 7 A Which page is this exhibit?
- 8 Q Let's focus on pages 7 and 9. And 9, I believe, is just
- 9 the footnote.
- 10 A Seven. Refresh my memory how the numbering goes here.
- 11 You're using the journal page number, right?
- 12 Q No. I'm using the -- there should be a DX 1741 on the
- 13 bottom?
- 14 | A **Okay**.
- 15 Q And then it's page 9 of that exhibit cite.
- 16 A Okay. Page 9 is the references.
- 17 Q Yeah. I'm sorry. Page 7 -- you probably want to look at
- page 7 because page 9 is just the footnote.
- 19 A Okay. Can you please direct me to where on the page it
- 20 | is -- I have it.
- 21 Q Okay. You got it?
- 22 A **Yes**.
- 23 Q Okay. Now, just for some context, you understand this
- 24 | article reported on the MARINE study results in 2011, right?
- 25 A **Yes.**

- 1 Q And you know Dr. Bays, correct?
- 2 A I do.
- 3 Q And do you have a lot of respect for Dr. Bays?
- 4 A Sure. Of course.
- 5 Q And Dr. Bays wrote, in DX 1741, that,
- "In several small studies, although DHA

  treatment generally increased LDL cholesterol levels,
- 8 EPA therapy did not."
- 9 Do you see that?
- 10 | A **I do**.
- 11 Q And in support, among other cites, Dr. Bays cited the
- 12 Mori article from 2000, right?
- 13 A **Yes.**
- 14 Q And Dr. Bays did not mischaracterize the Mori article,
- 15 right?
- 16 A No. He wouldn't do that.
- 17 I'm just reading, counsel. Give me 30 seconds.
- Okay. Go ahead.
- 19 | Q You got it?
- 20 A I do.
- 21 Q Okay.
- 22 A But, he also notes that,
- 23 "These previous studies were generally in patients with normal to borderline triglycerides and
- 25 none included patients with very high triglycerides."

1 Right. And we know that from Mori. I didn't say Mori 2 treated very high triglyceride patients. 3 Okay. 4 MR. KLEIN: Okay. Let's go to DDX 10.28. BY MR. KLEIN: 6 One of the other references -- we're now on page 9, DDX 7 1741. Dr. Bays also says, 8 "Smaller trials suggested that purified EPA 9 might reduce triglyceride levels without increasing 10 the LDL cholesterol levels." 11 Do you see that? 12 But, again, page 9 is the references. Α I do. 13 Maybe the note -- I might have a wrong page number. 14 MS. HUTTNER: It's page 1. 15 MR. KLEIN: It's page 9? MS. HUTTNER: No. 16 It's 1. 17 MR. KLEIN: Oh. It's page 1. 18 THE WITNESS: Page 1. 19 MR. KLEIN: Yes. It's right above Methods --20 oh, I see. It does say 1. Okay. 21 THE WITNESS: It's just above Methods, on page 22 1? 23 It looks like three sentences above MR. KLEIN: 24 Methods, on the column on the right-hand side. 25 THE WITNESS: Yes, I have it. "Smaller trials

1	of p	atients with normal to moderate" Okay.
2		Thank you.
3	BY M	R. KLEIN:
4	Q	All right. I'll start again so the record is clear.
5		On page 1, Dr. Bays says,
6		"Smaller trials of patients with normal to
7		moderately elevated triglyceride levels suggested
8		that purified EPA might reduce triglyceride levels
9		without increasing the LDL cholesterol levels."
10		That's what Dr. Bays said in the article, right?
11	А	Yes.
12	Q	And he cited, among other references, the Kurabayashi
13	refe	rence, right?
14	А	Yes.
15	Q	And Dr. Bays did not mischaracterize the Kurabayashi
16	refe	rence, correct?
17	А	That's his interpretation. I would never suggest he
18	misc	haracterized. But, papers are subject to interpretation.
19		MR. KLEIN: Now, let's move on to DDX 10.30.
20	BY M	R. KLEIN:
21	Q	This is the Rambjør article, DX 1961. And I've got
22	page	3 on the screen.
23		You talked about this one on direct, right?
24	А	Yes.
25	Q	And Rambjør summarizes the results of three small

- 1 separate studies, right?
- 2 A Yes.
- 3 Q And there were nine patients who took DHA, right?
- 4 A Yes.
- 5 Q And 25 took EPA?
- 6 A Yes.
- 7 Q And the dose was 3 grams per day, right?
- 8 A Um --
- 9 | Q It's in the middle.
- 10 A It's -- EPA -- yes.
- 11 Q Okay. And Mori used 4 grams, right?
- 12 A **Yes.**
- 13 Q And the claims require 4 grams, right?
- 14 A **Yes.**
- 15 MR. KLEIN: Okay. Let's go to DDX 10.31.
- 16 BY MR. KLEIN:
- 17 Q And in the abstract, Rambjør studied 91 percent pure EPA,
- 18 | right?
- 19 | A **Yes.**
- 20 Q Okay. And you said omega-3s are complex, right? So that
- 21 other 9 percent, we have no idea what that is, right?
- 22 A That's right.
- 23 Q Okay. Mori used 96 percent pure EPA, correct?
- 24 A **Yes.**
- 25 Q And the claims require 96 percent pure EPA, right?

- 1 A Yes.
- 2 MR. KLEIN: Let's go to DDX 10.32.
- 3 BY MR. KLEIN:
- 4 Q And here, Mori says that,
- The percent change in LDL-C was identical

  for both EPA and DHA, plus 6 percent; but the smaller

  number of subjects in the latter group prevented the

  difference from being significant," right?
- 9 A Yeah. Sort of a similar conclusion to Mori, yeah.
- 10 Q Right. Well -- and then Rambjør says,
- "Further studies are needed to clearly define individual effects of EPA and DHA on human lipid metabolism," right?
- 14 | A **Yes.**
- Q Okay. And Mori 2000 is actually one of those further
- 16 | studies that did that, correct?
- 17 A **Yes.**
- 18 MR. KLEIN: Okay. Let's go to DDX 10.33.
- 19 BY MR. KLEIN:
- 20 Q And Mori referenced the Rambjør paper, right?
- 21 A Yeah -- um, Mori -- may I see it?
- 22 Q Well, it's on the screen.
- 23 | A **Okay**.
- 24 Q You can look at it, too. It's DDX 1538.
- 25 | A **1538.**

- 1 | Q Page 1.
- 2 A Counsel, you said page 1?
- 3 Q **Yes.**
- 4 A I have it.
- 5 \ \ \ \ \ Yeah. It's near the bottom of the second column.
- 6 A I have it.
- 7 Q Okay. And Mori said that,
- 8 "Rambjør concluded that EPA is responsible
  9 for the triglyceride lowering effect of fish oils in
  10 humans, but their study had small numbers of subjects
  11 and was of short duration," correct?
- A Yeah, but they actually had 25 patients in the EPA arm and Mori had 19.
- Q Okay. But Mori concluded that its study was superior to the one in Rambjør because it's criticizing Rambjør, correct?
- 16 A Well, they had more patients in Rambjør.
- Okay. But can we agree that Mori is critiquing the study
- 18 in Rambjør?
- 19 A Critiquing it? Where is he critiquing?
- 20 Q But that their study had small numbers of subjects and
- 21 | was of short duration?
- 22 A Yeah. I don't know how he can critique it when the EPA group had 25 and they had 19.
- 24 That's incongruous to me. The DHA group was
  25 smaller, but 25 in Rambjør, 19 in Mori, I don't see how Mori

- 1 | could criticize that study being smaller.
- 2 Q Okay. But a skilled artisan looking at Mori will see
- 3 Mori's comments with regard to the earlier Rambjør study,
- 4 correct?
- 5 A Sure. They can read it.
- 6 MR. KLEIN: Yeah.
- 7 Let's go to DDX10.34.
- 8 BY MR. KLEIN:
- 9 Q This is DX 1605, the von Schacky paper from 2006. And
- 10 | I'm on page 9.
- 11 A Yes.
- 12 Q You talked about this one on direct, right?
- 13 A **Yes.**
- 14 Q And I think you agree that it's a review article, right?
- 15 A **Yes.**
- 16 Q So von Schacky is not presenting any new data.
- 17 A No. It would be a synthesis of the available data.
- 18 Q Okay. And you relied on this Table 1 from von Schacky,
- 19 right?
- 20 A **Yes.**
- 21 Q And this chart talks about semi-quantitatively reflecting
- 22 | the findings from the literature?
- 23 A **Yes.**
- 24 Q This chart, though, is not very scientific.
- 25 **Do you agree?**

- 1 A Oh, I disagree.
- 2 Q You think this is a -- you can tell whether there
- 3 was statistically significant results for LDL-C from the
- 4 | literature from this chart?
- 5 A That's not the point. It's a chart to synthesize a large
- 6 amount of data from different papers, and people find charts
- 7 like this very valuable because, at a glance, it gives you a
- 8 summary of changes, and also provides you with a feel for
- 9 magnitude of change.
- Okay. And can you agree that this chart is on a very,
- 11 | very high level?
- 12 That's the goal, right?
- 13 A wery, very, high level?
- 14 Q Well, this chart is trying to synthesize the literature
- 15 | at a very high level.
- 16 Do you agree?
- 17 A Oh, sure.
- 18 Q And this is not getting into the details of what -- what
- 19 | studies in the literature actually showed.
- 20 A Well, it does get at what the studies actually showed.
- 21 It just provides you with a semi-quantitative presentation of
- 22 that information.
- 23 Q Okay. And then in the notes on Table 1, von Schacky
- 24 talks about Rambjør and Mori, among other references, right?
- 25 A Yes, he does.

- 1 Q Okay. Now, on direct, you didn't talk about any of the
- 2 | text from this article, right?
- 3 A The text?
- 4 Q Yes.
- 5 | A **Oh. We can.**
- 6 MR. KLEIN: Let's go to DDX 10.125.
- 7 THE WITNESS: Which, uh --
- 8 BY MR. KLEIN:
- 9 Q It's going to go on the screen and it's page -- it's DX
- 10 | 1605, page 5. And you should be able to find it because the
- 11 heading is there.
- 12 A **1605?**
- 13 0 **Yes**.
- 14 A I have it.
- 15 Q Okay. And you see the heading is "EPA versus DHA"?
- 16 | A **Yes**.
- 17 Q And what the author here says with regard to Mori 2000,
- 18 is that,
- "In more recent comparative studies, no
- effects of either EPA or DHA were seen on total --
- 21 were seen on LDL levels."
- 22 Do you see that?
- 23 A **Yes.**
- 24 Q And by the way, with regard to Rambjør, on the last
- 25 | sentence, it says,

1	"After either EPA or DHA, no clear-cut
2	effects on HDL were demonstrated."
3	Do you see that?
4	A Yes. But, that's just for those five papers.
5	Q Right. And that's citing Rambjør it's not citing
6	Rambjør for the effects on LDL, correct?
7	A Yes. But, clearly, he included that in the table.
8	Q Okay. What von Schacky said about Mori, when he said "no
9	effects of either EPA or DHA were seen on LDL," that's
10	incorrect, right?
11	A What sentence is that?
12	Q The one that I have highlighted.
13	"In more recent comparative studies, no
14	effects of either EPA or DHA were seen on LDL
15	levels."
16	That's not what Mori said, right?
17	A Correct.
18	MR. KLEIN: Let's go to DDX 10.126.
19	BY MR. KLEIN:
20	Q And this is a demonstrative that compares DX 1605,
21	page 5, which is von Schacky, to DX 1538, page 1, which is
22	Mori. And Mori held that the effects of DHA were seen on LDL
23	levels, and they were significant, correct?
24	A Yes.
25	Q And so von Schacky did not even characterize the Mori

- 1 | 2000 -- did not even accurately characterize the Mori
- 2 2000 reference, correct?
- 3 A Well, it would have been his interpretation.
- 4 Q Okay. Now, clearly, a skilled artisan, as of March 2008,
- 5 | looking at the literature, including the von Schacky
- 6 | reference, would look at the underlying clinical studies, such
- 7 | as Mori, right?
- 8 A Yes.
- 9 MR. KLEIN: All right. Let's go to DDX 10.123.
- 10 BY MR. KLEIN:
- 11 Q Okay. This is a snapshot of PX 833, which is a document
- 12 | that you discussed on direct.
- Do you remember that?
- 14 A I do.
- 15 Q Okay. And the document is titled "The Editor's
- 16 | Roundtable Hypertriglyceridemia, "right?
- 17 A **Yes.**
- 18 Q And you testified that this article showed praise of the
- 19 | MARINE study; in particular, the LDL neutral effect, right?
- 20 A **Yes.**
- 21 Q Okay. Now we're at -- PX 833, page 1, discloses that the
- 22 | article is sponsored by a grant from Amarin, right?
- 23 You can see that in that middle box?
- 24 A **Yes.**
- 25 Q And the article discloses that Drs. Ballantyne, Bays, and

- 1 Jones have all received compensation from Amarin, right?
- 2 A Yes.
- 3 Q And you didn't mention this on your direct testimony,
- 4 right?
- 5 A No.
- 6 Q Okay. Now, Dr. Toth, this isn't industry praise. It's
- 7 self-praise, correct?
- 8 A Well, no. I'm sure these -- well, I know all of these
- guys, and they would be able to differentiate themselves from
- whether or not it's coming from them, or because they're
- 11 | somehow sponsored by industry.
- 12 Q Do you consider and article sponsored by Amarin as
- objective evidence of praise by, by the -- a community?
- 14 That's a stretch, right?
- 15 A Well, what Harold said in this paper, he also said in the
- 16 paper on the MARINE Trial. So there's no -- there's no
- 17 discrepancy there.
- 18 Q Okay. But, the article was sponsored by Amarin, correct?
- 19 A Yes. It's indisputable.
- 20 Q Let's switch gears.
- 21 Again, all patent claims require 4 grams of purified
- 22 **EPA**, right?
- 23 A **Yes.**
- 24 Q And Lovaza is a 4-gram combination of EPA, DHA and
- 25 | whatever else is in there.

1	A Correct.
2	Q Okay. And as of March 2008 well, I think you said
3	that.
4	Okay. A number now, on direct I want to
5	clarify something that you said yesterday. On direct, you
6	said that the medical literature provided a reason not to use
7	a 4-gram dose of and omega-3 fatty acid to treat severe
8	hypertriglyceridemia.
9	Do you remember that, in the context of whether a
10	4-gram dose would be obvious?
11	A You know, I don't remember that.
12	Can you say that one more time, please, counsel.
13	Q Yes. So I won't put it up but you were asked, on
14	page 167 of the rough,
15	"As of March 2008, did the medical literature
16	provide a reason not to use a 4-gram dose of and
17	omega-3 fatty acid?"
18	And you said, "Yes."
19	A Oh, yeah. That was citing the paper, I believe by
20	Nilsen. I might be wrong on the specific paper.
21	Q I believe that's correct.
22	A But, it was one that evaluated 300 patients with
23	myocardial infarction. And they, in the discussion,
24	speculated that, perhaps, they had exceeded some critical
25	threshold beyond which there might be toxicity instead of

- 1 benefit.
- 2 Q Okay. But as of March 2008, a skilled artisan would be
- 3 very well aware that the FDA had approved a 4-gram fish oil
- 4 | product to treat severe hypertriglyceridemia, right?
- 5 A Yes.
- 6 MR. KLEIN: Okay. Now, let's go to DDX 10.35.
- 7 BY MR. KLEIN:
- 8 Q Oh, yeah. And Mori disclosed a clinical trial that used
- 9 4-gram of pure EPA, right?
- 10 A Yes.
- 11 Q And other prior art studies disclosed 4 grams of pure EPA
- 12 | to reduce triglycerides as well, right?
- 13 A Yeah, there were some.
- 14 MR. KLEIN: Okay. Let's go to DDX 10.36.
- 15 BY MR. KLEIN:
- 16 Q And this is DX 2263. Do you recognize this as the
- Woodman 2002 reference?
- 18 A **Yes.**
- 19 Q And this is prior art, correct?
- 20 MR. KLEIN: And, Your Honor, I move into
- 21 evidence DX 2263.
- 22 THE COURT: Any objection?
- MR. ELIKAN: None.
- 24 THE COURT: 2263 is admitted.
- (Defendants' Exhibit 2263 received in evidence.)

- 1 BY MR. KLEIN:
- 2 Q Okay. And Woodman 2002 disclosed a clinical trial in
- 3 | which 4 grams per day of purified EPA was administered to
- 4 reduce triglycerides, correct?
- 5 A Yes.
- 6 MR. KLEIN: Let's go DDX 10.37.
- 7 BY MR. KLEIN:
- 8 Q Woodman also found that 4 grams per day reduced -- 4
- 9 grams per day of purified EPA decreased triglycerides by 19
- 10 | percent, right?
- 11 A Yes.
- 12 Q And so that's about 20 percent, correct?
- 13 A **Yes.**
- 14 Q And DDX 10.38, this is DX 2258, page 1. Do you recognize
- 15 this as the Woodman 2003 reference?
- 16 A **Yes.**
- 17 Q Okay. And this is prior art, right?
- 18 A **Yes**.
- 19 MR. KLEIN: I move into evidence 2258.
- THE COURT: Any objection?
- MR. ELIKAN: None, Your Honor.
- 22 THE COURT: 2258 is admitted.
- (Defendants' Exhibit 2258 received in evidence.)
- 24 BY MR. KLEIN:
- 25 Q Woodman 2003 discloses clinical trial in which a 4-gram

```
1
     per day purified EPA dose was used to reduce triglycerides,
 2
     right?
 3
      A Yes, for six weeks.
                   MR. KLEIN: Okay. Let's go DDX 10.39.
 4
     BY MR. KLEIN:
 6
          And Woodman also found that EPA and DHA significantly
     decreased serum triglycerides by a similar extent relative to
 8
     placebo, right?
 9
      Α
          Yes.
10
                   MR. KLEIN: Let's go to DDX 10.40.
                   This is DX 2264 --
11
12
                   THE COURT: Mr. Klein, before you proceed
13
     to 2264, would this be a good time for us to take our morning
14
     break?
15
                   MR. KLEIN: We can do that.
16
                   THE COURT: All right. I'll note that you were
     about to introduce 2264. And we'll take our morning recess.
17
18
                   Thank you.
19
                          (A recess was taken.)
20
                   THE COURT: Please be seated.
21
                   Mr. Klein?
22
                   MR. KLEIN: Thank you, Your Honor.
2.3
     BY MR. KLEIN:
24
          Welcome back, Dr. Toth.
               We were on DDX 10.40, which is DX2264.
25
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1 Do you recognize this as the Grimsgaard 1998 2 reference? 3 Α Yes. 4 Okay. And this one is prior art, right? Q Α Yes. 6 MR. KLEIN: I'd move this into evidence, 7 DDX 2264. 8 MR. ELIKAN: No objection. 9 THE COURT: 2264 is admitted. 10 (Defendants' Exhibit 2264 received in evidence.) BY MR. KLEIN: 11 12 Grimsgaard 1998 is another reference that disclosed 13 4 grams of pure EPA, right? 14 Α Yes. 15 MR. KLEIN: Okay. Let's go to DDX 10.41. is DX 1545. 16 17 BY MR. KLEIN: 18 Do you recognize this as the Park reference from 2003? 19 Α I don't recall this, but I see the paper in front of me. 20 Okay. And this is, obviously, prior art, right? Q 21 Α Yes. 22 MR. KLEIN: Okay. I'd move into evidence 23 DX 1545. 24 MR. ELIKAN: No objection. 25

- 1 BY MR. KLEIN:
- 2 Q And Park discusses a study that used 4 grams per day of
- purified EPA to reduce triglycerides, right?
- 4 A Yes.
- 5 | Q **Let's go to --**
- 6 THE COURT: And let me interject. 1545 is
- 7 admitted.
- 8 (Defendants' Exhibit 1545 received in evidence.)
- 9 MR. KLEIN: Oh, I'm sorry.
- 10 Okay. Let's go to DDX 10.42. This is DX 1551.
- 11 BY MR. KLEIN:
- 12 Q Do you recognize this as the Wojenski article from 1990?
- 13 A **Yes.**
- 14 O And I believe this one is in evidence.
- 15 Wojenski is prior art, right?
- 16 A **Yes.**
- 17 Q And Wojenski disclosed a clinical trial with 4 grams per
- 18 | day of pure EPA, right?
- 19 A Yes.
- 20 | Q So, to recap, there are at least six prior art
- 21 | references, Mori 2000, Wojenski, Woodman 2002, Grimsgaard
- 22 1998, Woodman 2003, and Park, that disclosed the use of
- 4 grams per day of purified EPA to reduce triglycerides,
- 24 right?
- 25 A **Yes.**

- Q Okay. Now, are you offering the opinion, today, that as of March 2008, using 4 grams per day of purified EPA to reduce
- 3 triglycerides would not be obvious?
- 4 A It would not be obvious in very high triglycerides. But,
- 5 | these papers didn't look at very high triglycerides. So this
- 6 | would be -- it was used in patients with triglycerides less
- 7 | than 500.
- 8 Q Okay. So it certainly would be obvious to use 4 grams
- 9 | pure EPA to reduce triglycerides in patients below 500, right?
- 10 A Yes. It was done.
- 11 Q And in order for it to be obvious above 500, are you
- 12 saying there would need to be a clinical study addressing 4
- grams pure EPA, reducing triglycerides in patients above 500?
- 14 A Well, yes, we would like to see that.
- 15 Q Okay. Now, you don't know if that's the appropriate
- 16 | legal standard, correct?
- 17 A I'm not sure.
- 18 Q Now, as of March 2008, can we agree that the prior art
- 19 | would have at least motivated a skilled artisan to use 4 grams
- 20 per day of pure EPA in patients above 500?
- 21 A No, I would not agree to that.
- 22 Q Okay. So your opinion is the prior art wouldn't have
- 23 | even motivated a skilled artisan to use 4 grams per day of per
- 24 EPA in a patient population that has triglycerides above 500?
- 25 A That's correct.

- 1 Q Now, there were a finite number of pure EPA doses that
- were generally used in the prior art, do you agree?
- 3 A Yes.
- $4 \quad | \quad \bigcirc$  Okay. And generally, they were within the range of
- 5 2 grams to 4 grams a day, right?
- 6 A They were all over the place.
- 7 Q But most of them, the focus of the successful trials was
- 8 on 2 grams to 4 grams; is that right?
- 9 A I would have to look. I would have to look at what each
- one showed. But it's probably not unreasonable. But, I'm
- 11 | sure there were papers with lower doses as well.
- MR. KLEIN: Okay. Let's look at a document for
- 13 reference, DDX 10.44. This is DX 1862, page 93.
- 14 This is going back to that Amarin presentation
- 15 | from August 3, 2009, and I'm using this as a reference because
- 16 here Amarin went through a bunch of prior art clinical
- studies, and you can see -- actually, let's go back to DDX
- 18 | 10.43 because that might be a little easier to read.
- 19 BY MR. KLEIN:
- 20 Q Okay. So can you see that what Amarin did back in 2009
- 21 | was just summarize the doses used in various prior art
- 22 references. Do you see that?
- 23 | A I do.
- 24 Q And generally, most of them are in the 2 to 4 range.
- 25 Do you see that?

1	A Yeah, to me, most of them are in the 1.8 to 2.7 range.
2	MR. KLEIN: Okay. Now, let's go back to 10.44.
3	BY MR. KLEIN:
4	Q And it's the same document, but underneath you see,
5	"Amarin concluded that the analysis provides
6	reasonable evidence that doses of 2 to 4 grams per
7	day will be at or close to the maximum triglyceride
8	lowering activity of EPA."
9	Do you see that?
10	A I do see that.
11	${f Q}$ That's a reasonable reading of the prior art with regard
12	to dosing, correct?
13	A Yeah. I'd have to say based on the studies shown here,
14	yes.
15	Q And that's a finite number of available doses for pure
16	EPA, correct?
17	A Well, yeah, it's finite, but these, by no means,
18	established optimal. But, they are two doses you could have
19	used. Yes.
20	${\mathbb Q}$ Okay. Now, given that purified EPA lowered triglyceride
21	levels in patients below 500, you'd want to see if it also
22	lowered triglyceride levels in patients above 500, correct?
23	A Sure. You could try them, among the myriad of other
24	possibilities. But, yes, it would be of clinical interest.
25	Q Yeah. And it would have been of clinical interest back

- 1 | in March 2008, right?
- 2 A Sure.
- 3 Q And now the reason for distinguishing between patients
- 4 | below 500 and above 500 relates to pancreatitis risk, right?
- 5 A Yes. But, also reducing cardiovascular risk.
- 6 Q Right. But that 500 level is -- you talked about it in
- 7 ATP III -- that's really set because above 500, doctors should
- 8 be primarily concerned about pancreatitis risk, right?
- 9 A Well, that was the first priority. The second priority
- 10 was reducing cardiovascular risk.
- 11 Q Right. But that's why the 500 threshold is set for that
- 12 | first priority, correct?
- 13 A **Yes.**
- 14 Q Okay. Now -- and you talked about how pancreatitis is a
- 15 | serious condition, right?
- 16 A Yes. I sure did.
- 17 Q And so that 500-milligram threshold is set conservatively
- 18 to make sure you capture patients before they get
- 19 | pancreatitis, right?
- 20 A You want to capture and identify as many people at risk
- 21 | as possible.
- 22 Q Okay. And that 500 threshold has nothing to do with how
- 23 | a drug is going to affect LDL, right?
- 24 A The 500 threshold does, in fact, identify another
- 25 group of patients who responds very differently to

1	triglyceride-lowering medications in terms of how their
2	LDL increases. It very much defines a separate population.
3	${\tt Q}$ All right. And listen carefully to the question, please.
4	The 500 threshold was not set because above 500 you
5	are expected to have a greater increase in LDL-C in response
6	to a drug like Vascepa, correct?
7	A That's correct. But, people were aware of the problem.
8	$\cite{thirder}$ Okay. And a skilled artisan would know that a drug that
9	reduces triglycerides in a patient at 400, is very likely to
LO	also reduce triglycerides in a patient at 600, right?
L1	A Yeah. I don't think that would be contested.
L2	$\cite{thickness}$ Okay. And so based on the prior art, a skilled artisan,
L3	as of March 2008, would have reasonably expected purified EPA
L 4	to reduce triglyceride levels above 500, right?
L5	A Yeah.
L 6	MR. KLEIN: Let's go to DDX 10 point hold on.
L7	Okay. Let's go to DDX 10.45, and this is DX
L8	1705, page 6.
L9	BY MR. KLEIN:
20	Q This is a sentence from your response of expert report,
21	and I want to clarify whether this is and opinion you're
22	presenting today.
23	So, in your expert report, you said,
24	"A person of ordinary skill, in March 2008,
25	would not have been motivated to use a composition of

1 high purity EPA and substantially no DHA to lower 2 triglycerides in persons with very high 3 triglycerides." 4 Are you offering that opinion today and 5 yesterday? I sure am. 6 Α Okay. Now, that's a pretty extreme position in view of 8 the prior art, wouldn't you say? 9 Α Oh, not at all. 10 Okay. Doctor, using purified EPA to treat patients with 11 triglycerides of at least 500 was actually done in the prior 12 art, right? 13 In one or two people without much information on their 14 LDL? No, I would not say that that's true. 15 MR. KLEIN: Okay. Let's go to DDX 10.46. 16 BY MR. KLEIN: 17 And this was a slide that was used with Dr. Heinecke. 18 don't know if you've seen this. 19 I have seen it. 20 Okay. And for the record, there are five references on Q 21 this slide, DX 1532, page 5, DX 1550, page 32, DX 1546, 22 page 14, DX 1539, page 2, and DX 1537, page 23. 23 And you see on the screen there are references to

Hayashi from 1995, Saito from 1998, Takaku from 1991, and

Matsuzawa from 1991, and Nakamura from 1999.

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1 Do you see that? 2 Α I do, counsel. 3 Okay. And Dr. Heinecke testified that each of these 4 studies contains at least one patient with triglycerides above 500. 5 6 Are you aware of that? Α I am. 8 Do you dispute Dr. Heinecke's testimony? 9 Α I do. 10 So you dispute that these five references included at 11 least one patient above 500? 12 Well, as you know, I strongly disputed that there was one 13 patient over 500 in Hayashi. In Saito, Nakamura, Matsuzawa, Takaku, they do have one, and, in another case, three patients 14 15 over 500. 16 This does not constitute adequate evidence to me. 17 Okay. And let's -- let's unpack a little bit --18 Yeah. 19 -- to make sure I understand what you dispute. 20 You dispute that there's a patient above 500 in 21 Hayashi, correct? 22 Α Yes. 23 Do you dispute that there was at least one patient 24 treated with pure EPA, who had triglycerides above 500 in the 25 Saito, Takaku, Matsuzawa, and Nakamura references?

1 A I don't dispute that.

What I dispute is the reporting of the LDL. In two of those four references they used the Friedewald equation to estimate the LDL cholesterol which invalidates the analysis.

And Takaku also has missing data at two time points, and he also notes that six patients had insufficient sample with which to run measurements.

This is a very difficult set of papers to prove that EPA was used in a convincing way in patients with triglycerides over 500.

- Q Okay. And, Doctor, it's important to listen carefully to my question. I didn't ask anything about LDL. Okay?
- 13 A **Okay**.

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- Q So, to be clear, you don't dispute that at least one patient was treated with pure EPA, and the patient had triglycerides above 500 in Saito, Takaku, Matsuzawa, and Nakamura; is that correct?
- A I don't dispute that there were at least one patient in those four papers with triglycerides over 500. Hayashi, yes.
- 20 Q Okay. Good.
  - Now -- and we'll talk about Hayashi -- before we do so, on direct you testified there was nothing in the Epadel label that would lead a skilled artisan that Epadel could be used in patients above 500.
- 25 Do you remember that?

- 1 A Yes. It's too indistinct and nebulous to provide any
- 2 guidance on that issue.
- 3 MR. KLEIN: Okay. Let's go to DDX 10.127.
- 4 BY MR. KLEIN:
- 5 Q And, Doctor, this is DX 1528, which is the Epadel label.
- 6 And I'm focusing on pages 8 to 9.
- 7 You recall that there is a section called "Main
- 8 References" in the Epadel label, right?
- 9 A Yes, counsel.
- 10 Q Okay. And two of the references in the Epadel label are
- 11 Takaku, which is reference 8, and Matsuzawa, which is
- 12 reference 10, right?
- 13 A **Yes.**
- 14 Q And you agree that those two references included at least
- 15 one patient with triglycerides above 500, right?
- 16 A Without any information about what happened to -- okay.
- Say it again, counsel. I'm so sorry.
- 18 Q You don't dispute that these two references, Takaku and
- 19 Matsuzawa, included at least one patient with triglycerides
- 20 above 500, correct?
- 21 A That's correct.
- MR. KLEIN: Okay. Now let's go to DDX 10.47,
- 23 and this is DX 1542. In particular, I have page 4.
- 24 BY MR. KLEIN:
- 25 Q Do you recognize this as the Hayashi reference from 1995?

- 1 A I do, counsel.
- Q All right. And you don't dispute that this is prior art,
- 3 correct?

- A Oh, no.
- 5 Q Okay. And Hayashi says,
- of the ethylester of icosapent purified from fish
  oils on plasma lipids" -- and then if you skip a
  little bit, it says -- "in patients with familial
  combined hyperlipidemia (FCH) showing phenotype" -and among others, phenotype Type IV, right?
- A Well, the problem is familial combined hyperlipidemia -and they are referring to the Fredrickson system -- is Type

  IIb, not IIa, not IV, it's IIb. So FCH is inappropriately

  labeled Type IV here.
- Okay. But you recognize the Type IV as the same label we saw in the LIPITOR label, right?
- 18 | A **Uh** --
- 19 Q The same -- the same category.
- 20 A Okay, it might be. I don't know.
- Because if you're calling this a study of familial combined hyperlipidemia, which is strictly IIb, by the definition, IIa is familial hypercholesterolemia, and Type IV is an elevation of VLDL.
- So, no. I mean, I don't know if they followed,

- 1 | rigorously the definitions because -- clearly, they didn't.
- 2 Q Okay. But the paper is reporting that it's investigating
- 3 the effects of EPA in patients who fall within Type IV of the
- 4 Fredrickson system. That's what the paper's saying.
- 5 A Well, I dispute it because they say "patients with
- 6 | FCH" -- that is Type IIb alone.
- 7 Q Okay. But putting aside that maybe that was a typo, I
- 8 | don't know, but --
- 9 A Yes. Would I put it aside?
- 10 Q No, no. I'm just saying it because I'm asking you a
- 11 question. Phenotype Type IV is under the Fredrickson system,
- 12 right?
- 13 A **Yes.**
- 14  $\mid$  Q And that is the phenotype type that we looked at in the
- 15 | LIPITOR label and hour ago, right?
- 16 A Yes. But I have no indication that these people have any
- 17 | clue as to what they're talking about when they're mixing FCH
- with IIa, IIb, and Type IV. I'm sorry, I cannot do it.
- 19 Q Okay. I'm just asking you what the paper is saying.
- 20 A I'm telling you what the paper is saying.
- 21 Q Okay. Phenotype Type IV can include patients above 500,
- 22 right?
- 23 A It's typically to 499.
- 24 Q Okay. But in the LIPITOR label we saw is goes above 500,
- 25 | right?

- 1 A In the LIPITOR label, whatever standard they used. I
- 2 | can't speak for that --
- $3 \mid Q \quad \mathbf{Okay}.$
- 4 A -- but they called it IV.
- 5  $\mathbb{Q}$  And just to be clear, the standard being used in the
- 6 | LIPITOR label is the FDA standard, right?
- 7 A Did they say that?
- 8 Q FDA approved the LIPITOR label, correct?
- 9 A Yes, they did.
- 10 MR. KLEIN: All right. Let's go to DDX 10.49.
- 11 BY MR. KLEIN:
- 12 Q You are aware that Dr. Philip Lavin submitted a
- declaration during prosecution saying that there was not even
- 14 one patient in the study, the Hayashi study, that would be
- 15 expected to have a triglyceride level of 450 milligrams per
- 16 deciliter or higher, correct?
- 17 A My understanding was he said no one would be over 500 --
- 18 s, this is directly quoted from the declaration of Dr. Lavin?
- 19 Q Yeah. And that's not really material to my question --
- 20 A **Okay**.
- 21 Q -- but you understand Dr. Lavin submitted a declaration
- 22 to the patent office saying no one over 500 was -- no patient
- over 500 was in the Hayashi study, right?
- 24 A Yes, that I'm aware of.
- 25 Q And, for the record, we're looking at DX 1589, page 2.

- 1 A Could you please tell me which item that is.
- 2 | Q No. I -- I'm just establishing that one point. I don't
- 3 | think you need to look at the declaration to answer my next
- 4 question.
- 5 A **Okay**.
- 6 Q You didn't offer and independent opinion to corroborate
- 7 what Dr. Lavin said to the patent office, correct?
- 8 A That I provided the patent office with an independent
- 9 opinion?
- 10 Q No. You didn't offer an opinion -- Dr. Lavin is a
- 11 statistician, right?
- 12 | A **Yes.**
- 13 Q You didn't offer any type of statistical opinion to
- 14 | corroborate what Dr. Lavin told the patent office. That's
- 15 beyond your report and your testimony, correct?
- 16 A That's correct.
- 17 Q Okay. But you understand that Dr. Lavin later testified
- 18 | at deposition?
- 19 A **Yes.**
- 20 MR. KLEIN: Okay. Let's go to DDX 10.50.
- 21 BY MR. KLEIN:
- 22 Q And this is the Lavin deposition transcript at 103 --
- 23 | page 103, lines 8 to 21. And he was asked,
- 24 "Well, how could you have an average distance
- from the mean of 233 and not have people above the

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"ANSWER: Well, let's put it this way, in statistics it is possible. It is likely that you have at least one or two observations above 533. It isn't zero. Let's go on record there, it is not zero. But because the standard deviation is calculated from the numbers, you know that there must be at least one subject that is greater than one standard deviation to the plus.

"QUESTION: So given that, you would rewrite paragraph 12?

"ANSWER: I would."

Have you seen that testimony before?

- A I have.
- Q Okay. And do you dispute Dr. Lavin's testimony that it is likely that you will have at least one or two patients above 533 in the Hayashi study?
- 18 A I don't agree with it.

When I look at the graphs in the paper -- and I looked at all three very carefully, there are 25, 22 and 24 patients in that figure, there is no explanation as to what happened to the missing data.

And, counsel, you use the word "typo" when I talked about FCH in the Fredrickson classification. I strongly suspect that that standard deviation is a typo. If the data

- 1 isn't there, I do not believe in imputing it, and, there's no 2 way to estimate it.
- 3 Okay. That's because you are a data driven physician and 4 researcher, right?
- Α Yeah. Where's the data? If there's someone over 500 in 6 that paper, no one can show me where that patient is.
- 7 MR. KLEIN: Okay. Now let's go back to DDX
- 8 10.51.

- 9 BY MR. KLEIN:
- 10 We're back at Hayashi, which was DX 1532.
- 11 And you don't dispute that the patients in the
- Hayashi who were treated with EPA, showed a significant reduction in triglycerides have 41 percent, right?
- 14 That's in the paper. No.
- 15 Okay. And you don't dispute that EPA treatment had no
- 16 statistically significant effect on LDL-C as reported in
- 17 Hayashi, correct?
- 18 I do not dispute that. It's in the table --
- 19 0 Okay.
- 20 -- a statistically not significant 7 percent reduction.
- 21 MR. KLEIN: Let's go to DDX 10.52.
- 22 BY MR. KLEIN:
- And in the Discussion and Conclusion section of 2.3
- 24 Hayashi -- this is DX 1532 at page 7 -- the authors concluded,
- 25 "Although the effects of fish oils on plasma

- LDL-C and HDL-C are complex, judging from the present study, purified EPA apparently has no deleterious effect on plasma, LDL-C, or HDL-C in patients with
- 4 FCH," correct?
- 5 A Yes. Triglycerides less than 500.
- Okay. And the authors did not limit this conclusion in any way, right?
- A Well, they have to limit it to the data they have and they have no one with triglycerides over 500.
- 10 Q The authors did not say we would expect LDL-C spikes once you get above 500.
- A Well, that just might mean they don't know what to expect.
- 14 MR. KLEIN: All right. Let's go to DDX 10.588.
- 15 BY MR. KLEIN:
- 16 Q And I'm changing topics. I want to go back to your
- 17 testimony that Lovaza was -- had been prescribed with statins,
- 18 okay, to orient you.
- 19 A Thank you.
- 20 Q All right. So on the screen is DX 1578, page -- Table 2,
- 21 | page 1.
- 22 Do you recognize this as the Lovaza label?
- 23 | A **Yes.**
- Q Okay. And, again, the Lovaza label talks about how using
- 25 the drug to reduce very high triglycerides may result in LDL-C

- 1 elevations in some individuals, right?
- 2 A Yes.
- Now, to be clear, the Lovaza label isn't saying that the
- 4 drug always causes LDL-C increases, right?
- 5 A No drug always does one thing, and I think we've
- 6 established that. So, no, you're not going to see a uniform
- 7 response. There will be a distribution of responses.
- 8 Q Right -- except for cyanide, right?
- 9 A Yeah. There's one response to that.
- 10 MR. KLEIN: Okay. All right. So let's go to
- 11 DDX 10.59.
- 12 **BY MR. KLEIN:**
- 13 Q This is Table 1 from the Lovaza label -- still DX 1578,
- 14 page 1 -- and this table discusses Lovaza when used with
- 15 | simvastatin, right?
- 16 A **Yes**.
- 17 Q And simvastatin is, obviously, a statin, correct?
- 18 A **Yes.**
- 19 Q Okay. And this teaches that when Lovaza is used with
- 20 simvastatin, apo B is reduced by 4.2 percent, right?
- 21 A **Yes.**
- 22 Q Okay. And when Lovaza is used with simvastatin, there's
- 23 | barely any LDL-C increase, correct?
- 24 A **Yes.**
- 25 Q And that's -- and it says .7 percent, but that's not

- 1 | clinically significant, right?
- 2 A We'll take that as zero.
- 3 MR. KLEIN: Okay. Let's go to DDX 10.60. This
- 4 is DX 2005, page 8.
- 5 BY MR. KLEIN:
- 6 Q Do you recognize this as the Zocor simvastatin
- 7 | indication?
- 8 A Yes.
- 9 MR. KLEIN: I'll move into evidence DX 2005.
- 10 MR. ELIKAN: No objection.
- 11 THE COURT: 2005 is admitted.
- 12 (Defendants' Exhibit 2005 received in evidence.)
- 13 BY MR. KLEIN:
- 14 Q Simvastatin was approved to reduce elevated total
- 15 | cholesterol, LDL-C, apo B, among other things, right?
- 16 | A **Yes**.
- 17 Q Okay. Now focusing back on the Lovaza, you prescribed
- 18 | that drug frequently before March 2008, right?
- 19 A **Yes.**
- 20 Q Okay. And when you did so, you knew that the drug could
- 21 | increase LDL-C in some patients, right?
- 22 A Certainly.
- 23 Q Okay. And it didn't always increase LDL-C in your
- 24 patients, right?
- 25 A I would say it usually did. But, there's no blanket

- 1 statement.
- 2 Q Okay. And when you prescribed Lovaza, you didn't intend
- 3 for your patient's LDL-C to increase, right?
- 4 A No. I kept a close eye on that.
- 5 Q Right. You hoped it wouldn't increase, right?
- 6 A Yes.
- 7 Q And if it did increase, you would then prescribe a
- 8 | lipid-altering therapy, like a statin, correct?
- 9 A Yes. I was in attack mode then.
- 10 Q Okay. And a skilled artisan would know from the Lovaza
- 11 label, that taking 4 grams of Lovaza with a statin could
- 12 prevent LDL-C increases in patients with very high
- 13 | triglycerides, right?
- 14 A It could depending on the dose, depending upon the statin
- 15 potency. It could. I would qualify it with the word "could."
- 16 Q And a skilled artisan, as of March 2008, would understand
- 17 | that if a patient is experiencing LDL-C increases because of
- 18 Lovaza, a statin could be added, right?
- 19 A **Yes.**
- 20 Q And the label itself makes that clear, right?
- 21 A **Yes.**
- 22 Q Okay. And as of March 2008, it was known that Lovaza
- 23 | could be safely administered with statins, correct?
- 24 A **Yes.**
- MR. KLEIN: Let's go to DDX 10.61.

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1	D 37	M	T/T T7 T3T .
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- 2 Q I will represent to you that this comes from Amarin's validity contentions, and it's DX 1953, page 233.
- And Amarin -- these are -- this is something that

  Amarin created for this case -- said that,
- "The rise in LDL-C was often offset by

  concurrent treatment with statins. The safety and

  efficacy of using prescription Omega-3 in combination

  with a statin has been well-established."
- 10 Do you see that?
- 11 A I do.
- 12 Q That's an accurate statement, correct?
- 13 A It is accurate.
- 14 Q And, in fact, Lovaza was administered safely with statins
- all the time before March 2008, right?
- 16 A Yes. It could be safely co-administered.
- MR. KLEIN: Okay. Let's go to DDX 10.62.
- 18 BY MR. KLEIN:
- 19 Q Now, this is DX 1502, page 22. You recognize this as
- 20 claims 13 and 14 of the '715 patent, right?
- 21 A **Yes.**
- 22 Q And I'm including claim 13 because claim 14 depends on
- 23 | claim 13, you understand that?
- 24 A **Yes.**
- 25 Q Okay. And claim 13 includes a limitation "Who does not

- 1 receive a concurrent lipid-altering therapy."
- 2 Do you see that?
- $3 \mid A \quad Yes.$
- 4 Q Okay. And the claim also requires that there be "no
- 5 statistically significant increase in LDL-C or apo B," right?
- 6 A Yes.
- 7 Q Okay. I want to unpack these limitations to make it
- 8 clear how they relate to one another. Okay?
- 9 A **Okay**.
- 10 Q Now, a statin is, obviously, an example of a concurrent
- 11 lipid-altering therapy, right?
- 12 A Yes.
- 13 Q And as we discussed, statins can reduce LDL-C and apo B.
- 14 | They're approved for that, right?
- 15 A **Yes.**
- 16 Q Okay. And so this limitation requiring that the patient
- does not receive a concurrent lipid-altering therapy, makes it
- 18 clear that the pure EPA is having no effect on LDL-C or apo B.
- 19 Is that how you understand it?
- 20 A **Yes.**
- 21 Q Right.
- 22 A Yeah. So the apo B would, on average, go down; the LDL
- 23 | would, on average, be neutral.
- 24 Q Right.
- Now, by March 2008, it was known that EPA could be

- 1 used with a statin, correct?
- 2 A Yes.
- 3 MR. KLEIN: Okay. Let's go to DDX 10.62. This
- 4 is DX 1539.
- 5 BY MR. KLEIN:
- 6 Q Do you recognize this as the Nakamura reference?
- 7 A Yes.
- 8 Q And page 1, in Nakamura, used 900 to 18 [sic] milligrams
- 9 per day of EPA to patients with hyperlipidemia who had been
- 10 treated with HMG-CoA reductase inhibitors for 30 plus months,
- 11 | right?
- 12 A **Yes.**
- Okay. And just so we're clear, "HMG-CoA reductase
- 14 | inhibitors" is a fancy word for statin, right?
- 15 A Yeah. Hydroxymethylglutaryl coenzyme A reductase
- 16 inhibitors.
- 17 Q I was trying to avoid that.
- 18 A Yes, counsel, HMG-CoA.
- 19 Q Okay. And, by the way, Nakamura is one of those
- 20 references that included a patient above 500, right?
- 21 A Can you show me where? Let me see that.
- 22 Show me the paper, which --
- 23 | O Well --
- 24 A I just -- these papers are starting to float around in my
- 25 head.

1 Why don't we go back -- it might be easier to go back 2 to --3 THE COURT: Would it help to go back to the 4 chart where all the papers are listed? 5 MR. KLEIN: I'm just going to go back to 6 Dr. Heinecke's chart because I don't think it's disputed. 7 DDX 10.46, please. 8 THE WITNESS: Nakamura -- okay. Thank you. 9 Thank you, counsel. 10 BY MR. KLEIN: 11 All right. And so it was known by March 2008, that pure 12 EPA could be given with statins, even in patients above 500, 13 right? 14 Are you saying in Nakamura based on one patient, or based 15 on the label? 16 I'm saying based on the fact that pure EPA was given to 17 at least one patient above 500 with a statin, it was known 18 that pure EPA could be given to patients above 500 with a 19 statin, right? 20 If you take one patient seriously, okay. Yeah. 21 Okay. It was actually done in the art, in other words, 22 even if it's one patient --23 One patient. Yes.

Now -- and we'll talk about JELIS later, but JELIS

involved pure EPA with a statin as well, right?

24

- 1 A Yes.
- MR. KLEIN: Okay. Let's go back to DDX10.65. I
- 3 want to go back to claim 14 of the '715 patent. Again, this
- 4 | is DX 1502, page 22.
- 5 BY MR. KLEIN:
- 6 Q And so this claim expressly excludes use of a concurrent
- 7 | lipid-altering therapy, right?
- 8 A Yes.
- 9 Q And so -- and that's because a skilled artisan would know
- 10 that a patient taking pure EPA with a statin will not have an
- 11 LDL-C increase because statins reduce LDL-C, right?
- 12 A Depending upon the magnitude of the LDL elevation, yeah.
- 13 | So with that one qualification, the statin can neutralize that
- 14 | LDL elevation, but it depends on the baseline triglyceride.
- 15 **Yes**.
- 16 Q Right. So a skilled artisan, in 2008, would understand
- 17 | that if you give pure EPA with a statin, you're not going to
- 18 have a LDL-C increase, right?
- 19 A Well, you won't have as much of an LDL increase, or
- 20 perhaps you won't increase LDL.
- 21 Q Okay. And the same thing with apo B, a skilled artisan,
- 22 in March 2008, would understand that if you give a pure EPA
- 23 | with a statin, you're likely to have an apo B decrease,
- 24 correct?
- 25 A Yes, that would be logical.

- Okay. And that would be true whether the triglyceride level is 400 or 550, right?
  - A Again, no blanket statements. But, the odds are yes.
  - Q All right. So going back to claim 14, what claim 14 of the '715 patent is doing is it's avoiding this known method of using pure EPA with a statin to reduce LDL-C and apo B by saying the patient cannot receive a concurrent lipid-altering

9 Is that your understanding?

- A Repeat that, please.
- 11 | Q Okay. I'll try.

therapy.

- Claim 14 is -- the point of claim 14 is to carve out
  the known use of pure EPA with a statin to reduce not only
  triglycerides, but also LDL-C and apo B, by expressly saying
  the patient can't take a concurrent lipid-altering therapy,
  right?
- 17 A Okay. Well, let me unpack that a little bit.
- 18 | Q **Okay**.

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- A So, basically, they're saying that if you use 4 grams of purified EPA, 96 percent pure, you will induce a statistically significant reduction in triglycerides without affecting the statistically significant increase of apo B.
- 23 Q **Okay**.
- 24 A That's my reading.
- 25 Q All right. Let me try to simplify it a little bit.

- We talked about how pure EPA could be used with statins to reduce apo B and LDL-C, right?
- $3 \mid A \quad Yes.$
- 4 Q And that was known in March 2008?
- 5 A Yes.
- And so what this claim, claim 14 of the '715 patent is doing, is saying we're only claiming the use of EPA without a statin, and that pure EPA, itself, has to have no LDL-C
- 10 Is that your understanding?

increase and apo B reduction.

11 A Yes.

- 12 Q Okay. Now, to be clear, the prior art also taught that
- pure EPA, even 4 grams pure EPA, could be used without a
- 14 | statin to reduce triglycerides, right?
- 15 A **Yes.**
- 16 \Q And that's the Mori reference?
- 17 A No. No. No, no, no. No, no, no. Correct that.
- 18 Repeat that question, please.
- 19 Q I don't -- let's go to DDX 10.66 because I don't think
- 20 this will be disputed. So maybe you misheard my --
- 21 A Okay. Yeah.
- 22 Q This is DX 1538, pages 2 and 3.
- Do you recognize this as coming from the Mori 2000
- 24 reference?
- 25 A Yes, counsel.

- 1 Q And Mori used 4 grams pure EPA without a lipid-lowering
- 2 drug, correct?
- 3 A Yes.
- 4 Q Okay. That's all I was asking.
- 5 A Yes.
- 6 Q Okay. So there were clinical studies in the prior art
- 7 | that discuss using pure EPA to reduce triglycerides with and
- 8 without a statin, right?
- 9 A Yes, below 500.
- 10 Q Okay. Now, it would have been obvious to a skilled
- 11 artisan, before March 2008, to give a patient pure EPA, either
- 12 | with or without a statin below 500, right?
- 13 A Yes, it -- yes. Yes.
- 14 Q Okay. And you didn't provide any opinion disputing that
- 15 | it would be obvious to use pure EPA without a statin, right?
- 16 A I -- that I didn't dispute that you could use pure EPA
- 17 | without a statin?
- 18 Q Well, let's go back to the claim, which is DDX 10.62.
- 19 A Thank you.
- 20 Q All right. So with regard to the limitation "who does
- 21 | not receive a concurrent lipid-altering therapy, " you're not
- disputing that it would be obvious to use pure EPA without a
- 23 | concurrent lipid-altering therapy, right?
- 24 A Am I disputing claim 13?
- 25 Q No, not just -- I'm just focusing on that one limitation.

- 1 You're not disputing that it would have been obvious 2 to skilled artisan, in March 2008, to use pure EPA without a 3 concurrent lipid-altering therapy to reduce triglycerides, 4 correct? Based on this claim, no. All right. Now --6 Q You mean in patients with triglycerides of 500 to 1500? 8 Well, I -- well, I know you dispute above 500, right, so 9 I didn't ask the question above 500. 10 Α Okay. 11 MR. KLEIN: Okay. To be fair. 12 So let's go to DDX 10.67. This is another claim 13 in the patent that's being asserted, claim -- '677, claim 8, 14 and it's DX 1504, pages 21 and 22. 15 BY MR. KLEIN: 16 Do you see that? Q 17 Α Yes.
- 18 Q And you understand that claim 8 depends on claim 1?
- 19 A **Yes**.
- 20 Q Okay. And claim 8 requires a reduction in apo B.
- 21 Do you see that?
- 22 A **Yes.**
- 23 Q Claim 1 requires use of the drug without substantially
- 24 increasing LDL-C, right?
- 25 A **Yes.**

1 But claim 8 of the '677 patent does not exclude using a 2 concurrent lipid-altering therapy, correct? 3 A method of claim1 comprising administering to the 4 subject of 4 grams --5 THE COURT: Are you reading it to yourself? If you want to read it, just read it. Don't 6 7 read in out loud because, otherwise, you have to slow down if 8 you want to read it out loud. 9 THE WITNESS: Thank you. Thank you, Your Honor. 10 (Witness reviews document.) 11 Okay, counsel. So your question is? 12 BY MR. KLEIN: 13 Okay. Remember we looked at the limitation in one of the claims that had -- that says you must exclude a concurrent 14 15 lipid-altering therapy? 16 Α That you must exclude it? 17 Yeah. Remember, we just looked at that? It was -- do 18 you want me to put the claim back on? 19 Α If you would, please. 20 MR. KLEIN: Let's go to DDX 10.62 again. 21 THE WITNESS: I just don't recall that "you must 22 exclude it." 2.3 BY MR. KLEIN: 24 Q Okay, 62. 25 The first highlighting, remember, we talked about

- 1 | that limitation "who does not receive a concurrent
- 2 lipid-altering therapy"?
- 3 A Yes.
- 4 Q And you understand that that limitation in claim 14 means
- 5 | the claim doesn't cover situations where, for example, 4 grams
- 6 pure EPA is with a statin.
- 7 A That it, necessarily, excludes a statin?
- 8 Q Well, I mean the -- I'm not -- I'm not trying to trick
- 9 you here.
- 10 The limitation in claim 13 set a requirement of this
- 11 patent claim is that the patient not received a concurrent
- 12 | lipid-altering therapy, right?
- 13 A It states "who does not receive a concurrent
- 14 | lipid-altering therapy, " yes.
- 15 Q And so your understanding is to practice claim 14 of the
- 16 | '715 patent, you can't give the patient a statin in addition
- 17 to the EPA.
- 18 Do you understand that's how that claim works?
- 19 A So that you can't?
- 20 Q You can't, because the claim says the "patient does not
- 21 | receive a concurrent lipid-altering therapy."
- 22 A But it doesn't say that you can't receive a concurrent --
- 23 THE COURT: Perhaps, Mr. Klein, you could
- 24 rephrase your question and say assuming that --
- MR. KLEIN: Okay.

- 1 THE COURT: -- you have to accept this premise.
- 2 BY MR. KLEIN:
- 3 Q Now, Doctor, I know you're not a patent lawyer, okay,
- 4 so --
- 5 A Oh, I am not a patent lawyer.
- 6 Q All right. So do you have general understanding that
- some of the asserted claims in this case allow for the use of
- 8 a statin with icosapent, and some say you can't take icosapent
- 9 | with a statin?
- 10 A **Yes.**
- 11 Q Okay. And do you have general understanding that seven
- of the ten claims asserted in this case allow for the use of a
- 13 | statin with icosapent?
- 14 A **Yes.**
- 15 Q Okay. And so those claims that allow for the use of a
- 16 statin would include using 4 grams pure icosapent with a
- 17 | statin to -- and not have an LDL-C increase.
- 18 You understand that, right?
- 19 A **Yes.**
- 20 Q Okay. And those claims would also allow the use of
- 21 | 4 grams pure EPA -- again above 500 -- with a statin, to
- 22 reduce apo B, right?
- 23 A That would be one manifestation of the statin use would
- 24 be to help reduce apo B.
- MR. KLEIN: Okay. Thank you.

- Now, I want to switch gears a little bit here
  and talk about something you discussed on direct.
- 3 Mr. Gross, can you put up PX 989.
- 4 BY MR. KLEIN:
- Do you recognize PX 989 as the ATP III quidelines?
- 6 A Yes, counsel.
- 7 MR. KLEIN: Okay. Let's go to page 90 of the 8 exhibit. Hold on. I must have the wrong -- 190, I'm sorry.
- 9 Okay. Can you highlight the chart in the upper
- 10 right.
- 11 BY MR. KLEIN:
- 12 Q And do you remember talking about this chart on direct?
- 13 A **Yes.**
- 14 Q All right. And you talked about two genetic causes for
- 15 | very high triglycerides on the bottom right of this table,
- 16 | right?
- 17 A **Yes.**
- 18 Q And they are familial lipoprotein lipase deficiency, and
- 19 | familial apolipoprotein C-II deficiency, right?
- 20 A That was pretty good.
- 21 Q And those are the only two genetic causes of very high
- 22 | triglycerides listed in Table 7.2-1 of the ATP III guidelines,
- 23 right?
- 24 A In the Table; there's a third in the text.
- Q Okay. But the text also talks about how these two -- I

- 1 | won't repeat them again -- are the most frequently reported,
- 2 common genetic defects that cause very high triglycerides,
- 3 | right?
- 4 A Yes.
- 5 Q Okay. And to be clear, the first bullet says usually --
- 6 | the first bullet under very high triglycerides, says "usually
- 7 | combined causes," same for high triglycerides, right?
- 8 A Yes, it states that.
- 9 Q Okay. And though -- and that's referring back up to all
- 10 | the other causes of borderline high triglycerides and high
- 11 triglycerides, right?
- 12 A Some of them can be included, yes.
- 13 Q And so what this chart is teaching a skilled artisan is
- 14 that, you know, some patients can have these genetic defects,
- 15 and others may have all these other potential causes, right?
- 16 A It could be a mixed picture, yes. But, generally, it's
- qenetic. But, yeah, there could be combinations of causes.
- 18 Q Okay. And you talked about the MARINE study, right?
- 19 A **Yes**.
- 20 Q Okay. Now, the MARINE study focused on all these other
- 21 causes, and not those two genetic causes we talked about,
- 22 right?
- 23 A Well, I'm not sure that that's right.
- 24 Where does MARINE state that it's due to all these
- 25 other causes?

1	MR. KLEIN: All right. Let's go to DX 1694.
2	BY MR. KLEIN:
3	${\mathbb Q}$ Do you recognize DX 1694 as the Clinical Study Report for
4	MARINE?
5	A Yes, counsel. I'm just pulling up the paper here.
6	Q Sure. Let me know when you have it.
7	A Doesn't look like it's in this binder, but we can look at
8	the pages.
9	MR. KLEIN: Okay. Yeah. Let's go to pages 31
10	and 32.
11	Okay. You see let's highlight 9.3.2.
12	BY MR. KLEIN:
13	Q And do you see at the top it talks about "exclusion
L 4	criteria" for the study?
15	A Yes.
16	Q It says,
17	"Patients were to be excluded from
18	participation in the study if any of the following
19	criteria apply"
20	Do you see that?
21	A I do.
22	MR. KLEIN: Okay. Let's close that and go to
23	paragraph 11 on the next page.
24	This is, for the record, DX 1694, at page 32.
25	

- 1 BY MR. KLEIN:
- 2 Q Okay. And one of the exclusion criteria is known
- 3 | familial lipoprotein lipase impairment or deficiency,
- 4 Fredrickson Type I, apolipoprotein C-II deficiency, and also
- 5 | familial --
- 6 A Dysbetalipoproteinemia -- and court reporter, I'll spell
- 7 | that for you --
- 8 COURT REPORTER: I have it.
- 9 THE WITNESS: Okay. Thank you.
- 10 BY MR. KLEIN:
- 11 Q Okay. Fredrickson Type III, correct?
- 12 A **Yes**.
- 13 Q Okay. And so you understand that patients with these
- 14 genetic conditions for severe hypertriglyceridemia were
- 15 | excluded from the MARINE study?
- 16 A Based on the criteria, yes.
- 17 Q Now, let's turn to unmet need. You talked about that on
- 18 | direct, right?
- 19 A Yes.
- 20 Q That was one of the bases on which the examiner allowed
- 21 | the patents, right?
- 22 A **Yes.**
- 23 Q And in your opinion, Lovaza is one of the closest prior
- 24 | art to Vascepa, right?
- 25 A **Yes.**

- 1 Q Or the claims, really.
- 2 A Yes.
- 3 Q And there's no dispute that Lovaza and Vascepa are
- 4 | indicated for the same method of treatment, correct?
- 5 A Yes. They both have indications for severe
- 6 hypertriglyceridemia.
- 7 Q Okay. And some background, Lovaza was a very successful
- 8 drug, right?
- 9 A Yes.
- 10 Q It was a blockbuster, more than a billion dollars per
- 11 | year, right?
- 12 A That I don't know. But, yes, it was widely used.
- 13 Q Okay. And the LDL-C side effect of Lovaza did not stop
- doctors from prescribing the drug all the time, right?
- 15 A It's the best we had.
- 16 Q Including you; you prescribed it many, many times, right?
- 17 A I did.
- 18 Q And as discussed, the FDA-approved label allowed for the
- 19 use of Lovaza with a statin, if there were LDL-C issues,
- 20 right?
- 21 A You could. Yes.
- 22 Q And a skilled artisan, as of March 2008, would understand
- 23 | that if a patient experiences LDL-C increase from Lovaza, the
- 24 statin could be added to address that side effect, right?
- 25 A It could.

- 1 Q Yeah. And you served on the GSK Speakers Bureau for
- 2 Lovaza, right?
- 3 | A **I did.**
- 4 Q And when talking to doctors about Lovaza you discussed
- 5 | the LDL-C side effect, right?
- 6 A Of course.
- 7 Q And you told doctors to add an LDL lowering agent, such
- 8 as a statin, to address LDL effects from Lovaza, right?
- 9 A Yes.
- 10 Q And you told doctors that, in your experience, using a
- 11 statin helps reduce the LDL-C effects from Lovaza, right?
- 12 A **Yes.**
- 13 Q And I think you testified earlier that the vast majority
- 14 of patients who take Lovaza with a statin are able to tolerate
- 15 | the statin, correct?
- 16 A No, I did not say that the vast majority of patients who
- 17 take a statin with Lovaza have no problem tolerating the
- 18 statin.
- 19 Q **Okay**.
- 20 A What I did say in testimony yesterday -- and I think I
- 21 reiterate that today -- was that you could use a statin, but
- 22 there are limitations.
- 23 I mean, obviously, we would love to be able to use
- 24 high dose high potency statins for everybody who needs them,
- 25 | but not everyone can tolerate them. Some people don't

tolerate statins at all, unfortunately. Some people only
tolerate lower doses.

And my other caveat there was that if the LDL elevation was particularly severe, you might have to burn all of you LDL reducing capacity with a high dose high potency statin just to get them back to baseline.

But, yes, some patients you could get that LDL down just fine but not everyone.

- Q Okay. But you found that the use of statins by your patients taking Lovaza was typically well-tolerated, correct?
- 11 A It was typically well-tolerated.

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- Q Okay. And you did not see situations where Lovaza's patient's LDL-C increased to such a degree that the patient could not use the medication anymore, right?
  - A Well, okay. If the patient's LDL increase was severe, I might have to use two drugs to lower that LDL, like statin and, by way of example, acetamide. So, it would complicate the management of the patient. It would increase the expense of managing the LDL elevation.

But we did what we could to control it.

- Now, in the large majority of cases you saw no instance
   where patient's LDL-C increased to such a degree that you
   could not use the medication anymore; is that fair?
- A Well, again, it depends if the patient tolerated the statin, tolerated LDL-lowering medication. Again, I'm not

- 1 | going to make a blanket statement, but generally I was able to
- 2 deal with it. I'll say that.
- MR. KLEIN: Okay. Let's talk about REDUCE-IT.
- 4 Let's go to DDX 10.76.
- 5 BY MR. KLEIN:
- 6 Q And you'll probably recognize this as PDX 6.23 from your
- 7 | direct, right?
- 8 A Yes.
- 9 Q And you discussed whether REDUCE-IT has a nexus to the
- 10 | asserted claims, right?
- 11 A Yes.
- 12 \ Q Now, REDUCE-IT focused on patients with triglycerides
- 13 | below 500, right?
- 14 A **Yes.**
- 15 Q Okay. And you understand that none of the patent claims
- 16 at issue in this case have a limitation with regard to
- 17 | reducing cardiovascular risk?
- 18 A **Yes.**
- 19 Q And that none of the patent claims require patients to
- 20 have any cardiovascular risk factors, right?
- 21 A Well, having hypertriglyceridemia is a risk factor.
- 22 Q Okay. Well, aside from severe high triglycerides,
- 23 | there's no other risk factory required by the patents related
- 24 to cardiovascular issues, correct?
- 25 A That's correct.

- Q Okay. And you're not offering any opinion related to this rebuttable presumption that's on the screen, right?
- 3 | A **No.**
- Q Okay. But you do understand that Amarin has separate patents covering the method used in the REDUCE-IT study,
- 6 correct?
- 7 A Yes.

- Q And you understand that those patents are not being asserted in this case?
- 10 A **Yes.**
- 11 Q All right. And, of course, you understand the claims in
- 12 this case focus on treating patients for at least 12 weeks?
- 13 A **Yes.**
- 14 Q And you didn't offer any opinion that REDUCE-IT showed 15 any cardiovascular benefit with -- as of 12 weeks, right?
- A That's correct, with the caveat that by taking it for
  17 12 weeks, you would be altering that patient's lipid profile,
- inflammatory mediator profile, in ways that would be expected
- 19 to yield cardiovascular benefit over time.
- 20 Q But understand the patents cover situations where a 21 patient takes Vascepa for just four months, then stops, right?
- 22 A I must say I can't think of a patient that I started on 23 Vascepa and stopped in four months.
- Q Well, I mean -- and I don't want to get into issues of infringement. That's not my purpose here.

You understand that there -- that the claims cover a situation where the drug could be taken for four months and stopped, and that's within the scope of the claims.

You understand that, right?

A Yes.

right?

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- Okay. But you're not offering an opinion that a patient who takes the drug for four months and stops is going to have the cardiovascular benefits received in the REDUCE-IT trial,
- A Well, it takes time to accrue the benefit, and if you stop it at four months, the four months certainly laid the foundation to approach a period of time where you would expect benefit. But if you stop it at four months, then you're going to lose that benefit.
- Q And all the patients in REDUCE-IT were taking statins, right?
- 17 A **Yes.**
- 18 Q And -- so 100 percent, right?
- 19 A **Yes.**
- 20 Q And 25 percent of the patients in MARINE were taking 21 statins, right?
- 22 A That's correct.
- 23 Q And none the asserted claims require a statin, right?
- 24 A They don't require a statin. No.
- 25 Q And three of them actually say you can't take a statin,

- 1 | right? We talked about that earlier.
- 2 A Well, I didn't see the word "can't" in there, but I'm not
- 3 | a patent lawyer so --
- 4 Q I don't think that's disputed; just kidding.
- Now, REDUCE-IT did not have a monotherapy arm,
- 6 | right, with just Vascepa?
- 7 A Well, it would have been unethical to have just a Vascepa
- 8 monotherapy arm. The FDA would never allow it because statin
- 9 | therapy is the standard of care for patients in secondary
- 10 prevention for high risk diabetic patients.
- 11 Q Right. And statins like estrogen can affect lipids,
- 12 right?
- 13 A Well, of course.
- 14 MR. KLEIN: All right. Let's go to DDX 10.77.
- 15 BY MR. KLEIN:
- 16 Q And you will recognize this as PDX 6.29 from your direct,
- 17 | right?
- 18 | A I do.
- 19 Q And this is a chart entitled "Omega-3 Fatty Acid
- 20 Cardiovascular Outcomes Trial Underway As of March 2008,"
- 21 right?
- 22 A **Yes.**
- 23 Q And so there were eight Omega-3 fatty acids trials in
- 24 progress as of the alleged conception date, right?
- 25 A **Yes.**

- 1 | Q And in fact, all these trials were still pending when
- 2 Amarin filed its application in 2009, right?
- 3 A I have to refresh my memory about --
- 4 Q You can look at the dates. You can look at the dates in
- 5 | the first column.
- 6 A So you're not asking were they done, just were they
- 7 initiated?
- 8 Q Well, they weren't -- let me put this way.
- None of these study results were published by the
- 10 | time Amarin filed its application in 2009, correct?
- 11 A I don't believe so.
- 12 Q Okay. And the fact that there were eight cardiovascular
- 13 | studies, as of March 2008, and as of 2009, showed that there
- 14 | were high expectations that fish oil would have cardiovascular
- 15 | benefits, right?
- 16 A There were high expectations.
- 17 Q Yeah. And all eight of these failed.
- 18 You talk about that, right?
- 19 A Yes.
- 20 Q Okay. But a skilled artisan, as of March 2008, would not
- 21 | know that any of these trials were going to fail, right?
- 22 A As of 2008?
- 23 Q Right.
- 24 A That's correct. They were completed after.
- 25 Q Yeah. And even in 2009, a skilled artisan wouldn't know

- 1 | that any of these studies were going to fail, right?
- 2 A Correct.
- 3 Q And none of these trials used pure EPA?
- 4 A None of them used pure EPA.
- 5 Q And none of these trials were addressing patients with
- 6 | very high triglycerides, right?
- 7 A That's correct.
- 8 Q All right. Now, you talked on direct about how your
- 9 opinion is that REDUCE-IT showed unexpected results, right?
- 10 A **Oh**, yes.
- 11 Q But Amarin is not the first company to show that purified
- 12 EPA improves cardiovascular outcomes, can we agree on that?
- 13 A The JELIS trial had a positive primary composite
- 14 | endpoint, yes.
- 15 MR. KLEIN: Let's go to DDX 10.78.
- 16 BY MR. KLEIN:
- 17 Q And do you recognize DX 1553 as the Yokoyama 2007
- 18 reference discussing JELIS, right?
- 19 | A I do.
- 20 Q Okay. And this was published in the Lancet?
- 21 A **Yes.**
- 22 Q Which is a top medical journal, right?
- 23 | A **Yes.**
- 24 Q And it had a very strong reputation in the medical
- 25 **community?**

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- 1 A Yes.
- 2 | Q In fact, you were a peer reviewer, right?
- 3 A I'm still a peer reviewer. Yes.
- 4 Q Okay. You still are?
- 5 A **Yeah**.
- 6 Q Okay. And the peer review process is rigorous at the
- 7 | Lancet, right?
- 8 A Yes, it is.
- 9 MR. KLEIN: Okay. Let's go to DDX 0.79.
- We're still on DX 1553, page 1.
- 11 BY MR. KLEIN:
- 12 Q I don't think this is disputed either, but the study was
- 13 very large. It involved more than 18,000 Japanese patients
- 14 | with a five-year follow-up, right?
- 15 A **Yes.**
- 16 MR. KLEIN: Okay. And let's go to DDX 10.80.
- 17 | This is DX 1553, at page 2.
- 18 BY MR. KLEIN:
- 19 Q And Yokoyama used more than 98 percent pure EPA from
- 20 Mochida, correct?
- 21 A **Yes.**
- 22 Q And Mochida, you understand, makes Epadel?
- 23 A **Yes.**
- MR. KLEIN: Okay. Let's go to DDX 10.81.

- 1 BY MR. KLEIN:
- 2 Q The authors of the Yokoyama reference reported in the
- 3 | Lancet that major coronary events were reduced by 19 percent,
- 4 right?
- 5 | A **Yes.**
- 6 Q That's not disputed, correct?

patients," correct.

- 7 A **No.**
- 8 MR. KLEIN: Okay. And let's go to DDX 10.82.
- 9 BY MR. KLEIN:
- Q And this is the interpretation of the data, in the summary, where the author said,
- "EPA is a promising treatment for prevention of major coronary events, and especially nonfatal coronary events, in Japanese hypercholesterolemic
- 16 A **Yes.**
- Okay. And that conclusion was peer reviewed as well,
- 18 right?

- 19 A **Yes.**
- 20 Q And this is a pretty simple, straightforward conclusion,
- 21 right?
- 22 A It is. There were caveats in the paper, but that is a
- 23 | simple conclusion.
- Q Okay. And so in view of the JELIS study, a skilled
- 25 artisan, in March 2008, would have reasonably expected

- purified EPA to be a promising treatment to prevent major coronary events, correct?

  A Unstable angina? Yeah.
- Q Okay. And JELIS did not study DHA, right?
- 5 A It did not.

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- Q So JELIS provides at least one reason for a skilled artisan, in March 2008, to focus on pure EPA instead of pure DHA, correct?
  - A It -- the JELIS trial did demonstrate some efficacy, but it wasn't in -- here's the problem. And I know that I have stated that JELIS was a nice trial, but in the United States the interpretation would have been as follows.

The use of statins in this trial was so low, 5 milligrams of Simvastatin, 90 percent of the patients received Simvastatin 5, which no one even uses in the United States at that dose.

Ten percent were on Pravastatin 10. The patients had a baseline triglyceride 153. Their LDL was through the ceiling at 184.

The problem is that it's not convincing that the use of EPA, over and above a full therapeutic dose of a statin, reduced events.

Now, I get it, the primary composite endpoint was positive, but, even the FDA agreed that this study was not applicable to the U.S.

- 1 Q Okay. And we'll talk about that, I promise. But, it
- 2 | wasn't my question. So, please, listen carefully to my
- 3 question.
- 4 A I will, counsel.
- 5 Q Okay. JELIS provides at least one reason for a skilled
- 6 artisan to focus on using pure EPA over pure DHA, correct?
- 7 A Yes, that would be a reasonable conclusion.
- 8 Q Okay. And just in a short response to your last answer,
- 9 and we'll get into it in more depth --
- 10 A **Okay**.
- 11 Q -- what you're saying is that JELIS may have -- well, let
- 12 me ask you the question.
- Do you agree that the JELIS study reported in the
- 14 | Lancet, would have motivated a skilled artisan to run a
- 15 | similar type of study in the United States, to confirm that
- 16 | the results seen in JELIS would apply to a Western population?
- 17 A Yeah, it is an unsettled issue.
- 18 Q Okay. And by the way, on direct, you talked about a
- 19 | number of DHA studies related to cardiovascular issues, right?
- 20 A **Yes.**
- 21 Q None of those were outcome studies, correct?
- 22 A No, but they were also studies that would suggest it
- 23 | would not be smart to throw out the DHA.
- 24 Q Okay. But those studies were based on biomarkers, right?
- 25 A Correct. Like all of the studies you used as your

- 1 | principal prior art, none of them were outcome studies either.
- 2 Q JELIS was an outcome study, right?
- 3 A Yes. But, this was not part of your principal prior art.
- 4 Q Okay. Now, you -- and obviously, pure EPA was approved
- 5 by a regulatory body in Japan, right?
- 6 A Yes. That's correct.
- 7 | Q But on direct, you didn't talk about any approved pure
- 8 DHA product, correct?
- 9 A Approved --
- 10 Q To reduce -- yeah, to reduce triglycerides.
- 11 A Yes, that's correct. It was just used investigationally.
- MR. KLEIN: Now, let's go to DDX 10.122.
- 13 BY MR. KLEIN:
- 14 Q This is another document you used during your direct, PX
- 15 | **959**, pages 1 to 2.
- 16 Do you remember this one?
- 17 A Oh, yes.
- 18 Q Okay. And this is an editorial in the New England
- 19 | Journal of Medicine called "Fishing For the Miracle of EPA,"
- 20 right?
- 21 A Yes. It accompanied publication of the REDUCE-IT trial.
- 22 Q Right. And you cited this article to discuss praise for
- 23 | REDUCE-IT, right?
- 24 A **Yes.**
- 25 Q And you see the authors also discuss JELIS, right?

- 1 A Yes.
- 2 And they said,
- "We find it reassuring that the results
  reported by Bhatt are similar to those of the Japan
  EPA Lipid Intervention Study, JELIS, an open label
  trial, that reported that the risk of major adverse
  cardiovascular events was 19 percent lower," right?
- 8 A Yes.
- 9 Q And they're citing Yokoyama?
- 10 A They are.
- 11 Q Yeah. So the authors are not only praising REDUCE-IT,
- 12 | they're also praising all the effort that went into the JELIS
- 13 | study, right?
- 14 A They are citing it here.
- 15 Q And they're citing it in support, right?
- 16 They are citing JELIS to -- for the proposition that
- 17 | they are happy to see that REDUCE-IT confirmed the results of
- 18 | JELIS in a Western population, right?
- 19 A Well, they didn't say "confirm." They said are "similar
- 20 to" those of JELIS. Yes.
- 21 Q Okay. "Similar to," right?
- So to the authors of the New England Journal of
- 23 | Medicine editorial are reporting that the results of REDUCE-IT
- 24 | are similar to the results seen in JELIS, correct?
- 25 A That's what they state.

1	Q Okay. And you understand that Amarin's own documents
2	repeatedly say that JELIS showed that pure EPA reduces
3	cardiovascular risk?
4	A I don't know which documents you're talking about,
5	counsel. I don't know.
6	MR. KLEIN: Okay. Let's go and I understand
7	you weren't here for Dr. Ketchum, but let's go to DDX 10.83.
8	And this is DX 1829, page 10.
9	BY MR. KLEIN:
10	Q And here, this is an Amarin internal document, can you
11	see that. There's an Appendix 3. EPA and the JELIS study.
12	And Amarin said in this document, that,
13	"JELIS was set up to test the hypothesis that
14	long-term use of EPA is effective in reduction of
15	major coronary events in Japanese
16	hypercholesterolemia patients given statins," right?
17	A Yes.
18	MR. KLEIN: Okay. Let's go to DDX 10.84, and
19	we're in the same document, DX 1829, page 10.
20	BY MR. KLEIN:
21	<pre>Q And in this document they say,</pre>
22	"In summary, the JELIS study showed that the
23	frequency of major coronary events is reduced with
24	EPA 19 percent compared to controls."
25	Do you see that?

- 1 A I do.
- 2 Q And that's accurately characterizing the JELIS study
- 3 results, right?
- 4 A Yes. Based on the primary composite endpoint, yes.
- 5 MR. KLEIN: Okay. Let's go to DDX 10.85. This
- 6 is another document we looked at earlier, DX 1862, page 54.
- 7 BY MR. KLEIN:
- 8 Q This is the August 2009 presentation that Amarin prepared
- 9 | for a partner, Arisaph. Do you remember talking about that?
- 10 We talked about that earlier.
- 11 A Yes, I do.
- 12 Q Okay. And on this slide, this slide is called "Proven
- 13 | Cardiovascular Outcomes, JELIS Study."
- 14 Do you see that?
- 15 A I do.
- 16 Q And Amarin's description of the JELIS study in this
- document, for one of its potential partners, is an accurate
- 18 characterization of the JELIS study results, correct?
- 19 A "More than 18,000 Japanese patients; all
- administered statins, primary and secondary
- 21 prevention; five-year follow-up; 1.8 grams of EPA per
- 22 day or nothing." Yes.
- 23 Q Okay. Including the title, "Proven Cardiovascular
- 24 Outcomes," that accurately characterizes the JELIS study
- 25 results, right?

- 1 A For the primary composite endpoint nonstable angina, yes.
- 2 Q And you didn't see any limitation in this slide to the
- 3 primary composite endpoint, right?
  - A That's correct, counsel.
- 5 MR. KLEIN: Okay. Let's go down to DDX 10.86.
- 6 Here's another slide, DX 1862, page 55.
- 7 BY MR. KLEIN:

- 8 Q And this study, this slide says "JELIS Study, EPA Reduces
- 9 | Coronary Events?"
- 10 Do you see that?
- 11 A Yes.
- 12 Q And underneath it says,
- 13 "EPA Decreased Risks By 53 Percent in
- 14 Coronary Events in the Patient Subgroup with both
- 15 high triglycerides and low HDL cholesterol," correct?
- 16 A It states that.
- 17 Q Right. And we'll talk about that later.
- 18 But Amarin is accurately characterizing the JELIS
- 19 | study in slide 55 -- or in DX 1862, page 55, correct?
- 20 A It's factually correct.
- 21 Q And you understand that Amarin made similar statements to
- 22 | it's regulator, the FDA, right?
- 23 A May I see?
- 24 MR. KLEIN: Sure. Let's go to DDX 10.87, and
- 25 | this is DX 1836. I just have page 71.

- 1 BY MR. KLEIN:
- 2 Q But you are familiar with this document where Amarin
- 3 | submitted a formal dispute resolution request related to
- 4 | ANCHOR study, right?
- 5 | A **Yes.**
- 6 Q And I'm not going to go through this document in detail
- 7 | because we've done that with another witness, but Amarin told
- 8 | the FDA that it believes that the JELIS study results should
- 9 | not be dismissed lightly, right?
- 10 A It says that here.
- 11 Q Okay. But you're not testifying that Amarin overstated
- 12 the results of the JELIS study to the FDA, right?
- 13 A No, I'm just offering my own opinion.
- MR. KLEIN: Okay. Let's go to DDX 10.88. This
- 15 is a -- this is DX 2235 at page 70.
- 16 BY MR. KLEIN:
- 17 Q And can you see that this is a presentation from Amarin
- 18 to the FDA advisory committee for Vascepa?
- 19 A Yes.
- 20 Q Do you see that?
- 21 A This I haven't seen before.
- 22 Q Okay. Well, this is the more recent document. You see
- 23 | it's called "Mineral Oil Placebo Analyses"?
- 24 A **Yes.**
- 25 Q And the last bullet says,

- 1 "A prior trial reported a cardiovascular
- benefit with EPA consistent with REDUCE-IT," right?
- 3 A It states that.
- 4 Q And you can see that Amarin is referring to JELIS as the
- 5 prior trial that reported a cardiovascular benefit with EPA
- 6 | consistent with REDUCE-IT, right?
- 7 A It suggests that, yes.
- 8 Q Okay. And that's an accurate statement that Amarin made
- 9 to the FDA, right?
- 10 A I wouldn't dispute what Amarin said.
- MR. KLEIN: Okay. Let's go to DDX 10.89, and
- 12 | this is PX 583.
- 13 BY MR. KLEIN:
- 14 Q This is a 2017 Vascepa operating plan. It's quantitative
- 15 research by a company called GFK from 2017. Do you see that?
- 16 | A I do.
- Okay. And I'll represent to you -- have you seen this
- 18 document before?
- 19 | A **No, sir.**
- 20 Q Okay. I'll represent to you that it was produced to us
- 21 from Amarin. Okay?
- MR. KLEIN: Your Honor, I move into evidence PX
- 23 **583.**
- 24 THE COURT: Any objection?
- MR. ELIKAN: No objection.

1 MR. KLEIN: Okay. 2 THE COURT: 583 is admitted. 3 (Plaintiffs' Exhibit 583 received in evidence.) BY MR. KLEIN: 4 And so the document is called Vascepa SFE, sales force effectiveness, Q3 2017, Quantitative Research. Do you see 6 7 that? 8 Α Yes. 9 And do you understand that Amarin was presenting JELIS 10 data to physicians when marketing Vascepa? 11 Α Yes. 12 MR. KLEIN: Okay. Let's go to DDX 10.90. And 13 you can see -- this is PX 583 at page 6. 14 BY MR. KLEIN: 15 You can see according to this, this document, the 16 recommendation is to continue to leverage the JELIS data as 17 reduction in cardiovascular events with EPA to explain it is a 18 compelling part of the Vascepa story. Do you see that? 19 I do. 20 And do you understand that Amarin was telling doctors that JELIS data showed a reduction in cardiovascular events? 21 22 Α Yes. 23 And Amarin was not mischaracterizing JELIS to 24 physicians, right?

No, I don't imagine they would.

- 1 Q Okay. Now -- and, Doctor, you personally have praised
- 2 | the JELIS trial as demonstrating that the addition of EPA to
- 3 ongoing statin therapy incurred benefit, right?
- 4 A Say that again, counsel?
- 5 Q You personally praised the JELIS trial, right?
- 6 A I have.
- 7 MR. KLEIN: Let's go to DDX 10.91. This is DX
- 8 | 3009. I don't believe this is on the exhibit list so I'll
- 9 | flag that upfront, but I will -- it's being used for
- 10 impeachment.
- 11 BY MR. KLEIN:
- 12 Q This is an article you wrote in 2018 called "Elevated
- 13 | Triglycerides: Diabetes May Be Predictors of Major
- 14 | Cardiovascular Events, "right?
- 15 A Counsel, I didn't write it. It was an article about some
- 16 research I did.
- 17 Q I'm sorry, I stand corrected. You were discussed in this
- 18 | article, right?
- 19 A **Yes.**
- 20 Q Okay. You're right.
- 21 And it says that you and colleagues conducted a
- 22 retrospective administrative claims analysis of the Optum
- 23 research database to identify outcomes of patients treated
- 24 | with a statin drug, right?
- 25 A **Yes**.

1	Q And the purpose of this study was to further understand
2	the real-world burdens of elevated triglyceride level and
3	diabetes, right?
4	A Yes.
5	Q And if I didn't say this, it was published June 23rd,
6	2018, right?
7	A Well, yeah. But I'll be honest with you, I don't know
8	what the contents of this is, so you'll have it take me
9	through it.
10	MR. KLEIN: Okay. Well, let's go to DDX 10.92.
11	This is a statement attributed to you in the article.
12	THE WITNESS: Okay.
13	MR. KLEIN: Like you said, you didn't write the
14	article.
15	THE WITNESS: Okay.
16	BY MR. KLEIN:
17	Q I want to skip the first sentence, but the next sentence
18	starts,
19	"If the patient's primary residual issue was
20	elevated triglyceride, there is support from the
21	JELIS trial which demonstrated that the addition of
22	EPA to ongoing statin therapy, particularly in
23	patients with triglycerides over 150, incurred
24	benefit."
25	Do you see that?

- 1 A Yes.
- 2 Q Is that a statement that you made?
- 3 A I'm sure it is.
- 4 Q Okay. And so -- and this is as recent as 2018, right?
- 5 A Yes.
- 6 Q Okay. And what -- again, what you said here just to
- 7 emphasize, is that you characterized the JELIS trial as
- 8 demonstrating that the addition of EPA to statin therapy
- 9 | incurred cardiovascular benefit, right?
- 10 A **Yes.**
- MR. KLEIN: Okay. Now, let's go to DDX -- oh, I
- want to move into evidence DX 3009.
- 13 MR. ELIKAN: Your Honor, it's just been used as
  14 impeachment, it's not on the exhibit list. We don't believe
- 15 it's properly admitted into evidence.
- He hasn't written it, he's never seen the

  contents. Principally it's not on the exhibit list which was

  supposed to be final in January.
- So, while it's being used as impeachment, that's fine, but we don't understand why it should be admitted.
- 21 THE COURT: Mr. Klein?
- MR. KLEIN: The local rule doesn't -- the local
  rule and the pretrial order just say that impeachment evidence
  does not have to be on the exhibit list. It doesn't say it
- 25

can't be introduced during the cross-examination, and Dr. Toth

1	adopted this statement. It's attributed to him in the
2	article.
3	THE COURT: Any response, counsel?
4	MR. ELIKAN: I don't understand how that makes
5	the article admissible. There's a statement, it's attributed
6	to him, all of that is in the record. And the local rules
7	don't say that things that are used for impeachment can be
8	added to the exhibit list.
9	THE COURT: I'm sorry, so is the objection that
10	this is not a document that's been marked as an exhibit or
11	does the objection go to relevance?
12	MR. ELIKAN: It's hearsay, and it's also not on
13	the exhibit list. This is pure hearsay. It's being offered,
14	I think, to prove the truth of the matter asserted. If not,
15	then it's impeachment, and it's being used as such.
16	THE COURT: The objection is overruled.
17	To the extent that the objection is that it's
18	not on the exhibit list, I agree with Mr. Klein, the local
19	rules allow for an exception of impeachment evidence. You
20	don't have to share impeachment evidence in advance of
21	impeaching the witness.
22	As to relevance, Dr. Toth has adopted the
23	statement, and so that would overcome any hearsay objection.
24	The objection is overruled and Exhibit DX 3009
25	will be admitted.

1	(Defendants' Exhibit 3009 received in evidence.)
2	MR. KLEIN: Thank you. Let's go to another
3	exhibit, DDX 10.112.
4	BY MR. KLEIN:
5	Q Now, Dr. Toth, this is one of your articles, right?
6	A Yes. "Drug Treatment of Hypertriglyceridemia." Yep.
7	Q This is DX 3020, page 12. This is another document being
8	used for impeachment that is not on the exhibit list.
9	This was published in Drugs 2010, right?
10	A Yes, that's the date.
11	MR. KLEIN: Okay. And, well, why don't I go
12	ahead and move DX 3020 into evidence.
13	MR. ELIKAN: Your Honor, I object on the same
14	bases as before.
15	THE COURT: Mr. Klein, you need to establish the
16	relevance.
17	MR. KLEIN: Okay.
18	BY MR. KLEIN:
19	Q Section 3.6 of your chart is called Fish Oils, right?
20	A Yes.
21	Q And you say,
22	"The cardiovascular benefits of omega-3 fatty
23	acids, fish oils, EPA, and DHA are well documented,"
24	right?
25	A Yes.

1	MR. KLEIN: And let's go to DDX 10.113.
2	BY MR. KLEIN:
3	Q This is the conclusions of your article, right?
4	A Yes.
5	$\mathbb Q$ And here I'm just going to read what's highlighted on the
6	screen, and just for the record, it's DX 3020 at page 13.
7	You said,
8	"There is strong evidence to support the use
9	of statins, fibrates, niacin, BAS, and fish oils.
L O	Each of these drugs exerts its effects through
11	distinct but often complementary mechanisms."
12	Then you say, "The combination of statins
13	with niacin and fish oils has been studied
L 4	prospectively in the Haas and JELIS trials
15	respectfully. These combinations are effective and
16	provide incremental benefit beyond statin
17	monotherapy."
18	Is that what you said in the article?
19	A Clearly.
20	MR. KLEIN: Okay. Now I move into evidence DX
21	3020.
22	MR. ELIKAN: No objection.
23	THE COURT: Without any objection DX 3020
24	admitted.
25	

1 (Defendants' Exhibit 3020 received in evidence.) 2 MR. KLEIN: Let's go to DDX 10.96, and this is 3 DX 1709, pages 16 through 17. BY MR. KLEIN: 4 5 And do you recognize this document as 6 "Hypertriglyceridemia: Managing Triglycerides to Reduce 7 Cardiovascular Risk"? 8 Yes, counsel. You and I have been through this before. 9 Q Yes, right, and this one is on the exhibit list. 10 It was released or published in March 2015, right? 11 Α Yes. 12 MR. KLEIN: Okay. I'll go ahead and move in DX 13 1709. 14 MR. ELIKAN: No objection. 15 THE COURT: 1709 is admitted. 16 (Defendants' Exhibit 1709 received in evidence.) 17 BY MR. KLEIN: 18 And this article related to an interview that you had 19 with Dr. Bays, right? 2.0 Α Yes. 21 And we had talked about Dr. Bays, and you talked about 22 him, right? 23 Α Yes. 24 He was the primary investigator for MARINE? 25 Α Yes.

1 Q And he asked,

"Do we have any clinical trial evidence that administering omega-3 fatty acids reduces atherosclerotic cardiovascular events?"

And you replied, "We do. We have two important studies and there are two others in process."

I'm not going to read your whole answer, but later on you said,

"There is also a nice Japanese study called JELIS in which all the participants were on background statin therapy. The study included both primary and secondary prevention patients. Of note, there was a statistically significant important reduction in the primary composite endpoint, and, once again, in the subgroup of patients with high triglyceride, low HDL, there was a whopping 53 percent reduction in risk for the primary composite endpoint."

Is that the answer you gave to Dr. Bays' question?

- A That's the answer I gave.
- Q And so you told your colleagues back in 2015 and at other points in time that the JELIS cardiovascular results showed promise at a very minimum, right?

A Yes, I did. And I take responsibility for that.

But I also take responsibility for the fact that I didn't do a great job of looking under the hood of the entire spectrum of results in the study, and, instead, I just focused on the primary composite endpoints.

And when I say "looking under the hood," I didn't do a very critical analysis of all the endpoints that were offered in the study which showed considerable weaknesses in the study.

But that quote is mine.

- Q Okay. When you referred to "looking under the hood," what you're talking about is the efforts that you undertook as an expert witness retained by Amarin for this case, right?
- A Well, actually, it stemmed from a lot of issues.

When the REDUCE-IT trial first came out, there were lots of questions swirling about how well do the studies stack up together, and when you did look under the hood and read the FDA report, there were lots of issues concerning the individual endpoints, and we've revealed that in testimony yesterday and today.

- Q And the issues you're talking about are issues relating to whether the JELIS trial study design would meet the FDA requirements for a clinical study to support a new indication, right?
- 25 A And the large number of differences between the outcomes

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- of the studies and how significant different outcomes were
- 2 between the two. So, yeah, there are a lot of differences
- 3 between them.
- 4 Q Okay. And you understand when the FDA addressed Amarin's
- 5 characterizations of the JELIS trial, that was in the context
- 6 of Amarin requesting a new FDA-approved indication, right?
- 7 A I would imagine. But JELIS also did not get Epadel any
- 8 approval in the United States, and the reason for that is
- 9 there were weaknesses in the study.
- 10 Q And you certainly understand that to get approval of a
- drug by the FDA in the United States is a very rigorous
- 12 process, right?
- 13 A Yes, it is.
- 14 MR. KLEIN: Now, let's go to DDX 10.97.
- 15 BY MR. KLEIN:
- 16 Q And remember you talked in the interview with Dr. Bays
- 17 | about a whopping 53 percent increase?
- 18 A Yes, I did.
- 19 Q Okay. You were referring to this Saito article, I
- 20 believe?
- 21 A **Yes.**
- 23 | A I was.
- 24 MR. KLEIN: And Saito is DX 1547, and I'm
- 25 referring to pages 1 and 5. This is on the exhibit list so I

1	would move it into evidence.
2	MR. ELIKAN: No objection.
3	THE COURT: 1547 is admitted.
4	(Defendants' Exhibit 1547 received in
5	evidence.) BY MR. KLEIN:
6	${\mathbb Q}$ Okay. And I'm just going to summarize the results at the
7	bottom of the snapshot on the screen.
8	Saito reported that,
9	"Those with abnormal levels, triglycerides
10	above 500, and HDL under 40 milligrams per deciliter
11	had significantly higher CAD hazard ratio. In this
12	higher risk group EPA treatment suppressed the risk
13	of CAD by 53 percent," right?
14	A Yes, when you look at the Yokoyama parent manuscript, it
15	said that the study was not powered to perform subgroup
16	analyses, and so this particular analysis would have to be
17	regarded as hypothesis generating only.
18	Q But this hypothesis was published, correct?
19	A Yeah, sure, it was.
20	${\mathbb Q}$ And a skilled artisan at least as of June 2008 would have
21	seen Saito, right?
22	A They could have, yes.
23	Q And, now, I want to talk about that date because
24	June 2008 is after March 25th, 2008, right?
25	A Yes.

- 1 MR. KLEIN: Okay. Let's go to DDX 10.98, and
- 2 that is DX 1524 pages 39, and 13 and 14.
- 3 BY MR. KLEIN:
- 4 Q And this is the WO '118 reference. Do you remember this?
- 5 A Yes.
- 6 Q And it's dated December 13th, 2007, right?
- 7 A Do you I remember this?
- 8 Can I see another part of the document just to 9 refresh my memory?
- \_ \_
- 10 Q Sure, you should have DX 1524 in your binder, I hope.
- 11 A **1524.** I do.
- Okay. Go ahead, counsel.
- 13 Q All right. This reference from 2007 talks about -- well,
- 14 | you see the bottom Figure 2, you see Figure 2 is a graph
- 15 prepared by plotting the incidence of cardiovascular event for
- 16 patients having risk factors of triglycerides of at least
- 17 | 150 milligrams per deciliter?
- 18 A **Yes.**
- 19 Q Okay. If we go DDX 10.99, this is DX 1524, page 2, this
- 20 is a figure that's representing what the Saito reference was
- 21 talking about, right?
- 22 A **Yes.**
- 23 Q Okay. And then if we go to DDX 10.100, this reference
- 24 says,
- 25 "As evident from Table 3 and Figure 2, EPA

- significantly suppressed occurrence of cardiovascular
  events in the patients having the risk factors of
  triglycerides of at least 150, and the rate of
  suppression of the cardiovascular event occurrence
  was 53 percent," referring back to Figure 2, right?
- 6 A Yes.
- Q So, in short, this reference from 2007 is revealing to a skilled artisan the same information that the Saito 2008 reference talked about?
- 10 A Yes. But, it was hypothesis generating only.
- 11 Q Okay. And this, just to be clear, was before March 25th,
- 12 **2008**, right?
- 13 A **Yes.**
- 14 Q Now, Doctor, in view of all the documents we reviewed
- 15 from the prior art and Amarin and your own articles, JELIS
- 16 clearly provided at least a reasonable expectation of
- achieving the same type of cardiovascular events and outcomes
- 18 | that we saw in REDUCE-IT, right?
- 19 A With big differences between the studies.
- 20 | Q Yeah, but JELIS would have provided a reasonable
- 21 expectation that what we saw in REDUCE-IT, we would get
- 22 | something similar, right?
- 23 A Perhaps.
- 24 Q **Okay**.
- 25 A My beef with it is that the statins were profoundly

- 1 | underdosed, and you don't know if would you have reproduced
- 2 that data with more appropriate Western level statin dosing,
- 3 and that's a big problem.
- 4 Q Okay. And, in your view, what REDUCE-IT did was prove
- 5 | that the JELIS study results can translate to a western
- 6 population correct?
- 7 A No, I wouldn't say that.
- 8 Q JELIS didn't prove that?
- 9 A That -- that it proves what JELIS -- say it again.
- 10 Q Okay. JELIS proved -- sorry.
- REDUCE-IT proved that pure EPA can be used and
- achieve coronary benefits similar to those that were achieved
- 13 in Japanese patients in the JELIS study, correct?
- 14 A The REDUCE-IT trial went far beyond that, but it did show
- 15 that the use of EPA in combination with a statin does provide
- 16 | across-the-board, incremental reductions in cardiovascular
- 17 | events, yes.
- MR. KLEIN: Okay. Now, let's go back to DDX
- 19 **10.101** where we started.
- 20 BY MR. KLEIN:
- 21 Q Okay. Now, despite everything we've discussed so far, do
- you still dispute the simple logic of defendants' obviousness
- 23 | theory?
- 24 A Yes, I do.
- Q Okay. Now, Doctor, you've got a long -- you've had

- 1 | longstanding business relationships with Amarin, right?
- 2 A Yes, counsel. Here we go.
- 3 Q Yep. Okay.
- 4 You've been a member of Amarin's Speakers Bureau for
- 5 | five, six years, something like that?
- 6 A Lay it on me, man.
- 7 Q You have to say yes or no.
- 8 A Yes. Yes, counsel.
- 9 Q And you lecture to other physicians and healthcare
- 10 providers about Vascepa?
- 11 A I do; very proudly, too.
- 12 Q Okay. And you're still a member of Amarin's Speakers
- 13 | Bureau, right?
- 14 A **Yes.**
- 15 Q You've consulted with Amarin on a variety of research
- 16 | projects?
- 17 A Yes, important projects.
- 18 Q Over the years you've entered into a number of consulting
- 19 | agreements was Amarin, right?
- 20 A Probably -- well, one that led to 14 publications.
- 21 | That's the major one. I don't know if there's another
- 22 consulting arrangement. I am a member of the Speakers Bureau,
- 23 **uh-huh**.
- 24 Q Well, you were a consultant to Amarin in connection with
- 25 | the REDUCE-IT study, right?

- 1 A No, I was not an investigator in REDUCE-IT.
- 2 | Q **Uh** --
- 3 A I was an investigator in STRENGTH, but not REDUCE-IT.
- 4 Q So you did not have a consultancy relationship with
- 5 Amarin concerning the REDUCE-IT study?
- 6 A No, sir, not apart from this case.
- 7 Q All right. But you've repeatedly worked with Amarin to
- 8 | publish articles, right?
- 9 A Yeah, yeah.
- 10 Q And you know the scientists at Amarin?
- 11 A You know, I don't know scientists at Amarin. We've done
- 12 | strictly clinical database research, and I have not had
- 13 | contact with Amarin scientists per se.
- 14 Q What about Seffy Philip and Craig Granowitz?
- 15 A Yeah, they're not Amarin scientists, they're -- Craig is
- 16 the medical director and Seffy Philip is a pharmacologist, but
- 17 he doesn't do research.
- 18 Q I see, okay. I'm sorry to use the term scientist. But
- 19 you certainly know those individuals at Amarin, right?
- 20 A **Yes, I do.**
- 21 MR. KLEIN: Okay. Let's go to DDX 10.114.
- 22 BY MR. KLEIN:
- 23 | Q And I'm going to go through these slides quickly. I'm
- 24 | not going to discuss the substance or even move them into
- 25 **evidence**.

1	But generally there are three references on DDX
2	10.114 where you were co-authoring articles in the last two
3	years with individuals from Amarin, right?
4	A Yes.
5	Q Okay. And some of these articles even disclose that
6	you're a consultant or speaker for Amarin, right?
7	A Oh, they all do.
8	MR. KLEIN: And, for the record, I don't think I
9	need to move them in, it's DX 3010, DX 3011 and DX 3012.
10	And could we go to DDX 10.115.
11	BY MR. KLEIN:
12	Q This demonstrative shows three more articles along the
13	same lines, right?
L 4	A Oh, there will be more.
15	Q Yeah, that was my next question. Okay.
16	And Amarin has paid you substantial sums for
17	consulting work unrelated to this case, right?
18	A I wouldn't call it substantial sums, but they've paid me.
19	MR. KLEIN: Okay. Let's go to DDX 10.108.
20	BY MR. KLEIN:
21	Q Doctor, you're aware that payments to you from Pharma
22	companies, not just you but all doctors, are publicly
23	available on a government website?
24	A Yes, it's a favorite site for newspaper reporters and
25	lawyers.

- 1 Q I know what you're referring to. I'm not getting into 2 those newspaper articles so you'll be relieved.
  - All right. On the screen is DX 3017 which is not in evidence and was not on the exhibit list, although we've disclosed it to counsel.
  - I will represent to you that this comes from cms.gov which is the government website that hosts the database on payments to doctors. You're familiar with that, right?
- 9 A Yeah, it's part of the Sunshine Act.
- 10 Q CMS is a Center for Medicare and Medicaid Services,
  11 right?
- 12 A **Yes.**

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- Q And the page or on the screen discusses the process for submitting payments to the open payment database. Are generally familiar with that process?
- 16 A I'm not because I pay no attention to it.
- Q Okay. But generally, according to the website, the way it works is that companies like Amarin submit data to the government. You understand that, right?
- 20 A I do.
- 21 Q And then there's a process where the physicians and
  22 teaching hospitals can review and dispute the data. Do you
  23 understand that?
- 24 A I do.
- 25 Q And then the data is displayed on the public -- the CMS

- 1 | public website, right?
- 2 A Yes, in bright, fluorescent light.
- 3 Q And CMS -- I can't remember if I said this, for the
- 4 record, that's Center For Medicare and Medicaid Service,
- 5 right?
- 6 A Yes; known for it's accuracy.
- 7 Q **Okay.**
- 8 A No, that's not true.
- 9 MR. KLEIN: Let's go to DDX 10.109.
- 10 BY MR. KLEIN:
- 11 Q And just to be clear, you understand that CMS requires
- organizations like Amarin to keep records for at least five
- 13 | years?
- 14 | A I do.
- 15 Q All right. And that there are stiff penalties, up to a
- 16 million dollars. If the pharma company fails to report
- 17 | information in a timely, accurate, or complete manner?
- 18 A That I didn't know. But they do report timely, yes.
- 19 MR. KLEIN: Okay. Let's go to DDX 10.110.
- 20 BY MR. KLEIN:
- 21 Q Okay. Now, Doctor, I will represent to you that DX 3006
- 22 on the screen summarizes data from the documents that are
- 23 cited, which is DX 3000 through DX 3005, and those are
- 24 spreadsheets from the CMS website reflecting payments from
- 25 Amarin to physicians from 2013 to 2018. Okay? I'm

- 1 representing that to you.
- 2 A Sure.
- 3 Q And I'll also represent to you that when we prepared
- 4 this, we removed any expenses that you were reimbursed for
- 5 | food, lodging, et cetera.
- 6 A Okay, counsel.
- 7 Q Okay. And according to -- I'll also for the record
- 8 represent that this document has been disclosed to the other
- 9 | side in advance.
- And so if we look at DX 3006, according to the
- exhibit, Amarin over the years from 2013 to 2018 has paid you
- 12 | about \$140,000. Do you see that?
- 13 A That's what the figure says.
- 14 Q **Okay**.
- 15 A But there's a problem.
- 16 Q Okay. Well, I'm going to ask you the next question. Has
- 17 Amarin paid you about \$140,000 from 2013 to 2018?
- 18 A I'm not sure. I haven't tallied it. But I'll tell you
- 19 right now, based on 1099s for 2016, the accurate number was
- 20 | \$4,875. For 2017, my 1099 was for 10,800.
- 21 That's a three-fold difference for both of those
- years, and the CMS database is notoriously inaccurate.
- So, no, I don't agree, and I don't know how much
- 24 they paid me, but for those two years the figures are off
- 25 three fold.

- 1 Q Okay. Doctor, you knew I was going ask you these
- 2 questions, right?
- 3 A Of course I knew you were going to ask me these
- 4 questions, yes.
- Okay. Did you do any investigation to find out how much
- 6 Amarin did, in fact, pay you?
- 7 A I did not.
- 8 Q Okay. And has Amarin paid you additional funds in 2019?
- 9 A Yes. In the same way that you have billable hours, they
- 10 did pay me for being part of this case, yes.
- 11 Q No, just to be clear, I'm not asking about any payments
- 12 about this case. Has Amarin made payments to you unrelated to
- 13 this case in 2019?
- 14 A Yes, they did.
- 15 O About how much?
- 16 A Again, I haven't received my 1099 yet. But I probably
- 17 | gave five or six talks last year. But, again, I'm not sure.
- 18 Q Doctor, I understand you're not sure, but is it fair to
- say that Amarin has paid you about a hundred thousand dollars
- 20 unrelated to this case?
- 21 A Again, I'm not sure.
- 22 Q Okay. Would that surprise you?
- 23 A Would it surprise me? That would surprise me.
- 24 Q That would surprise you.
- Okay. So Amarin, at a minimum, has paid you at

1	least \$70,000. Do you agree with that?
2	A Counsel, I would have to look. And I'm being very honest
3	with you. I have so many things to do, the last thing that I
4	thought of was to come in here and add up what Amarin paid me
5	last year.
6	MR. KLEIN: Okay. Let's play page 334 of his
7	deposition, lines 15 to 23.
8	(Deposition video recording played.
9	BY MR. KLEIN:
10	Q Was that your testimony?
11	A You just saw it.
12	Q Okay. I have to ask you that question.
13	A Yes, counsel.
14	MR. KLEIN: Okay. I have no further questions
15	at this time, but I would like to move into evidence the CMS
16	documents that we reviewed which were used for impeachment, DX
17	3000 to 3006; and 3017 and 3018.
18	THE COURT: Any objection?
19	MR. ELIKAN: Your Honor, may I have one moment?
20	THE COURT: Yes.
21	(Discussion held off the record.)
22	MR. ELIKAN: We do object, Your Honor.
23	This includes 7,000 pages of spreadsheets that
24	were produced to us on Saturday night. We've been unable to
25	review them, at least not thoroughly. There are 6,000 or

7,000 pages.

I would love to hand up a tiny bit so you can see what we're talking about. It's not restricted to Dr. Toth, it's an entire spreadsheet produced to us in pdf form. We don't think it's admissible for a variety of reasons.

But at the end of the day, it's hearsay, and it doesn't fit under any possible exception to the hearsay rule, and, additionally, it's a set of documents that is notoriously suspect.

So, we don't see how this is -- how this should be admitted under any hearsay exception or that the Court -- I think the other argument is that judicial notice should be taken of it.

We have a variety of articles from the AMA, from Endovascular Today, both pointing out that the CMS website is erroneous and erroneous to very high degree. I think Endovascular Today said it was shockingly erroneous with an error rate of, I believe, 30 percent.

So we don't see why this document should be coming into evidence. It's clearly hearsay. It's not the statements of Amarin, but instead of CMS. It may be based on materials provided by Amarin but not simply passed through.

And there's absolutely no foundation for Dr. Toth to address the entirety of this vast spreadsheet

1	which concerns every doctor to whom Amarin has made any
2	payment.
3	So we don't see that as being any we don't
4	see it fitting under any hearsay rule, but, more broadly, it's
5	something that's there's been no foundation laid for it.
6	There's a summary slide, but Dr. Toth has said that the
7	summary slide is erroneous.
8	You need to have the bottom line is you need
9	to have the spreadsheets underneath be admissible. They
10	haven't even called a witness to sponsor it.
11	If a witness were called, we'd be asking about
12	the AMA position and the accountings taken of it, taken by
13	Endovascular Today and variety of other sources.
14	How Dr. Toth's testimony about the summary sheet
15	not being accurate could somehow lead to admissibility of
16	7,000 pages is we just think it's not supported.
17	THE COURT: So let me take this one step at a
18	time.
19	DX 3018 is a cms.gov website, and I haven't
20	looked at the actual document, but am I assuming that there
21	are voluminous I'm sorry, do DX 3017 and 3018 both relate
22	to information on cms.gov; is that right?
23	MR. KLEIN: Correct. Those are just website
24	pages, I believe.
25	THE COURT: So they're not they just consist
	<b>1</b>

1	of basically two pages.
2	MR. KLEIN: Correct. Yes. I think that's
3	right.
4	THE COURT: So let me take that objection first.
5	With respect to DX 3017 and 3018, why can't I just take
6	judicial notice of the website?
7	MR. ELIKAN: That we don't have any objection
8	to, it's about the spreadsheet and the summary.
9	THE COURT: All right. So that's why I'm taking
10	this one at a time. There's no objection to DX 3017 and 3018.
11	Therefore I'm admitting those two exhibits.
12	(Defendants' Exhibit 3017 and 3018 received in evidence.)
13	THE COURT: And then there are two more
14	documents, 3000, and then 3006 is just a summary.
15	MR. KLEIN: I think it's 3000 through 3006. The
16	way this is organized, it's one spreadsheet per year, and each
17	spreadsheet shows Amarin's payments to physicians.
18	THE COURT: It would be 3000 to 3005.
19	MR. KLEIN: Those are the spreadsheets.
20	THE COURT: And 3006 is the summary.
21	MR. KLEIN: Correct.
22	THE COURT: And as I understand the objection
23	is the main objection, Mr. Elikan, that DX 3000 to 3005
24	contain information about payments to others aside from
25	Dr. Toth?

1	MR. ELIKAN: Yes. And additionally it's
2	inadmissible hearsay as to Dr. Toth.
3	There's nobody who has authenticated it. It
4	seems to be clearly inadmissible hearsay. It doesn't fall
5	within the sort of matter that's usually addressed by judicial
6	notice. For example
7	THE COURT: Hang on. Is there any dispute that
8	they come from the cms.gov website?
9	MR. ELIKAN: I am I don't know for sure, but
10	I would accept Mr. Klein's representation that
11	THE COURT: Why is that not a public record
12	exception?
13	MR. ELIKAN: I'm sorry, Your Honor?
14	THE COURT: Why doesn't it fall within the
15	public records exception?
16	MR. ELIKAN: So the public records exception, it
17	has to lay out set out the offices activities or fit within
18	one of the other requirements.
19	We don't see it fitting into any of the rules in
20	803-8, and it also asked not indicate a lack of
21	trustworthiness.
22	We already heard from Dr. Toth that it's
23	inaccurate, and I have a bevy materials that, if there were a
24	witness sponsoring it, we could ask that witness about that
25	show a lack of trustworthiness.

THE COURT: Does Amarin have a record of how 1 2 much it's paid Dr. Toth within the last -- from 2013 and 2018 3 that's different than what's indicated on the CMS.gov website? MR. ELIKAN: As far as whether there's a 4 5 different record, I don't know. We got these in the middle of 6 trial. We would have to decipher the spreadsheet and figure 7 that out. THE COURT: So here's my issue. I think that 8 9 it's proper impeachment evidence to show how much a witness 10 has been paid by a party unrelated, whether its an expert fee 11 or other relationship. So I think it's a fair area of 12 inquiry. 13 And if the only information that is available is 14 is what is on a government website, I can take weight of that 15 evidence if I have testimony that information on that website 16 might not be entirely accurate. 17 But if what is shown is what Amarin submitted to 18 the agency, then I certainly can admit that. But, if Amarin 19 is telling me that what's on that -- the website is incorrect, 2.0 I would want to give Amarin the opportunity to say here's a 21 correct record of what we paid. 2.2 I think this is all a fair area of inquiry. 2.3 shouldn't be any surprise to anyone. Dr. Toth recognized that 24 he would be asked. He was asked in his deposition. 25 So I don't want there to be any gamesmanship, in

1	other words. I don't have to have the exact number of
2	payments, but there was at least testimony that he was paid
3	around 70, \$69,000.
4	MR. KLEIN: Something like that.
5	THE COURT: As of July 2019.
6	MR. ELIKAN: So, Your Honor
7	THE COURT: So I want you to be able to resolve
8	this issue is my point, otherwise I'll admit it and give it
9	whatever weight it deserves.
10	MR. ELIKAN: Your Honor, just two brief points.
11	We think in any event, if Your Honor was to admit these
12	spreadsheets, they ought to be redacted so they only have
13	Dr. Toth's
14	THE COURT: Yes, I agree with that, yes.
15	MR. ELIKAN: And we
16	THE COURT: But that's not your sole objection
17	because that's an easy objection, I already decided that
18	because your objection is that it includes information
19	relating to other individuals. I agree I would redact that.
20	MR. ELIKAN: And as far as the summary chart
21	goes, there hasn't been any
22	THE COURT: So does that mean you no longer have
23	objection to 3000 to 30005? Let's focus on that first. If I
24	redact the information relating to payments to others?
25	MR. ELIKAN: I'm advised that we're okay with

1 that. If that's --2 THE COURT: All right. 3 MR. KLEIN: Can I speak that, please? To what issue, payments to others? 4 THE COURT: To redaction, the redaction issue. MR. KLEIN: THE COURT: Uh-huh. 6 7 MR. KLEIN: We would request -- we're okay with 8 redactions, but we would ask that the information with regard 9 to Dr. Budoff not be redacted, and because, in view of his 10 testimony a couple weeks ago where he testified at deposition 11 that he received \$300,000 personally, and then he testified on 12 the stand that it went to his institution, the database is 13 consistent with his deposition. 14 And I think that maybe the heart of this 15 dispute, and I've been trying to work it out with counsel to 16 try to find out how much these experts have actually been 17 paid, which is the information that I personally would like, 18 but the information as to Dr. Budoff we submit is relevant to 19 his trial testimony. 2.0 And I'm okay with redacting out everyone else, 21 but I would request that we keep in Dr. Toth and Dr. Budoff 22 for the spreadsheets given that both of these witnesses 2.3 testified. 24 THE COURT: Is there any objection to that 25 proposal?

1	MR. ELIKAN: Yes. Dr. Budoff is not here to
2	answer questions about any of this information. He's back
3	in at his home.
4	And Your Honor mentioned the ability that Your
5	Honor can take it with weight. Without a sponsoring witness,
6	we don't have anyone to cross-examine with these many
7	statements about the inaccuracies, the very high level of
8	inaccuracies in the database.
9	THE COURT: Well, I do have Dr. Toth just
10	testified that he thinks the database is not reliable.
11	MR. ELIKAN: You have testimony from Dr. Toth to
12	that effect, but, Your Honor, we can't introduce all these
13	articles about the
L 4	THE COURT: Wait. So I thought there was no
15	objection to the data at least with respect to this witness.
L 6	MR. ELIKAN: Were that to resolve the issue,
17	Your Honor, we
18	THE COURT: So are you withdrawing your
19	representation that there's no objection?
20	And maybe let's do this. Let's to be fair,
21	let's do this. We're kind of at a break point anyways.
22	I'll take a lunch break, I want counsel to work
23	out this issue if you're able to, but, I can tell you my
24	inclination is to admit the spreadsheet with respect to
25	Dr. Toth.
	<b>1</b>

1	But, the summary I mean, if the summary is
2	just summarizing all the numbers as added up, I don't see any
3	objection. It will avoid me having to add up the numbers on
4	my own.
5	With respect to Dr. Budoff, I'm a little
6	concerned that this information was not introduced during his
7	examination to allow him the opportunity to say to
8	challenge the information.
9	I know that I have his testimony about how much
10	he was paid and he disputes some of the payments whether they
11	went to him or his institution. So with him, I'm inclined not
12	to admit the information because he's not here.
13	MR. KLEIN: Can I
14	THE COURT: But you can try to resolve it if you
15	can.
16	MR. KLEIN: Can I just respond to that last
17	point real quickly?
18	Obviously in his deposition he said he was paid
19	personally 300,000. So there was no reason for me to believe
20	that he would contradict that on the stand.
21	THE COURT: But you have his deposition
22	testimony, that's already in.
23	MR. KLEIN: Right.
24	THE COURT: You used that to impeach him.
25	MR. KLEIN: Right. But as we prepared for

1	Dr. Toth's deposition and went through the spreadsheet, we
2	realized that the information for Dr. Budoff did not say the
3	payments went to his institution, they went to him personally,
4	and that's why we would want that information introduced as
5	well.
6	Now, we did raise this issue with counsel and
7	said if it went to his institution, by all means, let us know,
8	and that's fine, and we'll drop the issue but they did not
9	give us any evidence.
10	THE COURT: But my point is you didn't offer
11	this during Dr. Budoff's testimony.
12	MR. KLEIN: No. That's true. That's true. But
13	I did not focus on whether the payments went to him or his
L 4	institution because he admitted it went to him personally.
15	THE COURT: All right. That's I gave you my
16	preliminary thoughts. You can try to see if you can resolve
17	it. If not, I'll give you my ruling after lunch.
18	MR. KLEIN: Thank you, Your Honor.
19	MR. ELIKAN: Thank you, Your Honor.
20	(The noon recess was taken.)
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1	RENO, NEVADA, TUESDAY, JANUARY 28, 2020, 1:27 P.M.
2	00
3	
4	THE COURT: Please be seated.
5	All right. When we recessed, I asked counsel to
6	confer on the disputed exhibits.
7	Do you have a resolution?
8	MR. SIPES: Your Honor, I'm not sure. This is
9	Christopher Sipes on behalf Amarin.
L O	We had proposed this all arose this Saturday
11	night when we received this exhibit. We're not in a position
12	to commit what we could collect. Apparently, a lot of it is,
13	we think, may be third-party vendors, so we can't quite get
L 4	it.
15	What we would propose is to allow the admission
16	of the information relating to Dr. Toth and Dr. Budoff, but we
L7	would then have the opportunity tomorrow, since we haven't had
L8	an opportunity, to put things in through an actual
19	knowledgeable custodian, just submit as part of the record a
20	couple of articles that would explain the accuracy of the CMS
21	website and what the problems are.
22	But, Mr. Klein has indicated they do not want to
23	agree to that.
24	MR. KLEIN: Your Honor, our position we'll
25	defer to the Court, but our position is that either Amarin

1	should come up with what the numbers are, it's in Amarin's
2	possession, and then we'll work with them and submit something
3	to let you know what the numbers are, or, you should just go
4	ahead and rule.
5	THE COURT: Well, I'm going to rule. I'm going
6	to give Amarin, though, the opportunity to present evidence
7	that Mr. Sipes just indicated.
8	So, I'm going to I've already admitted
9	DX 3017 and 3018. I will admit 3000 to 3005, but with all the
10	information redacted other than Dr. Toth and Dr. Budoff.
11	Now, the reason I'm allowing Dr. Budoff is
12	because I'm going to give Amarin the opportunity to present
13	the information that Mr. Sipes indicated. Otherwise, I would
14	exclude that portion as well, and, I will admit the summary
15	exhibit which is 3006.
16	(Defendants' Exhibits 3000 through 3006 received in evidence.)
17	MR. SIPES: Thank you.
18	MR. KLEIN: Thank you, Your Honor.
19	THE COURT: Are you ready for redirect?
20	MR. ELIKAN: Sure.
21	THE COURT: All right.
22	REDIRECT EXAMINATION
23	BY MR. ELIKAN:
24	Q Dr. Toth, do you recall you were questioned about von
25	Schacky on cross-examination?

- 1 A Yes, counsel.
- 2 Q And you were asked about Table 1?
- $3 \mid A \quad Yes.$
- 4 MR. ELIKAN: I want to ask you about some other
- 5 portions of the article. Can we have DX 1605 at page 2. I
- 6 | want to pull up the title "Method" and the paragraph below.
- 7 BY MR. ELIKAN:
- 8 Q What does von Schacky indicate here about how he found
- 9 | the articles to include in his review?
- 10 A He performed a Medline search, and he also used
- 11 publications from a Cochrane review, and, also used articles
- 12 | from his personal library.
- 13 Q Does it appear to you to be a reasonably thorough review
- 14 of the literature?
- 15 A Well, when you refer to Medline and Cochrane review, I
- 16 would say yes.
- 17 MR. ELIKAN: Can we have the von Schacky paper,
- 18 | PX 905 and -- oh, you already have it on the screen.
- 19 BY MR. ELIKAN:
- 20 Q Let me ask you, you were asked about other passages in
- 21 | von Schacky as well. I want to talk about a passage on
- 22 **page 5.**
- 23 MR. ELIKAN: Can we have page 5, Mr. Brooks?
- 24 **BY MR. ELIKAN:**
- 25 Q Is that the passage you were asked about? And it appears

- 1 in the left-hand column.
- 2 A EPA and versus DHA, yes.
- 3 Q And I want to look little above that, the bottom of
- 4 page 4, to the lower right-hand corner. Do you see the
- 5 heading "Effects on Other Lipids"?
- 6 A Yes.
- 7 Q And under this heading it discusses the effects of fish
- 8 | oil on serum lipids. That's in the line right below the
- 9 | title, right?
- 10 A Yes, counsel.
- 11 Q And I want to look below that to the heading, "DHA-EPA"
- 12 in the right-hand column with page 4. EPA-DHA.
- 13 A I see it.
- 14 Q Okay. And that column then -- that section continues on
- 15 | to the next page, right?
- 16 A **Yes**.
- 17 Q And that is immediately above the passage that you were
- 18 asked about.
- 19 A **Yes.**
- 20 Q Okay. I want to look at the first full sentence that
- 21 | starts, "Rather consistently..."
- 22 A "LDL has" --
- 23 MR. ELIKAN: Can we highlight that, Mr. Brooks.
- 24 BY MR. ELIKAN:
- 25 Q And what does von Schacky here say?

- 1 A "Rather consistently, LDL has been seen to be
  2 increased with a few exceptions. This may be due to
  3 the fact that the more buoyant" --
- 4 Q Hold on. I'm just asking about that sentence. It seems
  5 like it's going on to other issues here.
- What does this sentence state, if anything, about the absolute effect of both EPA and DHA on LDL?
- A That the tendency is for it to -- that the tendency for UDL is to increase in response to exposure to both omega-3s.
- 10 Q Does that support the table, Table 1 -- which I would
  11 like to return to now, it's at page 9.
- 12 A It does support the table.
- 13 | O And how so?
- A Because in the table, both EPA and DHA are associated with a single upgoing arrow.
- Q And I believe you testified on direct as well about the von Schacky reference in Table 1?
- 18 A **Yes**.
- Q And is it the case that of the different parameters, to the extent they vary, they favor DHA?
- 21 A **Yes.**
- 22 Q Let me ask you a question you haven't been asked and --
- 23 A There's a question I haven't been asked yet?
- Q Would any person of ordinary skill in the art want to
- 25 | make Lovaza worse?

- 1 A Of course not.
- 2 MR. ELIKAN: I want to talk to you, now, about
- 3 the Saito article. Can we have DX1547, and I want to turn to
- 4 page 5, and can we pull up on the screen the second paragraph
- 5 in the right-hand column.
- 6 BY MR. ELIKAN:
- 7 Q Do you see in the first sentence Saito reports, risk
- 8 reduction by 53 percent was achieved in JELIS in what he calls
- 9 the high TG, low HDL-C group?
- 10 A Yes, counsel.
- 11 MR. ELIKAN: Okay. I want to look at how high
- 12 TG and low HDL-C was defined.
- Can we go to the bottom of page 2, and I want to
- 14 grab the last paragraph, and then the five categories on the
- 15 next page. So, the "furthermore."
- 16 BY MR. ELIKAN:
- 17 Q And which of these is the high TG, low HDL-C group.
- 18 A Number 4.
- 19 Q And is that a group that is severely
- 20 hypertriglyceridemic?
- 21 A No, counsel.
- 22 Q Explain.
- 23 A Well, the triglyceride of greater than or equal to 150,
- 24 that is the cut point for defining hypertriglyceridemia.
- 25 And these authors do provide a mean and a standard

- deviation for this group on triglycerides. But, of course,
- very high triglycerides would be above 500.
- 3 Q Is this group even close to a patient population with
- 4 | very high triglycerides?
- 5 A **No, sir.**
- 6 MR. ELIKAN: Now, I want to turn to Table 1 on
- 7 page 4. And can we highlight the title of the table.
- 8 BY MR. ELIKAN:
- 9 0 What does the title indicate is in this table?
- 10 A "Patient Background Factors At Time of Registration, and
- 11 Triglyceride and HDL Cholesterol Levels."
- 12 Now, I want to look at the bottom of the table under
- 13 lipid profile. Does this table provide the mean triglyceride
- 14 and LDL-C levels for those Saito designates as the high
- 15 triglyceride, low HDL-C patients?
- 16 A **Yes**.
- 17 O And what's the mean for LDL-C?
- 18 A It's 200 -- the mean for LDL-C?
- 19 O Correct.
- 20 A Is 186.
- 21 Q And the mean for triglyceride?
- 22 A **272.**
- 23 Q Does it also provide a range of triglyceride levels for
- 24 patients in that group?
- 25 A Yes, 207 to 399.

- 1 Q Again, this isn't a patient population of very high 2 triglycerides, right?
- 3 A No, counsel.
- 4 MR. ELIKAN: Can we have PDX 6-7, please.
- 5 BY MR. ELIKAN:
- 6 Q Based on their LDL-C and triglyceride levels, which group 7 on PDX 6-7 is the high TG, low LDL-C group in Saito most like?
- 8 A The mixed dyslipidemia with a mean of approximately 232,
- 9 the farthest one to the left.
- 10 Q You testified earlier that the prior art showed that in a
- 11 | population with very high triglycerides, the approved
- 12 | triglyceride-lowering agents raised LDL-C while lowering
- 13 | triglycerides, right?
- 14 A Yes.
- 15 Q Based on review of Saito 2008, would the person of
- 16 ordinary skill have had any reason to believe that patients
- with very high triglycerides would avoid an increase in LDL-C
- 18 | after administration of Epadel?
- 19 A No.
- MR. ELIKAN: Let's turn to Yokoyama, DX 1553,
- 21 and I want to go to page 8, and I want to highlight the last
- 22 | sentence in the last paragraph.
- 23 BY MR. ELIKAN:
- Q What does Yokoyama have to state here about whether the
- 25 results observed in JELIS can be expected in other countries?

1	A Well, they note that,
2	"Because their population was exclusively
3	Japanese, we cannot generalize our results to other
4	populations. We need to investigate whether EPA is
5	effective for prevention of major coronary events in
6	hypercholesterolemic patients without or with
7	coronary artery disease in other countries."
8	MR. ELIKAN: Let's go back to Saito, DX 1547.
9	And I want to go to page 2 in the left-hand column.
10	BY MR. ELIKAN:
11	Q In the second paragraph under "Introduction," six lines
12	down in the middle paragraph, what does this state if we
13	can highlight "from and EPA suppressed CAD" until the end of
14	that sentence. What does this state about the eating habits
15	of the patients who were studied?
16	A "EPA suppressed coronary artery disease even
17	in Japanese hypercholesterolemic patients who
18	routinely consume a large amount of EPA and DHA from
19	fish."
20	Q And what, if anything, does this indicate about whether
21	Saito I'm sorry.
22	What, if anything, does this indicate about whether
23	JELIS, as seen by Dr. Saito, was actually measuring the
24	effects of pure EPA in a population?
25	A Well, he appears to be thinking that supplemental EPA on

- 1 top of dietary EPA and DHA appears to suppress CAD.
- 2 Q Is there any indication in Saito that the same results
- 3 | could be obtained -- would be obtained by administering pure
- 4 | EPA to a population that was not already taking in large
- 5 amounts of DHA as part of their fish diet?
- 6 A No.
- During your direct examination, we looked at a Cochrane
- 8 collaboration, PX 953. I want to take a look at that now.
- 9 And I believe this is the reference that you
- 10 testified concluded in 2018 that Omega-3 fatty acids are
- 11 probably not useful for preventing or treating cardiovascular
- 12 disease. Do I have that right?
- 13 A **Yes.**
- 14 Q Let's go to page 74.
- And do you see that the right-hand column lists
- 16 materials considered relating to JELIS?
- 17 A **Yes.**
- 18 Q And if we look at the bottom, under JELIS 2007, what do
- 19 | we see there?
- 20 A It's the Saito reference that we have been discussing
- 21 from Atherosclerosis in 2008.
- 22 **DX 1547?**
- 23 | A **Yes.**
- 24 Q Does this indicate that the Saito article was considered
- 25 by the authors before reaching their conclusion that Omega-3

- 1 | fatty acids are probably not useful for preventing or treating
- 2 | cardiovascular disease?
- $3 \mid A \quad Yes.$
- 4 Q On cross-examination, you were also asked questions about
- 5 Dr. Bays' article about the Marine trial?
- 6 A Yes.
- 7 Q DX 1741. So, I want to look a little bit closer at the
- 8 passage you were shown on cross.
- 9 MR. ELIKAN: Can we have page 7, right column,
- 10 | the first full paragraph, beginning with "in several small
- 11 | studies..."
- 12 **BY MR. ELIKAN:**
- 13 Q First, do you see that the first sentence provides a
- 14 citation to five different studies, concluding that both EPA
- 15 and DHA lowered triglyceride levels?
- 16 | A **Yes**.
- 17 Q And those are references 4, 5, and 14 through 16?
- 18 A **Yes**.
- 19 MR. ELIKAN: Okay. Let's go to page 9, and can
- 20 we blow-up reference 14.
- 21 **BY MR. ELIKAN:**
- 22 Q What's the date of publication of reference 14?
- 23 | A **2009**.
- 24 Q Does citation to this reference indicate that the
- 25 statement made by Dr. Bays was informed by later publications

- predating March 2008; or, instead, informed as well by later
  events and publications?
  - A By later events and publications.
- 4 Q Let's go back to the same paragraph we were looking at on 5 page 7.
- Do you see a citation after the next sentence,

  "However, although DHA treatment generally

  increased LDL cholesterol levels, EPA therapy did

  not"?
- 10 A I see it.

3

- 11 | O Is there a citation after that sentence?
- 12 A No, counsel.
- 13 Q In reading this section of the paragraph as a whole, 14 before the discussion in the Marine trial, which follows 15 below, is there a primary citation that Dr. Bays uses to
- 17 **DHA?**

16

- 18 A No.
- 19 Q Which article is cited to most often in that paragraph?

support his understanding of prior experience with EPA and

- 20 A **Uh** --
- 21 Q I just want the reference number. Do you see a reference
- 22 **to --**
- 23 A Yes, there is -- 17 appears twice.
- 24 Q So do you understand that to be the primary citation he 25 uses to support his understanding of prior experience with EPA

- and DHA in this paragraph?
- 2 A Yes, sir.
- 3 Q And let's turn to page 9, the left column. And let's
- 4 look at reference 17.
- 5 When was it published?
- 6 A That's a paper by Ernie Schaefer, in Circulation in 2010.
- 7 O Not available in 2008?
- 8 A No, I don't believe it would be, no.
- 9 O Does reliance on that reference indicate that the
- 10 statements made by Dr. Bays were informed by events and
- 11 publications post-dating March 2008?
- 12 | A **Post-dating 2008.**
- 13 Q Let's go back to page 7, and I want to look at the
- 14 paragraph we were looking at before.
- 15 All right. The sentence, "in several small previous
- 16 | studies..."
- And if we look down a little bit further, do you see
- 18 | that that links up to another sentence beginning, "These
- 19 | previous studies..."
- 20 A **Yes.**
- 21 Q And looking further down in that sentence, "These
- 22 previous studies," what does Dr. Bays say about the population
- 23 | studied in these previous studies?
- 24 A He notes,
- 25 "These previous studies were generally in

1	patients with normal to borderline high triglyceride
2	levels, and none included patients with very high
3	triglyceride levels, namely, greater than
4	500 milligrams per deciliter."
5	Q Let's look at the last sentence. Does Dr. Bays say that
6	the results achieved were confirmatory or something else?
7	A They were not confirmatory. It was an unexpected finding
8	that Vascepa or AMR101 produced no significant increase in the
9	LDL cholesterol levels.
10	MR. ELIKAN: Can we have DX 1578 at page 1. Can
11	we blow-up Table 1.
12	BY MR. ELIKAN:
13	Q Looking at the title, do you recall being shown this on
14	cross-examination?
15	A I do, counsel.
16	Q And what was the can you describe the patient
17	population in Table 1. Was it specifically, was it one
18	with very high triglycerides or not?
19	A It was not.
20	Q How does Table 1 describe the patient population?
21	A The baseline triglycerides for the Lovaza and simvastating
22	group had a baseline 268, and the placebo and simvastatin
23	group had a baseline triglyceride of 271.
24	MR. ELIKAN: Can we go DX 1553 at page 3.
25	So, this is the Yokoyama study that you were

- 1 asked about.
- 2 Can we blow-up the serum lipid levels in the
- 3 | left-hand side.
- 4 BY MR. ELIKAN:
- 5 Q Doctor, looking at these units of measurements -- they're
- 6 in millimoles per liter -- but can you tell whether these --
- 7 | can you tell approximately what the milligrams per deciliter
- 8 equivalents are?
- 9 A Yes. For the LDL it would have been approximately 184;
- 10 for triglycerides it was, in the EPA group, 153; and in the
- 11 | placebo group, 154.
- 12 Q What types -- what type of patients, then, does the JELIS
- 13 | study concern?
- 14 A Well, they were specifically labeled as
- 15 hypercholesterolemic patients, and with LDLs -- Japanese
- 16 patients especially, with LDLs of 183, that's a remarkably
- 17 high mean, mean baseline LDL for a Japanese population, and
- 18 their triglycerides were, essentially, the mean was near
- 19 | normal.
- 20 So, again, not a patient population with very high
- 21 triglycerides?
- 22 A No. There weren't any patients with very high
- 23 | triglycerides as the Saito article showed us where the maximal
- 24 triglyceride was actually 399.
- 25 Q And I'm not sure I followed your answer fully a couple of

1	answers ago. Is this a patient population that you would
2	describe as hypercholesterolemic or something else?
3	A Yes, hypercholesterolemic.
4	MR. ELIKAN: Can we have D can I ask you to
5	put up DDX 10.90. Is that okay? Thank you very much?
6	THE CLERK: Are you asking for defense
7	litigation tech to do that?
8	MR. ELIKAN: Yes, because we don't have their
9	slides.
10	THE CLERK: Okay. Let me transfer it over.
11	MR. ELIKAN: Oh. Thank you very much.
12	And thank you.
13	BY MR. ELIKAN:
14	Q Do you recall being shown this slide before?
15	A No.
16	Q Well, I assure you were shown it on cross-examination
17	A Okay. I do now.
18	Q Now you do.
19	And you were referred to the highlighted matter. I
20	want to ask you about the last sentence in the 2017 Vascepa
21	Operating Plan, specifically I shouldn't say the last
22	sentence, the last sentence that's called out in this cutout.
23	What does is say there?
24	A That Vascepa being LDL neutral and other efficacy
25	messages are also very relevant.

1	MR. ELIKAN: Let's go to DX 1524, WO '118, and I
2	want to go to oh, I'm sorry. We have to switch over.
3	And thank you once again.
4	Can we go to page 4, the middle of the page.
5	BY MR. ELIKAN:
6	Q Do you see in the middle of the page a description of
7	if we can scroll down a little bit I'm sorry. I'm on the
8	wrong page. It's page 7 of the exhibit.
9	Do you see a statement,
10	"There has been reported in the there has
11	also been reported in the Heart Failure Society of
12	America 2005 Annual Meeting that based on such
13	action, such high purity EPA-E was expected to have
14	the effects of improving cardiovascular events in
15	Hyperlipidemia patients,.
16	And combined use with HMG-CoA RI was
17	effective in inhibiting cardiac events in a large
18	scale clinical trial".
19	A Yes.
20	Q And then immediately below an identification of that
21	trial as the JELIS trial.
22	Do you see that, it says, "In this large clinical
23	trial of JELIS"?
24	A I do, counsel.
25	Q And remind me, in the context of W this is WO '118,

- 1 but what were the baseline triglycerides in the JELIS study?
- 2 A The baseline triglyceride value in the EPA group was
- 3 | 153 milligrams per deciliter, and in the placebo arm,
- 4 | 154 milligrams per deciliter.
- 5 O And the baseline LDL-C?
- 6 A Approximately 183.
- 7 Q Are those patients with very high triglycerides?
- 8 A No.
- 9 Q Anywhere close?
- 10 A Not even close. And Saito did mention that the highest
- 11 triglyceride value observed in JELIS was 399.
- MR. ELIKAN: Can we go to page 12 now, and the
- 13 | paragraph under "Merits of the Invention."
- 14 BY MR. ELIKAN:
- 15 Q Do you see that it says, "The invention contains at least
- 16 **EPA"?**
- 17 A **Yes.**
- 18 Q And what does that mean?
- 19 A Well, that would suggest that there are other components
- 20 in the capsule.
- 21 Q And it says it's effective --
- 22 A **Yes, as --**
- 23 Q -- in preventing occurrence of cardiovascular events in
- 24 hypercholesterolemia patients.
- 25 A **Yes.**

- 1 Q What exactly are those?
- 2 A And are we still talking about JELIS here?
- $\Im$   $\mathbb{Q}$  Well, you can give me a general definition, and then we
- 4 can -- I can ask you about JELIS as well.
- 5 A Sure.
- 6 Q But what hypercholesterolemia patients?
- 7 A Well, they would be patients who have LDL levels higher
- 8 | than what their risk stratum would -- that they would be
- 9 higher than where you would want them to be based on their
- 10 risk strata.
- 11 Q Are they different or the same as a very high
- 12 triglyceride patient population?
- 13 A Oh, they're different.
- 14 MR. ELIKAN: Let's go to page 25, and I want to
- 15 | highlight the sentence at the bottom of the page beginning
- 16 | with, "another preferable fatty acid."
- 17 BY MR. ELIKAN:
- 18 Q What is that other preferable fatty acid in WO '118?
- 19 A It's DHA.
- 20 Q And what does the passage go on to say about ratio?
- 21 A It says,
- 22 "While the compositional ratio of EPA over
- 23 DHA, content of EPA and DHA, in the total fatty acid
- and dosage of EPA plus DHA, are not particularly
- 25 limited. As long as intended effects of the present

1	invention are attained, the composition is preferably
2	the one having a purity of EPA and DHA, for example,
3	the one having"
4	Q Doctor, I think you missed a word. It says "high
5	purity," is that right?
6	A "The composition is preferably the one having
7	a high purity of EPA and DHA, for example, the one
8	having a proportion of the EPA plus DHA in the total
9	fatty acid and derivatives thereof, of preferably
10	40 percent by weight or higher."
11	Would you like me to keep reading?
12	Q Nope. That's good.
13	MR. ELIKAN: I'd like to go to page 35 now, and
L 4	can you highlight, please, the sentence beginning with "the
15	soft capsule product," and you can continue all the way down
16	through the paragraph.
L7	BY MR. ELIKAN:
18	Q What does this have to say here about whether you can use
L9	Omacor or Lovaza with this invention?
20	A It says,
21	"The soft capsule, Omacor, containing about
22	46 percent by weight of EPA, and about 38 percent by
23	weight of DHA, is commercially available in the U.S.,
24	Europe, and other countries, as a drug applied for
25	hypertriglyceridemia."

- 1 Q Does that mean can you use Omacor with this invention?
- 2 A Yes.
- 3 Q Do you recall being asked about Hayashi, as well, on
- 4 cross-examination?
- 5 A Yes, counsel.
- 6 O I want to take a look at your definition of the
- 7 | credentials of the person of ordinary skill in the art and
- 8 | compare them to Dr. Heinecke's.
- 9 MR. ELIKAN: Can we have your PDX 6-13? Can we
- 10 put it next, Mr. Brooks, to DDX 6.10.
- 11 BY MR. ELIKAN:
- 12 Q And these are the two sets of credentials that you and
- 13 Dr. Heinecke testified about, correct?
- 14 A **Yes.**
- 15 Q Looking at these definitions, do either you or
- 16 Dr. Heinecke understand the person of ordinary skill in the
- 17 | art to be a statistician?
- 18 A No.
- 19 Q Or as having advanced training in statistics?
- 20 A No.
- 21 Q So would the person of ordinary skill in the art,
- 22 | irrespective of which set of credentials is accepted by the
- 23 | Court, be essentially viewing Hayashi from the perspective of
- 24 a clinician?
- 25 A **Yes.**

- 1 0 Not a statistician.
- 2 A No.
- 3 Q Now, you were shown a snippet of deposition testimony
- 4 relating to Dr. Lavin's declaration.
- 5 | A **Yes.**
- 6 Q The deposition was of Dr. Lavin, do you recall that?
- 7 | A **I do.**
- 8 Q And you saw that he testified he could have written
- 9 his -- he would have written his declaration differently if he
- 10 | could; is that right?
- 11 A Yes.
- 12 Q And in the course of forming your opinions in this case,
- did you read the entirety of that deposition at one time?
- 14 A At one time.
- 15 Q Did he later provide additional testimony about whether
- 16 he would have written his declaration differently?
- 17 A He did.
- 18 MR. ELIKAN: Can we have on the screen pages
- 19 | 110, 11 -- line 11, through page 111, line 12.
- 20 And these, Your Honor, have been admitted as
- 21 part of the deposition designations in this case.
- 22 **BY MR. ELIKAN:**
- 23 Q And can you read this, please, to yourself, Doctor, and
- 24 | then I'm going ask a question.
- 25 A From where to where? The whole thing here?

- $1 \quad \bigcirc \quad \mathbf{Yes.}$
- 2 A (Witness complies.)
- 3 Okay, counsel.
- Q Do you see he says -- and this is later in the deposition, I'll represent to you, that his calculations
- 6 represent his best estimate?
- 7 A Yes.
- S Q Considering both this passage, and the one you looked at earlier on cross-examination, do you understand Dr. Lavin to
- 10 have clearly admitted that he erred in his statistical
- 11 | calculations?
- 12 A That he clearly erred?
- He notes here it was the best estimate that he could

  come up with given that he only had data parameters, the mean

  and the standard deviation. I think what he's alluding to

  there is he would have needed the raw data to perform a better
- analysis.
- 18 Q Setting aside the issues surrounding Dr. Lavin's
- declaration, to your knowledge, was any statistical analysis
- of Hayashi publically available as of March 2008?
- 21 A No.
- 22 Q And whether or not there were a few patients with higher
- 23 | triglycerides than recorded in -- I think it was Figure 2, is
- 24 | that right?
- 25 A Yes. Figure 2.

Q that we talked about on direct examination, is there
anything in Hayashi that provides posttreatment LDL-C levels
for any individuals over 500?

A No.

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- Q You were shown a slide with some articles in which Amarin provided some assistance in writing -- in your articles. Can you describe what Amarin's role was.
- A So the papers that Mr. Klein showed all addressed research in the Optum database, which is a national healthcare database, and we published a series of papers looking at the impact of hypertriglyceridemia on risks from a broad spectrum of cardiovascular events.

And Amarin provided the statistical support with a statistician at Optum. They also paid for the folks at Optum to run the numbers. They paid for publication charges, and then we did have editorial assistance.

- Q Were they in charge of the final content of the article, so that we look at those and don't see that they're your opinions but, instead, those of Amarin's?
- A No. My colleagues and I had complete academic freedom. We were not steered in one direction or another. The data were the data.
- MR. ELIKAN: Is it possible to switch over to your box there? And if I could ask, once again, for your assistance.

1	Could we have DDX 10.92?
2	BY MR. ELIKAN:
3	Q Do you recall being asked about DX 3009 and this passage
4	from the article that you wrote?
5	A I didn't write this. This was
6	Q I'm sorry. You're absolutely
7	A This was an interview.
8	Q This is the interview. Okay.
9	A Apparently, this was an interview at the American
L O	Diabetes Scientific Sessions in 2018.
11	$\cite{thm}$ And what there are you saying about the JELIS trial and
12	the level of triglycerides of those patients?
13	A "If the patient's primary residual issue is
L 4	elevated triglyceride, there is support from the
15	JELIS trial which demonstrated that the addition of
16	EPA to ongoing statin therapy, particularly in
17	patients with triglycerides over 150, incurred
18	benefit."
L9	There, I was referring to the Saito paper.
20	Q And, again, what is that patient population one that
21	has that has very high triglycerides?
22	${ t A}$ No. The highest triglyceride value was 399 in that
23	subgroup analysis.
24	$\cite{thm}$ And was there something comparable to the MARINE study
25	studying Epadel and showing, demonstrating that in very high

1	triglyceride patients, there's no rise in LDL-C?
2	A No.
3	Q And if you wanted to replicate these results in JELIS or
4	Saito, in a lower triglyceride population, but in a country
5	that doesn't eat quite as much fish, would you want to add
6	DHA, or just use pure EPA?
7	A You would want to add DHA because the DHA in the Japanese
8	diet was already so high, and fish contains a lot of DHA.
9	Q During cross-examination, you were asked numerous times
10	about LDL-C, and it was described in the questioning as a side
11	effect.
12	Before MARINE, did a person of ordinary skill in the
13	art see the rise in LDL-C in while reducing triglycerides
14	in a very high triglyceride patient population as a general
15	phenomenon or as a side effect?
16	A It was a general phenomenon.
17	MR. ELIKAN: Let's turn to LIPITOR and the
18	statins. Can we go to PX 989.
19	Oh, I'm sorry. I forgot to ask you to switch it
20	over. I apologize. Thanks once again.
21	I want to see what ATP III has to say about
22	statins and their ability to lower LDL-C.
23	Can we go to page 108, and I want to bring up
24	the very high triglyceride section in the bottom of Table
25	7.2-4.

- 1 MR. SIPES: What page?
- 2 MR. ELIKAN: Sorry. Your Honor, I've got the
- 3 wrong page. I'll get the right one momentarily.
- 4 Thank you, Mr. Brooks.
- 5 So we're on page 190. And can we look, again,
- 6 at Table 7.2-1, and the entry for very high triglycerides at
- 7 | the bottom. Page 194.
- 8 BY MR. ELIKAN:
- 9 Q And do you see the heading Treatment Considerations For
- 10 | Elevated Serum Triglycerides?
- 11 A I do.
- 12 Q And we've looked at this table before, right?
- 13 A **Yes.**
- 14 Q And we discussed goals of therapy?
- 15 A **Yes.**
- 16 Q I would like to look at what the ATP III had to say about
- 17 | statins. Is there a line for statins here?
- 18 | A Yes, there is.
- 19 MR. ELIKAN: Can we highlight that, Mr. Brooks.
- 20 Sorry. Lower on down, under "very high triglycerides."
- 21 **BY MR. ELIKAN:**
- 22 Q And for very high triglycerides, what does the ATP III
- 23 | have to say about statins?
- 24 A "Not first line agent for very high
- 25 triglycerides, statins not powerful triglyceride

- 1 lowering drugs."
- 2 Q Is that consistent with your own clinical experience?
- 3 | A Yes, it is.
- 4 Q And is that why, in some of the papers that
- 5 | we've seen, statins are given along with a true
- 6 triglyceride-lowering agent?
- 7 | A **Yes.**
- 8 Q And are statins approved to treat very high
- 9 triglycerides?
- 10 A No.
- MR. ELIKAN: Can we have PX 486, the Bays 2008
- 12 paper.
- One moment, Your Honor.
- 14 BY MR. ELIKAN:
- 15 Q In looking at page 2, the bottom left, do you see a
- sentence starting, "Statins and ezetimibe..."
- 17 A **Yes.**
- 18 Q And what does Dr. Bays have here to say about statins?
- 19 A "Statins and ezetimibe are approved lipid
- altering drugs that may modestly reduce triglyceride
- 21 levels."
- 22 Q And what do you understand from the word "modestly"?
- 23 A Well, it would be suboptimal or it's not a very
- 24 significant effect.
- 25 Q And do you see after that it says, Dr. Bays says, "They

- 1 | are mainly used to lower LDL cholesterol, LDL-C levels"?
- 2 A Yes.
- 3 Q Is that consistent with your clinical experience?
- 4 A Yes.
- 5 Q Does Dr. Bays go on to report what agents are useful to
- 6 reduce triglyceride levels?
- 7 | A **Yes.**
- 8 Q Which ones? What does he have to say?
- 9 A He notes that other lipid altering agents that are used
- 10 more specifically to reduce triglyceride levels include
- 11 | niacin, fibrates, and omega-3 fatty acids.
- 12 Q And are those the agents that were available in 2008
- 13 | specifically to reduce triglycerides in a very high
- 14 triglyceride population?
- 15 A **Yes.**
- 16 MR. ELIKAN: Is it possible to do that switch
- 17 | thing again?
- 18 THE CLERK: Absolutely.
- 19 MR. ELIKAN: Thank you very much.
- 20 Could we have DDX 8.8.
- 21 **BY MR. ELIKAN:**
- 22 Q I'll represent to you that this was defendants'
- demonstrative that they used while examining Mr. Hofmann, an
- 24 economist, a few days ago.
- 25 Based on what we've been discussing, do you have an

1	understanding as to why there is no LIPITOR or other statin in
2	this market share analysis of triglyceride reducing drugs?
3	MR. KLEIN: Objection, Your Honor. This is
4	beyond the scope of my cross.
5	MR. ELIKAN: It's squarely within the scope of
6	the cross. The cross was trying to establish that LIPITOR and
7	other statins were a triglyceride-lowering agent. It's
8	inconsistent with the position taken by Mr. Hofmann. It's
9	spot-on the cross.
10	MR. KLEIN: Your Honor, I went through the
11	LIPITOR label, and it says what it is, and it is approved for
12	patients above 500. I don't know what that has to do with
13	this prescription share analysis which I never used.
14	THE COURT: I agree, Mr. Klein, you didn't use
15	this DDX 8.8, but I assume the point that's made here is
16	consistent with this line of redirect, and, that is, that
17	statin is not used to reduce TG levels.
18	Is that right? I mean, that's what you're
19	trying to ask the witness.
20	MR. ELIKAN: That's right. It's really not even
21	considered a triglyceride reducing agent, other than with the
22	limited utility that was pointed to in ATP III and in
23	Dr. Bays' article.
24	THE COURT: But what you're using this
25	demonstrative for is to ask Dr. Toth if he knows why this

1	chart doesn't include statins. Is that asking him to
2	speculate why somebody prepared a chart?
3	MR. ELIKAN: No. I'm asking him whether has he
4	an understanding as to whether a statin is part of the
5	triglyceride-lowering or reducing drug market, and that, as a
6	physician who has ready access to different
7	triglyceride-reducing drugs will know full-well what the
8	options are.
9	THE COURT: All right. I'm sustaining the
10	objection. I'm not going to allow the doctor to testify as to
11	this demonstrative.
12	He certainly can testify as to what his
13	understanding is as a treating physician and what's available
14	in the market, which I think he's testified to repeatedly.
15	So if you want to ask him the question without
16	the chart, you may do so.
17	MR. ELIKAN: I'm going to move on, Your Honor.
18	BY MR. ELIKAN:
19	Q Let's go back to the Bays' article, PX 486, and I want to
20	look at page 9 under the heading, "Statins and P-OM3"
21	prescription omega-3 fatty acids, "Reduce Triglyceride Levels
22	By Different Mechanisms."
23	Do you see that heading?
24	A Yes.
25	Q And is it correct that statins and omega-3 fatty acids

- reduce triglycerides by different mechanisms?

  A Yes.
- 3 Q Are statins HMG-CoA inhibitors?
- 4 A Yes.
- 5 Q And do they inhibit cholesterol biosynthesis?
- 6 A They sure do.
- 7 Q Does that lead to increased clearance of LDL from the
- 8 blood?
- 9 A It does.
- 10 Q And do you see that Dr. Bays says,
- "Up-regulated LDL receptors may also increase
- clearance of other TG-containing lipoproteins at
- least partially accounting for the modest TG lowering
- effects of statins"?
- 15 A I do see that.
- 16 Q Is there any evidence that either EPA or DHA inhibits
- 17 **HMG-CoA?**
- 18 A No, there's no evidence for that.
- 19 Q And whatever EPA and DHA do, is it fair to say they don't
- 20 | act like statins?
- 21 A **Yes.**
- 22 MR. ELIKAN: I would like to go DX 3007.
- Can we go to page 15.
- 24 THE COURT: Are you looking at -- are you asking
- 25 | to switch the monitor?

1 MR. ELIKAN: Oh, I'm so sorry. 2 THE COURT: That's okay. Sorry. 3 MR. ELIKAN: Yes. 4 And can we have the paragraph two up from the 5 Table, Mr. Brooks. "LIPITOR has not been studied..." 6 What does the LIPITOR label here report? 7 Α "LIPITOR has not been studied in conditions 8 where the major lipoprotein abnormality is elevation 9 of chylomicrons, Fredrickson Types I and V." 10 I believe you've testified about this already, but we 11 call this HLP V; is that right? 12 That -- yes, it would be HLP V. Α Yes. 13 And is that the same as very high triglycerides? Yes. 14 Α 15 I want to look at the table you were shown. That's on 16 page 12, Table 9 -- I'm sorry, I'm on page 21. I know it's Table 9. 17 18 Let's go to pages 11 and 12, then, that's where 19 Table 4 is? 20 Do you see for Atorvastatin, 10 milligrams, N equals 21 37? 22 Α Yes. What are the numbers right below that? The minus 41, and 23 24 then it has something in parentheses. 25 Minus 76.2 and 49.4.

- 1 Is that the range of response? 2 Α Yes. 3 That mid max percent change from baseline? 4 Α Yes. And if we look at the 80-milligram, what is that range of 6 response? For 80 milligrams, it was minus 60 to minus 8 13.8 percent -- I'm sorry, minus 82 and up to 41.3. 9 And there was N equals 14? 10 Α Yes. 11 Does this indicate that Atorvastatin is well controlling 12 the triglycerides, or not? 13 No. It's pretty bizarre that you would see a 40 and 14 50 percent elevation, at least in one patient, in the 15 triglyceride. It's not an effect you would want to see. 16 MR. ELIKAN: One moment, Your Honor. 17 At this time, no more questions, Your Honor.
- 19 recross?

18

- 20 THE COURT: Yes.
- 21 RECROSS-EXAMINATION
- 22 BY MR. KLEIN:
- 23 Q Dr. Toth, do you remember on redirect counsel asked you

MR. KLEIN: Your Honor, may I have a brief

- 24 | about Dr. Bays' 2011 article on MARINE?
- 25 A **Yes.**

1	${\mathbb Q}$ And, in particular, he pointed you to the sentence in the
2	article that said that the LDL neutral effects seen were an
3	unexpected finding?
4	A Yes, counsel.
5	Q Okay. And for the record, I'm referring to DX 1741.
6	Are you aware that Dr. Bays was rather ambivalent
7	about that particular language?
8	A I'm not aware that he was ambivalent about it.
9	MR. KLEIN: Okay. Let's go to DX 1740. And
10	let's first, let's start in the bottom e-mail.
11	BY MR. KLEIN:
12	Q Okay. And you see this is an e-mail to Dr. Bays'
13	first name is Harold, right?
14	A Yes, it is.
15	Q And you can see this is an e-mail from someone at Amarin
16	to Dr. Bays?
17	A Yes.
18	${\mathbb Q}$ Okay. And they are sending Dr. Bays the manuscript for
19	what became the 2011 article, and they said,
20	"Please see the latest version attached. We
21	have made a minor tweak at the top of page 15. This
22	is very important for Amarin. We can give you a call
23	if you wish to explain it. Otherwise, if this change
24	is acceptable to you, please let us know. The paper

is being cleaned up more, and full references added

after which it will be distributed to the other 1 2 co-authors by tonight as we discussed." 3 Do you see that? I do. 4 Α 5 MR. KLEIN: Okay. Let's go to the top and blow-up doctor -- the -- yeah, that's fine. 6 7 BY MR. KLEIN: 8 Okay. You see Dr. Bays is responding here? 9 Α I do. 10 And he says, "Rene, I am rather ambivalent regarding the below." 11 12 Do you see that? 13 Yes. 14 And the below is quoted from the manuscript. 15 And you can see, if you look at the last sentence, 16 it says, 17 "The unexpected finding in the current trial 18 was that AMR 101 did not increase LDL levels, no 19 statistically significant change." 20 Do you see that? 21 Α I do. 22 MR. KLEIN: And if you take off that last 23 highlighting, Mr. Gross. 24 BY MR. KLEIN: 25 I don't know if you can see it, but it looks like

1	"unexpected" was highlighted in the original. Do you see it's
2	a little there's, like, a dark box around "unexpected"?
3	A Yes.
4	Q Okay. And so Dr. Bays goes on to say,
5	"However, please be aware that the statement
6	below, 'that this finding was unexpected," in quotes,
7	"is in contradiction to the rest of the manuscript.
8	My initial sense is that it largely guts the current
9	storyline of the paper, and the reality of this drug
10	development program."
11	Is this an e-mail that Amarin had shown you in
12	connection with this case?
13	A A long time ago. I recall it now.
14	MR. KLEIN: Okay. No further questions, Your
15	Honor.
16	THE COURT: Is that e-mail admitted yet, 1740?
17	MR. KLEIN: Yes, it came in with designations.
18	THE COURT: All right. Thank you.
19	MR. ELIKAN: Your Honor, I have a few brief
20	questions.
21	THE COURT: You want to do a re-redirect based
22	on the recross?
23	MR. ELIKAN: That was my intention.
24	THE COURT: I'm going to permit brief
25	re-redirect and re-recross if needed.

## 1 REDIRECT EXAMINATION 2 BY MR. ELIKAN: 3 You were just shown an e-mail, and my question to you is 4 whether you know whether there were any further exchanges between Dr. Bays and Amarin about this sentence, whether by 6 e-mail or telephone. I do not. 8 Are you in a position to put yourself in his head and 9 determine what he meant by the statements he made in his 10 e-mail? 11 Of course I'm not. 12 Did Dr. Bays, and the other authors, ultimately decide to 13 include the sentence about an unexpected finding in the final 14 manuscript? 15 It is in the paper. 16 MR. ELIKAN: I want to look at the article 17 itself. Can we have DX 1741. Can we look at the bottom and 18 see when it was published. The bottom of the 19 abstract actually -- or that will work, too. 20 THE WITNESS: In 2011. 21 MR. ELIKAN: And can we scroll up to the end of 22 the abstract? 2.3 BY MR. ELIKAN:

What journal was this published in?

The American Journal of Cardiology.

24

- 1 Q Have you served as a peer reviewer for that journal?
- 2 A Yes.
- 3 | Q In your experience, does it maintain a rigorous peer
- 4 review process?
- 5 A It does.
- 6 Q Based on the final manuscript, does it appear that the
- 7 | peer reviewers insisted on the removal of the sentence?
- 8 A No.
- 9 Q We discussed during your direct examination an Editor's
- 10 Roundtable, PX 833.
- 11 A Yes.
- 12 O In which doctor --
- 13 THE COURT: Does this now exceed the scope of
- 14 | the re-recross?
- 15 MR. ELIKAN: This goes exactly into Dr. Bays'
- 16 | mindset, so I think it's squarely --
- 17 THE COURT: This witness already testified he
- 18 can't go into Dr. Bays' mindset.
- MR. ELIKAN: Well, Dr. Bays is very clear about
- 20 his mindset in the Editor's Roundtable.
- 21 THE COURT: Then the document will speak for
- 22 itself.
- 23 MR. ELIKAN: I guess, then, there are no further
- 24 questions.
- 25 THE COURT: Thank you.

1	Mr. Klein, do you have any?
2	MR. KLEIN: I do not, Your Honor.
3	THE COURT: All right. Thank you.
4	Dr. Toth, that means you may be excused.
5	THE WITNESS: Thank you so much, Your Honor.
6	(The witness was excused.)
7	MR. SIPES: Your Honor, we have no further live
8	witnesses. We just have some deposition excerpts to move in.
9	My colleague, Alaina Whitt, will do that.
10	MS. WHITT: As Mr. Sipes mentioned, we have some
11	final deposition designations to submit from Peter Mathers and
12	Howard Weintraub, and with those designations we have a few
13	exhibits to also move into evidence, if I may read those off.
14	There's just about ten.
15	THE COURT: Yes, Ms. Whitt.
16	MS. WHITT: Okay. So we're starting with PX
17	289, which is the same as DX 1701. So we'll move both of
18	those in together;
19	Same goes for PX 572 and DX 1678;
20	PX 573 and DX 1681;
21	PX 776 and DX 1682.
22	And those are all for the deposition of Peter
23	Mathers.
24	And then we have two exhibits for the deposition
25	of Howard Weintraub, and those are DX 1897 and DX 1906.

1	And I would also note
2	THE COURT: So just those two exhibits for
3	MS. WHITT: For Dr. Weintraub's designations,
4	yes. So those are the exhibits that we would move in.
5	THE COURT: And then you started to say more,
6	and I interrupted you.
7	MS. WHITT: I can wait until those are moved
8	into evidence.
9	THE COURT: Are you moving those into evidence?
10	MS. WHITT: Yes, please.
11	THE COURT: Is there any objection?
12	MR. KLEIN: No objection.
13	THE COURT: All right. The motion is granted.
14	(Plaintiffs' Exhibits 289, 572 and 573 received in evidence.)
15	(Defendants' Exhibits 1701, 1678, 1682,
16	1897 and 1906 received in evidence.) MS. WHITT: And then just one final note that
17	we'll be submitting the final transcripts for all of the
18	designations that have been submitted in court or during
19	trial, and those will have links to the exhibits that have
20	also been admitted, and we'll be submitting those tomorrow.
21	THE COURT: All right. Thank you.
22	MS. SUN: Your Honor, this is Caroline Sun for
23	defendants. At this time, defendants would like to offer the
24	designated deposition testimony of Aaron Berg into the record.
25	There are no exhibits to move in.

1	And it is my understanding that our paralegal
2	will drop off a flash drive before the close of business
3	today.
4	THE COURT: Thank you.
5	Any objection?
6	MR. SIPES: No objections, Your Honor.
7	THE COURT: All right. The motion is granted.
8	All right. Does the plaintiff rest then?
9	MR. SIPES: Yes, Your Honor. We close our
10	rebuttal case.
11	THE COURT: Okay. Thank you.
12	Do defendants have rebuttal witnesses to offer?
13	MR. KLEIN: No, Your Honor.
14	THE COURT: Ms. Huttner, is that correct?
15	MS. HUTTNER: Yes, Your Honor, it is.
16	THE COURT: All right. Then the evidence is in.
17	I have some housekeeping matters, and then I
18	want to ask counsel about what I had promised to do in terms
19	of issuing the bench order.
20	Mr. Sipes, you had indicated that Amarin would
21	like to offer some articles or some additional information to
22	give context to the exhibits that I admitted, the 3000 to 3005
23	series of exhibits.
24	MR. SIPES: That's correct.
25	THE COURT: What do you plan to offer?

Τ	MR. SIPES: We plan to offer a couple of
2	articles that discuss what is included in the CMS open
3	payments report and the reliability of that report, and we
4	will get them to you by tomorrow.
5	THE COURT: I'm anticipating that if there's an
6	objection or if Mr. Klein and his colleague want to address
7	any issue raised by these additional exhibits, how I would
8	resolve them. So do you have an idea of what you would be
9	offering?
LO	MR. SIPES: My colleague, Mr. Kennedy, is more
L1	familiar what we will be offering, and Mr. Elikan. But, I
L2	believe it's a number of published articles on the CMS open
L3	payments.
L 4	We can send it to defendants in advance of
L5	submitting it to the Court, Your Honor.
L6	THE COURT: Yes. Thank you.
L7	And I'll permit Mr. Klein and his colleague to
L 8	
LO	offer any response, and I'll consider give the information
L9	offer any response, and I'll consider give the information whatever weight it deserves in the bench order.
L 9	whatever weight it deserves in the bench order.
L9 20	whatever weight it deserves in the bench order.  MR. SIPES: Thank you, Your Honor.
L9 20 21	whatever weight it deserves in the bench order.  MR. SIPES: Thank you, Your Honor.  THE COURT: So the deadline for you to submit
19 20 21 22	whatever weight it deserves in the bench order.  MR. SIPES: Thank you, Your Honor.  THE COURT: So the deadline for you to submit  the articles will be tomorrow, and then I will give Mr. Klein
19 20 21 22 23	whatever weight it deserves in the bench order.  MR. SIPES: Thank you, Your Honor.  THE COURT: So the deadline for you to submit  the articles will be tomorrow, and then I will give Mr. Klein and Ms. Huttner what's tomorrow, Wednesday?

1 Next, I know that I need to resolve -- do I need 2 to resolve the issue of sealing any exhibits? I know I kept 3 deferring that until the end of the trial. 4 MR. SIPES: Yes, Your Honor. We would like the 5 opportunity to redact some of the exhibits before they're put 6 in a public exhibit room. 7 We would -- and I think we haven't done that, 8 Your Honor, but we can also, tomorrow, submit a list of the 9 exhibits we would like the opportunity to redact. 10 THE COURT: I would like for the process to be 11 clearer because we're talking about extensive exhibits, and I 12 did not keep track to look at the bottom which has been 13 designated as confidential. 14 I assumed -- so this is the process. Unless I 15 see a designation to seal, I assume everything else is 16 unsealed. 17 For the designation to seal, I want a list that 18 includes the exhibit number, the relevant page, a sentence 19 stating why it should be -- compelling reason exists to seal, 20 and if there's a dispute by the other side that it shouldn't 21 be seal, then a sentence responding why it shouldn't be 22 sealed. 2.3 I don't think -- because of the number of 24 exhibits, I'm trying to make this less burdensome. My concern

is if you actually submit the redacted version, it's going to

1	be pretty onerous.
2	So let's try that process first. Just the list
3	and I can look through if it becomes too difficult for me,
4	I'll let you know.
5	MR. SIPES: All right. Thank you.
6	THE COURT: And the same for I don't know if
7	the defendants have any exhibits that you've designated that
8	you think should be sealed.
9	MS. HUTTNER: I don't believe so, Your Honor.
10	THE COURT: All right. So it will just be on
11	Amarin's part to submit their information, and I would like
12	the information well, I'll give you more time since how
13	much time do you need?
14	MR. SIPES: Can we next week, Your Honor?
15	Could we do it sometime towards the end of next week.
16	THE COURT: Next Friday.
17	MR. SIPES: That sounds great.
18	THE COURT: Well, you need to give the list to
19	defense counsel to review first. So, you have until next
20	Friday to give the other side the list.
21	And then so next Friday will be February 7th,
22	and I would like to know so do the Amarin will provide
23	defense counsel the list of exhibits and what will be proposed
24	to be redacted and the reason, by February 7th.
25	And I will give defense counsel until

1	February 14th well, you have until February 12th to
2	respond. If there's still any disagreement that still needs
3	to be resolved, then both sides will submit the information to
4	the Court by February 14th.
5	So, what I'd like to know is I want to get the
6	information by February 14th so I have a deadline.
7	As I said, I want to avoid as much redaction as
8	necessary. I don't want the bench order to be sealed. So,
9	that's my goal. If I refer to exhibits that are redacted, I
10	probably wouldn't seal the order anyway.
11	MR. SIPES: And, Your Honor, I'm pretty
12	confident that what we will be redacting will not be portions
13	of documents that were discussed in open court.
14	THE COURT: Thank you.
15	That leads me to when the bench order needs to
16	be issued. I realize I think I'm trying to think back
17	to what I agreed to do. I thought I remembered a March the
18	end of March date.
19	Is that when I should have the bench order
20	issued, by the end of March, or is it earlier?
21	MR. SIPES: I recall March 31st, Your Honor.
22	MS. HUTTNER: Yeah.
23	MR. SIPES: But, I won't speak for the
24	defendants.
25	MS. HUTTNER: I think Your Honor had mentioned

1	that you had some issue with the court administration or the
2	age of the case in selecting that. But that's my
3	recollection.
4	THE COURT: I don't remember. I just remember
5	March 31st as the date.
6	MS. HUTTNER: That's what I heard as well.
7	THE COURT: I don't recall counsel proposed
8	requesting post-trial briefs.
9	MR. SIPES: I think we would like some form of
10	post-trial brief or post-trial findings of fact and
11	conclusions of law.
12	THE COURT: Did you submit any proposed
13	deadline?
14	I'm getting trials mixed up. I have another
15	trial coming up in two weeks where there are actually
16	deadlines proposed from the date of the transcript becomes
17	available. So I'm trying to I don't want to get the two
18	cases mixed up.
19	So, here's what I would like to do. I think it
20	would be I know you may like to have a post-trial brief.
21	What would be very helpful for me is as I said, the
22	pretrial brief I found to be very helpful to give me the
23	framework and the issues that I was supposed to be thinking
24	about in listening to evidence at trial, so thank you for
25	doing that.

But proposed findings are also helpful, and I'm going to ask you to do one more thing with respect to the proposed findings, which will save me a lot of time, and that is that you cite to the record that's now available because I always endeavor to cite to the record to support my proposed finding.

So the order is going to consist, in the proposed findings of fact section, facts that I may take from one party or the other, depending on who I agree with -- for the most part, you agree on a lot of things -- and then I want to offer a citation to the trial to support that finding.

So if you want to revise your proposed findings and cite to the record, that would be much appreciated.

And if you think it's necessary to have a closing -- a closing brief to present the arguments that you want to present, I will permit that as well. But, I don't want to delay that for too long because I don't want to forget what I've heard so far in the last few weeks.

So I would set that deadline from the date the official transcript becomes available, but I don't know when we would have a time for that.

What do you think? What's your timeframe?

MR. SIPES: That sounds good to us. I'm not

sure when the final transcript will be due. But, we were

thinking something along the lines of the -- each party submit

2.3

its post-trial findings of fact, conclusions of law on, say, 1 2 the 14th -- if I have the Friday right. So, that would leave 3 Valentine's Day evening free. And then a post-trial brief that would then be 4 5 submitted a week later, so that would give us a chance, as 6 well, to comment on each side's proposed findings of fact, 7 conclusions of law, which if I'm doing the math right, would be the 21st. 8 9 THE COURT: If I give you the 13th to submit 10 post-trial proposed findings, would that give you enough time? 11 MR. SIPES: I think so, Your Honor. I don't know when -- do you have --12 THE COURT: 13 I know you have the rough transcript. I don't know if you 14 have the official transcript though. 15 MR. SIPES: We have two. The first two days are 16 in final, I believe, and we will probably be conferring if 17 there are any errata. But we have the first two days. 18 But I think the 13th for the post-trial proposed 19 findings of fact and conclusions of law would be fine. 2.0 should make Valentine's Day a little better. 21 MS. HUTTNER: My only concern is when the final 22 transcript will be available. 2.3 MR. SIPES: But I think we can probably start 24 working from the redacted so long as we think we might get the 2.5 final in a week?

1	THE COURT: I don't know. Let's ask.
2	(Conversation with the court reporter and the
3	Court held off the record.)
4	MR. SIPES: Your Honor, if it would help, we
5	have a proposal, if it works for the Court, which would be to
6	submit our post-trial findings of fact and conclusions of law
7	two weeks after we get the final, and then the brief one week
8	thereafter, and that way, we'll just work from whenever the
9	final becomes available.
10	THE COURT: If we follow that schedule so two
11	weeks after the final, let's assume that you have the final by
12	February 7th, two weeks would be the 21st, and then you would
13	propose the closing well, why would you need to delay the
L 4	closing briefs?
15	MR. SIPES: To have the opportunity to review
16	the other side's proposed findings of fact and conclusions of
17	law, and comment on that as well.
18	THE COURT: So that everything would be
19	submitted by the end of February? That would give me then the
20	month of March.
21	All right. I'll approve that schedule.
22	But even though I'm going to set the deadline
23	for filing the proposed findings two weeks from when the
24	official transcripts are filed, essentially, I'm not going to
25	extend that deadline.

1	So I'm hoping the court reporter would have the
2	transcript ready for you. You may get less than two weeks.
3	I'm going to change the proposal. Proposed
4	findings with citations would be submitted on February 14th
5	sorry, Mr. Sipes. Hopefully, they'll be done before then,
6	before the 14th, Valentine's Day, and the closing briefs are
7	due on the 28th. And I will make sure that I follow-up to see
8	that you get the transcripts within that time.
9	MR. SIPES: So it will be the 14th and the 28th,
10	Your Honor?
11	THE COURT: Yes.
12	MR. SIPES: Perfect.
13	MR. KLEIN: Your Honor, may I ask a point of
14	clarification?
15	THE COURT: Yes.
16	MR. KLEIN: So for the proposed findings, I take
17	it you're asking more than we just add cites to what we had
18	said before. If there are additional findings based on what
19	happened at trial, would you like us to revise what we already
20	submitted?
21	THE COURT: I think that's fair.
22	MR. KLEIN: Okay.
23	MR. SIPES: That's fine.
24	THE COURT: And, of course, if there are
25	findings you don't think are necessary, you could remove them,

1	too.
2	MR. KLEIN: That's true, too.
3	THE COURT: All right. Is there anything else,
4	then, that I need to address before I recess today?
5	MS. HUTTNER: Nothing from DRL, Your Honor.
6	MR. KLEIN: Nothing from Hikma. Thank you.
7	MR. SIPES: Nothing from Amarin.
8	THE COURT: For the proposed findings of fact
9	with citations, in addition to filing them, would you also
LO	submit a Word version to Miss Clerk. It will make it easier
11	on me.
12	MR. SIPES: I guess, Your Honor, there is one
13	question I have, which is whether you have a page limit in
L 4	mind for the post-trial brief.
L5	THE COURT: Yes. There's always a page limit.
L 6	MR. SIPES: That's why I thought I'd ask.
L7	THE COURT: I think it was 30 pages for the
L8	opening brief. I hope you don't exceed the 30 pages, but I'll
L9	give you 30 pages.
20	MR. SIPES: Thank you, Your Honor.
21	THE COURT: There's no limit on the proposed
22	findings of fact.
23	Actually, why don't you, in addition to
24	submitting the Word version of the proposed findings, go ahead
25	and submit the Word version of your post-trial briefs.

1	Because if you agree on the standard, I'll probably just take
2	your legal standard and so on, so it will make it easy as
3	well.
4	MR. SIPES: Fine.
5	THE COURT: Which, actually, I think we started
6	to do anyway with the opening pref.
7	All right. Is there anything else I need to
8	address?
9	MR. SIPES: No, Your Honor.
10	THE COURT: Thank you, counsel. I want to thank
11	everyone for making this trial, with voluminous documents, so
12	seamless.
13	And I want to thank you for being so patient
14	with my schedule and the fact you didn't get consecutive days.
15	But you've all been exemplary and professional, and for that,
16	I thank you.
17	MR. SIPES: Thank you, Your Honor.
18	MS. HUTTNER: Thank you, Your Honor.
19	MR. KLEIN: Thank you, Your Honor.
20	(Court adjourned.)
21	-000-
22	I certify that the foregoing is a correct transcript from the record of proceedings
23	in the above-entitled matter.
24	/s/Kathryn M. French 2/4/2020 Kathryn M. French, CCR #392, RPR
25	Official Reporter

			1997 <b>_</b> _
1	INDEX		
2			
3	PLAINTIFF'S WITNESSES:		PAGE:
4	TOTH, Peter Paul, M.D.,		
	Direct Examination by Mr. Elikan		1759
5	Cross-examination by Mr. Klein Redirect Examination by Mr. Elikan		1784 1945
6	Recross-Examination by Mr. Klein		1977
_	Redirect Examination by Mr. Elikan		1981
7			
8			
0	DIATMITTELIC BYHTDIEC	TO	E1115-22-
9	PLAINTIFF'S EXHIBITS:	ID	EVIDENCE
10	289 -		1984
11	572 and 573		1984
11	583 - 951 -		1911
12	1767		
13	PLAINTIFFS' DEMONSTRATIVE EXHIBITS:		
13	PLAINIIFFS DEMONSTRATIVE EARLBITS.		
14	6-31		1765
15			
	DEFENDANTS' EXHIBITS:		
16	1545		1055
17	1545 - 1547 -		1855 1922
	1678 -		1984
18	1682 -		1984
19	1701 - 1709 -		1984 1918
	1897 -		1984
20	1906 -		1984
21	2005 - 2258 -		1873 1852
	2263 -		1851
22	2264 -		1854
23	3000 through 3006 - 3007 -		1945 1812
	3009 -		1916
24	3017 and 3018 -		1936
25	3020 -		1918

#	1839:17, 1839:18,	<b>10.22</b> [1] - 1830:17	<b>10.9</b> [1] - 1817:9	1800:11, 1809:2,
	1839:20, 1839:22,	<b>10.23</b> [1] - 1831:25	<b>10.90</b> [2] - 1911:12,	1813:6, 1815:7,
<b>#392</b> [2] - 1757:22,	1840:5, 1843:1,	<b>10.24</b> [1] - 1833:2	1959:5	1861:22, 1875:20,
1996:24	1843:2, 1844:18,	<b>10.25</b> [1] - 1834:19	<b>10.91</b> [1] - 1912:7	1875:22, 1879:3,
	1845:23, 1847:21,	<b>10.26</b> [1] - 1835:5	<b>10.92</b> [2] - 1913:10,	1880:4, 1880:12,
\$	1848:21, 1852:14,	<b>10.27</b> [1] - 1836:18	1968:1	1881:6, 1885:4,
Ψ	1871:21, 1872:13,	<b>10.28</b> [1] - 1839:4	<b>10.96</b> [1] - 1918:2	1885:15, 1923:2,
<b>\$140,000</b> [2] -	1872:14, 1877:8,	<b>10.3</b> [1] - 1802:5	<b>10.97</b> [1] - 1921:14	1926:20, 1954:17,
1931:12, 1931:17	1883:18, 1883:23,	<b>10.30</b> [1] - 1840:19	<b>10.98</b> [1] - 1923:1	1954:20, 1954:22,
<b>\$300,000</b> [1] - 1940:11	1900:10, 1904:15,	<b>10.31</b> [1] - 1841:15	<b>10.99</b> [1] - 1923:19	1977:9
<b>\$4,875</b> [1] - 1931:20	1921:25, 1946:2,	<b>10.32</b> [1] - 1842:2	<b>100</b> [1] - 1896:18	<b>14th</b> [7] - 1989:1,
<b>\$69,000</b> [1] - 1939:3	1948:10, 1948:17,	<b>10.32</b> [1] - 1842:18	<b>1006</b> [1] - 1765:14	1989:4, 1989:6,
<b>\$70,000</b> [1] - 1933:1	1950:6, 1957:10,	<b>10.35</b> [1] - 1851:6	<b>101</b> [3] - 1833:15,	1992:2, 1994:4,
. , .,	1957:11, 1957:17,	<b>10.36</b> [1] - 1851:14	1833:18, 1979:18	1994:6, 1994:9
1	1957:20	<b>10.37</b> [1] - 1852:6	<b>103</b> [2] - 1868:22,	<b>15</b> [3] - 1933:7,
	<b>1.02</b> [1] - 1771:4	<b>10.38</b> [1] - 1852:14	1868:23	1975:23, 1978:21
<b>'118</b> [4] - 1923:4,	<b>1.8</b> [4] - 1761:15,	<b>10.39</b> [1] - 1853:4	<b>108</b> [1] - 1969:23	<b>150</b> [5] - 1913:23,
1960:1, 1960:25,	1762:5, 1858:1,	<b>10.39</b> [1] - 1853.4 <b>10.4</b> [1] - 1803:14	<b>109</b> [1] - 1909.23	1923:17, 1924:3,
1962:18	1907:21	<b>10.4</b> [1] - 1803.14 <b>10.40</b> [2] - 1853:10,	1932:16	1949:23, 1968:17
<b>'560</b> [2] - 1781:2,	<b>10</b> [15] - 1759:15,	1 <b>0.40</b> [2] - 1853:10, 1853:25	<b>1099s</b> [1] - 1931:19	<b>1500</b> [5] - 1793:11,
1782:10	1770:11, 1775:5,		<b>11</b> [8] - 1815:6,	1794:6, 1798:5,
<b>'652</b> [1] - 1782:14	1798:17, 1799:6,	<b>10.41</b> [1] - 1854:15	1815:21, 1816:5,	1800:11, 1883:7
<b>'677</b> [4] - 1778:22,	1816:14, 1816:19,	<b>10.42</b> [1] - 1855:10 <b>10.43</b> [1] - 1857:18	1830:17, 1889:23,	<b>1502</b> [2] - 1875:19,
1782:5, 1883:13,	1833:4, 1834:18,		1965:19, 1976:18	1879:4
1884:1	1860:16, 1864:12,	<b>10.44</b> [2] - 1857:13,	<b>110</b> [1] - 1965:19	<b>1504</b> [1] - 1883:14
<b>'715</b> [7] - 1779:2,	1902:17, 1906:8,	1858:2 <b>10.45</b> [1] - 1860:17	<b>111</b> [1] - 1965:19	<b>1522</b> [1] - 1802:12
1782:7, 1875:20,	1906:19, 1976:20		<b>112</b> [7] - 1794:24,	<b>1524</b> [5] - 1923:2,
1879:3, 1880:5,	<b>10,800</b> [1] - 1931:20	<b>10.46</b> [2] - 1861:15,	1796:6, 1796:17,	1923:10, 1923:11,
1881:6, 1885:16	<b>10.1</b> [1] - 1784:16	1878:7	1799:24, 1800:3,	1923:19, 1960:1
<b>'728</b> [8] - 1778:11,	<b>10.10</b> [1] - 1821:3	<b>10.47</b> [1] - 1864:22	1800:4	<b>1528</b> [2] - 1823:8,
1778:15, 1781:1,	<b>10.100</b> [1] - 1923:23	<b>10.49</b> [1] - 1867:10 <b>10.5</b> [1] - 1804:21	<b>12</b> [20] - 1762:16,	1864:5
1782:4, 1793:12,	<b>10.101</b> [1] - 1925:19		1776:3, 1776:7,	<b>153</b> [4] - 1769:23,
1794:3, 1797:10,	<b>10.108</b> [1] - 1928:19	<b>10.50</b> [1] - 1868:20	1776:8, 1776:22,	1902:18, 1958:10,
1800:11	<b>10.109</b> [1] - 1930:9	<b>10.51</b> [1] - 1870:8	1776:23, 1815:21,	1961:3
<b>'782</b> [3] - 1780:24,	<b>10.11</b> [1] - 1822:2	<b>10.52</b> [1] - 1870:21	1816:6, 1817:12,	<b>1532</b> [3] - 1861:21,
1781:11, 1781:22	<b>10.110</b> [1] - 1930:19	<b>10.588</b> [1] - 1871:14	1821:24, 1835:16,	1870:10, 1870:24
<b>'929</b> [4] - 1778:25,	<b>10.112</b> [1] - 1916:3	<b>10.59</b> [1] - 1872:11	1869:11, 1895:12,	<b>1535</b> [2] - 1817:13,
1782:22, 1783:2	<b>10.113</b> [1] - 1917:1	<b>10.6</b> [1] - 1809:2	1895:15, 1895:17,	1822:4
'that [1] - 1980:6	<b>10.114</b> [2] - 1927:21,	<b>10.60</b> [1] - 1873:3	1916:7, 1961:12,	<b>1537</b> [1] - 1861:22
	1928:2	<b>10.61</b> [1] - 1874:25	1965:19, 1976:16,	<b>1538</b> [8] - 1800:13,
/	<b>10.115</b> [1] - 1928:10	<b>10.62</b> [4] - 1875:17,	1976:18	1824:15, 1825:22,
	<b>10.118</b> [1] - 1819:20	1877:3, 1882:18,	12-week [1] - 1761:20	1829:12, 1842:24,
/s/Kathryn [1] -	<b>10.119</b> [1] - 1793:9	1884:20 <b>10.66</b> [1] - 1881:19	<b>12th</b> [1] - 1989:1	1842:25, 1847:21,
1996:24	<b>10.12</b> [1] - 1823:8	<b>10.66</b> [1] - 1881:19 <b>10.67</b> [1] - 1883:12	<b>13</b> [10] - 1835:15,	1881:22
^	<b>10.120</b> [1] - 1793:23	<b>10.67</b> [1] - 1803.12 <b>10.7</b> [1] - 1813:22	1835:17, 1875:20,	<b>1539</b> [2] - 1861:22,
0	<b>10.121</b> [1] - 1800:9	<b>10.7</b> [1] - 1813:22 <b>10.76</b> [1] - 1894:4	1875:22, 1875:23,	1877:4
<b>0.79</b> [1] - 1900:9	<b>10.122</b> [1] - 1904:12		1875:25, 1882:24,	<b>154</b> [2] - 1958:11,
<b>0.79</b> [1] - 1900.9	<b>10.123</b> [1] - 1848:9	<b>10.77</b> [1] - 1897:14 <b>10.78</b> [1] - 1899:15	1885:10, 1917:6,	1961:4
v3[i] - 1//2.11	<b>10.125</b> [1] - 1846:6		1923:2	<b>1542</b> [1] - 1864:23
4	<b>10.126</b> [1] - 1847:18	<b>10.8</b> [1] - 1815:19	<b>13.8</b> [1] - 1977:8	<b>1545</b> [5] - 1854:16,
1	<b>10.127</b> [1] - 1864:3	<b>10.80</b> [1] - 1900:16	<b>1326</b> [1] - 1795:11	1854:23, 1855:6,
<b>1</b> [46] - 1771:9,	<b>10.13</b> [1] - 1824:13	<b>10.81</b> [1] - 1900:24	<b>1331</b> [1] - 1795:11	1855:8, 1997:16
1771:10, 1778:10,	<b>10.14</b> [1] - 1825:2	<b>10.82</b> [1] - 1901:8	<b>1362</b> [1] - 1795:9	<b>1546</b> [1] - 1861:21
1778:14, 1780:24,	<b>10.15</b> [1] - 1825:15	<b>10.83</b> [1] - 1906:7	<b>1364</b> [1] - 1795:5	<b>1547</b> [6] - 1921:24,
1770:14, 1700:24,	<b>10.16</b> [1] - 1825:21	<b>10.84</b> [1] - 1906:18	<b>1369</b> [1] - 1795:9	1922:3, 1922:4,
1781:21, 1782:4,	<b>10.17</b> [1] - 1826:3	<b>10.85</b> [1] - 1907:5	<b>1374</b> [1] - 1795:6	1952:8, 1953:22,
1782:5, 1782:14,	<b>10.18</b> [1] - 1826:10	<b>10.86</b> [1] - 1908:5	13th [3] - 1923:6,	1997:17
1782:22, 1783:1,	<b>10.19</b> [1] - 1827:6	<b>10.87</b> [1] - 1908:24	1992:9, 1992:18	<b>1550</b> [1] - 1861:21
1825:22, 1836:19,	<b>10.20</b> [1] - 1827:12	<b>10.88</b> [1] - 1909:14	<b>14</b> [24] - 1779:2,	<b>1551</b> [1] - 1855:10
1839:14, 1839:16,	<b>10.21</b> [1] - 1829:9	<b>10.89</b> [1] - 1910:11	1782:7, 1794:6,	<b>1553</b> [8] - 1763:5,
,,				

1932:13, 1939:5  2020 [3] - 1757:6, 1759:1, 1944:1  207 [1] - 1950:25  21 [3] - 1868:23, 1883:14, 1976:16  210 [1] - 1833:12  211 [1] - 1833:13  21st [2] - 1992:8, 1993:12  22 [4] - 1869:20, 1875:19, 1879:4, 1883:14  2235 [1] - 1909:15
2241 [1] - 1830:17 2258 [5] - 1852:14, 1852:19, 1852:22, 1852:23, 1997:21 2263 [5] - 1851:16, 1851:21, 1851:24, 1851:25, 1997:21 2264 [7] - 1853:11, 1853:13, 1853:17, 1854:7, 1854:9, 1854:10, 1997:22 23 [2] - 1861:22, 1933:7 232 [1] - 1951:8
233 [2] - 1868:25, 1875:3 23rd [1] - 1913:5 24 [1] - 1869:20 24th [1] - 1767:14 25 [8] - 1762:11, 1841:5, 1843:12, 1843:23, 1843:25, 1869:20, 1896:20, 1962:14 25th [3] - 1831:4, 1922:24, 1924:11 26 [1] - 1762:12
26.5 [1] - 1816:22 268 [1] - 1857:22 271 [1] - 1957:23 272 [5] - 1759:13, 1770:10, 1772:5, 1775:4, 1950:22 28 [5] - 1757:6, 1759:1, 1771:15, 1771:23, 1944:1 289 [3] - 1983:17, 1984:14, 1997:10 28th [2] - 1994:7, 1994:9 2:16-cv-02525-MMD- NJK [1] - 1757:5
*

1770:21, 1772:15, 1836<sub>[1]</sub> - 1908:25 1899:17, 1900:10, 184 [2] - 1902:19, 1900:17, 1951:20, 1958:9 1957:24 **1851** [1] - 1997:21 **1578** [3] - 1871:20, **1852** [1] - 1997:21 1872:13, 1957:10 1854 [1] - 1997:22 **1587** [1] - 1803:14 **1855** [1] - 1997:16 1589 [1] - 1867:25 **186** [1] - 1950:20 1591 [1] - 1805:10 1862 [5] - 1832:1, **16** [5] - 1794:6. 1857:13, 1907:6, 1800:11, 1821:20, 1908:6, 1908:19 1918:3, 1954:17 1873<sub>[1]</sub> - 1997:20 **1605** [5] - 1844:9, 1897<sub>[3]</sub> - 1983:25, 1846:10, 1846:12, 1984:15, 1997:19 1847:20, 1946:5 **19** [9] - 1769:17, **1635** [1] - 1821:6 1803:15, 1843:13, **167** [1] - 1850:14 1843:23, 1843:25, **1678** [3] - 1983:19, 1852:9, 1901:3, 1984:15, 1997:17 1905:7, 1906:24 **1681** [1] - 1983:20 **190** [2] - 1887:8, **1682** [3] - 1983:21, 1970:5 1984:15, 1997:18 **1906** [3] - 1983:25, **1694** [3] - 1889:1, 1984:15, 1997:20 1889:3, 1889:24 **1911** [1] - 1997:11 **17** [5] - 1781:2, **1916** [1] - 1997:23 1782:10, 1918:3, 1918[2] - 1997:19, 1955:23, 1956:4 1997:24 **170** [2] - 1761:18, **1922** [1] - 1997:17 1762:8 1936 [1] - 1997:24 **1701** [3] - 1983:17, **194** [1] - 1970:7 1984:15, 1997:18 **1945** [2] - 1997:5, **1705** [1] - 1860:18 1997:22 **1709** [5] - 1918:3, **1953** [1] - 1875:3 1918:13, 1918:15, **1961** [1] - 1840:21 1918:16, 1997:19 **1966** [1] - 1816:1 **1740** [2] - 1978:9, **1977** [1] - 1997:6 1980:16 **1981** [1] - 1997:6 **1741** [9] - 1836:19, 1984 [7] - 1997:10, 1836:25, 1837:4, 1997:10, 1997:17, 1837:12, 1838:5, 1997:18, 1997:18, 1839:7, 1954:7, 1997:19, 1997:20 1978:5, 1981:17 **1986** [4] - 1809:5, **1759** [1] - 1997:4 1812:21, 1814:24 1765<sub>[1]</sub> - 1997:14 **1990** [1] - 1855:12 1767 [1] - 1997:12 1990s [1] - 1823:4 **1784** [1] - 1997:5 1991 [2] - 1861:24, **18** [6] - 1798:17, 1861:25 1799:7, 1826:21, **1995** [2] - 1861:24, 1826:24, 1827:5, 1864:25 1877.8 **1998** [4] - 1854:1, **18,000** [2] - 1900:13, 1854:12, 1855:22, 1907:19 1861:24 **1800** [2] - 1833:4, **1999** [1] - 1861:25 1834.18 **1:27** [1] - 1944:1 1812<sub>[1]</sub> - 1997:23 **1829** [3] - 1830:17, 2 1906:8, 1906:19

1857:5, 1857:8, 1857:24, 1858:6, 1861:22, 1867:25, 1871:20, 1881:22, 1900:17, 1904:15, 1923:14, 1923:19, 1923:25, 1924:5, 1946:5, 1949:13, 1952:9, 1966:23, 1966:25, 1971:15 2.4 [1] - 1765:9 2.7 [1] - 1858:1 2/4/2020 [1] - 1996:24 20 [11] - 1772:9, 1773:12, 1816:15, 1816:24, 1826:21, 1826:25, 1827:4, 1831:3, 1831:21, 1833:12, 1852:12 **200** [1] - 1950:18 2000 [18] - 1800:13, 1800:14, 1811:23, 1825:9, 1826:12, 1829:22, 1830:1, 1830:8. 1831:13. 1832:19, 1835:20, 1838:12, 1842:15, 1846:17, 1848:1, 1848:2, 1855:21, 1881.23 **2002** [3] - 1851:17, 1852:2, 1855:21 2003 [4] - 1852:15, 1852:25, 1854:18, 1855:22 2005 [7] - 1795:6, 1873:4, 1873:9, 1873:11, 1873:12, 1960:12, 1997:20 **2006** [1] - 1844:9 2007 [13] - 1810:7, 1810:16, 1811:8, 1812:24, 1813:1, 1813:8, 1814:19, 1816:17, 1899:17, 1923:6, 1923:13, 1924:7, 1953:18 2008 [78] - 1762:20, 1764:19, 1765:1, 1765:6, 1765:10, 1769:10, 1770:7, 1779:7, 1786:7, 1807:13, 1807:19, 1808:9, 1808:11, 1809:7, 1809:13,

1953:21, 1955:1, 1956:7, 1956:11, 1956:12, 1966:20, 1971:11, 1972:12 2009 [13] - 1793:15, 1800:25, 1801:8, 1832:5, 1832:12, 1857:15, 1857:20, 1898:2, 1898:10, 1898:13, 1898:25, 1907:8, 1954:23 2010 [7] - 1793:3, 1793:6, 1833:6, 1836:3, 1916:9, 1956:6 2011 [7] - 1762:21, 1802:12, 1836:21, 1837:24, 1977:24, 1978:19, 1981:20 2012[1] - 1795:9 2013 [4] - 1930:25, 1931:11, 1931:17, 1938:2 2014[1] - 1795:11 2015 [2] - 1918:10, 1919:23 2016 [2] - 1762:21, 1931:19 2017 [5] - 1910:14, 1910:15, 1911:6, 1931:20, 1959:20 2018 [10] - 1767:14, 1912:12, 1913:6, 1914:4, 1930:25, 1931:11, 1931:17, 1938:2, 1953:10, 1968:10 2019 [3] - 1932:8,

1823:21, 1824:4,

1827:3, 1829:21,

1829:25, 1830:7,

1831:3, 1831:4,

1831:21, 1835:3,

1835:17, 1848:4,

1850:2, 1850:15,

1851:2, 1856:2,

1856:18, 1859:1,

1860:13, 1860:24,

1873:18, 1874:16,

1874:22, 1875:15,

1876:25, 1878:11,

1879:16, 1879:22,

1881:4, 1882:11,

1883:2, 1891:22,

1897:20, 1898:13,

1898:20. 1898:22.

1901:25, 1902:7,

1921:22, 1922:20,

1922:24, 1924:8,

1924:12, 1951:15,

MARGARET E. GRIENER, RDR, CCR NO. 3, OFFICIAL REPORTER (775) 329-9980

1811:2, 1811:9,

1812:17, 1821:13,

1821:23, 1822:8,

1822:12, 1822:18,

1823:2, 1823:19,

2 [26] - 1767:25,

1771:12, 1794:7,

1800:12, 1817:16,

**183** [4] - 1761:22,

1961:6

1762:9, 1958:16,

**3** [15] - 1768:7,

		_		
1770:21, 1772:15,	1918:1, 1997:24	1949:18, 1950:7,	1818:21, 1818:25,	6
1817:13, 1821:6,	<b>31</b> [1] - 1889:9	1954:17, 1960:4,	1819:1, 1819:4,	6
1822:4, 1823:8,	<b>31st</b> [2] - 1989:21,	1976:19	1819:12, 1820:15,	<b>6</b> [6] - 1772:20,
1829:12, 1840:22,	1990:5	4-gram [10] - 1785:12,	1820:18, 1821:15,	1805:10, 1836:12,
1841:7, 1857:15,	<b>32</b> [3] - 1861:21,	1785:20, 1821:15,	1834:3, 1856:7,	1842:6, 1860:18,
1881:22, 1906:11,	1889:10, 1889:24	1849:24, 1850:7,	1856:9, 1856:11,	1911:13
1923:25, 1957:24	<b>334</b> [1] - 1933:6	1850:10, 1850:16,	1856:13, 1856:20,	<b>6,000</b> [1] - 1933:25
<b>3.6</b> [2] - 1781:3,	<b>35</b> [1] - 1963:13	1851:3, 1851:9,	1856:24, 1858:21,	<b>6-10</b> [2] - 1774:1,
1916:19	<b>350</b> [2] - 1813:20,	1852:25	1858:22, 1859:4,	1774:4
<b>30</b> [6] - 1838:17,	1820:5	<b>4.2</b> [1] - 1872:20	1859:6, 1859:7,	<b>6-13</b> [1] - 1964:9
1877:10, 1934:19,	<b>354</b> [3] - 1798:16,	<b>40</b> [3] - 1922:10,	1859:11, 1859:22,	<b>6-31</b> [5] - 1764:21,
1995:17, 1995:18,	1798:20, 1799:6	1963:10, 1977:13	1859:24, 1860:4,	1765:14, 1765:16,
1995:19	<b>37</b> [2] - 1794:7,	<b>40.5</b> [1] - 1817:7	1860:14, 1861:11,	1765:17, 1997:14
<b>30.4</b> [1] - 1817:2	1976:21	<b>400</b> [3] - 1765:8,	1862:5, 1862:11,	<b>6-32</b> [1] - 1766:2
<b>300</b> [1] - 1850:22	<b>38</b> [1] - 1963:22	1860:9, 1880:2	1862:13, 1862:15,	<b>6-33</b> [1] - 1769:1
<b>300,000</b> [1] - 1942:19	<b>39</b> [2] - 1816:25,	<b>41</b> [3] - 1816:19,	1862:20, 1862:24,	<b>6-34</b> [1] - 1773:23
<b>3000</b> [11] - 1930:23,	1923:2	1870:13, 1976:23	1863:10, 1863:16,	<b>6-35</b> [1] - 1778:19
1933:17, 1936:14,	<b>395</b> [1] - 1795:5	<b>41.3</b> [1] - 1977:8	1863:19, 1863:24,	<b>6-36</b> [1] - 1781:24
1936:15, 1936:18,	<b>399</b> [4] - 1950:25,	<b>432</b> [1] - 1820:9	1864:15, 1864:20,	<b>6-37</b> [1] - 1782:23
1936:23, 1939:23,	1958:24, 1961:11,	<b>450</b> [1] - 1867:15	1866:21, 1866:24, 1867:17, 1867:22	<b>6-7</b> [2] - 1951:4,
1945:9, 1945:16,	1968:22	<b>46</b> [2] - 1794:8,	1867:17, 1867:22, 1867:23, 1870:5	1951:7
1985:22, 1997:22	<b>3rd</b> [1] - 1832:5	1963:22	1867:23, 1870:5, 1871:5, 1871:9,	<b>6.10</b> [1] - 1964:10
<b>30005</b> [1] - 1939:23		<b>47</b> [2] - 1832:1, 1832:8	1871:11, 1877:20,	<b>6.23</b> [1] - 1894:6
<b>3005</b> [5] - 1930:23,	4	<b>486</b> [2] - 1971:11,	1878:12, 1878:17,	<b>6.29</b> [1] - 1897:16
1936:18, 1936:23,	4 4750.45	1974:19	1878:18, 1882:9,	<b>6.7</b> [1] - 1819:22
1945:9, 1985:22 <b>3006</b> [9] - 1930:21,	<b>4</b> [76] - 1759:15,	<b>49.3</b> [1] - 1817:17	1882:12, 1883:7,	<b>6.75</b> [1] - 1784:24
1931:10, 1933:17,	1761:16, 1761:20, 1762:4, 1765:11,	<b>49.4</b> [1] - 1976:25	1883:8, 1883:9,	<b>60</b> [1] - 1977:7
1936:14, 1936:15,	1765:21, 1765:23,	<b>499</b> [4] - 1813:20,	1886:21, 1894:13,	<b>600</b> [2] - 1765:8,
1936:20, 1945:15,	1770:21, 1703:23, 1770:11, 1772:5,	1820:5, 1820:15,	1922:10, 1950:2,	1860:10
		1866:23	1957:4, 1967:3,	<b>62</b> [1] - 1884:24
1945 In 1997 //	1//5/20 1//9//			
1945:16, 1997:22 <b>3007</b> [16] - 1809:2.	1775:20, 1779:7, 1779:12, 1780:2	5	1973:12	<b>64</b> [1] - 1814:1
<b>3007</b> [16] - 1809:2,	1779:12, 1780:2,	5		<b>64</b> [1] - 1814:1 <b>687</b> [1] - 1795:8
<b>3007</b> [16] - 1809:2, 1809:5, 1809:9,	1779:12, 1780:2, 1781:1, 1781:2,	-	1973:12	<b>687</b> [1] - 1795:8
<b>3007</b> [16] - 1809:2,	1779:12, 1780:2,	<b>5</b> [18] - 1770:21,	1973:12 <b>500-milligram</b> [1] -	
<b>3007</b> [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10,	-	1973:12 <b>500-milligram</b> [1] - 1859:17	<b>687</b> [1] - 1795:8
<b>3007</b> [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8,	<b>5</b> <sub>[18]</sub> - 1770:21, 1772:15, 1778:25,	1973:12 <b>500-milligram</b> [1] - 1859:17 <b>52</b> [1] - 1817:5	<b>687</b> [1] - 1795:8 <b>7 7</b> [13] - 1757:8,
<b>3007</b> [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9,	<b>5</b> <sub>[18]</sub> - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5,	<b>7 7 7 1795:8 7 7 1795:8 7 1763:15</b> , 1836:19,
<b>3007</b> [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7,	<b>5</b> <sub>[18]</sub> - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8	<b>7 7 7 17 17 17 17 17 17</b>
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15,	<b>5</b> <sub>[18]</sub> - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1,	<b>7 7 7 1 1 7 1 7 1 1 1 1 1 1 1 1 1 1</b>
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23,	<b>5</b> <sub>[18]</sub> - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17	<b>7 7 7 17 17 17 17 17 17</b>
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17,	<b>5</b> [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6	<b>7 7 7 13 7 17 13 17 1837:18 1870:20 1870:24 1872:25</b>
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25,	<b>5</b> [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7,	<b>7 7 7 13 7 17 13 17 1837:18 1870:20 1870:24 1870:25 1954:9 1955:5</b>
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6,	<b>5</b> [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 <b>50</b> [1] - 1977:14	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19	<b>7 7</b> [13] - 1795:8 <b>7</b> [13] - 1757:8,
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13,	<b>5</b> [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 <b>50</b> [1] - 1977:14 <b>500</b> [98] - 1770:3,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2	<b>7 7 7 13 15 1837:18 1837:18 1837:18 1837:18 1837:18 1837:18 1837:20 1870:20 1870:24 1870:25 1954:9 1955:5 1956:13 1960:8 7,000 13 1933:23</b>
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13,	<b>5</b> [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 <b>50</b> [1] - 1977:14 <b>500</b> [98] - 1770:3, 1770:8, 1785:14,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4,	7 7 [13] - 1795:8 7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3012 [1] - 1928:9	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11,	<b>5</b> [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 <b>50</b> [1] - 1977:14 <b>500</b> [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12,	7 7 [13] - 1795:8 7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3012 [1] - 1928:9 3017 [8] - 1929:3,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1852:8,	<b>5</b> [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 <b>50</b> [1] - 1977:14 <b>500</b> [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23	7 7 [13] - 1795:8 7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3012 [1] - 1928:9 3017 [8] - 1929:3, 1933:17, 1935:21,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1852:8, 1854:13, 1855:2,	<b>5</b> [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 <b>50</b> [1] - 1977:14 <b>500</b> [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19,	7 7 [13] - 1795:8 7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3017 [8] - 1929:3, 1936:5, 1936:10,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1852:8, 1854:13, 1855:2, 1855:17, 1855:23,	5 [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 50 [1] - 1977:14 500 [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10	7 7 7 [13] - 1795:8 7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3017 [8] - 1929:3, 1936:5, 1936:10, 1936:12, 1945:9,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1852:8, 1854:13, 1855:2, 1855:17, 1855:23, 1856:2, 1856:8,	5 [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 50 [1] - 1977:14 500 [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16, 1794:13, 1801:9,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10  573 [3] - 1983:20,	7 7 7 [13] - 1795:8 7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1 71 [1] - 1908:25
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3017 [8] - 1929:3, 1936:5, 1936:10, 1936:12, 1945:9, 1997:24	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1852:8, 1854:13, 1855:2, 1855:17, 1855:23, 1856:12, 1856:19,	<b>5</b> [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 <b>50</b> [1] - 1977:14 <b>500</b> [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16, 1794:13, 1801:9, 1805:5, 1805:14,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10  573 [3] - 1983:20, 1984:14, 1997:10	7 7 7 [13] - 1795:8 7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3017 [8] - 1929:3, 1933:17, 1935:21, 1936:5, 1936:10, 1936:12, 1945:9, 1997:24 3018 [8] - 1933:17,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1852:8, 1854:13, 1855:2, 1855:17, 1855:23, 1856:12, 1856:19, 1856:23, 1857:5,	5 [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 50 [1] - 1977:14 500 [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16, 1794:13, 1801:9, 1805:5, 1805:14, 1805:19, 1805:25,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10  573 [3] - 1983:20, 1984:14, 1997:10  583 [6] - 1910:12,	7 7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1 71 [1] - 1908:25 714 [1] - 1774:6 726 [1] - 1820:23
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3017 [8] - 1929:3, 1933:17, 1935:21, 1936:5, 1936:10, 1936:12, 1945:9, 1997:24 3018 [8] - 1933:17, 1935:19, 1935:21,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:7, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1852:8, 1854:13, 1855:2, 1855:17, 1855:23, 1856:12, 1856:19, 1856:23, 1857:5, 1857:8, 1857:24,	5 [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 50 [1] - 1977:14 500 [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16, 1794:13, 1801:9, 1805:5, 1805:14, 1805:19, 1805:25, 1806:9, 1807:14,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10  573 [3] - 1983:20, 1984:14, 1997:10  583 [6] - 1910:12, 1910:23, 1911:2,	7 7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1 71 [1] - 1908:25 714 [1] - 1774:6 726 [1] - 1820:23 74 [1] - 1953:14
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3012 [1] - 1928:9 3017 [8] - 1929:3, 1933:17, 1935:21, 1936:5, 1936:10, 1935:19, 1935:21, 1935:19, 1935:21, 1936:5, 1936:10,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1855:2, 1855:17, 1855:23, 1856:12, 1856:19, 1856:19, 1856:23, 1857:5, 1857:8, 1857:24, 1858:6, 1864:23,	5 [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 50 [1] - 1977:14 500 [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16, 1794:13, 1801:9, 1805:5, 1805:14, 1805:19, 1805:25, 1806:9, 1807:14, 1807:24, 1807:25,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10  573 [3] - 1983:20, 1984:14, 1997:10  583 [6] - 1910:12, 1910:23, 1911:2, 1911:3, 1911:13,	7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1 71 [1] - 1908:25 714 [1] - 1774:6 726 [1] - 1820:23 74 [1] - 1953:14 748 [1] - 1795:10
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3012 [1] - 1928:9 3017 [8] - 1929:3, 1933:17, 1935:21, 1936:5, 1936:10, 1936:12, 1945:9, 1936:5, 1936:10, 1936:5, 1936:10, 1936:5, 1936:10, 1936:12, 1945:9,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1856:2, 1855:2, 1856:12, 1856:19, 1856:19, 1856:23, 1857:5, 1857:8, 1857:24, 1858:6, 1864:23, 1874:11, 1880:19,	5 [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 50 [1] - 1977:14 500 [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16, 1794:13, 1801:9, 1805:5, 1805:14, 1805:19, 1805:25, 1806:9, 1807:14, 1807:24, 1807:25, 1808:23, 1811:3,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10  573 [3] - 1983:20, 1984:14, 1997:10  583 [6] - 1910:12, 1910:23, 1911:2, 1911:3, 1911:13, 1997:11	7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1 71 [1] - 1908:25 714 [1] - 1774:6 726 [1] - 1820:23 74 [1] - 1953:14 748 [1] - 1795:10 76.2 [1] - 1976:25
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3017 [8] - 1929:3, 1933:17, 1935:21, 1936:5, 1936:10, 1936:12, 1945:9, 1997:24 3018 [8] - 1933:17, 1936:5, 1936:10, 1936:12, 1945:9, 1997:24	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1855:2, 1855:17, 1855:23, 1856:12, 1856:19, 1856:19, 1856:23, 1857:5, 1857:8, 1857:24, 1858:6, 1864:23,	5 [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 50 [1] - 1977:14 500 [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16, 1794:13, 1801:9, 1805:5, 1805:14, 1805:19, 1805:25, 1806:9, 1807:14, 1807:24, 1807:25, 1808:23, 1811:3, 1813:18, 1813:20,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10  573 [3] - 1983:20, 1984:14, 1997:10  583 [6] - 1910:12, 1910:23, 1911:2, 1911:3, 1911:13,	7 7 [13] - 1795:8 7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1 71 [1] - 1908:25 714 [1] - 174:6 726 [1] - 1820:23 74 [1] - 1953:14 748 [1] - 1795:10 76.2 [1] - 1976:25 772 [1] - 1802:12
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3017 [8] - 1929:3, 1933:17, 1935:21, 1936:5, 1936:10, 1936:12, 1945:9, 1997:24 3018 [8] - 1933:17, 1936:5, 1936:10, 1936:12, 1945:9, 1997:24 3020 [7] - 1916:7,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1856:2, 1855:2, 1856:12, 1856:19, 1856:19, 1856:23, 1857:5, 1857:8, 1857:24, 1858:6, 1864:23, 1874:11, 1880:19, 1881:13, 1882:1,	5 [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 50 [1] - 1977:14 500 [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16, 1794:13, 1801:9, 1805:5, 1805:14, 1805:19, 1805:25, 1806:9, 1807:14, 1807:24, 1807:25, 1808:23, 1811:3, 1813:18, 1813:20, 1815:13, 1815:14,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10  573 [3] - 1983:20, 1984:14, 1997:10  583 [6] - 1910:12, 1910:23, 1911:2, 1911:3, 1911:13, 1997:11	7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1 71 [1] - 1908:25 714 [1] - 174:6 726 [1] - 1820:23 74 [1] - 1953:14 748 [1] - 1775:10 76.2 [1] - 1976:25 772 [1] - 1802:12 776 [1] - 1983:21
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3012 [1] - 1928:9 3017 [8] - 1929:3, 1933:17, 1935:21, 1936:5, 1936:10, 1936:12, 1945:9, 1997:24 3010 [7] - 1916:7, 1936:12, 1945:9, 1997:24 3020 [7] - 1916:7, 1916:12, 1917:6,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1856:2, 1855:2, 1856:12, 1856:19, 1856:12, 1856:19, 1856:23, 1857:5, 1857:8, 1857:24, 1858:6, 1864:23, 1874:11, 1880:19, 1881:13, 1882:1, 1884:4, 1885:5,	5 [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 50 [1] - 1977:14 500 [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16, 1794:13, 1801:9, 1805:5, 1805:14, 1805:19, 1805:25, 1806:9, 1807:14, 1807:24, 1807:25, 1808:23, 1811:3, 1813:18, 1813:20, 1815:13, 1815:14, 1817:25, 1818:3,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10  573 [3] - 1983:20, 1984:14, 1997:10  583 [6] - 1910:12, 1910:23, 1911:2, 1911:3, 1911:13, 1997:11	7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1 71 [1] - 1908:25 714 [1] - 174:6 726 [1] - 1820:23 74 [1] - 1953:14 748 [1] - 1795:10 76.2 [1] - 1802:12 776 [1] - 1883:21 7th [3] - 1988:21,
3007 [16] - 1809:2, 1809:5, 1809:9, 1809:12, 1812:24, 1813:3, 1813:6, 1813:7, 1814:17, 1814:18, 1814:23, 1814:24, 1816:4, 1817:12, 1975:22, 1997:23 3009 [6] - 1912:8, 1914:12, 1915:24, 1916:1, 1968:3, 1997:23 3010 [1] - 1928:9 3011 [1] - 1928:9 3017 [8] - 1929:3, 1933:17, 1935:21, 1936:5, 1936:10, 1936:12, 1945:9, 1997:24 3018 [8] - 1933:17, 1936:5, 1936:10, 1936:12, 1945:9, 1997:24 3020 [7] - 1916:7,	1779:12, 1780:2, 1781:1, 1781:2, 1781:3, 1782:10, 1788:7, 1788:8, 1789:2, 1791:9, 1792:1, 1792:23, 1794:20, 1797:11, 1799:21, 1800:13, 1800:15, 1801:8, 1815:23, 1816:14, 1816:17, 1819:3, 1825:25, 1827:3, 1831:6, 1832:19, 1833:13, 1841:11, 1841:13, 1849:21, 1851:11, 1852:3, 1856:2, 1855:17, 1855:23, 1856:12, 1856:19, 1856:23, 1857:5, 1857:8, 1857:24, 1858:6, 1864:23, 1874:11, 1880:19, 1881:13, 1882:1, 1884:4, 1885:5, 1886:16, 1886:21,	5 [18] - 1770:21, 1772:15, 1778:25, 1782:11, 1782:22, 1783:2, 1794:7, 1805:10, 1846:10, 1847:21, 1861:21, 1902:13, 1902:15, 1921:25, 1946:22, 1946:23, 1949:4, 1954:17 50 [1] - 1977:14 500 [98] - 1770:3, 1770:8, 1785:14, 1785:22, 1790:7, 1790:22, 1790:23, 1791:5, 1791:21, 1792:8, 1792:16, 1794:13, 1801:9, 1805:5, 1805:14, 1805:19, 1805:25, 1806:9, 1807:14, 1807:24, 1807:25, 1808:23, 1811:3, 1813:18, 1813:20, 1815:13, 1815:14,	1973:12  500-milligram [1] - 1859:17  52 [1] - 1817:5  53 [6] - 1908:13, 1919:18, 1921:17, 1922:13, 1924:5, 1949:8  533 [3] - 1869:1, 1869:4, 1869:17  54 [1] - 1907:6  55 [4] - 1794:7, 1908:6, 1908:19  550 [1] - 1880:2  565 [5] - 1814:4, 1815:10, 1815:12, 1815:14, 1817:23  572 [3] - 1983:19, 1984:14, 1997:10  573 [3] - 1983:20, 1984:14, 1997:10  583 [6] - 1910:12, 1910:23, 1911:2, 1911:3, 1911:13, 1997:11	7 7 [13] - 1757:8, 1763:15, 1836:19, 1837:8, 1837:17, 1837:18, 1870:20, 1870:24, 1872:25, 1954:9, 1955:5, 1956:13, 1960:8 7,000 [3] - 1933:23, 1934:1, 1935:16 7.2-1 [2] - 1887:22, 1970:6 7.2-4 [1] - 1969:25 70 [2] - 1909:15, 1939:3 700 [1] - 1821:1 71 [1] - 1908:25 714 [1] - 174:6 726 [1] - 1820:23 74 [1] - 1953:14 748 [1] - 1775:10 76.2 [1] - 1976:25 772 [1] - 1802:12 776 [1] - 1983:21

8	1887:5, 1969:18	1908:18	1965:15, 1985:21,	1914:20, 1915:25,
0 4700.F	Λ	acetamide [1] - 1893:17	1986:7, 1994:18  additionally [2] -	1917:24, 1918:15, 1922:3, 1934:12,
<b>8</b> [13] - 1763:5, 1778:22, 1827:10,	Α	achieve [2] - 1791:23,	1934:9, 1937:1	1943:14, 1945:8,
1828:5, 1864:6,	<b>A.M</b> [1] - 1759:1	1925:12	address [8] - 1783:21,	1965:20, 1966:10,
1864:11, 1868:23,	<b>Aaron</b> [1] - 1984:24	achieved [4] -	1822:13, 1891:24,	1980:16, 1984:20,
1873:4, 1883:13,	ability [2] - 1941:4,	1760:10, 1925:12,	1892:8, 1934:25,	1985:22
1883:18, 1883:20,	1969:22	1949:8, 1957:6	1986:6, 1995:4,	admitting [1] -
1884:1, 1951:21	able [13] - 1766:25,	achievement [1] -	1996:8	1936:11
<b>8.8</b> [2] - 1972:20,	1773:8, 1793:5,	1773:14	addressed [3] -	adopted [2] - 1915:1,
1973:15	1795:21, 1799:3,	achieving [1] -	1921:4, 1937:5,	1915:22
<b>80</b> [3] - 1816:15,	1812:7, 1846:10,	1924:17	1967:8	adult [1] - 1821:10
1817:4, 1977:7	1849:9, 1892:14,	acid [15] - 1764:18,	addressing [3] -	advance [4] - 1812:7,
80-milligram [1] -	1892:23, 1894:1,	1764:25, 1780:20,	1824:23, 1856:12,	1915:20, 1931:9,
1977:5	1939:7, 1941:23	1786:1, 1786:5,	1899:5	1986:14
<b>800</b> [2] - 1818:18,	abnormal [1] - 1922:9	1803:18, 1803:20,	adequate [1] -	advanced [1] -
1819:18	abnormality [1] -	1803:23, 1821:17,	1862:16	1964:19
<b>803-8</b> [1] - 1937:20	1976:8	1850:7, 1850:17,	adequately [1] -	advantage [1] -
<b>81</b> [1] - 1772:22	above-entitled [1] -	1962:16, 1962:18,	1793:1	1776:8
<b>816</b> [1] - 1817:20	1996:23	1962:23, 1963:9	adjourned [1] -	adverse [1] - 1905:6
<b>82</b> [1] - 1977:8	absolute [1] - 1948:7	Acid [1] - 1897:19	1996:20	advised [1] - 1939:25
<b>833</b> [3] - 1848:11,	absolutely [3] - 1934:24, 1968:6,	acids [19] - 1760:14,	adjunct [1] - 1813:12	advisory [1] - 1909:18
1848:21, 1982:10	1972:18	1761:5, 1764:6,	adjutant [2] - 1773:6, 1773:7	affect [2] - 1859:23,
<b>8:30</b> [1] - 1759:1	abstract [4] - 1827:15,	1765:11, 1766:6, 1767:7, 1804:1,	administered [10] -	1897:11
	1841:17, 1981:19,	1804:4, 1825:5,	1761:14, 1761:25,	affected [1] - 1827:9 affecting [1] - 1880:21
9	1981:22	1825:11, 1825:18,	1761:14, 1761:23,	age [1] - 1990:2
<b>9</b> [19] - 1760:6,	academic [1] -	1897:23, 1916:23,	1781:12, 1852:3,	•
1836:19, 1837:8,	1967:20	1919:3, 1953:10,	1874:23, 1875:14,	agency [1] - 1938:18 agent [6] - 1760:19,
1837:15, 1837:16,	accept [2] - 1886:1,	1954:1, 1972:11,	1875:16, 1907:20	1892:7, 1970:24,
1837:18, 1839:6,	1937:10	1974:21, 1974:25	administering [6] -	1971:6, 1973:7,
1839:12, 1839:15,	acceptable [1] -	acknowledged [1] -	1775:20, 1779:7,	1973:21
1841:21, 1844:10,	1978:24	1763:1	1781:22, 1884:3,	agents [6] - 1760:13,
1864:6, 1948:11,	accepted [1] - 1964:22	across-the-board [2] -	1919:3, 1953:3	1790:17, 1951:12,
1954:19, 1956:3,	accepting [1] -	1759:18, 1925:16	administration [2] -	1972:5, 1972:9,
1974:20, 1976:16,	1769:19	act [1] - 1975:20	1951:18, 1990:1	1972:12
1976:17	access [1] - 1974:6	Act [1] - 1929:9	administrative [1] -	<b>ago</b> [6] - 1809:22,
<b>9.3.2</b> [1] - 1889:11	accompanied [1] -	action [1] - 1960:13	1912:22	1866:15, 1940:10,
<b>90</b> [2] - 1887:7,	1904:21	active [4] - 1785:24,	admissibility [1] -	1959:1, 1972:24,
1902:14	according [6] -	1786:3, 1786:10,	1935:15	1980:13
<b>900</b> [1] - 1877:8	1816:17, 1821:15,	1786:12	admissible [3] -	agree [35] - 1768:23,
<b>902</b> [1] - 1774:5 <b>905</b> [1] - 1946:18	1911:15, 1929:17, 1931:7, 1931:10	activities [1] - 1937:17 activity [1] - 1858:8	1915:5, 1934:5, 1935:9	1773:15, 1773:19, 1773:22, 1774:21,
<b>903</b> [1] - 1940.18	accounting [1] -	activity [1] - 1802:17,	admission [3] -	1773.22, 1774.21, 1778:5, 1785:12,
<b>93</b> [1] - 1857:13	1975:13	1935:20, 1944:18	1765:13, 1767:15,	1776.5, 1765.12, 1785:19, 1788:7,
<b>951</b> [6] - 1767:9,	accountings [1] -	Adam [1] - 1767:10	1944:15	1788:12, 1797:25,
1767:16, 1767:20,	1935:12	add [6] - 1892:7,	admit [10] - 1809:9,	1830:4, 1830:10,
1767:22, 1767:23,	accrue [2] - 1777:2,	1933:4, 1942:3,	1812:8, 1812:24,	1843:17, 1844:14,
1997:11	1896:10	1969:5, 1969:7,	1938:18, 1939:8,	1844:25, 1845:10,
<b>952</b> [1] - 1774:5	accuracy [2] - 1930:6,	1994:17	1939:11, 1941:24,	1845:16, 1856:18,
<b>953</b> [2] - 1766:10,	1944:20	added [7] - 1809:19,	1942:12, 1945:9,	1856:21, 1857:2,
1953:8	accurate [9] -	1813:24, 1874:18,	1945:14	1864:14, 1869:18,
<b>954</b> [1] - 1766:15	1772:25, 1875:12,	1891:24, 1915:8,	admitted [27] -	1899:12, 1903:13,
<b>959</b> [1] - 1904:15	1875:13, 1907:17,	1942:2, 1978:25	1765:16, 1767:22,	1915:18, 1931:23,
<b>96</b> [7] - 1805:5,	1910:8, 1930:17,	addition [7] - 1885:16,	1809:24, 1810:12,	1933:1, 1939:14,
1826:5, 1830:8,	1931:19, 1935:15,	1912:2, 1913:21,	1810:16, 1812:21,	1939:19, 1944:23,
1832:19, 1841:23,	1938:16	1914:8, 1968:15,	1814:18, 1851:24, 1852:22, 1854:9,	1973:14, 1991:9, 1991:10, 1996:1
1841:25, 1880:20	accurately [5] - 1831:21, 1848:1,	1995:9, 1995:23 additional [6] -	1855:7, 1873:11,	agreed [2] - 1902:24,
<b>98</b> [1] - 1900:19 <b>989</b> [3] - 1887:3,	1907:2, 1907:24,	1761:9, 1932:8,	1911:2, 1914:15,	1989:17
JUJ [0] - 1001.3,	, 1001.27,	1101.0, 1002.0,	-,	

				5
agreement [1] -	1833:6, 1833:14,	1981:25	apolipoprotein [5] -	1802:22, 1803:2
1786:24	1834:5, 1834:13,	amount [3] - 1764:16,	1778:23, 1779:1,	arguing [1] - 1800:19
agreements [1] -	1834:21, 1835:17,	1845:6, 1952:18	1779:3, 1887:19,	argument [9] - 1797:3,
1926:19	1836:2, 1836:6,	amounts [2] - 1764:8,	1890:4	1800:5, 1801:12,
ahead [6] - 1838:18,	1836:11, 1836:14,	1953:5	apologize [1] -	1802:7, 1802:8,
1916:12, 1918:12,	1848:22, 1849:1,	<b>AMR</b> [3] - 1833:15,	1969:20	1802:9, 1802:10,
1923:12, 1945:4,	1849:12, 1849:18,	1833:18, 1979:18	Apotex [2] - 1795:8,	1804:3, 1934:13
1995:24	1857:14, 1857:16,	<b>AMR101</b> [1] - 1957:8	1795:10	arguments [3] -
<b>al</b> [2] - 1757:8, 1831:7	1857:20, 1858:5,	Analyses [1] -	appear [3] - 1780:24,	1803:7, 1803:9,
<b>Alaina</b> [1] - 1983:9	1875:4, 1875:5,	1909:23	1946:13, 1982:6	1991:15
Alcon [1] - 1795:8	1895:4, 1898:2,	analyses [1] - 1922:16	Appearances [1] -	Arisaph [4] - 1832:4,
ALISON [1] - 1758:3	1898:10, 1899:11,	analysis [11] -	1757:25	1832:18, 1832:23,
alleged [2] - 1831:4,	1906:10, 1906:12,	1770:22, 1858:5,	APPEARANCES[2] -	1907:9
1897:24	1907:8, 1908:18,	1863:4, 1912:22,	1757:13, 1758:1	arm [4] - 1843:12,
<b>ALLEN</b> [1] - 1758:7	1908:21, 1909:2,	1920:7, 1922:16,	appeared [1] -	1897:5, 1897:8,
allow [12] - 1795:25,	1909:7, 1909:11,	1966:17, 1966:19,	1787:24	1961:3
1796:23, 1797:1,	1909:17, 1910:4,	1968:23, 1973:2,	Appendix [2] - 1831:6,	<b>arms</b> [1] - 1777:8
1886:7, 1886:12,	1910:8, 1910:10,	1973:13	1906:11	arose [1] - 1944:10
1886:15, 1886:20,	1910:21, 1911:9,	anatomical [1] -	applicable [2] -	arrangement [1] -
1897:8, 1915:19,	1911:20, 1911:23,	1777:3	1774:14, 1902:25	1926:22
1942:7, 1944:15,	1920:13, 1921:6,	<b>ANCHOR</b> [1] - 1909:4	application [3] -	<b>arrow</b> [1] - 1948:15
1974:10	1924:15, 1926:1,	angina [4] - 1759:22,	1801:1, 1898:2,	art [64] - 1762:19,
Allowance [1] -	1926:15, 1926:19,	1759:24, 1902:3,	1898:10	1764:3, 1769:11,
1805:1	1926:24, 1927:5,	1908:1	applications [1] -	1769:20, 1770:6,
allowed [2] - 1890:20,	1927:7, 1927:10, 1927:11, 1927:13,	animal [1] - 1799:18	1793:15	1779:6, 1779:11,
1891:18	1927:15, 1927:19,	<b>Annual</b> [1] - 1960:12	applied [2] - 1793:17,	1780:1, 1780:12,
<b>allowing</b> [2] - 1814:23,	1927:15, 1927:19,	answer [12] - 1762:21,	1963:24	1780:19, 1786:7,
1945:11	1928:16, 1929:18,	1788:15, 1789:9,	applies [4] - 1781:7,	1788:1, 1789:16,
<b>allows</b> [2] - 1810:9,	1930:12, 1930:25,	1798:7, 1801:22,	1781:19, 1782:18,	1790:1, 1790:7,
1811:11	1931:11, 1931:17,	1868:3, 1903:8,	1783:3	1790:21, 1792:14,
alluding [1] - 1966:15	1932:6, 1932:8,	1919:8, 1919:20,	apply [4] - 1769:4,	1804:13, 1804:17,
alone [2] - 1764:14,	1932:12, 1932:19,	1919:22, 1941:2,	1769:25, 1778:11,	1805:3, 1805:13, 1805:18, 1806:23,
1866:6	1932:25, 1933:4,	1958:25	1903:16	1811:6, 1811:17,
altering [24] - 1777:13,	1934:22, 1934:23,	<b>ANSWER</b> [2] - 1869:2, 1869:12	apply [1] - 1889:19	1811:22, 1822:24,
1781:10, 1781:12,	1935:1, 1938:1,	answers [1] - 1959:1	appreciate [2] - 1787:18, 1788:3	1824:10, 1830:13,
1781:14, 1781:17, 1874:8, 1876:1,	1938:17, 1938:18,	anticipating [1] -	appreciated [1] -	1834:10, 1834:11,
1876:11, 1876:17,	1938:20, 1944:9,	1986:5	1991:13	1834:15, 1835:2,
1879:7, 1880:7,	1944:25, 1945:6,	anyway [3] - 1811:9,	approach [3] - 1799:4,	1835:10, 1851:11,
1880:15, 1882:21,	1945:12, 1967:5,	1989:10, 1996:6	1815:2, 1896:12	1851:19, 1852:17,
1882:23, 1883:3,	1967:13, 1978:15,	anyways [1] - 1941:21	appropriate [2] -	1854:4, 1854:20,
1884:2, 1884:15,	1978:22, 1980:11,	apart [3] - 1760:10,	1856:15, 1925:2	1855:15, 1855:20,
1885:2, 1885:12,	1981:5, 1985:20,	1760:11, 1927:6	approval [2] - 1921:8,	1856:18, 1856:22,
1885:14, 1885:21,	1988:22, 1995:7	<b>apo</b> [32] - 1776:16,	1921:10	1857:2, 1857:16,
1895:17, 1971:20,	AMARIN[2] - 1757:4,	1778:16, 1778:17,	approve [1] - 1993:21	1857:21, 1858:11,
1972:9	1757:4	1778:20, 1779:4,	approved [21] -	1860:12, 1861:8,
<b>AMA</b> [2] - 1934:15,	Amarin's [15] -	1779:8, 1779:12,	1785:12, 1785:20,	1861:12, 1865:2,
1935:12	1800:16, 1802:12,	1780:2, 1780:5,	1802:22, 1806:25,	1878:21, 1881:12,
Amarin [111] -	1804:3, 1835:9, 1875:2, 1906:1	1780:9, 1780:14,	1807:23, 1808:21,	1882:6, 1890:24,
1767:10, 1793:14,	1875:2, 1906:1, 1907:16, 1921:4,	1780:17, 1780:20,	1811:3, 1823:4,	1904:1, 1904:3,
1793:17, 1800:25,	1926:4, 1926:12,	1780:23, 1799:22,	1851:3, 1867:8,	1924:15, 1948:24,
1802:6, 1802:16,	1936:17, 1945:1,	1801:10, 1872:20,	1873:14, 1876:14,	1951:10, 1964:7,
1802:22, 1803:2,	1967:7, 1967:19,	1873:15, 1876:5,	1891:18, 1904:4,	1964:17, 1964:21,
1803:6, 1807:20,	1988:11	1876:13, 1876:18,	1904:7, 1904:9,	1969:13
1823:15, 1830:12,	ambivalent [3] -	1876:22, 1879:21,	1921:6, 1951:11,	artery [3] - 1763:22, 1952:7, 1952:16
1830:15, 1831:2,	1978:6, 1978:8,	1879:23, 1880:6,	1971:8, 1971:19,	article [51] - 1762:15,
1831:6, 1831:7,	1979:10	1880:14, 1880:22,	1973:11	1762:24, 1766:14,
1831:13, 1831:21, 1832:1, 1832:18,	America [1] - 1960:12	1881:2, 1881:9, 1883:20, 1886:22	area [2] - 1938:11,	1767:10, 1767:13,
1832:22, 1833:5,	American [2] - 1968:9,	1883:20, 1886:22, 1886:24	1938:22	1775:4, 1825:1,
1002.22, 1000.0,		1000.27	argued [3] - 1802:16,	, ,

				6
1826:15, 1826:16,	1898:20, 1898:25,	1758:11	1919:12	1982:19
1831:10, 1836:21,	1901:25, 1902:7,	attributable [1] -	balance [1] - 1834:11	Bays' [8] - 1919:20,
1836:23, 1837:24,	1903:6, 1903:14,	1761:6	Ballantyne [1] -	1954:5, 1973:23,
1838:12, 1838:14,	1922:20, 1924:8	attributed [6] -	1848:25	1974:19, 1977:24,
1840:10, 1840:21,	aside [6] - 1775:18,	1787:19, 1801:23,		1974:19, 1977:24,
1844:14, 1846:2,	1866:7, 1866:9,	1829:18, 1913:11,	<b>bar</b> [3] - 1771:6, 1819:25, 1820:23	1970:12, 1902:13,
1848:18, 1848:22,	1894:22, 1936:24,	1915:1, 1915:5	•	became [1] - 1978:19
1848:25, 1849:12,	1966:18	•	BARABAS[1] -	
1849:18, 1855:12,	asserted [23] -	audience [1] - 1833:11	1758:10	becomes [4] - 1988:3,
1904:22, 1912:12,	1774:19, 1774:24,		BARBARA[1] -	1990:16, 1991:20, 1993:9
1912:15, 1912:18,	1774:19, 1774:24,	<b>August</b> [4] - 1832:5, 1832:12, 1857:15,	1757:15	beef [1] - 1924:25
1913:11, 1913:14,	1778:9, 1778:12,	1907:8	barely [1] - 1872:23	BEFORE [1] - 1757:2
1915:2, 1915:5,	1778:14, 1780:23,	Aung [1] - 1766:15	BAS [1] - 1917:9	
1917:3, 1917:18,	1770:14, 1700:25,	authenticated [1] -	based [32] - 1762:18,	begin [1] - 1776:1 beginning [6] -
1918:18, 1921:19,	1794:1, 1796:7,	1937:3	1772:12, 1779:13,	• • • • • • • • • • • • • • • • • • • •
1946:5, 1949:3,	1796:9, 1796:16,	author [4] - 1763:9,	1780:3, 1797:1,	1761:10, 1775:7,
1953:24, 1954:5,	1818:20, 1819:17,	1763:19, 1846:17,	1799:19, 1805:2,	1954:10, 1956:18,
1955:19, 1958:23,	1883:13, 1886:7,	1901:11	1805:8, 1806:23,	1962:15, 1963:14
1967:17, 1968:4,	1886:12, 1894:10,	authoring [1] - 1928:2	1809:20, 1814:19, 1814:23, 1819:7,	<b>behalf</b> [2] - 1759:8, 1944:9
1973:23, 1974:19,	1895:9, 1896:23,	authors [12] -	1858:13, 1860:12,	believes [2] - 1795:20,
1977:24, 1978:2,	1915:14	1829:16, 1870:24,	1878:14, 1878:16,	1909:8
1978:19, 1981:16	assess [2] - 1791:13,	1871:6, 1871:10,	1883:5, 1890:16,	below [23] - 1770:8,
articles [19] - 1774:14,	1826:12	1901:2, 1904:25,	1903:24, 1907:4,	1790:22, 1805:25,
1916:5, 1924:15,	assessing [1] - 1830:2	1905:11, 1905:22,	1931:19, 1934:22,	1807:25, 1814:3,
1927:8, 1928:2,	assessment[1] -	1949:25, 1953:25,	1951:6, 1951:15,	1818:7, 1832:15,
1928:5, 1928:12,	1773:22	1979:2, 1981:12	1960:12, 1962:9,	1856:9, 1858:21,
1929:2, 1934:15,	assistance [3] -	available [17] -	1972:25, 1980:21,	1859:4, 1882:9,
1941:13, 1944:20,	1967:6, 1967:16,	1762:19, 1788:1,	1982:6, 1994:18	1882:12, 1894:13,
1946:9, 1946:11,	1967:25	1808:9, 1844:17,	baseline [25] -	1946:6, 1947:8,
1967:5, 1967:6,	associated [4] -	1858:15, 1928:23,	1769:22, 1782:15,	1947:11, 1955:15,
1985:21, 1986:2,	1787:9, 1787:12,	1938:13, 1956:7,	1788:21, 1794:11,	1960:20, 1976:23,
1986:12, 1986:22	1831:18, 1948:14	1963:23, 1966:20,	1806:13, 1807:2,	1979:11, 1979:14,
artisan [65] - 1786:23,	assume [3] - 1973:15,	1972:12, 1974:13,	1814:4, 1815:8,	1980:6
1787:7, 1787:17,	1987:15, 1993:11	1990:17, 1991:4,	1817:19, 1817:22,	bench [5] - 1985:19,
1787:20, 1787:23,	assumed [1] - 1987:14	1991:20, 1992:22,	1818:9, 1818:16,	1986:19, 1989:8,
1787:25, 1788:2,	assuming [2] -	1993:9	1827:21, 1879:14,	1989:15, 1989:19
1789:13, 1789:14,	1885:24, 1935:20	average [5] - 1763:19,	1893:6, 1902:18,	BENCH [1] - 1757:12
1789:17, 1790:13,	assure [1] - 1959:16	1763:23, 1868:24,	1957:21, 1957:22,	beneficial [3] -
1791:2, 1791:8,	Atherosclerosis [1] -	1876:22, 1876:23	1957:23, 1958:17,	1768:6, 1776:15,
1791:25, 1792:6,	1953:21	avoid [6] - 1789:3,	1961:1, 1961:2,	1776:19
1792:13, 1792:22,	atherosclerotic [1] -	1822:9, 1877:17,	1961:5, 1977:3	benefit [25] - 1761:1,
1801:16, 1804:3,	1919:4	1942:3, 1951:17,	bases [2] - 1890:20,	1761:4, 1766:7,
1805:13, 1805:18,	Atorvastatin [3] -	1989:7	1916:14	1767:1, 1771:15,
1806:8, 1806:20,	1816:12, 1976:20,	avoiding [1] - 1880:5	basing [1] - 1801:2	1776:12, 1776:20,
1808:11, 1818:12,	1977:11	aware [15] - 1804:2,	<b>Bays</b> [32] - 1836:21,	1777:3, 1778:1,
1818:15, 1821:13,	<b>ATP</b> [7] - 1859:7,	1808:1, 1811:2,	1838:1, 1838:3,	1778:3, 1787:21,
1821:22, 1822:8,	1887:5, 1887:22,	1823:2, 1823:12,	1838:5, 1838:11,	1788:3, 1851:1,
1822:18, 1823:12,	1969:21, 1970:16,	1830:13, 1851:3,	1838:14, 1839:7,	1895:15, 1895:19,
1823:21, 1823:24,	1970:22, 1973:22	1860:7, 1862:6,	1840:5, 1840:10,	1896:10, 1896:13,
1824:4, 1827:3,	attached [1] - 1978:20	1867:12, 1867:24,	1840:15, 1848:25,	1896:14, 1910:2,
1828:4, 1829:6,	attack [1] - 1874:9	1928:21, 1978:6,	1918:19, 1918:21,	1910:5, 1912:3,
1829:21, 1829:25,	attained [4] - 1761:19,	1978:8, 1980:5	1921:16, 1954:25,	1913:24, 1914:9,
1830:7, 1844:2,	1761:23, 1762:1,	awful [1] - 1837:3	1955:15, 1956:10,	1917:16, 1968:18
1848:4, 1851:2,	1963:1		1956:22, 1957:5,	Benefit [1] - 1767:11
1856:19, 1856:23,	attention [1] - 1929:16	В	1971:11, 1971:18,	benefits [13] -
1860:8, 1860:12,	Attorney [4] - 1758:3,		1971:25, 1972:5,	1773:16, 1774:8,
1863:23, 1874:10,	1758:5, 1758:7,	Background [1] -	1975:10, 1978:6,	1774:11, 1774:18,
1874:16, 1879:9, 1870:16, 1870:21	1758:13	1950:10	1978:16, 1978:18,	1775:19, 1775:22,
1879:16, 1879:21, 1882:11, 1883:2,	Attorneys [3] -	background [3] -	1979:8, 1980:4,	1776:21, 1778:6,
1888:13, 1891:22,	1757:17, 1757:20,	1825:4, 1891:7,	1981:5, 1981:12,	1787:24, 1896:8,
1000.10, 1091.22,				

				7
1898:15, 1916:22,	<b>board</b> [2] - 1759:18,	1987:24	1900:18, 1901:1,	1759:19, 1760:2,
1925:12	1925:16	Bureau [4] - 1892:1,	1900:10, 1901:1,	1760:18, 1761:1,
		• •		
Berg [1] - 1984:24	<b>body</b> [5] - 1828:20,	1926:4, 1926:13,	1906:9, 1906:20,	1764:18, 1764:25,
best [4] - 1777:24,	1828:22, 1828:23,	1926:22	1907:7, 1908:7,	1765:20, 1765:22,
1891:15, 1966:6,	1829:1, 1904:5	burn [1] - 1893:4	1909:1, 1909:16,	1766:7, 1766:12,
1966:13	borderline [4] -	business [2] - 1926:1,	1910:13, 1911:4,	1767:7, 1768:19,
<b>better</b> [2] - 1966:16,	1803:5, 1838:24,	1985:2	1911:14, 1912:11,	1768:24, 1769:17,
1992:20	1888:10, 1957:1	<b>BY</b> [171] - 1759:11,	1913:16, 1916:4,	1771:19, 1772:6,
between [14] -	<b>bottom</b> [23] - 1763:16,	1759:16, 1760:8,	1916:18, 1917:2,	1772:8, 1772:10,
1774:18, 1775:25,	1770:22, 1775:5,	1762:17, 1763:8,	1918:4, 1918:17,	1772:19, 1773:2,
1777:8, 1778:6,	1798:1, 1831:12,	1763:18, 1764:22,	1921:15, 1922:5,	1773:4, 1773:13,
1813:20, 1827:21,	1837:13, 1843:5,	1765:18, 1766:4,	1923:3, 1925:20,	1773:16, 1774:8,
1828:14, 1830:2,	1887:15, 1922:7,	1767:18, 1767:24,	1927:22, 1928:11,	1774:25, 1775:9,
1859:3, 1920:25,	1923:14, 1935:8,	1769:3, 1770:14,	1928:20, 1930:10,	1775:19, 1775:21,
1921:2, 1921:3,	1947:3, 1949:13,	1771:1, 1772:17,	1930:20, 1933:9,	1776:2, 1776:6,
1924:19, 1981:5	1950:12, 1953:18,	1774:3, 1779:24,	1945:23, 1946:7,	1776:7, 1776:19,
bevy [1] - 1937:23	1962:15, 1969:24,	1782:1, 1782:24,	1946:19, 1946:24,	1777:4, 1777:18,
beyond [6] - 1780:23,	1970:7, 1971:15,	1784:18, 1788:17,	1947:24, 1949:6,	1777:20, 1777:23,
1850:25, 1868:15,	1978:10, 1981:17,	1793:10, 1793:24,	1949:16, 1950:8,	1808:14, 1825:7,
1917:16, 1925:14,	1981:18, 1987:12	1797:8, 1797:24,	1951:5, 1951:23,	1825:12, 1859:5,
1973:4	<b>box</b> [3] - 1848:23,	1798:6, 1799:10,	1952:10, 1954:12,	1859:10, 1894:17,
Bhatt [8] - 1759:14,	1967:24, 1980:2	1800:8, 1813:4,	1954:21, 1957:12,	1894:20, 1894:24,
1760:9, 1760:24,	break [4] - 1796:23,	1813:23, 1814:16,	1958:4, 1959:13,	1895:15, 1895:19,
1761:11, 1761:13,	1853:14, 1941:21,	1815:5, 1816:11,	1960:5, 1961:14,	1896:8, 1898:12,
1770:11, 1775:4,	1941:22	1817:10, 1819:21,	1962:17, 1963:17,	1898:14, 1899:12,
1905:4	brief [14] - 1795:14,	1820:22, 1821:4,	1964:11, 1965:22,	1903:19, 1905:7,
Bhatt's [1] - 1760:21	1795:19, 1939:10,	1822:3, 1823:9,	1968:2, 1970:8,	1906:3, 1910:1,
big [2] - 1924:19,	1977:18, 1980:19,	1824:14, 1825:3,	1970:21, 1971:14,	1910:5, 1911:17,
1925:3	1980:24, 1990:10,	1825:16, 1825:23,	1972:21, 1974:18,	1911:21, 1914:9,
billable [1] - 1932:9	1990:20, 1990:22,	1826:4, 1826:11,	1977:22, 1978:11,	1916:22, 1919:4,
billion [1] - 1891:10	1991:15, 1992:4,	1827:7, 1827:13,	1979:7, 1979:24,	1919:24, 1923:15,
binder [5] - 1798:4,	1993:7, 1995:14,	1829:10, 1830:19,	1981:2, 1981:23	1924:1, 1924:4,
1814:17, 1837:2,	1995:18	1832:2, 1833:3,		1924:17, 1925:16,
1889:7, 1923:10	briefing [1] - 1795:15	1834:20, 1836:20,	С	1953:11, 1954:2,
biochemical [1] -	briefs [4] - 1990:8,	1839:5, 1840:3,		1960:14, 1961:23,
1776:14	1993:14, 1994:6,	1840:20, 1841:16,	<b>C-II</b> [2] - 1887:19,	1967:12
biologically [1] -	1995:25	1842:3, 1842:19,	1890:4	Cardiovascular [6] -
1803:19	bright [1] - 1930:2	1844:8, 1846:8,	<b>CAD</b> [4] - 1922:11,	1767:11, 1897:20,
biomarkers [1] -	bring [1] - 1969:23	1847:19, 1848:10,	1922:13, 1952:13,	1907:13, 1907:23,
1903:24	broad [1] - 1967:11	1851:7, 1851:15,	1953:1	1912:14, 1918:7
biosynthesis [1] -	broadly [1] - 1935:4	1852:1, 1852:7,	calculated [1] -	<b>care</b> [1] - 1897:9
1975:5	<b>broke</b> [1] - 1759:13	1852:24, 1853:5,	1869:7	carefully [4] - 1860:3,
<b>bit</b> [9] - 1862:17,	Brooks [8] - 1770:12,	1853:23, 1854:11,	calculations [2] -	1863:11, 1869:20,
1865:9, 1880:17,	1770:23, 1946:23,	1854:17, 1855:1,	1966:5, 1966:11	1903:2
1880:25, 1887:1,	1947:23, 1964:10,	1855:11, 1857:19,	<b>California</b> [1] - 1758:6	Caroline [1] - 1984:22
				carries [1] - 1763:17
1934:2, 1954:7,	1970:4, 1970:19,	1858:3, 1860:19,	cannot [5] - 1763:13,	
1934:2, 1954:7,	1970:4, 1970:19, 1976:5	1861:16, 1864:4,	1803:25, 1866:18,	carrying [1] - 1775:6
1934:2, 1954:7, 1956:17, 1960:7			1803:25, 1866:18, 1880:7, 1952:3	
1934:2, 1954:7,	1976:5	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9,	1803:25, 1866:18, 1880:7, 1952:3 <b>capacity</b> [1] - 1893:5	<b>carrying</b> [1] - 1775:6 <b>carve</b> [1] - 1880:12 <b>case</b> [28] - 1766:5,
1934:2, 1954:7, 1956:17, 1960:7 <b>bizarre</b> [1] - 1977:13	1976:5 <b>Budoff</b> [9] - 1940:9,	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15,	1803:25, 1866:18, 1880:7, 1952:3 capacity [1] - 1893:5 capsule [3] - 1961:20,	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25,	1976:5 <b>Budoff</b> [9] - 1940:9, 1940:18, 1940:21,	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5,	1803:25, 1866:18, 1880:7, 1952:3 capacity [1] - 1893:5 capsule [3] - 1961:20, 1963:15, 1963:21	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25, 1880:3, 1894:1	1976:5 <b>Budoff</b> [9] - 1940:9, 1940:18, 1940:21, 1941:1, 1942:5,	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5, 1873:13, 1875:1,	1803:25, 1866:18, 1880:7, 1952:3 capacity [1] - 1893:5 capsule [3] - 1961:20, 1963:15, 1963:21 Capsule [1] - 1767:11	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21, 1819:17, 1820:25,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25, 1880:3, 1894:1 blind [1] - 1825:24	1976:5 <b>Budoff</b> [9] - 1940:9, 1940:18, 1940:21, 1941:1, 1942:5, 1943:2, 1944:16,	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5, 1873:13, 1875:1, 1875:18, 1877:5,	1803:25, 1866:18, 1880:7, 1952:3 capacity [1] - 1893:5 capsule [3] - 1961:20, 1963:15, 1963:21 Capsule [1] - 1767:11 capture [2] - 1859:18,	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21, 1819:17, 1820:25, 1834:18, 1862:14,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25, 1880:3, 1894:1 blind [1] - 1825:24 blockbuster [1] -	1976:5 <b>Budoff</b> [9] - 1940:9, 1940:18, 1940:21, 1941:1, 1942:5, 1943:2, 1944:16, 1945:10, 1945:11	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5, 1873:13, 1875:1, 1875:18, 1877:5, 1878:10, 1879:5,	1803:25, 1866:18, 1880:7, 1952:3  capacity [1] - 1893:5  capsule [3] - 1961:20, 1963:15, 1963:21  Capsule [1] - 1767:11  capture [2] - 1859:18, 1859:20	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21, 1819:17, 1820:25, 1834:18, 1862:14, 1875:5, 1886:7,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25, 1880:3, 1894:1 blind [1] - 1825:24 blockbuster [1] - 1891:10	1976:5 <b>Budoff</b> [9] - 1940:9, 1940:18, 1940:21, 1941:1, 1942:5, 1943:2, 1944:16, 1945:10, 1945:11 <b>Budoff's</b> [1] - 1943:11	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5, 1873:13, 1875:1, 1875:18, 1877:5, 1878:10, 1879:5, 1883:15, 1884:12,	1803:25, 1866:18, 1880:7, 1952:3  capacity [1] - 1893:5  capsule [3] - 1961:20, 1963:15, 1963:21  Capsule [1] - 1767:11  capture [2] - 1859:18, 1859:20  cardiac [1] - 1960:17	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21, 1819:17, 1820:25, 1834:18, 1862:14, 1875:5, 1886:7, 1886:12, 1894:16,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25, 1880:3, 1894:1 blind [1] - 1825:24 blockbuster [1] - 1891:10 blood [1] - 1975:8	1976:5 <b>Budoff</b> [9] - 1940:9, 1940:18, 1940:21, 1941:1, 1942:5, 1943:2, 1944:16, 1945:10, 1945:11 <b>Budoff's</b> [1] - 1943:11 <b>bullet</b> [4] - 1765:24,	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5, 1873:13, 1875:1, 1875:18, 1877:5, 1878:10, 1879:5, 1883:15, 1884:12, 1884:23, 1886:2,	1803:25, 1866:18, 1880:7, 1952:3  capacity [1] - 1893:5  capsule [3] - 1961:20, 1963:15, 1963:21  Capsule [1] - 1767:11  capture [2] - 1859:18, 1859:20  cardiac [1] - 1960:17  cardiologist [1] -	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21, 1819:17, 1820:25, 1834:18, 1862:14, 1875:5, 1886:7, 1886:12, 1894:16, 1895:9, 1895:12,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25, 1880:3, 1894:1 blind [1] - 1825:24 blockbuster [1] - 1891:10 blood [1] - 1975:8 blow [4] - 1954:20,	1976:5 <b>Budoff</b> [9] - 1940:9, 1940:18, 1940:21, 1941:1, 1942:5, 1943:2, 1944:16, 1945:10, 1945:11 <b>Budoff's</b> [1] - 1943:11 <b>bullet</b> [4] - 1765:24, 1888:5, 1888:6,	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5, 1873:13, 1875:1, 1875:18, 1877:5, 1878:10, 1879:5, 1883:15, 1884:12, 1884:23, 1886:2, 1887:4, 1887:11,	1803:25, 1866:18, 1880:7, 1952:3  capacity [1] - 1893:5  capsule [3] - 1961:20, 1963:15, 1963:21  Capsule [1] - 1767:11  capture [2] - 1859:18, 1859:20  cardiac [1] - 1960:17  cardiologist [1] - 1768:1	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21, 1819:17, 1820:25, 1834:18, 1862:14, 1875:5, 1886:7, 1886:12, 1894:16, 1895:9, 1895:12, 1920:13, 1927:6,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25, 1880:3, 1894:1 blind [1] - 1825:24 blockbuster [1] - 1891:10 blood [1] - 1975:8 blow [4] - 1954:20, 1957:11, 1958:2,	1976:5 <b>Budoff</b> [9] - 1940:9, 1940:18, 1940:21, 1941:1, 1942:5, 1943:2, 1944:16, 1945:10, 1945:11 <b>Budoff's</b> [1] - 1943:11 <b>bullet</b> [4] - 1765:24, 1888:5, 1888:6, 1909:25	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5, 1873:13, 1875:1, 1875:18, 1877:5, 1878:10, 1879:5, 1883:15, 1884:12, 1884:23, 1886:2, 1887:4, 1887:11, 1889:2, 1889:12,	1803:25, 1866:18, 1880:7, 1952:3  capacity [1] - 1893:5  capsule [3] - 1961:20, 1963:15, 1963:21  Capsule [1] - 1767:11  capture [2] - 1859:18, 1859:20  cardiac [1] - 1960:17  cardiologist [1] - 1768:1  Cardiology [1] -	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21, 1819:17, 1820:25, 1834:18, 1862:14, 1875:5, 1886:7, 1886:12, 1894:16, 1895:9, 1895:12, 1920:13, 1927:6, 1928:17, 1932:10,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25, 1880:3, 1894:1 blind [1] - 1825:24 blockbuster [1] - 1891:10 blood [1] - 1975:8 blow [4] - 1954:20, 1957:11, 1958:2, 1979:6	1976:5 <b>Budoff</b> [9] - 1940:9, 1940:18, 1940:21, 1941:1, 1942:5, 1943:2, 1944:16, 1945:10, 1945:11 <b>Budoff's</b> [1] - 1943:11 <b>bullet</b> [4] - 1765:24, 1888:5, 1888:6, 1909:25 <b>bunch</b> [1] - 1857:16	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5, 1873:13, 1875:1, 1875:18, 1877:5, 1878:10, 1879:5, 1883:15, 1884:12, 1884:23, 1886:2, 1887:4, 1887:11, 1889:2, 1889:12, 1890:1, 1890:10,	1803:25, 1866:18, 1880:7, 1952:3  capacity [1] - 1893:5  capsule [3] - 1961:20, 1963:15, 1963:21  Capsule [1] - 1767:11  capture [2] - 1859:18, 1859:20  cardiac [1] - 1960:17  cardiologist [1] - 1768:1  Cardiology [1] - 1981:25	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21, 1819:17, 1820:25, 1834:18, 1862:14, 1875:5, 1886:7, 1886:12, 1894:16, 1895:9, 1895:12, 1920:13, 1927:6, 1928:17, 1932:10, 1932:12, 1932:13,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25, 1880:3, 1894:1 blind [1] - 1825:24 blockbuster [1] - 1891:10 blood [1] - 1975:8 blow [4] - 1954:20, 1957:11, 1958:2, 1979:6 blow-up [4] - 1954:20,	1976:5  Budoff [9] - 1940:9, 1940:18, 1940:21, 1941:1, 1942:5, 1943:2, 1944:16, 1945:10, 1945:11  Budoff's [1] - 1943:11  bullet [4] - 1765:24, 1888:5, 1888:6, 1909:25  bunch [1] - 1857:16  buoyant [1] - 1948:3	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5, 1873:13, 1875:1, 1875:18, 1877:5, 1878:10, 1879:5, 1883:15, 1884:12, 1884:23, 1886:2, 1887:4, 1887:11, 1889:2, 1889:12, 1890:1, 1890:10, 1894:5, 1897:15,	1803:25, 1866:18, 1880:7, 1952:3  capacity [1] - 1893:5  capsule [3] - 1961:20, 1963:15, 1963:21  Capsule [1] - 1767:11  capture [2] - 1859:18, 1859:20  cardiac [1] - 1960:17  cardiologist [1] - 1768:1  Cardiology [1] -	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21, 1819:17, 1820:25, 1834:18, 1862:14, 1875:5, 1886:7, 1886:12, 1894:16, 1895:9, 1895:12, 1920:13, 1927:6, 1928:17, 1932:10,
1934:2, 1954:7, 1956:17, 1960:7 bizarre [1] - 1977:13 blanket [3] - 1873:25, 1880:3, 1894:1 blind [1] - 1825:24 blockbuster [1] - 1891:10 blood [1] - 1975:8 blow [4] - 1954:20, 1957:11, 1958:2, 1979:6 blow-up [4] - 1954:20, 1957:11, 1958:2,	1976:5  Budoff [9] - 1940:9, 1940:18, 1940:21, 1941:1, 1942:5, 1943:2, 1944:16, 1945:10, 1945:11  Budoff's [1] - 1943:11  bullet [4] - 1765:24, 1888:5, 1888:6, 1909:25  bunch [1] - 1857:16  buoyant [1] - 1948:3  burdens [1] - 1913:2	1861:16, 1864:4, 1864:24, 1867:11, 1868:21, 1870:9, 1870:22, 1871:15, 1872:12, 1873:5, 1873:13, 1875:1, 1875:18, 1877:5, 1878:10, 1879:5, 1883:15, 1884:12, 1884:23, 1886:2, 1887:4, 1887:11, 1889:2, 1889:12, 1890:1, 1890:10,	1803:25, 1866:18, 1880:7, 1952:3  capacity [1] - 1893:5  capsule [3] - 1961:20, 1963:15, 1963:21  Capsule [1] - 1767:11  capture [2] - 1859:18, 1859:20  cardiac [1] - 1960:17  cardiologist [1] - 1768:1  Cardiology [1] - 1981:25	carrying [1] - 1775:6 carve [1] - 1880:12 case [28] - 1766:5, 1767:5, 1777:22, 1795:4, 1818:21, 1819:17, 1820:25, 1834:18, 1862:14, 1875:5, 1886:7, 1886:12, 1894:16, 1895:9, 1895:12, 1920:13, 1927:6, 1928:17, 1932:10, 1932:12, 1932:13,

8
1856:12, 1857:16, 1858:24, 1858:25, 1882:6, 1919:2, 1920:23, 1927:12, 1960:18, 1960:22,
1971:2, 1972:3 clinically [1] - 1873:1
<b>clinician</b> [2] - 1776:10, 1964:24
<b>close</b> [11] - 1762:8, 1772:22, 1826:24,
1858:7, 1874:4, 1889:22, 1950:3,
1961:9, 1961:10, 1985:2, 1985:9
closer [2] - 1776:24, 1954:7 closest [1] - 1890:23
<b>closing</b> [5] - 1991:15, 1993:13, 1993:14,
1994:6 <b>clue</b> [1] - 1866:17
<b>CMS</b> [12] - 1929:10, 1929:25, 1930:3,
1930:11, 1930:24, 1931:22, 1933:15,
1934:16, 1934:22, 1944:20, 1986:2,
1986:12 CMS.gov [1] - 1938:3 cms.gov [4] - 1929:6,
1935:19, 1935:22, 1937:8
<b>co</b> [3] - 1875:16, 1928:2, 1979:2
<b>co-administered</b> [1] - 1875:16
co-authoring [1] - 1928:2
co-authors [1] - 1979:2
<b>CoA</b> [6] - 1877:10, 1877:13, 1877:18, 1960:16, 1975:3, 1975:17
Cochrane [4] - 1766:10, 1946:11, 1946:15, 1953:7
code [1] - 1833:18 coenzyme [1] - 1877:15
<b>collaboration</b> [2] - 1766:10, 1953:8
colleague [4] -

1965:12, 1965:21, characterization [1] -1795:2, 1795:6, 1980:12, 1985:10, 1907:18 1795:9, 1795:11, 1990:2 characterizations [1] -1804:17, 1837:15, cases [12] - 1795:2, 1921:5 1991:4, 1991:5, 1991:13 1795:12, 1795:13, characterize [2] -1795:18, 1795:22, 1847:25, 1848:1 cited [7] - 1835:14, 1796:1, 1796:18, 1835:17, 1838:11, characterized [1] -1796:20, 1796:23, 1840:12, 1904:22, 1914:7 1797:3, 1893:21, 1930:23, 1955:19 characterizes [1] -1990:18 cites [2] - 1838:11, 1907:24 categories [1] characterizing [2] -1994:17 1949:14 1907:2, 1908:18 citing [8] - 1836:6, category [1] - 1865:19 charge [1] - 1967:17 1847:5, 1850:19, causes [11] - 1786:25, 1905:9, 1905:14, charges [1] - 1967:15 1872:4, 1887:14, CHARLES [1] -1905:15, 1905:16 1887:21, 1888:7, claim [53] - 1778:10, 1757:19 1888:10, 1888:15, 1778:14, 1778:22, Charles [1] - 1784:14 1888:17, 1888:21, 1778:25, 1779:2, chart [17] - 1844:21, 1888:25 1780:24, 1781:1, 1844:24, 1845:4, caveat [2] - 1893:3, 1781:11, 1781:21, 1845:5, 1845:10, 1895:16 1782:4, 1782:5, 1845:14, 1878:4, caveats [2] - 1830:11, 1782:7, 1782:14, 1878:6, 1887:9, 1783:1, 1796:7, 1901:22 1887:12, 1888:13, CCR [2] - 1757:22, 1796:12, 1799:21, 1897:19, 1916:19, 1996:24 1818:20, 1819:4, 1939:20, 1974:1, 1819:9, 1820:25, Cedars [1] - 1768:8 1974:2, 1974:16 1875:22, 1875:23, Cedars-Sinai [1] charts [1] - 1845:6 1875:25, 1876:4, 1768:8 Chicago [1] - 1758:4 1879:3, 1879:6, ceiling [1] - 1902:19 Cholesterol [1] -1880:4, 1880:12, Center [3] - 1768:8, 1950:11 1881:6, 1882:18, 1929:10, 1930:4 cholesterol [16] -1882:24, 1883:5, certainly [14] -1760:15, 1777:19, 1883:12, 1883:13, 1776:14, 1791:11, 1789:20, 1827:10, 1883:18, 1883:20, 1792:13, 1796:15, 1829:13, 1831:19, 1883:23, 1884:1, 1814:12, 1828:8, 1838:7, 1839:10, 1884:18, 1885:4, 1828:19, 1856:8, 1840:9, 1863:4, 1885:5, 1885:10, 1873:22, 1896:11, 1873:15, 1908:15, 1885:11, 1885:15, 1921:10, 1927:19, 1955:8, 1957:9, 1885:18, 1885:20 1938:18, 1974:12 1972:1, 1975:5 claim1 [1] - 1884:3 certify [1] - 1996:22 cholesterol...were [1] claimed [4] - 1775:20, cetera [2] - 1802:25, - 1827:9 1778:15, 1785:13, 1931:5 Christopher [1] -1785:21 challenge [1] - 1942:8 1944:9 claiming [1] - 1881:7 chance [3] - 1773:12, CHRISTOPHER [1] claims [55] - 1774:19, 1795:24, 1992:5 1757:14 1774:24, 1776:1, change [15] - 1768:11, chylomicrons [1] -1777:12, 1778:6, 1771:21, 1777:3, 1976:9 1778:9, 1778:12, 1783:24, 1783:25, circuit [1] - 1795:2 1778:14, 1778:17, 1802:17, 1832:20, Circuit [3] - 1795:6, 1778:20, 1780:23, 1836:3, 1842:5, 1795:9, 1795:11 1781:1, 1781:2, 1845:9, 1977:3, Circulation [1] -1781:5, 1781:8, 1978:23, 1979:19, 1956:6 1781:13, 1781:16, 1994:3 citation [8] - 1762:11, 1781:19, 1781:21. changed 131 -1954:14, 1954:24, 1782:2, 1782:3, 1809:10, 1812:13, 1955:6, 1955:11, 1782:10, 1782:16, 1816:18 1955:15, 1955:24, 1782:19, 1782:21, changes [2] -1991:11 1782:22, 1783:1, 1776:14, 1845:8 citations [2] - 1994:4, 1783:4, 1783:7, changing [1] -1995:9 1796:9, 1796:16, 1871:16

cite [10] - 1780:19,

1801:8, 1819:12, 1820:18, 1821:10, 1822:22, 1826:7, 1841:13, 1841:25, 1849:21, 1875:20, 1884:14, 1886:7, 1886:12, 1886:15, 1886:20, 1891:1, 1894:10, 1894:15, 1894:19, 1895:11, 1896:1, 1896:3, 1896:23, 1912:22 **CLAIRE** [1] - 1757:19 clarification [1] -1994:14 clarify [2] - 1850:5, 1860:21 classes [1] - 1801:18 classification [1] -1869:24 cleaned [1] - 1978:25 clear [21] - 1760:25, 1800:19, 1810:6, 1810:17, 1810:25, 1811:6, 1840:4, 1847:1, 1863:14, 1867:5, 1872:3, 1874:20, 1876:8, 1876:18, 1877:13, 1881:12, 1888:5, 1924:11, 1930:11, 1932:11, 1982:19 clear-cut [1] - 1847:1 clearance [2] - 1975:7, 1975:12 clearer [1] - 1987:11 clearly [13] - 1801:2, 1803:3, 1829:8, 1842:11, 1847:7, 1848:4, 1866:1, 1917:19, 1924:16, 1934:21, 1937:4, 1966:10, 1966:12 **CLERK** [6] - 1783:23, 1784:1, 1959:6, 1959:10, 1972:18, 1986:24 Clerk [1] - 1995:10 Clinical [1] - 1889:3 clinical [33] - 1760:25, 1771:15, 1790:16, 1791:10, 1791:13, 1791:16. 1791:20. 1792:6. 1798:1. 1799:12, 1799:15, 1800:19, 1800:21, 1814:3, 1821:18, 1821:19, 1848:6, 1851:8, 1852:2, 1852:25, 1855:17,

1983:9, 1986:6,

colleagues [3] -

1967:20

1986:10, 1986:17

1912:21, 1919:23,

collect [1] - 1944:12

contested [1] -
1860:11
context [5] - 1837:23,
1850:9, 1921:5, 1960:25, 1985:22
continue [4] -
1757:25, 1797:5,
1911:16, 1963:15
CONTINUED [1] -
1758:1
<b>continues</b> [1] - 1947:14
contradict [1] -
1942:20
contradiction [1] -
1980:7
contrast [1] - 1817:22
control [4] - 1778:24,
1782:6, 1782:13,
1893:20 controlled [1] -
1825:24
controlling [1] -
1977:11
controls [1] - 1906:24
Conversation [1] -
1993:2
<b>conversion</b> [1] - 1789:21
convinced [1] -
1768:9
convincing [2] -
1863:9, 1902:20
<b>copy</b> [1] - 1799:3
corner [1] - 1947:4
coronary [13] -
1763:22, 1766:18, 1772:16, 1901:3,
1901:13, 1901:14,
1902:2, 1906:15,
1906:23, 1925:12,
1952:5, 1952:7,
1952:16
Coronary [2] - 1908:9,
1908:14
<b>correct</b> [156] - 1785:14, 1786:4,
1786:15, 1787:1,
1787:9, 1787:22,
1788:4, 1788:8,
1788:11, 1788:20,

1970:9

1973:21

1966:8

1991.7

1790:3

considered [3] -

considering [1] -

consistency [1] -

consistent (8) -

1760:21. 1834:9.

1910:2, 1910:6,

1940:13, 1971:2,

1972:3, 1973:16

consistently [1] -

consistently.. [1] -

CONSTANCE [1] -

1948:1

1947:21

1758:10

1862:16

1792:20

1927:4

constitute [1] -

constituted [1] -

consultancy [1] -

consultant [2] -

consulted [1] -

consulting [3] -

1926:15

1928:17

1952:18

1936:24

containing [2] -

contains [5] -

1969:8

1786:2

1760:12

1967:17

1805:20

1875:3

1914:17

contention [1] -

contentions [1] -

contents [2] - 1913:8,

1926:24, 1928:6

1926:18, 1926:22,

consume [2] - 1764:7,

consumption [2] -

1825:5, 1825:10

contact [1] - 1927:13

contain [2] - 1764:1,

1963:21, 1975:12

1800:15, 1800:21,

1862:4, 1961:15,

contaminants [1] -

contemporary [1] -

content [4] - 1811:13,

1812:11, 1962:23,

1953:16. 1953:24.

consist [2] - 1935:25,

colored [1] - 1768:4 1804:17, 1812:4 1901:23, 1903:7, column [18] - 1760:6, compelling [2] -1953:25 1911:18, 1987:19 Conclusion [2] -1763:16, 1763:17, compensation [1] -1827:15, 1870:23 1775:5, 1775:6, 1794:7, 1839:24, 1849.1 conclusions [7] -1843:5, 1898:5. complementary [1] -1917:3, 1990:11, 1947:1, 1947:12, 1917:11 1992:1, 1992:7, 1947:14, 1949:5, complete [2] -1992:19, 1993:6, 1952:9, 1953:15, 1930:17, 1967:20 1993:16 1954:9, 1956:3 concomitant [1] completed [2] combination [4] -1793:8, 1898:24 1777:13 1849:24, 1875:8, concurrent [22] complex [2] -1917:12, 1925:15 1778:7, 1781:10, 1841:20, 1871:1 combinations [2] complicate [1] -1781:12, 1781:14, 1888:17, 1917:15 1781:17, 1875:7, 1893:17 combined [5] complications [1] -1876:1, 1876:10, 1865:10, 1865:12, 1876:17, 1879:6, 1771:19 1865:22, 1888:7, 1880:7, 1880:15, complies [1] - 1966:2 1882:21, 1882:23, 1960:16 components [3] coming [6] - 1784:1, 1883:3, 1884:2, 1786:10, 1786:12, 1884:14, 1885:1, 1835:1, 1849:10, 1961:19 1885:11, 1885:13, 1881:23, 1934:21, composite [9] -1885:21, 1885:22 1990:15 1759:20, 1899:13, condition [1] comment [3] -1902:23, 1907:4, 1859:15 1811:18, 1992:6, 1908:1, 1908:3, conditions [2] -1993:17 1919:15, 1919:19, comments [1] -1890:14, 1976:7 1920:5 conducted [2] -1844:3 composition [4] commercially [1] -1823:15, 1912:21 1764:6, 1860:25, confer [1] - 1944:6 1963:23 1963:1, 1963:6 commit [1] - 1944:12 conferring [1] compositional [1] -1992:16 committee [1] -1962:22 1909:18 comprising [1] confident [1] -1989:12 common [2] - 1807:1, 1884:3 1888:2 confidential [1] conception [2] -1987:13 community [3] -1831:4. 1897:24 1768:16, 1849:13, confirm [3] - 1830:5, concern [3] - 1958:13, 1987:24, 1992:21 1903:15, 1905:19 1899:25 companies [2] confirmatory [2] concerned [2] -1957:6, 1957:7 1928:22, 1929:18 1859:8, 1942:6 confirmed [1] company [4] - 1832:4, concerning [2] -1899:11, 1910:15, 1905:17 1920:18, 1927:5 1930:16 connection [2] concerns [1] - 1935:1 comparable [1] -1926:24, 1980:12 conclude [1] -1968:24 1771:12 consecutive [1] -1996:14 comparative [2] concluded 191 -1846:19, 1847:13 consequence [1] -1805:3, 1826:20, 1763:9 compare [4] -1829:16, 1831:17, 1759:17, 1761:24, conservatively[1] -1843:8, 1843:14, 1812:13, 1964:8 1858:5, 1870:24, 1859:17 compared [10] consider [7] -1953:10 1761:12, 1773:3, 1766:20, 1768:13, concludes [1] -1773:20, 1776:9, 1771:23, 1786:24, 1831:13 1778:23, 1782:6, 1787:8, 1849:12, concluding [1] -1782:12, 1782:15, 1954:14 1986:18 1803:4, 1906:24 considerable [1] conclusion [11] -1920.8 compares [3] -1791:10, 1801:2, 1763:20, 1816:14, considerations [1] -1827:17, 1827:24, 1847:20 1805.9 1842:9, 1871:6, Considerations [1] comparing [2] -1901:17, 1901:20,

**-**9 1788:24, 1789:4, 1791:6, 1791:7, 1791:10, 1792:17, 1793:7, 1800:16, 1800:21, 1801:1, 1801:10, 1801:19, 1801:24, 1801:25, 1802:2, 1803:10, 1804:8, 1804:12,

MARGARET E. GRIENER, RDR, CCR NO. 3, OFFICIAL REPORTER (775) 329-9980

				<b></b> 1(
1804:19, 1805:10,	1950:19, 1964:13,	1989:4, 1993:3,	1980:21, 1980:24,	[1] - 1997:5
1805:19, 1806:3,	1974:25, 1985:14,	1993:5	1982:13, 1982:17,	cross-examination
1806:7, 1806:12,	1985:24, 1996:22	court [9] - 1796:21,	1982:21, 1982:25,	[10] - 1783:22,
1808:15, 1810:13,	corrected [1] -	1809:20, 1890:6,	1983:3, 1983:15,	1795:14, 1914:25,
1812:22, 1815:25,	1912:17	1984:18, 1989:13,	1984:2, 1984:5,	1945:25, 1954:4,
1816:3, 1818:18,	corroborate [2] -	1990:1, 1993:2,	1984:9, 1984:11,	1957:14, 1959:16,
1819:19, 1820:13,	1868:6, 1868:14	1994:1, 1996:20	1984:13, 1984:21,	1964:4, 1966:9,
1821:2, 1822:20,	counsel [68] -	COURT [156] - 1757:1,	1985:4, 1985:7,	1969:9
1822:25, 1823:17,	1759:18, 1765:2,	1759:3, 1759:5,	1985:11, 1985:14,	CROSS-
1824:8, 1824:11,	1771:16, 1772:13,	1759:5, 1759:5,	1985:16, 1985:25,	EXAMINATION[1] -
1827:10, 1827:22,		, ,	1986:5, 1986:16,	1784:17
1828:1, 1828:7,	1773:25, 1783:15,	1767:20, 1767:22,	· ·	-
	1787:15, 1790:12,	1779:19, 1783:11,	1986:21, 1986:25,	cross-examine [1] -
1828:14, 1829:19,	1791:19, 1799:9,	1783:21, 1784:4,	1987:10, 1988:6,	1941:6
1830:9, 1831:22,	1804:12, 1805:16,	1784:7, 1788:15,	1988:10, 1988:16,	current [7] - 1761:23,
1832:14, 1832:23,	1808:3, 1808:16,	1795:16, 1796:2,	1988:18, 1989:14,	1766:16, 1809:4,
1833:7, 1834:10,	1815:20, 1823:11,	1796:25, 1797:17,	1990:4, 1990:7,	1812:13, 1865:6,
1835:2, 1835:18,	1836:23, 1837:5,	1798:12, 1798:15,	1990:12, 1992:9,	1979:17, 1980:8
1835:21, 1836:16,	1838:17, 1843:2,	1798:18, 1799:5,	1992:12, 1993:1,	custodian [1] -
1838:1, 1840:16,	1850:12, 1862:2,	1800:7, 1809:10,	1993:10, 1993:18,	1944:19
1841:23, 1842:16,	1864:9, 1864:17,	1809:14, 1810:8,	1994:11, 1994:15,	cut [3] - 1820:21,
1843:11, 1843:15,	1865:1, 1869:23,	1810:14, 1810:19,	1994:21, 1994:24,	1847:1, 1949:24
1844:4, 1847:6,	1877:18, 1878:9,	1810:23, 1811:7,	1995:3, 1995:8,	cutout [1] - 1959:22
1847:17, 1847:23,	1881:25, 1884:11,	1811:18, 1811:21,	1995:15, 1995:17,	cyanide [1] - 1872:8
1848:2, 1849:7,	1887:6, 1889:5,	1812:9, 1812:18,	1995:21, 1996:5,	• • • • • • • • • • • • • • • • • • • •
1849:18, 1850:1,	1903:4, 1906:5,	1812:23, 1814:8,	1996:10	D
1850:21, 1851:19,	1908:4, 1912:4,	1814:18, 1815:3,	cover [4] - 1781:3,	
1852:4, 1852:12,	1912:15, 1915:3,	1816:3, 1851:22,	1885:5, 1895:20,	<b>D.C</b> [2] - 1757:17,
1856:16, 1856:25,	1918:8, 1923:12,	1851:24, 1852:20,	1896:1	1757:20
1858:12, 1858:16,	1926:2, 1926:8,	1852:22, 1853:12,	covered [2] - 1821:9,	daily [9] - 1761:15,
1858:22, 1859:12,	1929:5, 1931:6,	1853:16, 1853:20,	1826:7	1761:17, 1761:20,
1860:6, 1860:7,	1933:2, 1933:13,	1854:9, 1855:6,	covering [1] - 1895:5	1764:16, 1765:7,
1862:21, 1863:17,	1940:15, 1941:22,	1873:11, 1878:3,	covers [1] - 1818:21	1765:8, 1765:9,
1864:20, 1864:21,	1943:6, 1944:5,	1884:5, 1885:23,	Craig [2] - 1927:14,	1781:3
1865:3, 1867:8,	1946:1, 1947:10,	1886:1, 1890:8,	1927:15	<b>DANIEL</b> [1] - 1757:16
1867:16, 1868:7,	1949:10, 1949:21,	1910:24, 1911:2,	created [1] - 1875:5	dark [2] - 1766:1,
1868:15, 1868:16,	1951:3, 1955:12,	1914:21, 1915:3,	credentials [3] -	1980:2
1870:17, 1871:4,	1957:15, 1960:24,	1915:9, 1915:16,	1964:7, 1964:12,	
1872:17, 1872:23,	1964:5, 1966:3,	1916:15, 1917:23,	1964:22	data [45] - 1789:7,
1874:8, 1874:23,	1977:23, 1978:4,	1918:15, 1922:3,		1789:15, 1790:1,
1875:12, 1877:1,	1985:18, 1988:19,	1933:18, 1933:20,	criteria [4] - 1889:14,	1790:5, 1790:6,
1879:24, 1881:17,		1935:17, 1935:25,	1889:19, 1890:2,	1790:16, 1790:20,
1882:2, 1883:4,	1988:23, 1988:25, 1990:7, 1996:10	1936:4, 1936:9,	1890:16	1791:5, 1791:13,
1884:2, 1890:11,	countries [6] -		critical [3] - 1807:10,	1798:1, 1799:12,
1891:4, 1892:15,		1936:13, 1936:18,	1850:24, 1920:7	1799:15, 1799:18,
1893:10, 1894:24,	1763:21, 1763:25,	1936:20, 1936:22,	criticize [1] - 1844:1	1800:18, 1800:20,
1894:25, 1895:6,	1764:15, 1951:25,	1937:7, 1937:11, 1937:14, 1938:1	criticizing [1] -	1800:21, 1801:11,
1895:16, 1896:22,	1952:7, 1963:24	1937:14, 1938:1,	1843:15	1804:20, 1818:5,
	country [1] - 1969:4	1938:8, 1939:5,	critique [1] - 1843:22	1833:7, 1835:12,
1898:10, 1898:24,	couple [4] - 1940:10,	1939:7, 1939:14,	critiquing [3] -	1844:16, 1844:17,
1899:2, 1899:7, 1900:20, 1901:6	1944:20, 1958:25,	1939:16, 1939:22,	1843:17, 1843:19	1845:6, 1863:5,
1900:20, 1901:6,	1986:1	1940:2, 1940:4,	Cross [1] - 1997:5	1869:22, 1869:25,
1901:15, 1902:2,	course [12] - 1794:24,	1940:6, 1940:24,	cross [16] - 1783:22,	1870:3, 1870:5,
1902:8, 1903:6,	1808:3, 1838:4,	1941:9, 1941:14,	1795:14, 1914:25,	1871:8, 1901:10,
1903:21, 1903:25,	1892:6, 1895:11,	1941:18, 1942:14,	1941:6, 1945:25,	1911:10, 1911:16,
1904:6, 1904:8,	1897:13, 1932:3,	1942:21, 1942:24,	1954:4, 1954:8,	1911:21, 1925:2,
1904:11, 1905:24,	1949:1, 1950:1,	1943:10, 1943:15,	1957:14, 1959:16,	1929:18, 1929:22,
1907:18, 1908:4,	1965:12, 1981:11,	1944:4, 1945:5,	1964:4, 1966:9,	1929:25, 1930:22,
1908:15, 1908:19,	1994:24	1945:19, 1945:21,	1969:9, 1973:4,	1941:15, 1966:14,
1908:20, 1922:18,	Court [8] - 1757:23,	1973:14, 1973:24,	1973:6, 1973:9	1966:16, 1967:21,
1925:6, 1925:13,	1934:12, 1944:25,	1974:9, 1975:24,	CROSS [1] - 1784:17	1967:22
1935:23, 1936:2,	1964:23, 1986:15,	1976:2, 1977:20,	Cross-examination	database [10] -
	- ·	4000.40 4000.40	J. J.J. JAMIIII MILION	• •
1936:21, 1938:21,		1980:16, 1980:18,		
1936:21, 1938:21,		1980:16, 1980:18,		

				11
1912:23, 1927:12,	1894:4, 1897:14,	1757:19, 1758:3,	DEMONSTRATIVE[1]	deviation [5] - 1869:6,
1929:7, 1929:14,	1899:15, 1900:9,	1758:10	- 1997:13	1869:9, 1869:25,
1931:22, 1940:12,	1900:16, 1900:24,	defendants [7] -	demonstrative [5] -	1950:1, 1966:15
1941:8, 1941:10,	1901:8, 1904:12,	1784:15, 1984:23,	1847:20, 1928:12,	<b>DHA</b> [99] - 1761:7,
1967:9, 1967:10	1906:7, 1906:18,	1985:12, 1986:14,	1972:23, 1973:25,	1764:1, 1764:8,
date [16] - 1767:13,	1907:5, 1908:5,	1988:7, 1989:24	1974:11	1764:16, 1785:13,
1812:11, 1831:1,	1908:24, 1909:14,	Defendants [1] -	Deposition [1] -	1785:20, 1785:25,
	•		-	
1831:2, 1831:3,	1910:11, 1911:12,	1757:9	1933:8	1786:3, 1786:6,
1831:4, 1832:12,	1912:7, 1913:10,	DEFENDANTS' [1] -	deposition [23] -	1786:9, 1786:25,
1833:6, 1897:24,	1914:11, 1916:3,	1997:15	1784:11, 1798:8,	1787:7, 1787:9,
1916:10, 1922:23,	1917:1, 1918:2,	Defendants' [12] -	1798:21, 1800:22,	1787:12, 1787:19,
1954:22, 1989:18,	1921:14, 1923:1,	1813:3, 1851:25,	1868:18, 1868:22,	1787:23, 1788:8,
1990:5, 1990:16,	1923:19, 1923:23,	1852:23, 1854:10,	1933:7, 1938:24,	1788:11, 1788:18,
1991:19	1925:18, 1927:21,	1855:8, 1873:12,	1940:10, 1940:13,	1790:18, 1801:17,
dated [5] - 1809:7,	1928:1, 1928:10,	1916:1, 1918:1,	1942:18, 1942:21,	1801:23, 1821:15,
1809:13, 1832:5,	1928:19, 1930:9,	1918:16, 1922:4,	1943:1, 1965:3,	1822:24, 1823:22,
1835:17, 1923:6	1930:19, 1959:5,	1936:12, 1945:16	1965:6, 1965:13,	1824:1, 1824:18,
dates [3] - 1762:18,	1964:10, 1968:1,	defendants' [5] -	1965:21, 1966:5,	1825:18, 1825:25,
1898:4	1972:20, 1973:15	1785:8, 1836:9,	1983:8, 1983:11,	1826:13, 1826:21,
dating [2] - 1956:11,	<b>DDX10.34</b> [1] - 1844:7	1925:22, 1972:22,	1983:22, 1983:24,	1827:10, 1827:17,
1956:12	<b>DDX10.65</b> [1] - 1879:2	1984:15	1984:24	1827:21, 1828:4,
days [4] - 1972:24,	deadline [7] -	defense [4] - 1959:6,	depth [2] - 1806:6,	1828:5, 1828:14,
1992:15, 1992:17,	1809:21, 1986:21,	1988:19, 1988:23,	1903:9	1828:17, 1828:19,
1996:14	1989:6, 1990:13,			1829:4, 1829:7,
DDX [109] - 1784:16,	1909.0, 1990.13, 1991:19, 1993:22,	1988:25	derivatives [1] -	1829:13, 1829:22,
		defer [1] - 1944:25	1963:9	,
1793:9, 1793:23,	1993:25	deferring [1] - 1987:3	<b>derive</b> [2] - 1778:1,	1830:3, 1831:7,
1802:5, 1803:14,	deadlines [1] -	deficiency [4] -	1778:3	1831:9, 1831:14,
1804:21, 1809:2,	1990:16	1887:18, 1887:19,	describe [5] -	1831:18, 1834:5,
1813:22, 1815:19,	deal [1] - 1894:2	1890:3, 1890:4	1781:22, 1957:16,	1834:12, 1834:22,
1817:9, 1819:20,	death [10] - 1763:22,	define [1] - 1842:11	1957:20, 1959:2,	1838:6, 1841:3,
1821:3, 1822:2,	1772:6, 1772:8,	defined [3] - 1820:7,	1967:7	1842:6, 1842:12,
1823:8, 1824:13,	1772:10, 1772:16,	1821:17, 1949:12	described [2] -	1843:24, 1846:15,
1825:2, 1825:21,	1772:19, 1773:3,	defines [1] - 1860:2	1831:22, 1969:10	1846:20, 1847:1,
1826:3, 1826:9,	1773:4, 1773:11,	defining [1] - 1949:24	describes [1] - 1831:8	1847:9, 1847:14,
1827:6, 1827:12,	1773:12	definitely [1] -	description [3] -	1847:22, 1849:24,
1829:9, 1829:12,	<b>December</b> [1] - 1923:6	1768:11	1832:15, 1907:16,	1853:6, 1861:1,
1830:17, 1831:25,	decide [1] - 1981:12	definition [3] -	1960:6	1902:4, 1902:8,
1833:2, 1834:19,	decided [1] - 1939:17	1865:23, 1962:3,	deserves [2] - 1939:9,	1903:6, 1903:19,
1835:5, 1836:18,	deciliter [9] - 1794:14,	1964:6	1986:19	1903:23, 1904:8,
1839:4, 1839:6,	1834:3, 1867:16,		design [2] - 1825:24,	1916:23, 1947:2,
1840:19, 1841:15,	1922:10, 1923:17,	definitions [2] -		1947:11, 1947:12,
1842:2, 1842:18,		1866:1, 1964:15	1920:22	1948:7, 1948:14,
1842:24, 1846:6,	1957:4, 1958:7,	degree [7] - 1771:24,	designated [3] -	1948:20, 1952:18,
1847:18, 1848:9,	1961:3, 1961:4	1772:3, 1773:3,	1984:24, 1987:13,	1953:1, 1953:5,
	decipher [1] - 1938:6	1773:20, 1893:13,	1988:7	1954:15, 1955:7,
1851:6, 1851:14, 1852:6, 1852:14,	decks [1] - 1833:5	1893:22, 1934:17	designates [1] -	1955:17, 1956:1,
, ,	declaration [8] -	delay [2] - 1991:17,	1950:14	1962:19, 1962:23,
1853:4, 1853:10,	1867:13, 1867:18,	1993:13	designation [2] -	
1853:25, 1854:7,	1867:21, 1868:3,	deleterious [1] -	1987:15, 1987:17	1962:24, 1963:2,
1854:15, 1855:10,	1965:4, 1965:9,	1871:2	designations [6] -	1963:7, 1963:8,
1857:13, 1857:17,	1965:16, 1966:19	demonstrate [6] -	1965:21, 1980:17,	1963:23, 1969:6,
1860:16, 1860:17,	decrease [2] -	1760:25, 1767:1,	1983:11, 1983:12,	1969:7, 1969:8,
1861:15, 1864:3,	1776:18, 1879:23	1773:9, 1834:22,	1984:3, 1984:18	1975:16, 1975:19
1864:22, 1867:10,	Decreased [1] -	1835:5, 1902:9	despite [1] - 1925:21	DHA-EPA [1] -
1868:20, 1870:7,	1908:13	demonstrated [5] -	detail [1] - 1909:6	1947:11
1870:21, 1871:14,	decreased [2] -	1776:17, 1835:10,	details [1] - 1845:18	Diabetes [2] -
1872:11, 1873:3,	1852:9, 1853:7	1847:2, 1913:21,	determine [2] -	1912:13, 1968:10
1874:25, 1875:17,	defects [2] - 1888:2,		• •	diabetes [1] - 1913:3
1877:3, 1878:7,	1888:14	1968:15	1825:17, 1981:9	diabetic [1] - 1897:10
1881:19, 1882:18,		demonstrating [3] -	develop [1] - 1822:19	diet [5] - 1763:20,
1883:12, 1884:20,	defend [1] - 1801:4	1912:2, 1914:8,	development [1] -	1813:12, 1953:5,
	DEFENDANT [3] -	1968:25	1980:10	, ,
		4	4	

MARGARET E. GRIENER, RDR, CCR NO. 3, OFFICIAL REPORTER (775) 329-9980

1869.8   1869.2   1867.2   1					
dietary pi - 1769.23,   1887.2, 1887.12,   1769.12,   1769.13,	1969:8	1850:5 1863:22	1870:23 1933:21	1932:1 1932:18	1761:16 1761:20
1764-12, 1953-1   1890-18, 1894-7,   1766-12, 1766-18,   1963.4, 1974-10,   1772-2, 1772-2, 1772-4,   1903-18, 1904-7,   1962-7, 1962-16,   1962-7, 1966-1, 1797-1,   1772-7, 1772-4,   1904-14, 1948-16,   1953-7, 1967-1,   1953-7, 1967-1,   1953-7, 1967-1,   1953-7, 1967-1,   1953-7, 1967-1,   1953-7, 1967-1,   1953-7, 1967-1,   1952-1,   1952-9,   1773-21,   1806-1,   1952-9,   1773-21,   1806-1,   18					
			• •		
1778.10, 1771-23,   1903.18, 1904.7,   1953.12, 1954.2   1956.6, 1793.11,   1773.21,   1773.21,   1952.3, 1967.1,   1952.3, 1973.5   1952.3, 1952.5   1952.5   1952.5   1952.5   1952.5   1952.5   1952.5   1952.5   1952.5   1952.5   1952.5   1952.5   1952.5   1952.5   1952.5	·		,		· · · · · · · · · · · · · · · · · · ·
1772_2, 1772_4, 1906_1, 1961_4, 1948_16, 1909_9   1786_1, 1783_1, 1787_1, 1906_1, 1909_9   1786_1, 1783_1, 1806_10, 1800_16, 1909_9   1786_1, 1787_1, 1807_10, 1802_16, 1909_9   1786_1, 1785_1, 1802_14, 1802_24, 1803_5, 1909_9   1786_1,				· ·	· · · · · · · · · · · · · · · · · · ·
1773.11, 1773.20, 1982.9   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.1   1982.2   1982.3   1	· · · · · · · · · · · · · · · · · · ·				•
14773-21, 11773-20, 1982-9   1982-9   1997-4   1992-19   1997-4   1992-19   1997-4   1992-19   1997-4   1992-19   1997-4   1992-19   1997-4   1992-19   1997-4   1992-19   1997-4   1992-19   1997					
1772.21, 1810.6, 1842.8, 1931.21   1872.1, 1852.1   1872.2, 1872.1, 1810.6, 1842.8, 1931.21   1872.2, 1872.1, 1852.1   1872.2, 1872.1, 1852.2, 1872.1, 1852.2, 1872.1, 1852.2, 1872.1, 1852.2, 1872.1, 1852.2, 1872.2, 1872.2, 1872.2, 1872.2, 1872.2, 1872.3, 1872.2, 1872.	1773:11, 1773:20,	1982:9	displayed [1] -	1801:4, 1807:13,	1892:24, 1893:5,
differences       1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1760:3,   1760:2, 1862:10,   1862:10,	1773:21, 1810:6,	Direct [1] - 1997:4	• •	1813:5, 1815:6,	1902:16, 1902:21
1780.2, 1780.3   1833:10   1967:21   1867:1, 1827:22, 1828:14, 1828:16, 1920.25, 1921.2, 1924:19   1967:18   1811.22, 1812.14, 1828:18, 1828:16, 1920.25, 1921.2, 1924:19   1862.20, 1862.23, 1862.11, 1862.19, 1862.20, 1862.23, 1862.10, 1862.19, 1862.20, 1862.23, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.19, 1862.10, 1862.10, 1862.11, 1862.13, 1862.13, 1862.14, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.14, 1862.15, 1862.2, 1862.15, 1862.2, 1862.15, 1862.2, 1862.15, 1862.2, 18	1842:8, 1931:21	<b>DIRECT</b> [1] - 1759:10	disposed [1] -	1863:11, 1864:5,	doses [11] - 1764:17,
1777.1, 1827.22, 1828.14, 1828.16, 1828.12, 1828.14, 1828.16, 1828.16, 1828.17, 1827.14, 1828.18, 18	differences [9] -	directed [2] - 1774:24,	1794:24	1886:3, 1912:1,	1765:5, 1765:19,
	1760:2, 1760:3,	1833:10	dispositive [1] -	1924:14, 1925:25,	1765:24, 1857:1,
1920.25, 1921.2,	1777:1, 1827:22,	direction [1] - 1967:21	1795:4	1930:21, 1965:23	1857:11, 1857:21,
1924:19   disagree(p  -1785:8, 1800:2, 1845:1   1800:2, 1845:1   1800:2, 1845:1   1800:2, 1862:10, 1862:10, 1862:10, 1862:10, 1862:10, 1862:10, 1862:10, 1862:10, 1862:10, 1862:10, 1862:10, 1863:14, 1863:18, 1863:2, 1863:14, 1863:18, 1863:2, 1863:14, 1863:18, 1863:2, 1863:14, 1863:18, 1863:2, 1863:14, 1863:18, 1863:2, 1863:19, 1814:12, 1803:0se [2] - 1812:6, 1928:5   1862:6, 1813:14, 1863:18, 1863:2, 1863:19, 186		directly [1] - 1867:18	dispute [30] - 1811:21,	doctors [8] - 1859:7,	
1800.2, 1845.1   1802.20, 1862.20, 1862.23, 1929.8   1802.21, 1814, 1781.6, 1772.73   1802.10   1803.1, 1863.2, 1803	1920:25, 1921:2,	director [1] - 1927:16	1811:22, 1812:14,	1891:14, 1892:4,	1858:18, 1893:2
1862.4, 1770.9,   1828.10   1828.10   1862.20, 1862.23,   1892.8   1785.5, 1798.8,   1863.14, 1863.14, 1863.14, 1863.14, 1863.14, 1863.14, 1863.14, 1863.14, 1863.14, 1863.14, 1863.14, 1863.18, 1865.2, 1863.18, 1865.2, 1863.18, 1865.2, 1863.18, 1865.2, 1862.63, 1862.63, 1862.63, 1862.63, 1862.63, 1862.63, 1862.64, 1862.64, 1862.65, 1869.15, 1862.15, 1862.15, 1862.15, 1862.15, 1862.65, 1869.15, 1862.15, 1862.15, 1862.15, 1862.15, 1862.15, 1862.65, 1869.15, 1862.15, 1	1924:19	disagree [3] - 1785:8,	1822:5, 1862:8,		
1882.10   1883.1, 1863.12   1883.1, 1863.13   1885.1, 1863.14   1785.5, 1798.6   1785.5, 1798.6   1785.5, 1798.6   1785.5, 1799.6   1885.1, 1863.14   1885.1, 1863.14   1885.1, 1865.2   1815.7, 1815.8   1815.7, 1815.8   1825.24   1885.1, 1831.1, 1831.2   1885.1, 1831.1, 1831.2   1885.1, 1831.1, 1831.2   1885.1, 1831.1, 1831.2   1885.1, 1831.1, 1831.2   1885.2, 1882.2, 1882.2, 1882.2, 1829.2   1882.2, 1829.2   1885.1, 1851.1, 1851.1, 1851.1, 1851.8, 1851.11   1851.8, 1851.11   1855.1, 1855.2, 1852.2, 1854.12   1855.1, 1855.2, 1855.2, 1854.12   1855.1, 1855.2,	different [37] -	1800:2, 1845:1	1862:10, 1862:19,		
17814, 17816,   178217,   178217,   178225, 179721,   180319, 181412,   180522, 180319, 181412,   180520, 180218, 180218, 180208 [p] - 181216,   19285   180208 [p] - 181216,   182826, 180813, 18294,   18292, 18293, 18294,   18292, 18293, 18294,   18292, 18293, 18294,   18292, 18293, 18294,   18292, 18293, 18294,   18292, 18293, 18294,   18292, 18293, 18294,   18292, 18293, 18294,   18292, 19295, 19318,   182925, 19318,   182926, 19377, 194015,   190812, 190619,   190812, 190619,   190812, 190819,   190812, 190819,   190812, 19098, 190922,   18284, 183410, 18311, 183124,   182925, 19318,   183224, 183224, 183224, 183224, 183234, 1848174,   18174, 18177, 182720, 18284, 184812,	·	disagreed [1] -			
178:115, 1781:21,   1989:2   1864:18, 1865:2, 1869:15, 1782:15, 1797:21, 1803:19, 1814:12, 1828:59, 1828:21, 1828:25, 1829:2, 1828:8, 1845:6, 1829:4, 1829:4, 1849:9, 1826:14, 1829:1, 1828:4, 1828:17, 1828:19, 1828:14, 1828:17, 1828:19, 1828:14, 1828:14, 1828:17, 1828:19, 1828:17, 1828:19, 1828:14, 1828:14, 1828:17, 1828:18, 1828:14, 1828:17, 1828:18, 1828:14, 1828:17, 1828:18, 1828:14, 1828:17, 1828:18, 1828:18, 1828:19,	· · · · · · · · · · · · · · · · · · ·	1828:10			• •
1782:16, 1782:17,	*	disagreement [1] -	1863:14, 1863:18,		
1782:25, 1797:21,   disclose   2  - 1812:6,   1928:5	, ,				
1803:19, 1814:12, 1828:15, 1820:13, 1828:20, 1828:21, 1820:21, 1830:31, 1832:4, 1830:4, 1832:4, 1832:4, 1832:4, 1832:4, 1832:4, 1832:4, 1832:4, 1832:4, 1832:4, 1832:4, 1832:4, 1832:4, 1832:1, 1832:6, 1833:4, 1833:4, 1833		disagrees [1] - 1828:9			
1881-15, 1826-13, 1828-21, 1826-22, 1828-21, 1828-22, 1828-23, 1829-24, 1829-23, 1829-3, 1829-4, 1829-3, 1829-3, 1829-4, 1829-3, 1829-13, 1829-3, 18		,			
1828:20, 1828:21,   1810:10, 1811:11,   1909:3, 1910:10,   1848:15, 1857:12,   1876:22, 1884:7,   1829:3, 1845:6,   1852:2, 1854:12,   1855:22, 1855:22, 1855:22, 1855:22, 1855:23, 1929:5, 1931:8   1856:17, 1855:22, 1929:22,   1987:20   1906:12, 1906:19,   1956:21, 1966:17,   1956:21, 1966:17,   1956:21, 1966:17,   1956:21, 1966:17,   1956:21, 1966:17,   1956:21, 1966:17,   1956:21, 1966:17,   1956:21, 1966:17,   1956:21, 1966:17,   1956:21, 1960:7,   1956:21, 1966:17,   1956:21, 1960:7,   1956:21, 1966:17,   1956:21, 1960:7,   1956:21, 1				, ,	
1828:25, 1829:2,   1851:8, 1851:11,   1925:22, 1929:22,   1829:3, 1829:4,   1852:2, 1854:12,   1937:7, 1940:15,   1904:14, 1906:10,   1956:21, 1960:7,   1956:21, 1970:1,   1956:21, 1960:7,   1956:21, 1960:7,   1956:21, 1960:7,   1956:21, 1960:7,   1956:21, 1960:7,   1956:21, 1960:7,   1956:21, 1960:7,   1960:21, 1907:6,   1906:21, 1907:6,   1906:21, 1907:6,   1906:21, 1907:6,   1906:21, 1907:6,   1906:21, 1907:6,   1906:21, 1907:6,   1906:21, 1907:6,   1906:21, 1907:6,   1906:21, 1909:2,   1776:10,   1910:18, 1911:5,   1960:7,   1960:21, 1907:6,   1909:22,   1776:10,   1910:18, 1911:5,   1960:7,   1960:21, 1907:10,   1910:18, 1911:5,   1960:7,   1960:21, 1907:10,   1910:18, 1911:5,   1960:7,   1960:21, 1907:10,   1910:18, 1911:5,   1909:14, 1910:18, 1911:5,   1910:18, 1911:5,   1910:18, 1911:5,   1		disclosed [10] -			•
1829:3, 1829:4,   1852:2, 1854:12,   1937:7, 1940:15,   1904:14, 1906:10,   1952:12, 1956:17,   1929:13, 1938:3,   1929:5, 1931:8   discloses [3] - 1774:23, 1833:24,   1962:11, 1962:13, 1974:6,   1975:1   1848:21, 1848:25,   1882:25   1882:25   1881:20, 1897:4,   1910:18, 1911:5, 1915:10,   1911:15, 1915:10,   1944:6   1916:7, 191					
18928, 18456, 1921.1, 1938.3, 1938.3, 1938.5, 1948.19, 1956.21, 1960.18, 1938.18, 1948.19, 1956.21, 1960.21, 1976.6, 1956.21, 1960.21, 1976.6, 1956.21, 1960.21, 1976.6, 1956.21, 1960.21, 1976.6, 1956.21, 1976.6, 1956.21, 1976.6, 1956.21, 1976.6, 1956.21, 1976.6, 1956.21, 1976.6, 1956.21, 1976.6, 1956.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.6, 1960.21, 1976.2, 1960.21, 1960.					· · · · · ·
1921:1, 1938:3, 1938:5, 1948:19, 1928:5, 1931:8   1928:5, 1931:8   1928:5, 1931:8   1928:5, 1931:8   1938:5, 1948:19, 1958:13, 1978:6, 1952:13, 1974:6, 1952:15   1848:21, 1848:25, 1848:25, 1852:25   1881:20, 1897:4, 1910:18, 1911:5, 1910:10, 1911:15, 1910:10, 1911:15, 1916:10, 1916:7, 1918:5, 1760:2, 1760:2, 1948:6, 1952:1, 1948:10   1948:6, 1948:1, 1948					
1938:5, 1948:19, 1952:11, 1962:11, 1962:11, 1962:11, 1962:13, 1974:6, 1862:12, 1878:6, 1862:12, 1878:6, 1862:12, 1878:6, 1862:12, 1878:6, 1862:12, 1878:6, 1909:6, 1909:2, 1776:12   1776:12   1848:21, 1848:25, 1881:20, 1897:4, 1900:12, 1901:6, 1911:15, 1915:10, 1944:6   1944:6   1944:6   1944:6   1944:6   1948:5, 1862:11, 1862:11, 1862:11, 1862:11, 1862:12, 1878:6, 1944:6   1948:6   1934:20, 1897:20, 1828:4, 1927:24, 1986:2   1882:22, 1882:24, 1882:22, 1882:24, 1927:24, 1986:2   1862:14, 1774:2, 1849:9   1830:11, 1848:12, 1809:4, 1965:16   1830:11, 1848:12, 1869:4, 1995:13   1964:14, 1862:0, 1796:23, 1998:3   1821:18, 1855:2, 1927:24, 1982:9, 1996:1, 1803:10,					
1954:14, 1962:11,   1962:13, 1974:6,   1952:25   1852:25   1852:25   1851:20, 1897-4,   1900:12, 1901:6,   1911:15,   1911:15,   1915:10,   1914:6   1916:7, 1918:5,   1760:21, 1760:17, 1760:		·	• • • •		•
1862:13, 1974:6, 1975:1					
1975:1   1900:12, 1901:6,   1911:15, 1915:10,   1916:7, 1918:5,   1760:21, 1760:21, 1760:22,   1825:18, 1827:17,   1904:25,   1827:20, 1828:4,   1927:24, 1986:2   discussed [1] - 1764:24, 1774:2,   1849:19   1766:21, 1824:16,   1830:11, 1848:12,   1806:16   1894:8, 1988:3   1894:8, 1912:17,   1898:3   1894:8, 1912:17,   1898:3   1894:9, 1912:17,   1898:3   1894:9, 1912:17,   1898:3   1894:9, 1912:17,   1806:24, 1806:24, 1806:10, 1806:10, 1806:10, 1806:10, 1806:10, 1806:10, 1806:10, 1806:10, 1806:10, 1806:24, 1806:10, 1806:24, 1806:10, 1806:10, 1806:10, 1806:10, 1806:10, 1806:10, 1806:24, 1806:10,					
1944:6   1946:6   1946:7   1948:5   1760:9, 1760:17, 1760:24, 17	· ·				
Differential [1]					
1824:19	• •				
differential [5] - 1804:13, 1882:7, 1904:25, 1825:18, 1827:17, 1904:22, 1904:25, 1827:20, 1828:4, 1927:24, 1986:2 discussed [17] - 1868:24, 1883:1 distance [1] - 1868:24 discussed [17] - 1764:24, 1774:2, 1849:9 distinct [1] - 1917:11 distinction [1] - 1803:3, 1829:7, 1859:25, 1965:9, 1891:18, 1892:4, 1988:3 discussed [17] - 1806:16, 1803:10, 1888:3 distinctly [1] - 1770:9 distinctly [2] - 1868:8, 1979:2, 1982:9, 1988:3 discusses [5] - 1872:14, 1929:13, 1804:7, 1806:24, 1804:13, 1804:7, 1806:24, 1805:25, 1955:14 discussion [2] - 1866:16, 1837:19, 1850:23, 1955:14 discussion [2] - 1860:28, 1806:29, 1808:2, 1814:17, 1806:24, 1829:10, 182					
1825:18, 1827:17, 1904:22, 1904:25, 1906:24, 1769:16, 1773:15, 1769:16, 1773:15, 1769:16, 1773:15, 1774:23, 1809:37, 1809:37, 1809:37, 1809:37, 1809:37, 1809:37, 1804:13, 1809:37, 1804:77, 1806:24, 1809:31, 1809:18, 1809:18, 1809:18, 1809:31, 1809:17, 1806:24, 1809:31, 1904:7, 1806:24, 1809:31, 1904:77, 1806:24, 1809:31, 1905:25, 1909:18, 1809:31, 1809:31, 1905:26, 1909:18, 1809:31, 1905:26, 1909:18, 1809:31, 1905:26, 1909:18, 1809:31, 1905:26, 1909:18, 1809:31, 1905:26, 1909:18, 1809:31, 1905:26, 1809:18, 1809:31, 1905:26, 1809:18, 1809:31, 1809:31, 1905:26, 1809:31, 18			. 0		,
1827:20, 1828:4, 1827:24, 1986:2 discussed [17] - distance [1] - 1868:24 distinct [1] - 1764:24, 1774:2, 1849:9 1796:21, 1824:16, 1830:33, 1829:7, 1859:25, 1965:9, 1891:18, 1892:4, 1965:16 1884:9, 1912:17, difficult [2] - 1863:8, 1979:2, 1982:9, 1796:6, 1794:23, 1801:16, 1803:10, 1784:24, 1786:20, 1796:6, 1794:23, 1801:16, 1803:10, 1804:7, 1804:13, 1804:7, 1804:13, 1804:7, 1804:13, 1804:7, 1804:13, 1804:17, 1806:24, 1826:16, 1837:19, 1826:26, 1826:16, 1837:19, 1826:26, 1826:10, 1846:12, 1826:26, 1826:10, 1846:12, 1826:26, 1826:2				documented [1] -	
discussed [17]				1916:23	
differentiate [i] - 184:9         1764:24, 1774:2,         distinct [i] - 1917:11         1810:1, 1830:18,         1774:17, 1774:23,           differently [5] - 1803:3, 1829:7,         1830:11, 1848:12,         1830:11, 1848:12,         1817:24         1806:4, 1924:14,         1778:5, 1779:10,         1779:524, 1777:10,         1779:524, 1777:10,         1779:524, 1777:10,         1779:5, 1780:19,         1779:5, 1780:19,         1779:5, 1780:19,         1779:5, 1780:19,         1784:8, 1784:19,         1784:9, 1936:14,         1784:9, 1936:14,         1784:9, 1936:14,         1784:9, 1936:14,         1784:9, 1936:14,         1784:9, 1936:14,         1784:9, 1936:14,         1784:9, 1936:14,         1784:8, 1784:19,         1784:24, 1786:20,         1979:2, 1982:9,         1979:1         distributed [i] -         1930:16, 1932:19         1797:19, 1797:22,         1797:9, 1797:22,         1797:9, 1797:22,         1797:9, 1797:22,         1797:19, 1797:22,         1797:9, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,         1797:19, 1797:22,				documents [12] -	
1849:9	differentiate [1] -	• •		1810:1, 1830:18,	
differently [5] - 1830:11, 1848:12, 1876:13, 1887:2, 1891:18, 1892:4, 1965:16 1894:9, 1912:17, 1988:3 1979:2, 1982:9, 1989:13 1820:11, 1848:12, 1898:13 1979:2, 1982:9, 1996:4, 1924:14, 1996:4, 1924:14, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1930:14, 1989:13, 1996:11 1784:24, 1797:9, 1989:13 1817:24 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1933:16, 1930:22, 1930:14, 1989:13, 1996:11 1989:13, 1996:11 1996:4, 1924:14, 1989:13, 1996:14, 1990:14, 1930:12, 1930:16, 1932:19 1930:16, 1932:19 1930:16, 1932:19 1930:16, 1932:19 1930:16, 1932:19 1930:16, 1932:19 1930:16, 1930:19 1791:24, 1791:24, 1791:24, 1791:24, 1824:4, 1778:5, 1779:10, 1779:25, 1780:19, 1791:24, 1791:24, 1791:24, 1824:4, 1778:5, 1779:10, 1779:25, 1780:19, 1791:25, 1780:19, 1791:24, 1824:4, 1791:24, 1791:14, 1990:1, 1781:14, 1791:24, 1824:14, 1990:1, 1930:12, 1791:24, 1930:14, 1989:13, 1996:11 1791:24, 1824:4, 1791:24, 1791:14, 1791:24, 1824:4, 1791:24, 1791:14, 1791:25, 1780:19, 1791:24, 1824:4, 1791:24, 1791:10, 1791:25, 1780:19, 1791:24, 1824:4, 1791:24, 1791:14, 1791:25, 1780:19, 1791:25, 1780:19, 1791:25, 1780:19, 1791:24, 1824:4, 1791:24, 1791:14, 1791:25, 1780:19, 1791:24, 1822:4, 1791:24, 1824:24, 1791:24, 1824:14, 1791:24,	1849:9			1830:25, 1906:1,	1775:24, 1777:10,
1803:3, 1829:7,       1876:13, 1887:2,       distinctly [1] - 1770:9       1930:22, 1933:16,       1779:25, 1780:19,         1859:25, 1965:9,       1891:18, 1892:4,       distinguishing [2] -       1833:15, 1859:3       1934:9, 1936:14,       1784:8, 1784:19,         1965:16       1894:9, 1912:17,       distributed [1] -       1833:15, 1859:3       dollars [3] - 1891:10,       179:21, 1797:22,         1988:3       1979:2, 1982:9,       1979:1       distributed [1] -       1930:16, 1932:19       1797:19, 1797:22,         direct [36] - 1784:19,       1989:13       distribution [1] -       1930:16, 1932:19       1797:25, 1798:15,         direct [36] - 1784:29,       1989:13       distribution [1] -       1930:16, 1932:19       1797:25, 1798:15,         discusses [5] -       1872:7       1871:24, 1824:2,       1830:20, 1833:9,         1872:14, 1929:13,       1872:14, 1929:13,       1875:11, 1757:2       1856:10, 1861:11,       1833:13, 1838:1,         1804:17, 1806:24,       1826:16, 1837:19,       1953:20, 1972:25       divergence [1] -       1987:7, 1994:5       1840:10, 1840:15,         1840:23, 1844:12,       1850:23, 1955:14       1808:2, 1814:17,       1761:10, 1761:11,       1862:3,         1862:8, 1867:12,       1862:8, 1867:12,	differently [5] -				1778:5, 1779:10,
1859:25, 1965:9,       1891:18, 1892:4,       distinguishing [2] -       1934:9, 1936:14,       1784:8, 1784:19,         1965:16       1894:9, 1912:17,       distributed [1] -       1898:13, 1996:11       1784:24, 1797:9,         difficult [2] - 1863:8,       1925:21, 1970:14,       distributed [1] -       1930:16, 1932:19       1797:19, 1797:22,         1988:3       1979:2, 1982:9,       1979:1       distribution [1] -       1930:16, 1932:19       1797:25, 1798:15,         direct [36] - 1784:19,       1989:13       distribution [1] -       1930:16, 1932:19       1797:25, 1798:15,         discusses [5] -       1872:7       District [1] - 1757:23       1856:10, 1861:11,       1833:13, 1838:1,         1801:16, 1803:10,       1872:14, 1929:13,       19STRICT [3] - 1757:1,       1878:21, 1898:6,       1838:3, 1838:5,         1804:17, 1806:24,       1850:22, 1824:16,       1757:1, 1757:2       1987:7, 1994:5       1839:7, 1840:5,         1826:16, 1837:19,       1953:20, 1972:25       divergent [1] - 1776:2       dosage [1] - 1962:24       1849:6, 1853:24,         1846:1, 1848:12,       1850:23, 1955:14       1808:2, 1814:17,       1761:10, 1761:11,       1862:8, 1867:12,	1803:3, 1829:7,		distinctly [1] - 1770:9		1779:25, 1780:19,
1894:9, 1912:17,  difficult [2] - 1863:8, 1988:3  direct [36] - 1784:19, 1784:24, 1786:20, 1790:6, 1794:23, 1801:16, 1803:10, 1804:7, 1806:24, 1819:22, 1824:16, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1846:1, 1848:12, 1850:23, 1955:14  1833:15, 1859:3  distributed [1] - 1979:1  distribution [1] - 1930:16, 1932:19  done [11] - 1785:4, 1799:6, 1811:2, 1799:6, 1811:2, 1799:6, 1811:2, 1799:6, 1811:2, 1799:6, 1811:2, 1850:10, 1861:11, 1878:21, 1898:6, 1838:3, 1838:5, 1909:7, 1927:11, 1838:11, 1838:14, 1909:7, 1927:11, 1878:21, 1898:6, 1909:7, 1927:11, 1838:11, 1838:14, 1909:7, 1927:11, 1838:11, 1838:14, 1909:7, 1927:11, 1878:21, 1898:6, 1830:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:9, 1800:20, 1830:20, 1830:10, 1800:20, 1830:20, 1830:20, 1800:20, 1830:20, 1800:20, 1830:20, 1800:20, 1830:20, 1800:20, 1830:20, 1800:20, 1830:20, 1800:20, 1830:20, 1800:20, 1800:20, 1800:20, 1800:20, 1800:20, 1800:20, 1800:20, 1800:20, 1800:20, 1800:20, 1800:20, 1	1859:25, 1965:9,		• • • •	,	· · · · · · · · · · · · · · · · · · ·
difficult [2] - 1863:8, 1988:3         1925:21, 1970:14, 1979:2, 1982:9, 1979:1         distributed [1] - 1930:16, 1932:19         1797:19, 1797:22, 1797:22, 1797:22, 1797:22, 1797:25, 1798:15, 1790:6, 1794:23, 1790:6, 1794:23, 1801:16, 1803:10, 1804:7, 1804:13, 1804:7, 1806:24, 1819:22, 1824:16, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1836:24, 1826:24, 1824:2, 1830:20, 1833:9, 1836:1, 1878:21, 1898:6, 1838:3, 1838:5, 1909:7, 1927:11, 1838:11, 1838:14, 1909:7, 1927:11, 1838:11, 1838:14, 1838:14, 1839:7, 1840:5, 1839:7, 1840:5, 1839:7, 1840:5, 1839:7, 1840:5, 1839:7, 1840:5, 1839:7, 1840:15, 1840:22, 1849:6, 1853:24, 1861:17, 1862:3, 1861:17, 1862:3, 1862:8, 1867:12, 1866:23, 1867:12, 1866:23, 1867:12, 1866:23, 1867:12, 1867:18, 1867:21, 18	1965:16		1833:15, 1859:3	,	1784:24, 1797:9,
direct [36] - 1784:19,         1989:13         distribution [1] -         done [11] - 1785:4,         1799:6, 1811:2,           1784:24, 1786:20,         1790:6, 1794:23,         1821:18, 1855:2,         1872:7         1856:10, 1861:11,         1830:20, 1833:9,           1801:16, 1803:10,         1872:14, 1929:13,         1947:7         1875:1, 1757:2,         1878:21, 1898:6,         1838:3, 1838:1,           1804:7, 1806:24,         1819:22, 1824:16,         1759:12, 1899:18,         1953:20, 1972:25,         1877:6         1909:7, 1927:11,         1838:11, 1838:14,           1826:16, 1837:19,         1856:10, 1861:2,         1878:21, 1898:6,         1878:21, 1898:6,         1878:21, 1898:6,         1838:3, 1838:5,           1804:17, 1806:24,         1819:22, 1824:16,         1759:12, 1899:18,         1777:6         1987:7, 1994:5         1839:7, 1840:5,           1826:16, 1837:19,         1953:20, 1972:25         1840:20, 1876:24         1860:11, 1848:12,         1860:11, 1848:12,           1846:1, 1848:12,         1850:23, 1955:14         1808:2, 1814:17,         1761:10, 1761:11,         1862:8, 1867:12,           1867:18, 1867:24         1868:2, 1867:12,         1867:11, 1761:14,         1867:11, 1867:14         1867:11, 1867:14	difficult [2] - 1863:8,		distributed [1] -	,	
1784:24, 1786:20,   1791:24, 1824:2,   1830:20, 1833:9,   1801:16, 1803:10,   1872:14, 1929:13,   1804:7, 1804:13, 1806:24,   1819:22, 1824:16, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1826:16, 1837:19, 1839:18, 1953:20, 1972:25   1804:22, 1826:14, 1826:14, 1836:14,	1988:3	1979:2, 1982:9,	1979:1	,	, , , , , , , , , , , , , , , , , , , ,
1790:6, 1794:23, 1821:18, 1855:2, 1801:16, 1803:10, 1804:7, 1804:13, 1947:7	• •	1989:13	distribution [1] -	• • •	
1801:16, 1803:10, 1872:14, 1929:13, 1947:7 1804:7, 1806:24, 1819:22, 1824:16, 1826:16, 1837:19, 1840:23, 1844:12, 1846:1, 1848:12, 1850:24, 1850:24, 1850:24, 1850:24, 1850:24, 1850:24, 1850:23, 1955:14 1850:24,		discusses [5] -	1872:7		
1804:7, 1804:13, 1947:7 1806:24, 1806:24, 1819:22, 1824:16, 1826:16, 1837:19, 1840:23, 1844:12, 1846:1, 1848:12, 1850:24		, , ,	District [1] - 1757:23	· · · · · ·	'
1804:17, 1806:24, 1819:22, 1824:16, 1826:16, 1837:19, 1840:23, 1844:12, 1846:1, 1848:12, 1850:23, 1955:14  1804:17, 1806:24, discussing [4] - 1759:12, 1899:18, 1953:20, 1972:25 divergent [1] - 1776:2 doctor [13] - 1804:22, 1808:2, 1814:17, 1808:2, 1814:17, 1980:3, 1950:4, 1987:7, 1994:5 door [1] - 1795:20 dosage [1] - 1962:24 dose [23] - 1761:6, 1861:17, 1862:3, 1862:8, 1867:12, 1867:18, 1867:31			<b>DISTRICT</b> [3] - 1757:1,	, ,	
1819:22, 1824:16, 1759:12, 1899:18, 1777:6 1953:20, 1972:25 1840:23, 1844:12, 1846:1, 1848:12, 1850:23, 1955:14 1808:2, 1814:17, 1814:18, 181			•		
1826:16, 1837:19, 1953:20, 1972:25 divergent [1] - 1776:2 doctor [13] - 1804:22, 1846:1, 1848:12, 1850:23, 1955:14 1808:2, 1814:17, 1808:2, 1814:17, 1862:3, 1867:12, 1867:31					
1840:23, 1844:12, 1846:1, 1848:12, 1850:23, 1955:14 1808:2, 1814:17, 1808:2, 1814:17, 1861:17, 1862:3, 1861:17, 18					
1846:1, 1848:12, 1850:23, 1955:14 1808:2, 1814:17, 1761:10, 1761:11, 1862:8, 1867:12, 1862:3, 1850:3,		•	•	<u> </u>	
1000.23, 1000.14	· · · · · · · · · · · · · · · · · · ·			• •	
1861:10, 1928:21, 1701:14, 170		•			
1 1 1	1049.3, 1030.4,	Discussion [2] -	1861:10, 1928:21,	1701.12, 1701.14,	1007.10, 1007.21,

				13
1868:7, 1868:10,	1963:24, 1974:5,	1889:3, 1889:24,	1775:13, 1778:15,	1846:20, 1847:1,
1868:14, 1868:17,	1980:9	1899:17, 1900:10,	1778:23, 1779:2,	1847:9, 1847:14,
1869:15, 1878:6,	<b>Drug</b> [1] - 1916:6	1900:17, 1906:8,	1780:13, 1786:14,	1882:11, 1900:12,
1906:7, 1914:25,	drugs [10] - 1760:10,	1906:19, 1907:6,	1787:1, 1787:8,	1904:1, 1944:25,
1915:22, 1916:5,	1801:19, 1806:25,	1908:6, 1908:19,	1787:14, 1787:19,	1964:15, 1975:16
1918:19, 1918:21,	1808:6, 1893:16,	1908:25, 1909:15,	1787:21, 1789:3,	<b>ELAINA</b> [1] - 1757:15
1919:20, 1921:16,	1917:10, 1971:1,	1912:7, 1914:12,	1790:14, 1790:22,	Elevated [2] -
1934:4, 1934:25,	1971:20, 1973:2,	1915:24, 1916:7,	1790:25, 1797:12,	1912:12, 1970:10
1935:6, 1935:14,	1974:7	1916:12, 1917:6,	1801:22, 1801:23,	elevated [6] - 1813:13,
1936:25, 1937:2,	<b>Drugs</b> [1] - 1916:9	1917:20, 1917:23,	1806:24, 1819:3,	1840:7, 1873:14,
1937:22, 1938:2,	<b>DU</b> [1] - 1757:2	1918:3, 1918:12,	1819:11, 1822:6,	1913:2, 1913:20,
1938:23, 1939:13,	due [5] - 1827:21,	1921:24, 1923:2,	1828:6, 1829:3,	1968:14
1940:9, 1940:18,	1888:24, 1948:2,	1923:10, 1923:19,	1831:8, 1833:20,	elevates [1] - 1833:21
1940:21, 1941:1,	1991:24, 1994:7	1928:9, 1929:3,	1843:9, 1848:19,	elevation [9] - 1807:1,
1941:9, 1941:11,	duration [2] - 1843:11,	1930:21, 1930:23,	1870:16, 1871:3,	1834:6, 1865:24,
1941:25, 1942:5,	1843:21	1931:10, 1933:16,	1876:18, 1891:13,	1879:12, 1879:14,
1943:1, 1943:2,	during [14] - 1784:24,	1935:19, 1935:21,	1891:24, 1892:5,	1893:4, 1893:19,
1943:11, 1944:16,	1794:24, 1795:13,	1936:5, 1936:10,	1941:12, 1948:7,	1976:8, 1977:14
1945:10, 1945:11,	1796:23, 1804:22,	1936:23, 1945:9,	1969:11, 1969:15,	elevations [2] -
1945:24, 1952:23,	1867:13, 1904:14,	1946:5, 1951:20,	1971:24, 1977:15	1834:12, 1872:1
1954:5, 1954:25,	1914:25, 1942:6,	1952:8, 1953:22,	effecting [1] - 1782:8	eleven [1] - 1816:6
1955:15, 1956:10,	1943:11, 1953:7,	1954:7, 1957:10,	effective [6] - 1778:25,	<b>ELIKAN</b> [163] -
1956:22, 1957:5,	1969:9, 1982:9,	1957:24, 1960:1,	1906:14, 1917:15,	1757:15, 1759:4,
1964:8, 1964:13,	1984:18	1968:3, 1975:22,	1952:5, 1960:17,	1759:6, 1759:11,
1964:16, 1965:4,	<b>DX</b> [136] - 1763:5,	1978:5, 1978:9,	1961:21	1759:15, 1759:16,
1965:6, 1966:9,	1770:21, 1772:15,	1981:17, 1983:17,	effectiveness [1] -	1760:5, 1760:8,
1966:18, 1971:18,	1784:24, 1793:11,	1983:19, 1983:20,	1911:6	1762:14, 1762:17,
1971:25, 1972:5,	1794:6, 1798:5,	1983:21, 1983:25	effects [41] - 1775:15,	1763:4, 1763:8,
1973:23, 1973:25,	1798:22, 1800:9,	<b>DX1547</b> [1] - 1949:3	1781:22, 1787:12,	1763:15, 1763:18,
1975:10, 1977:23,	1800:11, 1800:13,	<b>DX2264</b> [1] - 1853:25	1793:6, 1794:16,	1764:21, 1764:22,
1977:24, 1978:6,	1802:12, 1803:14,	dysbetalipoproteine	1794:21, 1800:15,	1765:13, 1765:18,
1978:12, 1978:16,	1805:10, 1809:2,	<b>mia</b> [1] - 1890:6	1801:9, 1804:18,	1766:2, 1766:4,
1978:18, 1979:8,	1809:5, 1809:9,	dyslipidemia [1] -	1818:15, 1825:18,	1767:15, 1767:18,
1980:4, 1981:5,	1809:12, 1812:24,	1951:8	1826:13, 1827:18,	1767:21, 1767:24,
4004.40.4000.45	1000.12, 1012.24,			1707.21, 1707.24,
1981:12, 1982:15,	1813:6, 1813:7,	_	1827:20, 1828:4,	1769:1, 1769:3,
1982:18, 1982:19,	1813:6, 1813:7, 1814:17, 1814:18,	E	1827:20, 1828:4, 1828:20, 1828:21,	1769:1, 1769:3, 1770:10, 1770:14,
1982:18, 1982:19, 1983:4, 1984:3	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4,		1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13,	<b>e-mail</b> [8] - 1978:10,	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11 <b>draw</b> [1] - 1817:24	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4,	<b>e-mail</b> [8] - 1978:10, 1978:12, 1978:15,	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11 <b>draw</b> [1] - 1817:24 <b>drawn</b> [1] - 1827:24	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15,	<b>e-mail</b> [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16,	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11 <b>draw</b> [1] - 1817:24 <b>drawn</b> [1] - 1827:24 <b>dreaded</b> [1] - 1771:19	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6,	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11 <b>draw</b> [1] - 1817:24 <b>drawn</b> [1] - 1827:24 <b>dreaded</b> [1] - 1771:19 <b>drive</b> [1] - 1985:2	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11 <b>draw</b> [1] - 1817:24 <b>drawn</b> [1] - 1827:24 <b>dreaded</b> [1] - 1771:19 <b>drive</b> [1] - 1985:2 <b>driven</b> [1] - 1870:3	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:9,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11 <b>draw</b> [1] - 1817:24 <b>drawn</b> [1] - 1827:24 <b>dreaded</b> [1] - 1771:19 <b>drive</b> [1] - 1985:2 <b>driven</b> [1] - 1870:3 <b>driver</b> [1] - 1759:25	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:9, 1783:12, 1783:18,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11 <b>draw</b> [1] - 1817:24 <b>drawn</b> [1] - 1827:24 <b>dreaded</b> [1] - 1771:19 <b>drive</b> [1] - 1985:2 <b>driven</b> [1] - 1870:3 <b>driver</b> [1] - 1759:25 <b>DRL</b> [1] - 1995:5	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18,	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1771:19  drive [1] - 1985:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1771:19  drive [1] - 1985:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17,	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1771:19  drive [1] - 1985:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1771:19  drive [1] - 1885:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25  drug [26] - 1777:2,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1854:16,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4,	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1771:19  drive [1] - 1885:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25  drug [26] - 1777:2, 1789:19, 1791:13,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1854:16, 1854:23, 1855:10,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5,	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19, 1947:5	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1771:19  drive [1] - 1885:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25  drug [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1854:16, 1854:23, 1855:10, 1857:13, 1860:17,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19, 1947:5  efficacy [3] - 1875:8,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:18, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1771:19  drive [1] - 1855:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25  drug [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14, 1811:2, 1818:16,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1852:14, 1854:23, 1855:10, 1857:13, 1860:17, 1861:21, 1861:22,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5 eating [1] - 1952:14	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19, 1947:5  efficacy [3] - 1875:8, 1902:9, 1959:24	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:18, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23, 1852:21, 1854:8,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11 <b>draw</b> [1] - 1817:24 <b>drawn</b> [1] - 1827:24 <b>dreaded</b> [1] - 1771:19 <b>drive</b> [1] - 1985:2 <b>driven</b> [1] - 1759:25 <b>DRL</b> [1] - 1995:5 <b>drop</b> [2] - 1943:8, 1985:2 <b>Drs</b> [1] - 1848:25 <b>drug</b> [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14, 1811:2, 1818:16, 1859:23, 1860:6,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1852:14, 1854:23, 1855:10, 1857:13, 1860:17, 1861:21, 1861:22, 1864:5, 1864:23,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5 eating [1] - 1952:14 economist [1] -	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19, 1947:5  efficacy [3] - 1875:8, 1902:9, 1959:24 effort [1] - 1905:12	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:1, 1782:23, 1782:24, 1783:18, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23, 1852:21, 1854:8, 1854:24, 1873:10,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11 <b>draw</b> [1] - 1817:24 <b>drawn</b> [1] - 1827:24 <b>dreaded</b> [1] - 17771:19 <b>drive</b> [1] - 1985:2 <b>driven</b> [1] - 1759:25 <b>DRL</b> [1] - 1995:5 <b>drop</b> [2] - 1943:8, 1985:2 <b>Drs</b> [1] - 1848:25 <b>drug</b> [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14, 1811:2, 1818:16, 1859:23, 1860:6, 1860:8, 1871:25,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1852:14, 1854:23, 1855:10, 1857:13, 1860:17, 1861:21, 1861:22, 1864:5, 1864:23, 1867:25, 1870:10,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5 eating [1] - 1952:14 economist [1] - 1972:24	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19, 1947:5  efficacy [3] - 1875:8, 1902:9, 1959:24 effort [1] - 1905:12 efforts [1] - 1905:12	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23, 1852:21, 1854:8, 1854:24, 1873:10, 1910:25, 1914:13,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1771:19  drive [1] - 1985:2  driven [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25  drug [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14, 1811:2, 1818:16, 1859:23, 1860:6, 1860:8, 1871:25, 1872:4, 1872:5,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1854:16, 1854:23, 1855:10, 1857:13, 1860:17, 1861:21, 1861:22, 1864:5, 1864:23, 1867:25, 1870:10, 1870:24, 1871:20,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5 eating [1] - 1952:14 economist [1] - 1972:24 Editor's [3] - 1848:15,	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19, 1947:5  efficacy [3] - 1875:8, 1902:9, 1959:24 effort [1] - 1905:12 efforts [1] - 1920:12 eight [4] - 1770:16,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23, 1852:21, 1854:8, 1854:24, 1873:10, 1910:25, 1914:13, 1915:4, 1915:12,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1771:19  drive [1] - 1855:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25  drug [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14, 1811:2, 1818:16, 1859:23, 1860:6, 1860:8, 1871:25, 1872:4, 1872:5, 1873:18, 1873:20,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1854:16, 1854:23, 1855:10, 1857:13, 1860:17, 1861:21, 1861:22, 1864:5, 1864:23, 1867:25, 1870:10, 1870:24, 1871:20, 1872:13, 1873:4,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5 eating [1] - 1952:14 economist [1] - 1972:24 Editor's [3] - 1848:15, 1982:9, 1982:20	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2 Effects [2] - 1824:19, 1947:5 efficacy [3] - 1875:8, 1902:9, 1959:24 effort [1] - 1905:12 efforts [1] - 1920:12 eight [4] - 1770:16, 1897:23, 1898:12,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23, 1852:21, 1854:8, 1854:24, 1873:10, 1910:25, 1914:13, 1915:4, 1915:12, 1916:13, 1917:22,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1771:19  drive [1] - 1885:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25  drug [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14, 1811:2, 1818:16, 1859:23, 1860:6, 1860:8, 1871:25, 1872:4, 1872:5, 1873:18, 1873:20, 1882:2, 1883:23,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1852:14, 1853:11, 1854:16, 1854:23, 1855:10, 1857:13, 1860:17, 1861:21, 1861:22, 1864:5, 1864:23, 1867:25, 1870:10, 1870:24, 1871:20, 1872:13, 1873:4, 1873:9, 1875:3,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5 eating [1] - 1952:14 economist [1] - 1972:24 Editor's [3] - 1848:15, 1982:9, 1982:20 editorial [3] - 1904:18,	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2 Effects [2] - 1824:19, 1947:5 efficacy [3] - 1875:8, 1902:9, 1959:24 effort [1] - 1905:12 efforts [1] - 1920:12 eight [4] - 1770:16, 1897:23, 1898:12, 1898:17	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23, 1852:21, 1854:8, 1854:24, 1873:10, 1910:25, 1914:13, 1915:4, 1915:12, 1916:13, 1917:22, 1918:14, 1922:2,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1777:19  drive [1] - 1985:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25  drug [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14, 1811:2, 1818:16, 1859:23, 1860:6, 1860:8, 1871:25, 1872:4, 1872:5, 1873:18, 1873:20, 1882:2, 1883:23, 1891:8, 1891:14,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1854:16, 1854:23, 1855:10, 1857:13, 1860:17, 1861:21, 1861:22, 1864:5, 1864:23, 1867:25, 1870:10, 1870:24, 1871:20, 1872:13, 1873:4, 1873:9, 1875:3, 1875:19, 1877:4,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5 eating [1] - 1952:14 economist [1] - 1972:24 Editor's [3] - 1848:15, 1982:9, 1982:20 editorial [3] - 1904:18, 1905:23, 1967:16	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19, 1947:5  efficacy [3] - 1875:8, 1902:9, 1959:24 effort [1] - 1905:12 efforts [1] - 190:12 eight [4] - 1770:16, 1897:23, 1898:12, 1898:17 EIMERIC [1] - 1758:5	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23, 1852:21, 1854:8, 1854:24, 1873:10, 1910:25, 1914:13, 1915:4, 1915:12, 1916:13, 1917:22, 1918:14, 1922:2, 1933:19, 1933:22,
1982:18, 1982:19, 1983:4, 1984:3 <b>Dramatic</b> [1] - 1767:11 <b>draw</b> [1] - 1817:24 <b>drawn</b> [1] - 1827:24 <b>dreaded</b> [1] - 1771:19 <b>drive</b> [1] - 1985:2 <b>driver</b> [1] - 1759:25 <b>DRL</b> [1] - 1995:5 <b>drop</b> [2] - 1943:8, 1985:2 <b>Drs</b> [1] - 1848:25 <b>drug</b> [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14, 1811:2, 1818:16, 1859:23, 1860:6, 1860:8, 1871:25, 1872:4, 1872:5, 1873:18, 1873:20, 1882:2, 1883:23, 1891:8, 1891:14, 1896:2, 1896:7,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1854:16, 1854:23, 1855:10, 1857:13, 1860:17, 1861:21, 1861:22, 1864:5, 1864:23, 1867:25, 1870:10, 1870:24, 1871:20, 1872:13, 1873:4, 1873:9, 1875:3, 1875:19, 1877:4, 1879:4, 1881:22,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5 eating [1] - 1952:14 economist [1] - 1972:24 Editor's [3] - 1848:15, 1982:9, 1982:20 editorial [3] - 1904:18, 1905:23, 1967:16 Effect [1] - 1832:9	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19, 1947:5  efficacy [3] - 1875:8, 1902:9, 1959:24 effort [1] - 1905:12 efforts [1] - 1920:12 eight [4] - 1770:16, 1897:23, 1898:12, 1898:17  EIMERIC [1] - 1758:5 either [13] - 1799:18,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1779:23, 1779:24, 1781:24, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23, 1852:21, 1854:8, 1854:24, 1873:10, 1910:25, 1914:13, 1915:4, 1915:12, 1916:13, 1917:22, 1918:14, 1922:2, 1933:19, 1933:22, 1936:7, 1937:1,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1777:19  drive [1] - 1985:2  driven [1] - 1870:3  driver [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25  drug [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14, 1811:2, 1818:16, 1859:23, 1860:6, 1860:8, 1871:25, 1872:4, 1872:5, 1873:18, 1873:20, 1882:2, 1883:23, 1891:8, 1891:14,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1854:16, 1854:23, 1855:10, 1857:13, 1860:17, 1861:21, 1861:22, 1864:5, 1864:23, 1867:25, 1870:10, 1870:24, 1871:20, 1872:13, 1873:4, 1873:9, 1875:3, 1875:19, 1877:4,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5 eating [1] - 1952:14 economist [1] - 1972:24 Editor's [3] - 1848:15, 1982:9, 1982:20 editorial [3] - 1904:18, 1905:23, 1967:16	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19, 1947:5  efficacy [3] - 1875:8, 1902:9, 1959:24 effort [1] - 1905:12 efforts [1] - 190:12 eight [4] - 1770:16, 1897:23, 1898:12, 1898:17 EIMERIC [1] - 1758:5	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1774:3, 1779:21, 1779:23, 1779:24, 1781:24, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23, 1852:21, 1854:8, 1854:24, 1873:10, 1910:25, 1914:13, 1915:4, 1915:12, 1916:13, 1917:22, 1918:14, 1922:2, 1933:19, 1933:22,
1982:18, 1982:19, 1983:4, 1984:3  Dramatic [1] - 1767:11  draw [1] - 1817:24  drawn [1] - 1827:24  dreaded [1] - 1777:19  drive [1] - 1985:2  driven [1] - 1759:25  DRL [1] - 1995:5  drop [2] - 1943:8, 1985:2  Drs [1] - 1848:25  drug [26] - 1777:2, 1789:19, 1791:13, 1806:21, 1807:14, 1811:2, 1818:16, 1859:23, 1860:6, 1860:8, 1871:25, 1872:4, 1872:5, 1873:18, 1873:20, 1882:2, 1883:23, 1891:8, 1891:14, 1896:2, 1896:7,	1813:6, 1813:7, 1814:17, 1814:18, 1816:1, 1816:4, 1817:12, 1817:13, 1821:6, 1822:4, 1823:8, 1824:15, 1830:17, 1832:1, 1833:4, 1834:18, 1836:19, 1836:25, 1837:12, 1838:5, 1840:21, 1844:9, 1846:9, 1847:20, 1847:21, 1851:16, 1851:21, 1852:14, 1853:11, 1854:16, 1854:23, 1855:10, 1857:13, 1860:17, 1861:21, 1861:22, 1864:5, 1864:23, 1867:25, 1870:10, 1870:24, 1871:20, 1872:13, 1873:4, 1873:9, 1875:3, 1875:19, 1877:4, 1879:4, 1881:22,	e-mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 e.g [1] - 1802:24 early [1] - 1809:21 easier [3] - 1857:18, 1878:1, 1995:10 easy [2] - 1939:17, 1996:2 eat [4] - 1764:4, 1764:14, 1768:5, 1969:5 eating [1] - 1952:14 economist [1] - 1972:24 Editor's [3] - 1848:15, 1982:9, 1982:20 editorial [3] - 1904:18, 1905:23, 1967:16 Effect [1] - 1832:9	1827:20, 1828:4, 1828:20, 1828:21, 1828:25, 1829:2, 1829:3, 1829:4, 1829:8, 1842:12, 1846:20, 1847:2, 1847:6, 1847:9, 1847:14, 1847:22, 1865:6, 1866:3, 1870:25, 1892:8, 1892:11, 1917:10, 1947:7, 1952:24, 1960:14, 1962:25, 1975:14, 1978:2  Effects [2] - 1824:19, 1947:5  efficacy [3] - 1875:8, 1902:9, 1959:24 effort [1] - 1905:12 efforts [1] - 1920:12 eight [4] - 1770:16, 1897:23, 1898:12, 1898:17  EIMERIC [1] - 1758:5 either [13] - 1799:18,	1769:1, 1769:3, 1770:10, 1770:14, 1770:20, 1771:1, 1772:14, 1772:17, 1774:1, 1779:23, 1779:24, 1781:24, 1782:24, 1783:9, 1783:12, 1783:18, 1784:5, 1794:22, 1795:17, 1796:6, 1796:11, 1796:14, 1799:23, 1809:15, 1811:20, 1811:24, 1814:7, 1814:9, 1814:14, 1851:23, 1852:21, 1854:8, 1854:24, 1873:10, 1910:25, 1914:13, 1915:4, 1915:12, 1916:13, 1917:22, 1918:14, 1922:2, 1933:19, 1933:22, 1936:7, 1937:1,

4007.40.4000.4	1000 00 1000 10	40044 40045	1000.04 1000.0	1
1937:16, 1938:4,	1989:20, 1993:19	1804:1, 1804:5,	1886:21, 1899:3,	1958:8
1939:6, 1939:10,	endeavor [1] - 1991:5	1804:8, 1804:19,	1899:4, 1899:12, 1900:19, 1901:12,	ERIC [1] - 1757:16
1939:15, 1939:20, 1939:25, 1941:1,	Endovascular [3] - 1934:16, 1934:18,	1805:5, 1805:14, 1805:19, 1805:24,	1900.19, 1901.12,	Ernie [1] - 1956:6 errata [1] - 1992:17
1941:11, 1941:16,	1934.10, 1934.10,	1819:3, 1821:15,	1902:1, 1902:7,	errada[1] - 1992.17 erred [2] - 1966:10,
1943:19, 1945:20,	endpoint [12] -	1822:22, 1822:24,	1904:4, 1904:19,	1966:12
1945:23, 1946:4,	1759:21, 1759:22,	1823:18, 1823:22,	1905:5, 1906:2,	erroneous [4] -
1946:7, 1946:17,	1759:25, 1771:11,	1823:25, 1824:4,	1906:11, 1906:14,	1934:17, 1934:18,
1946:19, 1946:23,	1772:6, 1899:14,	1824:10, 1824:18,	1906:24, 1907:21,	1935:7
1946:24, 1947:23,	1902:23, 1907:4,	1825:18, 1825:25,	1908:8, 1908:13,	error [2] - 1820:15,
1947:24, 1949:2,	1908:1, 1908:3,	1826:5, 1826:13,	1910:2, 1910:5,	1934:19
1949:6, 1949:11,	1919:15, 1919:19	1826:22, 1827:3,	1911:17, 1912:2,	especially [2] -
1949:16, 1950:6,	endpoints [4] -	1827:9, 1827:17,	1913:22, 1914:8,	1901:13, 1958:16
1950:8, 1951:4,	1759:19, 1920:5,	1827:21, 1828:4,	1916:23, 1922:12,	essentially [4] -
1951:5, 1951:20,	1920:7, 1920:19	1828:6, 1828:14,	1923:25, 1925:11,	1802:15, 1958:18,
1951:23, 1952:8,	England [2] - 1904:18,	1828:19, 1829:4,	1925:15, 1947:2,	1964:23, 1993:24
1952:10, 1954:9,	1905:22	1829:7, 1829:14,	1947:11, 1947:12,	establish [4] -
1954:12, 1954:19,	enjoy [1] - 1774:11	1829:18, 1829:23,	1948:7, 1948:14,	1812:16, 1831:1,
1954:21, 1957:10,	enormous [2] -	1830:3, 1830:8,	1952:4, 1952:13,	1916:15, 1973:6
1957:12, 1957:24,	1771:22	1830:13, 1831:7,	1952:16, 1952:18,	established [4] -
1958:4, 1959:4,	enormously [1] -	1831:9, 1831:14,	1952:24, 1952:25,	1790:24, 1858:18,
1959:8, 1959:11,	1771:16	1832:9, 1832:19,	1953:1, 1953:4,	1872:6, 1875:9
1959:13, 1960:1,	entered [1] - 1926:18	1834:12, 1835:6,	1954:14, 1955:8,	establishing [2] -
1960:5, 1961:12, 1961:14, 1962:14,	<b>entire</b> [5] - 1797:18,	1835:10, 1838:8, 1839:8, 1840:8,	1955:16, 1955:25,	1812:25, 1868:2
1961:14, 1962:14, 1962:13,	1797:20, 1797:22,	1841:5, 1841:10,	1958:10, 1960:13, 1961:2, 1961:16,	<b>ester</b> [1] - 1760:15
1963:17, 1964:9,	1920:3, 1934:4	1841:17, 1841:23,	1962:22, 1962:23,	<b>esters</b> [3] - 1786:1,
1964:11, 1965:18,	entirely [1] - 1938:16	1841:25, 1842:6,	1962:24, 1963:2,	1786:5, 1821:17
1965:22, 1967:23,	entirety [2] - 1934:25,	1842:12, 1843:8,	1963:7, 1963:8,	estimate [5] - 1773:1,
1968:2, 1969:17,	1965:13	1843:12, 1843:22,	1963:22, 1968:16,	1863:4, 1870:2,
1970:2, 1970:8,	entitled [3] - 1767:10,	1846:15, 1846:20,	1969:6, 1975:16,	1966:6, 1966:13
1970:19, 1970:21,	1897:19, 1996:23	1847:1, 1847:9,	1975:19	estrogen [1] - 1897:11
1971:11, 1971:14,	<b>entry</b> [2] - 1772:16, 1970:6	1847:14, 1849:22,	EPA-DHA [1] -	et [4] - 1757:8,
1972:16, 1972:19,	<b>EPA</b> [239] - 1761:6,	1849:24, 1851:9,	1947:12	1802:24, 1831:7, 1931:5
1972:21, 1973:5,	1761:14, 1761:16,	1851:11, 1852:3,	<b>EPA-E</b> [2] - 1803:20,	Ethan [1] - 1768:1
1973:20, 1974:3,	1761:14, 1761:16,	1852:9, 1853:1,	1960:13	ethyl [6] - 1761:21,
1974:17, 1974:18,	1762:9, 1764:14,	1853:6, 1854:13,	EPA-equivalent [1] -	1775:13, 1786:1,
1975:22, 1976:1,	1765:21, 1768:19,	1855:3, 1855:18,	1761:16	1786:5, 1805:5,
1976:3, 1977:16,	1768:24, 1775:21,	1855:23, 1856:2,	<b>Epadel</b> [17] - 1769:12,	1821:17
1980:19, 1980:23,	1779:7, 1779:12,	1856:9, 1856:13,	1803:22, 1823:2,	ethylester [1] - 1865:7
1981:2, 1981:16,	1780:2, 1780:14,	1856:20, 1856:24,	1823:4, 1823:10,	Europe [1] - 1963:24
1981:21, 1981:23,	1781:2, 1781:12,	1857:1, 1858:8,	1823:13, 1823:18,	evaluated [2] -
1982:15, 1982:19, 1982:23	1785:13, 1785:20,	1858:16, 1858:20, 1860:13, 1861:1,	1824:7, 1863:22,	1759:20, 1850:22
1962.23 Elikan [7] - 1795:16,	1785:24, 1786:3,	1861:10, 1862:24,	1863:23, 1864:5,	evening [1] - 1992:3
1811:19, 1936:23,	1786:6, 1786:10,	1863:9, 1863:15,	1864:8, 1864:10, 1900:22, 1921:7,	event [4] - 1796:15,
1986:11, 1997:4,	1786:25, 1787:7,	1866:3, 1870:12,	1900.22, 1921.7, 1951:18, 1968:25	1923:15, 1924:4,
1997:5, 1997:6	1787:9, 1787:12,	1870:15, 1871:2,	equal [7] - 1772:11,	1939:11
elsewhere [1] -	1787:20, 1788:1,	1876:18, 1876:25,	1781:7, 1781:19,	<b>Events</b> [3] - 1908:9,
1829:12	1788:3, 1788:8,	1877:9, 1878:12,	1782:18, 1783:3,	1908:14, 1912:14
embodiment [1] -	1788:11, 1788:19, 1789:2, 1790:8,	1878:16, 1878:18,	1819:1, 1949:23	events [28] - 1773:13,
1794:10	1790:14, 1790:18,	1878:25, 1879:10,	equally [2] - 1769:5,	1775:14, 1776:2,
embraced [1] -	1790:14, 1790:16, 1790:22, 1791:1,	1879:17, 1879:22,	1774:14	1776:6, 1777:4,
1768:16	1791:4, 1791:9,	1880:6, 1880:13,	equals [2] - 1976:20,	1777:5, 1901:3,
emphasize [2] -	1792:1, 1792:7,	1880:20, 1881:1,	1977:9	1901:13, 1901:14,
1790:6, 1914:7	1792:15, 1792:23,	1881:7, 1881:8,	equation [2] -	1902:2, 1902:22, 1905:7, 1906:15,
<b>end</b> [9] - 1762:15,	1794:20, 1797:11,	1881:13, 1882:1,	1790:11, 1863:3	1906:23, 1911:17,
1934:7, 1952:13,	1799:21, 1800:16,	1882:7, 1882:11,	equivalent [1] -	1911:21, 1919:4,
1981:21, 1987:3,	1801:8, 1801:17,	1882:15, 1882:16,	1761:16	1924:2, 1924:17,
1988:15, 1989:18,	1801:23, 1803:20,	1882:22, 1883:2, 1885:6, 1885:17,	equivalents [1] -	1925:17, 1952:5,
		1000.0, 1000.17,		

5	ı	
Ĭ	ı	

				15
1955:2, 1955:3,	1966:9, 1967:1,	1832:8, 1837:7,	1773:17, 1779:7,	1801:21, 1835:14,
1956:10, 1960:14,	1969:9, 1982:9,	1837:15, 1887:8,	1779:11, 1780:1,	1859:24, 1875:14,
1960:17, 1961:23,	1997:5	1912:8, 1914:14,	1792:23, 1860:5,	1878:16, 1898:1,
1967:12	<b>examine</b> [1] - 1941:6	1914:17, 1914:24,	1860:13, 1867:15,	1898:12, 1900:2,
Evidence [1] -	examiner [6] -	1915:8, 1915:10,	1895:18, 1901:25,	1920:2, 1932:6,
				, , ,
1765:14	1803:16, 1803:24,	1915:13, 1915:18,	1951:25, 1960:13	1948:3, 1990:10,
EVIDENCE [1] -	1804:2, 1805:1,	1916:3, 1916:8,	expense [1] - 1893:18	1991:8, 1992:1,
1997:9	1805:8, 1890:20	1918:9, 1921:25,	<b>expenses</b> [1] - 1931:4	1992:6, 1992:19,
evidence [65] -	examining [1] -	1929:4, 1931:11,	experience [7] -	1993:6, 1993:16,
1765:17, 1767:23,	1972:23	1944:11, 1945:15,	1772:1, 1892:10,	1995:8, 1995:22,
1773:17, 1802:17,	example [10] -	1960:8, 1987:6,	1955:16, 1955:25,	1996:14
1809:4, 1809:8,	1786:25, 1787:12,	1987:18	1971:2, 1972:3,	factor [1] - 1894:21
1809:12, 1809:24,	1794:4, 1806:18,	<b>Exhibit</b> [17] - 1765:17,	1982:3	Factors [1] - 1950:10
1810:3, 1810:9,	1876:10, 1885:5,	1767:22, 1767:23,	experiences [1] -	factors [3] - 1894:20,
1810:20, 1811:11,	1893:17, 1937:6,	1812:21, 1813:3,	1891:23	1923:16, 1924:2
1812:1, 1812:7,	1963:2, 1963:7	1851:25, 1852:23,	experiencing [2] -	factory [1] - 1894:23
1812:16, 1813:3,	examples [3] -	1854:10, 1855:8,	1783:16, 1874:17	facts [1] - 1991:8
1849:13, 1851:21,	1766:20, 1768:13,	1873:12, 1911:3,	expert [4] - 1860:20,	factually [1] - 1908:20
1851:25, 1852:19,	1774:6	1915:24, 1916:1,	1860:23, 1920:13,	fail [3] - 1760:25,
1852:23, 1854:6,	<b>exceed</b> [2] - 1982:13,	1918:1, 1918:16,	1938:10	1898:21, 1899:1
1854:10, 1854:22,	1995:18	1922:4, 1936:12	experts [1] - 1940:16	failed [2] - 1768:4,
1855:8, 1855:14,	exceeded [1] -	Exhibits [3] - 1945:16,	explain [4] - 1911:17,	1898:17
1858:6, 1862:16,	1850:24	1984:14, 1984:15	1944:20, 1949:22,	fails [1] - 1930:16
1873:9, 1873:12,	except [2] - 1811:16,	<b>EXHIBITS</b> [3] - 1997:9,	1978:23	<b>Failure</b> [1] - 1960:11
1910:22, 1911:3,	1872:8	1997:13, 1997:15	explained [2] -	failure [1] - 1760:18
1914:12, 1914:15,	exception [8] -	exhibits [20] -	1759:24, 1775:15	
1914:23, 1915:19,	•	1809:21, 1936:11,	•	fair [10] - 1789:18,
1915:20, 1916:1,	1810:8, 1810:19,	1944:6, 1983:13,	explains [1] - 1775:18	1797:17, 1883:11,
1916:12, 1917:8,	1915:19, 1934:8,	1983:24, 1984:2,	explanation [3] -	1893:23, 1932:18,
1917:20, 1918:1,	1934:12, 1937:12,	1984:4, 1984:19,	1760:25, 1777:24,	1938:11, 1938:22,
1918:16, 1919:2,	1937:15, 1937:16	1984:25, 1985:22,	1869:21	1941:20, 1975:19,
1922:1, 1922:4,	exceptions [1] -	1985:23, 1986:7,	<b>exposure</b> [1] - 1948:9	1994:21
1927:25, 1929:4,	1948:2	1987:2, 1987:5,	<b>expressly</b> [2] - 1879:6,	fairly [1] - 1821:6
	<b>excerpts</b> [1] - 1983:8		1880:14	<b>fall</b> [3] - 1866:3,
1933:15, 1934:21,	exchanges [1] -	1987:9, 1987:11,	extend [1] - 1993:25	1937:4, 1937:14
1936:12, 1938:9,	1981:4	1987:24, 1988:7,	extended [1] -	falls [1] - 1789:25
1938:15, 1943:9,	<b>exclude</b> [5] - 1884:1,	1988:23, 1989:9	1760:14	familial [8] - 1865:9,
1945:6, 1945:16,	1884:14, 1884:16,	existed [1] - 1769:10	extensive [1] -	1865:12, 1865:21,
1975:16, 1975:18,	1884:22, 1945:14	existence [4] -	1987:11	1865:23, 1887:18,
1983:13, 1984:8,	excluded [2] -	1810:16, 1811:23,	extent [3] - 1853:7,	1887:19, 1890:3,
1984:9, 1984:14,	1889:17, 1890:15	1813:1, 1814:19	1915:17, 1948:20	1890:5
1984:15, 1985:16,	excludes [2] - 1879:6,	exists [1] - 1987:19	extrapolate [2] -	familiar [8] - 1808:2,
1990:24	1885:7	expect [8] - 1769:21,	1803:25, 1804:3	1808:3, 1808:12,
evident [1] - 1923:25	exclusion [2] -	1776:12, 1790:14,	extrapolated [1] -	1819:16, 1909:2,
exact [1] - 1939:1	1889:13, 1890:2	1793:5, 1818:15,	1804:7	1929:8, 1929:15,
<b>exactly</b> [4] - 1810:18,	exclusively [4] -	1871:10, 1871:13,	extrapolating [1] -	1986:11
1819:4, 1962:1,	1763:1, 1763:10,	1896:12	1806:6	fancy [1] - 1877:14
1982:15	1763:12, 1952:2	expectation [16] -	<b>extreme</b> [1] - 1861:7	far [6] - 1824:9,
EXAMINATION [5] -	excuse [1] - 1837:3	1780:13, 1787:4,	eye [1] - 1874:4	1925:14, 1925:21,
1759:10, 1784:17,	excused [2] - 1983:4,	1787:17, 1789:10,	ezetimibe [1] -	1938:4, 1939:20,
1945:22, 1977:21,	1983:6	1789:14, 1789:25,	1971:19	1991:18
1981:1	exemplary [1] -	1791:17, 1791:22,	ezetimibe [1] -	FARNOLY [1] -
Examination [4] -	1996:15	1792:3, 1792:10,		1757:16
1997:4, 1997:5,	exerts [1] - 1917:10	1800:5, 1800:20,	1971:16	farthest [1] - 1951:9
1997:6, 1997:6	exhibit [36] - 1809:6,	1801:13, 1805:24,	F	Fatal [1] - 1770:12
examination [15] -	,	1924:16, 1924:21	F	
1783:22, 1795:14,	1809:8, 1809:16,	expectations [2] -	E 2d ro. 1705.5	fatty [29] - 1760:14,
1914:25, 1942:7,	1809:17, 1809:20,	1898:14, 1898:16	<b>F.3d</b> [3] - 1795:5,	1761:5, 1764:6,
1945:25, 1953:7,	1810:2, 1810:12,	expected [16] -	1795:9, 1795:11	1764:18, 1764:25,
1954:4, 1957:14,	1810:24, 1811:1,	1769:20, 1770:18,	face [1] - 1769:19	1765:11, 1766:6,
1959:16, 1964:4,	1811:14, 1811:25,	1772:12, 1773:16,	fact [24] - 1776:5,	1767:6, 1780:20,
	1816:3, 1816:10,	,,	1778:5, 1801:9,	1803:20, 1803:22,

FDA					
1825.5, 1825.10,   1806.17, 1917.9,   1764.1, 1764.5,   1837.18,   1807.23, 1916.22,   1919.33, 1953.10,   1923.20, 1931.13,   1902.26, 1962.18, 1962.26,   1962.18, 1962.26,   1962.21, 1972.11,   1974.21, 1974.21, 1974.22,   1974.21, 1974.22,   1974.21, 1974.22,   1974.22,   1974.22,   1974.22,   1974.23,   1974.23,   1974.24,   1974.24,   1974.25,   1974.24,   1974.26,   1966.25,   1966.25,   1866.17, 1866.26,   1866.17, 1866.26,   1866.17, 1866.26,   1866.17, 1869.24,   1898.10,   1993.24,   1993.22,   1994.24,   1897.28,   1897.28,   1995.22,   1999.22,   1992.24,   1992.24,   1992.24,   1992.26,   1999.27,   1991.24,   1992.24,   1992.26,   1993.31,   1909.31,   1909.32,   1909.38,   1909.31,   1909.32,   1909.38,   1909.38,   1909.38,   1909.38,   1909.38,   1909.39,   1909.38,   1909.38,   1909.39,   1909.38,   1909.39,   1909.38,   1909.39,   1909.38,   1909.39,   1909.38,   1909.38,   1909.39,   1909.38,   1909.39,   1909.39,   1909.38,   1909.39,   1909.	1804·1 1804·4	1804·18 1806·6	fish [17] - 1763:23	footnote (2) - 1837:9	1978:25
1850.7, 1850.17, 1860.7, 1850.7, 186					
1867/23, 1916/22,   1923/20, 1931/13,   1952/1, 1962/15, 1962/16, 1962/16, 1962/16, 1962/16, 1962/16, 1962/17, 1974/21, 1974/21, 1974/25, 1972/11, 1974/21, 1974/25, 1972/16, 1972/16, 1972/17, 1974/21, 1974/25, 1972/17, 1974/21, 1974/25, 1972/17, 1974/25, 1972/17, 1974/21, 1974/26, 1972/17, 1974/27, 1974/26, 1972/17, 1982/17					
1993, 1962.16, 1962.18, 1962.23, 1979.23, 1963.9, 1972.11, 1970.21, 1938.6   1962.18, 1962.23, 1979.23, 1963.9, 1972.11, 1770.21, 1770.21, 1952.19, 1955.5, 1969.8   1972.5, 1972.5, 1770.11, 1770.21, 1952.19, 1955.5, 1969.8   1972.5, 1972.5, 1972.5, 1972.5, 1972.5, 1972.5, 1972.5, 1966.25   1966.25   1966.25   1966.25   1966.25   1966.26   1966.27   1966.27   1966.27   1966.27   1966.29   19			· · · · · · · · · · · · · · · · · · ·	• • •	
1984.1, 1982.23, 1982.23, 1982.21, 1992.31, 1923.25, 1986.23, 1982.21, 1982.32, 1986.23, 1986.20   1986.25   1986.23, 1986.27   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.25   1986.26   1986.26   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.27   1986.28   1989.21   1989.21   1989.22   1989.23   1989.24   1989.23   1989.24   1989.24   1989.27   1989.27   1989.27   1989.27   1989.28   1989.28   1989.29   1989.29   1989.21   1989.27   1989.29   1989.21   1989.27   1989.3   1989.27   1989.28   1989.28   1989.29   1989.2		•			
1962:18, 1962:23, 1963:9, 1972:11, 1770:21, 1770:12, 1770:11, 1770:21, 1974:21, 1974:25, 1974:25, 1972:15, 1969:5, 1969:8, 1972:14, 1923:25, 1966:23, 1966:25, 1966:23, 1966:25, 1966					
1963.9, 1972.11, 1770.21, 1770.21, 1762.1, 1969.5, 1969.8   1783.3, 1911.5   1949.15   1923.14, 1923.25, 1966.23, 1966.25   1924.5, 1966.23, 1966.25   196	, , , , , , , , , , , , , , , , , , ,		, ,	,	
1974-21, 1974-25   1772-15, 1772-15, 1792-15, 1792-15, 1792-15, 1982-27, 1984-20   1992-17, 1984-20   1992-17, 1984-20   1992-18, 1992-1		_			
Fatty     - 1897:19   1923:14, 1923:25,   1966:25   1967:27, 1866:4, 1866:6, 1866:6, 1866:6, 1866:7, 1869:24   1995:24   1995:24   1995:24   1995:24   1967:17, 1861:13, 1867:6, 1867:8, 1968:21, 1967:17, 1881:13, 1867:6, 1867:8, 1968:21, 1992:26, 1992:21, 1992:25, 1992:24, 1992:25, 1992:24, 1992:25, 1992:24, 1992:25, 1992:25, 1992:24, 1992:25, 1992:25, 1992:24, 1992:25, 1992:27, 1992:25, 1992:27, 1992:28, 1992:27, 1992:29, 1992:29, 1992:29, 1992:29, 1992:29, 1992:19, 1992:19, 1993:7, 1993:7, 1993:9, 1991:13, 1991:3, 1991:3, 1991:3, 1991:4, 1992:6, 1993:11, 1992:19, 1993:4, 1993:6, 1993:16, 1993:16, 1993:16, 1993:19, 1993:10, 1993:4, 1993:6, 1993:16, 1993:16, 1993:16, 1993:16, 1993:19, 1993:1				*	
Favorig  - 1828:17, 1948:20   1966:23, 1966:23, 1966:25   1960:25   1960:25   1960:26   1960:2	· · · · · · · · · · · · · · · · · · ·		,	<b>U U</b>	tuture [1] - 1830:2
1948:20	•				
Favorite [1] - 1928:24   Filled [s] - 1793:124   filled [s] - 1793:124   filled [s] - 1793:14, 1865:14, 1865:6, 1866:17, 1869:24, 1898:10, 1993:23   filling [s] - 1935:4, 1897:19   1995:9   1895:12, 1898:10, 1993:23   filling [s] - 1935:4, 1995:9   1897:19   1897:19   1898:10, 1993:23   filling [s] - 1935:4, 1995:9   final [s] - 1914:18, 1897:19   1995:19   1897:19, 1898:13, 1867:6, 1867:8, 1898:16, 1984:17, 1902:24, 1908:22, 1991:24, 1992:16, 1909:18, 1909:12, 1992:21, 1992:25, 1909:18, 1909:12, 1992:21, 1992:21, 1992:21, 1992:21, 1992:21, 1992:21, 1992:21, 1992:21, 1992:21, 1992:11   findings [s2] - 1807:24, 1992:6, 1992:10, 1992:7, 1992:8, 1999:10, 1992:10, 1992:10, 1992:10, 1992:10, 1993:12, 1993:12, 1993:10, 1993:10, 1993:10, 1993:10, 1993:10, 1993:21, 1993:10					G
FCH (iii) - 1865:10,			<u> </u>		
1865:14, 1866.6, 1860:25, 1898:2, 1898:10, 1993:24   1937:19   1936:17, 1869:24, 1866:17, 1869:24, 1895:12, 1995:9   1932:3, 1967:17, 1981:13, 1867:6, 1867:8, 1897:8, 1992:26, 1992:26, 1992:27, 1992:26, 1992:27, 1992:27, 1992:18, 1992:22, 1992:19, 1992:29, 1992:11   1914:18, 1927:16   1993:3, 1991:18, 1991:12, 1993:4, 1995:1, 1992:6, 1993:15, 1988:24, 1989:4, 1989:6, 1993:1, 1993:2, 1993:1, 1993:2, 1993:1, 1993:2, 1993:1, 1993:2, 1993:1, 1993:2, 1993:1, 1993:3, 1993:4, 1993:2, 1993:1, 1993:3, 1993:4, 1993:2, 1993:1, 1993:3, 1993:4, 1993:2, 1993:1, 1993:6, 1993:1, 1993:6, 1993:1, 1993:2, 1993:1, 1993:2, 1993:1, 1993:2, 1993:1, 1993:3, 1994:4, 1993:12, 1993:19, 1993:2, 1993:4,			,	,	-
1886:17, 1869:24, 1891:10, 1993:24   1937:19	• •		· ·	1990:9	
1871:4   filing   2  - 1993:23,   1995:9   1768:24,   1768:12,   1768:20, 1807:23,   1895:9   1808:21, 1851:3,   1967:17, 1981:13,   1867:6, 1867:8,   1982:6, 1983:11,   1907:21, 1926:5,   1891:18, 1897:8,   1982:6, 1983:11,   1909:24, 1909:2,   1999:24, 1992:25,   1999:12,   1999:21, 1999:22,   1999:21,   1999:22,   1999:14,   1992:6,   1999:11   1807:23, 1891:18,   1991:1,   1991:3,   1991:1,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:16,   1999:19,   1999:16,   1999:19,   1999:16,   1999:19,   1999:16,   1999:19,   1999:16,   1999:19,   1999:19,   1999:4,   1999:24,   1999:24,   1999:24,   1999:24,   1999:24,   1999:24,   1999:24,   1999:24,   1999:24,   1999:26,   1999:24,   1999:26,   1999:27,   1999:18,   1999:16,   1999:18,   1999:16,   1999:18,   1999:16,   1999:18,   1999:16,   1999:19,   1999:16,   1999:19,   1999:19,   1999:16,   1999:19,   1999:19,   1999:16,   1999:19,   1999:24,   1999:16,   1999:29,   1999:2			•	formal [1] - 1909:3	•
FDA   20  - 1785:12,   1995:9   1764:15, 1765:7,   1785:20, 1807:23,   1808:21, 1851:3,   1967:17, 1981:13,   1867:6, 1867:8,   1982:6, 1983:11,   1907:21, 1926:5,   1891:18, 1897:8,   1984:16, 1984:17,   1990:12, 1992:16,   1990:18, 1910:9,   1993:7, 1993:9,   1990:14, 1909:22,   1999:22,   1999:22,   1999:21,   1993:11   1862:10, 1909:18, 1909:12,   1993:11   1862:10, 1909:18, 1909:12,   1993:11   1862:10, 1909:18, 1909:12,   1993:11   1893:12,   1993:13,   1993:13, 1993:14, 1991:3, 1993:15, 1988:21, 1999:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1993:19, 1994:4, 1995:2, 1995:24, 1995:34, 1995:36, 1995:34, 1995:36, 1995:36, 1995:36, 1995:36, 1995:37, 1809:27, 1903:16, 1809:42, 1995:40, 1995:6, 1995:84, 1995:7, 1905:6, 1795:9, 1806:19, 1888:20, 1884:12, 1920:4, 1866:13, 1866:4, 1888:16, 1888:16, 1886:11, 1809:44, 1866:13, 1866:44, 1888:16, 1889:44, 1886:14, 1996:24, 1996:24, 1996:14, 1900:			1937:19	forming [2] - 1780:13,	1887:1
1785:20, 1807:23, 1806:21, 1851:3, 1967:17, 1981:13, 1862:10, 1900:14, 1780:20 1780:16 1867:8, 1891:18, 1897:8, 1984:16, 1984:17, 1930:12, 1932:17, 1909:8, 1909:12, 1992:25, 1991:24, 1992:25, 1993:11 1992:14, 1992:16, 1993:7, 1993:9, 1993:7, 1993:9, 1990:14, 1921:6, 1921:11 1760:12, 1775:25, 1807:22, 1893:12, 1921:4, 1921:6, 1991:1, 1991:1, 1991:3, 1991:1, 1991:3, 1991:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1992:1, 1993:	1871:4	filing [2] - 1993:23,	five [13] - 1763:24,	1965:12	general [6] - 1768:15,
1808:21, 1851:3, 1967:17, 1981:13, 1862:10, 1900:14, 1780:20   1969:16   1969:16   1808:26, 1863:11, 1907:21, 1926:5, 1891:18, 1897:8, 1908:12, 1991:24, 1992:25, 1991:24, 1992:25, 1992:25, 1990:18, 1900:12, 1992:21, 1992:25, 1993:7, 1993:9, 1900:14, 1907:21   1900:18, 1900:22, 1993:11   1900:14, 1907:21   1900:18, 1900:22, 1993:11   1760:12, 1775:25, 1991:14, 1921:11   1760:12, 1775:25, 1991:1, 1991:3, 1991:1, 1991:3, 1991:1, 1991:3, 1991:1, 1991:3, 1991:1, 1991:3, 1991:1, 1991:3, 1991:1, 1991:3, 1991:1, 1992:6, 1992:10, 1992:10, 1992:10, 1992:10, 1992:10, 1993:10, 1993:10, 1993:10, 1993:23, 1994:4, 1994:4, 1994:4, 1994:25, 1995:8, 1995:24,	<b>FDA</b> [20] - 1785:12,		1764:15, 1765:7,	formulate [1] - 1764:4	1886:6, 1886:11,
1867:6, 1867:8, 1982:6, 1983:11, 1907:21, 1926:5, 1891:18, 1897:8, 1984:16, 1984:17, 1930:12, 1932:17, 1902:24, 1908:22, 1991:24, 1992:25, 1992:24, 1992:25, 1992:25, 1992:21, 1992:25, 1993:11 1900:18, 1910:9, 1993:7, 1993:9, 1900:14, 1907:21 1900:18, 1920:22, 1993:11 1900:14, 1907:21 1900:18, 1920:22, 1993:11 1900:14, 1907:21 1900:14, 1907:21 1900:18, 1920:22, 1993:11 1900:14, 1907:21 1900:14, 19	1785:20, 1807:23,	final [15] - 1914:18,	1847:4, 1861:20,	formulation [1] -	1962:3, 1969:14,
1891:18, 1897:8,   1984:16, 1984:17,   1930:12, 1932:17,   1949:4, 1954:14   1952:24, 1990:22,   1991:24, 1992:25,   1992:25,   1993:7, 1993:9,   1990:14, 1997:21   1825:12, 1896:12,   1934:24, 1935:5   1807:22, 1838:7,   1900:14, 1907:21   1825:12, 1896:12,   1934:24, 1935:5   1807:22, 1838:7,   1800:14, 1907:21   1825:14, 1825:12, 1896:12,   1836:23, 1836:2,   1837:24, 1836:24,   1836:24, 1836:24,   1836:24,	1808:21, 1851:3,	1967:17, 1981:13,	1862:10, 1900:14,	1780:20	1969:16
1891:18, 1897:8,   1994:16, 1994:17,   1993:17, 1992:16,   1991:24, 1992:25,   1993:7, 1993:9,   1990:14, 1992:9,   1993:7, 1993:9,   1990:14, 1992:9,   1993:7, 1993:9,   1990:14, 1992:9,   1993:11   1992:14, 1921:6,   1992:14, 1921:6,   1992:14, 1921:6,   1992:14, 1992:15,   1844:22, 1990:10,   1807:23, 1891:18,   1991:1, 1991:3,   1991:12,   1992:1, 1992:6,   1992:1, 1992:6,   1992:1, 1992:6,   1993:1, 1991:12,   1992:1, 1992:6,   1993:1, 1992:1, 1992:6,   1993:1, 1993:6,   1993:3, 1994:4,   1993:6, 1993:3, 1994:4,   1993:6, 1993:3, 1994:4,   1993:4, 1993:6, 1993:23, 1994:4,   1994:2, 1995:8,   1994:2, 1995:2,   1995:24,   1995:11   1995:2, 1995:2,   1995:24,   1995:11   1816:19, 1838:10,   1995:11   1819:15, 1893:8,   1819:15, 1893:8,   1914:20, 1943:8,   1964:16, 1994:18,   1995:11   1816:19, 1838:10,   1979:6, 1992:19,   1819:15, 1893:8,   1914:20, 1943:8,   1964:6, 1994:18,   1994:20, 1993:16,   1994:20, 1993:16,   1994:20, 1993:16,   1994:20, 1993:16,   1995:11   1858:15, 1858:17,   1864:6, 1873:17,   1864:6, 1873:17,   1866:11, 1869:24,   1	1867:6, 1867:8,	1982:6, 1983:11,	1907:21, 1926:5,	foundation [6] -	generalize [2] -
1902:24, 1908:22, 1991:24, 1992:16, 1992:25, 1999:8, 1909:12, 1992:27, 1992:25, 1993:7, 1993:9, 1993:11   1902:14, 1907:21   1902:14, 1907:21   1903:11   1760:12, 1775:25, 1907:21, 1909:18, 1909:10, 1909:18, 1909:10, 1909:18, 1909:10, 1909:18, 1909:10, 1909:18, 1909:10, 1909:19, 1909:21, 1909:26, 1909:21, 1909:26, 1909:21, 1909:26, 1909:21, 1909:26, 1909:23, 1909:44, 1909:44, 1909:44, 1909:44, 1909:44, 1909:44, 1909:44, 1909:44, 1909:24, 1909:24, 1909:24, 1909:24, 1909:24, 1909:24, 1909:24, 1909:24, 1909:24, 1909:25, 1909:27, 1909:27, 1909:27, 1909:27, 1909:27, 1909:28, 1909:29,	1891:18, 1897:8,	1984:16, 1984:17,	1930:12, 1932:17,		1763:13, 1952:3
1909:18, 1909:12, 1909:25, 1909:18, 1910:9, 1903:7, 1903:9, 1900:14, 1907:21   1900:14, 1907:21   1900:14, 1907:21   1900:14, 1907:21   1806:3, 1807:22, 1838:7, 1807:22, 1809:21, 1807:22, 1809:22, 1809:21, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:10, 1909:11, 1909:22, 1909:23, 1909:10, 1909:23, 1909:10, 1909:23, 1909:10, 1909:23, 1909:10, 1909:23, 1909:10, 1909:23, 1909:10, 1909:23, 1909:10, 1909:23, 1909:24, 1900:24, 19	1902:24, 1908:22,	1991:24, 1992:16,	1949:14, 1954:14	· · · · · · · · · · · · · · · · · · ·	generally [13] -
1909:18, 1910:9, 1993:7, 1993:9, 1900:14, 1907:21   flag [i] - 1912:9   flash [i] - 1985:2   1863:19, 1895:21, 1857:4, 1857:24, 1921:11   1760:12, 1775:25,   flip [i] - 1783:19   float [i] - 1873:23   1896:7, 1896:11, 1928:1, 1929:15, 1897:24   fluorescent [i] - 1807:24   fluorescent [i] - 1988:24, 1989:1, 1993:10, 1992:19, 1993:10, 1993:10, 1993:23, 1994:4, 1993:12, 1993:19, 1994:25, 1995:24   1995:22, 1995:24   1995:24   1995:22, 1995:24   1995:24   1995:22, 1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   1995:24   19	1909:8, 1909:12,			, , , , , , , , , , , , , , , , , , , ,	1807:22, 1838:7,
1920:18, 1920:22, 1993:11   findings [22] - 1921:4, 1921:6, 1760:12, 1775:25, 1991:10   1807:23, 1891:18, 1991:12, 1991:8, 1991:12, 1992:16, 1992:16, 1992:16, 1992:16, 1992:16, 1992:16, 1992:16, 1993:19, 1994:16, 1994:18, 1994:16, 1994:18, 1994:25, 1995:8, 1994:4, 1795:6, 1795:9, 1795:11   1995:22, 1995:24   1995:24   1995:22, 1995:24   1995:22, 1995:24   1995:22, 1995:24   1995:22, 1995:24   1995:24   1995:22   1995:24   1995:22   1995:24	1909:18, 1910:9,	1993:7, 1993:9,	•	•	
1921:4, 1921:6, 1921:11	1920:18, 1920:22,	1993:11	flag [1] - 1912:9	,	
1921:11		findings [22] -	- · ·		
The first of the		•			
1807:23, 1891:18,   1991:1, 1991:3,   1991:6,   1991:1, 1991:1,   1991:1,			• • •		
1921:6	• •				
Tebruary   10  -   1992:1, 1992:6, 1992:10, 1992:19, 1993:15, 1988:21, 1993:16, 1993:16, 1993:23, 1994:4, 1993:4, 1993:19, 1994:16, 1994:18, 1994:25, 1995:8, 1995:22, 1995:24 1995:22, 1995:24 1995:22, 1995:24 1995:22, 1995:24 1995:3, 1795:6, 1795:9, 1795:11 1904:20, 1943:8, 1796:11   1910:15					
1793:15, 1988:21, 1992:10, 1992:19, 1993:6, 1993:16, 1993:23, 1994:4, 1989:6, 1993:12, 1993:19, 1994:16, 1994:18, 1994:25, 1995:8, 1994:25, 1995:24 1995:22, 1995:24 1795:6, 1795:9, 1795:11		· · · · · · · · · · · · · · · · · · ·			
1988:24, 1989:1,   1993:6, 1993:16,   1790:20, 1816:9,   1813:14, 1813:17   187:21, 1888:2, 1893:12, 1993:19,   1994:16, 1994:18,   1994:25, 1995:8,   1994:25, 1995:8,   1995:22, 1995:24   1995:22, 1995:24   1995:22, 1995:24   1995:22, 1995:24   1995:21, 1795:11   1819:15, 1893:8,   1994:20, 1943:8,   1979:6, 1992:19,   1979:6, 1992:19,   1979:6, 1992:19,   1816:9, 1822:5   1800:14, 1820:7   1858:20, 1869:10, 1820:7   1858:20, 1858:10, 1820:7   18	•	· · · · · · · · · · · · · · · · · · ·		• • •	
1989:4, 1989:6, 1993:23, 1994:4, 1993:12, 1993:19, 1994:16, 1994:18, 1994:25, 1995:8, 1995:22, 1995:24 1995:22, 1995:24 1995:6, 1795:9, 1795:11				• • •	•
1993:12, 1993:19, 1994:16, 1994:18, 1994:25, 1995:8, 1995:22, 1995:24  Federal [4] - 1765:14, 1995:22, 1995:24  1795:6, 1795:9, 1795:11  federal [1] - 1795:2  federal [1] - 1795:2  fell [1] - 1826:20  felt [1] - 1807:8  finite [3] - 1857:1, 1858:17  fenofibrate [1] - 1760:15  fenofibric [1] - 1774:23, 1789:15, 1803:18  Feuerstein [1] - 1760:7, 1809:14, 1760:24, 1809:14, 1809:14, 1809:14, 1809:14, 1809:14, 1809:14, 1809:14, 1809:14, 1809:14, 1809:14, 1809:11, 1809:14, 1809:11, 1976:9  Fredrickson's [1] - 1820:7  free [1] - 1992:3  fold [2] - 1931:21, 1820:4  follow [4] - 1900:14, 1906:24  frequency [1] - 1967:20  Freuerstein [1] - 1807:20, 1859:19, 1807:23, 1859:9, 1807:23, 1859:9, 1859:12, 1884:25, 1888:6  follow-up [3] - 1873:18, 1888:1  follow-up [3] - 1873:18, 1888:1		· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	·	•
1994:4	· · · · · · · · · · · · · · · · · · ·				
Federal [4] - 1765:14,         1995:22, 1995:24         1990:24, 1990:14         1866:11, 1869:24, 1890:11, 1976:9         1880:11, 1869:24, 1890:11, 1976:9         1880:11, 1869:24, 1890:11, 1976:9         1880:11, 1869:24, 1890:11, 1976:9         1878:5, 1787:24, 1976:9         1878:5, 1787:24, 1976:9         1822:13, 1823:18         1822:13, 1823:18         1820:7         1820:7         1820:7         1820:7         1878:12, 1878:16         1878:12, 1878:16         1878:12, 1878:16         1878:12, 1878:16         1878:12, 1878:16         1878:12, 1878:16         1878:12, 1878:16         1878:12, 1878:16         1878:12, 1878:16         1878:12, 1878:16         1878:18, 1906:16         1878:18, 1906:16         1878:18, 1906:16         1878:18, 1906:16         1878:18, 1906:16         1878:18, 1906:16         1878:18, 1906:16         1878:18, 1906:16         1878:18, 1906:16         190		· · · · · ·		, , , , , , , , , , , , , , , , , , , ,	
1795:6, 1795:9, 1795:11   1819:15, 1893:8, 1894:12, 1920:4   1976:9   1778:5, 1787:24, 1894:12, 1920:4   1979:6, 1992:19, 1819:23, 1996:4   1994:23, 1996:4   1894:25   1858:17   1858:15, 1858:17   1858:15, 1858:17   1858:15, 1858:17   1803:18   1774:23, 1789:15, 1803:18   1790:4, 1790:20, 1803:18   1807:23, 1859:9, 1767:10   1859:12, 1884:25, 1884:25, 1884:25, 1888:6   1888:6   1888:6   1888:6   1888:6   1888:1   1890:11, 1803:24, 1890:11, 1906:24, 1890:11, 1976:9   1778:5, 1787:24, 1976:9   1778:5, 1787:24, 1976:9   1778:5, 1787:24, 1976:9   1778:5, 1787:24, 1976:9   1778:5, 1787:24, 1976:9   1778:5, 1787:24, 1976:9   1778:5, 1787:24, 1822:13, 1823:18   1822:13, 1823:18   1822:13, 1823:18   1822:13, 1823:18   1822:13, 1823:18   1822:13, 1823:18   1822:13, 1823:18   1822:13, 1823:18   1822:13, 1823:18   1822:13, 1823:18   1822:13, 1823:18   1822:13, 1823:18   1820:7   1858:20, 1869:10   1822:13, 1823:18   1822				•	· ·
1795:11	,		*		
federal [1] - 1795:2         1914:20, 1943:8,         focusing [4] - 1794:7,         Fredrickson's [1] -         1822:13, 1823:18           fee [1] - 1938:10         1979:6, 1992:19,         focusing [4] - 1794:7,         1864:6, 1873:17,         1820:7         1858:20, 1869:10           fell [1] - 1826:20         1994:23, 1996:4         finite [3] - 1857:1,         floid [2] - 1931:21,         free [1] - 1992:3         1878:12, 1878:16           fenofibrate [1] -         1858:15, 1858:17         flist [29] - 1760:7,         folks [1] - 1967:14         freedom [1] - 1967:20,         French [3] - 1757:22,         1940:22, 1966:14           fenofibric [1] -         1774:23, 1789:15,         follow [4] - 1900:14,         1996:24, 1996:24         1971:5         glance [1] - 1845:7           feuerstein [1] -         1807:23, 1859:9,         1807:23, 1859:9,         1994:7         follow-up [3] -         1873:18, 1888:1         1989:9           feuerstein [1] -         1859:12, 1884:25,         1888:5, 1888:6         1888:5, 1888:6         1888:5, 1888:6		• •			•
fee [1] - 1938:10       1979:6, 1992:19,       1864:6, 1873:17,       1820:7       1858:20, 1869:10         fell [1] - 1826:20       1994:23, 1996:4       1882:25       free [1] - 1992:3       1878:12, 1878:16         felt [1] - 1807:8       finite [3] - 1857:1,       fold [2] - 1931:21,       freedom [1] - 1967:20       1878:18, 1906:16         fenofibrate [1] -       1858:15, 1858:17       folks [1] - 1967:14       french [3] - 1757:22,       1940:22, 1966:14         fenofibric [1] -       1774:23, 1789:15,       follow [4] - 1900:14,       1996:24, 1996:24       1971:5         feuerstein [1] -       1807:23, 1859:9,       1807:23, 1859:9,       1994:7       1906:23       Glucose [1] - 1824         feuerstein [1] -       1859:12, 1884:25,       1884:25,       follow-up [3] -       1873:18, 1888:1       1989:9			· ·	1976:9	
fell [1] - 1826:20       1994:23, 1996:4       1882:25       free [1] - 1992:3       1878:12, 1878:16         felt [1] - 1807:8       finite [3] - 1857:1,       1858:15, 1858:17       fold [2] - 1931:21,       freedom [1] - 1967:20       1878:18, 1906:16         1760:15       first [29] - 1760:7,       folks [1] - 1967:14       french [3] - 1757:22,       1940:22, 1966:14         fenofibric [1] -       1774:23, 1789:15,       follow [4] - 1900:14,       1996:24, 1996:24       1971:5         feuerstein [1] -       1807:23, 1859:9,       1807:21, 1993:10,       1994:7       frequently [2] -       Glucose [1] - 1824         follow-up [3] -       1873:18, 1888:1       1989:9			• • • • • • • • • • • • • • • • • • • •		
felt [1] - 1807:8         finite [3] - 1857:1,         fold [2] - 1931:21,         freedom [1] - 1967:20         1878:18, 1906:16           fenofibrate [1] - 1760:15         first [29] - 1760:7,         folks [1] - 1967:14         freench [3] - 1757:22,         1940:22, 1966:14           fenofibric [1] - 1803:18         1779:4, 1790:20,         folks [1] - 1900:14,         frequency [1] - 1906:24         glance [1] - 1845:7           Feuerstein [1] - 1767:10         1859:12, 1884:25,         1884:25,         follow-up [3] - 1873:18, 1888:1         1888:1         1989:9			1864:6, 1873:17,		
fenofibrate [1] - 1760:15       1858:15, 1858:17       1931:25       French [3] - 1757:22, 1940:22, 1966:14       1940:22, 1966:14       1971:5       French [3] - 1757:22, 1996:24       1971:5       1971:5       Golks [1] - 1900:14, 1996:24, 1996:24       1996:24, 1996:24       1971:5       glance [1] - 1845:7       Glucose [1] - 1845:7       1906:23       Glucose [1] - 1824       Glucose [1] - 1824       1994:7       Fequently [2] - 1873:18, 1888:1       1989:9         follow-up [3] - 1843:10       1888:5, 1888:6       1888:5, 1888:6       1888:1       1989:9				free [1] - 1992:3	1878:12, 1878:16,
1760:15   first [29] - 1760:7,   folks [1] - 1967:14   1996:24, 1996:24   1971:5   1971:5   1980:18   1790:4, 1790:20,   1807:23, 1859:9,   1767:10   1859:12, 1884:25,   1888:6   18			fold [2] - 1931:21,	freedom [1] - 1967:20	
fenofibric [1] -       1774:23, 1789:15,       follow [4] - 1900:14,       frequency [1] -       glance [1] - 1845:7         1803:18       1790:4, 1790:20,       1907:21, 1993:10,       1906:23       Glucose [1] - 1824         Feuerstein [1] -       1859:12, 1884:25,       1859:12, 1888:6       frequently [2] -       goal [2] - 1845:12,         1873:18, 1888:1       1989:9		·	1931:25	French [3] - 1757:22,	1940:22, 1966:14,
1803:18     1790:4, 1790:20,     1907:21, 1993:10,     1906:23     Glucose [1] - 1824       Feuerstein [1] - 1859:12, 1884:25,     1859:12, 1884:25,     follow-up [3] - 1873:18, 1888:1     1989:9       1807:21, 1993:10,     1994:7     frequently [2] - 1845:12,       1873:18, 1888:1     1989:9			folks [1] - 1967:14	1996:24, 1996:24	
1803:18       1790:4, 1790:20,       1907:21, 1993:10,       1906:23       Glucose [1] - 1824         Feuerstein [1] - 1807:23, 1859:9,       1994:7       frequently [2] - 1845:12,       1859:12, 1884:25,         1807:23, 1859:9,       1859:12, 1884:25,       1888:5 1888:6       1873:18, 1888:1       1989:9			follow [4] - 1900:14,	frequency [1] -	glance [1] - 1845:7
1767:10 1859:12, 1884:25, follow-up [3] - 1873:18, 1888:1 1989:9			1907:21, 1993:10,		Glucose [1] - 1824:20
1767:10 1859:12, 1884:25, follow-up [3] - 1873:18, 1888:1 1989:9	Feuerstein [1] -	, ,	1994:7	frequently [2] -	goal [2] - 1845:12,
favor 4040:40 1888:5 1888:6 4070:44	1767:10	1859:12, 1884:25,	follow-up [3] -		1989:9
1500.14, 1507.21, Filiday  4  - 1900.10, 900.01	few [7] - 1813:19,	1888:5, 1888:6,	1900:14, 1907:21,	Friday [4] - 1988:16,	goals [1] - 1970:14
1948:2, 1966:22, 1898:5, 1899:11, 1994:7 1988:20, 1988:21, <b>government</b> [4] -	1948:2, 1966:22,	1898:5, 1899:11,		• • • •	government [4] -
4040.47 4000.45	1972:24, 1980:19,	1913:17, 1920:15,		, , , , , , , , , , , , , , , , , , , ,	1928:23, 1929:7,
1000.4 1000.00		1936:4, 1939:23,			1929:19, 1938:14
fibrate [3] - 1804:1, 1947:20, 1949:7, 1958:25 1790:10, 1863:3 grab [1] - 1949:14	fibrate [3] - 1804:1,	1947:20, 1949:7,			
1804:4, 1804:8 1954:10, 1954:13, following [1] - front [2] - 1801:11, gram [1] - 1765:7		1954:10, 1954:13,		·	•
fibrates up 1700:19 1970:24 1978:10		1970:24, 1978:10,	<del>-</del>		grams [63] - 1761:15,
1700:2 1904:14 1978:13 1988:2	• •	1978:13, 1988:2,			1761:16, 1761:21,
1988:19 1992:15		1988:19, 1992:15,			
1902:12 1904:14 1992:17		1992:17			1765:9, 1765:11,
1803:12, 1804:14, food [1] - 1931:5 1954:10, 1974:7, 1765:9, 1765:11,	.5552, 1551.11,		100u [1] - 1801.0	1954.10, 1974:7,	1700.0, 1700.11,

				17
1765:21, 1765:23,	guess [3] - 1834:1,	1926:9, 1967:9	1874:12, 1887:15,	1877:13, 1877:18,
1775:20, 1779:7,	1982:23, 1995:12	heard [4] - 1796:20,	1887:21, 1888:2,	1960:16, 1975:3,
1779:12, 1780:2,	guidance [1] - 1864:2	1937:22, 1990:6,	1888:6, 1888:7,	1975:17
1781:2, 1781:3,	guidelines [2] -	1991:18	1888:10, 1892:24,	HMG-CoA [6] -
1788:8, 1789:2,	1887:5, 1887:22	hearing [1] - 1795:18	1893:5, 1894:22,	1877:10, 1877:13,
1791:9, 1792:1,	guts [1] - 1980:8	hearsay [10] -	1897:10, 1898:14,	1877:18, 1960:16,
1792:7, 1792:23,	guys [1] - 1849:9	1915:12, 1915:13,	1898:16, 1899:6,	1975:3, 1975:17
1794:20, 1797:11,	<b>3 7</b>	1915:23, 1934:7,	1908:15, 1919:16,	Hoffman [1] - 1795:10
1799:21, 1800:16,	Н	1934:8, 1934:12,	1934:17, 1941:7,	Hofmann [2] -
1801:8, 1819:3,		1934:21, 1935:4,	1949:9, 1949:11,	1972:23, 1973:8
1825:25, 1827:3,	Haas [1] - 1917:14	1937:2, 1937:4	1949:17, 1950:2,	hold [5] - 1780:7,
1832:19, 1841:7,	habits [1] - 1952:14	Heart [1] - 1960:11	1950:4, 1950:14,	1799:2, 1860:16,
1841:11, 1841:13,	half [1] - 1793:18	heart [2] - 1766:18,	1951:1, 1951:7,	1887:8, 1948:4
1849:21, 1851:11,	HAN [1] - 1757:15	1940:14	1951:11, 1951:17,	holding [1] - 1795:7
1852:3, 1852:8,	hand [16] - 1760:6,	Heinecke [17] -	1957:1, 1957:2,	holdings [3] -
1852:9, 1854:13,	1763:16, 1763:17,	1760:17, 1768:18,	1957:18, 1958:17,	1795:13, 1795:23,
1855:2, 1855:17,	1775:5, 1775:6,	1768:23, 1769:16,	1958:20, 1958:22,	1796:20
1855:23, 1856:2,	1803:22, 1804:18,	1773:15, 1774:17,	1960:13, 1961:7,	home [1] - 1941:3
1856:8, 1856:13,	1839:24, 1934:2,	1774:23, 1775:24,	1962:11, 1963:4,	honest [2] - 1913:7,
1856:19, 1856:23,	1947:1, 1947:4,	1777:10, 1778:5,	1963:7, 1968:21,	1933:2
1857:5, 1857:8, 1858:6, 1874:11	1947:12, 1949:5,	1779:10, 1779:25,	1968:25, 1969:8,	Honor [76] - 1759:4,
1858:6, 1874:11, 1880:19, 1881:13,	1952:9, 1953:15,	1780:19, 1861:17,	1969:14, 1969:24, 1970:6, 1970:20,	1767:15, 1767:21,
1882:1, 1884:4,	1958:3	1862:3, 1964:13,	1970:0, 1970:20,	1783:9, 1783:12,
1885:5, 1886:16,	hang [2] - 1797:17,	1964:16	1970:22, 1970:24,	1794:22, 1795:1,
1886:21, 1907:21	1937:7	Heinecke's [6] -	1976:13	1795:3, 1800:1,
Granowitz [1] -	happy [2] - 1795:19,	1760:21, 1784:19,	higher [12] - 1763:24,	1809:4, 1809:15,
1927:14	1905:17	1784:24, 1862:8, 1878:6, 1964:8	1771:8, 1771:10,	1809:25, 1811:24,
grant [1] - 1848:22	harmful [1] - 1788:2	held [3] - 1847:22,	1806:13, 1818:8,	1814:7, 1815:1,
granted [2] - 1984:13,	<b>Harold</b> [2] - 1849:15, 1978:13	1933:21, 1993:3	1867:16, 1922:11,	1851:20, 1852:21, 1853:22, 1884:9,
1985:7	Hayashi [18] -	help [5] - 1787:13,	1922:12, 1962:7,	1910:22, 1914:13,
graph [1] - 1923:14	1861:24, 1862:13,	1798:11, 1878:3,	1962:9, 1963:10,	1916:13, 1933:19,
graphs [1] - 1869:19	1862:21, 1863:19,	1886:24, 1993:4	1966:22	1933:22, 1937:13,
great [3] - 1772:25,	1863:21, 1864:25,	helpful [6] - 1798:7,	highest [2] - 1961:10,	1939:6, 1939:10,
1920:3, 1988:17	1865:5, 1867:14,	1818:4, 1818:5,	1968:22	1939:11, 1941:4,
greater [5] - 1819:1,	1867:23, 1869:17,	1990:21, 1990:22,	highlight [15] -	1941:5, 1941:12,
1860:5, 1869:8,	1870:10, 1870:12,	1991:1	1760:6, 1763:6,	1941:17, 1943:18,
1949:23, 1957:3	1870:17, 1870:24,	helps [1] - 1892:11	1763:16, 1770:12,	1943:19, 1944:8,
Grimsgaard [5] -	1964:3, 1964:23,	HEYDORN [1] -	1770:23, 1772:15,	1944:24, 1945:18,
1779:13, 1780:3,	1966:20, 1967:2	1758:3	1887:9, 1889:11,	1965:20, 1970:2,
1854:1, 1854:12,	hazard [3] - 1771:4,	Heydorn [1] - 1815:2	1947:23, 1950:7,	1971:13, 1973:3,
1855:21	1771:10, 1922:11	high [92] - 1775:20,	1951:21, 1952:13,	1973:10, 1974:17,
gross [3] - 1784:16,	HDL [11] - 1847:2,	1779:5, 1779:8,	1962:15, 1963:14,	1977:16, 1977:17,
1887:3, 1979:23	1871:1, 1871:3,	1779:13, 1780:2,	1970:19	1977:18, 1980:15,
ground [1] - 1774:24	1908:15, 1919:17,	1780:9, 1780:14,	highlighted [6] -	1980:19, 1983:2,
group [22] - 1794:11,	1922:10, 1949:9,	1780:18, 1780:21,	1802:15, 1835:23,	1983:5, 1983:7,
1820:12, 1826:21,	1949:12, 1949:17,	1789:2, 1789:7,	1847:12, 1917:5, 1959:19, 1980:1	1984:22, 1985:6,
1826:22, 1842:7,	1950:11, 1950:15	1789:16, 1789:22,	highlighting [3] -	1985:9, 1985:13,
1843:23, 1843:24, 1850:25, 1022:12	HDL-C [6] - 1871:1,	1790:15, 1792:2,	1794:13, 1884:25,	1985:15, 1986:15,
1859:25, 1922:12,	1871:3, 1949:9,	1794:20, 1797:12,	1979:23	1986:20, 1987:4, 1987:8, 1988:9,
1949:9, 1949:17, 1949:19, 1950:1,	1949:12, 1949:17,	1801:18, 1802:19,	highly [1] - 1795:1	1987:0, 1988:9,
1949.19, 1950.1, 1950:3, 1950:24,	1950:15	1802:23, 1803:3, 1803:5, 1804:15,	Hikma [1] - 1995:6	1989:21, 1989:25,
1950:5, 1950:24,	<b>head</b> [2] - 1877:25, 1981:8	1806:21, 1819:25,	HIKMA [3] - 1757:8,	1992:11, 1993:4,
1957:22, 1957:23,	heading [8] - 1846:11,	1820:23, 1821:10,	1757:19, 1758:3	1994:10, 1994:13,
1958:10, 1958:11,	1846:15, 1947:5,	1838:25, 1839:2,	history [2] - 1766:17,	1995:5, 1995:12,
1961:2	1947:7, 1947:11,	1845:11, 1845:13,	1790:17	1995:20, 1996:9,
groups [2] - 1788:14,	1970:9, 1974:20,	1845:15, 1856:4,	<b>HLP</b> [2] - 1976:11,	1996:17, 1996:18,
1788:16	1974:23	1856:5, 1861:1,	1976:12	1996:19
<b>GSK</b> [1] - 1892:1	healthcare [2] -	1861:2, 1871:25,	<b>HMG</b> [6] - 1877:10,	HONORABLE [1] -
	.,			

**-**18 1757:2 1814:2, 1815:9, 1810:11, 1810:15, 1864:19, 1877:20, 1806:22, 1807:25, 1888:12, 1919:12, hood [4] - 1920:3, 1815:16, 1815:18, 1811:13, 1942:24 1839:9, 1840:9, impeaching [1] -1920:6, 1920:11, 1821:24, 1822:10, 1957:2, 1986:2 1883:24 1822:20, 1850:8, 1920:17 1915:21 includes [6] incremental [3] hope [2] - 1923:10. 1851:4, 1890:14, impeachment [29] -1813:17, 1818:24, 1773:9, 1917:16, 1875:25, 1933:23, 1995:18 1891:6, 1894:21, 1798:10, 1809:5, 1925:16 1949:24, 1963:25, 1809:19, 1809:23, 1939:18, 1987:18 incurred [4] - 1912:3, hoped [1] - 1874:5 1967:11 hopeful [2] - 1766:24, 1810:2, 1810:9, including [6] -1913:23, 1914:9, Hypertriglyceridemi 1810:10, 1810:21, 1760:14, 1790:18, 1968:17 1767.2 hopefully [4] - 1807:5, **a** [3] - 1848:16, 1810:24, 1811:4, 1848:5, 1875:22, indented [1] - 1803:1 1811:11, 1811:12, 1818:14, 1837:2, 1916:6, 1918:6 1891:16, 1907:23 independent [3] -1994:5 hypertriglyceridemic 1811:16, 1812:3, incongruous [1] -1774:9, 1868:6, [2] - 1774:10, 1812:7, 1812:8, 1868:8 hoping [5] - 1766:25, 1843:24 1949:20 1812:11, 1812:12, inconsistency [1] -1783:19. 1792:8. indicate [9] - 1937:20, hypothesis [4] -1912:10, 1914:14, 1790:25 1821:5, 1994:1 1946:8, 1950:9, hospitals [1] -1906:13, 1922:17, 1914:19, 1914:23, inconsistent [1] -1952:20, 1952:22, 1915:7, 1915:15, 1922:18, 1924:10 1973:8 1953:24, 1954:24, 1929:22 1915:19, 1915:20, incorrect [2] -1956:9, 1977:11 hosts [1] - 1929:7 1916:8, 1933:16, 1847:10, 1938:19 indicated [9] hour [1] - 1866:15 1938:9 increase [42] -1808:17, 1813:10, hours [1] - 1932:9 icosapent [7] importance [1] housekeeping [2] -1771:11, 1782:8, 1813:21, 1891:4, 1761:21, 1775:13, 1771:22 1788:18, 1788:19, 1938:3, 1944:22, 1809:3, 1985:17 1865:7, 1886:8, important 191 -1945:7, 1945:13, 1789:20, 1791:4, Howard [2] - 1983:12, 1886:13, 1886:16 1771:15, 1771:16, 1985:20 1983:25 1794:16, 1802:25, ID [1] - 1997:9 1785:16, 1786:18, 1804:14, 1806:9, indicates [1] human [1] - 1842:12 idea [4] - 1796:7, 1863:11, 1919:6, 1802:17 1806:10, 1806:15, humans [1] - 1843:10 1818:1, 1841:21, 1919:14, 1926:17, 1818:10, 1820:13, indication [7] hundred [1] - 1932:19 1986:8 1978:22 1822:6, 1829:17, 1808:19, 1821:9, Huttner [2] - 1985:14, identical [3] - 1794:1, importantly [1] -1829:24, 1831:18, 1866:16, 1873:7, 1986:23 1809:7, 1842:5 1815:15 1860:5, 1872:23, 1920:23, 1921:6, HUTTNER [11] identification [1] improve [2] - 1825:6, 1873:21, 1873:23, 1953:2 1758:10, 1839:14, 1960:20 1825:11 1874:3, 1874:5, indications [2] -1839:16, 1985:15, identified [1] - 1810:2 improves [1] -1874:7, 1876:5, 1834:2, 1891:5 1988:9, 1989:22, identifies [1] -1899:12 1879:11, 1879:18, indisputable [1] -1989:25, 1990:6, 1778:16 improving[1] -1879:19, 1879:20, 1849:19 1992:21, 1995:5, identify [3] - 1859:20, 1960:14 1880:22, 1881:9, indistinct [1] - 1864:1 1996:18 1886:17, 1891:23, 1859:24, 1912:23 imputing [1] - 1870:1 individual [2] hydroxymethylglutar ignore [1] - 1797:4 inability [1] - 1771:20 1893:15, 1893:18, 1842:12, 1920:19 yl [1] - 1877:15 1921:17, 1948:9, **II** [2] - 1887:19, 1890:4 inaccuracies [2] individuals [5] hypercholesterolemi 1951:17, 1957:8, Ila [3] - 1865:14, 1941:7, 1941:8 1872:1, 1927:19, a [4] - 1865:23, 1975:11, 1979:18 1865:23, 1866:18 inaccurate [2] -1928:3, 1939:19, 1906:16, 1961:24, increased [16] -IIb [5] - 1865:14, 1931:22, 1937:23 1967:3 1962:6 1785:15, 1786:14, inadmissible [2] -1865:22, 1866:6, induce [3] - 1776:14, hypercholesterolemi 1788:10, 1788:14, 1866:18 1937:2, 1937:4 1834:12, 1880:20 c [6] - 1901:14, 1788:16, 1789:21, **III** [8] - 1859:7, 1887:5, inappropriately [1] induced [1] - 1834:6 1952:6, 1952:17, 1827:10, 1828:5, 1887:22, 1890:11, 1865:14 industry [2] - 1849:6, 1958:15, 1959:2, 1829:13, 1830:11, 1969:21, 1970:16, INC [2] - 1757:4, 1849:11 1959:3 1838:7, 1893:13, 1970:22, 1973:22 1757:8 infarction [1] -Hyperlipidemia [1] -1893:22, 1948:2, Illinois [1] - 1758:4 incidence [1] -1850:23 1960:15 1955:8, 1975:7 imagine [2] - 1911:25, 1923:15 inflammatory [2] hyperlipidemia [4] increases [11] -1921:7 inclination [1] -1776:18, 1895:18 1865:10, 1865:12, 1941:24 1786:17, 1822:9, imbalance [1] information [32] -1865:22, 1877:9 1822:13, 1822:20, 1788.21 inclined [1] - 1942:11 1791:15, 1800:15, Hyperlipidemic [1] -1824:8, 1829:23, immediately [2] include [7] - 1835:20, 1800:17, 1845:22, 1824:20 1831:9, 1860:2. 1866:21, 1886:16, 1947:17, 1960:20 1861:13, 1864:16, hypertriglyceridemia 1872:4. 1874:12. 1946:9. 1972:10. impact [3] - 1771:6, 1924:8. 1930:17. [24] - 1769:5, 1874:17 1802:19, 1967:11 1974:1, 1981:13 1935:22, 1936:24, 1769:13. 1770:1. increasing [9] impairment [1] included [11] - 1764:7, 1938:13, 1938:15, 1774:15, 1787:2, 1782:6. 1782:11. 1890:3 1838:25, 1847:7, 1939:18, 1939:24, 1806:25, 1808:18, 1782:12, 1782:15, 1940:8, 1940:17, impeach [4] -1862:10, 1864:14, 1808:19, 1813:25,

				1
1940:18, 1941:2,	interview [5] -	1986:7, 1987:2,	JANUARY [2] -	1962:2, 1962:4,
1942:6, 1942:8,	1918:18, 1921:16,	1990:1	1759:1, 1944:1	1968:11, 1968:15,
1942:12, 1943:2,	1968:7, 1968:8,	issued [3] - 1805:8,	Japan [6] - 1763:22,	1969:3
	, ,		•	
1943:4, 1944:16,	1968:9	1989:16, 1989:20	1764:12, 1823:6,	<b>JELIS'</b> [1] - 1773:3
1945:10, 1945:13,	introduce [2] -	issues [14] - 1794:24,	1823:7, 1904:5,	<b>Jersey</b> [1] - 1758:11
1985:21, 1986:18,	1853:17, 1941:12	1796:7, 1796:17,	1905:4	<b>job</b> [1] - 1920:3
1988:11, 1988:12,	introduced [3] -	1891:19, 1894:24,	Japanese [17] -	Jones [1] - 1849:1
1989:3, 1989:6	1914:25, 1942:6,	1895:24, 1903:19,	1761:18, 1763:1,	JOSEPH [1] - 1757:15
informed [3] -	1943:4	1920:14, 1920:18,	1763:10, 1763:13,	journal [4] - 1837:11,
1954:25, 1955:1,	Introduction [1] -	1920:21, 1948:5,	1763:20, 1764:6,	1899:22, 1981:24,
1956:10	1952:11	1966:18, 1990:23	1900:13, 1901:14,	1982:1
infringement [1] -	invalidates [1] -	issuing [1] - 1985:19	1906:15, 1907:19,	Journal [3] - 1904:19,
1895:25	1863:4	IT [52] - 1759:14,	1919:10, 1925:13,	
ingredients [3] -	invention [5] -	1760:11, 1761:12,	1952:3, 1952:17,	1905:22, 1981:25
•				JUDGE [1] - 1757:2
1785:24, 1786:3,	1800:25, 1961:15,	1761:16, 1761:25,	1958:15, 1958:17,	judging [1] - 1871:1
1786:25	1963:1, 1963:19,	1762:4, 1762:10,	1969:7	judgment [2] -
inhibit [1] - 1975:5	1964:1	1767:7, 1768:15,	JEFFREY [1] -	1794:25, 1796:5
inhibiting [1] -	Invention [1] -	1769:4, 1772:7,	1757:14	judicial [3] - 1934:13,
1960:17	1961:13	1772:9, 1773:2,	<b>JELIS</b> [89] - 1759:12,	1936:6, 1937:5
inhibitors [5] -	inventors [1] - 1801:7	1773:16, 1773:20,	1759:17, 1759:20,	July [1] - 1939:5
1760:16, 1877:10,	investigate [1] -	1774:6, 1774:9,	1761:12, 1761:15,	June [4] - 1802:12,
1877:14, 1877:16,	1952:4	1774:18, 1775:1,	1761:24, 1762:4,	1913:5, 1922:20,
1975:3	investigated [1] -	1775:19, 1775:22,	1762:9, 1769:16,	1922:24
inhibits [1] - 1975:16	1865:6	1775:25, 1776:1,	1770:18, 1770:20,	1922.24
initial [1] - 1980:8	investigating [1] -	1776:7, 1777:11,	1771:3, 1771:7,	1/
initiate [1] - 1776:11	1866:2	1778:6, 1894:3,	1772:12, 1772:18,	K
initiated [1] - 1770.11		1894:9, 1894:12,	1773:21, 1823:13,	<b>Vetherum</b> (4) 1000:04
	investigation [1] -	1895:5, 1895:14,	1823:15, 1878:24,	Kathryn [1] - 1996:24
inquiry [2] - 1938:12,	1932:5	1896:8, 1896:15,	1899:13, 1899:18,	Kathyrn [1] - 1757:22
1938:22	investigationally [1] -	1897:5, 1899:9,	1901:24, 1902:4,	<b>KEANE</b> [1] - 1757:14
insisted [1] - 1982:7	1904:11	1904:21, 1904:23,	1901:24, 1902:4,	keep [4] - 1930:12,
instance [1] - 1893:21	investigator [3] -	1905:11, 1905:17,	1902:11, 1903:5,	1940:21, 1963:11,
instead [7] - 1798:12,	1918:24, 1927:1,	1905:23, 1910:2,		1987:12
1850:25, 1902:7,	1927:3		1903:11, 1903:13,	keeping [1] - 1776:16
1920:4, 1934:22,	investor [1] - 1833:10	1910:6, 1920:15,	1903:16, 1904:2,	KENNEDY [2] -
1955:1, 1967:19	investors [8] - 1834:5,	1924:18, 1924:21,	1904:25, 1905:5,	1757:14, 1757:15
institution [5] -	1834:9, 1834:14,	1925:4, 1925:11,	1905:12, 1905:16,	Kennedy [1] - 1986:10
1940:12, 1942:11,	1834:22, 1835:10,	1925:14, 1926:25,	1905:18, 1905:20,	kept [2] - 1874:4,
1943:3, 1943:7,	1836:3, 1836:11,	1927:1, 1927:3,	1905:24, 1906:2,	1987:2
1943:14	1836:16	1927:5	1906:11, 1906:13,	Ketchum [2] - 1833:9,
insufficient [2] -	involved [3] - 1788:7,	item [1] - 1868:1	1906:22, 1907:2,	1906:7
1791:22, 1863:6	1878:25, 1900:13	itself [9] - 1771:25,	1907:13, 1907:16,	Ketchum's [1] -
Insulin [1] - 1824:20	IRELAND <sub>[1]</sub> - 1757:5	1773:18, 1800:21,	1907:18, 1907:24,	1830:20
intake [1] - 1763:23	irrespective [1] -	1801:21, 1830:12,	1908:8, 1908:18,	kidding [1] - 1897:4
intend [1] - 1874:2	1964:22	1874:20, 1881:8,	1909:8, 1909:12,	kind [9] - 1771:24,
intended [1] - 1962:25	ischemic [1] - 1775:14	1981:17, 1982:22	1910:4, 1911:9,	1771:25, 1772:2,
intended [1] - 1902:23	isolated [1] - 1814:2	IV [15] - 1813:14,	1911:16, 1911:21,	1771.23, 1772.2,
		1813:17, 1813:19,	1911:23, 1912:2,	
interest [2] - 1858:24,	issue [30] - 1783:14,	1813:25, 1820:7,	1912:5, 1913:21,	1773:5, 1773:11,
1858:25	1783:22, 1785:18,	1865:11, 1865:14,	1914:7, 1917:14,	1773:21, 1941:21
interesting [1] -	1789:10, 1792:18,	1865:15, 1865:16,	1919:11, 1919:24,	kinds [1] - 1794:16
1795:3	1795:19, 1796:1,	1865:23, 1866:3,	1920:22, 1921:5,	<b>KLEIN</b> [312] - 1757:19,
interject [1] - 1855:6	1796:4, 1796:21,	1866:11, 1866:18,	1921:7, 1924:15,	1765:15, 1767:17,
internal [1] - 1906:10	1797:2, 1809:3,	1866:21, 1867:4	1924:20, 1925:5,	1783:17, 1784:6,
interpretation [5] -	1812:1, 1812:10,	IVs [1] - 1820:7	1925:8, 1925:9,	1784:8, 1784:11,
1840:17, 1840:18,	1819:15, 1864:2,	173[1] - 1020.7	1925:10, 1925:13,	1784:14, 1784:18,
1848:3, 1901:10,	1894:16, 1903:17,	ı		1788:17, 1793:9,
1902:12	1913:19, 1938:8,	J	1949:8, 1951:25,	1793:10, 1793:23,
interrupted [1] -	1939:8, 1940:4,	IAMEQ (4) 1750-10	1952:23, 1953:16,	1793:24, 1795:1,
1984:6	1940:5, 1941:16,	JAMES [1] - 1758:10	1953:18, 1958:12,	1796:10, 1796:12,
Intervention [1] -	1941:23, 1943:6,	January [3] - 1757:6,	1960:21, 1960:23,	1797:7, 1797:8,
1905:5	1943:8, 1968:13,	1809:22, 1914:18	1961:1, 1961:11,	1797:21, 1797:24,

14788-4, 1798-16,   1887-12, 1857-19,   1926-20,   1930-19, 1930-20,   1930					20
1789.20, 1799.23,   1860.16, 1860.19,   1930.19, 1930.20,   1867.1799.1799.6,   1861.15, 1861.16, 1861.6,   1862.2, 1862.24, 1862.24, 1862.24, 1862.24, 1862.24, 1862.24, 1862.24, 1862.24, 1860.8, 1860.1,   1860.25, 1860.24, 1861.20, 1862.24, 18	1798:4, 1798:6,	1857:12, 1857:19,	1928:19, 1928:20,	KURYS [1] - 1757:15	<b>Las</b> [1] - 1758:8
1799-10, 1800-1, 1806.13, 1864-1, 1806.16, 1800-1, 1	1798:14, 1798:16,	1858:2, 1858:3,	1930:9, 1930:10,		last [23] - 1763:6,
1799-10, 1800-1,   1804-2, 1864-24,   1802-2, 1806-24, 1800-1,   1800-25,   1807-1, 1806-24	1798:20, 1798:23,	1860:16, 1860:19,	1930:19, 1930:20,	L	1763:7, 1768:7,
1809.14, 1809.25, 1867.07, 1870.95, 1936.21, 1936.21, 1936.24, 1809.11, 1809.25, 1810.13, 1810.18, 1810.25, 1810.13, 1810.18, 1810.25, 1810.13, 1810.18, 1810.25, 1810.26, 1810.27, 1	1799:2, 1799:6,	1861:15, 1861:16,	1933:6, 1933:9,		1835:16, 1846:24,
1809.11, 1809.25,   1867-10, 1867-11,   1806.19, 1809.16,   1809.11, 1809.16,   1809.11,   1809.1	1799:10, 1800:1,	1864:3, 1864:4,			1903:8, 1909:25,
1810-12, 1810-15, 1810-25, 1870-7, 1870-9, 1870-9, 1870-9, 1870-9, 1870-9, 1870-9, 1870-9, 1870-9, 1870-9, 1870-9, 1870-9, 1870-11, 1870-22, 1813-22, 1813-22, 1813-22, 1813-22, 1813-22, 1813-22, 1813-23, 1814-13, 1813-16, 1813-39, 1873-13, 1873-39, 1873-13, 1814-24, 1945-18, 1816-24, 1812-25, 1813-24, 1813-24, 1813-24, 1816-24, 1813	· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·		1928:2, 1932:17,
1810-122, 1810-25, 1812-10,					1933:3, 1933:5,
1811-16, 1812-10, 1870-22, 1873-3, 1873-15, 1813-22, 1813-22, 1813-22, 1813-23, 1814-15, 1814-16, 1813-23, 1873-3, 1873-15, 1814-16, 1816-24, 1816-64, 1877-3, 1877-5, 1877-5, 1879-55, 1878-66, 1816-62, 1816-64, 1877-3, 1877-5, 1879-55, 1879-66, 1816-62,					
1812.22, 1813.22, 1814.13, 1872.10, 1872.12, 1943.18, 1811.25, 1811.25, 1813.22, 1813.22, 1813.23, 1814.13, 1873.3, 1873.5, 1844.24, 1945.18, 1812.24, 1812.25, 181		· · · · · · · · · · · · · · · · · · ·	· · · · ·		
1813:22, 1814:13,   1872:10, 1872:12,   1943:12, 1943:18,   1811:25, 1812:5,   1812:20,   1812:21				, ,	
1812.23, 1814:13, 1873.3, 1873.13, 18			, ,		
1814:15, 1814:16,	· · · · · · · · · · · · · · · · · · ·				
1815.1, 1815.5,   1874.25, 1875.1,   1977.18, 1977.22,   1813.6, 1813.24,   1813.21, 1813.21, 1813.24,   1813.21, 1813.24,   1813.21, 1813.24,   1813.21, 1813.24,   1813.21, 1813.24,   1813.21, 1813.24,   1814.21, 1813.24,   1814.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.21,   1815.21, 1815.22,   1884.21, 1884.21,   1884.21, 1884.21,   1884.21, 1884.21,   1889.21, 1889.22,   1899.1, 1814.21, 1813.21, 1813.21, 1813.21, 1813.21, 1813.21, 1813.21, 1813.21, 1813.21, 1813.21, 1813.21, 1813.21, 1813.21, 1813.21, 1813.21,   1813.21, 181					·
1816.2, 1816.4, 1817.9, 1875.18, 1877.3, 1877.5, 1883.11, 1883.15, 1883.1, 1983.2, 1984.12, 1884.22, 1884.23, 1883.15, 1883.2, 1984.12, 1821.16, 1827.13, 1821.24, 1822.2, 1822.3, 1822.3, 1822.3, 1822.3, 1822.3, 1822.3, 1823.7, 1886.2, 1			· · · · · · · · · · · · · · · · · · ·		
1816.6, 1816.8, 1816.1, 1817.9, 1877.5, 1877.5, 1979.7, 1816.11, 1817.9, 1879.5, 1879.5, 1979.2, 1979.24, 1816.11, 1814.19, 1815.24, 1816.18, 1817.12, 1819.21, 1820.21, 1820.21, 1821.3, 1820.21, 1821.3, 1821.21, 1820.21, 1821.3, 1821.2, 1822.3, 1822.3, 1822.3, 1822.3, 1822.3, 1822.3, 1822.3, 1822.3, 1822.3, 1822.3, 1822.4, 1825.2, 1887.4, 1887.7, 1825.2, 1825.3, 1825.4, 1825.2, 1887.14, 1829.9, 1784.14, 1795.20, 1825.16, 1825.2, 1826.3, 1826.3, 1826.4, 1826.9, 1826.1, 1827.7, 1827.12, 1829.9, 1822.1, 1829.1, 18	· · · · · · · · · · · · · · · · · · ·				
1816-11, 1817-9,   1878-5, 1878-10,   1979-22, 1979-24,   1816-18, 1817-12,   1816-1					
1817-10, 1819-20,   1879-2, 1879-5,   1896-14, 1980-17,   1816-18, 1817-12,   1816-18, 1816-18,   1817-12,   1816-18, 1816-18,   1817-12,   1816-18, 1816-17,   1866-18, 1866-18					
1810-21, 1820-21, 1823-13, 1883-15, 1883-12, 1884-12, 1884-20, 1895-25, 1995-13, 1994-13, 1821-14, 1825-2, 1822-3, 1823-7, 1826-21, 1825-21, 1825-3, 1825-14, 1825-2, 1825-3, 1825-14, 1825-12, 1825-23, 1825-14, 1825-2, 1825-23, 1825-14, 1825-2, 1825-23, 1825-14, 1825-2, 1825-23, 1826-3, 1825-14, 1825-2, 1825-23, 1826-3, 1825-14, 1825-2, 1825-23, 1826-3, 1825-14, 1825-2, 1825-23, 1826-3, 1825-14, 1827-2, 1825-2, 1825-23, 1826-3, 1825-14, 1825-2, 1825-23, 1826-3, 1825-14, 1827-15, 1825-17, 1827-17, 1827-12, 1825-17, 1827-17, 1827-12, 1825-12, 1825-23, 1826-3, 1825-14, 1825-12, 1825-13, 1829-9, 1825-13, 1829-9, 1825-14, 1825-12, 1825-13, 1829-9, 1825-14, 1825-14, 1825-15, 1825-17, 1825-17, 1825-17, 1825-17, 1825-17, 1825-17, 1825-17, 1825-18,			, , , , , , , , , , , , , , , , , , ,		
1820:22, 1821:3,   1884:23, 1885:25,   1894:13,   1821:16, 1821:18,   1822:2,   1884:23, 1885:25,   1894:16, 1994:22,   1824:7, 1863:23,   1824:13,   1826:2,   1886:2,   1886:2,   1886:2,   1886:2,   1886:2,   1886:2,   1886:2,   1886:2,   1886:2,   1886:3,   1825:14,   1825:14,   1825:14,   1825:14,   1825:14,   1825:14,   1826:14,   18					
1821-4, 1822-2,   1884:23, 1885:25,   1994:16, 1994:22,   1823-7, 1823-7,   1886:24, 1886:25,   1995:2, 1995:6,   1824:13, 1823-2,   1824:13,   1825:2,   1887:4,   1889:1,   1889:1,   1889:1,   1889:1,   1889:2,   1784:14, 1795:20,   1825:13, 1825:3,   1826:4,   1826:1,   1827:3,   1827:3,   1827:3,   1827:3,   1827:3,   1827:3,   1827:3,   1827:3,   1827:3,   1827:3,   1827:3,   1826:3,   1826:4,   1867:1,   1868:17,   1868:12,   1868:17,   1868:22,   1868:15,   1868:22,   1868:15,   1868:22,   1868:15,   1868:22,   1868:15,   1868:22,   1868:16,   1868:17,   1868:12,   1868:17,   1868:12,   1868:12,   1868:17,   1868:12,   1868:13,   1868:14,   1868:12,   1868:15,   1868:15,   1868:14,   1868:17,   1868:15,   1868:15,   1868:14,   1868:17,   1868:12,   1868:15,   1868:			· · · · · · · · · · · · · · · · · · ·		
1822.3, 1823.7,   1886.2, 1886.25,   1995.2, 1995.6,   1864.5, 1864.8,   1867.1, 1867.21,   1829.9, 1824.13,   1825.1,   1825.2,   1825.1,   1825.2,   1825.2, 1825.2,   1825.2, 1826.3,   1826.4, 1826.9,   1826.4, 1826.9,   1826.4, 1826.9,   1826.4, 1826.9,   1826.1, 1826.4, 1826.9,   1826.1, 1826.1,   1826.1, 1826.4, 1826.9,   1826.1, 1826.1, 1826.1,   1826.1, 1826.1,   1826.1, 1827.6,   1827.7, 1827.12,   1829.9,   1900.11,   1900.18,   1827.1, 1829.9,   1900.18,   1900.18,   1900.24, 1901.1,   1902.2, 1901.1,   1902.3, 1833.2,   1833.2,   1833.2,   1833.4,   1904.13,   1906.6, 1906.9,   1907.7,   1839.2, 1839.1,   1839.16,   1839.16,   1839.2,   1839.1,				*	· ·
1823.9, 1824.13,   1887.4, 1887.7,   1996.19   1864.10, 1865.16, 1865.16, 1865.17, 1866.15, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1825.21, 1827.12, 1827.12, 1827.12, 1827.13, 1822.9, 1822.11, 1827.12, 1827.13, 1822.9, 1822.10, 1830.16, 1825.11, 1900.16, 1900.18, 1900.19, 1822.10, 1830.16, 1832.2, 1	· · · · · · · · · · · · · · · · · · ·				,
1824:14, 1825:2,   1887:11, 1889:1,   1825:3, 1825:3, 1825:4,   1889:2, 1889:9,   1794:14, 1795:20,   1866:24, 1867:8, 1866:22, 1866:6,   1867:6, 1866:24, 1867:8, 1866:22, 1866:9,   1899:1, 1890:10,   1899:15, 1899:16,   1827:1, 1827:1, 1827:1, 1829:9,   1900:9, 1900:11,   1900:18, 1900:9, 1900:14,   1900:18, 1900:9, 1900:14,   1900:18, 1900:9, 1900:14,   1900:18, 1900:9, 1900:14,   1900:18, 1900:9, 1900:14,   1900:18, 1900:9, 1900:19,   1831:24,   1900:8, 1901:9,   1933:3, 1834:17,   1839:4,   1906:8, 1906:9,   1906:6, 1906:9,   1839:4, 1839:4, 1839:4, 1839:4, 1839:4, 1839:4, 1839:4, 1839:4, 1839:4, 1839:4, 1842:19, 1840:19, 1840:20, 1841:16, 1841:16, 1841:16, 1842:18, 1842:19, 1842:18, 1842:19, 1842:18, 1842:19, 1842:18, 1842:19, 1842:18, 1842:19, 1843:10, 1847:18, 1847:19, 1846:8, 1848:10, 1847:18, 1847:19, 1851:1, 1851:17, 1851:10, 1852:7, 1852:1, 1852:2, 1853:2, 1853:2, 1853:2, 1853:2, 1853:2, 1853:2, 1853:2, 1853:2, 1853:2, 1853:15, 18	· · ·			, ,	
1825:3, 1825:14,   1889:2, 1889:9,   1784:14, 1795:20,   1866:24, 1867:1,   1866:24, 1866:18,   1866:24, 1867:1,   1866:24, 1867:1,   1866:24, 1867:1,   1866:24, 1867:1,   1866:24, 1867:1,   1866:24, 1867:1,   1866:24, 1867:1,   1866:24, 1867:1,   1866:24, 1867:1,   1866:24, 1	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·			
1825:16, 1825:21, 1889:12, 1889:22, 1890:1, 1890:10, 1890:10, 1826:3, 1826:3, 1826:3, 1890:4, 1890:10, 1890:15, 1892:16, 1826:4, 1827:3, 1827:13, 1829:9, 1900:9, 1900:11, 1829:10, 1830:16, 1900:16, 1900:18, 1830:19, 1831:24, 1900:24, 1901:1, 1830:19, 1831:24, 1900:24, 1901:1, 1834:20, 1836:21, 1836:21, 1836:18, 1333, 1834:17, 1904:12, 1904:13, 1834:20, 1836:18, 1390:5, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:17, 1839:19, 1836:20, 1839:4, 1906:18, 1906:19,	· · · · · · · · · · · · · · · · · · ·				
1825:23, 1826:3,   1890:1, 1890:10,   1797:2, 1797:6,   1871:24, 1872:3, 1872:13, 1826:11, 1827:6,   1894:3, 1894:5,   1894:5,   1892:14, 1892:15, 1899:16,   1899:15, 1899:16,   1899:15, 1899:16,   1899:15, 1899:16,   1899:15, 1899:16,   1890:18, 1890:19, 1800:11,   1900:18, 1900:19, 1900:11,   1900:24, 1901:1,   1900:24, 1901:1,   1900:24, 1901:1,   1900:24, 1901:1,   1900:24, 1901:1,   1900:33, 1833:1, 1834:17,   1901:19, 1900:19, 1900:19,   1833:1, 1834:17,   1901:19, 1906:19, 1833:1, 1834:17,   1901:19, 1906:19, 1833:1, 1834:17,   1906:18, 1906:0, 1839:5, 1839:15,   1906:18, 1906:20, 1839:4,   1906:18, 1906:20, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:15, 1839:14, 1900:24, 1909:1, 1839:13, 1840:20, 1834:14, 1841:16, 1841:16, 1842:18, 1842:19, 1844:6, 1844:8, 1844:19, 1844:6, 1846:8, 1842:19, 1844:6, 1846:8, 1842:19, 1844:6, 1846:8, 1841:16, 1851:15, 1851:14, 1851:15, 1851:14, 1851:15, 1851:2, 1852:1, 1852:4, 1916:17, 1916:17, 1852:6, 1852:7, 1916:2, 1916:4, 1855:15, 1916:17, 1916:17, 1852:6, 1855:7, 1916:2, 1916:4, 1853:16, 1853:2, 1853:2, 1853:23, 1854:6, 1854:17, 1916:18, 1917:1, 1853:10, 1853:15, 1925:3, 1854:16, 1854:17, 1916:18, 1917:1, 1855:19, 1853:2, 1853:2, 1853:23, 1921:24, 1922:5, 1853:22, 1853:23, 1854:6, 1854:17, 1916:17, 1916:17, 1855:16, 1855:17, 1916:18, 1917:1, 1855:16, 1855:17, 1916:18, 1917:1, 1855:16, 1855:17, 1916:18, 1917:1, 1855:16, 1855:17, 1916:18, 1917:1, 1855:16, 1855:17, 1916:18, 1917:1, 1855:16, 1855:17, 1916:18, 1917:1, 1855:16, 1855:17, 1916:18, 1917:1, 1855:16, 1855:17, 1916:18, 1917:17, 1855:18, 1935:14, 1853:15, 1916:17, 1916:17, 1855:18, 1935:14, 1853:15, 1916:17, 1916:17, 1855:18, 1935:14, 1853:15, 1916:17, 1916:17, 1855:18, 1935:14, 1853:15, 1916:17, 1916:17, 1855:18, 1935:14, 1853:15, 1916:17, 1916:17, 1855:18, 1935:14, 1853:15, 1916:17, 1916:17, 1855:18, 1935:14, 1853:15, 1916:17, 1916:17, 1855:18, 1916:17, 1916:17, 1916:17, 1916:17, 1916:17, 1916:17, 1916:17, 1916:17, 1916:17, 1916:17, 1916:17, 1916:17, 1916:17, 1916:17,					· · · · · ·
1826.4, 1826.9,   1894.3, 1894.5,   1897.14, 1897.15,   1844.20, 1830.16,   1890.16, 1900.16, 1900.18, 1830.19, 1831.24,   1900.24, 1901.1, 1832.2, 1833.2, 1834.17,   1904.12, 1904.13, 1839.15, 1839.15, 1839.15, 1839.15, 1839.15, 1839.15, 1839.17, 1839.19, 1908.5, 1908.7, 1839.19, 1842.2, 1842.3, 1910.22, 1911.1, 1910.13, 1842.2, 1842.3, 1910.22, 1911.1, 1910.13, 1842.2, 1842.3, 1910.22, 1911.1, 1913.10, 1842.18, 1842.19, 1844.8, 1911.14, 1912.7, 1844.6, 1844.8, 1912.11, 1913.10, 1847.18, 1847.19, 1848.9, 1848.10, 1848.10, 1848.10, 1848.10, 1848.10, 1848.10, 1848.10, 1848.10, 1848.10, 1848.10, 1848.10, 1848.10, 1848.11, 1851.15, 1853.2, 1853.2, 1853.2, 1853.23, 1853.2, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.23, 1853.21, 1923.3, 1923.3, 1853.24, 1903.3, 1923.3, 1853.24, 1903.3, 1933.3, 1853.15, 1907.5, 1907.7, 1909.14, 1909.16, 1909.16, 1909.1			· · · · · · · · · · · · · · · · · · ·		
1826:11, 1827:6, 1897:14, 1897:15, 1899:16, 1827:17, 1827:12, 1899:16, 1827:13, 1829:9, 1900:9, 1900:11, 1829:10, 1830:16, 1900:16, 1900:18, 1910:12, 1967:8, 1973:14, 1916:15, 1944:22, 1833:2, 1834:47, 1904:12, 1904:13, 1834:20, 1836:18, 1906:6, 1906:9, 1839:4, 1836:18, 1906:6, 1906:9, 1839:45, 1839:19, 1839:19, 1839:19, 1839:23, 1840:3, 1908:24, 1909:1, 1840:19, 1840:19, 1840:19, 1840:19, 1840:19, 1840:19, 1840:18, 1842:19, 1842:1, 1842:19, 1842:1, 1842:19, 1842:1, 1842:19, 1842:1, 1842:19, 1842:1, 1842:19, 1843:1, 1943:1, 1943:10, 1843:1, 1843:19, 1943:1, 1943:10, 1843:1, 1843:19, 1943:1, 1943:10, 1843:1, 1845:17, 1853:15, 1853:24, 1853:15, 1853:25, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:24, 1853:15, 1853:25, 1853:23, 1853:23, 1853:24, 1853:14, 1853:15, 1853:25, 1853:23, 1853:23, 1853:24, 1953:3, 1853:25, 1853:23, 1853:23, 1853:24, 1953:3, 1853:25, 1853:23, 1853:23, 1853:24, 1853:4, 1853:5, 1853:23, 1853:23, 1853:24, 1953:3, 1853:25, 1853:23, 1853:23, 1853:3, 1853:35, 1853:17, 1853:10, 1853:15, 1853:17, 1953:1, 1953:3, 1853:17, 1853:24, 1853:4, 1853:5, 1921:14, 1921:7, 1853:52, 1853:23, 1921:24, 1922:5, 1853:6, 1853:17, 1953:1, 1953:3, 1853:25, 1921:24, 1922:5, 1853:6, 1853:17, 1953:1, 1953:3, 1853:25, 1921:24, 1922:5, 1853:4, 1853:4, 1853:5, 1921:14, 1921:7, 1953:3, 1853:15, 1921:14, 1921:7, 1953:3, 1853:15, 1921:14, 1921:5, 1853:24, 1853:17, 1923:3, 1923:3, 1853:17, 1923:3, 1853:24, 1853:4, 1853:17, 1923:1, 1923:3, 1833:3, 1836:15, 1840:12, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:21, 1927:22, 1855:1, 1927:22, 1855:1, 1927:22, 1855:1, 1927:22, 1855:1, 1927:22, 1855:1, 1927:22, 1855:1, 1927:22, 1855:1, 1927:22, 1855:1, 1927:22, 1855:1, 1927:22, 1855:1, 1927:22, 1855:1, 1927:22, 1855:1, 19	· · · · · · · · · · · · · · · · · · ·				
1827.7, 1827.12, 1899:15, 1899:16, 1853:21, 1885:23, 1878:15, 1891:18, 1757:20, 1758:3, 1827:19, 1829:10, 1830:16, 1900:16, 1900:11, 190:16, 1900:16, 1900:14, 1901:1, 1904:12, 1904:13, 1832:2, 1833:2, 1901:8, 1901:9, 1983:1, 1986:6, 1986:2, 1839:4, 1906:6, 1906:1, 1907:7, 1907:7, 1907:7, 1908:5, 1907:7, 1908:5, 1908:7, 1908:5, 1908:7, 1908:24, 1909:1, 1909:1, 1909:1, 1					· ·
1827:13, 1829:9, 1900:16, 1900:16, 1900:16, 1900:16, 1900:16, 1900:16, 1900:16, 1900:14, 1901:1, 1906:78, 1973:14, 1832:2, 1833:2, 1901:8, 1906:3, 1986:17, 1986:2, 1834:20, 1836:18, 1906:6, 1906:8, 1906:0, 1839:4, 1906:18, 1906:20, 1839:4, 1839:17, 1839:19, 1806:5, 1908:7, 1909:14, 1909:16, 1841:16, 1841:16, 1841:16, 1842:2, 1842:3, 1842:2, 1842:3, 1844:8, 1911:14, 1912:7, 1844:6, 1844:8, 1911:14, 1912:7, 1844:6, 1844:8, 1911:14, 1912:7, 1844:6, 1846:18, 1847:19, 1845:15, 1851:16, 1851:7, 1851:0, 1852:1, 1851:20, 1852:24, 1918:17, 1852:2, 1853:23, 1853:23, 1853:3, 1918:12, 1918:17, 1852:2, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:21, 1952:18, 1922:5, 1853:23, 1853:21, 1923:3, 1853:23, 1853:22, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:21, 1922:1, 1922:2, 1855:18, 1922:1, 1927:21, 192		1899:15, 1899:16,		1878:15, 1891:18,	
1829:10, 1830:16, 1800:18, 1900:18, 1830:19, 1831:24, 1900:24, 1901:1, 1900:27, 1907:3, 1833:2, 1833:2, 1834:17, 1904:12, 1904:13, 1836:20, 1839:4, 1836:20, 1839:4, 1906:6, 1906:0, 1839:4, 1906:5, 1908:7, 1839:17, 1839:19, 1908:5, 1908:7, 1839:23, 1840:3, 1840:11, 1910:11, 1910:13, 1842:18, 1842:19, 1841:16, 1842:18, 1842:19, 1844:19, 1844:19, 1844:19, 1844:19, 1844:19, 1844:19, 1848:9, 1848:10, 1848:9, 1848:10, 1852:24, 1852:24, 1852:24, 1852:24, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:21, 1925:18, 1925:20, 1854:21, 1854:21, 1925:18, 1925:20, 1854:21, 1854:21, 1927:21, 1927:22, 1855:10, 1927:21, 1927:22, 1856:5, 1860:15, 1890:24, 1900:14, 1901:3, 1903:6, 1903:7, 1903:6, 1903:7, 1903:6, 1903:7, 1903:6, 1903:7, 1903:6, 1903:7, 1903:6, 1903:7, 1903:6, 1903:7, 1903:6, 1903:7, 1903:6, 1903:7,	1827:13, 1829:9,	1900:9, 1900:11,		1905:5, 1973:11,	•
1830:19, 1831:24,   1900:24, 1901:1,   1967:8, 1973:14,   1986:15,   1986:15,   1986:17, 1986:22,   1986:22,   1833:3, 1834:17,   1906:6, 1906:9,   1997:5, 1997:6,   1844:21   1993:17   1839:19,   1908:24, 1909:1,   1966:19   1908:24, 1909:1,   1908:24, 1909	1829:10, 1830:16,	1900:16, 1900:18,		1976:6	
1832:2, 1833:2,   1901:8, 1901:9,   1983:1, 1986:6,   1986:17, 1986:22,   1833:3, 1834:17,   1904:12, 1904:13,   1906:6, 1906:9,   1997:5, 1997:6   1814:21   1993:17   1839:25, 1839:15,   1907:5, 1907:7,   1937:10   1908:5, 1908:7,   1908:5, 1908:7,   1908:24, 1909:1, 1840:20,   1840:20, 1842:18, 1842:19, 1844:8, 1844:19, 1844:8, 1844:19, 1844:8, 1844:10, 1845:15, 1851:14, 1851:15, 1851:14, 1851:15, 1851:24, 1852:24, 1918:2, 1918:4, 1918:17, 1853:22, 1853:23, 1853:23, 1853:23, 1854:21, 1853:32, 1853:23, 1854:21, 1925:18, 1925:20, 1855:21, 1855:17, 1955:18, 1925:22, 1855:17, 1927:21, 1927:22,   1856:15, 1895:17, 1854:22, 1855:1, 1925:18, 1925:20, 1854:21, 1925:18, 1927:22, 1840:15, 1851:14, 1854:17, 1925:18, 1925:20, 1854:21, 1854:21, 1925:18, 1925:20, 1854:22, 1855:1, 1927:21, 1927:22,   1840:15   1840:12, 1980:8	1830:19, 1831:24,	1900:24, 1901:1,	1967:8, 1973:14,	labeled [2] - 1865:15,	·
1833:3, 1834:17,   1904:12, 1904:13,   1906:6, 1906:9,   1906:6, 1906:9,   1906:18, 1906:20,   1907:5, 1907:7,   1937:10,   1758:10,   1839:15, 1839:15, 1839:15, 1839:19, 1839:23, 1840:3, 1840:19, 1840:20, 1841:16, 1844:16, 1844:8, 1844:19, 1846:6, 1846:8, 1847:19, 1848:9, 1848:10, 1847:18, 1845:15, 1851:7, 1851:20, 1852:1, 1851:20, 1852:24, 1918:21, 1918:17, 1852:29, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1855:17, 1925:18, 1925:20, 1856:17, 1925:21, 1925:20, 1856:17, 1925:21, 1925:20, 1856:17, 1925:21, 1925:20, 1856:17, 1925:18, 1925:20, 1856:17, 1925:21, 1925:20, 1856:17, 1925:18, 1925:20, 1856:17, 1925:21, 1925:20, 1856:15, 1927:21, 1927:22, 1840:15, 1860:17, 1926:14, 1927:22, 1840:15, 1840:12, 1920:8, 1920:14, 1921:27, 1927:22, 1840:15, 1840:12, 1920:8, 1920:24, 1925:20, 1856:15, 1927:21, 1927:22, 1840:15, 1840:15, 1840:12, 1920:8, 1927:21, 1927:22, 1840:15, 1840:12, 1920:18, 1921:14, 1921:15, 1927:22, 1840:15, 1840:12, 1920:8, 1920:14, 1920:24, 1921:4, 1921:5, 1920:14, 1920:24, 1920:5, 1820:14, 1920:25, 1820:14, 1920:1	1832:2, 1833:2,	1901:8, 1901:9,	1983:1, 1986:6,	1958:14	
1834:20, 1836:18, 1836:20, 1839:4, 1906:6, 1906:9, 1907:5, 1907:7, 1839:15, 1839:15, 1839:15, 1839:17, 1839:19, 1840:20, 1841:16, 1842:13, 1842:13, 1842:19, 1844:6, 1844:8, 1911:14, 1912:7, 1846:6, 1846:8, 1851:6, 1851:7, 1852:19, 1852:24, 1853:15, 1853:23, 1853:24, 1853:15, 1854:17, 1925:18, 1925:20, 1854:21, 1925:18, 1925:20, 1854:21, 1854:21, 1925:18, 1925:20, 1854:21, 1854:21, 1925:18, 1925:20, 1854:21, 1854:21, 1855:15, 1854:21, 1925:18, 1925:20, 1854:21, 1855:15, 1855:1, 1925:18, 1925:20, 1855:1, 1927:22, 1825:0, 1856:17, 1925:18, 1925:20, 1856:14, 1855:15, 1856:17, 1925:18, 1925:20, 1856:15, 1856:17, 1925:18, 1925:20, 1856:15, 1856:17, 1925:18, 1925:20, 1856:15, 1856:17, 1925:18, 1925:20, 1856:15, 1856:17, 1925:18, 1925:20, 1856:15, 1856:17, 1925:18, 1925:20, 1856:15, 1856:17, 1925:18, 1925:20, 1856:15, 1856:17, 1925:18, 1925:20, 1856:27, 1927:21, 1927:22, 1856:20, 1856:17, 1925:18, 1925:20, 1856:45, 1856:17, 1925:18, 1925:20, 1856:42, 1855:1, 1925:18, 1925:20, 1856:42, 1855:1, 1927:21, 1927:22, 1840:15	1833:3, 1834:17,	1904:12, 1904:13,	1986:17, 1986:22,	labels [2] - 1812:4,	
1839:15, 1839:19, 1907:5, 1907:7, 1908:5, 1908:7, 1908:5, 1908:7, 1908:5, 1908:7, 1908:5, 1908:7, 1908:24, 1909:1, 1908:24, 1909:16, 1909:14, 1909:16, 1910:11, 1910:13, 1840:20, 1840:20, 1840:21, 1842:3, 1910:22, 1911:1, 1911:4, 1911:12, 1911:4, 1911:12, 1911:4, 1912:7, 1844:6, 1844:8, 1912:11, 1913:10, 1847:18, 1847:19, 1848:10, 1848:10, 1848:10, 1851:6, 1851:7, 1851:20, 1852:1, 1852:24, 1853:5, 1853:22, 1853:23, 1853:23, 1853:23, 1854:6, 1854:17, 1852:18, 1853:1, 1853:22, 1853:23, 1854:15, 1854:15, 1854:15, 1854:17, 1852:18, 1854:17, 1852:18, 1854:17, 1852:18, 1854:22, 1855:1, 1927:21, 1927:22, 1854:20, 1854:22, 1855:1, 1927:22, 1855:1, 1927:21, 1927:22, 1854:22, 1855:1, 1927:21, 1927:22, 1854:22, 1855:1, 1927:21, 1927:22, 1827:22, 1855:4, 1854:22, 1855:1, 1927:21, 1927:22, 1827:22, 1855:4, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15, 1854:15, 1854:22, 1855:1, 1927:21, 1927:22, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15, 1840:12, 1840:15, 1840:12, 1840:15, 1840:12, 1840:15, 1840:12, 1840:15, 1840:12, 1840:15, 1840:12, 1840:13, 1840:12, 1840:13, 1840:13, 1840:13, 1840:13, 1840:14, 1840:12, 1840:15, 1840:14,	1834:20, 1836:18,	1906:6, 1906:9,	1997:5, 1997:6	1814:21	
1839:17, 1839:19, 1839:23, 1840:3, 1908:5, 1908:7, 1908:24, 1909:1, 1908:24, 1909:1, 1908:24, 1909:1, 1908:24, 1909:1, 1909:14, 1909:16, 1841:15, 1841:16, 1910:11, 1910:13, 1842:2, 1842:3, 1910:22, 1911:1, 1913:10, 1847:18, 1847:19, 1913:13, 1913:16, 1848:9, 1848:10, 1851:6, 1851:15, 1851:20, 1852:1, 1852:24, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1853:23, 1854:16, 1854:17, 1854:22, 1855:1, 1854:17, 1854:22, 1855:1, 1925:18, 1925:20, 1854:15, 1854:15, 1854:15, 1854:17, 1854:22, 1855:14, 1854:17, 1854:22, 1855:14, 1854:17, 1854:22, 1855:14, 1854:17, 1854:22, 1855:14, 1854:17, 1854:22, 1855:14, 1854:17, 1855:15, 1854:15, 1854:17, 1855:18, 1855:20, 1852:24, 1918:2, 1918:4, 1918:2, 1918:4, 1918:2, 1918:4, 1918:2, 1918:4, 1918:17, 1855:20, 1855:15, 1855:21, 1855:2	1836:20, 1839:4,	1906:18, 1906:20,	Klein's [2] - 1795:18,	LABORATORIES[1] -	lawyer [3] - 1886:3,
1839:17, 1839:19, 1840:3, 1840:20, 1841:15, 1841:16, 1842:18, 1842:19, 1846:6, 1846:8, 1846:10, 1851:15, 1851:20, 1852:1, 1852:20, 1852:17, 1852:20, 1853:23, 1853:22, 1853:23, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:17, 1854:22, 1855:1, 1854:25, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:1, 1854:25, 1854:2			1937:10		1886:5, 1897:3
1840:19, 1840:20, 1841:16, 1841:16, 1841:16, 1842:2, 1842:3, 1842:18, 1842:19, 1844:6, 1844:8, 1847:19, 1847:19, 1848:9, 1848:10, 1851:15, 1851:14, 1851:15, 1851:20, 1852:1, 1852:19, 1852:24, 1853:21, 1853:22, 1853:23, 1853:22, 1853:23, 1854:6, 1854:17, 1854:22, 1854:15, 1854:15, 1853:22, 1853:23, 1854:6, 1854:17, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:1, 1854:22, 1855:16, 1851:7, 1853:22, 1853:23, 1853:23, 1853:22, 1853:23, 1854:6, 1854:17, 1854:22, 1855:10, 1853:15, 1854:20, 1853:15, 1854:20, 1853:15, 1854:20, 1853:15, 1854:21, 1854:22, 1855:1, 1855:20, 1855:14, 1853:5, 1855:20, 1855:14, 1853:5, 1853:22, 1853:23, 1854:22, 1855:14, 1855:15, 1855:14, 1853:15, 1854:21, 1855:15, 1855:20, 1855:14, 1853:5, 1855:14, 1853:5, 1855:14, 1853:5, 1855:14, 1853:5, 1855:14, 1853:5, 1855:14, 1853:5, 1855:14, 1853:5, 1855:14, 1853:5, 1855:14, 1853:5, 1855:14, 1853:5, 1855:14, 1855:20, 1855:20, 1855:15, 1855:14, 1855:15, 1855:17, 1925:18, 1925:20, 1856:15, 1856:15, 1856:15, 1856:15, 1856:15, 1856:15, 1856:14, 1925:18, 1925:20, 1856:15, 1856:15, 1856:15, 1856:15, 1856:15, 1856:14, 1925:21, 1925:22, 1856:25, 1856:14, 1925:14, 1925:15, 1856:15, 1856:14, 1925:14, 1925:15, 1856:15, 1856:14, 1925:14, 1925:15, 1856:15, 1856:14, 1925:14, 1925:15, 1856	1839:17, 1839:19,	1908:5, 1908:7,			
1840:19, 1840:20,   1909:14, 1909:16,   1910:11, 1910:13,   1944:19,   1910:22, 1911:1,   1910:12, 1911:12,   1911:4, 1911:12,   1946:6, 1846:8,   1912:11, 1913:10,   1847:18, 1847:19,   1914:11, 1914:22,   1851:6, 1851:7,   1966:2, 1916:4,   1916:17, 1852:20, 1853:22, 1853:23,   1854:6, 1854:11,   1912:4, 1922:5,   1853:22, 1853:23,   1854:6, 1854:17,   1925:18, 1925:20,   1854:22, 1855:1,   1925:18, 1925:20,   1854:15, 1854:17,   1925:18, 1925:20,   1854:15, 1854:22, 1855:1,   1927:21, 1927:22,   1836:15, 1840:15,   1852:24, 1855:14, 1854:17,   1925:18, 1925:20,   1854:22, 1855:1,   1927:21, 1927:22,   1836:15, 1840:12,   1825:20,   1854:22, 1855:1,   1927:21, 1927:22,   1840:15,   1840:15,   1840:15,   1840:15,   1840:15,   1840:15,   1840:15,   1840:15,   1840:15,   1840:15,   1840:15,   1840:15,   1840:15,   1890:20,   18937:26,   19937:26,   19937:27,   19937:27,   19937:27,   19937:25,   19937:26,   19937:26,   19937:26,   19937:26,   19937:27,   19937:27,   19937:27,   19937:25,   1841:4, 1899:20,   1937:25,   1841:4, 1899:20,   1937:25,   1900:14, 19937:25,   1900:14, 19937:25,   19937:17,   19937:25,   19937:26,   19937:27,   19937:25,   19937:26,   19937:27,   19				1789:25, 1790:4,	lay [2] - 1926:6,
1841:15, 1841:16, 1910:13, 1910:13, 1910:13, 1910:22, 1911:1, 1910:22, 1911:1, 1910:22, 1911:1, 1911:4, 1911:12, 1911:4, 1911:14, 1912:7, 1846:6, 1846:8, 1847:19, 1913:13, 1913:16, 1848:10, 1848:9, 1848:10, 1851:6, 1851:7, 1851:14, 1851:15, 1852:6, 1852:7, 1853:24, 1853:5, 1853:2, 1853:23, 1854:6, 1854:17, 1854:15, 1854:15, 1854:17, 1854:15, 1854:17, 1854:22, 1855:1, 1854:17, 1854:22, 1855:1, 1854:17, 1854:22, 1855:1, 1854:17, 1854:22, 1855:1, 1854:17, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15			knowledgeable [1] -		
1842:2, 1842:3,   1910:22, 1911:1,   1911:12,   1786:7, 1787:13,   1913:5.5   1776:16, 1777:19,   1844:6, 1844:8,   1911:14, 1911:12,   1793:3, 1803:23,   1800:24, 1807:13,   1900:7, 1901:3,   1782:3, 1782:6,   1782:3, 1782:6,   1848:9, 1848:10,   1841:15,   1851:6, 1851:7,   1851:20, 1852:1,   1852:21, 1853:22, 1853:23,   1853:22, 1853:23, 1854:6, 1854:17,   1854:15, 1854:15,   1854:15, 1854:17,   1854:22, 1855:1,   1854:15,   1854:15,   1854:22, 1855:1,   1855:21,   1855:21,   1855:21,   1855:22, 1855:27,   1854:21, 1855:21,   18					
1844:6, 1844:8, 1911:14, 1912:7, 1793:3, 1803:23, 1806:6, 1846:8, 1847:18, 1847:19, 1913:13, 1913:16, 1807:17, 1848:9, 1848:10, 1914:11, 1914:22, 1851:14, 1851:15, 1851:20, 1852:1, 1852:6, 1852:7, 1852:19, 1852:24, 1853:4, 1853:5, 1853:22, 1853:23, 1854:6, 1854:17, 1854:22, 1854:6, 1854:17, 1854:22, 1855:1, 1854:25, 1854:21, 1854:22, 1855:1, 1854:25, 1854:17, 1854:22, 1855:1, 1854:25, 1854:21, 1854:22, 1855:1, 1916:21, 1927:22, 1927:22, 1825:20, 1854:6, 1854:17, 1854:22, 1855:1, 1917:21, 1927:22, 1825:8, 1918:4, 1927:21, 1927:22, 1856:15, 1826:15	· · · · · · · · · · · · · · · · · · ·	'	• •		
1846:6, 1846:8, 1847:19, 1847:19, 1847:18, 1847:19, 1848:9, 1848:10, 1851:6, 1851:14, 1851:15, 1851:20, 1852:1, 1852:19, 1852:24, 1853:22, 1853:23, 1854:6, 1854:11, 1854:22, 1855:1,       1912:11, 1913:10, 1803:24, 1807:13, 1807:13, 1800:7, 1901:3, 1782:3, 1782:6, 1782:1, 1807:16, 1807:17, 1854:22, 1876:25, 1916:4, 1916:17, 1854:22, 1876:25, 1916:11, 1916:17, 1854:22, 1876:25, 1916:11, 1916:17, 1854:22, 1876:25, 1927:21, 1927:22, 1854:6, 1854:17, 1854:22, 1855:1,       1803:24, 1807:13, 1900:7, 1901:3, 1782:3, 1782:6, 1782:3, 1782:6, 1782:11, 1903:14       1900:7, 1901:3, 1900:13, 1900:13, 1782:8, 1782:6, 1782:11, 1782:15, 1782:15, 1782:15, 1782:15, 1782:15, 1782:15, 1782:15, 1782:15, 1878:17, 1878:17, 1878:17, 1878:17, 1878:17, 1878:17, 1880:5, 1880:13, 1781:21, 1809:7, 1881:4, 1809:2, 1811:6, 1812:17, 1787:21, 1788:1, 1930:6       1777:13, 1780:13, 1780:25, 1845:5, 1893:21, 1789:3, 1789:15, 1789:20, 1789:17, 1789:20, 1789:21, 1790:5, 1790:14, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15					1776:16, 1777:19,
1847:18, 1847:19, 1913:13, 1913:16, 1807:17, 1848:9, 1848:10, 1914:11, 1914:22, 1851:6, 1851:7, 1916:2, 1916:4, 1851:14, 1851:15, 1916:11, 1916:17, 1851:20, 1852:1, 1916:18, 1917:1, 1852:6, 1852:24, 1853:4, 1853:5, 1853:22, 1853:23, 1854:6, 1854:17, 1854:22, 1855:1, 1916:18, 1927:21, 1927:22, 1854:6, 1854:17, 1854:25, 1854:6, 1854:17, 1927:21, 1927:22, 1850:20, 1854:6, 1854:17, 1854:22, 1855:1, 1917:21, 1927:22, 1850:20, 1854:6, 1854:17, 1927:21, 1927:22, 1840:15	· · ·				
1848:9, 1848:10, 1914:11, 1914:22, 1807:22, 1825:8, 1851:6, 1851:7, 1916:2, 1916:4, 1916:17, 1851:20, 1852:1, 1916:18, 1917:1, 1852:6, 1852:7, 1852:19, 1852:24, 1918:2, 1918:4, 1853:4, 1853:5, 1853:22, 1853:23, 1854:6, 1854:11, 1854:15, 1854:17, 1854:22, 1855:1, 1917:21, 1927:22, 1825:8, 1851:20, 1854:6, 1854:17, 1927:21, 1927:22, 1825:8, 1865:15, 1854:17, 1854:22, 1855:1, 1917:21, 1927:22, 1825:8, 1865:15, 1851:20, 1852:10, 1854:17, 1927:21, 1927:22, 1825:8, 1867:22, 1858:10, 1854:17, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15 1807:22, 1825:8, 1846:15, 1846:15, 1840:15, 1	· · ·				1782:3, 1782:6,
1851:6, 1851:7, 1916:2, 1916:4, 1876:25, 1876:25, 1916:11, 1916:17, 1916:18, 1917:1, 1851:20, 1852:1, 1916:18, 1917:20, 1852:19, 1852:24, 1853:4, 1853:5, 1853:22, 1853:23, 1854:6, 1854:11, 1854:15, 1854:17, 1854:25, 1855:14, 1917:21, 1927:22, 1852:20, 1854:6, 1854:17, 1854:25, 1854:17, 1857:21, 1927:22, 1852:20, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1854:22, 1855:1, 1918:4, 1927:22, 1855:20, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1856:17, 1927:22, 1840:15 1878:13, 1780:3, 1780:3, 1780:3, 1854:01, 1854:15, 1854:15, 1854:17, 1927:22, 1855:14, 1927:22, 1856:15, 1840:15, 1854:15, 1858:14, 1927:21, 1927:22, 1840:15					1782:8, 1782:11,
1851:14, 1851:15, 1916:11, 1916:17, 1851:20, 1852:1, 1916:18, 1917:2, 1917:20, 1852:19, 1852:24, 1918:2, 1918:4, 1853:4, 1853:5, 1853:15, 1853:22, 1853:23, 1854:6, 1854:11, 1854:15, 1854:15, 1854:15, 1854:21, 1854:22, 1855:1, 1916:18, 1917:2, 1917:22, 1851:20, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1854:22, 1855:1, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1855:18, 1927:21, 1927:22, 1856:17, 1927:22, 1856:18, 1926:18, 1927:21, 1927:22, 1840:15 1878:17, 1782:21, 1785:18, 1786:15, 1785:18, 1786:15, 1786:15, 1786:15, 1786:17, 1787:1, 1858:18, 1786:15, 1858:17, 1928:17, 1788:1, 1786:15, 1858:17, 1787:21, 1788:1, 1930:6, 1836:11, 1854:15, 1854:17, 1927:21, 1927:22, 1840:15, 1840:12, 1840:15, 1854:14, 1851:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:17, 1927:22, 1856:17, 1927:22, 1840:15, 1840:1					1782:12, 1782:15,
1851:20, 1852:1, 1916:18, 1917:1, 1880:5, 1880:13, 1781:21, 1809:7, 1786:17, 1787:1, 1852:19, 1852:24, 1918:2, 1918:4, 1930:6 1978:7 1853:4, 1853:15, 1921:14, 1921:15, 1853:22, 1853:23, 1854:6, 1854:11, 1854:15, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1854:6, 1854:17, 1927:21, 1927:22, 1856:15, 1809:7, 1781:21, 1809:7, 1786:17, 1787:1, 1788:17, 1788:18, 1978:7 1788:3, 1788:5, 1978:3, 1788:18, 1978:7 1789:20, 1789:3, 1789:17, 1789:20, 1789:21, 1790:5, 1789:21, 1790:5, 1790:14, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15 1840:15 1854:15, 1854:17, 190:21, 1791:4, 1790:21, 1791:4, 1854:15, 1854:17, 1927:21, 1927:22, 1840:15					
1852:6, 1852:7, 1917:2, 1917:20, 1881:4, 1890:2, 1918:2, 1918:4, 1930:6 1978:7 1787:21, 1788:1, 1787:21, 1788:1, 1787:21, 1788:1, 1930:6 1978:7 1853:4, 1853:15, 1921:14, 1921:15, 1853:22, 1853:23, 1921:24, 1922:5, 1854:6, 1854:11, 1854:15, 1854:17, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15 1840:15 1878:7, 1780:3, 1780:3, 1780:3, 1780:3, 1780:3, 1780:3, 1780:3, 1780:3, 1780:3, 1854:10, 1788:10, 1788:18, 1789:3, 1789:15, 1779:13, 1780:3, 1900:13, 1920:25, 1789:17, 1789:20, 1780:17, 1780:17, 1780:18, 178	· · · · · · · · · · · · · · · · · · ·				1785:18, 1786:15,
1852:19, 1852:24, 1918:2, 1918:4, 1930:6 1978:7 1787:21, 1760:17, 1788:3, 1788:5, 1918:310, 1853:15, 1853:22, 1853:23, 1854:6, 1854:11, 1854:15, 1854:15, 1854:22, 1855:1, 1927:21, 1927:22, 1854:6, 1855:1, 1927:21, 1927:22, 1854:6, 1854:17, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15 1854:15, 1854:16, 1854:17, 1927:21, 1927:22, 1840:15 1854:17, 1854:18, 1918:2, 1918:4, 1930:6 1978:7 1978:3, 1788:3, 1788:5, 1788:10, 1788:18, 1789:25, 1789:3, 1789:15, 1789:3, 1789:15, 1799:14, 1952:18, 1952:18, 1952:4, 1960:17, 1960:22 1790:6, 1790:14, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15 1854:17, 1980:8	· · · · · · · · · · · · · · · · · · ·				
1853:4, 1853:5,       1918:12, 1918:17,       knows [1] - 1973:25       large [9] - 1792:25,       1788:10, 1788:18,         1853:10, 1853:15,       1921:14, 1921:15,       Kurabayashi [7] -       1845:5, 1893:21,       1789:3, 1789:15,         1853:22, 1853:23,       1921:24, 1922:5,       1779:13, 1780:3,       1900:13, 1920:25,       1789:17, 1789:20,         1854:16, 1854:17,       1925:18, 1925:20,       1836:15, 1840:12,       1960:17, 1960:22       1790:6, 1790:14,         1854:22, 1855:1,       1927:21, 1927:22,       1840:15       largely [1] - 1980:8       1790:21, 1791:4.					
1853:10, 1853:15, 1921:14, 1921:15, 1853:22, 1853:23, 1921:24, 1922:5, 1854:6, 1854:17, 1854:15, 1854:22, 1855:1, 1927:21, 1927:22, 1854:05, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:15, 1854:22, 1855:1, 1927:22, 1840:15 1845:25, 1893:21, 1789:3, 1789:3, 1789:3, 1789:15, 1789:3, 1789:15, 1789:4, 1789:20, 1789:4, 1789:21, 1790:5, 1789:4, 1789:21, 1790:5, 1789:4, 1789:21, 1790:14, 1790:21, 1791:4, 1790:21, 1791:4, 1790:21, 1791:4, 1790:21, 1791:4, 1790:21, 1791:4, 1789:21, 1790:21, 1791:4, 1789:21, 1790:21, 1791:4, 1789:21, 1790:21, 1791:4, 1789:21, 1789:15, 1788:16, 1788:16, 1788:16, 1788:16, 1788:16, 1788:16, 1788:16, 1788:16, 1788:16, 1788:17, 1789:3, 1788:16, 1789:3, 1789:3, 1789:15, 1789:3, 1789:3, 1789:15, 1789:3, 1789:3, 1789:15, 1789:3,		'			
1853:22, 1853:23,       1921:24, 1922:5,       1779:13, 1780:3,       1900:13, 1920:25,       1789:17, 1789:20,         1854:6, 1854:11,       1923:1, 1923:3,       1836:6, 1836:11,       1952:18, 1953:4,       1789:21, 1790:5,         1854:15, 1854:17,       1925:18, 1925:20,       1836:15, 1840:12,       1960:17, 1960:22       1790:6, 1790:14,         1854:22, 1855:1,       1927:21, 1927:22,       1840:15       largely [1] - 1980:8       1790:21, 1791:4.					
1854:6, 1854:11, 1923:1, 1923:3, 1836:6, 1836:11, 1952:18, 1953:4, 1789:21, 1790:5, 1854:15, 1854:17, 1925:18, 1925:20, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15 1850:18, 1925:26, 1789:17, 1789:20, 1789:21, 1790:5, 1789:21, 1790:5, 1789:21, 1790:5, 1789:20, 1789:21, 1790:5, 1789:21, 1790:5, 1836:15, 1840:12, 1960:17, 1960:22 1790:6, 1790:14, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15 1840:15			•		
1854:15, 1854:17, 1925:18, 1925:20, 1854:22, 1855:1, 1927:21, 1927:22, 1840:15 1860:17, 1960:17, 1960:22 1790:6, 1790:14, 1854:22, 1855:1, 1927:22, 1840:15 1840:15 1860:17, 1960:17, 1960:22 1790:6, 1790:14, 1790:21, 1791:4.					
1854:22, 1855:1, 1927:21, 1927:22, 1840:15   largely [1] - 1980:8 1790:21, 1791:4.					
18 18 18 18 18 18 18 18 18 18 18 18 18 1					
			1040.10	iai geiy [i] - 1800.0	1790:21, 1791:4,
	· ,	·			

				21
1791:9, 1791:13,	1893:7, 1893:13,	1880:6, 1880:14,	1819:15, 1856:16,	limitation [12] -
1791:21, 1792:9,	1893:15, 1893:16,	1881:2, 1881:8,	1996:2	1781:6, 1782:3,
1792:15, 1792:23,	1893:19, 1893:22,	1883:24, 1886:17,	<b>Lepor</b> [1] - 1768:8	1875:25, 1876:16,
1793:6, 1794:17,	1893:25, 1902:18,	1891:13, 1891:19,	less [5] - 1813:19,	1882:20, 1882:25,
1794:21, 1797:12,	1947:22, 1948:1,	1891:23, 1892:5,	1856:6, 1871:5,	1884:13, 1885:1,
1799:21, 1800:15,	1948:7, 1948:9,	1892:11, 1893:13,	1987:24, 1994:2	1885:4, 1885:10,
1801:9, 1801:17,	1950:14, 1950:17,	1893:22, 1950:14,	•	1894:16, 1908:2
			level [23] - 1761:17,	· ·
1801:21, 1802:18,	1950:18, 1951:6,	1950:17, 1950:18,	1769:23, 1794:12,	limitations [6] -
1802:19, 1802:25,	1951:7, 1951:12,	1951:6, 1951:7,	1806:9, 1806:14,	1778:20, 1780:24,
1804:14, 1804:18,	1951:17, 1955:8,	1951:12, 1951:17,	1814:4, 1815:9,	1782:2, 1819:5,
1806:11, 1806:15,	1957:9, 1958:9,	1961:5, 1967:2,	1817:22, 1818:2,	1876:7, 1892:22
1806:22, 1807:1,	1958:17, 1959:24,	1969:1, 1969:10,	1818:17, 1818:18,	limited [3] - 1812:25,
1807:15, 1807:25,	1961:5, 1962:7,	1969:13, 1969:22,	1818:25, 1820:9,	1962:25, 1973:22
1816:22, 1817:2,	1967:2, 1969:1,	1972:1	1845:11, 1845:13,	<b>LIMITED</b> [1] - 1757:5
1817:7, 1817:17,	1969:10, 1969:13,	LDL-lowering [1] -	1845:15, 1859:6,	line [12] - 1770:24,
1818:10, 1818:15,	1969:22, 1972:1,	1893:25	1867:15, 1880:2,	1772:23, 1795:21,
1819:3, 1819:11,	1975:7, 1975:11,	<b>LDLs</b> [2] - 1958:15,	1913:2, 1925:2,	1833:12, 1833:13,
1820:13, 1822:6,	1978:2, 1979:18	1958:16	1941:7, 1968:12	1935:8, 1947:8,
1822:9, 1822:13,	<b>LDL-C</b> [114] - 1769:7,	<b>Le</b> [1] - 1795:10	Levels [2] - 1950:11,	1965:19, 1970:17,
1822:20, 1824:8,	1769:14, 1777:20,	lead [3] - 1863:23,	1974:21	1970:24, 1973:16
1824:19, 1827:8,	1781:23, 1782:3,	1935:15, 1975:7	levels [54] - 1760:13,	lines [9] - 1794:7,
1827:10, 1828:4,	1782:6, 1782:8,	leads [1] - 1989:15	1762:1, 1762:7,	1798:17, 1799:6,
1828:5, 1829:2,	1782:11, 1782:12,	learn [1] - 1799:17	1774:9, 1781:23,	
1829:12, 1829:17,	1782:15, 1782:22,		, ,	1868:23, 1928:13,
1829:23, 1830:1,	1785:15, 1785:18,	least [37] - 1775:12,	1794:17, 1803:5,	1933:7, 1952:11,
	, , , , , , , , , , , , , , , , , , ,	1783:15, 1787:8,	1805:25, 1806:22,	1991:25
1830:2, 1830:8,	1786:15, 1786:17,	1789:1, 1793:17,	1807:15, 1808:22,	links [2] - 1956:18,
1830:13, 1831:8,	1787:21, 1788:1,	1794:13, 1814:9,	1813:13, 1815:12,	1984:19
1831:19, 1832:9,	1788:10, 1788:18,	1821:24, 1855:20,	1816:19, 1818:21,	lipase [2] - 1887:18,
1832:20, 1833:20,	1789:3, 1789:15,	1856:19, 1861:11,	1819:4, 1819:18,	1890:3
1833:21, 1834:12,	1789:17, 1790:5,	1862:4, 1862:11,	1820:15, 1821:11,	<b>Lipid</b> [1] - 1905:5
1834:23, 1835:6,	1790:6, 1790:14,	1862:23, 1863:14,	1821:14, 1823:19,	lipid [29] - 1761:20,
1835:10, 1836:4,	1790:21, 1791:4,	1863:18, 1864:14,	1823:23, 1824:1,	1777:13, 1781:10,
1836:11, 1838:7,	1792:15, 1792:23,	1864:19, 1869:4,	1824:5, 1838:7,	1781:12, 1781:14,
1839:10, 1840:9,	1793:6, 1794:17,	1869:8, 1869:16,	1839:9, 1839:10,	1781:17, 1842:12,
1842:5, 1845:3,	1794:21, 1797:12,	1878:17, 1895:12,	1840:7, 1840:8,	1874:8, 1876:1,
1846:21, 1847:6,	1801:17, 1801:21,	1902:6, 1903:5,	1840:9, 1846:21,	1876:11, 1876:17,
1847:9, 1847:14,	1802:25, 1804:18,	1922:20, 1923:16,	1847:15, 1847:23,	1879:7, 1880:7,
1847:22, 1848:19,	1806:11, 1806:15,	1924:3, 1924:16,	1858:21, 1858:22,	1880:15, 1882:1,
1859:23, 1860:2,	1806:22, 1807:15,	1930:12, 1933:1,	1860:14, 1922:9,	
1860:5, 1861:14,	1807:25, 1816:22,	1933:25, 1939:2,	1950:14, 1950:23,	1882:21, 1882:23,
1863:2, 1863:4,	1817:2, 1817:7,	, ,		1883:3, 1884:2,
1863:12, 1870:16,	1817:17, 1818:10,	1941:15, 1961:15,	1951:6, 1954:15,	1884:15, 1885:2,
1871:1, 1871:3,	1818:15, 1820:13,	1975:13, 1977:14	1955:8, 1957:2,	1885:12, 1885:14,
1871:10, 1871:25,	1822:6, 1822:9,	leave [2] - 1771:20,	1957:3, 1957:9,	1885:21, 1895:17,
		1992:2	1958:2, 1962:7,	1950:13, 1958:2,
1872:4, 1872:23, 1873:15, 1873:21	1822:13, 1822:20,	lecture [1] - 1926:9	1967:2, 1971:21,	1971:19, 1972:9
1873:15, 1873:21,	1824:8, 1828:4,	<b>led</b> [2] - 1789:20,	1972:1, 1972:6,	lipid-altering [17] -
1873:23, 1874:3,	1828:5, 1829:2,	1926:20	1972:10, 1973:17,	1777:13, 1874:8,
1874:12, 1874:17,	1829:17, 1829:23,	left [12] - 1763:16,	1979:18	1876:1, 1876:11,
1875:6, 1876:5,	1830:1, 1830:2,	1772:21, 1775:5,	leverage [1] - 1911:16	1876:17, 1879:7,
1876:13, 1876:18,	1833:21, 1834:23,	1800:10, 1817:11,	library [1] - 1946:12	1880:7, 1880:15,
1876:22, 1879:11,	1842:5, 1845:3,	1835:25, 1947:1,	light [2] - 1768:22,	1882:21, 1882:23,
1879:12, 1879:14,	1860:5, 1870:16,	1951:9, 1952:9,	1930:2	1883:3, 1884:2,
1879:18, 1879:19,	1871:1, 1871:3,	1956:3, 1958:3,	lightly [1] - 1909:9	1884:15, 1885:2,
1879:20, 1880:6,	1871:10, 1871:25,	1971:15	likely [6] - 1806:14,	1885:12, 1885:14,
1880:14, 1881:2,	1872:4, 1872:23,	left-hand [5] -	1818:9, 1860:9,	1885:21
1881:8, 1883:24,	1873:15, 1873:21,	1763:16, 1775:5,	1869:3, 1869:16,	lipid-lowering [1] -
1886:17, 1891:13,	1873:23, 1874:3,		1879:23	1882:1
1891:19, 1891:23,	1874:12, 1874:17,	1947:1, 1952:9,		
1892:5, 1892:7,	1875:6, 1876:5,	1958:3	limit [5] - 1871:6,	<b>Lipids</b> [2] - 1824:19,
1892:8, 1892:11,	1876:13, 1876:18,	leftward [1] - 1772:21	1871:8, 1995:13,	1947:5
1893:3, 1893:5,	1879:11, 1879:18,	legal [4] - 1819:14,	1995:15, 1995:21	<b>lipids</b> [7] - 1825:6,
	, 10, 0. 10,			

**-**22

1825:11, 1825:18,
1827:18, 1865:8,
1897:11, 1947:8
LIPITOR [41] - 1808:2,
1808:3, 1808:9,
1808:12, 1808:14,
1808:17, 1808:21,
1809:4, 1809:8,
1809:10, 1809:16,
1811:1, 1811:22,
1811:25, 1812:24,
1813:6, 1813:7,
1813:10, 1814:1,
1815:9, 1815:24,
1816:12, 1816:14,
1816:17, 1816:20,
1817:11, 1817:23,
1818:1, 1865:17,
1866:15, 1866:24,
1867:1, 1867:6,
1867:8, 1969:17,
1973:1, 1973:6,
1973:11, 1976:5,
1976:6, 1976:7
lipoprotein [4] -
1776:15, 1887:18,
1890:3, 1976:8
lipoproteins [1] -
1975:12
Lipoproteins [1] -
1824:19
list [23] - 1809:6,
1809:16, 1809:17,
1809:20, 1810:2,
1811:25, 1912:8,
1914:14, 1914:17,
1914:24, 1915:8,
1915:13, 1915:18,
1916:8, 1918:9,
1921:25, 1929:4,
1987:8, 1987:17,
1988:2, 1988:18,
1988:20, 1988:23
listed [5] - 1762:15,
1774:4, 1805:9,
1878:4, 1887:22
listen [4] - 1785:16,
1860:3, 1863:11,
1903:2
listening [1] - 1990:24
lists [1] - 1953:15
liter [1] - 1958:6
literally [1] - 1799:20
literature [8] -
1844:22, 1845:4,
1845:14, 1845:19,
1848:5, 1850:6,
1850:15, 1946:14
litigation [1] - 1959:7
live [1] - 1983:7
- [.]

```
1964:15, 1967:10,
local [5] - 1809:25,
 1914:22, 1915:6,
 1915:18
lodging [1] - 1931:5
logic [3] - 1785:7,
 1785:8, 1925:22
logical [1] - 1879:25
long-felt [1] - 1807:8
long-term [1] -
 1906:14
longstanding [1] -
 1926:1
look [59] - 1762:14,
 1770:20, 1770:22,
 1772:6, 1780:17,
 1791:12, 1795:25,
 1796:23, 1797:18,
 1813:6, 1815:7,
 1815:19, 1816:8,
 1816:10, 1829:24,
 1830:1, 1830:16,
 1837:17, 1842:24,
 1848:6, 1856:5,
 1857:9, 1857:12,
 1868:3, 1869:19,
 1889:7, 1898:4,
 1920:17, 1922:14,
 1931:10, 1933:2,
 1947:3, 1947:11,
 1947:20, 1949:11,
 1950:12, 1953:8,
 1953:18, 1954:7,
 1956:4, 1956:13,
 1956:17, 1957:5,
 1964:6, 1967:18,
 1970:5, 1970:16,
 1974:20, 1976:15,
 1977:5, 1979:15,
 1981:16, 1981:17,
 1987:12, 1988:3
looked [16] - 1759:14,
 1762:23, 1766:9,
 1780:12, 1796:19,
 1801:14, 1827:23,
 1866:14, 1869:20,
 1884:13, 1884:17,
 1907:6, 1935:20,
 1953:7, 1966:8,
 1970:12
looking [25] - 1761:8,
 1766:14, 1787:6,
 1787:17, 1791:3,
 1801:18, 1802:11,
 1811:8, 1813:5,
 1817:12, 1844:2,
 1848:5, 1867:25,
 1920:3, 1920:6,
 1920:11, 1955:4,
 1956:14, 1956:21,
 1957:13, 1958:5,
```

1971:15, 1975:24 looks [3] - 1772:23, 1839:23, 1979:25 Lopid [2] - 1802:24, 1803:12 lose [1] - 1896:14 loud [2] - 1884:7, 1884:8 Lovaza [64] - 1779:4, 1785:12, 1785:20, 1785:24, 1786:3, 1786:14, 1786:17, 1787:6, 1787:7, 1787:18, 1788:2, 1789:3, 1789:18, 1790:1, 1801:14, 1801:21, 1802:24, 1804:14, 1806:17, 1817:13, 1817:16, 1817:20, 1817:25, 1821:6, 1821:9, 1821:16, 1822:4, 1822:6, 1822:12, 1822:16, 1833:15, 1833:20, 1849:24, 1871:17, 1871:22, 1871:24, 1872:3, 1872:13, 1872:14, 1872:19, 1872:22, 1873:17, 1874:2, 1874:10, 1874:11, 1874:18, 1874:22, 1875:14, 1890:23, 1891:3, 1891:7, 1891:13, 1891:19, 1891:23, 1892:2, 1892:4, 1892:8, 1892:11, 1892:14, 1892:17, 1893:10, 1948:25, 1957:21, 1963:19 Lovaza's [2] -1786:24, 1893:12 love [2] - 1892:23, 1934:2 loved [1] - 1771:20 low [10] - 1761:6, 1902:13, 1908:15, 1919:17, 1949:9, 1949:12, 1949:17, 1950:15, 1951:7 lower [20] - 1760:13, 1761:15, 1765:21, 1767:7, 1775:14, 1777:17, 1777:20, 1777:22, 1786:12, 1803:23, 1857:11, 1861:1. 1893:2. 1893:16, 1905:7,

1947:4, 1969:4, 1969:22, 1970:20, 1972:1 lowered [4] - 1786:10, 1858:20, 1858:22, 1954:15 lowering [20] -1760:19, 1775:2, 1775:10, 1775:18, 1777:20, 1802:23, 1803:4, 1843:9, 1858:8, 1860:1, 1882:1, 1892:7, 1893:25, 1951:12, 1971:1, 1971:6, 1973:7, 1974:5, 1975:13 lunch [2] - 1941:22, 1943:17

М M.D [2] - 1759:8, 1997:4 Madison [1] - 1758:11 magic [1] - 1765:24 magnitude [3] -1807:1, 1845:9, 1879:12 mail [8] - 1978:10, 1978:12, 1978:15, 1980:11, 1980:16, 1981:3, 1981:6, 1981:10 main [1] - 1936:23 Main [1] - 1864:7 maintain [1] - 1982:3 major [9] - 1901:3, 1901:13, 1902:1, 1905:6, 1906:15, 1906:23 1926:21 1952:5, 1976:8 Major [1] - 1912:13 majority [4] - 1767:3, 1892:13, 1892:16, 1893:21 man [1] - 1926:6 management[1] -1893:18 Managing [1] - 1918:6 managing [1] -1893:19 manifestation [1] -1886:23 manner [1] - 1930:17

manuscript [6] -

1922:14, 1978:18,

1979:14, 1980:7,

1981:14, 1982:6

March [73] - 1762:20,

1764:19, 1764:25, 1765:6, 1765:10, 1769:10, 1770:6, 1779:7, 1786:7, 1807:19, 1808:9, 1808:11, 1809:7, 1809:13, 1811:2, 1811:8, 1811:9, 1812:17, 1821:13, 1821:23, 1822:8, 1822:12, 1822:18, 1823:2, 1823:19, 1823:21, 1824:4, 1827:3, 1829:21, 1829:25, 1830:7, 1831:3, 1831:4, 1831:21, 1833:6, 1848:4. 1850:2. 1850:15, 1851:2, 1856:2, 1856:18, 1859:1, 1860:13, 1860:24, 1873:18, 1874:16, 1874:22, 1875:15, 1876:25, 1878:11, 1879:22, 1881:4, 1882:11, 1883:2, 1891:22, 1897:20, 1898:13, 1898:20, 1901:25, 1902:7, 1918:10, 1922:24, 1924:11, 1955:1, 1956:11, 1966:20, 1989:17, 1989:18, 1989:20, 1989:21, 1990:5, 1993:20 Marine [2] - 1954:5, 1955:14 **MARINE** [27] -1762:10, 1769:6, 1776:13, 1776:17, 1776:22, 1792:19, 1792:24, 1793:2, 1793:6, 1793:18, 1825:6, 1825:11, 1832:13. 1833:7. 1837:24. 1848:19. 1849:16. 1888:18. 1888:20, 1888:24, 1889:4, 1890:15, 1896:20, 1918:24, 1968:24, 1969:12, 1977:24 marked [1] - 1915:10 Market [1] - 1767:12 market [3] - 1973:2, 1974:5, 1974:14 marketing [1] -1911:10 material [2] - 1812:20,

1867:19 materials [9] - 1765:3, 1766:5, 1767:5, 1768:22, 1812:8, 1814:24, 1934:23, 1937:23, 1953:16 math [1] - 1992:7 Mathers [2] - 1983:11, 1983:23 Matsuzawa [6] -1861:25, 1862:13, 1862:25, 1863:16, 1864:11, 1864:19 matter [5] - 1761:1, 1915:14, 1937:5, 1959:19, 1996:23 matters [1] - 1985:17 max [1] - 1977:3 maximal [1] - 1958:23 maximum [1] - 1858:7 MEAGAN[1] -1757:14 mean [30] - 1769:22, 1771:8, 1776:7, 1776:24, 1811:20, 1820:9, 1820:23, 1865:25, 1868:25, 1871:12, 1883:7, 1885:8, 1892:23, 1895:24, 1939:22, 1942:1, 1949:25, 1950:13, 1950:17, 1950:18, 1950:21, 1951:8. 1958:17. 1958:18. 1961:18. 1964:1, 1966:14, 1973:18 means [6] - 1771:10, 1772:25, 1858:17, 1885:4, 1943:7, 1983:4 meant [1] - 1981:9 measurement [1] -1820:16 measurements [2] -1863:7, 1958:5 measuring [1] -1952:23 mechanism [3] -1777:17, 1780:8, 1803:24 Mechanisms [1] -1974.22 mechanisms [3] -1777:23, 1917:11, 1975:1 median [7] - 1791:12, 1814:3, 1814:4, 1817:19 1817:22 1818:2, 1818:5

mediator [1] - 1895:18 mediators [1] -1776:18 Medicaid [2] -1929:10, 1930:4 **Medical** [1] - 1768:8 medical [6] - 1768:16, 1850:6, 1850:15, 1899:22, 1899:24, 1927:16 Medicare [2] -1929:10, 1930:4 medication [4] -1777:12, 1893:14, 1893:23. 1893:25 medications [2] -1802:22, 1860:1 Medicine [2] -1904:19, 1905:23 Medline [2] - 1946:10, 1946:15 meet [1] - 1920:22 Meeting [1] - 1960:12 member [3] - 1926:4, 1926:12, 1926:22 memory [3] - 1837:10, 1898:3, 1923:9 Men [1] - 1824:21 mention [4] - 1782:22. 1790:10, 1849:3, 1961:10 mentioned [5] -1795:23, 1796:18, 1941:4, 1983:10, 1989:25 Merck [1] - 1795:5 merely [1] - 1773:20 Merits [1] - 1961:13 messages [1] -1959:25 met [1] - 1784:11 metabolic [2] -1775:15, 1776:14 metabolism [1] -1842:13 metadata [1] - 1831:1 Method [1] - 1946:6 method [9] - 1774:24, 1775:20, 1785:13, 1785:21, 1821:9, 1880:5, 1884:3, 1891:4, 1895:5 Methods [3] -1839:19, 1839:21, 1839:24 MICHAEL [2] -1757:14, 1758:12 micrograms [4] -

1761:18, 1761:22,

1762:8, 1762:9

mid [1] - 1977:3 middle [6] - 1841:9, 1848:23, 1938:5, 1952:12, 1960:4, 1960.6 might [13] - 1839:9, 1839:13, 1840:8, 1850:20, 1850:25, 1857:18, 1865:20, 1871:12, 1878:1, 1893:4, 1893:16, 1938:16, 1992:24 Mildly [1] - 1824:20 milligrams [22] -1765:8, 1794:13, 1805:5, 1816:14, 1816:15, 1816:19, 1816:24, 1817:4, 1834:3, 1867:15, 1877:8, 1902:14, 1922:10, 1923:17, 1957:4, 1958:7, 1961:3, 1961:4, 1976:20, 1977:7 milliliter [4] - 1761:18, 1761:22, 1762:8, 1762:9 millimoles [1] -1958:6 million [1] - 1930:16 mimic [2] - 1764:5, 1764:11 mind [1] - 1995:14 mindset 131 - 1982:16. 1982:18. 1982:20 mine [1] - 1920:10 Mineral [1] - 1909:23 minimum [3] -1823:13, 1919:25, 1932:25 minor [1] - 1978:21 minority [2] - 1767:3, 1767:4 minus [5] - 1976:23, 1976:25, 1977:7, 1977:8 Miracle [1] - 1904:19 MIRANDA [1] - 1757:2 mischaracterize [2] -1838:14, 1840:15 mischaracterized [2] -1836:15, 1840:18 mischaracterizing [2] - 1834:14, 1911:23 misheard [1] -1881:20 misrepresent [1] -1832:22 Miss [1] - 1995:10 missed [2] - 1834:18,

1963:4 missing [2] - 1863:5, 1869:22 mixed [4] - 1888:16, 1951:8, 1990:14, 1990:18 mixing [1] - 1866:17 mixture [5] - 1785:13, 1785:20, 1786:1, 1786:2. 1821:15 Mochida [2] -1900:20, 1900:22 mode [1] - 1874:9 moderate [1] - 1840:1 moderately [1] -1840:7 modest [1] - 1975:13 modestly [2] -1971:20, 1971:22 moment [6] - 1783:10, 1787:3, 1789:23, 1933:19, 1971:13, 1977:16 momentarily [1] -1970:3 Monday [1] - 1986:25 monitor [1] - 1975:25 monotherapy [3] -1897:5, 1897:8, 1917:17 month [1] - 1993:20 months [10] - 1776:13, 1776:22, 1877:10, 1895:21, 1895:23, 1896:2, 1896:7, 1896:11, 1896:13 Mori [77] - 1788:7, 1788:10, 1788:13, 1788:18, 1788:23, 1789:1, 1791:3, 1800:13, 1800:14, 1800:17, 1824:15, 1824:18, 1824:23, 1825:8. 1825:17. 1826:5, 1826:12, 1826:20, 1827:8, 1827:20, 1827:25, 1828:3, 1828:8, 1828:13, 1828:19, 1829:2, 1829:3, 1829:6, 1829:11, 1829:16, 1829:22, 1830:1, 1830:8, 1830:12, 1831:7, 1831:8. 1831:13. 1831:22, 1832:15, 1832:19, 1832:22, 1835:20, 1835:24, 1836:3, 1836:15, 1838:12, 1838:14,

1839:1. 1841:11. 1841:23, 1842:4, 1842:9, 1842:15, 1842:20, 1842:21, 1843:7, 1843:13, 1843:14, 1843:17, 1843:25, 1844:2, 1845:24, 1846:17, 1847:8, 1847:16, 1847:22, 1847:25, 1848:1, 1848:7, 1851:8, 1855:21, 1881:16, 1881:23, 1882:1 Mori's [1] - 1844:3 morning [7] - 1759:3, 1759:4, 1759:5, 1784:8, 1784:9, 1853:13, 1853:17 mortality [1] - 1773:9 most [11] - 1771:19, 1776:14, 1791:11, 1808:6, 1857:7, 1857:24, 1858:1, 1888:1, 1951:7, 1955:19, 1991:10 motion [2] - 1984:13, 1985.7 motivated [8] -1805:13, 1805:18, 1822:9, 1822:19, 1856:19, 1856:23, 1860:25, 1903:14 move [31] - 1765:13, 1767:15, 1795:25, 1796:22, 1798:11, 1809:8, 1809:12, 1811:5, 1821:3, 1821:5, 1840:19, 1851:20, 1852:19, 1854:6. 1854:22. 1873:9. 1910:22. 1914:12, 1916:12, 1917:20, 1918:12, 1922:1, 1927:24, 1928:9, 1933:15, 1974:17, 1983:8, 1983:13, 1983:17, 1984:4, 1984:25 moved [1] - 1984:7 moving [4] - 1797:2, 1810:3, 1812:1, 1984:9 MR [510] - 1759:4, 1759:6, 1759:11, 1759:15, 1759:16, 1760:5, 1760:8, 1762:14, 1762:17, 1763:4. 1763:8. 1763:15, 1763:18,

1784-121, 1784-122, 1786-136, 1866-146, 1866-166, 1866-156, 1866-146, 1866-166, 1866-156, 1866-146, 1866-146, 1866-156, 1866-1466-1466-1466-1466-1466-1466-1466-	1764:01 1764:00				24
1765:13, 1765:15, 1766:2, 1277, 1827:12, 1889:10, 1889:2, 1890:1, 1995:20, 1995:21, 1995:12, 1995:12, 1996:3, 1766:14, 1767:15, 1767:15, 1767:18, 1261:0, 1830:16, 1831:24, 1890:16, 1900:19, 1900:18, 1900:19, 1907:21, 1767:24, 1767:24, 1767:24, 1769:3, 1322:2, 1833:2, 1830:2, 1800:18, 1900:18, 1900:24, 1997:19, 1998:19, 1998:16, 1998:3, 1998:17, 1998:19, 1998:17, 1998:19	1/04.21. 1/04.22.	1826:4, 1826:9.	1889:9. 1889:12.	1945:17, 1945:18,	1995:6, 1995:7.
1765.18, 1766.2   1827.7, 1827.12   1890.10, 1894.3, 1994.6.7, 1946.7, 1946.7, 1967.15, 1767.15, 1767.15, 1767.21, 1767.24, 180.19, 1832.05, 1830.16, 1897.15, 1899.15, 1999.21, 1940.62, 1946.24, 1946.24, 1946.24, 1946.24, 1946.24, 1946.24, 1946.24, 1946.24, 1946.24, 1946.24, 1946.24, 1946.24, 1946.24, 1946.24, 1946.25, 1946.24, 1949.65, 1947.17.170.10, 1770.10, 1770.14, 1833.20, 1836.18, 1900.11, 1900.16, 1900.14, 1900.24, 1949.2, 1949.6, 1949.11, 1949.11, 1949.11, 1770.20, 1777.11, 1774.13, 1772.17, 1774.1774.3, 1832.0, 1836.18, 1901.13, 1900.12, 1901.13, 1900.12, 1901.13, 1900.18, 1905.13, 1906.18, 1905.13, 1906.18, 1905.13, 1906.18, 1906.190.18, 1906.190.18, 1906.190.18, 1906.190.18, 1906.190.18, 1906.190.18, 1906.190.18, 1906.190.18, 1906.190.18, 1906.190.18, 1906.190.190.18, 1906.190.190.18, 1906.190.190.18, 1906.190.190.18, 1906.190.190.18, 1906.190.190.18, 1906.190.190.18, 1906.190.190.18, 1906.190.190.18, 1906.190.190.18, 1906.190.190.18, 1906.190.190.190.190.190.190.190.190.190.190				· · · · · · · · · · · · · · · · · · ·	
1766.4, 1767-16, 1767-18, 1767-18, 1767-17, 1767-18, 1767-17, 1767-18, 1767-17, 1767-18, 1767-17, 1767-18, 1767-17, 1767-18, 1767-17, 1767-18, 17			·		
1767-21, 7767-18,   1820-10, 1830-16,   1897-15, 1809-15,   1906-23, 1946-24,   1767-24,   1768-24,   1868-25,   1868-16,   1907-1, 1908-16,   1908-16,   1908-16,   1908-16,   1908-16,   1908-17,				· ·	
1767.21, 1767.24,   1830.19, 1831.24,   1890.16, 1900.18,   1907.22, 1947.24,   1849.2, 1849.6,   1859.2, 1832.2, 1832.2,   1800.11, 1900.18,   1909.24,   1949.2, 1949.6,   1989.11, 1949.16,   1983.18, 1977.14, 1772.17,   1774.3,   1839.5, 1839.15,   1839.15,   1839.15,   1839.15,   1839.17,   1839.18,   1839.18,   1839.23, 1840.3,   1806.9, 1908.18,   1952.2, 1952.1,   1955.2, 1952.1,   1955.2,   195			· · · · ·		
17861. 17863.   18322. 18332.   1800:11. 1900:16.   19492. 1949.6.   1839:16. 1848.1.   1770:10.   1770:14.   1834:20. 1836:18.   1800:11. 1900:18.   1950:6. 1950.8.   1839:7. 1839:5. 1839:5.   1839:5. 1839:5.   1839:5. 1839:5.   1839:7. 1839:19.   1800.8.   1800:18.   1951:2. 1951:23.   1964:2. 1962:2.   1962:2.			· · · · · · · · · · · · · · · · · · ·		
1770:10, 1770:14, 1783:33, 1834:17, 1900:18, 1900:24, 1904:11, 1909:16, 1905:06, 1905:06, 1905:06, 1905:06, 1905:06, 1905:06, 1905:06, 1905:06, 1905:06, 1905:06, 1905:07, 1905:17, 1774:1, 1774:3, 1839:25, 1839:15, 1839:17, 1839:15, 1839:17, 1839:15, 1839:17, 1839:15, 1839:17, 1839:19, 1839:17, 1839:19, 1839:23, 1804:3, 1905:20, 1907:5, 1954:9, 1954:21, 1955:20, 1958:20, 1968:22, 1782:24, 1782:23, 1804:19, 1804:20, 1907:7, 1905:5, 1954:9, 1954:19, 1954:21, 1990:6, 1990:22, 1782:24, 1782:23, 1804:13, 1906:1, 1900:14, 1905:10, 1907:12, 1995:10, 1907:12, 1990:1892:24, 1783:18, 1783:19, 1784:3, 1844:18, 1842:19, 1909:16, 1910:11, 1905:11, 1959:13,		· ·			
1770.20, 1771-1,   1834-20, 1336-18,   1901-11, 1901-12,   1950-6, 1950-8,   1964-7, 1964-10,   1964-7, 1964-10,   1964-7, 1964-10,   1964-7, 1964-10,   1964-7, 1964-10,   1964-7, 1964-10,   1964-7, 1964-10,   1964-7, 1964-10,   1964-7, 1964-10,   1964-7, 1964-7,   1964-7			· · · · · · · · · · · · · · · · · · ·	•	
1772-14, 1772-17, 1836-20, 1839-1, 1901-9, 1904-12, 1961-1, 1961-12, 1961-12, 1961-12, 1961-1774-1774-3, 1839-1839-18, 1839-1839-18, 1906-18, 1906-18, 1962-1, 1961-12, 1961-12, 1962-1, 1962					
1774:1, 1774:2, 1839:5, 1839:15, 1904:13, 1906:6, 1952:10, 1951:20, 1951:23, 1779:24, 1781:24, 1839:23, 1840:3, 1906:20, 1907:5, 1956:5, 1954:19, 1954:21, 1956:210, 1957:12, 1782:24, 1782:24, 1782:24, 1782:24, 1782:24, 1782:24, 1782:24, 1782:24, 1782:24, 1782:24, 1783:9, 1841:15, 1841:16, 1906:7, 1906:5, 1957:10, 1957:12, 1956:17, 1957:12, 1957:10, 1957:12, 1957:10, 1957:12, 1955:17, 1957:17, 1957:12, 1959:11, 1959:13, 1959:14, 195			· · · · ·		
1779:21, 1779:23,   1339:17, 1839:19,   1906.9, 1906:18,   1952:10,   1952:10,   1952:12,   1782:24, 1782:23,   1840:19, 1840:20,   1907.7, 1908.5,   1954:19, 1954:12,   1995:5, 1996:18,   1952:24, 1783:12, 1783:12, 1783:17, 1783:17, 1783:17, 1783:17, 1783:17, 1783:18, 1783:19,   1842:18, 1842:19,   1909:11, 1909:14,   1957:24, 1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1958:4,   1959:13,   1959:11,   1959			· · · · ·		
1779.24, 1781.24,   1839.23, 1840.3,   1906.20, 1907.5,   1954.9, 1954.12,   1952.3, 1782.24, 1783.9,   1841.15, 1841.16,   1908.7, 1908.5,   1954.19, 1954.21,   1957.10, 1957.12,   1957.10, 1957.2,   1957.10, 1957.2,   1957.2, 1957.2,   1957.3,   1957.10, 1957.2,   1957.2,   1957.2,   1957.2,   1957.2,   1957.3,   1957.10, 1957.2,   1957.3,   1957.1,   1957.2,   1957.3,   1957.1,   1957.2,   1957.2,   1957.3,   1957.1,   1957.2,   1957.2,   1957.3,   1957.1,   1957.2,   1957.3,   1957.1,   1957.2,   1957.3,   1957.1,   1957.2,   1957.3,   1957.1,   1957.2,   1957.3,   1957.1,   1957.2,   1957.3,   1957.1,   1957.2,   1957.3,   1957.1,   1957.2,   1957.2,   1957.3,   1957.3,   1957.3,   1957.3,			·		
1782-1, 1782-23,   1240-19, 1840-20,   1907-7, 1908-5,   1954-19, 1957-12,   1957-12,   1957-13,   1957-12,   1957-13,			, , ,		
1782.24, 1783.9, 1841.16, 1841.16, 1783.17, 1783.18, 1783.19, 1842.2, 1842.3, 1909.1, 1909.14, 1957.24, 1958.4, 1958.4, 1783.19, 1783.25, 1784.3, 1844.6, 1844.8, 1910.13, 1910.22, 1959.11, 1959.13, 1959.13, 1959.13, 1842.10, 1828.9, 1848.6, 1846.8, 1840.8, 1910.25, 1911.1, 1900.15, 1911.1, 1900.15, 1911.1, 1900.15, 1911.1, 1900.15, 1911.1, 1900.17, 1900.1, 1900.1, 1842.1, 1847.18, 1847.19, 1847.18, 1847.18, 1849.19, 1849.18, 1849.19, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.18, 1849.11, 1849.1			·		
1783-12, 1783-17,   1842; 1842; 1   1909:16, 1910:11,   1959:4, 1959:8,   1842; 18, 1842; 19,   1909:16, 1910:11,   1959:4, 1959:8,   1844; 1844; 1844; 1910:13, 1910:22,   1959:11, 1959:13,   1844; 1844; 1847; 18, 1847; 19, 1844; 1962; 17, 1962; 14, 1962; 17, 1963; 18, 1965					
1783-18, 1783-19,   1842-18, 1842-19,   1900-16, 1910-11,   1959-4, 1959-8,   1959-13, 178-15, 178-45, 178-46,   1846-6, 1846-8,   1910-25, 1911-1,   1901-12, 1959-11, 1959-13, 1959-13,   1846-18, 1847-18, 1847-18, 1847-18, 1847-18, 1847-18, 1847-18, 1847-18, 1847-18, 1847-18, 1847-18, 1847-18, 1847-18, 1847-19, 1841-18, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1851-14, 1861-15,   1911-14, 1911-13,   1963-13, 1963-17,   1895-22, 1795-11, 1795-17,   1851-6, 1851-23,   1911-11, 1914-13,   1965-18, 1965-12,   1965-18, 1965-22,   1959-17, 1970-1,   1970-11, 1970-1, 1970-11, 1970-1,   1852-1, 1852-2, 1852-24,   1915-12, 1916-2,   1959-17, 1970-1,   1970-17, 1977-8, 1797-27,   1853-10, 1853-15,   1916-18, 1917-2,   1917-2, 1918-2,   1972-21, 1970-2,   1970-28, 1799-2,   1854-17, 1854-22,   1851-14, 1864-15,   1918-18, 1918-12,   1972-19, 1970-21, 1970-2,   1970-28, 1799-20,   1854-17, 1854-22,   1851-14, 1864-15,   1861-15, 1861-16,   1855-9, 1855-11,   1912-14, 1922-1, 1918-12,   1970-12, 1970-13,   1800-16, 1860-19,   1860-16, 1860-19,   1862-20, 1927-21,   1970-22, 1970-14,   1810-12,   1810-12,   1861-15, 1861-16,   1811-20, 1811-24,   1864-18, 1877-12,   1870-22, 1864-13, 1814-14,   1811-15,   1814-14,   1817-19,   1877-18, 1877-12,   1870-21, 1870-22,   1930-20, 1933-6,   1930-19,		·			• • •
1782.25, 1784.5, 1784.6, 1846.8, 1846		· · ·			· · · · ·
1784-5, 1784-6,   1846-6, 1846-8,   1910-25, 1911-1,   1960-1, 1960-5,   1847-18, 1847-19,   1911-14, 1911-12,   1961-12, 1961-14, 1962-14, 1962-17,   1848-18, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1848-19, 1851-14, 1851-15, 1851-15, 1851-15, 1851-15, 1851-15, 1851-15, 1851-17, 1851-13, 1851-12, 1852-19, 1962-1,		· ·			
1784:8, 1784:11,   1847:18, 1847:19,   1911:4, 1911:7,   1961:12, 1961:14,   1884:16,   1786:17, 1793:9,   1851:6, 1851:7,   1911:11, 1913:10,   1963:13, 1963:17,   1865:17, 1851:14, 1851:23,   1913:13, 1913:16,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1963:13, 1963:17,   1863:23, 1863:24,   1863:23,   1914:22, 1915:4,   1916:1,   1967:2, 1976:4,   1977:1, 1977:1,   1977:1, 1977:1,   1977:1, 1977:1,   1977:1, 1977:2,   1976:4, 1797:7,   1853:4, 1853:15,   1853:10, 1853:15,   1853:10, 1853:15,   1853:10, 1853:15,   1854:13, 1854:15,   1854:13, 1854:15,   1854:13, 1854:15,   1854:24,   1854:24,   1854:22,   1853:23,   1917:2, 1917:20,   1917:2,   1917:20,   1917:2,   1917:20,   1917:2,   1917:20,   1917:2,   1917:20,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:2,   1917:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:3,   1977:1,   1977:16,			· · · · · · · · · · · · · · · · · · ·		
1784:14, 1784:18,   1848:9, 1848:10,   1911:14, 1912:7,   1962:14, 1962:17,   1962:14, 1962:17,   1963:13, 1963:17,   1963:24, 1794:22,   1851:14, 1851:15,   1913:13, 1913:16,   1964:9, 1964:1, 1965:02,   1850:23,   1851:14, 1851:15,   1913:13, 1913:16,   1964:9, 1964:1, 1965:02,   1950:23, 1865:26,   1915:12, 1916:2,   1916:4, 1916:11,   1966:18, 1966:22,   1950:23, 1966:3, 1966:17, 1970:1,   1970:2, 1970:8,   1970:21, 1970:1,   1970:2, 1970:8,   1970:2, 1970:8,   1970:2, 1970:8,   1970:2, 1970:8,   1970:2, 1970:8,   1970:2, 1970:9,   1970:2,   1970:9,   1970:2,   1970:9,   1970:2,   1970:9,   1970:2,   1970:9,   1970:2,   1970:9,   1970:2,   1970:9,   19					· '
1788.17, 1793.29,   1851.14, 1851.15,   1913.13, 1913.16,   1963.13, 1963.17,   1994.22,   1795.17,   1795.17,   1851.24, 1851.29,   1851.24,   1851.29,   1851.24,   1852.24,   1852.24,   1852.24,   1852.24,   1852.24,   1852.24,   1916.24,   1916.22,   1970.24,   1796.14,   1797.7,   1853.44,   1853.25,   1853.15,   1853.15,   1853.16,		·	′		, , , , , , , , , , , , , , , , , , , ,
1793:10, 1793:23, 1851:14, 1851:15, 1851:20, 1851:23, 1914:11, 1914:13, 1916:18, 1965:18, 1965:18, 1965:22, 1795:1, 1795:17, 1795:17, 1795:17, 1795:17, 1796:10, 1852:1, 1852:24, 1916:24, 1916:11, 1916:12, 1916:22, 1852:24, 1853:5, 1916:13, 1916:17, 1970:19, 1970:21, 1970:8, 1797:24, 1798:4, 1797:24, 1798:4, 1853:510, 1853:15, 1916:18, 1917:1, 1971:11, 1971:11, 1971:11, 1971:11, 1971:11, 1971:12, 1917:22, 1798:4, 1798:4, 1853:52, 1853:23, 1917:2, 1917:20, 1918:2, 1972:21, 1973:3, 1917:22, 1918:2, 1972:21, 1973:3, 1917:22, 1918:2, 1972:21, 1973:3, 1917:22, 1918:2, 1972:21, 1973:3, 1917:22, 1918:17, 1973:10, 1973:20, 1974:3, 1852:18, 1854:12, 1854:15, 1858:14, 1854:15, 1918:14, 1918:17, 1973:20, 1974:3, 1852:25, 1853:17, 1859:23, 1859:11, 1921:24, 1922:2, 1975:2, 1976:1, 1859:23, 1800:1, 1855:11, 1858:2, 1858:3, 1923:3, 1925:18, 1975:22, 1976:1, 1800:15, 1800:15, 1858:2, 1858:3, 1923:3, 1925:18, 1977:18, 1977:22, 1978:4, 1813:2, 1813:4, 1866:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:2, 1867:10, 1867:11, 1870:22, 1813:23, 1814:4, 1814:14, 1814:14, 1814:14, 1814:14, 1814:14, 1814:14, 1814:14, 1814:14, 1814:14, 1814:14, 1814:16, 1870:21, 1875:5, 1936:1, 1930:10, 1930:10, 1930:10, 1930:10, 1836:1, 1866:1, 1866:1, 1865:1, 1873:3, 1873:5, 1936:1, 1930:10, 1930:10, 1930:20, 1933:6, 1930:10, 1836:1, 1866:1, 1866:2, 1864:24, 1930:10, 1930		· · · · · ·		· · · · · · · · · · · · · · · · · · ·	· '
1793:24, 1794:22,   1851:20, 1851:23,   1914:11, 1914:13,   1965:18, 1965:22,   1850:23   1850			· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	1895:22
1795-1, 1796-10,   1852-1, 1852-19,   1915-12, 1916-2,   1969-17, 1970-1,   1970-19, 1970-2,   1969-17, 1970-1,   1970-19, 1970-2,   1970-18, 1970-2, 1978-3, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2,   1970-2, 1970-2, 1970-2,   1970-2, 1970-2	· · · · · · · · · · · · · · · · · · ·	, , ,			•
1796:6, 1796:10,   1852:7, 1852:19,   1915:12, 1916:2,   1969:17, 1970:1,   1796:11, 1796:12,   1852:24,   1853:4,   1853:4,   1853:4,   1853:5,   1916:13, 1916:17,   1970:19, 1970:21,   1870:21,   1853:4,   1853:5,   1916:13, 1917:2,   1917:20,   1970:11,   1970:11,   1970:11,   1970:12,   1970:21,   1970:12,   1970:21,   197	1793:24, 1794:22,		1914:11, 1914:13,	1965:18, 1965:22,	1850:23
1796:11, 1796:12, 1852:21, 1852:24, 1916:4, 1916:11, 1970:2, 1970:8, 1970:19, 1970:21, 1853:4, 1853:5, 1916:18, 1916:17, 1971:14, 1971:14, 1971:14, 1853:16, 1853:15, 1916:18, 1917:1, 1971:1971:14, 1971:14, 1853:16, 1853:13, 1916:12, 1917:20, 1972:16, 1972:19, 1972:16, 1972:19, 1798:6, 1798:44, 1854:6, 1854:8, 1917:2, 1918:2, 1972:2, 1973:3, 1798:6, 1798:2, 1799:2, 1854:17, 1854:22, 1918:14, 1918:17, 1973:5, 1973:10, 1861:25, 1862:13, 1862:25, 1863:17, 1798:23, 1799:2, 1854:17, 1854:22, 1918:14, 1918:17, 1973:20, 1974:3, 1877:6, 1877:8, 1799:23, 1800:1, 1855:9, 1855:11, 1921:24, 1922:2, 1976:1, 1809:15, 1809:15, 1809:15, 1809:15, 1809:15, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1809:15, 1810:13, 1800:16, 1800:19, 1925:20, 1927:21, 1978:2, 1979:24, 1810:12, 1811:22, 1867:10, 1867:11, 1930:10, 1930:19, 1900:14, 1980:17, 1980:19, 1980	1795:1, 1795:17,	1852:1, 1852:6,	1914:22, 1915:4,	1967:23, 1968:2,	myriad [1] - 1858:23
1796:14, 1797.7, 1853:4, 1853:5, 1916:13, 1916:17, 1970:19, 1970:21, 1797:8, 1797:21, 1853:10, 1853:15, 1916:18, 1917:1, 1971:14, 1971:14, 1797:24, 1798:4, 1798:4, 1798:4, 1853:22, 1853:23, 1800:1, 1854:14, 1854:16, 1814:16, 1814:16, 1814:16, 1814:16, 1815:15, 1815:1, 1815:5, 1867:17, 1833:1, 1875:1, 1875:17, 1814:9, 1816:14, 1815:0, 1816:14, 1815:0, 1816:15, 1815:5, 1877:18, 1815:7, 1816:22, 1816:41, 1817:13, 1876:1, 1877:12, 1875:1, 1875:1, 1815:5, 1816:2, 1816:3, 1877:19, 1877:2, 1935:2, 1930:2	1796:6, 1796:10,	1852:7, 1852:19,	1915:12, 1916:2,	1969:17, 1970:1,	
1797:8, 1797:21,   1853:10, 1853:15,   1916:18, 1917:1,   1971:11, 1971:14,   1971:14,   1978:14,   1853:22, 1853:23,   1917:2, 1917:20,   1972:16, 1972:16, 1972:19,   1854:11, 1854:15,   1918:4, 1918:12,   1973:5, 1973:10,   1854:21, 1854:17, 1854:22,   1918:4, 1918:12,   1973:5, 1973:10,   1877:6, 1877:8,   1799:20, 1799:10,   1854:24, 1855:1,   1921:14, 1921:15,   1974:17, 1974:18,   1877:19, 1878:8,   1799:23, 1800:1,   1855:29, 1855:11,   1921:24, 1922:2,   1975:2, 1976:1,   1877:2, 1877:19,   1858:2, 1858:3,   1923:3, 1925:18,   1976:3, 1977:16,   1877:22, 1918:4,   1978:2, 1976:1,   1976:3, 1977:22, 1918:14,   1809:15,   1858:2, 1858:3,   1923:3, 1925:18,   1977:18, 1977:22, 1978:14,   1809:15,   1858:2, 1858:3,   1923:3, 1925:18,   1977:18, 1977:22, 1978:14,   1809:15,   1809:15, 1811:24,   1864:3, 1864:4,   1928:19,   1928:19,   1979:5, 1979:7,   1811:20, 1811:24,   1864:24,   1864:24,   1928:09, 1930:9,   1809:25, 1813:3,   1870:7, 1870:9,   1930:10, 1930:19,   1980:14, 1980:23,   1981:2, 1981:3,   1871:4, 1871:15,   1875:17,   1875:17,   1875:17,   1936:19, 1936:21,   1988:14, 1988:14, 1899:23,   1875:1, 1875:17,   1939:4,   1939:20,   1886:21, 1886:22,   1875:3, 1825:4,   1822:2,   1879:5, 1883:11,   1842:14, 1822:2,   1879:5, 1883:11,   1842:14, 1822:2,   1879:5, 1883:11,   1842:14, 1822:2,   1879:5, 1878:3,   1839:10,   1879:10, 1879:2,   1899:23,   1824:13,   1842:2,   1879:5, 1878:5,   1939:15, 1939:20,   1988:17, 1989:13,   1989:23,   1860:23, 1836:2,   1822:3, 1823:3,   1822:2,   1879:5, 1883:11,   1940:5, 1940:7,   1999:11, 1992:15,   1982:11, 1992:23,   1994:16, 1994:22,   1935:8,   1994:16, 1994:22,   1935:18,   1994:16, 1994:22,   1935:18,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 19	1796:11, 1796:12,	1852:21, 1852:24,	1916:4, 1916:11,	1970:2, 1970:8,	N
1797:24, 1798:4, 1853:22, 1853:23, 1917:2, 1917:20, 1972:16, 1972:19, 1854:11, 1854:16, 1854:8, 1917:22, 1918:2, 1972:21, 1973:3, 1862:25, 1862:13, 1798:26, 1799:20, 1854:17, 1854:22, 1918:14, 1918:17, 1973:20, 1974:3, 1799:2, 1854:17, 1854:22, 1918:14, 1918:17, 1973:20, 1974:3, 1877:6, 1877:8, 1877:9, 1854:24, 1855:1, 1921:14, 1921:15, 1974:17, 1974:18, 1877:19, 1878:8, 1799:23, 1800:1, 1855:9, 1855:11, 1921:24, 1922:2, 1975:22, 1976:1, 1877:19, 1878:8, 1877:19, 1800:8, 1809:1, 1809:15, 1855:19, 1857:19, 1922:5, 1923:1, 1975:32, 1977:16, 1877:19, 1878:8, 1877:19, 1809:15, 1809:15, 1860:16, 1860:19, 1925:20, 1927:21, 1978:9, 1977:11, 1879:11, 1809:25, 1811:16, 1864:3, 1864:4, 1928:11, 1928:19, 1979:22, 1979:24, 1861:10, 1867:14, 1870:22, 1864:24, 1928:20, 1909:9, 1980:14, 1980:17, 1980:19, 1980:12, 1981:2, 1981:16, 1811:22, 1813:2, 1813:4, 1868:20, 1868:21, 1930:20, 1933:6, 1981:2, 1981:23, 1814:14, 1814:14, 1814:16, 1870:21, 1870:22, 1933:19, 1933:22, 1982:23, 1983:2, 1814:16, 1872:10, 1872:12, 1936:7, 1936:15, 1988:13, 1985:24, 1865:10, 1875:1, 1875:17, 1938:4, 1939:4, 1816:11, 1817:9, 1875:17, 1875:17, 1876:18, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 1876:10, 187	1796:14, 1797:7,	1853:4, 1853:5,	1916:13, 1916:17,	1970:19, 1970:21,	
1798:6, 1798:14, 1854:6, 1854:8, 1917:22, 1918:2, 1972:21, 1973:3, 1861:25, 1862:13, 1798:16, 1798:20, 1854:11, 1854:15, 1918:4, 1918:12, 1973:5, 1973:10, 1862:25, 1863:17, 1798:23, 1799:2, 1854:17, 1854:22, 1918:14, 1918:17, 1974:15, 1974:17, 1974:18, 1877:6, 1877:8, 1879:23, 1800:1, 1855:9, 1855:11, 1921:24, 1922:2, 1975:22, 1976:1, 1800:8, 1809:1, 1809:15, 1858:2, 1858:3, 1923:3, 1925:18, 1977:16, 1877:19, 1878:8, 1925:20, 1927:21, 1976:3, 1977:16, 1878:14, 1809:25, 1810:13, 1860:16, 1860:19, 1925:20, 1927:21, 1978:9, 1978:11, 1809:15, 1861:15, 1861:16, 1861:16, 1927:22, 1928:8, 1979:5, 1979:7, 1918:11, 1928:19, 1979:22, 1979:24, 1811:20, 1811:22, 1864:22, 1864:24, 1928:20, 1930:9, 1980:14, 1980:17, 1967:9, 1933:14, 1931:14, 1871:14, 1871:15, 1870:22, 1933:14, 1931:22, 1813:23, 1870:7, 1870:9, 1933:14, 1931:22, 1813:23, 1870:7, 1870:22, 1933:14, 1931:24, 1981:24, 1864:12, 1871:14, 1871:15, 1875:17, 1875:17, 1875:17, 1875:17, 1875:18, 1873:3, 1873:5, 1936:19, 1938:21, 1988:74, 1988:11, 1988:11, 1988:11, 1988:11, 1988:11, 1988:11, 1988:11, 1988:11, 1988:21, 1989:23, 1816:10, 1819:20, 1821:3, 1875:18, 1877:3, 1939:6, 1939:10, 1988:7, 1988:11, 1989:11, 1820:21, 1870:2, 1877:5, 1878:5, 1939:15, 1939:20, 1988:17, 1989:11, 1806:23, 1851:7, 1822:3, 1823:7, 1823:3, 1824:4, 1825:2, 1825:2, 1884:23, 1824:4, 1825:2, 1825:2, 1885:24, 1886:2, 1885:4, 1825:2, 1825:14, 1885:24, 1886:2, 1887:4, 1825:2, 1825:21, 1885:14, 1885:14, 1887:11, 1879:14, 1879:14, 1884:12, 1844:16, 1844:16, 1879:2, 1879:5, 1883:11, 1940:5, 1940:7, 1909:19, 1991:23, 1816:10, 1818:6, 1863:14, 1844:16, 1879:2, 1879:5, 1883:11, 1940:5, 1940:7, 1990:19, 1991:24, 1860:10, 1885:7, 1860:20, 1860:10, 1885:7, 1860:20, 1860:1	1797:8, 1797:21,	1853:10, 1853:15,	1916:18, 1917:1,	1971:11, 1971:14,	<b>n-3</b> [1] - 1825:5
1798:16, 1798:20, 1854:11, 1854:15, 1918:4, 1918:12, 1973:5, 1973:10, 1862:25, 1863:17, 1799:23, 1799:2, 1854:17, 1854:22, 1918:14, 1918:17, 1974:3, 1877:6, 1877:8, 1877:8, 1877:8, 1877:9, 1875:8, 1859:185:11, 1921:14, 1921:15, 1974:17, 1974:18, 1877:19, 1878:8, 1809:11, 1809:10, 1865:21, 1857:19, 1922:5, 1923:1, 1976:3, 1977:16, 1877:10, 1878:8, 1809:15, 1868:2, 1858:3, 1923:3, 1925:18, 1977:18, 1977:22, 1978:13, 1809:25, 1810:13, 1860:16, 1860:19, 1925:20, 1927:21, 1978:8, 1979:5, 1979:7, 1810:25, 1811:16, 1864:3, 1864:4, 1928:11, 1928:19, 1979:5, 1979:7, 1811:20, 1811:22, 1867:10, 1867:11, 1930:10, 1930:19, 1930:20, 1933:6, 1812:2, 1813:23, 1870:7, 1870:9, 1933:9, 1933:14, 1981:21, 1981:23, 1814:14, 1877:14, 1871:15, 1873:9, 1873:0, 1872:10, 1872:12, 1936:7, 1936:15, 1982:21, 1982:24, 1866:10, 1867:11, 1879:9, 1875:1, 1875:17, 1876:10, 1879:2, 1875:1, 1875:17, 1876:10, 1879:2, 1877:5, 1878:5, 1873:3, 1874:25, 1875:1, 1875:17, 1878:10, 1879:2, 1879:5, 1863:17, 1936:12, 1939:20, 1939:4, 1939:20, 1939:4, 1939:20, 1939:4, 1939:21, 1939:20, 1939:4, 1939:21, 1939:20, 1939:4, 1939:21, 1939:23, 1939:24, 1939:23, 1939:24, 1939:23, 1939:24, 1939:23, 1939:24, 1939:23, 1939:4, 1939:23, 1939:4, 1939:23, 1939:4, 1939:23, 1939:4, 1939:23, 1939:4, 1939:23, 1939:4, 1940:5, 1940:7, 1939:41, 1992:15, 1939:4, 1940:5, 1940:7, 1939:41, 1994:12, 1994:13, 1935:4, 1994:14, 1994:12, 1994:13, 1935:4, 1994:14, 1941:11	1797:24, 1798:4,	1853:22, 1853:23,	1917:2, 1917:20,		Nakamura [9] -
1798:23, 1799:2, 1854:17, 1854:22, 1918:14, 1918:17, 1973:20, 1974:3, 1877:6, 1877:8, 1799:6, 1799:10, 1854:24, 1855:1, 1921:24, 1922:2, 1975:22, 1976:1, 1877:19, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1855:11, 1855:9, 1856:13, 1855:11, 1855:9, 1856:13, 1856:14, 1855:9, 1856:15, 1860:19, 1856:15, 1861:15, 1861:16,	1798:6, 1798:14,	1854:6, 1854:8,	1917:22, 1918:2,	1972:21, 1973:3,	1861:25, 1862:13,
1799:6, 1799:10, 1854:24, 1855:1, 1921:14, 1921:15, 1974:17, 1974:18, 1877:19, 1878:8, 1799:23, 1800:1, 1856:9, 1855:11, 1922:5, 1923:1, 1976:3, 1977:16, 1878:4, 1878:14, 1809:15, 1809:11, 1809:15, 1858:2, 1858:3, 1923:3, 1925:18, 1977:18, 1977:22, 1978:9, 1977:16, 1809:15, 1810:13, 1860:16, 1860:19, 1925:20, 1927:21, 1978:9, 1978:11, 1809:25, 1811:16, 1864:3, 1864:4, 1826:2, 1864:24, 1864:24, 1928:11, 1928:19, 1979:2, 1979:2, 1979:2, 1979:2, 1979:7, 1957:3, 1810:10, 1811:24, 1864:2, 1864:24, 1864:24, 1928:11, 1928:19, 1930:19, 1930:19, 1930:19, 1930:19, 1930:19, 1930:19, 1930:19, 1930:19, 1930:10, 1930:19,	1798:16, 1798:20,	1854:11, 1854:15,	1918:4, 1918:12,	1973:5, 1973:10,	1862:25, 1863:17,
1799:23, 1800:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:1, 1809:2, 1810:13, 1809:2, 1810:13, 1809:2, 1810:2, 1811:2, 1	1798:23, 1799:2,	1854:17, 1854:22,	1918:14, 1918:17,	1973:20, 1974:3,	1877:6, 1877:8,
1800:8, 1809:1, 1809:15, 1857:12, 1857:19, 1809:11, 1809:15, 1810:15, 1810:13, 1800:16, 1860:19, 1810:22, 1810:22, 1801:16, 1861:16, 1866:16, 1860:19, 1811:20, 1811:24, 1864:2, 1864:24, 1928:11, 1928:20, 1930:9, 1811:20, 1811:22, 1813:34, 1818:22, 1813:23, 1870:7, 1870:9, 1814:13, 1814:14, 1871:15, 1814:15, 1814:16, 1815:5, 1815:15, 1815:5, 1815:16, 1816:8, 1816:2, 1816:4, 1873:9, 1873:10, 1816:11, 1817:9, 1816:11, 1817:9, 1816:11, 1817:9, 1816:12, 1817:0, 1819:22, 1817:5, 1878:5, 1817:14, 1879:22, 1823:3, 1823:7, 1822:3, 1823:7, 1822:3, 1823:7, 1822:2, 1883:11, 1822:3, 1823:7, 1822:2, 1823:3, 1823:7, 1822:2, 1833:11, 1822:3, 1823:7, 1822:2, 1823:3, 1823:7, 1822:2, 1833:11, 1822:3, 1823:7, 1823:14, 1822:2, 1833:15, 1884:12, 1823:2, 1823:13, 1824:14, 1822:2, 1833:14, 1886:20, 1886:2, 1823:3, 1823:14, 1822:2, 1823:3, 1823:14, 1823:2, 1823:13, 1824:14, 1822:2, 1823:2, 1823:3, 1823:1, 1823:14, 1823:2, 1823:15, 1883:15, 1884:12, 1823:2, 1823:13, 1824:14, 1822:2, 1823:2, 1823:3, 1823:14, 1823:2, 1823:14, 1823:2, 1823:14, 1825:2, 1823:3, 1823:14, 1825:2, 1823:3, 1823:14, 1825:2, 1823:3, 1823:14, 1825:2, 1825:3, 1825:14, 1825:2, 1825:14, 1825:2, 1825:14, 1825:2, 1825:14, 1825:2, 1825:14, 1825:2, 1825:14, 1825:2, 1825:16, 1825:21, 1823:11, 1943:19, 1943:18, 1943:19, 1994:16, 1994:22, 1993:13, 1	1799:6, 1799:10,	1854:24, 1855:1,	1921:14, 1921:15,	1974:17, 1974:18,	1877:19, 1878:8,
1809:11, 1809:15,   1858:2, 1858:3,   1923:3, 1925:18,   1977:18, 1977:22,   1833:18, 1978:13,   1809:25, 1810:13,   1860:16, 1860:19,   1925:20, 1927:21,   1978:9, 1978:11,   1979:22, 1979:21,   1978:9, 1978:11,   1979:22, 1979:24,   1810:25, 1811:16,   1864:3, 1864:4,   1928:11, 1928:19,   1979:22, 1979:24,   1810:20, 1811:24,   1864:22, 1864:24,   1928:20, 1930:9,   1980:14, 1980:17,   1812:22,   1867:10, 1867:11,   1930:10, 1930:19,   1980:19, 1980:23,   1813:2, 1813:4,   1868:20, 1868:21,   1930:20, 1933:6,   1981:2, 1981:16,   1813:22, 1813:23,   1870:7, 1870:9,   1933:9, 1933:14,   1981:21, 1981:23,   1814:13, 1814:14,   1871:14, 1871:15,   1935:23, 1936:2,   1982:15, 1982:19,   1864:1,   1872:10, 1872:12,   1936:19, 1936:2,   1988:37, 1984:12,   1886:6, 1816:8,   1873:3, 1873:5,   1936:19, 1936:21,   1885:6, 1885:7,   1816:6, 1816:8,   1873:3, 1873:5,   1936:19, 1936:21,   1986:0, 1987:4,   1886:0, 1866:10,   1816:11, 1817:9,   1875:1, 1875:17,   1938:4, 1939:4,   1988:17, 1989:11,   1820:21, 1820:21,   1877:5, 1878:5,   1939:15, 1939:20,   1988:17, 1989:11,   1822:2,   1879:5, 1883:11,   1940:5, 1940:7,   1990:9, 1991:23,   1816:0, 1816:0, 1816:0,   1822:2,   1879:5, 1884:12,   1941:1, 1941:11,   1992:15,   1866:3, 1890:17,   1916:15, 1928:9,   1935:8, 1825:14,   1825:2,   1885:25, 1886:2,   1942:5, 1943:12,   1994:12, 1994:13,   1992:14, 1994:13,   1992:14, 1998:13,   1988:18, 1993:13,   1988:18, 1993:13,   1988:18, 1993:13,   1988:18, 1993:13,   1988:18, 1993:13,   1988:18, 1993:13,   1988:18, 1993:13,   1988:18, 1993:13,   1988:18, 1993:13,   1994:16, 1994:22,   1988:18, 1993:13,   1988:18, 1993:13,   1994:16, 1994:22,   1988:18, 1993:13,   1988:18, 1993:13,   1994:16, 1994:22,   1988:18, 1993:13,   1994:16, 1994:22,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1994:13,   1994:16, 1994:22,   1998:13,   1994:16, 1994:22,   1998:13,   1998:13,   1998:13,   1998:13,   1994:16,   1994:16,   1994:22,	1799:23 1800:1	10EE:0 10EE:11	1021-24 1022-2	1075.22 1076.1	
1809:25, 1810:13, 1860:16, 1860:19, 1861:15, 1861:16, 1	,	1000.9, 1000.11,	1921.24, 1922.2,	1973.22, 1976.1,	1878:14
1809:25, 1810:13, 1860:16, 1860:19, 1810:18, 1810:22, 1861:15, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1861:16, 1810:22, 1867:10, 1867:11, 1930:10, 1930:19, 1980:14, 1980:23, 1813:2, 1813:2, 1813:2, 1813:2, 1813:2, 1813:2, 1813:2, 1813:2, 1870:7, 1870:9, 1814:15, 1814:16, 1870:21, 1870:22, 1933:9, 1933:14, 1981:21, 1981:23, 1814:14, 1871:15, 1935:23, 1936:12, 1935:23, 1936:12, 1815:1, 1815:5, 1873:3, 1873:5, 1816:2, 1816:4, 1873:9, 1873:10, 1816:6, 1816:8, 1873:3, 1873:5, 1816:11, 1817:9, 1875:18, 1877:3, 1819:20, 1819:21, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1822:3, 1823:7, 1820:22, 1823:14, 1825:2, 1820:21, 1820:21, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1820:3, 1820:14, 1820:24, 1820:24, 1820:24, 1820:24, 1820:24, 1820:24, 1820:24, 182					
1810:18, 1810:22,   1861:15, 1861:16,   1927:22, 1928:8,   1979:5, 1979:7,   1979:22, 1979:24,   1810:25, 1811:16,   1864:24, 1864:24,   1928:11, 1928:19,   1980:14, 1980:17,   1812:10, 1812:22,   1867:10, 1867:21,   1868:21,   1930:20, 1933:6,   1981:2, 1981:16,   1813:2, 1813:2, 1813:23,   1870:7, 1870:9,   1814:13, 1814:14,   1871:14, 1871:15,   1872:10, 1872:12,   1815:1, 1815:5,   1873:3, 1873:5,   1816:6, 1816:8,   1873:13, 1874:25,   1816:11, 1817:9,   1875:11, 1875:17,   1817:10, 1819:20,   1819:21, 1820:21,   1875:5, 1878:5,   1821:24, 1822:2,   1823:3, 1823:7,   1883:15, 1884:12,   1822:3, 1823:7,   1883:15, 1884:2,   1822:3, 1825:14,   1825:16, 1825:21,   1887:7, 1887:11,   1885:18, 1887:13, 1885:21,   1885:25, 1886:2,   1885:25, 1886:2,   1885:18, 1993:13,   1894:12,   1994:16, 1994:12,   1994:16, 1994:22,   1998:13, 1998:13,   1994:16, 1994:12,   1998:13, 1998:13, 1998:13,   1998:13, 1998:13,   1998:13, 1998:13,   1998:13, 1998:13,   1998:13,   1998:13,   1998:13,   1998:13,   1998:13,   1998:13,   1998:13,   1998:14,   1998:	1800:8, 1809:1,	1857:12, 1857:19,	1922:5, 1923:1,	1976:3, 1977:16,	name [3] - 1816:12,
1811:20, 1811:24, 1864:22, 1864:24, 1928:20, 1930:9, 1980:14, 1980:17, 1958:18 1813:210, 1812:22, 1867:10, 1867:11, 1930:10, 1930:19, 1980:19, 1980:23, 1958:18 1813:22, 1813:23, 1870:7, 1870:9, 1933:9, 1933:14, 1814:13, 1814:14, 1871:14, 1871:15, 1935:23, 1936:2, 1814:15, 1814:16, 1872:10, 1872:12, 1936:7, 1936:15, 1936:19, 1936:21, 1816:2, 1816:4, 1873:9, 1873:10, 1816:6, 1816:8, 1873:3, 1874:25, 1816:61, 1819:20, 1819:21, 1820:21, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1822:3, 1823:7, 1822:3, 1823:7, 1822:3, 1823:7, 1822:3, 1823:7, 1822:3, 1823:7, 1823:15, 1884:12, 1941:11, 1941:11, 1941:11, 1941:11, 1941:13, 1942:15, 1942:25, 1943:12, 1994:12, 1994:12, 1994:13, 1985:14, 1998:13, 1985:24, 1992:11, 1992:15, 1932:4, 1922:3, 1825:14, 1825:2, 1885:25, 1887:4, 1942:25, 1943:12, 1994:12, 1994:12, 1994:13, 1988:13, 1985:13, 1985:14, 1998:13, 1985:24, 1992:21, 1992:15, 1992:3, 1993:4, 1992:23, 1993:4, 1992:23, 1993:4, 1992:24, 1992:14, 1992:25, 1993:13, 1994:16, 1994:22, 1998:13, 1988:13, 1988:13, 1988:13, 1993:13, 1994:16, 1994:22, 1998:13, 1988:18, 1993:13, 1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15,	1857:12, 1857:19, 1858:2, 1858:3,	1922:5, 1923:1, 1923:3, 1925:18,	1976:3, 1977:16, 1977:18, 1977:22,	<b>name</b> [3] - 1816:12, 1833:18, 1978:13
1811:20, 1811:24, 1812:20, 1813:24, 1812:10, 1812:22, 1813:24, 1813:22, 1813:24, 1813:24, 1813:25, 1813:24, 1813:25, 1813:24, 1813:25, 1813:26, 1813:27, 1813:27, 1813:27, 1813:29, 1813:29, 1813:29, 1813:29, 1813:29, 1813:21, 1813:29, 1813:21, 1814:14, 1814:14, 1814:15, 1814:16, 1814:16, 1816:2, 1816:4, 1813:21, 1815:5, 1816:2, 1816:4, 1813:20, 1816:4, 1813:20, 1816:4, 1813:20, 1816:21, 1815:17, 1815:17, 1815:17, 1816:11, 1817:9, 1816:11, 1817:9, 1816:11, 1817:9, 1816:11, 1817:9, 1816:11, 1819:20, 1816:21, 1820:21, 1820:21, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1821:3, 1820:22, 1823:7, 1820:22, 1823:7, 1820:22, 1823:7, 1820:22, 1823:7, 1820:22, 1823:7, 1820:22, 1823:7, 1820:22, 1823:7, 1820:22, 1823:7, 1820:22, 1825:3, 1825:14, 1825:2, 1825:3, 1825:14, 1825:2, 1825:3, 1825:14, 1825:2, 1825:3, 1825:14, 1825:21, 1887:7, 1887:11, 1943:18, 1943:19,       1928:20, 1930:9, 1980:14, 1980:17, 1980:17, 1980:17, 1980:19, 1980:23, 1980:23, 1980:23, 1980:23, 1980:23, 1980:23, 1980:21, 1981:23, 1981:24, 1981:16, 1980:19, 1980:23, 1980:19, 1980:23, 1980:19, 1980:23, 1980:19, 1980:23, 1980:19, 1980:23, 1980:19, 1980:23, 1980:23, 1980:23, 1982:19, 1886:21, 1930:20, 1933:14, 1980:19, 1980:19, 1980:23, 1980:23, 1980:23, 1982:14, 1980:19, 1980:19, 1980:19, 1980:23, 1980:23, 1980:23, 1980:19, 1980:19, 1980:23, 1980:23, 1980:19, 1980:19, 1980:23, 1980:23, 1980:23, 1980:19, 1980:23, 1980:23, 1980:24, 1982:23, 1983:24, 1982:23, 1983:24, 1982:23, 1983:24, 1982:23, 1983:24, 1982:23, 1983:24, 1982:23, 1982:34, 1982:23, 1982:44, 1825:2, 1886:25, 1887:4, 1942:25, 1943:12, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1982:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:16, 1994:22, 1994:13, 1994:13, 1994:13, 1994:16, 1994:22, 1994:13, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5,
1812:10, 1812:22,       1867:10, 1867:11,       1930:10, 1930:19,       1980:19, 1980:23,       1958:18         1813:2, 1813:4,       1868:20, 1868:21,       1930:20, 1933:6,       1981:2, 1981:16,       1864:1         1813:22, 1813:23,       1870:7, 1870:9,       1933:9, 1933:14,       1981:2, 1981:16,       1864:1         1814:13, 1814:14,       1870:21, 1870:22,       1933:19, 1933:22,       1982:15, 1982:19,       1864:1         1815:1, 1815:5,       1873:3, 1873:5,       1936:7, 1936:15,       1983:7, 1984:12,       1806:9, 1806:10,         1816:2, 1816:4,       1873:3, 1873:5,       1937:13, 1937:16,       1985:13, 1985:24,       1865:13, 1985:24,         1816:11, 1817:9,       1875:1, 1875:17,       1938:4, 1939:4,       1986:20, 1987:4,       1986:20, 1987:4,         1819:21, 1820:21,       1878:10, 1879:2,       1939:6, 1939:10,       1988:7, 1989:11,       1986:20, 1987:4,         1820:22, 1821:3,       1878:10, 1879:2,       1939:25, 1940:3,       1989:21, 1989:23,       1899:11, 1992:3,         1822:3, 1823:7,       1883:15, 1884:12,       1941:1, 1941:11,       1992:23, 1993:4,       1868:3, 1890:17,         1823:9, 1825:14,       1885:25, 1886:2,       1942:16, 1942:23,       1993:15, 1994:9,       1935:8, 1995:4,         1825:16, 1825:21,       1886:25, 1887:4,       1942:25, 194	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3
1813:2, 1813:4,       1868:20, 1868:21,       1930:20, 1933:6,       1981:2, 1981:16,       1864:1       1864:1         1813:22, 1813:23,       1870:7, 1870:9,       1933:9, 1933:14,       1981:21, 1981:23,       1864:1       1864:1         1814:7, 1814:9,       1870:21, 1870:22,       1933:19, 1933:22,       1982:23, 1983:2,       1864:1       1866:9, 1866:10,         1814:13, 1814:14,       1871:14, 1871:15,       1935:23, 1936:2,       1982:23, 1983:2,       1806:9, 1806:10,         1815:1, 1815:5,       1873:3, 1873:5,       1936:19, 1936:21,       1985:6, 1985:9,       1885:7       1885:7         1816:2, 1816:4,       1873:13, 1874:25,       1937:13, 1937:16,       1985:13, 1985:24,       1986:10, 1885:0,       1885:7         1816:11, 1817:9,       1875:1, 1875:17,       1938:4, 1939:4,       1986:20, 1987:4,       1986:20, 1987:4,       1996:20, 1987:4,       1999:11, 1986:10,       1885:7       1866:20, 1889:8,       1991:14, 1994:25       1866:20, 1887:4,       1999:11, 1986:10,       1885:7       1866:20, 1886:20,       1886:20, 1886:20,       1988:13, 1988:14,       1986:20, 1987:4,       1986:20, 1987:4,       1986:20, 1987:4,       1986:20, 1987:4,       1986:20, 1987:4,       1988:17, 1989:21,       1989:21, 1989:23,       1816:23, 1815:7,       1816:23, 1815:7,       1816:23, 1815:7,       1816:23, 184:12,       1989:23	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9
1813:22, 1813:23,       1870:7, 1870:9,       1933:9, 1933:14,       1981:21, 1981:23,       1864:1       1864:1         1814:7, 1814:9,       1870:21, 1870:22,       1933:19, 1933:22,       1982:15, 1982:19,       1802:23, 1983:2,       1806:9, 1806:10,       1806:9, 1806:10,       1806:9, 1806:10,       1885:7         1815:1, 1815:5,       1873:3, 1873:5,       1936:19, 1936:21,       1985:6, 1985:9,       1985:6, 1985:9,       1885:7       1866:9, 1806:10,       1885:7         1816:2, 1816:4,       1873:9, 1873:10,       1937:1, 1937:9,       1985:13, 1985:24,       196:1, 1986:10,       1885:7       1862:8, 1989:8,       1991:14, 1994:25       186:1, 1986:10,       1885:7       186:2, 1886:4,       1994:14, 1994:25       1886:2, 1886:4,       1994:14, 1994:25       1886:2, 1886:4,       1899:14, 1994:25       1886:2, 1886:4,       1899:14, 1994:25       1886:2, 1886:4,       1899:14, 1994:25       1886:2, 1886:4,       1899:14, 1994:25       1886:2, 1886:4,       1899:14, 1994:25       1886:25, 1886:4,       1899:15, 1939:20,       1988:17, 1989:11,       1816:10, 1818:6,       1816:23, 1815:7,       1816:10, 1818:6,       1899:21, 1989:23,       1816:10, 1818:6,       1899:225, 1807:8,       1816:10, 1818:6,       1899:225, 1807:8,       1816:10, 1818:6,       1899:225, 1807:8,       1816:10, 1818:6,       1899:23, 1899:21,       1816:10, 1818:6,       1899:23, 1899:21,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5,
1814:7, 1814:9, 1870:21, 1870:22, 1933:19, 1933:22, 1982:15, 1982:19, 1814:13, 1814:14, 1871:15, 1814:16, 1872:10, 1872:12, 1936:15, 1936:15, 1983:7, 1984:12, 1816:2, 1816:4, 1873:9, 1873:10, 1816:11, 1817:9, 1817:10, 1819:20, 1819:21, 1820:21, 1820:22, 1821:3, 1821:4, 1822:2, 1822:3, 1823:7, 1822:3, 1823:7, 1823:9, 1824:13, 1824:14, 1825:2, 1825:3, 1825:14, 1825:16, 1825:21, 1885:21, 1825:16, 1825:21, 1885:21, 1887:11, 1825:16, 1825:21, 1885:21, 1887:11, 1825:16, 1825:21, 1885:21, 1887:11, 1825:16, 1825:21, 1887:11, 1825:16, 1825:21, 1887:11, 1825:16, 1825:21, 1887:7, 1887:11, 1847:11, 1943:18, 1943:19, 1994:16, 1994:22, 1994:13, 1998:13, 199	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18
1814:13, 1814:14,       1871:14, 1871:15,       1935:23, 1936:2,       1982:23, 1983:2,       1806:9, 1806:10,         1814:15, 1814:16,       1872:10, 1872:12,       1936:7, 1936:15,       1983:7, 1984:12,       1885:7         1815:1, 1815:5,       1873:3, 1873:5,       1936:19, 1936:21,       1985:6, 1985:9,       1985:6, 1985:9,         1816:2, 1816:4,       1873:9, 1873:10,       1937:1, 1937:9,       1985:13, 1985:24,       1764:5, 1989:8,         1816:11, 1817:9,       1875:1, 1875:17,       1938:4, 1939:4,       1986:20, 1987:4,       1991:14, 1994:25         1817:10, 1819:20,       1875:18, 1877:3,       1939:6, 1939:10,       1988:17, 1989:11,       1992:25, 1807:8,         1820:22, 1821:3,       1878:10, 1879:2,       1939:25, 1940:3,       1989:21, 1989:23,       1816:10, 1818:6,         1822:3, 1823:7,       1883:15, 1884:12,       1941:1, 1941:11,       1992:11, 1992:15,       1868:3, 1890:17,         1823:9, 1824:13,       1885:25, 1886:2,       1942:16, 1942:23,       1993:15, 1934:19,       1994:16, 1994:22,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1985:13, 1983:2,         1892:23, 1983:4,       1993:13,       1985:24,       1993:15, 1985:24,       1990:11, 1992:15,       1868:3, 1890:17,         1806:25, 1887:4, <t< td=""><td>1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4,</td><td>1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21,</td><td>1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6,</td><td>1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16,</td><td>name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9,</td></t<>	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9,
1814:15, 1814:16,       1872:10, 1872:12,       1936:7, 1936:15,       1983:7, 1984:12,       1885:7         1815:1, 1815:5,       1873:3, 1873:5,       1936:19, 1936:21,       1985:6, 1985:9,       186:6, 1885:7         1816:2, 1816:4,       1873:9, 1873:10,       1937:1, 1937:9,       1985:13, 1985:24,       1764:5, 1989:8,         1816:11, 1817:9,       1875:1, 1875:17,       1938:4, 1939:4,       1986:20, 1987:4,       1991:14, 1994:25         1817:10, 1819:20,       1875:18, 1877:3,       1939:6, 1939:10,       1988:5, 1988:14,       1792:25, 1807:8,         1819:21, 1820:21,       1877:5, 1878:5,       1939:15, 1939:20,       1988:17, 1989:21,       1810:23, 1815:7,         1820:22, 1821:3,       1878:10, 1879:2,       1939:25, 1940:3,       1990:9, 1991:23,       1816:10, 1818:6,         1822:3, 1823:7,       1883:15, 1884:12,       1941:1, 1941:11,       1992:11, 1992:15,       1868:3, 1890:17,         1823:9, 1824:13,       1884:20, 1884:23,       1941:16, 1942:13,       1992:23, 1993:4,       1916:15, 1928:9,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:12, 1994:13,       1987:1, 1988:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1983:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1
1815:1, 1815:5,       1873:3, 1873:5,       1936:19, 1936:21,       1985:6, 1985:9,       necessary [4] -         1816:2, 1816:4,       1873:9, 1873:10,       1937:1, 1937:9,       1985:13, 1985:24,       1764:5, 1989:8,         1816:6, 1816:8,       1873:13, 1874:25,       1937:13, 1937:16,       1986:10, 1986:10,       1991:14, 1994:25         1816:11, 1817:9,       1875:1, 1875:17,       1938:4, 1939:4,       1986:20, 1987:4,       1991:14, 1994:25         1817:10, 1819:20,       1875:18, 1877:3,       1939:6, 1939:10,       1988:5, 1988:14,       1792:25, 1807:8,         1819:21, 1820:21,       1877:5, 1878:5,       1939:15, 1939:20,       1988:17, 1989:11,       1810:23, 1815:7,         1820:22, 1821:3,       1878:10, 1879:2,       1939:25, 1940:3,       1990:9, 1991:23,       1816:10, 1818:6,         1822:3, 1823:7,       1883:15, 1884:12,       1940:5, 1940:7,       1990:9, 1991:23,       1866:23, 1856:12,         1823:9, 1824:13,       1884:20, 1884:23,       1941:16, 1942:13,       1992:21, 1992:15,       1868:3, 1890:17,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:12, 1994:13,       1987:1, 1988:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] -
1816:2, 1816:4,       1873:9, 1873:10,       1937:1, 1937:9,       1985:13, 1985:24,       1764:5, 1989:8,         1816:6, 1816:8,       1873:13, 1874:25,       1937:13, 1937:16,       1986:1, 1986:10,       1991:14, 1994:25         1816:11, 1817:9,       1875:1, 1875:17,       1938:4, 1939:4,       1986:20, 1987:4,       1991:14, 1994:25         1817:10, 1819:20,       1875:18, 1877:3,       1939:6, 1939:10,       1988:5, 1988:14,       1792:25, 1807:8,         1819:21, 1820:21,       1877:5, 1878:5,       1939:15, 1939:20,       1988:17, 1989:11,       1810:23, 1815:7,         1820:22, 1821:3,       1878:10, 1879:2,       1939:25, 1940:3,       1990:9, 1991:23,       1816:10, 1818:6,         1822:3, 1823:7,       1883:15, 1884:12,       1940:5, 1940:7,       1990:9, 1991:23,       1868:3, 1890:17,         1823:9, 1824:13,       1884:20, 1884:23,       1941:1, 1941:11,       1992:211, 1992:15,       1868:3, 1890:17,         1824:14, 1825:2,       1885:25, 1886:2,       1942:16, 1942:23,       1993:15, 1994:9,       1935:8, 1952:4,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:16, 1994:22,       1985:13, 1983:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1983:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10,
1816:6, 1816:8,       1873:13, 1874:25,       1937:13, 1937:16,       1986:1, 1986:10,       1991:14, 1994:25         1816:11, 1817:9,       1875:1, 1875:17,       1938:4, 1939:4,       1986:20, 1987:4,       1991:14, 1994:25         1817:10, 1819:20,       1875:18, 1877:3,       1939:6, 1939:10,       1988:5, 1988:14,       1792:25, 1807:8,         1819:21, 1820:21,       1877:5, 1878:5,       1939:15, 1939:20,       1988:17, 1989:11,       1810:23, 1815:7,         1820:22, 1821:3,       1878:10, 1879:2,       1939:25, 1940:3,       1990:9, 1991:23,       1816:10, 1818:6,         1822:3, 1823:7,       1883:15, 1884:12,       1940:5, 1940:7,       1992:11, 1992:15,       1868:3, 1890:17,         1823:9, 1824:13,       1884:20, 1884:23,       1941:16, 1942:13,       1992:23, 1993:4,       1916:15, 1928:9,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:12, 1994:13,       1987:1, 1988:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1814:15, 1814:16,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:12,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7
1816:11, 1817:9,       1875:1, 1875:17,       1938:4, 1939:4,       1986:20, 1987:4,       need [23] - 1777:5,         1817:10, 1819:20,       1875:18, 1877:3,       1939:6, 1939:10,       1988:5, 1988:14,       1792:25, 1807:8,         1819:21, 1820:21,       1877:5, 1878:5,       1939:15, 1939:20,       1988:17, 1989:11,       1810:23, 1815:7,         1820:22, 1821:3,       1878:10, 1879:2,       1939:25, 1940:3,       1989:21, 1989:23,       1816:10, 1818:6,         1821:4, 1822:2,       1879:5, 1883:11,       1940:5, 1940:7,       1990:9, 1991:23,       1816:10, 1818:6,         1822:3, 1823:7,       1883:15, 1884:12,       1941:1, 1941:11,       1992:11, 1992:15,       1868:3, 1890:17,         1823:9, 1824:13,       1884:20, 1884:23,       1941:16, 1942:13,       1992:23, 1993:4,       1916:15, 1928:9,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:12, 1994:13,       1987:1, 1988:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1814:15, 1814:16, 1815:1, 1815:5,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:12, 1873:3, 1873:5,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] -
1817:10, 1819:20,       1875:18, 1877:3,       1939:6, 1939:10,       1988:5, 1988:14,       1792:25, 1807:8,         1819:21, 1820:21,       1877:5, 1878:5,       1939:15, 1939:20,       1988:17, 1989:11,       1810:23, 1815:7,         1820:22, 1821:3,       1878:10, 1879:2,       1939:25, 1940:3,       1989:21, 1989:23,       1816:10, 1818:6,         1821:4, 1822:2,       1879:5, 1883:11,       1940:5, 1940:7,       1990:9, 1991:23,       1816:10, 1818:6,         1822:3, 1823:7,       1883:15, 1884:12,       1941:1, 1941:11,       1992:11, 1992:15,       1868:3, 1890:17,         1823:9, 1824:13,       1884:20, 1884:23,       1941:16, 1942:13,       1992:23, 1993:4,       1916:15, 1928:9,         1824:14, 1825:2,       1885:25, 1886:2,       1942:16, 1942:23,       1993:15, 1994:9,       1935:8, 1952:4,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:16, 1994:22,       198:18, 1993:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1814:15, 1814:16, 1815:1, 1815:5, 1816:2, 1816:4,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:12, 1873:3, 1873:5, 1873:9, 1873:10,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8,
1819:21, 1820:21,       1877:5, 1878:5,       1939:15, 1939:20,       1988:17, 1989:11,       1810:23, 1815:7,         1820:22, 1821:3,       1878:10, 1879:2,       1939:25, 1940:3,       1989:21, 1989:23,       1816:10, 1818:6,         1821:4, 1822:2,       1879:5, 1883:11,       1940:5, 1940:7,       1990:9, 1991:23,       1836:23, 1856:12,         1823:3, 1823:7,       1883:15, 1884:12,       1941:1, 1941:11,       1992:11, 1992:15,       1868:3, 1890:17,         1823:9, 1824:13,       1884:20, 1884:23,       1941:16, 1942:13,       1992:23, 1993:4,       1916:15, 1928:9,         1824:14, 1825:2,       1885:25, 1886:2,       1942:16, 1942:23,       1993:15, 1994:9,       1935:8, 1952:4,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:16, 1994:22,       198:18, 1993:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:2, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1814:15, 1814:16, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:12, 1873:3, 1873:5, 1873:9, 1873:10, 1873:13, 1874:25,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25
1820:22, 1821:3,       1878:10, 1879:2,       1939:25, 1940:3,       1989:21, 1989:23,       1816:10, 1818:6,         1821:4, 1822:2,       1879:5, 1883:11,       1940:5, 1940:7,       1990:9, 1991:23,       1836:23, 1856:12,         1822:3, 1823:7,       1883:15, 1884:12,       1941:1, 1941:11,       1992:11, 1992:15,       1868:3, 1890:17,         1823:9, 1824:13,       1884:20, 1884:23,       1941:16, 1942:13,       1992:23, 1993:4,       1916:15, 1928:9,         1824:14, 1825:2,       1885:25, 1886:2,       1942:16, 1942:23,       1993:15, 1994:9,       1935:8, 1952:4,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:12, 1994:13,       1987:1, 1988:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1814:15, 1814:16, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1816:11, 1817:9,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:12, 1873:3, 1873:5, 1873:9, 1873:10, 1873:13, 1874:25, 1875:1, 1875:17,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5,
1821:4, 1822:2,       1879:5, 1883:11,       1940:5, 1940:7,       1990:9, 1991:23,       1836:23, 1856:12,         1822:3, 1823:7,       1883:15, 1884:12,       1941:1, 1941:11,       1992:11, 1992:15,       1868:3, 1890:17,         1823:9, 1824:13,       1884:20, 1884:23,       1941:16, 1942:13,       1992:23, 1993:4,       1916:15, 1928:9,         1824:14, 1825:2,       1885:25, 1886:2,       1942:16, 1942:23,       1993:15, 1994:9,       1935:8, 1952:4,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:12, 1994:13,       1987:1, 1988:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1814:15, 1814:16, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1816:11, 1817:9, 1817:10, 1819:20,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:24, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:12, 1873:3, 1873:5, 1873:9, 1873:10, 1873:13, 1874:25, 1875:1, 1875:18, 1877:3,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4, 1939:6, 1939:10,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4, 1988:5, 1988:14,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5, 1792:25, 1807:8,
1822:3, 1823:7,       1883:15, 1884:12,       1941:1, 1941:11,       1992:11, 1992:15,       1868:3, 1890:17,         1823:9, 1824:13,       1884:20, 1884:23,       1941:16, 1942:13,       1992:23, 1993:4,       1916:15, 1928:9,         1825:3, 1825:14,       1886:25, 1886:2,       1942:16, 1942:23,       1993:15, 1994:9,       1935:8, 1952:4,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1816:11, 1817:9, 1817:10, 1819:20, 1819:21, 1820:21,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:24, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:12, 1873:3, 1873:5, 1873:9, 1873:10, 1873:13, 1874:25, 1875:1, 1875:17, 1875:18, 1877:3, 1877:5, 1878:5,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4, 1939:6, 1939:10, 1939:15, 1939:20,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4, 1988:5, 1988:14, 1988:17, 1989:11,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5, 1792:25, 1807:8, 1810:23, 1815:7,
1823:9, 1824:13,       1884:20, 1884:23,       1941:16, 1942:13,       1992:23, 1993:4,       1916:15, 1928:9,         1824:14, 1825:2,       1885:25, 1886:2,       1942:16, 1942:23,       1993:15, 1994:9,       1935:8, 1952:4,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:12, 1994:13,       1987:1, 1988:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1816:11, 1817:9, 1817:10, 1819:20, 1819:21, 1820:21, 1820:22, 1821:3,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:24, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:10, 1872:10, 1873:3, 1873:5, 1873:9, 1873:10, 1873:13, 1874:25, 1875:1, 1875:17, 1875:18, 1877:3, 1877:5, 1878:5, 1878:10, 1879:2,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4, 1939:6, 1939:10, 1939:15, 1939:20, 1939:25, 1940:3,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4, 1988:5, 1988:14, 1988:17, 1989:11, 1989:21, 1989:23,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5, 1792:25, 1807:8, 1810:23, 1815:7, 1816:10, 1818:6,
1824:14, 1825:2,       1885:25, 1886:2,       1942:16, 1942:23,       1993:15, 1994:9,       1935:8, 1952:4,         1825:3, 1825:14,       1886:25, 1887:4,       1942:25, 1943:12,       1994:12, 1994:13,       1987:1, 1988:13,         1825:16, 1825:21,       1887:7, 1887:11,       1943:18, 1943:19,       1994:16, 1994:22,       1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1817:10, 1819:20, 1819:21, 1820:21, 1820:22, 1821:3, 1809:25, 1820:21,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:10, 1872:10, 1873:3, 1873:5, 1873:9, 1873:10, 1873:13, 1874:25, 1875:1, 1875:17, 1875:18, 1877:3, 1877:5, 1878:5, 1878:10, 1879:2, 1879:5, 1883:11,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4, 1939:6, 1939:10, 1939:15, 1939:20, 1939:25, 1940:3, 1940:5, 1940:7,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4, 1988:5, 1988:14, 1988:17, 1989:11, 1989:21, 1989:23, 1990:9, 1991:23,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5, 1792:25, 1807:8, 1810:23, 1815:7, 1816:10, 1818:6, 1836:23, 1856:12,
1825:3, 1825:14, 1886:25, 1887:4, 1942:25, 1943:12, 1994:12, 1994:13, 1987:1, 1988:13, 1943:18, 1943:19, 1994:16, 1994:22, 1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1814:15, 1814:16, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1816:11, 1817:9, 1817:10, 1819:20, 1819:21, 1820:21, 1820:22, 1821:3, 1821:4, 1822:2, 1822:3, 1823:7,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:10, 1873:3, 1873:5, 1873:9, 1873:10, 1873:13, 1874:25, 1875:1, 1875:17, 1875:18, 1877:3, 1877:5, 1878:5, 1878:10, 1879:2, 1879:5, 1883:11, 1883:15, 1884:12,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:14, 1933:19, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4, 1939:6, 1939:10, 1939:15, 1939:20, 1939:25, 1940:3, 1940:5, 1940:7, 1941:1, 1941:11,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4, 1988:5, 1988:14, 1988:17, 1989:11, 1989:21, 1989:23, 1990:9, 1991:23, 1992:11, 1992:15,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5, 1792:25, 1807:8, 1810:23, 1815:7, 1816:10, 1818:6, 1836:23, 1856:12, 1868:3, 1890:17,
1825:16, 1825:21, 1887:7, 1887:11, 1943:18, 1943:19, 1994:16, 1994:22, 1988:18, 1993:13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:15, 1814:16, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1816:11, 1817:9, 1817:10, 1819:20, 1819:21, 1820:21, 1820:22, 1821:3, 1821:4, 1822:2, 1823:9, 1824:13,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:10, 1873:3, 1873:5, 1873:9, 1873:10, 1873:13, 1874:25, 1875:1, 1875:17, 1875:18, 1877:3, 1877:5, 1878:5, 1878:10, 1879:2, 1879:5, 1883:11, 1883:15, 1884:20, 1884:23,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4, 1939:6, 1939:10, 1939:15, 1939:20, 1939:25, 1940:3, 1941:1, 1941:11, 1941:16, 1942:13,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4, 1988:5, 1988:14, 1988:17, 1989:11, 1989:21, 1989:23, 1990:9, 1991:23, 1992:23, 1993:4,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5, 1792:25, 1807:8, 1810:23, 1815:7, 1816:10, 1818:6, 1836:23, 1856:12, 1868:3, 1890:17, 1916:15, 1928:9,
1300.10, 1330.13,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1814:15, 1814:16, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1816:11, 1817:9, 1817:10, 1819:20, 1819:21, 1820:21, 1820:22, 1821:3, 1821:4, 1822:2, 1823:9, 1824:13, 1824:14, 1825:2,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:9, 1870:21, 1870:22, 1871:14, 1871:15, 1872:10, 1872:10, 1872:10, 1873:3, 1873:5, 1873:9, 1873:10, 1873:13, 1874:25, 1875:1, 1875:17, 1875:18, 1877:3, 1877:5, 1878:5, 1878:10, 1879:2, 1879:5, 1883:11, 1883:15, 1884:20, 1884:23, 1885:25, 1886:2,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4, 1939:6, 1939:10, 1939:15, 1939:20, 1939:25, 1940:3, 1941:1, 1941:11, 1941:16, 1942:13, 1942:16, 1942:23,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4, 1988:5, 1988:14, 1988:17, 1989:11, 1989:21, 1989:23, 1990:9, 1991:23, 1992:11, 1992:15, 1992:23, 1993:4, 1993:15, 1994:9,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5, 1792:25, 1807:8, 1810:23, 1815:7, 1816:10, 1818:6, 1836:23, 1856:12, 1868:3, 1890:17, 1916:15, 1928:9, 1935:8, 1952:4,
. , , , , ,	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:19, 1814:13, 1814:14, 1814:15, 1814:16, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1816:11, 1817:9, 1817:10, 1819:20, 1819:21, 1820:21, 1820:22, 1821:3, 1821:4, 1822:2, 1823:9, 1824:13, 1824:14, 1825:2, 1825:3, 1825:14,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:22, 1871:14, 1871:15, 1872:10, 1872:12, 1873:3, 1873:5, 1873:9, 1873:13, 1874:25, 1875:1, 1875:18, 1877:3, 1877:5, 1878:10, 1879:2, 1879:5, 1883:11, 1883:15, 1884:20, 1884:23, 1885:25, 1886:2, 1886:25, 1887:4,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4, 1939:6, 1939:10, 1939:15, 1939:20, 1939:25, 1940:3, 1940:5, 1940:7, 1941:1, 1941:11, 1941:16, 1942:13, 1942:16, 1942:23, 1942:25, 1943:12,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4, 1988:5, 1988:14, 1988:17, 1989:11, 1989:21, 1989:23, 1990:9, 1991:23, 1992:11, 1992:15, 1992:23, 1993:4, 1994:12, 1994:13,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5, 1792:25, 1807:8, 1810:23, 1815:7, 1816:10, 1818:6, 1836:23, 1856:12, 1868:3, 1890:17, 1916:15, 1928:9, 1935:8, 1952:4, 1987:1, 1988:13,
	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1814:15, 1814:16, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1816:11, 1817:9, 1817:10, 1819:20, 1819:21, 1820:21, 1820:22, 1821:3, 1821:4, 1822:2, 1823:9, 1824:13, 1824:14, 1825:2, 1825:3, 1825:14, 1825:16, 1825:21,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:22, 1871:14, 1871:15, 1872:10, 1872:12, 1873:3, 1873:5, 1873:9, 1873:13, 1874:25, 1875:1, 1875:18, 1877:3, 1877:5, 1878:10, 1879:2, 1879:5, 1883:11, 1883:15, 1884:12, 1884:20, 1884:23, 1885:25, 1887:4, 1887:7, 1887:11,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4, 1939:6, 1939:10, 1939:15, 1939:20, 1939:25, 1940:3, 1940:5, 1940:7, 1941:1, 1941:11, 1941:16, 1942:13, 1942:16, 1942:23, 1942:25, 1943:12, 1943:18, 1943:19,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4, 1988:5, 1988:14, 1988:17, 1989:11, 1989:21, 1989:23, 1990:9, 1991:23, 1992:11, 1992:15, 1992:23, 1993:4, 1994:16, 1994:22,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5, 1792:25, 1807:8, 1810:23, 1815:7, 1816:10, 1818:6, 1836:23, 1856:12, 1868:3, 1890:17, 1916:15, 1928:9, 1935:8, 1952:4, 1987:1, 1988:13,
	1800:8, 1809:1, 1809:11, 1809:15, 1809:25, 1810:13, 1810:18, 1810:22, 1810:25, 1811:16, 1811:20, 1811:24, 1812:10, 1812:22, 1813:2, 1813:4, 1813:22, 1813:23, 1814:7, 1814:9, 1814:13, 1814:14, 1814:15, 1814:16, 1815:1, 1815:5, 1816:2, 1816:4, 1816:6, 1816:8, 1816:11, 1817:9, 1817:10, 1819:20, 1819:21, 1820:21, 1820:22, 1821:3, 1821:4, 1822:2, 1823:9, 1824:13, 1824:14, 1825:2, 1825:3, 1825:14, 1825:16, 1825:21,	1857:12, 1857:19, 1858:2, 1858:3, 1860:16, 1860:19, 1861:15, 1861:16, 1864:3, 1864:4, 1864:22, 1864:24, 1867:10, 1867:11, 1868:20, 1868:21, 1870:7, 1870:22, 1871:14, 1871:15, 1872:10, 1872:12, 1873:3, 1873:5, 1873:9, 1873:13, 1874:25, 1875:1, 1875:18, 1877:3, 1877:5, 1878:10, 1879:2, 1879:5, 1883:11, 1883:15, 1884:12, 1884:20, 1884:23, 1885:25, 1887:4, 1887:7, 1887:11,	1922:5, 1923:1, 1923:3, 1925:18, 1925:20, 1927:21, 1927:22, 1928:8, 1928:11, 1928:19, 1928:20, 1930:9, 1930:10, 1930:19, 1930:20, 1933:6, 1933:9, 1933:22, 1935:23, 1936:2, 1936:7, 1936:15, 1936:19, 1936:21, 1937:1, 1937:9, 1937:13, 1937:16, 1938:4, 1939:4, 1939:6, 1939:10, 1939:15, 1939:20, 1939:25, 1940:3, 1940:5, 1940:7, 1941:1, 1941:11, 1941:16, 1942:13, 1942:16, 1942:23, 1942:25, 1943:12, 1943:18, 1943:19,	1976:3, 1977:16, 1977:18, 1977:22, 1978:9, 1978:11, 1979:5, 1979:7, 1979:22, 1979:24, 1980:14, 1980:17, 1980:19, 1980:23, 1981:2, 1981:16, 1981:21, 1981:23, 1982:15, 1982:19, 1982:23, 1983:2, 1983:7, 1984:12, 1985:6, 1985:9, 1985:13, 1985:24, 1986:1, 1986:10, 1986:20, 1987:4, 1988:5, 1988:14, 1988:17, 1989:11, 1989:21, 1989:23, 1990:9, 1991:23, 1992:11, 1992:15, 1992:23, 1993:4, 1994:16, 1994:22,	name [3] - 1816:12, 1833:18, 1978:13 namely [2] - 1828:5, 1957:3 national [1] - 1967:9 near [2] - 1843:5, 1958:18 nebulous [2] - 1824:9, 1864:1 necessarily [3] - 1806:9, 1806:10, 1885:7 necessary [4] - 1764:5, 1989:8, 1991:14, 1994:25 need [23] - 1777:5, 1792:25, 1807:8, 1810:23, 1815:7, 1816:10, 1818:6, 1836:23, 1856:12, 1868:3, 1890:17, 1916:15, 1928:9, 1935:8, 1952:4, 1987:1, 1988:13,

1995:4, 1996:7
<b>needed</b> [3] - 1842:11, 1966:16, 1980:25
needs [3] - 1892:24, 1989:2, 1989:15
negative [2] - 1760:12,
1768:4 neutral [26] - 1776:16,
1788:3, 1788:5, 1790:14, 1790:21,
1790:24, 1791:9,
1791:14, 1792:9, 1792:12, 1792:15,
1792:23, 1793:6,
1799:21, 1800:15, 1801:9, 1819:3,
1819:11, 1830:9, 1830:13, 1835:6,
1835:10, 1848:19,
1876:23, 1959:24,
1978:2 neutrality [2] -
1791:21, 1793:1
neutralize [1] - 1879:13
<b>NEVADA</b> [3] - 1757:1, 1759:1, 1944:1
Nevada [4] - 1757:7,
1757:23, 1758:8, 1758:13
never [7] - 1773:5,
1790:24, 1834:16, 1840:17, 1897:8,
1914:16, 1973:13
<b>new</b> [8] - 1786:18, 1791:10, 1791:20,
1810:15, 1811:14, 1844:16, 1920:23,
1844:16, 1920:23, 1921:6
<b>New</b> [3] - 1758:11, 1904:18, 1905:22
newer [1] - 1812:5
newspaper [2] - 1928:24, 1929:2
next [20] - 1757:25,
1760:24, 1800:24,
1825:14, 1835:4, 1868:3, 1889:23,
1913:17, 1928:15,
1931:16, 1947:15, 1949:15, 1955:6,
1964:10, 1987:1, 1988:14, 1988:15,
1988:14, 1988:15, 1988:16, 1988:19,
1988:21
nexus [5] - 1774:18, 1774:23, 1775:25,
1778:6, 1894:9
<b>niacin</b> [12] - 1760:15, 1789:19, 1790:2,

1004:14 1000:1
1801:14, 1802:1,
1804:14, 1804:18,
1806:6, 1806:18,
1917:9, 1917:13,
1972:11
nice [2] - 1902:11,
1919:10
night [2] - 1933:24,
1944:11
Nilsen [1] - 1850:20
nine [1] - 1841:3
nobody [1] - 1937:3
none [15] - 1773:8,
1783:8, 1838:25,
1851:23, 1852:21,
1894:15, 1894:19,
1896:23, 1898:9,
·
1899:3, 1899:4,
1899:5, 1903:21,
1904:1, 1957:2
Nonfatal [1] - 1770:13
nonfatal [1] - 1901:13
nonobviousness [6] -
1781:5, 1781:16,
1782:17, 1783:1,
1795:6, 1807:11

nonsignificant [1] -

noon [1] - 1943:20

1840:1, 1840:6,

1957:1, 1958:19

Norman [1] - 1768:7

1853:16, 1919:13,

note [6] - 1839:13,

1952:1, 1984:1,

noted [1] - 1834:11

notes [8] - 1761:13,

1763:11, 1838:22,

1845:23, 1863:6,

1956:24, 1966:13,

nothing [7] - 1824:7,

1859:22, 1863:22,

1907:22, 1995:5,

1995:6, 1995:7

Notice [1] - 1805:1

notice [4] - 1771:5,

notoriously [2] -

1931:22, 1934:9

Nozaki [1] - 1780:3

number [20] - 1771:8,

1796:14, 1798:19,

1813:11, 1837:11,

1839:13, 1842:7,

1850:4, 1857:1,

1934:13, 1936:6,

1984.16

1972:9

1937:6

nonstable [1] - 1908:1

normal [5] - 1838:24,

1773:4

## О object [2] - 1916:13, 1933:22 objection [49] -1765:15, 1767:17, 1794:22, 1796:3, 1796:4, 1796:25, 1799:23, 1800:7, 1809:14, 1809:23, 1812:23, 1814:8, 1851:22, 1852:20, 1854:8, 1854:24, 1873:10, 1910:24, 1910:25, 1915:9, 1915:11, 1915:16, 1915:17, 1915:23, 1915:24, 1917:22, 1917:23, 1918:14, 1922:2, 1933:18, 1936:4, 1936:7, 1936:10, 1936:22, 1936:23, 1939:16, 1939:17, 1939:18, 1939:23, 1940:24, 1941:15, 1941:19, 1942:3, 1973:3, 1974:10, 1984:11, 1984:12, 1985:5, 1986:6 objections [1] -1985:6 objective [3] -1825:15, 1825:17, 1849:13 objectives [1] -1825:19 observable [1] -

1858:15, 1903:19,

1920:25, 1926:18,

1931:19, 1939:1,

1949:18, 1955:21,

1986:12, 1987:18,

1843:10, 1843:20,

1869:7, 1942:2,

1942:3, 1945:1,

1945:3, 1967:15,

1987:23

1837:10

1976:23

1829:24

1788:16

numerical [1] -

numerically [1] -

numerous [2] -

1773:7, 1969:9

numbers [9] -

numbering [1] -

```
observations [4] -
 1760:22, 1775:8,
 1775:12, 1869:4
observed [11] -
 1771:17, 1774:18,
 1775:19, 1775:22,
 1776:21, 1776:22,
 1803:25, 1804:4,
 1804:8, 1951:25,
 1961:11
obtained [2] - 1953:3
obvious [29] -
 1765:21, 1778:11,
 1783:7, 1783:8,
 1786:23, 1789:1,
 1789:8, 1804:23,
 1805:4, 1819:2,
 1819:5, 1819:11,
 1819:12, 1821:14,
 1821:22, 1823:22,
 1823:25, 1824:3,
 1824:6, 1827:2,
 1850:10, 1856:3.
 1856:4, 1856:8,
 1856:11, 1882:10,
 1882:15, 1882:22,
 1883:1
obviously [11] -
 1795:14, 1810:5,
 1812:12, 1815:13,
 1833:24, 1854:20,
 1872:17, 1876:10,
 1892:23, 1904:4,
 1942:18
obviousness [11] -
 1785:9, 1795:2,
 1795:12, 1795:15,
 1796:19, 1797:2,
 1799:24, 1800:2,
 1800:5. 1819:9.
 1925:22
occur [2] - 1777:5.
 1787:24
occurrence [3] -
 1924:1, 1924:4,
 1961:23
odds [1] - 1880:3
OF [2] - 1757:1,
 1757:12
offer [13] - 1760:24,
 1868:6, 1868:10,
 1868:13, 1895:14,
 1943:10, 1984:23,
 1985:12, 1985:21,
 1985:25, 1986:1,
 1986:18, 1991:11
offered [2] - 1915:13,
 1920:8
offering [8] - 1806:2,
 1856:1, 1861:4,
```

2
1895:1, 1896:6,
1909:13, 1986:9,
1986:11
office [14] - 1802:7,
1802:13, 1802:16,
1803:7, 1804:10,
1804:23, 1805:12,
1805:17, 1805:21,
1805:23, 1867:22,
1868:7, 1868:8,
1868:14
Office [1] - 1806:3
offices [1] - 1937:17
official [3] - 1991:20,
1992:14, 1993:24
Official [2] - 1757:22,
1996:25
offset [1] - 1875:6
often [3] - 1875:6,
1917:11, 1955:19
<b>Oil</b> [2] - 1767:11,
1909:23
oil [4] - 1826:1,
1851:3, 1898:14,
1947:8 <b>Oils</b> [1] - 1916:19
oils [6] - 1843:9,
1865:8, 1870:25,
1916:23, 1917:9,
4047.40
1917:13
<b>older</b> [1] - 1812:5
older [1] - 1812:5 olive [1] - 1826:1
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] -
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11, 1974:21, 1974:25
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11, 1974:21, 1974:25 Omega-3s [1] -
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11, 1974:21, 1974:25 Omega-3s [1] - 1766:10
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11, 1974:21, 1974:25 Omega-3s [1] - 1766:10 omega-3s [3] -
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11, 1974:21, 1974:25 Omega-3s [1] - 1766:10 omega-3s [3] - 1766:25, 1841:20,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11, 1974:21, 1974:25 Omega-3s [1] - 1766:10 omega-3s [3] - 1766:25, 1841:20, 1948:9
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11, 1974:21, 1974:25 Omega-3s [1] - 1766:10 omega-3s [3] - 1766:25, 1841:20, 1948:9 once [5] - 1871:10,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11, 1974:21, 1974:25 Omega-3s [1] - 1766:10 omega-3s [3] - 1766:25, 1841:20, 1948:9 once [5] - 1871:10, 1919:16, 1960:3,
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11, 1974:21, 1974:25 Omega-3s [1] - 1766:10 omega-3s [3] - 1766:25, 1841:20, 1948:9 once [5] - 1871:10, 1919:16, 1960:3, 1967:24, 1969:20
older [1] - 1812:5 olive [1] - 1826:1 OM3 [1] - 1974:20 Omacor [3] - 1963:19, 1963:21, 1964:1 Omega-3 [5] - 1875:8, 1897:19, 1897:23, 1953:10, 1953:25 omega-3 [24] - 1760:14, 1761:5, 1764:4, 1764:6, 1764:18, 1764:24, 1765:11, 1766:6, 1767:6, 1780:20, 1786:1, 1803:20, 1803:22, 1804:1, 1804:4, 1821:17, 1825:10, 1850:7, 1850:17, 1916:22, 1919:3, 1972:11, 1974:21, 1974:25 Omega-3s [1] - 1766:10 omega-3s [3] - 1766:25, 1841:20, 1948:9 once [5] - 1871:10, 1919:16, 1960:3,

MARGARET E. GRIENER, RDR, CCR NO. 3, OFFICIAL REPORTER (775) 329-9980

1777:1

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/	n	
	U	

				26
1765:8, 1765:23,	1913:22, 1968:16	1948:24, 1951:16,	1821:6, 1822:4,	1815:6, 1836:19,
1768:6, 1771:18,	<b>open</b> [5] - 1905:5,	1964:7, 1964:16,	1823:8, 1825:22,	1837:8, 1864:6,
1771:20, 1771:23,	1929:14, 1986:2,	1964:21, 1969:12	1829:12, 1830:17,	1881:22, 1883:14,
1771:24, 1771:25,	1986:12, 1989:13	organic [1] - 1786:5	1832:1, 1832:8,	1889:8, 1889:9,
1773:21, 1776:2,	opening [2] - 1995:18,	organizations [1] -	1833:4, 1834:18,	1904:15, 1918:3,
1783:9, 1785:17,	1996:6	1930:12	1835:15, 1835:16,	1921:25, 1923:2,
1786:24, 1793:5,	opens [1] - 1795:20	organized [1] -	1835:17, 1835:22,	1933:23, 1934:1,
1793:18, 1794:16,	Operating [1] -	1936:16	1837:7, 1837:11,	1935:16, 1935:24,
1796:8, 1796:15,	1959:21	orient [3] - 1820:3,	1837:15, 1837:16,	1936:1, 1965:18,
1803:25, 1804:18,	operating [1] -	1833:13, 1871:18	1837:17, 1837:18,	1976:18, 1995:17,
1805:20, 1808:6,	1910:14	origin [2] - 1825:6,	1837:19, 1839:6,	1995:18, 1995:19
1810:16, 1821:19,	opinion [43] - 1774:4,	1825:11	1839:12, 1839:13,	paid [18] - 1928:16,
1825:19, 1826:12,	1776:5, 1779:5,	original [1] - 1980:1	1839:14, 1839:15,	1928:18, 1931:11,
1826:19, 1833:5,	1781:4, 1781:7,	otherwise [4] -	1839:17, 1839:18,	1931:17, 1931:24,
1834:2, 1835:16,	1781:15, 1781:18,	1884:7, 1939:8,	1839:21, 1840:5,	1932:8, 1932:19,
1836:8, 1837:3,	1782:16, 1782:18,	1945:13, 1978:23	1840:22, 1843:1,	1932:25, 1933:4,
1839:6, 1840:23,	1782:25, 1783:3,	ought [3] - 1795:21,	1843:2, 1844:10,	1938:2, 1938:10,
1842:15, 1843:15,	1783:6, 1786:17,	1812:3, 1939:12	1846:9, 1846:10,	1938:21, 1939:2,
1844:12, 1847:12,	1789:12, 1789:24,	outcome [7] -	1847:21, 1848:21,	1940:17, 1942:10,
1850:12, 1850:22,	1790:12, 1790:21,	1764:18, 1764:25,	1850:14, 1852:14,	1942:18, 1967:14,
1854:4, 1855:14,	1791:2, 1791:4,	1765:10, 1765:20,	1857:13, 1860:18,	1967:15
1857:10, 1861:13,	1791:8, 1791:18,	1903:21, 1904:1,	1861:21, 1861:22,	pancreatitis [4] -
1862:4, 1862:11,	1806:5, 1806:7,	1904:2	1864:23, 1867:25,	1859:4, 1859:8,
1862:12, 1862:14,	1806:13, 1807:7,	Outcomes [3] -	1868:23, 1870:24,	1859:14, 1859:19
1862:23, 1863:14,	1807:11, 1818:13,	1897:20, 1907:13,	1871:20, 1871:21,	paper [25] - 1763:6,
1863:18, 1864:15,	1822:8, 1856:1,	1907:24	1872:14, 1873:4,	1829:12, 1842:20,
1864:19, 1867:14,	1856:22, 1860:21,	outcomes [5] -	1875:3, 1875:19,	1844:9, 1849:15,
1867:17, 1867:22,	1861:4, 1868:6,	1899:12, 1912:23,	1877:8, 1879:4,	1849:16, 1850:19,
1868:2, 1869:4,	1868:9, 1868:10,	1920:25, 1921:1,	1887:7, 1889:23,	1850:20, 1854:19,
1869:8, 1869:16,	1868:13, 1882:14,	1924:17	1889:24, 1900:10,	1866:2, 1866:19,
1870:6, 1871:9,	1890:23, 1895:1,	outside [1] - 1794:23	1900:17, 1906:8,	1866:20, 1869:19,
1872:5, 1872:9,	1895:14, 1896:6,	overcome [1] -	1906:19, 1907:6,	1870:6, 1870:14,
1876:8, 1877:19,	1899:9, 1909:13	1915:23	1908:6, 1908:19,	1877:22, 1889:5,
1878:14, 1878:17,	opinions [2] -	overrule [2] - 1796:25,	1908:25, 1909:15,	1901:22, 1946:17,
1878:20, 1878:22,	1965:12, 1967:19	1812:23	1911:13, 1916:7,	1956:6, 1968:19,
1878:23, 1879:13,	opportunity [9] -	overruled [3] - 1800:7,	1917:6, 1923:19,	1971:12, 1978:24,
1882:25, 1884:13,	1938:20, 1942:7,		1929:13, 1933:6,	1980:9, 1981:15
1886:23, 1890:2,	1944:17, 1944:18,	1915:16, 1915:24	1946:5, 1946:22,	paper's [1] - 1866:4
1890:20, 1890:23,	1945:6, 1945:12,	overstated [1] -	1946:23, 1947:4,	papers [15] - 1828:9,
1902:6, 1902:15,	1987:5, 1987:9,	1909:11	1947:12, 1947:15,	1828:11, 1837:3,
1903:5, 1904:16,	1993:15	own [6] - 1800:16,	1948:11, 1949:4,	1840:18, 1845:6,
1907:17, 1916:5,	opposed [1] - 1818:17	1906:1, 1909:13,	1949:13, 1949:15,	1847:4, 1856:5,
1918:9, 1926:20,	optimal [1] - 1858:18	1924:15, 1942:4,	1950:7, 1951:21,	1857:11, 1863:8,
1926:21, 1933:19,	optimistic [1] -	1971:2	1952:9, 1953:14,	1863:19, 1877:24,
1935:17, 1936:10,	1766:24	Б	1954:9, 1954:19,	1878:4, 1967:8,
1936:16, 1937:18,	options [1] - 1974:8	Р	1955:5, 1956:3,	1967:10, 1971:4
1951:9, 1957:17,	Optum [4] - 1912:22,	<b>P-OM3</b> [1] - 1974:20	1956:13, 1957:10,	paragraph [25] -
1963:2, 1963:3,	1967:9, 1967:14		1957:24, 1960:4,	1760:6, 1761:8,
1963:6, 1963:7,	order [11] - 1777:6,	P.M [1] - 1944:1	1960:6, 1960:8,	1761:9, 1763:6,
1965:13, 1965:14,	1810:1, 1856:11,	page [147] - 1757:25,	1961:12, 1962:14,	1767:25, 1768:7,
1966:8, 1967:21,	1914:23, 1985:19,	1759:15, 1760:6,	1962:15, 1963:13,	1797:19, 1803:2,
1968:20, 1970:3,		1762:16, 1763:5,	1965:19, 1969:23,	1869:11, 1889:23,
1971:13, 1977:14,	1986:19, 1989:8, 1989:10, 1989:15,	1763:15, 1767:25,	1970:1, 1970:3,	1946:6, 1949:4,
1977:16, 1984:16,		1768:7, 1770:11,	1970:5, 1970:7,	1949:14, 1951:22,
1991:2, 1991:9,	1989:19, 1991:7	1770:21, 1772:15,	1971:15, 1974:20,	1952:11, 1952:12,
1993:7, 1995:12	ordinary [16] -	1775:5, 1798:16,	1975:23, 1976:16,	1954:10, 1955:4,
one-and-a-half [1] -	1762:19, 1764:3,	1798:20, 1800:13,	1978:21, 1987:18,	1955:13, 1955:19,
1793:18	1769:11, 1769:20,	1802:12, 1803:15,	1995:13, 1995:15	1956:1, 1956:14,
onerous [1] - 1988:1	1770:6, 1779:6,	1809:2, 1813:6,	PAGE [1] - 1997:3	1961:13, 1963:16,
ones [1] - 1972:8	1779:11, 1780:1,	1815:20, 1816:5,	pages [25] - 1794:6,	1976:4
ongoing [3] - 1912:3,	1780:12, 1860:24,	1817:12, 1817:13,	1800:11, 1805:10,	
] 5: 5:4 :5:=:5;			ļ , ,	

				2
paralegal [1] - 1985:1	1782:10, 1782:14,	1885:16, 1885:20,	1863:9, 1863:24,	1897:16, 1951:4,
parallel [1] - 1769:10	1782:22, 1783:2,	1891:23, 1893:13,	1865:9, 1866:3,	1951:7, 1964:9
parameters [2] -	1793:12, 1793:14,	1893:18, 1893:24,	1866:5, 1866:21,	peer [7] - 1900:2,
1948:19, 1966:14	1793:21, 1793:25,	1895:21, 1895:22,	1869:16, 1869:21,	1900:3, 1900:6,
parent [1] - 1922:14	1794:3, 1794:9,	1896:6, 1950:3,	1870:11, 1871:3,	1901:17, 1982:1,
	1794:19, 1797:10,	1950:10, 1951:1,	1873:21, 1873:24,	1982:3, 1982:7
parentheses [1] -	1794:19, 1797:10,	1957:16, 1957:20,	1874:12, 1877:9,	
1976:24	1797:10, 1797:20, 1797:25,	1957:10, 1957:20,	1878:12, 1878:18,	penalties [1] - 1930:15
Park [3] - 1854:18,		· · · · ·		
1855:2, 1855:22	1798:2, 1798:3,	1962:12, 1968:20,	1883:7, 1888:14,	pending [1] - 1898:1
PARK [1] - 1757:15	1799:12, 1799:15,	1969:14, 1977:14,	1890:13, 1892:14,	people [16] - 1763:20,
part [12] - 1811:16,	1799:18, 1800:11,	1996:13	1892:16, 1893:7,	1764:6, 1764:12,
1904:3, 1911:18,	1800:18, 1800:21,	Patient [1] - 1908:14	1893:10, 1894:12,	1764:15, 1765:24,
1923:8, 1929:9,	1801:1, 1802:7,	patient's [8] -	1894:19, 1895:12,	1766:17, 1766:22,
1932:10, 1944:19,	1802:13, 1802:16,	1776:15, 1874:3,	1896:15, 1896:20,	1768:6, 1845:6,
1953:5, 1965:21,	1803:7, 1804:10,	1893:13, 1893:15,	1897:9, 1897:10,	1859:20, 1860:7,
1974:4, 1988:11,	1804:23, 1805:8,	1893:22, 1895:17,	1899:5, 1900:13,	1861:13, 1866:16,
1991:10	1805:12, 1805:17,	1913:19, 1968:13	1901:15, 1902:14,	1868:25, 1892:25,
partial [1] - 1819:8	1805:21, 1805:23,	Patients [2] - 1767:12,	1902:17, 1906:16,	1893:1
partially [1] - 1975:13	1807:20, 1819:17,	1889:17	1907:19, 1912:23,	per [38] - 1761:18,
participants [2] -	1822:22, 1849:21,	patients [147] -	1913:23, 1919:13,	1761:22, 1762:8,
1774:10, 1919:11	1867:22, 1868:7,	1768:12, 1769:22,	1919:16, 1923:16,	1762:9, 1781:3,
participated [1] -	1868:8, 1868:14,	1769:25, 1770:8,	1924:2, 1925:13,	1785:12, 1785:20,
1764:12	1875:20, 1879:3,	1772:1, 1774:10,	1950:15, 1950:24,	1788:8, 1794:14,
participation [1] -	1880:5, 1881:6,	1774:14, 1775:21,	1951:16, 1952:6,	1821:15, 1832:19,
1889:18	1883:13, 1884:1,	1777:11, 1778:1,	1952:15, 1952:17,	1834:3, 1841:7,
Particle [1] - 1824:20	1885:11, 1885:16,	1778:7, 1779:5,	1957:1, 1957:2,	1852:3, 1852:8,
particle [1] - 1829:3	1886:3, 1886:5,	1779:8, 1779:12,	1958:12, 1958:15,	1852:9, 1853:1,
particular [5] -	1894:15, 1894:19,	1780:2, 1780:7,	1958:16, 1958:22,	1855:2, 1855:17,
1848:19, 1864:23,	1897:3	1780:9, 1780:14,	1961:7, 1961:24,	1855:23, 1856:2,
1922:16, 1978:1,	patents [12] - 1793:17,	1780:17, 1780:21,	1962:6, 1962:7,	1856:20, 1856:23,
1978:7	1794:1, 1797:11,	1785:14, 1785:21,	1966:22, 1968:12,	1858:6, 1867:15,
particularly [4] -	1799:20, 1800:16,	1787:2, 1787:13,	1968:17, 1969:1,	1877:9, 1891:10,
• • • • • • • • • • • • • • • • • • • •	1801:5, 1804:23,	1787:21, 1789:2,	1973:12	1907:21, 1922:10,
1893:4, 1913:22,	1890:21, 1894:23,	1789:16, 1789:21,	patients, [1] - 1960:15	1923:17, 1927:13,
1962:24, 1968:16	1895:5, 1895:8,	1790:7, 1790:15,	Paul [1] - 1997:4	1936:16, 1957:4,
parties [1] - 1811:21	1895:20	1790:18, 1790:22,	PAUL [1] - 1759:8	1958:6, 1958:7,
partner [3] - 1832:18,	patents-in-suit [1] -	1791:20, 1792:1,	pay [3] - 1929:16,	1961:3, 1961:4
1832:23, 1907:9	1801:5	1792:8, 1792:15,	1932:6, 1932:10	Percent [1] - 1908:13
partnering [1] -	patient [67] - 1769:12,	1801:8, 1801:17,	payment [2] -	percent [64] - 1769:17,
1832:3	1776:8, 1776:9,	1805:4, 1805:14,	1929:14, 1935:2	1770:16, 1771:12,
partners [1] - 1907:17	1776:24, 1776:25,	1805:19, 1806:8,	payments [16] -	1771:15, 1771:23,
party [4] - 1938:10,	1788:1, 1788:4,	1806:21, 1807:13,	1928:21, 1929:8,	1772:9, 1772:20,
1944:13, 1991:9,	1789:18, 1802:24,	1808:18, 1808:22,	1929:14, 1930:24,	1773:12, 1782:11,
1991:25	1815:12, 1815:14,	1811:3, 1813:13,	1932:11, 1932:12,	1805:5, 1816:19,
passage [10] - 1762:7,	1815:15, 1818:16,	1813:17, 1814:1,	1936:17, 1936:24,	1816:22, 1816:25,
1775:7, 1796:16,	1818:17, 1819:3,	1815:17, 1818:6,	1939:2, 1939:24,	1817:2, 1817:5,
1946:21, 1946:25,	1819:12, 1821:14,	1818:21, 1818:24,	1940:4, 1942:10,	1817:7, 1817:17,
1947:17, 1954:8,	1856:24, 1860:9,	1821:10, 1821:23,	1943:3, 1943:13,	1826:5, 1826:21,
1962:20, 1966:8,	1860:10, 1862:4,	1822:10, 1822:12,	1986:3, 1986:13	1826:24, 1826:25,
1968:3	1862:11, 1862:13,	1822:15, 1823:18,	pdf [1] - 1934:4	1820:24, 1820:25, 1827:4, 1827:5,
passages [1] -	1862:20, 1862:23,	1829:18, 1838:24,	PDR [4] - 1817:13,	1827:10, 1828:5,
1946:20	1863:15, 1863:18,	1838:25, 1839:2,	1817:20, 1821:7,	1830:8, 1832:19,
passed [1] - 1934:23	1864:15, 1864:19,	1840:1, 1840:6,	1822:4	1832:20, 1836:3,
Patent [1] - 1806:3	1867:14, 1867:22,	1841:3, 1843:12,	PDX [17] - 1764:21,	1836:12, 1841:17,
patent [71] - 1778:11,	1870:6, 1874:17,	1843:16, 1850:22,	1765:13, 1765:16,	1841:21, 1841:23,
1778:15, 1778:22,	1876:16, 1877:20,	1856:6, 1856:9,	, , ,	1841:25, 1842:5,
1778:25, 1779:2,	1878:14, 1878:17,	1856:13, 1856:20,	1766:2, 1769:1,	· · · · · · · · · · · · · · · · · · ·
1780:24, 1781:1,	1878:20, 1878:22,	1858:21, 1858:22,	1773:23, 1774:1,	1842:6, 1852:10,
1781:2, 1781:11,	1878:23, 1879:10,	1859:3, 1859:18,	1774:4, 1778:19,	1852:12, 1870:13,
1781:22, 1782:4,	1880:7, 1880:15,	1859:25, 1861:10,	1781:24, 1782:23,	1870:20, 1872:20,
1782:5, 1782:7,	1882:11, 1885:11,	1862:14, 1863:6,	1819:22, 1894:6,	1872:25, 1880:20,
	1002.11, 1000.11,	1002.17, 1000.0,		

1896:18, 1896:20, 1927:14, 1927:16 1805:20, 1806:2, 1859:21, 1869:3, 1963:9 1900:19, 1901:3, physician [3] - 1870:3, 1806:17, 1807:10, 1934:8, 1967:23, prejudice [1] - 1810:5 1974:6. 1974:13 1902:14, 1902:17, 1811:8, 1836:5, 1972:16 preliminary [1] -1845:5, 1860:16. 1905:7, 1906:24, physicians [6] possibly [1] - 1799:25 1943:16 1919:18, 1921:17, 1911:10. 1911:24. 1868:2, 1880:12, post [14] - 1795:15, premise [1] - 1886:1 1922:13, 1924:5, 1926:9, 1929:21, 1939:8, 1941:21, 1956:11, 1956:12, prepared [8] -1934:19, 1949:8, 1930:25, 1936:17 1942:17, 1943:10, 1990:8, 1990:10, 1764:17, 1778:16, 1963:10, 1963:22, 1949:24, 1973:15, physiologic [1] -1990:20, 1992:1, 1814:22, 1907:8, 1994:13 1977:3, 1977:8, 1992:4, 1992:10, 1923:15, 1931:3, 1777:3 1977:14 physiology [1] pointed [2] - 1973:22, 1992:18, 1993:6, 1942:25, 1974:2 perfect [1] - 1994:12 1978:1 1776:15 1995:14, 1995:25 prescribe [1] - 1874:7 perform [2] - 1922:15, PI [1] - 1823:10 pointing [2] - 1811:10, post-dating [2] prescribed [6] -1966:16 1934:16 1956:11, 1956:12 picture [1] - 1888:16 1808:4. 1808:6. performed [1] points [5] - 1789:25, post-trial [12] piece [1] - 1802:3 1871:17, 1873:17, 1946:10 1821:5, 1863:5, 1795:15. 1990:8. 1874:2, 1891:16 pill [1] - 1822:19 perhaps [5] - 1783:22, pills [1] - 1822:15 1919:24, 1939:10 1990:10, 1990:20, prescribing [1] -1850:24, 1879:20, population [32] -1992:1, 1992:4, pin [3] - 1795:5, 1891:14 1885:23, 1924:23 1761:19, 1761:22, 1992:10, 1992:18, 1795:9, 1795:11 prescription [3] -1993:6, 1995:14, period [2] - 1811:9, 1763:2, 1763:10, 1875:8, 1973:13, place [1] - 1857:6 1896:12 1763:12, 1769:5, 1995:25 1974:21 placebo [11] -1769:12, 1788:11, posttreatment [1] permit [3] - 1980:24, present [8] - 1784:20, 1775:15, 1778:24, 1789:18, 1802:24, 1967:2 1986:17, 1991:16 1800:3, 1871:1, 1782:6, 1782:12, 1856:24, 1860:2. person [17] - 1762:19, potency [3] - 1874:15, 1945:6, 1945:12, 1816:15, 1825:24, 1903:16, 1905:18, 1892:24. 1893:5 1764:3, 1764:7, 1826:1, 1853:8, 1962:25, 1991:15, 1925:6, 1950:3, 1769:11, 1769:20, potential [6] - 1767:6, 1957:22, 1958:11, 1991:16 1770:6, 1779:6, 1951:1, 1951:11, 1832:18, 1832:23, 1961:3 presentation [8] -1952:2, 1952:24, 1834:2, 1888:15, 1779:10, 1779:25, Placebo [1] - 1909:23 1832:4, 1833:10, 1953:4, 1956:22, 1907:17 1780:12, 1860:24, placebo-controlled 1834:14, 1834:21, 1957:17, 1957:20, 1948:24, 1951:15, Potentially [1] -1845:21, 1857:14, [1] - 1825:24 1958:17, 1958:20, 1964:7, 1964:16, 1767:12 1907:8, 1909:17 plaintiff [1] - 1985:8 1964:21, 1969:12 1959:1, 1962:12, powered [2] -PLAINTIFF'S [2] presenting [5] -1968:20, 1969:4, personal [1] - 1946:12 1792:25, 1922:15 1800:4, 1844:16, 1997:3, 1997:9 1969:14, 1972:14 personality [1] powerful [1] - 1970:25 1860:22. 1911:9 plaintiffs [2] - 1757:6, 1771:21 populations [3] practice [3] - 1768:11. presumption [1] -1759:8 1763:14, 1764:4, personally [7] -1794:25. 1885:15 1895:2 PLAINTIFFS [1] -1952:4 1912:1, 1912:5, praise [8] - 1773:24, pretrial [3] - 1810:1, 1757:14 portion [5] - 1810:11, 1940:11, 1940:17, 1774:6, 1774:13, 1914:23, 1990:22 PLAINTIFFS' [1] -1942:19, 1943:3, 1813:24, 1814:20, 1848:18, 1849:6, pretty [7] - 1826:24, 1997:13 1825:15, 1945:14 1943:14 1849:7, 1849:13, 1861:7, 1887:20, Plaintiffs' [4] portions [7] - 1809:11, persons [1] - 1861:2 1904:22 1901:20, 1977:13, 1765:17, 1767:23, 1814:11. 1817:11. perspective [1] praised [2] - 1912:1, 1988:1, 1989:11 1911:3, 1984:14 1824:25. 1828:13. 1964:23 1912:5 prevent [2] - 1874:12, plan [3] - 1910:14, 1946:5, 1989:12 praising [2] - 1905:11, **PETER** [1] - 1759:8 1902:1 1985:25, 1986:1 POSA [2] - 1786:9, Peter [3] - 1983:11, 1905:12 prevented [1] - 1842:7 Plan [1] - 1959:21 1827:23 1983:22, 1997:4 Pravastatin [1] preventing [4] plasma [4] - 1761:17, position [9] - 1760:21, **PHARMA**[1] - 1757:4 1902:17 1766:11, 1953:11, 1865:8, 1870:25, 1804:10, 1861:7, Pharma [1] - 1928:21 preclude [1] - 1810:3 1954:1, 1961:23 1871:3 1935:12, 1944:11, pharma [1] - 1930:16 predating [1] - 1955:1 prevention [5] play [2] - 1798:10, 1944:24, 1944:25, PHARMACEUTICAL prediction [2] -1897:10, 1901:12, 1933:6 1973:8, 1981:8 **S**[2] - 1757:4, 1792:14, 1792:17 1907:21, 1919:13, played [1] - 1933:8 positive [2] - 1899:13, 1757:8 predictive [1] -1952:5 playing [1] - 1798:12 1902:24 pharmacologist [1] -1802:18 previous [8] - 1761:5, **PLESSIS** [1] - 1758:5 possession [1] -1927:16 Predictors [1] -1761:19, 1838:23, plotting [1] - 1923:15 1945:2 phenomenon [2] -1912:13 1956:15, 1956:19, plus [5] - 1842:6, possibilities [1] -1956:22, 1956:23, 1969:15, 1969:16 pref [1] - 1996:6 1869:9, 1877:10, 1858:24 1956:25 phenotype [5] prefer [1] - 1795:12 1962:24, 1963:8 possibility [1] previously [1] -1865:10, 1865:11, preferable [2] point [24] - 1771:5, 1775:8 1759.9 1866:11, 1866:14, 1962:16, 1962:18 1776:25, 1777:1, possible [7] -1866:21 primarily [1] - 1859:8 1789:20, 1790:4, preferably [3] -1791:15, 1794:16, primary [18] - 1759:20, Philip [3] - 1867:12, 1963:1, 1963:6, 1790:16, 1804:10,

٠,	

				2.9
1777:17, 1808:14,	properly [1] - 1914:15	1937:15, 1937:16,	1883:2, 1885:6,	Q
1899:13, 1902:23,	proportion [1] -	1987:6	1886:16, 1886:21,	¥
1907:4, 1907:20,	1963:8	publically [1] -	1899:3, 1899:4,	<b>Q3</b> [1] - 1911:6
1908:1, 1908:3,	proportionate [1] -	1966:20	1900:19, 1902:7,	qualification [1] -
1913:19, 1918:24,	1807:1	publication [6] -	1903:6, 1904:4,	1879:13
1919:13, 1919:15,	proposal [3] -	1759:13, 1762:18,	1904:7, 1906:2,	qualify [1] - 1874:15
1919:18, 1920:5,	1940:25, 1993:5,	1770:11, 1904:21,	1915:13, 1925:11,	quantitative [2] -
1955:15, 1955:24,	1994:3	1954:22, 1967:15	1952:24, 1953:3,	1845:21, 1910:14
1968:13	<b>propose</b> [2] - 1944:15,	publications [6] -	1969:6	Quantitative [1] -
principal [2] - 1904:1,	1993:13	1926:20, 1946:11,	Purified [1] - 1824:18	1911:6
1904:3	proposed [20] -	1954:25, 1955:2,	purified [31] - 1786:6,	quantitatively [1] -
principally [1] -	1944:10, 1988:23,	1955:3, 1956:11	1789:2, 1804:8,	1844:21
1914:17	1990:7, 1990:12,	publicly [1] - 1928:22	1805:14, 1805:19,	QUESTION [1] -
priority [3] - 1859:9,	1990:16, 1991:1,	publish [1] - 1927:8	1822:22, 1822:25,	1869:10
1859:12	1991:3, 1991:5,	published [13] -	1823:18, 1824:4,	
problem [8] - 1786:18,	1991:8, 1991:12,	1762:21, 1825:8,	1825:25, 1829:18,	questioned [1] -
1860:7, 1865:12,	1992:6, 1992:10,	1898:9, 1899:20,	1830:3, 1839:8,	1945:24
1892:17, 1902:10,	1992:18, 1993:16,	1913:5, 1916:9,	1840:8, 1849:21,	questioning [2] -
1902:20, 1925:3,	1993:23, 1994:3,	1918:10, 1922:18,	1852:3, 1852:9,	1795:21, 1969:10
1931:15	1993.23, 1994.3, 1994:16, 1995:8,	1916.10, 1922.16, 1956:5, 1967:10,	1853:1, 1855:3,	questions [13] -
problems [1] -	1994.10, 1995.0,	1981:18, 1981:24,	1855:23, 1856:2,	1777:16, 1783:13,
1944:21	proposition [1] -	1986:12	1858:20, 1860:13,	1784:15, 1920:16,
proceed [4] - 1759:6,	1905:16	pull [9] - 1760:5,	1861:10, 1865:7,	1932:2, 1932:4,
		•	1871:2, 1880:20,	1933:14, 1941:2,
1784:6, 1814:23, 1853:12	prosecution [2] -	1762:16, 1763:5, 1770:10, 1774:1,	1899:11, 1902:1	1954:4, 1977:17,
	1804:22, 1867:13	, ,	purity [7] - 1775:21,	1980:14, 1980:20,
proceeding [1] -	prospectively[1] -	1782:23, 1836:23,	1826:5, 1861:1,	1982:24
1760:24	1917:14	1946:6, 1949:4	1960:13, 1963:2,	quickly [3] - 1821:6,
proceedings [1] -	protein [1] - 1760:16	pulling [1] - 1889:5	1963:5, 1963:7	1927:23, 1942:17
1996:22	protocol [1] - 1792:7	pure [84] - 1787:12,	purpose [3] - 1812:25,	quite [2] - 1944:13,
process [10] - 1900:6,	proudly [1] - 1926:11	1787:20, 1788:1,	1895:25, 1913:1	1969:5
1919:7, 1921:12,	<b>prove</b> [4] - 1863:8,	1788:8, 1790:7,	purposes [1] -	<b>quote</b> [2] - 1766:15,
1929:13, 1929:15,	1915:14, 1925:4,	1790:14, 1790:22,	1826:12	1920:10
1929:21, 1982:4,	1925:8	1791:4, 1791:9,		quoted [2] - 1867:18,
1987:10, 1987:14,	proved [2] - 1925:10,	1792:1, 1792:7,	<b>put</b> [14] - 1784:16, 1809:21, 1812:16,	1979:14
1988:2	1925:11	1792:15, 1792:23,	1850:13, 1866:9,	<b>quotes</b> [1] - 1980:6
produced [4] -	<b>Proven</b> [2] - 1907:12,	1794:20, 1797:11,		<b>quoting</b> [2] - 1766:11,
1910:20, 1933:24,	1907:23	1799:21, 1800:16,	1869:2, 1884:18,	1831:23
1934:4, 1957:8	<b>proves</b> [1] - 1925:9	1801:8, 1804:5,	1887:3, 1898:8,	
product [3] - 1851:4,	<b>provide</b> [14] - 1766:7,	1804:19, 1805:5,	1944:18, 1959:5,	R
1904:8, 1963:15	1791:17, 1791:22,	1819:3, 1823:22,	1964:10, 1981:8,	
professional [1] -	1792:9, 1850:16,	1823:25, 1824:1,	1987:5	raise [3] - 1796:1,
1996:15	1864:1, 1882:14,	1827:3, 1830:8,	putting [1] - 1866:7	1801:17, 1943:6
profile [3] - 1895:17,	1917:16, 1925:15,	1830:13, 1832:19,	<b>PX</b> [30] - 1759:13,	raised [2] - 1951:12,
1895:18, 1950:13	1949:25, 1950:13,	1841:17, 1841:23,	1766:10, 1766:15,	1986:7
profound [1] -	1950:23, 1965:15,	1841:25, 1851:9,	1767:9, 1767:16,	raises [1] - 1834:22
1773:11	1988:22	1851:11, 1854:13,	1770:10, 1772:5,	Rambjør [18] - 1828:9,
profoundly [1] -	provided [9] -	1855:18, 1856:9,	1774:5, 1775:4,	1828:11, 1840:21,
1924:25	1796:24, 1814:10,	1856:13, 1856:20,	1798:22, 1848:11,	1840:25, 1841:17,
program [1] - 1980:10	1850:6, 1868:8,	1857:1, 1858:15,	1848:21, 1887:3,	1842:10, 1842:20,
progress [1] - 1897:24	1924:16, 1924:20,	1862:24, 1863:15,	1887:5, 1904:14,	1843:8, 1843:15,
projects [2] - 1926:16,	1934:23, 1967:6,	1876:18, 1878:11,	1910:12, 1910:22,	1843:16, 1843:18,
1926:17	1967:13	1878:16, 1878:18,	1911:13, 1946:18,	1843:25, 1844:3,
promise [4] - 1785:17,	providers [1] -	1878:25, 1879:10,	1953:8, 1969:18,	1845:24, 1846:24,
1788:6, 1903:1,	1926:10	1879:17, 1879:22,	1971:11, 1974:19,	1847:5, 1847:6
1919:25	provides [7] - 1845:8,	1880:6, 1880:13,	1982:10, 1983:16,	range [6] - 1857:4,
promised [1] -	1845:21, 1858:5,	1880:20, 1881:1,	1983:19, 1983:20,	1857:24, 1858:1,
1985:18	1902:6, 1903:5,	1881:8, 1881:13,	1983:21	1950:23, 1977:1,
promising [2] -	1954:13, 1967:2	1882:1, 1882:7,		1977:5
1901:12, 1902:1	public [6] - 1929:25,	1882:11, 1882:15,		rare [1] - 1763:23
<b>proper</b> [1] - 1938:9	1930:1, 1937:11,	1882:16, 1882:22,		rate [2] - 1924:3,

				31
1934:19	1787:4, 1787:16,	recessed [1] - 1944:5	1987:9	1825:12, 1827:3,
rather [5] - 1773:21,	1789:10, 1789:14,	recognize [24] -	redacted [7] -	1836:12, 1839:9,
1776:3, 1948:1,	1789:24, 1791:17,	1793:11, 1813:7,	1939:12, 1940:9,	1840:8, 1851:12,
1978:6, 1979:10	1791:22, 1792:3,	1813:9, 1821:6,	1945:10, 1987:25,	1852:4, 1853:1,
Rather [1] - 1947:21	1792:10, 1792:16,	1823:10, 1836:21,	1988:24, 1989:9,	1855:3, 1855:23,
ratio [5] - 1761:6,	1800:5, 1800:20,	1851:16, 1852:14,	1992:24	1856:2, 1856:9,
1771:4, 1922:11,	1801:13, 1805:24,	1854:1, 1854:18,	redacting [2] -	1860:10, 1860:14,
1962:20, 1962:22	1858:6, 1858:11,	1855:12, 1864:25,	1940:20, 1989:12	1871:25, 1873:14,
raw [1] - 1966:16	1903:7, 1924:16,	1865:16, 1871:22,	redaction [3] - 1940:5,	1876:13, 1879:11,
re [4] - 1980:21,	1924:20	1873:6, 1875:19,	1989:7	1880:6, 1880:13,
1980:25, 1982:14	reasonably [10] -	1877:6, 1881:23,	redactions [1] -	1881:2, 1881:14,
re-recross [2] -	1779:6, 1779:11,	1887:5, 1889:3,	1940:8	1882:7, 1883:3,
1980:25, 1982:14	1780:1, 1790:14,	1894:6, 1897:16,	REDDY'S [1] -	1886:22, 1886:24,
•	1793:5, 1829:22,	1899:17, 1918:5	1758:10	1892:11, 1904:10,
re-redirect [2] -	1829:25, 1860:13,			1971:20, 1972:6,
1980:21, 1980:25	1901:25, 1946:13	recognized [1] - 1938:23	Redirect [2] - 1997:5,	1972:10, 1972:13,
reaching [1] - 1953:25	reasoning [8] -		1997:6	1973:17, 1975:1
read [31] - 1762:7,	_	recollection [3] -	redirect [5] - 1945:19,	•
1774:13, 1779:18,	1781:5, 1781:7,	1799:11, 1799:14,	1973:16, 1977:23,	REDUCE-IT [52] -
1784:21, 1785:1,	1781:16, 1781:18,	1990:3	1980:21, 1980:25	1759:14, 1760:11,
1785:3, 1793:21,	1782:17, 1782:18,	recommendation [1] -	REDIRECT[2] -	1761:12, 1761:16,
1794:12, 1795:17,	1782:25, 1783:3	1911:16	1945:22, 1981:1	1761:25, 1762:4,
1797:9, 1797:22,	reasons [3] - 1778:10,	recommendations [1]	<b>Reduce</b> [2] - 1918:6,	1762:10, 1767:7,
1797:25, 1802:14,	1789:15, 1934:6	- 1766:16	1974:21	1768:15, 1769:4,
1830:8, 1830:12,	reassuring [1] -	reconditions [1] -	REDUCE [52] -	1772:7, 1772:9,
1830:23, 1831:9,	1905:3	1764:12	1759:14, 1760:11,	1773:2, 1773:16,
1833:5, 1844:5,	rebuttable [1] - 1895:2	record [32] - 1784:14,	1761:12, 1761:16,	1773:20, 1774:6,
1857:18, 1884:6,	rebuttal [2] - 1985:10,	1802:17, 1805:10,	1761:25, 1762:4,	1774:9, 1774:18,
1884:7, 1884:8,	1985:12	1810:17, 1811:5,	1762:10, 1767:7,	1775:1, 1775:19,
1917:5, 1919:8,	recalled [1] - 1759:8	1825:22, 1833:12,	1768:15, 1769:4,	1775:22, 1775:25,
1920:17, 1965:13,	recap [1] - 1855:20	1834:17, 1835:16,	1772:7, 1772:9,	1776:1, 1776:7,
1965:23, 1983:13	receive [8] - 1876:1,	1840:4, 1861:20,	1773:2, 1773:16,	1777:11, 1778:6,
reading [7] - 1797:15,	1876:17, 1880:7,	1867:25, 1869:5,	1773:20, 1774:6,	1894:3, 1894:9,
1838:17, 1858:11,	1882:21, 1885:1,	1889:24, 1915:6,	1774:9, 1774:18,	1894:12, 1895:5,
1880:24, 1884:5,	1885:13, 1885:21,	1917:6, 1928:8,	1775:1, 1775:19,	1895:14, 1896:8,
1955:13, 1963:11	1885:22	1930:4, 1931:7,	1775:22, 1775:25,	1896:15, 1897:5,
ready [6] - 1759:5,	received [25] -	1933:21, 1937:11,	1776:1, 1776:7,	1899:9, 1904:21,
1773:23, 1837:6,	1765:17, 1767:23,	1938:1, 1938:5,	1777:11, 1778:6,	1904:23, 1905:11,
1945:19, 1974:6,	1787:21, 1813:3,	1938:21, 1944:19,	1894:3, 1894:9,	1905:17, 1905:23,
1994:2	1849:1, 1851:25,	1978:5, 1984:24,	1894:12, 1895:5,	1910:2, 1910:6,
real [2] - 1913:2,	1852:23, 1854:10,	1991:4, 1991:5,	1895:14, 1896:8,	1920:15, 1924:18,
1942:17	1855:8, 1873:12,	1991:13, 1993:3,	1896:15, 1897:5,	1924:21, 1925:4,
real-world [1] - 1913:2	1885:11, 1896:8,	1996:22	1899:9, 1904:21,	1925:11, 1925:14,
reality [1] - 1980:9	1902:14, 1911:3,	recorded [1] - 1966:23	1904:23, 1905:11,	1926:25, 1927:1,
realize [1] - 1989:16	1916:1, 1918:1,	recording [1] - 1933:8	1905:17, 1905:23,	1927:3, 1927:5
realized [1] - 1969.16	1918:16, 1922:4,	records [3] - 1930:12,	1910:2, 1910:6,	reduced [9] - 1759:23,
- · ·	1932:16, 1936:12,	1937:15, 1937:16	1920:15, 1924:18,	1780:20, 1816:19,
really [8] - 1768:6,	1940:11, 1944:11,	recross [4] - 1977:19,	1924:21, 1925:4,	1831:14, 1852:8,
1789:25, 1810:14,	1945:16, 1984:14,	1980:22, 1980:25,	1925:11, 1925:14,	1872:20, 1901:3,
1810:20, 1859:7,	1984:15	1980.22, 1980.23,	1926:25, 1927:1,	1902:22, 1906:23
1867:19, 1891:1,	receives [1] - 1781:14	Recross [1] - 1997:6	1920.23, 1927.1,	Reduces [1] - 1908:8
1973:20	receiving [1] -	RECROSS [1] - 1997.0	reduce [54] - 1760:18,	reduces [7] - 1807:14,
reason [16] - 1769:21,	1775:21		1768:19, 1768:24,	1807:15, 1824:4,
1788:5, 1811:5,		1977:21	1779:1, 1779:4,	1824:11, 1860:9,
1830:18, 1830:25,	recent [4] - 1846:19,	Recross-	· · · · · ·	1906:2, 1919:3
1850:6, 1850:16,	1847:13, 1909:22,	Examination [1] -	1779:8, 1779:12, 1780:2, 1787:13,	reducing [14] -
1859:3, 1902:6,	1914:4	1997:6	, ,	1773:12, 1774:25,
1903:5, 1921:8,	receptors [1] -	RECROSS-	1799:22, 1801:9,	1776:16, 1856:13,
1942:19, 1945:11,	1975:11	EXAMINATION[1] -	1805:24, 1806:21,	1859:5, 1859:10,
1951:16, 1987:19,	recess [4] - 1853:17,	1977:21	1807:24, 1808:22,	1893:5, 1894:17,
1988:24	1853:19, 1943:20,	redact [4] - 1939:19,	1823:19, 1823:22,	1969:13, 1973:2,
reasonable [20] -	1995:4	1939:24, 1987:5,	1824:1, 1825:6,	1000.10, 1070.2,

2 1

				31
1973:21, 1974:5,	1780:5, 1780:8,	rejection [1] - 1802:13	remove [2] - 1787:23,	1931:3, 1931:8,
	, ,	•		
1974:7	1780:13, 1790:1,	relate [4] - 1796:17,	1994:25	1966:5, 1966:6,
reductase [3] -	1805:2, 1835:3,	1799:25, 1876:8,	removed [1] - 1931:4	1972:22
1877:10, 1877:13,	1835:14, 1835:17,	1935:21	Rene [1] - 1979:10	representation [7] -
1877:15	1835:20, 1836:8,	related [6] - 1796:6,	renew [1] - 1799:23	1797:1, 1809:20,
reduction [33] -	1836:15, 1837:16,	1894:23, 1895:1,	<b>RENO</b> [2] - 1759:1,	1814:20, 1814:24,
1769:17, 1769:19,	1839:6, 1839:12,	1903:19, 1909:3,	1944:1	1835:9, 1937:10,
1769:21, 1770:15,	1840:12, 1845:24,	1918:18	Reno [3] - 1757:7,	1941:19
1771:2, 1771:14,	1855:21, 1857:22,	relates [4] - 1794:23,	1757:23, 1758:13	representing [3] -
1772:9, 1772:20,	1861:20, 1861:23,	1795:15, 1796:8,	repeat [7] - 1779:22,	1800:2, 1923:20,
1773:2, 1773:4,	1862:10, 1862:25,	1859:4		1931:1
1773:9, 1775:1,	1863:3, 1864:10,	relating [8] - 1778:20,	1785:19, 1791:19,	
	1864:14, 1864:18,	• • • • • • • • • • • • • • • • • • • •	1802:10, 1880:10,	represents [1] -
1775:9, 1775:16,	1877:20, 1928:1,	1800:5, 1920:21,	1881:18, 1888:1	1797:20
1776:2, 1776:6,		1939:19, 1939:24,	repeatedly [4] -	reproduced [1] -
1777:19, 1778:16,	1954:17, 1978:25	1944:16, 1953:16,	1804:23, 1906:2,	1925:1
1778:23, 1779:3,	referencing [1] -	1965:4	1927:7, 1974:14	reputation [1] -
1806:10, 1808:15,	1814:23	relationship [2] -	rephrase [1] - 1885:24	1899:24
1870:13, 1870:20,	referred [2] - 1920:11,	1927:4, 1938:11	replicate [1] - 1969:3	request [3] - 1909:3,
1880:21, 1881:9,	1959:19	relationships [1] -	replied [1] - 1919:5	1940:7, 1940:21
1883:20, 1906:14,	referring [11] - 1805:2,	1926:1	Report [1] - 1889:3	requesting [2] -
1911:17, 1911:21,	1815:6, 1865:13,	relative [2] - 1772:9,	report [15] - 1772:7,	1921:6, 1990:8
1919:15, 1919:18,	1888:9, 1910:4,	1853:7	1772:18, 1780:5,	require [10] - 1778:7,
1949:8	1921:19, 1921:25,	release [1] - 1760:14		1797:22, 1810:1,
reductions [6] -	1924:5, 1929:1,	released [1] - 1918:10	1780:8, 1780:9,	1822:22, 1841:13,
1759:19, 1777:4,	1968:19, 1978:5		1860:20, 1860:23,	
1778:17, 1780:5,	refers [1] - 1820:5	relevance [3] -	1868:15, 1920:18,	1841:25, 1849:21,
1780:9, 1925:16	reflect [1] - 1767:6	1915:11, 1915:22,	1930:16, 1930:18,	1894:19, 1896:23,
		1916:16	1972:5, 1976:6,	1896:24
<b>refer</b> [2] - 1946:15, 1989:9	reflected [1] - 1766:6	relevant [8] - 1768:19,	1986:3	required [2] - 1800:20,
	reflecting [2] -	1768:23, 1795:1,	reported [20] -	1894:23
reference [46] -	1844:21, 1930:24	1809:7, 1813:24,	1769:17, 1769:22,	requirement [1] -
1762:11, 1780:19,	reflects [1] - 1761:3	1940:18, 1959:25,	1771:2, 1772:9,	1885:10
1795:18, 1800:14,	refresh [4] - 1799:11,	1987:18	1786:14, 1788:23,	requirements [2] -
1824:16, 1825:9,	1837:10, 1898:3,	reliability [1] - 1986:3	1817:19, 1836:3,	1920:23, 1937:18
1828:25, 1831:22,	1923:9	reliable [1] - 1941:10	1837:24, 1870:16,	requires [6] - 1819:17,
1832:12, 1832:16,	regard [12] - 1789:24,	reliance [1] - 1956:9	1888:1, 1901:2,	1820:25, 1876:4,
1835:20, 1840:13,	1801:13, 1802:9,	relied [1] - 1844:18	1903:13, 1905:4,	1883:20, 1883:23,
1840:16, 1848:2,	1806:5, 1813:25,	relieved [1] - 1929:2	1905:6, 1910:1,	1930:11
1848:6, 1851:17,	1844:3, 1846:17,	rely [3] - 1802:1,	1910:5, 1922:8,	requiring [1] -
1852:15, 1854:2,	1846:24, 1858:11,	1817:16, 1829:22	1960:10, 1960:11	1876:16
1854:12, 1854:18,	1882:20, 1894:16,	*	Reported [1] -	Research [2] - 1795:8,
1857:13, 1857:15,	1940:8	relying [1] - 1836:9	1757:22	1911:6
1864:11, 1864:12,	regarded [1] - 1922:17	remaining [1] - 1778:9	reporter [3] - 1890:6,	research [7] -
1864:25, 1877:6,	regarding [1] -	remarkable [1] -		
1881:16, 1881:24,	1979:10	1790:3	1993:2, 1994:1	1910:15, 1912:16,
1899:18, 1901:2,		remarkably [1] -	Reporter [2] -	1912:23, 1926:15,
1923:4, 1923:13,	Registration [1] -	1958:16	1757:22, 1996:25	1927:12, 1927:17,
1923:20, 1923:23,	1950:10	remember [20] -	REPORTER [1] -	1967:9
1923:20, 1923:23,	Regular [1] - 1825:5	1801:14, 1819:22,	1890:8	researcher[1] -
1948:17, 1953:9,	regular [1] - 1825:10	1826:15, 1848:13,	reporters [1] -	1870:4
	regulated [1] -	1850:9, 1850:11,	1928:24	reserve [1] - 1777:4
1953:20, 1954:20,	1975:11	1863:25, 1884:13,	reporting [4] -	residual [2] - 1913:19,
1954:22, 1954:24,	regulator [1] - 1908:22	1884:17, 1884:25,	1780:20, 1863:2,	1968:13
1955:21, 1956:4,	regulatory [1] - 1904:5	1887:12, 1904:16,	1866:2, 1905:23	resolution [2] -
1956:9	<b>REIG</b> [1] - 1758:5	1907:9, 1921:16,	reports [1] - 1949:7	1909:3, 1944:7
referenced [1] -	REIG-PLESSIS [1] -	1923:4, 1923:7,	represent [17] -	resolve [7] - 1939:7,
1842:20	1758:5	1930:3, 1977:23,	1784:23, 1797:20,	1941:16, 1942:14,
References [1] -	reimbursed [1] -	1990:4	1800:10, 1816:18,	1943:16, 1986:8,
1864:8	1931:4	remembered [1] -	1831:2, 1832:3,	1987:1, 1987:2
references [34] -	reiterate [1] - 1892:21	1989:17	1833:9, 1875:2,	resolved [2] - 1796:5,
1762:11, 1762:16,	rejected [2] - 1804:2,	remind [1] - 1960:25	1910:17, 1910:20,	1989:3
1762:18, 1774:4,	1804:23	removal [1] - 1982:7	1929:6, 1930:21,	respect [7] - 1772:7,
		131110 val[i] = 1302.1	,,	

				32
1838:3, 1936:5,	1952:3, 1953:2,	1825:7, 1825:12,	<b>sales</b> [1] - 1911:5	1996:12
1941:15, 1941:24,	1957:6, 1969:3	1859:4, 1859:5,	<b>sample</b> [2] - 1827:22,	search [1] - 1946:10
1942:5, 1991:2	*	1859:8, 1859:10,	•	
	Results [3] - 1769:2,	, ,	1863:6	seated [3] - 1759:3,
respectfully [1] -	1827:8, 1827:14	1859:20, 1894:17,	<b>San</b> [1] - 1758:6	1853:20, 1944:4
1917:15	RESUMED [1] -	1894:20, 1894:21,	satisfied [1] - 1807:8	<b>second</b> [13] - 1760:5,
respond [6] - 1790:18,	1759:10	1894:23, 1897:10,	Saturday [2] -	1762:15, 1763:7,
1795:22, 1803:3,	retained [1] - 1920:13	1905:6, 1906:3,	1933:24, 1944:10	1773:12, 1789:17,
1942:16, 1986:25,	retrospective [1] -	1919:18, 1922:12,	save [1] - 1991:3	1801:12, 1803:1,
1989:2	1912:22	1923:16, 1924:2,	saw [8] - 1790:25,	1831:1, 1837:3,
responded [1] -	return [1] - 1948:11	1949:7, 1962:8,	1865:17, 1866:24,	1843:5, 1859:9,
1803:16	revealed [1] - 1920:19	1962:10	1893:21, 1924:18,	1949:4, 1952:11
responding [2] -	revealing [1] - 1924:7	risks [1] - 1967:11	1924:21, 1933:11,	secondary [4] -
1979:8, 1987:21	reversing [1] - 1795:6	Risks [1] - 1908:13	1965:8	1805:9, 1897:9,
responds [1] -		Roche [1] - 1795:10		1907:20, 1919:13
1859:25	review [15] - 1766:5,	role [1] - 1967:7	scale [1] - 1960:18	seconds [2] - 1785:3,
	1795:21, 1795:24,		Schacky [14] - 1844:9,	1838:17
response [14] -	1844:14, 1900:6,	room [1] - 1987:6	1844:16, 1844:18,	
1770:7, 1790:3,	1929:22, 1933:25,	rough [2] - 1850:14,	1845:23, 1847:8,	section [13] - 1814:1,
1802:12, 1814:1,	1946:9, 1946:11,	1992:13	1847:21, 1847:25,	1815:10, 1827:8,
1860:5, 1860:20,	1946:13, 1946:15,	ROUNDS [1] -	1848:5, 1945:25,	1827:14, 1833:20,
1872:7, 1872:9,	1951:15, 1982:4,	1758:12	1946:8, 1946:17,	1834:1, 1864:7,
1903:8, 1915:3,	1988:19, 1993:15	Roundtable [3] -	1946:21, 1947:25,	1870:23, 1916:19,
1948:9, 1977:1,	reviewed [6] - 1767:5,	1848:16, 1982:10,	1948:17	1947:14, 1955:13,
1977:6, 1986:18	1768:22, 1792:14,	1982:20	Schaefer [1] - 1956:6	1969:24, 1991:8
responses [1] -	1901:17, 1924:14,	routinely [1] - 1952:18	schedule [3] -	see [137] - 1759:18,
1872:7	1933:16	RPR [2] - 1757:22,	1993:10, 1993:21,	1762:11, 1765:7,
responsibility [2] -	reviewer [3] - 1900:2,	1996:24	1996:14	1777:6, 1783:21,
1920:1, 1920:2	1900:3, 1982:1	Rule [1] - 1765:14	scientific [1] -	1784:10, 1794:9,
responsible [1] -	•			1794:15, 1794:17,
1843:8	reviewers [1] - 1982:7	rule [10] - 1775:8,	1844:24	1797:16, 1798:1,
	reviewing [1] -	1775:17, 1810:9,	Scientific [1] -	1798:3, 1806:14,
rest [2] - 1980:7,	1800:12	1811:10, 1914:22,	1968:10	1808:24, 1809:23,
1985:8	reviews [3] - 1785:5,	1914:23, 1934:8,	scientist [1] - 1927:18	
restricted [1] - 1934:3	1799:8, 1884:10	1935:4, 1945:4,	scientists [4] -	1812:6, 1813:15,
result [8] - 1770:18,	revise [2] - 1991:12,	1945:5	1927:10, 1927:11,	1814:5, 1815:6,
1772:12, 1775:1,	1994:19	rules [4] - 1809:25,	1927:13, 1927:15	1815:8, 1817:14,
1775:9, 1775:21,	revised [2] - 1810:6,	1915:6, 1915:19,	<b>scope</b> [5] - 1794:23,	1831:7, 1831:15,
1791:23, 1792:20,	1813:7	1937:19	1896:3, 1973:4,	1832:4, 1832:10,
1871:25	rewrite [1] - 1869:10	ruling [2] - 1811:19,	1973:5, 1982:13	1833:14, 1833:16,
resulted [2] - 1761:17,	<b>RI</b> [1] - 1960:16	1943:17	screen [20] - 1763:6,	1833:22, 1834:1,
1775:13	right-hand [8] -	run [3] - 1863:7,	1793:11, 1794:6,	1834:7, 1834:24,
results [46] - 1759:17,	1760:6, 1763:17,	1903:14, 1967:15	1802:11, 1805:9,	1835:7, 1836:2,
1760:9, 1760:10,	1775:6, 1839:24,	runs [1] - 1772:23	1809:2, 1840:22,	1838:9, 1839:11,
1760:11, 1763:13,	1947:4, 1947:12,		1842:22, 1846:9,	1839:20, 1842:21,
1768:10, 1768:15,	1947.4, 1947.12,	S	1861:23, 1871:20,	1843:25, 1844:2,
1769:4, 1773:19,	· ·	3	1895:2, 1917:6,	1846:15, 1846:22,
1791:1, 1792:3,	rigorous [3] - 1900:6,	safely [3] - 1874:23,		1847:3, 1848:23,
1792:24, 1793:2,	1921:11, 1982:3	•	1922:7, 1929:3,	1854:19, 1856:14,
	rigorously [1] - 1866:1	1875:14, 1875:16	1929:13, 1930:22,	1857:17, 1857:20,
1793:18, 1803:25,	rise [5] - 1769:7,	safety [1] - 1875:7	1946:18, 1949:4,	1857:22, 1857:25,
1804:4, 1804:7,	1769:13, 1875:6,	Saito [25] - 1861:24,	1965:18	1858:4, 1858:9,
1807:8, 1830:2,	1969:1, 1969:13	1862:13, 1862:25,	screens [3] - 1783:14,	1858:10, 1858:21,
1830:5, 1832:13,	Risk [1] - 1918:7	1863:16, 1921:19,	1783:20, 1784:2	
1837:24, 1840:25,	risk [41] - 1760:18,	1921:24, 1922:8,	<b>scroll</b> [2] - 1960:7,	1861:23, 1862:1,
1845:3, 1898:9,	1765:22, 1767:7,	1922:21, 1923:20,	1981:21	1872:6, 1875:10,
1899:9, 1903:16,	1768:20, 1768:24,	1924:8, 1949:3,	<b>se</b> [1] - 1927:13	1876:2, 1877:21,
1905:3, 1905:17,	1769:17, 1769:19,	1949:7, 1950:14,	<b>seal</b> [5] - 1987:15,	1883:16, 1883:21,
1905:23, 1905:24,	1769:21, 1770:15,	1951:7, 1951:15,	1987:17, 1987:19,	1889:11, 1889:13,
1907:3, 1907:18,	1771:2, 1772:9,	1952:8, 1952:21,	1987:21, 1989:10	1889:20, 1893:12,
1907:25, 1909:8,	1772:18, 1773:4,	1952:23, 1953:2,	sealed [3] - 1987:22,	1897:2, 1904:25,
1909:12, 1919:24,	1774:25, 1775:14,	1953:20, 1953:24,	1988:8, 1989:8	1905:17, 1906:11,
1920:4, 1922:6,	1777:18, 1777:20,	1958:23, 1961:10,	sealing [1] - 1987:2	1906:25, 1907:14,
1925:5, 1951:25,	1777:10, 1777:20, 1777:23, 1808:14,	1968:19, 1969:4	seamless [1] -	1908:2, 1908:10,

_	_
)	٠,
`	``
_	$\sim$

				<b>-</b> 33
1908:23, 1909:17,	1956:15, 1956:18,	1893:4, 1893:15,	1969:10, 1969:15,	<b>SIPES</b> [38] - 1757:14,
1909:20, 1909:22,	1956:21, 1957:5,	1894:22	1987:20, 1988:20	1783:19, 1783:25,
1910:4, 1910:15,	1959:20, 1959:22,	severely [2] - 1774:10,	side's [2] - 1992:6,	1784:3, 1944:8,
		•		
1911:6, 1911:13,	1962:15, 1963:14,	1949:19	1993:16	1945:17, 1970:1,
1911:15, 1911:18,	1971:16, 1978:1,	<b>SFE</b> [1] - 1911:5	<b>sides</b> [1] - 1989:3	1983:7, 1985:6,
1913:25, 1923:8,	1979:15, 1981:5,	<b>share</b> [3] - 1915:20,	significance [1] -	1985:9, 1985:24,
1923:14, 1927:18,	1981:13, 1982:7,	1973:2, 1973:13	1772:22	1986:1, 1986:10,
1931:12, 1934:3,	1987:18, 1987:21	sheet [1] - 1935:14	significant [32] -	1986:20, 1987:4,
1934:11, 1934:20,	sentences [1] -	shift [1] - 1772:21	1759:19, 1760:3,	1988:5, 1988:14,
1935:3, 1935:4,	1839:23	shockingly [1] -	1770:17, 1771:5,	1988:17, 1989:11,
1937:19, 1942:2,	separate [4] - 1787:3,	1934:18	1771:13, 1771:14,	1989:21, 1989:23,
1943:16, 1947:4,	1841:1, 1860:2,	<b>shoe</b> [1] - 1768:5	1772:10, 1773:2,	1990:9, 1991:23,
1947:13, 1949:7,	1895:4	short [6] - 1791:16,	1776:6, 1779:3,	1992:11, 1992:15,
1953:15, 1953:19,	September [2] -	• •	1782:8, 1788:19,	1992:23, 1993:4,
1954:13, 1955:6,	1767:14, 1813:8	1791:20, 1843:11,		1993:15, 1994:9,
1955:10, 1955:21,		1843:21, 1903:8,	1791:4, 1820:12,	1994:12, 1994:23,
	series [2] - 1967:10,	1924:7	1828:6, 1829:17,	
1956:17, 1960:6,	1985:23	<b>show</b> [14] - 1776:1,	1842:8, 1845:3,	1995:7, 1995:12,
1960:9, 1960:22,	serious [1] - 1859:15	1791:24, 1793:1,	1847:23, 1870:12,	1995:16, 1995:20,
1961:15, 1966:4,	seriously [1] -	1798:15, 1814:18,	1870:16, 1870:20,	1996:4, 1996:9,
1967:18, 1969:13,	1878:20	1817:16, 1824:10,	1873:1, 1876:5,	1996:17
1969:21, 1970:9,	serum [12] - 1762:1,	1870:6, 1877:21,	1880:21, 1880:22,	site [1] - 1928:24
1971:15, 1971:25,	1762:2, 1762:6,	1877:22, 1899:11,	1919:14, 1921:1,	situation [1] - 1896:2
1974:23, 1975:10,	1762:7, 1813:13,	1925:14, 1937:25,	1957:8, 1971:24,	situations [3] -
1975:15, 1976:20,	1825:6, 1825:11,	1938:9	1979:19	1885:5, 1893:12,
1977:13, 1977:15,	1825:18, 1831:8,	showed [16] -	significantly [7] -	1895:20
1978:12, 1978:15,	1853:7, 1947:8,	1845:19, 1845:20,	1788:10, 1827:9,	six [8] - 1835:14,
1978:20, 1979:3,	1958:2	1848:18, 1857:10,	1829:13, 1831:9,	1835:17, 1853:3,
1979:8, 1979:12,	<b>Serum</b> [3] - 1824:19,	1870:12, 1895:14,	1853:6, 1922:11,	1855:20, 1863:6,
1979:15, 1979:20,	1829:12, 1970:10	1898:13, 1899:9,	1924:1	1926:5, 1932:17,
1979:25, 1980:1,	served [2] - 1892:1,	1906:2, 1906:22,	signify [1] - 1772:24	1952:11
1981:18, 1987:15,	1982:1	1911:21, 1919:24,	silent [2] - 1781:13,	sixth [1] - 1767:25
1994:7	<b>Service</b> [1] - 1930:4	1920:8, 1951:10,	1781:17	<b>Size</b> [1] - 1824:20
seeing [3] - 1787:7,	Services [1] - 1929:10	1958:23, 1967:8	similar [15] - 1761:19,	size [2] - 1827:22,
1799:19		showing [7] -	1761:23, 1762:10,	1829:3
seem [1] - 1811:12	Sessions [1] -	_	1797:10, 1816:24,	skeptical [1] - 1766:22
<b>Seffy</b> [2] - 1927:14,	1968:10	1764:17, 1790:21,	*	•
1927:16	set [12] - 1859:7,	1791:21, 1812:4,	1842:9, 1853:7,	skepticism [7] -
selecting [1] - 1990:2	1859:11, 1859:17,	1835:12, 1865:10,	1903:15, 1905:4,	1766:3, 1766:6,
self [1] - 1849:7	1860:4, 1863:8,	1968:25	1905:19, 1905:21,	1766:20, 1767:6,
• •	1885:10, 1906:13,	<b>shown</b> [17] - 1770:15,	1905:24, 1908:21,	1768:13, 1768:19,
self-praise [1] -	1934:9, 1937:17,	1773:5, 1773:16,	1924:22, 1925:12	1768:24
1849:7	1964:22, 1991:19,	1807:24, 1814:3,	simple [4] - 1785:7,	<b>skill</b> [17] - 1762:19,
semi [2] - 1844:21,	1993:22	1814:11, 1858:13,	1901:20, 1901:23,	1764:3, 1769:11,
1845:21	sets [1] - 1964:12	1938:17, 1954:8,	1925:22	1769:20, 1770:6,
semi-quantitative [1] -	setting [2] - 1775:18,	1957:13, 1959:14,	<b>simplify</b> [1] - 1880:25	1779:6, 1779:11,
1845:21	1966:18	1959:16, 1965:3,	<b>simply</b> [3] - 1792:14,	1780:1, 1780:12,
semi-quantitatively	settle [1] - 1792:18	1967:5, 1976:15,	1812:2, 1934:23	1828:3, 1860:24,
[1] - 1844:21	seven [2] - 1837:10,	1980:11, 1981:3	Simvastatin [2] -	1948:24, 1951:16,
send [1] - 1986:14	1886:11	<b>shows</b> [2] - 1928:12,	1902:14, 1902:15	1964:7, 1964:16,
sending [1] - 1978:18	several [5] - 1760:12,	1936:17	simvastatin [8] -	1964:21, 1969:12
sense [1] - 1980:8	1814:2, 1838:6,	<b>Shows</b> [1] - 1767:11	1872:15, 1872:17,	<b>skilled</b> [65] - 1786:23,
sentence [36] -	1954:10, 1956:15	<b>sic</b> [1] - 1877:8	1872:20, 1872:22,	1787:6, 1787:17,
1760:7, 1760:24,	severe [20] - 1769:5,	side [23] - 1783:15,	1873:6, 1873:14,	1787:20, 1787:23,
1761:9, 1763:7,	1769:12, 1769:25,	1786:14, 1787:1,	1957:21, 1957:22	1787:25, 1788:2,
1803:21, 1846:25,	1774:14, 1787:2,	1787:8, 1787:12,	Sinai [1] - 1768:8	1789:13, 1789:14,
1847:11, 1860:20,	1806:25, 1808:18,	1787:14, 1787:19,	single [3] - 1780:19,	1789:17, 1790:13,
1913:17, 1947:20,	1808:19, 1815:15,	1787:21, 1789:3,	1822:19, 1948:15	1791:2, 1791:8,
1948:4, 1948:6,	1815:17, 1821:23,	1801:22, 1822:6,	<b>Sipes</b> [6] - 1944:9,	1791:25, 1792:6,
1949:7, 1951:22,	1822:10, 1822:19,	1839:24, 1891:13,	1945:7, 1945:13,	1792:13, 1792:22,
1952:14, 1954:13,	1850:7, 1851:4,	1891:24, 1892:5,	1983:10, 1985:20,	1801:16, 1804:3,
1955:6, 1955:11,	1890:14, 1891:5,	1931:9, 1958:3,	1994:5	1805:13, 1805:18,
.000.0, 1000.11,	1030.14, 1031.3,	1001.0, 1000.0,	1007.0	,,

				34
1806:7, 1806:20,	1801:23, 1809:12,	speculated [1] -	1910:8, 1913:11,	statins [40] - 1777:17,
1808:11, 1818:12,	1812:24, 1814:18,	1850:24	1914:2, 1915:1,	1777:22, 1778:2,
1818:15, 1821:13,	1830:25	spell [1] - 1890:6	1915:5, 1915:23,	1778:4, 1871:17,
1821:22, 1822:8,	solutions [1] -	spent [2] - 1786:20,	1954:25, 1960:9,	1874:23, 1875:7,
1822:18, 1823:12,	1786:18	-	1980:5	1875:14, 1876:13,
1823:21, 1823:24,		1807:11		*
,	someone [2] - 1870:5,	<b>spikes</b> [2] - 1788:2,	statements [9] -	1878:12, 1879:11,
1824:3, 1827:2,	1978:15	1871:10	1797:9, 1797:10,	1881:2, 1892:24,
1828:3, 1829:6,	sometime [1] -	<b>sponsor</b> [1] - 1935:10	1830:1, 1880:3,	1893:1, 1893:9,
1829:21, 1829:25,	1988:15	sponsored [4] -	1908:21, 1934:22,	1896:15, 1896:21,
1830:7, 1844:2,	somewhere [1] -	1848:22, 1849:11,	1941:7, 1956:10,	1897:11, 1902:13,
1848:4, 1851:2,	1776:11	1849:12, 1849:18	1981:9	1906:16, 1907:20,
1856:19, 1856:23,	SONNENSCHEIN [1] -	sponsoring [2] -	<b>STATES</b> [1] - 1757:1	1917:9, 1917:12,
1860:8, 1860:12,	1757:16	1937:24, 1941:5	states [11] - 1761:3,	1924:25, 1969:18,
1863:23, 1874:10,	sorry [33] - 1767:21,	<b>spot</b> [1] - 1973:9	1778:22, 1778:25,	1969:22, 1970:17,
1874:16, 1879:9,	1776:23, 1779:15,	<b>spot-on</b> [1] - 1973:9	1779:2, 1782:5,	1970:23, 1970:25,
1879:16, 1879:21,	1779:17, 1788:15,	spreadsheet [8] -	1782:7, 1828:8,	1971:5, 1971:8,
1882:10, 1883:2,	1791:19, 1796:2,	1934:4, 1934:25,	1885:13, 1888:8,	1971:18, 1971:19,
1888:13, 1891:22,	1796:14, 1805:16,	· · · · · · · · · · · · · · · · · · ·	1908:16, 1910:3	1973:7, 1974:1,
1898:20, 1898:25,	1825:15, 1837:17,	1936:8, 1936:16,	States [5] - 1902:11,	1974:25, 1975:3,
1901:24, 1902:6,	1855:9, 1864:17,	1936:17, 1938:6,	1902:15, 1903:15,	1975:14, 1975:20
1903:5, 1903:14,	1866:18, 1887:8,	1941:24, 1943:1	1921:8, 1921:11	Statins [2] - 1971:16,
1922:20, 1924:8	, ,	spreadsheets [6] -	statin [72] - 1771:17,	1974:20
skip [3] - 1803:21,	1912:17, 1915:9,	1930:24, 1933:23,	• •	statistical [5] -
,	1925:10, 1927:18,	1935:9, 1936:19,	1773:6, 1773:8,	• • •
1865:8, 1913:17 <b>slide</b> [28] - 1764:17,	1935:21, 1937:13,	1939:12, 1940:22	1773:10, 1773:13,	1772:22, 1868:13,
	1952:21, 1960:2,	<b>squarely</b> [2] - 1973:5,	1777:11, 1778:7,	1966:10, 1966:19,
1778:16, 1784:23,	1960:7, 1968:6,	1982:16	1822:13, 1822:16,	1967:13
1784:25, 1785:1,	1969:19, 1970:2,	stack [1] - 1920:16	1872:17, 1874:8,	statistically [22] -
1785:4, 1785:11,	1970:20, 1976:1,	stand [5] - 1760:10,	1874:11, 1874:14,	1760:3, 1770:16,
1804:21, 1827:6,	1976:3, 1976:16,	1760:11, 1912:17,	1874:18, 1875:9,	1771:4, 1771:13,
1832:8, 1832:9,	1977:8, 1994:5	1940:12, 1942:20	1876:10, 1877:1,	1771:14, 1772:10,
1833:5, 1834:21,	sort [2] - 1842:9,	standard [12] -	1877:14, 1878:17,	1776:6, 1779:3,
1835:4, 1835:5,	1937:5	1856:16, 1867:1,	1878:19, 1878:25,	1782:8, 1788:19,
1835:16, 1861:17,	sounds [2] - 1988:17,	1867:5, 1867:6,	1879:10, 1879:13,	1791:3, 1820:12,
1861:21, 1907:12,	1991:23	1869:6, 1869:9,	1879:17, 1879:23,	1828:6, 1829:17,
1908:2, 1908:6,	source [1] - 1765:3	1869:25, 1897:9,	1880:6, 1880:13,	1845:3, 1870:16,
1908:8, 1908:19,	sources [1] - 1935:13	1949:25, 1966:15,	1881:8, 1881:14,	1870:20, 1876:5,
1935:6, 1935:7,	speaker [1] - 1928:6	1996:1, 1996:2	1882:8, 1882:12,	1880:20, 1880:22,
1959:14, 1967:5	Speakers [4] - 1892:1,	start [7] - 1776:10,	1882:15, 1882:17,	1919:14, 1979:19
slides [2] - 1927:23,	1926:4, 1926:12,	1792:1, 1795:5,	1885:6, 1885:7,	statistician [4] -
1959:9	1926:22	1820:18, 1840:4,	1885:16, 1886:8,	1868:11, 1964:17,
slight [1] - 1772:21	speaks [2] - 1771:25,	1978:10, 1992:23	1886:9, 1886:13,	1965:1, 1967:14
slightly [1] - 1781:6	1773:17	started [4] - 1895:22,	1886:16, 1886:17,	statistics [2] - 1869:3,
slow [1] - 1884:7	specific [2] - 1771:11,		1886:21, 1886:23,	1964:19
<b>small</b> [7] - 1830:5,	1850:20	1925:19, 1984:5,	1891:19, 1891:24,	steered [1] - 1967:21
1838:6, 1840:25,	specifically [6] -	1996:5	1892:8, 1892:11,	stemmed [1] -
1843:10, 1843:20,	. ,	starting [4] - 1775:5,	1892:14, 1892:15,	1920:14
1954:10, 1956:15	1808:17, 1957:17,	1877:24, 1971:16,	1892:17, 1892:18,	<b>step</b> [2] - 1785:17,
<b>Smaller</b> [3] - 1839:8,	1958:14, 1959:21,	1983:16	1892:21, 1893:6,	1935:17
1839:25, 1840:6	1972:10, 1972:13	starts [3] - 1770:22,	1893:16, 1893:25,	stiff [1] - 1930:15
smaller [3] - 1842:6,	specification [4] -	1913:18, 1947:21	1896:23, 1896:24,	still [21] - 1761:1,
1843:25, 1844:1	1796:13, 1796:17,	<b>state</b> [11] - 1760:9,	1896:25, 1897:8,	1761:8, 1764:16,
smart [1] - 1903:23	1797:10, 1800:12	1763:9, 1763:19,	1902:21, 1912:3,	, ,
	specifications [1] -	1782:10, 1829:20,	1912:24, 1913:22,	1766:25, 1792:2,
snapshot [2] -	1794:1	1888:24, 1905:25,	1912:24, 1913:22,	1808:21, 1815:24,
1848:11, 1922:7	<b>specifics</b> [1] - 1764:23	1948:6, 1951:24,	1914:8, 1917:10,	1822:4, 1825:22,
<b>snippet</b> [1] - 1965:3	<b>specifies</b> [1] - 1781:11	1952:12, 1952:14	1919.12, 1923.2,	1830:11, 1833:6,
Society [1] - 1960:11	<b>specify</b> [2] - 1777:12,	statement [17] -	1973:1, 1973:17,	1872:13, 1898:1,
<b>soft</b> [2] - 1963:15,	1778:15	1763:16, 1766:9,	1973.1, 1973.17, 1974:4	1900:3, 1900:4,
1963:21	spectrum [2] - 1920:4,	1766:14, 1834:9,		1900:10, 1925:22,
<b>sole</b> [1] - 1939:16	1967:11	1834:11, 1874:1,	stating [2] - 1782:14,	1926:12, 1962:2,
<b>solely</b> [7] - 1787:19,	speculate [1] - 1974:2	1875:12, 1894:1,	1987:19	1989:2
MADCADE	n e Coteneo	DDD CCD NO	2 OFFTCTAT	

<b>stop</b> [3] - 1891:13, 1896:11, 1896:13
<b>stopped</b> [2] - 1895:23,
1896:3 <b>stops</b> [2] - 1895:21,
1896:7 <b>story</b> [1] - 1911:18
storyline [1] - 1980:9
<b>straddling</b> [1] - 1771:6
straight [1] - 1799:24
straightforward [1] - 1901:20
strata [1] - 1962:10
<b>stratum</b> [1] - 1962:8
STRENGTH [1] -
1927:3 stretch [1] - 1849:14
strictly [2] - 1865:22,
1927:12
<b>Stroke</b> [1] - 1770:13
<b>stroke</b> [10] - 1770:15,
1770:20, 1770:22, 1770:23, 1771:2,
1770.23, 1771.2, 1771:7, 1771:12,
1771:14, 1771:18,
1772:1
<b>strong</b> [2] - 1899:24, 1917:8
strongly [3] - 1778:3,
1862:12, 1869:24
structurally [1] - 1803:19
studied [8] - 1763:2,
1765:5, 1788:11,
1841:17, 1917:13,
1952:15, 1956:23,
1976:7
studied [1] - 1976:5 studies [35] - 1768:4,
1824:10, 1834:22,
1835:5, 1838:6,
1838:23, 1841:1, 1842:11, 1842:16,
1842:11, 1842:16,
1845:19, 1845:20, 1846:19, 1847:13,
1848:6, 1851:11,
1857:17, 1858:13,
1862:4, 1882:6,
1898:13, 1899:1, 1903:19, 1903:21,
1903:19, 1903:21,
1903:22, 1903:24, 1903:25, 1904:1,
1919:6, 1920:16,
1921:1, 1924:19,
1954:14, 1956:22,
1956:23, 1956:25
<b>studies</b> [3] - 1954:11, 1956:16,
1956:19
<b>Study</b> [4] - 1889:3,

1905:5, 1907:13,
1908:8
study [87] - 1759:14,
1761:20, 1763:10,
1764:13, 1768:2,
1768:3, 1768:9,
1769:10, 1771:3,
1777:1, 1777:5,
1788:7, 1791:16,
1791:24, 1792:19,
1792:24, 1792:25,
1793:2, 1793:8,
1793:18, 1817:25,
1818:1, 1825:17, 1830:2, 1830:5,
1832:13, 1837:24,
1843:10, 1843:14,
1843:17, 1843:20,
1844:1, 1844:3,
1848:19, 1855:2,
1856:12, 1865:6,
1865:21, 1867:14,
1865:21, 1867:14, 1867:23, 1869:17,
1871:2, 1888:18,
1888:20, 1889:14,
1889:18, 1890:15,
1895:5, 1898:9,
1900:12, 1901:24,
1902:4, 1902:24,
1903:13, 1903:15,
1904:2, 1905:13,
1906:11, 1906:22, 1907:2, 1907:16,
1907:18, 1907:24,
1908:8, 1908:19,
1909:4, 1909:8,
1909:12, 1913:1,
1919:10, 1919:12,
1920:4, 1920:8,
1920:9, 1920:22,
1920:23, 1921:9,
1922:15, 1925:5,
1925:13, 1926:25,
1927:5, 1957:25,
1958:13, 1961:1,
1968:24
studying [1] - 1968:25
subgroup [3] -
1919:16, 1922:15, 1968:23
Subgroup [1] -
1908:14
subject [10] - 1781:13,
1781:17, 1782:9,
1782:11, 1782:12,
1794:10, 1794:11,
1840:18, 1869:8,
1884:4
subjects [7] - 1802:18,
1802:19, 1803:2,

```
1803:4, 1842:7,
 1843:10, 1843:20
submit [16] - 1929:18,
 1940:18, 1944:19,
 1945:2, 1983:11,
 1986:21, 1987:8,
 1987:25, 1988:11,
 1989:3, 1990:12,
 1991:25, 1992:9,
 1993:6, 1995:10,
 1995:25
submitted [10] -
 1807:20, 1867:12,
 1867:21, 1909:3,
 1938:17, 1984:18,
 1992:5, 1993:19,
 1994:4, 1994:20
submitting [5] -
 1929:14, 1984:17,
 1984:20, 1986:15,
 1995:24
suboptimal [1] -
 1971:23
subparagraphs [1] -
 1802:21
substance [1] -
 1927:24
substantial [6] -
 1764:8, 1764:16,
 1769:7, 1769:13,
 1928:16, 1928:18
substantially [4] -
 1782:6, 1782:15,
 1861:1, 1883:23
substantively [1] -
 1795:22
success [13] - 1787:4,
 1787:17, 1789:10,
 1789:15, 1789:25,
 1791:18, 1792:3,
 1792:10, 1792:17,
 1800:6, 1800:20,
 1801:13. 1805:24
successful [2] -
 1857:7, 1891:7
suggest [10] -
 1765:20, 1775:12,
 1777:25, 1778:3,
 1795:24, 1796:22,
 1807:21, 1840:17,
 1903:22, 1961:19
suggested [2] -
 1839:8, 1840:7
suggests [2] -
 1765:23, 1910:7
suit [1] - 1801:5
sum [1] - 1783:6
summarize [2] -
 1857:21, 1922:6
summarizes [2] -
```

```
summarizing [1] -
 1942:2
summary [17] -
 1773:15, 1773:19,
 1794:25, 1796:5,
 1845:8, 1901:11,
 1906:22, 1935:6,
 1935:7, 1935:14,
 1936:8, 1936:14,
 1936:20, 1939:20,
 1942:1, 1945:14
sums [2] - 1928:16,
 1928:18
SUN [1] - 1984:22
Sun [1] - 1984:22
Sunshine [1] - 1929:9
superior [1] - 1843:14
supplement [1] -
 1764:14
supplemental [1] -
 1952:25
supplements [1] -
 1766:17
support [19] -
 1766:16, 1797:3,
 1799:20, 1801:7,
 1835:1, 1835:9,
 1838:11, 1905:15,
 1913:20, 1917:8,
 1920:23, 1948:10,
 1948:12, 1955:16,
 1955:25, 1967:13.
 1968:14. 1991:5.
 1991:11
supported [1] -
 1935:16
supporting [1] -
 1807:10
supposed [2] -
 1914:18, 1990:23
suppress [1] - 1953:1
suppressed [4] -
 1922:12, 1924:1,
 1952:13, 1952:16
suppression [1] -
 1924:4
surprise [6] - 1799:17,
 1932:22, 1932:23,
 1932:24, 1938:23
surprised [1] - 1768:5
surrounding [1] -
 1966:18
suspect [2] - 1869:25,
 1934:10
sustaining [1] -
 1974:9
swirling [1] - 1920:16
switch [7] - 1849:20,
 1887:1, 1960:2,
```

1840:25, 1930:22

```
1967:23, 1969:19,

1972:16, 1975:25

sworn [1] - 1759:9

synonym [1] -

1826:18

synthesis [1] -

1844:17

synthesize [2] -

1845:5, 1845:14

system [3] - 1865:13,

1866:4, 1866:11
```

## Τ

```
table [16] - 1783:15,
 1814:3, 1816:9,
 1847:7, 1870:18,
 1872:14, 1887:15,
 1948:10, 1948:12,
 1948:14, 1950:7,
 1950:9. 1950:12.
 1950:13. 1970:12.
 1976:15
Table [25] - 1800:12,
 1815:23, 1816:14,
 1816:17, 1817:16,
 1844:18, 1845:23,
 1871:20, 1872:13,
 1887:22, 1887:24,
 1923:25, 1946:2,
 1948:10, 1948:17,
 1950:6, 1957:11,
 1957:17, 1957:20,
 1969:24, 1970:6,
 1976:5, 1976:16,
 1976:17, 1976:19
Takaku [7] - 1861:24,
 1862:14. 1862:25.
 1863:5, 1863:16,
 1864:11, 1864:18
talks [9] - 1794:15,
 1814:1, 1844:21,
 1845:24, 1871:24,
 1887:25, 1889:13,
 1923:13, 1932:17
tallied [1] - 1931:18
taught [4] - 1822:24,
 1831:13, 1834:10,
 1881.12
teach [1] - 1828:8
teaches [4] - 1828:3,
 1832:19, 1872:19
teaching [7] -
 1828:19, 1829:22,
 1830:8, 1830:13,
 1831:8, 1888:13,
 1929:22
tech [1] - 1959:7
technical [1] -
```

1783:14

				<b></b> 36
telephone [1] - 1981:6	1975:12, 1975:13	1942:21, 1942:24,	1919:12, 1955:8,	1934:18, 1935:13
ten [4] - 1785:3,	TG-containing [1] -	1943:10, 1943:15,	1968:16, 1970:14	together [2] - 1920:17,
	• • • • • • • • • • • • • • • • • • • •	1944:4, 1945:5,	*	1983:18
1886:12, 1902:17,	1975:12	, , , , , , , , , , , , , , , , , , ,	thereafter [1] - 1993:8	
1983:14	THE [186] - 1757:2,	1945:19, 1945:21,	therefore [1] - 1936:11	tolerate [4] - 1892:14,
tendency [2] - 1948:8	1757:14, 1759:3,	1959:6, 1959:10,	thereof [1] - 1963:9	1892:25, 1893:1,
term [3] - 1826:16,	1759:5, 1759:7,	1972:18, 1973:14,	they've [2] - 1812:13,	1893:2
1906:14, 1927:18	1765:16, 1767:20,	1973:24, 1974:9,	1928:18	tolerated [4] -
terms [5] - 1762:1,	1767:22, 1779:19,	1975:24, 1976:2,	thinking [4] - 1792:11,	1893:10, 1893:11,
1771:2, 1772:18,	1779:20, 1779:22,	1977:20, 1980:16,	1952:25, 1990:23,	1893:24, 1893:25
1860:1, 1985:18	1783:11, 1783:21,	1980:18, 1980:21,	1991:25	tolerating [1] -
test [1] - 1906:13	1783:23, 1784:1,	1980:24, 1981:20,	thinks [1] - 1941:10	1892:17
tested [1] - 1789:19	1784:4, 1784:7,	1982:13, 1982:17,	third [2] - 1887:24,	tomorrow [6] -
testified [34] - 1759:9,	1784:9, 1784:13,	1982:21, 1982:25,	1944:13	1944:17, 1984:20,
1760:17, 1768:18,	1788:15, 1788:16,	1983:3, 1983:5,	third-party [1] -	1986:4, 1986:22,
•	1795:16, 1796:2,	1983:15, 1984:2,		1986:23, 1987:8
1769:4, 1769:16,	1796:25, 1797:17,	1984:5, 1984:9,	1944:13	•
1774:5, 1774:8,			thorough [1] -	tonight [1] - 1979:2
1774:17, 1775:24,	1798:12, 1798:15,	1984:11, 1984:13,	1946:13	took [3] - 1822:12,
1777:10, 1778:10,	1798:18, 1798:19,	1984:21, 1985:4,	thoroughly [1] -	1841:3, 1841:5
1779:4, 1779:10,	1798:22, 1798:25,	1985:7, 1985:11,	1933:25	top [8] - 1763:17,
1779:25, 1801:16,	1799:5, 1799:8,	1985:14, 1985:16,	thoughts [1] - 1943:16	1773:8, 1798:1,
1818:8, 1833:10,	1800:7, 1809:10,	1985:25, 1986:5,	thousand [1] -	1889:13, 1899:22,
1848:18, 1862:3,	1809:14, 1810:8,	1986:16, 1986:21,	1932:19	1953:1, 1978:21,
1863:22, 1868:17,	1810:14, 1810:19,	1986:24, 1986:25,	thousands [1] -	1979:5
1892:13, 1940:10,	1810:23, 1811:7,	1987:10, 1988:6,	1808:4	topics [1] - 1871:16
1940:11, 1940:23,	1811:18, 1811:21,	1988:10, 1988:16,	three [15] - 1776:13,	total [5] - 1761:20,
1941:10, 1948:16,	1812:9, 1812:18,	1988:18, 1989:14,	1776:21, 1795:2,	1846:20, 1873:14,
1951:10, 1953:10,	1812:23, 1814:8,	1990:4, 1990:7,	1796:18, 1796:23,	1962:23, 1963:8
1964:13, 1965:8,	1814:18, 1815:3,	1990:12, 1992:9,	1801:18, 1839:23,	Toth [34] - 1766:22,
1974:14, 1976:10,	1815:4, 1816:3,	1992:12, 1993:1,	1840:25, 1862:14,	1784:8, 1784:19,
1982:17	1816:5, 1816:7,	1993:10, 1993:18,		1797:9, 1797:19,
testify [2] - 1974:10,	1839:18, 1839:21,	1994:11, 1994:15,	1869:20, 1896:25,	1797:3, 1797:13,
1974:12	1839:25, 1846:7,	1994:21, 1994:24,	1928:1, 1928:12,	
	1851:22, 1851:24,	1995:3, 1995:8,	1931:21, 1931:25	1798:15, 1799:6,
testifying [2] -	1852:20, 1852:22,	1995:15, 1995:17,	three-fold [1] -	1811:2, 1833:13,
1836:14, 1909:11	1853:12, 1853:16,	1995:21, 1996:5,	1931:21	1849:6, 1853:24,
testimony [33] -	1853:20, 1854:9,	1996:10	threshold [6] -	1914:25, 1915:22,
1769:8, 1777:14,	1855:6, 1873:11,	theme [1] - 1807:1	1850:25, 1859:11,	1916:5, 1934:4,
1784:21, 1785:2,			1859:17, 1859:22,	1934:25, 1935:6,
1797:1, 1797:4,	1878:3, 1878:8,	themselves [1] -	1859:24, 1860:4	1936:25, 1937:2,
1798:13, 1803:10,	1884:5, 1884:9,	1849:9	throughout [1] -	1937:22, 1938:2,
1806:2, 1830:21,	1884:21, 1885:23,	theory [3] - 1785:9,	1764:7	1938:23, 1940:21,
1830:23, 1834:13,	1886:1, 1890:9,	1800:25, 1925:23	throw [1] - 1903:23	1941:9, 1941:11,
1849:3, 1862:8,	1910:24, 1911:2,	therapeutic [1] -	tied [1] - 1776:19	1941:25, 1944:16,
1868:15, 1869:13,	1913:12, 1913:15,	1902:21	timeframe [1] -	1945:10, 1945:24,
1869:15, 1871:17,	1914:21, 1915:3,	therapies [1] - 1773:7	1991:22	1973:25, 1977:23,
1892:20, 1920:19,	1915:9, 1915:16,	therapy [35] - 1771:17,	timely [2] - 1930:17,	1983:4
1933:10, 1935:14,	1916:15, 1917:23,	1773:6, 1777:11,	1930:18	<b>TOTH</b> [2] - 1759:8,
1938:15, 1939:2,	1918:15, 1922:3,	1777:13, 1778:7,		1997:4
1940:10, 1940:19,	1933:18, 1933:20,	1781:10, 1781:13,	tiny [1] - 1934:2	Toth's [3] - 1935:14,
1941:11, 1942:9,	1935:17, 1935:25,	1781:14, 1781:18,	title [8] - 1824:18,	1939:13, 1943:1
1942:22, 1943:11,	1936:4, 1936:9,	1803:4, 1838:8,	1832:15, 1907:23,	towards [1] - 1988:15
1965:3, 1965:15,	1936:13, 1936:18,	1874:8, 1876:1,	1946:6, 1947:9,	
1984:24	1936:20, 1936:22,	1876:11, 1876:17,	1950:7, 1950:9,	toxicity [1] - 1850:25
testing [1] - 1792:1	1937:7, 1937:11,	1879:7, 1880:8,	1957:13	track [2] - 1813:5,
• • • • • • • • • • • • • • • • • • • •	1937:14, 1938:1,	1880:15, 1882:21,	titled [3] - 1831:6,	1987:12
Teva [1] - 1795:5	1938:8, 1939:5,	1882:23, 1883:3,	1832:9, 1848:15	training [1] - 1964:19
text [4] - 1846:2,	1939:7, 1939:14,	1884:2, 1884:15,	today [8] - 1806:2,	TRANSCRIPT[1] -
1846:3, 1887:24,	1939:16, 1939:22,	1885:2, 1885:12,	1856:1, 1860:22,	1757:12
1887:25	1940:2, 1940:4,		1861:4, 1892:21,	transcript [14] -
<b>TG</b> [7] - 1949:9,	1940:6, 1940:24,	1885:14, 1885:21,	1920:20, 1985:3,	1798:13, 1798:16,
1949:12, 1949:17,	1940:0, 1940:24,	1897:9, 1912:3,	1995:4	1798:18, 1798:24,
1951:7, 1973:17,	1941:18, 1942:14,	1913:22, 1914:8,	Today [3] - 1934:16,	1833:12, 1868:22,
	1071.10, 1372.14,			

1990-16, 1991-20, 1990-21, 391-21, 1910-5, 1990-21, 1990-21, 1990-22, 1912-2					3
1992-14, 1992-22,   1992-22,   1992-22,   1992-22,   1992-22,   1992-23,   1992-24,   1996-22   1913-21, 1914-7,   1866-01, 1860-14,   1862-4, 1862-9,   1869-23,   1869-13,   1869-14,   1869-24,   1869-25,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-15,   1869-16,	1990:16, 1991:20,	1904:21, 1905:6.	1840:7. 1840:8.	1826:20. 1827:4.	1789:3. 1810:20.
1992/14, 1992/22,   1912/2, 1912/5,   1986/20, 1868/20, 1868/24, 1852/2,   1942/21, 1949/27,   1919/2, 1920/15,   1969/17, 1992/34,   1992/34					
1994/2, 1996/22   1913/2, 1914/7,   1860/1, 1860/1, 1862/4, 1852/9, 1862/1, 1865/3, 1865/3, 1864/1, 1904/8   1904/8		, ,			
198-17, 1992-24, 1992-15, 198-17, 1992-18, 1994-18, 1994-18, 1994-18, 1994-18, 1994-18, 1994-18, 1995-19, 199	•				
1994.17, 1993.24,   1992.02, 1992.16,   1996.11,   1995.14, 1998.6,   1991.7, 1994.23,   1865.3, 1865.04,   1867.7, 1886.1,   1992.17, 1998.21,   1992.17, 1998.21,   1992.17,   1992.21,   1992.17,   1992.21,					
1994.8   1925.14, 1938.6,   1913.2, 1913.20,   1856.3, 1856.6,   1940.15, 1973.6,   1955.14, 1960.21,   1950.13, 1950.15,   1955.14, 1960.21,   1950.13, 1950.15,   1855.2, 1856.6,   1940.15, 1973.6,   1973.19, 1973.6,   1950.2, 1952.5,   1955.14, 1960.21,   1950.13, 1950.15,   1956.14, 1950.21,   1956.15,   1957.1,   1957.1,   1957.2,   1957.	• • • •		· · · · · ·		
				,	
1950-10   1955-14, 1960-21, 1950-13, 1950-15, 1950-15, 1950-2, 1960-15, 1960-23, 1968-11, 1950-23, 1968-11, 1950-23, 1968-11, 1950-23, 1968-11, 1950-24, 1961-12, 1960-18, 1960-10, 1960-17, 1960-18, 1960-10, 1960-18, 1960-10, 1960-18, 1960-10, 1960-18, 1960-10, 1960-18, 1960-10, 1960-18, 1960-10, 1960-18, 1960-19, 1960-18, 1960-11, 1					
	transfer [2] - 1760:15,	1940:19, 1954:5,	1919:17, 1949:23,	1856:5, 1856:6,	
1986.15, 1979.17, 1986.18, 1979.17, 1986.18, 1979.12, 1986.18, 1979.12, 1986.18, 1979.12, 1986.18, 1979.12, 1986.18, 1979.12, 1986.18, 1979.12, 1986.18, 1979.12, 1986.18, 1989.18, 1	1959:10	1955:14, 1960:21,	1950:13, 1950:15,	1856:9, 1856:13,	1973:19, 1987:24,
1925.5   1984.19, 1987.3,   1984.15, 1987.1,   1986.13, 1861.11,   1759.1, 1981.1,   1769.1, 1990.2,   1990.2,   1990.2,   1995.2,   1952.2,   1961.1,   1962.1,   1961.1,   1962.1,   1961.1,   1962.1,   1	translate [3] -	1960:23, 1968:11,	1950:21, 1950:23,	1856:24, 1860:9,	1989:16, 1990:17
	1790:22, 1791:5,	1968:15, 1979:17,	1951:6, 1951:12,	1860:10, 1861:2,	TUESDAY [2] -
	1925:5	1984:19, 1987:3,	1954:15, 1957:1,	1861:3, 1861:11,	1759:1, 1944:1
	translates [1] - 1812:7	1990:8, 1990:10,	1957:3, 1957:23,	1862:4, 1862:24,	turn [15] - 1759:13,
1794.20, 1797.12   1990.24, 1991.11, 1992.11, 1992.1, 1992.1, 1992.1, 1992.1, 1992.1, 1992.1, 1992.1, 1992.1, 1992.1, 1992.10, 1992.11, 1995.11, 1995.25, 1970.25, 1971.6, 1881.14, 1882.27, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.24, 1881.25, 1881.24, 1881.25, 1881.24, 1881.25, 1881.24, 1881.24, 1881.25, 1881.24, 1882.24, 1	• • •	1990:15, 1990:20,	1958:24, 1961:2,	1863:10, 1863:16,	
1806.4, 1808.17, 1801.10, 1992.10, 1992.11, 1992.10, 1992.18, 1992.10, 1992.18, 1992.10, 1992.18, 1992.10, 1992.18, 1992.10, 1992.18, 1993.6, 1994.19, 1996.14, 1996.24, 1801.25, 1861.10, 1901.13, 1801.11, 1901.13, 1801.11, 1906.11, 1901.12, 1901.11, 1814.2, 1821.25, 1862.24, 1863.15, 1870.12, 1760.25, 1761.5, 1973.2, 1973.7, 1862.2, 1863.15, 1870.12, 1762.3, 1764.18, 1973.2, 1973.7, 1868.7, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1762.3, 1764.25, 1765.10, 1765.20, 1773.7, 1805.11, 1974.21, 1955.11, 1974.21, 1955.11, 1974.21, 1955.11, 1974.13, 1839.8, 1839.25, 1839.21, 1955.11, 1974.13, 1839.8, 1839.25, 1839.21, 1955.20, 1766.11, 1974.13, 1809.14, 1975.20, 1976.15, 1809.21, 1976.15, 1809.21, 1976.15, 1809.21, 1976.15, 1809.21, 1976.15, 1809.21, 1976.15, 1809.21, 1976.15, 1809.21, 1976.15, 1809.21, 1976.15, 1809.21, 1976.15, 1809.21, 1809.21, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.21, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.25, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 1809.14, 1809.15, 18		1990:24, 1991:11,	1961:11, 1962:12,	1863:19, 1864:15,	
1808-19, 1821-13,   1992-18,   1993-6, 1994-19,   1996-18,   1995-6, 1994-19,   1996-19,   1995-6, 1994-19,   1996-19,					
182114, 182123, 1850.7, 1851.4, 1995.14, 1995.25, 1850.7, 1851.4, 1995.14, 1995.25, 1976.10, 1977.10, 1972.6, 1881.14, 1880.21, 1996.11 1977.20, 1972.6, 1881.14, 1880.21, 1956.3, 1969.17 1972.10, 1972.6, 1881.14, 1882.7, 1882.2, 1862.24, 1862.15, 1870.12, 1762.3, 1764.18, 1764.25, 1764.25, 1764.25, 1764.25, 1765.20, 1773.7, 1851.3, 1785.21, 1785.21, 1785.21, 1785.21, 1785.21, 1785.21, 1785.21, 1839.25, 1839.25, 1839.25, 1896.13, 1896.14, 1899.3, 1896.14, 1896.21, 1896.3, 1891.4, 1901.12, 1895.8, 1899.3, 1896.14, 1890.24, 1899.5, 1917.14, 1990.14 1778.15, 1875.7, 1870.15, 1875.7, 1807.15, 1875.7, 1807.15, 1875.7, 1807.15, 1875.7, 1809.21, 1902.21, 190					
1850.7, 1851.4, 18611.0, 1971.8   1996.11   1996.12   1970.25, 1971.6, 1861.10, 1971.8   1996.11   1996.11   1972.10, 1972.0, 1972.6, 1881.14, 1880.21, 1861.2, 1862.24, 1762.24, 1764.25, 1762.3, 1764.18, 1765.20, 1773.7, 1818.16, 1822.10, 1839.8, 1839.25, 1895.11, 1956.11, 1974.2   1974.12, 1895.12, 1955.31, 1899.1, 1956.11, 1974.13   1899.8, 1839.25, 1899.1, 1916.6, 1970.9   1898.21, 1899.3, 1899.24, 1899.3, 1870.24, 1813.12, 1838.7, 1899.14, 1901.12, 1766.24, 1766.25, 1776.6, 1979.25, 1814.4, 1915.2, 1800.14, 1802.20, 1802.21, 1922.12, 1766.20, 1776.14, 1766.19, 1776.16, 1779.5, 1802.21, 1922.12, 1766.23, 1766.19, 1776.16, 1779.5, 1802.21, 1922.12, 1766.23, 1766.19, 1776.16, 1779.5, 1802.21, 1922.12, 1766.23, 1774.9, 1766.10, 1775.10, 1775.10, 1775.20, 1775.10, 1775.20, 1775.10, 1775.20, 1775.10, 1775.20, 1775.10, 1775.20, 1775.10, 1775.20, 1775.10, 1775.20, 1775.10, 1775.20, 1802.23, 1802.23, 1802.23, 1802.24, 1802.25, 1802.24, 1802.24, 1802.24, 1802.25, 1802.24, 1					
1986:110, 1971:8   1996:11					
			, ,	· · · · · · · · · · · · · · · · · · ·	
1814-2, 1821-25, 1839-2, 1862-24, 1760-25, 1761-5, 1973-27, 1974-5, 1888-7, 1888-10, 1761-18, 1762-3, 1764-18, 1762-3, 1764-18, 1762-3, 1764-18, 1762-3, 1764-18, 1762-3, 1764-18, 1765-7, 1765-10, 1765-7, 1765-10, 1818-13, 1821-19, 1895-12, 1953-11, 1839-2, 1826-18, 1839-2, 1826-18, 1839-2, 1839-2, 1839-2, 1839-2, 1839-3, 1839-2, 1839-3, 183	′		· · · · · · · · · · · · · · · · · · ·		· ·
1839-2, 1862-24,   1760-25, 1761-5,   1973-21, 1974-5,   1888-1, 1888-6,   1761-10,	• •			· · · · · ·	
1883:15, 1870:12, 1876:10, 1912:23   1762:3, 1764:18, 1764:24, 1764:25, 1765:10, 1912:23   1765:7, 1765:10, 1775:1,					
1877:10, 1912:23   1764:24, 1764:25,   Triglyceride   2    1888:11, 1894:12,   1899:6,   1766:11,   1765:20,   1765:11,   1776:11,   1899:5,   1899:5,   1899:5,   1899:5,   1899:11,   1899:5,   197:14,   1899:11,   1899:1,			, ,	· · · · ·	• • • • • • • • • • • • • • • • • • • •
treating [9] - 1766:11, 1765:13, 1785:21, 1786:21, 1786:21, 1785:13, 1785:21, 1785:21, 1785:21, 1785:21, 1785:21, 1785:21, 1785:21, 1785:21, 1889:3.         1894:22, 1899:6, tweak [1] - 1978:21 twenty [1] - 1770:16 twenty [1] - 1770:17 trenty [1] - 1		, ,			1781:10
1785-13, 1785-21, 1814-3, 1821-19, 1891-13, 1891-12, 1951-13, 19	1877:10, 1912:23	1764:24, 1764:25,			turns [1] - 1797:3
1818:16, 1822:10,	treating [9] - 1766:11,	1765:7, 1765:10,	1950:11, 1974:21		tweak [1] - 1978:21
1895.12, 1953.11, 1839:8, 1839.25, 1860:1, 1951:12, 1953:16, 1924:3, 1770:16	1785:13, 1785:21,	1765:20, 1773:7,	triglyceride-lowering	1904:10, 1908:15,	twenty [1] - 1770:16
1895:12, 1953:11, 1839:8, 1839:25, 1860:1, 1951:12, 1950:2, 1950:2, 1950:2, 1950:4, 1951:2, 1974:5 1976:6, 1970:9 1898:21, 1899:3, 1977:14, 1990:14, 1990:14, 1990:14, 1990:14, 1990:14, 190:15, 1970:15, 1875:7, 1801:2, 1976:16, 1779:5, 1770:16, 1800:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:14, 190:15, 190:16,	1818:16, 1822:10,	1814:3, 1821:19,	[7] - 1760:19, 1803:4,	1913:23, 1922:9,	twenty-eight [1] -
1954:1, 1974:13   1840:6, 1857:7, 1897:23, 1898:1, 1897:23, 1898:1, 1974:5   1950:1, 1950:2, 1951:1, 1951:2, 1950:4, 1951:2, 1950:1, 1951:2, 1950:1, 1951:2, 1950:1, 1951:2, 1950:1, 1951:3, 1752:2, 1762:3, 1777:8, 1899:5, 1917:14, 1990:14   1775:20, 1776:11, 1990:14   1775:20, 1776:11, 1990:14   1776:15, 1807:24, 1813:12, 1838:7, 1809:3, 1760:19, 1870:15, 1875:7, 1801:3, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:14, 1780:18, 1790:14, 1770:20, 1775:18, 1780:22, 1780:14, 1780:12, 1760:13, 1760:19, 1775:18, 1780:20, 1776:16, 1806:22, 1780:14, 1806:25, 1806:9, 1780:16, 1806:21, 1806:12, 1806:14, 1806:22, 1760:13, 1760:19, 1807:20, 1760:13, 1760:19, 1807:20, 1760:13, 1760:19, 1760:13		1839:8, 1839:25,	1860:1, 1951:12,	1923:16, 1924:3,	
Treatment		1840:6, 1857:7,	1971:6, 1973:7,	1950:1, 1950:2,	
1916:6, 1970:9   1898:21, 1899:3,   1899:5, 1917:14,   1899:5, 1917:14,   1990:14   1990:14   1775:20, 1776:11,   1990:14   1776:23, 1777:8,   1990:14   1776:24, 1776:15, 1807:24,   1813:12, 1838:7,   1813:12, 1838:7,   1870:15, 1875:7,   1820:3   1776:16, 1779:5,   1779:13,   1968:12, 1968:17,   1821:19,   1776:13, 1779:13,   1968:12, 1968:17,   1822:19   1775:1, 1775:9,   1780:21, 1785:14, 1780:18,   1970:22, 1970:25,   1780:24, 1803:5,   1780:23, 1780:14,   1780:18,   1970:22, 1970:25,   1803:4, 1803:5,   1789:23, 1789:7,   1820:14, 1806:22,   1786:13, 1789:7,   1806:14, 1806:22,   1790:15, 1813:13,   1790:2, 1792:8,   1814:4, 1815:8,   1816:19,   1815:12, 1816:19,   1816:14, 1806:24,   1791:13, 1791:20,   1818:17, 1818:21,   1818:9, 1818:16,   1807:24, 1806:21,   1807:15, 1813:15,   1818:9, 1818:16,   1807:24, 1806:24,   1807:25, 1850:18,   1807:25, 1850:18,   1807:21, 1900:15,   1807:21, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17,   1900:15, 1800:17, 1800:18, 1800:20,   1800:18, 1800:20,   1800:18, 1800:20,   1800:18, 1800:20,   1800:18, 1800:20,   1800:18, 1800:20,   1800:18, 1800:20,   1800:18, 1800:20,   1800:18, 1800:17,   1900:15, 1800:18, 1800:20,   1800:18, 1800:20,   1800:19, 1800:18, 1800:20,   1800:19, 1800:18, 1800:20,   1800:19, 1800:18, 1800:20,   1800:19, 1800:18, 1800:20,   1800:19, 1800:19			1974:5	1950:4, 1951:2,	
1899;5, 1917;14,   1990;14   1990;14   1990;14   1776;20, 1776;11, 1778;15, 1807;24,   1776;16, 1770;3, 1770;8, 1770;3, 1770;8, 1813;12, 1838;7, 1820;3   1774;25, 1775;16, 1998;23, 1961;1, 1789;25, 1812;4, 1909;14   1776;16, 1779;5, 1891;4, 1901;12, 1909;14   1776;16, 1779;5, 1891;4, 1901;12, 1909;14, 1909;14, 1909;14, 1909;15, 1891;4, 1901;12, 1909;14, 1909;15, 1809;14, 1909;16, 1909;17, 1909;18, 1909;19, 1909;			trialvceride-	1951:11, 1951:13,	
Authority         1900:14         triglycerides[139]         1957:21, 1958:10, 1785:24, 1786:2, 1778:25, 1875:7, 1813:12, 1838:7, 1820:3         1770:3, 1770:8, 1770:8, 1770:8, 1770:3, 1770:8, 1813:12, 1838:7, 1820:3         1770:3, 1770:8, 1770:8, 1770:3, 1770:8, 1958:18, 1958:21, 1780:3, 1789:15, 1789:25, 1812:4, 1770:16, 1779:5, 1820:3         1770:16, 1779:5, 1958:13, 1958:23, 1961:1, 1789:25, 1812:4, 1961:7, 1966:23, 1813:11, 1821:19, 1962:12, 1962:12, 1760:13, 1760:19, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:23, 1774:9, 1780:14, 1780:18, 1790:26, 1970:20, 1858:18, 1861:13, 1780:21, 1780:14, 1780:18, 1780:22, 1775:1, 1775:9, 1780:21, 1785:14, 1970:22, 1970:25, 1858:18, 1861:13, 1780:21, 1786:10, 1971:9, 1972:13, 1863:2,			• •		
1778:15, 1807:24, 1813:12, 1838:7, 1870:15, 1875:7, 1870:15, 1875:7, 1820:3         1770:13, 1770:8, 1770:8, 1770:16, 1779:5, 1891:4, 1901:12, 1902:12, 1760:13, 1760:19, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:13, 1760:19, 1760:14, 1780:18, 1902:12, 1902:12, 1760:23, 1774:9, 1780:14, 1780:18, 1970:2, 1970:20, 1856:18, 1861:13, 1803:2, 1803:2, 1803:4, 1803:5, 1789:10, 1760:19, 1775:10, 1775:9, 1775:9, 1780:21, 1785:14, 1970:22, 1970:20, 1856:18, 1861:13, 1803:4, 1803:4, 1803:5, 1789:16, 1789:7, 1790:15, 1813:13, 1789:7, 1801:14, 1813:13, 1806:12, 1806:14, 1806:22, 1790:15, 1791:21, 1912:13, 1918:6, 1887:21, 1887:21, 1887:25, 1806:19, 1806:14, 1806:22, 1790:15, 1791:21, 1912:13, 1918:6, 1887:21, 1887:21, 1887:25, 1806:10, 1765:7, 1768:15, 1771:7, 1791:10, 1818:9, 1818:16, 1818:21, 1818:21, 1818:21, 1818:21, 1818:21, 1818:21, 1818:21, 1818:21, 1818:21, 1819:18, 1819:25, 1820:3, 1820:15, 1820:3, 1821:10, 1820:25, 1851:17, 1896:8, 1823:3, 1823:15, 1820:23, 1821:10, 1820:25, 1821:14, 1820:19, 1820:15, 1820:25, 1821:14, 1820:19, 1820:15, 1820:25, 1821:14, 1820:19, 1820:15, 1820:25, 1821:14, 1820:19, 1820:25, 1821:14, 1820:19, 1820:25, 1821:14, 1820:19, 1820:15, 1820:25, 1821:14, 1820:19, 1820:15, 1820:25, 1821:14, 1820:19, 1820:15, 1820:25, 1821:14, 1820:19, 1820:15, 1820:25, 1821:14, 1820:19, 1820:15, 1820:25, 1821:14, 1820:19, 1820:15, 1820:25, 1821:14, 1820:19, 1820:25, 1824:11, 1820:17, 1820:14, 1802:14, 1813:14, 1813:19, 1820:15, 1820:25, 1820:18, 1820:19, 1820:25, 1821:14, 1820:19, 1820:25, 1824:11, 1820:17, 1820:14, 1802:14, 1813:14, 1813:19, 1820:15, 1820:25, 1820:19, 1820:19, 1820:25, 1820:19, 1820:19, 1820:25, 1820:19, 1820:25, 1820:19, 1820:25, 1820:19, 1820:25, 1820:19, 1820:25, 1820:19, 1820:25, 1820:19, 1820:25, 1820:19, 1820:25, 1820:25, 1820:25, 1820:25, 1820:25, 1820:25, 1820:25, 1820:25, 1820:25, 1820:25, 1820:25, 182			<u> </u>		
1813:12, 1838:7, 1870:15, 1875:7, 1820:3   1774:25, 1775:16, 1891:4, 1901:12, 1902:1, 1922:12, 1760:13, 1760:19, 1780:3, 1780:10, 1955:7   1780:14, 1780:18, 1780:19, 1780:14, 1780:18, 1870:20, 1780:14, 1802:20, 1780:14, 1802:20, 1780:14, 1802:20, 1780:16, 1879:20, 1780:16, 1789:12, 1780:14, 1818:21, 1818:21, 1818:21, 1781:20, 1780:14, 1802:20, 1781:3, 1780:12, 1818:21			• • •		
1870:15, 1875:7,   1820:3   1776:16, 1779:5,   1961:7, 1966:23,   1813:11, 1821:19,   1902:1, 1922:12,   1760:13, 1760:19,   1780:3, 1780:10,   1780:3, 1780:10,   1968:21, 1968:17,   1822:15, 1830:18,   1902:1, 1922:12,   1769:23, 1774:9,   1780:14, 1780:18,   1790:6, 1970:20,   1858:18, 1861:13,   1970:6, 1970:20,   1858:18, 1861:13,   1970:6, 1970:20,   1858:18, 1861:13,   1970:6, 1970:20,   1858:18, 1861:13,   1970:22, 1970:25,   1803:2, 1863:5,   1789:3, 1789:7,   1786:10, 1803:4, 1803:5,   1789:3, 1789:7,   1789:16, 1789:22,   1789:16, 1789:22,   1790:15, 1791:21,   1805:25, 1806:9,   1790:15, 1791:21,   1805:21, 1786:10,   1807:15, 1813:13,   1792:2, 1792:8,   1761:23, 1762:10,   1814:4, 1815:8,   1794:20, 1797:12,   1803:14, 1806:24,   1807:15, 1818:21,   1808:14, 1806:8,   1791:10,   1818:9, 1818:16,   1817:22, 1818:24,   1809:4, 1821:18,   1809:4, 1821:18,   1809:4, 1821:19,   1809:13, 1803:3, 1803:2,   1809:14, 1809:15, 1851:8,   1820:23, 1821:10,   1822:15, 1820:5,   1807:24, 1808:22,   1937:21, 1939:25,   1939:12, 1939:12,   1939:12, 1939:12,   1939:12, 1939:12,   1939:23, 1939:12,   1809:13, 1902:9,   1824:5, 1827:21,   1820:17,   1866:17, 1966:23,   1813:11, 1821:19,   1820:15,   1830:18, 1780:10,   1968:12, 1968:17,   1862:15, 1830:18,   1820:15, 1820:9, 1820:9,   1820:9, 1820:9, 1820:9,   1820:9, 1820:9					
1891:4, 1901:12,   1792:12, 1760:13, 1760:19, 1779:8, 1779:13, 1968:12, 1968:17, 1968:21, 1969:13, 1902:1, 1922:12, 1760:13, 1760:19, 1780:3, 1780:10, 1780:3, 1780:10, 1968:21, 1969:13, 1830:25, 1834:2, 1970:6, 1970:20, 1858:18, 1861:13, 1970:6, 1970:20, 1970:20, 1775:18, 1788:22, 1775:14, 1786:10, 1770:20, 1775:18, 1788:22, 1785:21, 1786:10, 1970:22, 1970:25, 1863:2, 1863:5, 1870:23, 1789:1, 1780:14, 1780:14, 1780:18, 1970:22, 1970:25, 1863:2, 1863:5, 1870:23, 1780:10, 1970:20, 1970:20, 1863:2, 1863:5, 1971:9, 1972:13, 1864:10, 1864:14, 1866:14, 1806:23, 1789:7, 1789:7, 1789:7, 1789:16, 1789:22, 1789:16, 1789:22, 1790:15, 1791:21, 1805:25, 1806:9, 1807:15, 1813:13, 1792:2, 1792:8, 1814:4, 1815:8, 1794:20, 1797:12, 1791:10, 1818:9, 1818:16, 1806:10, 1806:14, 1806:24, 1790:15, 1800:4, 1821:18, 1819:4, 1819:4, 1819:4, 1806:10, 1806:14, 1					
1902:1, 1922:12,   1760:13, 1760:19,   1780:3, 1780:10,   1968:21, 1969:13,   1830:25, 1834:2,   1855:7   1769:23, 1774:9,   1780:14, 1780:18,   1970:6, 1970:20,   1858:18, 1861:13,   1970:6, 1970:20,   1858:18, 1861:13,   1970:6, 1970:20,   1858:18, 1861:13,   1970:22, 1970:25,   1863:2, 1863:5,   1863:2, 1863:5,   1863:2, 1863:5,   1863:2, 1863:5,   1863:2, 1863:5,   1863:2, 1863:5,   1863:2, 1863:5,   1863:2, 1863:5,   1863:2, 1863:5,   1863:2, 1863:5,   1863:2, 1863:5,   1864:10, 1864:14,   1866:14, 1806:22,   1789:16, 1789:22,   1790:15, 1791:21,   1805:25, 1806:9,   1789:16, 1789:22,   1790:15, 1791:21,   1805:25, 1806:9,   1790:15, 1791:21,   1970:10,   1814:4, 1815:8,   1794:20, 1797:12,   1816:19,   1815:12, 1816:19,   1817:22, 1818:2,   1803:3, 1803:23,   1804:1,   1791:10,   1818:9, 1818:16,   1806:10, 1806:21,   1790:17, 1791:10,   1818:17, 1818:21,   1805:14, 1806:8,   1792:7, 1795:15,   1818:24, 1819:4,   1806:10, 1806:21,   1790:14, 1820:17,   1820:17, 1820:15, 1800:4, 1821:18,   1820:9, 1820:15,   1820:23, 1821:10,   1823:23, 1823:15,   1820:23, 1824:1,   1820:25, 1820:13, 1900:9,   1820:23, 1820:10,   1820:25, 1820:11,   1820:17, 1820:17,   1820:25,   1821:14, 1823:19,   1820:25, 1824:11,   1820:25, 1820:13, 1900:9,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23, 1820:10,   1820:23,			· · · · · · · · · · · · · · · · · · ·		
1955:77   1769:23, 1774:9,   1780:14, 1780:18,   1970:6, 1970:20,   1858:18, 1861:13,   1970:22, 1970:25,   1863:2, 1863:5,   1862:16, 1826:17   1803:4, 1803:5,   1789:3, 1789:7,   1789:16, 1789:22,   1790:13,   1864:10, 1864:14,   1869:16, 1887:14,   1870:12, 1790:10   1818:17, 1818:19,   1818:21,   1819:18,   1802:20,   1818:18, 1819:25,   1819:18, 1819:25,   1800:4, 1821:18,   1823:13, 1823:15,   1820:23, 1821:10,   1820:25, 1820:5,   1820:25, 1820:5,   1820:25, 1820:9,   1820:26, 1820:19,   1820:25, 1820:9,   1820:21,   1820:25, 1820:9,   1820:21,   1820:25, 1820:9,   1820:21,   1820:25, 1820:9,   1820:21,   1820:25, 1820:9,   1820:21,   1820:25, 1820:9,   1820:21,   1820:20,   1823:23, 1824:1,   1820:20,   1820:25, 1820:9,   1820:21,   1820:25, 1820:17,   1820:25, 1820:9,   1820:21,   1820:25, 1820:9,   1820:21,   1820:25, 1820:9,   1820:21,   1820:25, 1824:11,   1820:27,   1820:25, 1820:8,   1820:20,   1820:23, 1820:10,   1820:25, 1820:17, 1896:8,   1820:20,   1820:25, 1820:21,   1820:25, 1824:11,   1820:27,   1820:25, 1824:11,   1820:27,   1820:25, 1824:11,   1820:27,   1820:25, 1824:11,   1820:27,   1820:25, 1824:11,   1820:27,   1820:25, 1824:11,   1820:27,					· · · · · · · · · · · · · · · · · · ·
treats [1] - 1822:19         1775:1, 1775:9,         1780:21, 1785:14,         1970:22, 1970:25,         1863:2, 1863:5,         1863:2, 1863:5,         1863:2, 1863:5,         1863:2, 1863:5,         1863:2, 1863:5,         1863:2, 1863:5,         1863:2, 1863:5,         1863:2, 1863:5,         1863:2, 1863:5,         1863:2, 1863:5,         1863:2, 1863:5,         1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:2, 1863:5,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1864:14, 1863:4,         1870:21, 1862:1,         1864:14, 1863:4,         1870:21, 1862:1,         1864:14, 1863:4,         1870:21, 1862:1,         1870:12, 1863:1,         1864:14, 1863:4,					1830:25, 1834:2,
trend [1] - 1772:20 trial [2] - 1805:25, 1806:9, 1806:14, 1806:22, 1761:23, 1762:10, 1765:7, 1768:15, 1771:7, 1791:10, 1791:13, 1791:20, 1791:13, 1791:20, 1791:13, 1791:20, 1791:13, 1791:21, 1818:24, 1819:25, 1818:24, 1819:25, 1818:24, 1819:25, 1818:24, 1819:25, 1825:25, 1851:8, 1820:23, 1827:21, 1820:23, 1827:21, 1820:23, 1827:21, 1820:23, 1827:21, 1820:23, 1827:21, 1820:23, 1827:21, 1820:23, 1827:21, 1820:23, 1827:21, 1820:23, 1827:21, 1820:25, 1820:25, 1820:24, 1820:29, 1820:25, 1820:25, 1820:25, 1820:25, 1820:21, 1820:29, 1820:21, 1820:29, 1820:23, 1827:21, 1820:23, 1827:21, 1820:25, 1820:25, 1820:21, 1820:29, 1820:23, 1827:21, 1820:23, 1827:21, 1820:24, 1820:25, 1820:25, 1820:5, 1820:25, 1820:5, 1820:25, 1820:5, 1820:25, 1820:5, 1820:24, 1820:25, 1820:25, 1820:5, 1820:25, 1820:5, 1820:24, 1820:25, 1820:25, 1820:5, 1820:25, 1820:5, 1820:24, 1820:25, 1820:25, 1820:5, 1820:25, 1820:5, 1820:24, 1820:25, 1820:25, 1820:5, 1820:25, 1820:5, 1820:24, 1820:25, 1820:25, 1820:5, 1820:25, 1820:5, 1820:25, 1820:5, 1820:25, 1820:5, 1820:25, 1820:5, 1820:25, 1820:5, 1820:25, 1820:5, 1820:21, 1820:21, 1820:22, 1820:25, 1820:23, 1827:21, 1820:23, 1823:10, 1820:23, 1827:21, 1820:25, 1820:5, 1820:25, 1820:5, 1820:25, 1820:5, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:22, 1820:25, 1820:23, 1827:21, 1820:22, 1820:25, 1820:24, 1820:25, 1820:25, 1820:4, 1820:25, 1820:4, 1820:25, 1820:4, 1820:25,	1955:7				
triacylglycerols[2] - 1826:16, 1826:17         1794:12, 1802:23, 1786:13, 1787:14, 1806:14, 1803:5, 1789:3, 1789:7, 1805:25, 1806:9, 1806:9, 1807:15, 1813:13, 1807:20         1789:16, 1789:22, 1792:8, 1790:15, 1791:21, 1806:14, 1806:22, 1790:15, 1791:21, 1806:14, 1806:22, 1790:15, 1791:21, 1807:15, 1813:13, 1792:2, 1792:8, 1761:23, 1762:10, 1765:7, 1768:15, 1817:22, 1818:2, 1818:24, 1819:4, 1791:10, 1791:13, 1791:20, 1792:7, 1795:15, 1800:4, 1821:18, 1823:13, 1823:15, 1823:15, 1823:15, 1823:15, 1823:15, 1823:25, 1851:8, 1825:25, 1851:8, 1825:25, 1851:8, 1825:25, 1851:8, 1825:25, 1851:8, 1825:25, 1851:7, 1896:8, 1899:13, 1902:9,         1794:12, 1802:23, 1789:7, 1785:14, 1806:14, 1806:14, 1806:22, 1790:15, 1791:14, 1820:17, 1820:17, 1820:15, 1820:25, 1820:5, 1820:5, 1820:29, 1820:18, 1820:29, 1820:	treats [1] - 1822:19				1863:2, 1863:5,
triacylglycerols[2] - 1826:16, 1826:17       1794:12, 1802:23, 1803:5, 1789:14, 1803:4, 1803:5, 1803:4, 1803:5, 1789:3, 1789:7, 1805:25, 1806:9, 1789:16, 1789:22, 1790:15, 1791:21, 1807:20       1789:16, 1789:22, 1790:15, 1791:21, 190:15, 1791:21, 190:15, 1791:21, 190:15, 1791:21, 1761:23, 1762:10, 1761:23, 1762:10, 1765:7, 1768:15, 1771:7, 1791:10, 1791:13, 1791:20, 1791:13, 1791:20, 1791:13, 1791:20, 1791:13, 1791:20, 1818:4, 1819:4, 1818:4, 1819:4, 1819:4, 1819:4, 1819:4, 1819:4, 1819:4, 1819:4, 1819:18, 1819:25, 1819:18, 1819:25, 1823:13, 1823:15, 1823:15, 1823:15, 1825:25, 1851:8, 1825:25, 1851:8, 1829:13, 1902:9, 1820:15, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:21, 1820:25, 1820:21, 1820:21, 1820:25, 1820:21, 1820:21, 1820:25, 1820:21, 1820:23, 1824:1, 1820:25, 1820:21, 1820:21, 1820:21, 1820:25, 1820:21, 1820:21, 1820:25, 1820:21, 1820:23, 1824:1, 1820:25, 1820:21, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:21, 1820:25, 1820:25, 1820:25, 1820:21, 1820:25, 1820:25, 1820:25, 1820:25, 1820:21, 1820:25, 1820	trend [1] - 1772:20	1775:18, 1788:22,	1785:21, 1786:10,		1864:10, 1864:14,
1826:16, 1826:17       1803:4, 1803:5,       1789:3, 1789:7,       1977:12       1869:16, 1887:14,         TRIAL [1] - 1757:12       1805:25, 1806:9,       1789:16, 1789:22,       1790:15, 1791:21,       1912:13, 1918:6,       1887:21, 1887:25,         Trial [2] - 1849:16, 1897:20       1807:15, 1813:13,       1792:2, 1792:8,       1970:10       1919:5, 1919:6,         trial [66] - 1759:12, 1761:23, 1762:10, 1765:7, 1768:15, 1771:7, 1791:10, 1791:13, 1791:20, 1791:13, 1791:20, 1791:13, 1791:20, 1791:13, 1791:20, 1791:13, 1791:20, 1792:7, 1795:15, 1800:4, 1821:18, 1800:4, 1821:18, 1800:4, 1821:18, 1823:13, 1823:15, 1823:13, 1823:15, 1823:15, 1823:15, 1823:15, 1823:15, 1823:23, 1821:10, 1852:2, 1852:25, 1851:8, 1852:2, 1852:25, 1851:8, 1852:2, 1852:25, 1851:8, 1853:17, 1896:8, 1899:13, 1902:9,       1803:4, 1803:5, 1789:7, 1789:7, 1789:10, 1789:10, 1789:10, 1789:10, 1790:15, 1791:21, 1791:10, 1806:12, 1803:17, 1806:14		1794:12, 1802:23,			1864:18, 1869:4,
TRIAL [1] - 1757:12         1805:25, 1806:9, 1806:9, 1806:14, 1806:22, 1806:14, 1806:22, 1807:15, 1813:13, 1807:20         1789:16, 1799:22, 1792:8, 1912:13, 1918:6, 1970:10         1887:21, 1887:25, 1888:21, 1893:16, 1970:10         1888:21, 1893:16, 1970:10         1888:21, 1893:16, 1970:10         1919:5, 1919:6, 1919:5, 1919:5, 1919:5, 1919:5, 1919:5, 1919:5, 1919:5, 1919:5, 1919:5, 1919:5, 1919:5, 1919:5, 1919:5, 1919:5, 191		1803:4, 1803:5,	, ,		1869:16, 1887:14,
Trial [2] - 1849:16, 1897:20         1806:14, 1806:22, 1807:15, 1813:13, 1792:2, 1792:8, 1790:15, 1791:21, 1807:15, 1813:13, 1792:2, 1792:8, 1790:10         1912:13, 1918:6, 1970:10         1888:21, 1893:16, 1919:6, 1919:5, 1919:6, 1919:6, 1919:6, 1919:5, 1919:6, 1919		1805:25, 1806:9,	1789:16, 1789:22,	• • • • • • • • • • • • • • • • • • • •	1887:21, 1887:25,
1897:20       1807:15, 1813:13,       1792:2, 1792:8,       1970:10       1919:5, 1919:6,         trial [66] - 1759:12,       1814:4, 1815:8,       1794:20, 1797:12,       1803:12, 1803:17,       1931:24, 1936:1,         1765:7, 1768:15,       1817:22, 1818:2,       1803:3, 1803:23,       1804:1       1936:11, 1936:13,         1791:13, 1791:20,       1818:17, 1818:21,       1805:14, 1806:8,       1791:11, 1820:17,       1939:10, 1964:12,         1792:7, 1795:15,       1818:24, 1819:4,       1806:10, 1806:21,       1791:11, 1820:17,       1930:8, 1943:12,         1800:4, 1821:18,       1820:9, 1820:15,       1807:24, 1808:22,       1807:24, 1808:22,       1930:8, 1943:12,         1852:25, 1851:8,       1820:23, 1821:10,       1813:18, 1816:24,       1817:4, 1817:19,       1993:21, 1937:25         1855:17, 1896:8,       1823:23, 1824:1,       1823:23, 1824:1,       1820:25, 1820:5,       1823:21, 1820:0,         1899:13, 1902:9,       1824:5, 1827:21,       1820:25, 1820:18,       1820:25, 1820:18,       1820:25, 1820:19,		1806:14, 1806:22,	1790:15, 1791:21,	1912:13, 1918:6,	
trial [66] - 1759:12,         1814:4, 1815:8,         1794:20, 1797:12,         Trillipix [4] - 1802:24,         1921:2, 1928:2,           1761:23, 1762:10,         1815:12, 1816:19,         1801:18, 1802:20,         1803:12, 1803:17,         1931:24, 1936:1,           1765:7, 1768:15,         1818:9, 1818:16,         1804:15, 1805:4,         1804:1         1936:11, 1936:13,           1791:13, 1791:20,         1818:17, 1818:21,         1805:14, 1806:8,         1791:11, 1800:17,         1939:10, 1964:12,           1792:7, 1795:15,         1818:24, 1819:4,         1806:10, 1806:21,         1791:11, 1820:17,         1976:4, 1983:24,           1800:4, 1821:18,         1820:9, 1820:15,         1807:2, 1807:14,         1861:14, 1880:1,         1990:17, 1992:15,           1825:25, 1851:8,         1820:23, 1821:10,         1813:18, 1816:24,         1971:5, 1995:2         1992:17, 1993:7,           1855:17, 1896:8,         1823:23, 1824:1,         1817:25, 1820:5,         1827:21, 1820:5,         1827:21, 1937:25         1813:14, 1813:19,           1899:13, 1902:9,         1824:5, 1827:21,         1820:25, 1820:18         1820:25, 1820:18         1820:25, 1820:18         1821:14, 1823:19,         1820:25, 1820:5,         1820:25, 1820:5,         1820:25, 1820:18         1821:14, 1813:19,		1807:15, 1813:13,	1792:2, 1792:8,	1970:10	
1761:23, 1762:10,   1815:12, 1816:19,   1801:18, 1802:20,   1803:12, 1803:17,   1931:24, 1936:1,   1936:13,   1771:7, 1791:10,   1818:9, 1818:16,   1804:15, 1805:4,   1792:7, 1795:15,   1818:24, 1819:4,   1806:10, 1806:21,   1801:14, 1820:17,   1800:4, 1821:18,   1820:9, 1820:15,   1820:9, 1820:15,   1820:23, 1821:10,   1852:2, 1852:25,   1851:8,   1823:23, 1824:1,   1823:23, 1824:1,   1823:23, 1824:1,   1820:23, 1821:10,   1823:23, 1820:9,   1823:23, 1824:1,   1823:24,   1823:24,   1823:24,   1823:24,   1823:24,   1823:25,   1823:25, 1823:30,   1823:26,   1823:23, 1824:1,   1823:29,   1823:24, 1823:21,   1823:24, 1823:29,   1823:24, 1823:21,   1823:21, 1823:17, 18		1814:4, 1815:8,	1794:20, 1797:12,	Trilipix [4] - 1802:24,	
1765:7, 1768:15,   1817:22, 1818:2,   1803:3, 1803:23,   1804:1   1936:11, 1936:13, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:13, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:10, 1964:12, 1939:13, 1939:10, 1964:12, 1939:13, 1939:10, 1964:12, 1939:13, 1939:10, 1964:12, 1939:13, 1939:10, 1964:12, 1939:13, 1939:10, 1964:12, 1939:13, 1939:10, 1964:12, 1939:13, 1939:10, 1964:12, 1939:13, 1939:13, 1939:13, 1939:13, 1939:13, 1939:13, 1939:13, 1939:13, 1939:13, 1939:13, 1939:13, 1939:13, 1939:13, 1939:13, 1939:14, 1839:13, 1939:14, 1839:13, 1939:14, 1839:13, 1939:14, 1839:14, 1839:18, 1819:18		1815:12, 1816:19,		1803:12, 1803:17,	
1765.7, 1768.18, 1771:7, 1791:10, 1818:9, 1818:16, 1804:15, 1805:4, 1806:8, 1792:7, 1795:15, 1818:24, 1819:4, 1819:25, 1823:13, 1823:15, 1825:25, 1851:8, 1852:2, 1852:25, 1852:25, 1855:17, 1896:8, 1899:13, 1902:9, 1820:0,				1804:1	
1771.7, 1791.10, 1791.13, 1791.20, 1791.13, 1791.20, 1818.17, 1818.21, 1818.21, 1818.24, 1819.4, 1806.10, 1806.21, 1791.11, 1820.17, 1818.21, 1819.18, 1819.25, 1823.13, 1823.15, 1820.9, 1820.15, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1821.10, 1820.23, 1820.25, 1820.2				Triplix [1] - 1803:17	
1791:7, 1795:7, 1795:15, 1800:4, 1821:18, 1819:4, 1800:4, 1821:18, 1823:13, 1823:15, 1825:25, 1851:8, 1852:2, 1852:25, 1852:25, 1855:17, 1896:8, 1899:13, 1902:9, 1820:0       1818:24, 1819:4, 1806:10, 1806:21, 1806:21, 1807:24, 1806:21, 1807:24, 1807:24, 1807:24, 1807:24, 1808:22, 1930:8, 1943:12, 1990:17, 1992:15, 1992:17, 1993:7, 1813:18, 1816:24, 1971:5, 1995:2       1990:17, 1992:15, 1992:15, 1992:17, 1993:7, 1993:10, 1993:12, 1817:4, 1817:19, 1817:4, 1817:19, 1817:25, 1820:5, 1820:5, 1820:5, 1820:5, 1820:5, 1820:5, 1820:24, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:18, 1820:25, 1820:25, 1820:18, 1820:25, 1820			, ,	• • •	
1800:4, 1821:18, 1819:18, 1819:25, 1807:2, 1807:14, 1801:14, 1800:1, 1990:17, 1992:15, 1823:13, 1823:15, 1820:9, 1820:15, 1820:23, 1821:10, 1820:23, 1821:10, 1820:23, 1821:10, 1820:23, 1821:14, 1823:19, 1820:25, 1852:25, 1852:25, 1852:25, 1852:25, 1852:25, 1852:25, 1852:25, 1852:25, 1852:25, 1820:23, 1824:1, 1823:24, 1823:24, 1823:24, 1823:24, 1823:24, 1823:24, 1823:24, 1823:25, 1824:1, 1823:24, 1823:25, 1824:1, 1823:25, 1824:1, 1823:29, 1820:25, 1824:11, 1823:29, 1820:25, 1824:11, 1823:29, 1820:25, 1824:11, 1823:29, 1820:25, 1823:21, 1820:25, 1824:11, 1823:29, 1820:25, 1823:21, 1820:25, 1823:21, 1820:25, 1823:21, 18					
1823:13, 1823:15, 1820:9, 1820:15, 1807:24, 1808:22, 1930:8, 1943:12, 1992:17, 1993:7, 1825:25, 1851:8, 1820:23, 1821:10, 1813:18, 1816:24, 1971:5, 1995:2 1993:10, 1993:12, 1852:2, 1852:25, 1852:25, 1852:25, 1823:3, 1824:1, 1823:23, 1824:1, 1823:24, 1823:24, 1823:24, 1823:25, 1824:1, 1823:24, 1823:24, 1823:24, 1823:25, 1824:1, 1823:25, 1824:1, 1823:27,					
1825:25, 1851:8,     1820:23, 1821:10,     1813:18, 1816:24,     1971:5, 1995:2     1993:10, 1993:12,       1852:2, 1852:25,     1821:14, 1823:19,     1817:4, 1817:19,     trustworthiness [2] -     1993:23, 1994:2       1855:17, 1896:8,     1823:23, 1824:1,     1817:25, 1820:5,     1937:21, 1937:25     Type [18] - 1813:14,       1899:13, 1902:9,     1824:5, 1827:21,     1820:25, 1824:11,     truth [1] - 1915:14     1813:17, 1813:19,	· · · · · · · · · · · · · · · · · · ·		, ,		
1852:2, 1852:25, 1821:14, 1823:19, 1817:4, 1817:19, trustworthiness [2] - 1823:23, 1824:1, 1823:25, 1820:5, 1820:5, 1820:5, 1820:5, 1820:5, 1820:5, 1820:5, 1820:25, 1824:11,					
1855:17, 1896:8, 1823:23, 1824:1, 1817:25, 1820:5, 1937:21, 1937:25 <b>Type</b> [18] - 1813:14, 1899:13, 1902:9, 1824:5, 1827:21, 1820:25, 1824:11, <b>truth</b> [1] - 1915:14 1813:19, 1820:23, 1820:0					
1899:13, 1902:9, 1824:5, 1827:21, 1820:25, 1824:11, truth [1] - 1915:14 1813:19, 1820:25, 1824:11, 182	1852:2, 1852:25,				
1000.10, 1002.0,	1855:17, 1896:8,				<b>Type</b> [18] - 1813:14,
1902:11, 1902:13, 1839:2, 1839:9, 1826:13, 1826:18, <b>try</b> [10] - 1764:11, 1813:25, 1820:7,	1899:13, 1902:9,				1813:17, 1813:19,
	1902:11, 1902:13,	1839:2, 1839:9,	1826:13, 1826:18,	<b>try</b> [10] - 1764:11,	1813:25, 1820:7,

**-**38

1865:11, 1865:13, 1865:15, 1865:16, 1865:23, 1866:3, 1866:6, 1866:11, 1866:18, 1866:21, 1890:4, 1890:11 type [5] - 1866:14, 1868:13, 1903:15, 1924:17, 1958:12 Types [1] - 1976:9 types [2] - 1803:6, 1958:12 typically [5] - 1813:19, 1813:20, 1866:23, 1893:10, 1893:11 typo [4] - 1803:17, 1866:7, 1869:23, 1869:25 U U.S [3] - 1757:23. 1902:25. 1963:23 UCSF [1] - 1768:1 ultimately [2] -

## 1805:8, 1981:12 unable [1] - 1933:24 uncertainty [3] -1761:2, 1761:3, 1772:25 under [21] - 1765:14, 1800:24, 1833:20, 1834:1, 1866:11, 1888:6, 1920:3, 1920:6, 1920:11, 1920:17, 1922:10, 1934:8, 1934:12, 1935:4, 1947:7, 1950:12, 1952:11, 1953:18, 1961:13, 1970:20, 1974:20 underdosed [1] -1925:1 underlying [1] -1848:6 underneath [3] -1858:4, 1908:12, 1935.9

understood [1] -

undertook [1] -

Underway [1] -

underway [3] -

1764:18, 1764:25,

unethical [1] - 1897:7

Unexpected [1] -

1770:7

1920:12

1897:20

1765:10

1769:2

1978:3, 1979:17, 1980:1, 1980:2, 1980:6, 1981:13 unfortunately [1] -1893:1 uniform [1] - 1872:6 United [5] - 1902:11, 1902:15, 1903:15, 1921:8, 1921:11 UNITED [1] - 1757:1 units [1] - 1958:5 unity [2] - 1771:6, 1772:21 unless [1] - 1987:14 unmet [1] - 1890:17 unpack [5] - 1762:6, 1806:5, 1862:17, 1876:7, 1880:17 unreasonable [1] -1857:10 unrelated [4] -1928:17, 1932:12, 1932:20, 1938:10 unsealed [1] -1987:16 unsettled [1] -1903:17 unstable [3] -1759:22, 1759:24, 1902:3 Up [1] - 1975:11 up [47] - 1760:5, 1762:16, 1763:5, 1770:10, 1771:12, 1774:1, 1782:23, 1784:1, 1789:17, 1792:6, 1792:14, 1798:25, 1817:17, 1826:15, 1836:23, 1850:13, 1887:3, 1888:9, 1889:5, 1900:14, 1906:13, 1907:21, 1920:17, 1930:15, 1933:4, 1934:2, 1942:2, 1942:3, 1945:1, 1946:6, 1949:4, 1954:20, 1956:18,

1957:11, 1958:2,

1959:5, 1966:14,

1969:23, 1976:4,

1977:8, 1978:25,

1979:6, 1981:21,

1990:14, 1990:15,

1990:18, 1994:7

Up-regulated [1] -

1975:11

unexpected [10] -

1792:20, 1807:8,

1899:9, 1957:7,

Upending [1] -1767:12 upfront [1] - 1912:9 upgoing [1] - 1948:15 upper [1] - 1887:9 **USA** [1] - 1757:8 useful [4] - 1766:11, 1953:11, 1954:1, 1972:5 uses [4] - 1826:16, 1902:15, 1955:15, 1955:25 utility [1] - 1973:22 V Valentine's [3] -1992:3, 1992:20, 1994:6

validity [2] - 1801:4, 1875:3 valuable [1] - 1845:7 value [5] - 1769:19, 1772:22, 1961:2, 1961:11, 1968:22 variations [1] - 1782:3 variety [4] - 1926:15, 1934:5, 1934:15, 1935:13 various [1] - 1857:21 vary [1] - 1948:20 Vascepa [31] - 1760:9, 1768:2, 1768:3, 1768:10, 1772:2, 1772:8, 1776:8,

1777:20, 1777:22, 1778:1, 1781:23, 1807:7, 1807:23, 1833:18, 1834:1, 1860:6, 1890:24, 1891:3, 1895:21, 1895:23, 1897:6, 1897:7, 1909:18, 1910:14, 1911:5, 1911:10, 1911:18, 1926:10, 1957:8, 1959:20, 1959:24 vast [3] - 1892:13, 1892:16, 1934:25 Vegas [1] - 1758:8 vendors [1] - 1944:13 version [6] - 1814:12, 1978:20, 1987:25, 1995:10, 1995:24, 1995:25 versus [5] - 1795:8,

view [16] - 1789:1, 1791:17, 1791:25, 1792:2, 1792:10, 1792:13, 1792:17, 1792:19, 1792:22, 1793:5, 1806:20, 1861:7, 1901:24, 1924:14, 1925:4, 1940.9 viewing [1] - 1964:23 virtually [1] - 1771:5 vitro [1] - 1799:18 VLDL [2] - 1789:21, 1865:24 Volume [1] - 1757:8 voluminous [2] -1935:21, 1996:11 von [14] - 1844:9, 1844:16, 1844:18, 1845:23, 1847:8, 1847:21, 1847:25, 1848:5, 1945:24, 1946:8, 1946:17, 1946:21, 1947:25, 1948:17 **vs** [1] - 1757:7

## W

wait [2] - 1941:14, 1984.7 walk [6] - 1764:23, 1771:20, 1781:23, 1782:2, 1785:11, 1825:1 warn [1] - 1824:9 warns [1] - 1824:7 warranted [1] - 1830:3 warranting [1] -1786:18 Washington [2] -1757:17, 1757:20 waste [1] - 1812:15 ways [1] - 1895:18 weaknesses [2] -1920:8, 1921:9 website [15] -1928:23, 1929:7, 1929:17, 1930:1, 1930:24, 1934:16, 1935:19, 1935:23, 1936:6, 1937:8, 1938:3, 1938:14, 1938:15, 1938:19, 1944:21 Wednesday [1] -1986:23 week [5] - 1988:14, 1988:15, 1992:5, 1992:25, 1993:7

weeks [20] - 1776:3, 1776:7, 1776:8, 1776:22, 1776:23, 1809:22, 1821:20, 1821:24, 1853:3, 1895:12, 1895:15, 1895:17, 1940:10, 1990:15, 1991:18, 1993:7, 1993:11, 1993:12, 1993:23, 1994:2 weight [7] - 1938:14, 1939:9, 1941:5, 1963:10, 1963:22, 1963:23, 1986:19 Weintraub [2] -1983:12, 1983:25 Weintraub's [1] -1984:3 Weiss [1] - 1768:1 welcome [2] -1816:10, 1853:24 well-established [1] -1875:9 well-tolerated [2] -1893:10, 1893:11 WEST [1] - 1758:7 Western [4] - 1761:21, 1903:16, 1905:18, 1925.2 western [1] - 1925:5 whereas [3] - 1759:20, 1781:2, 1781:11 WHITT [7] - 1757:15, 1983:10, 1983:16, 1984:3, 1984:7, 1984:10, 1984:16 Whitt [2] - 1983:9, 1983:15 whole [4] - 1802:14, 1919:8, 1955:13, 1965:25 whopping [2] -1919:17, 1921:17 wide [1] - 1772:24

MARGARET E. GRIENER, RDR, CCR NO. 3, OFFICIAL REPORTER (775) 329-9980

1795:10, 1831:7,

1846:15, 1947:2

vertical [1] - 1771:6

video [1] - 1933:8

widely [1] - 1891:12

willing [1] - 1768:5

wish [1] - 1978:23

withdrawing [1] -

witness [19] - 1759:8,

1785:5, 1799:8,

1815:2, 1884:10,

1909:7, 1915:21,

1920:13, 1935:10,

1935:11, 1937:24,

1938:9, 1941:5,

1983:6

1941:15, 1966:2,

1973:19, 1982:17,

1941:18

```
WITNESS [24] -
                           1931:11, 1931:22,
 1779:20, 1779:22,
                           1931:24
 1784:9, 1784:13,
                          yesterday[11] -
 1788:16, 1798:19,
                           1759:12, 1759:24,
 1798:22, 1798:25,
                           1762:23, 1764:24,
 1799:8, 1815:4,
                           1766:9, 1774:5,
 1816:5, 1816:7,
                           1779:4, 1850:5,
 1839:18, 1839:21,
                           1861:5, 1892:20,
 1839:25, 1846:7,
                           1920:20
 1878:8, 1884:9,
                          yield [1] - 1895:19
 1884:21, 1890:9,
                          Yokoyama [11] -
 1913:12, 1913:15,
                           1762:23, 1763:11,
 1981:20, 1983:5
                           1772:14, 1899:17,
WITNESSES [1] -
                           1900:19, 1901:2,
 1997:3
                           1905:9, 1922:14,
witnesses [3] -
                           1951:20, 1951:24,
 1940:22, 1983:8,
                           1957:25
 1985:12
                          yourself [4] - 1785:4,
WO [4] - 1923:4,
                           1884:5, 1965:23,
 1960:1, 1960:25,
                           1981:8
 1962:18
                                    Ζ
Wojenski [4] -
 1855:12, 1855:15,
 1855:17, 1855:21
                          zero [9] - 1771:23,
                           1832:20, 1836:3,
Woodman [8] -
 1851:17, 1852:2,
                           1836:5, 1869:5,
                           1869:6, 1873:2
 1852:8, 1852:15,
 1852:25, 1853:6,
                          Zocor [1] - 1873:6
 1855:21, 1855:22
word [7] - 1764:11,
 1869:23, 1874:15,
 1877:14, 1897:2,
 1963:4, 1971:22
Word [3] - 1995:10,
 1995:24, 1995:25
words [3] - 1810:23,
 1878:21, 1939:1
works [3] - 1885:18,
 1929:18, 1993:5
world [1] - 1913:2
worse [1] - 1948:25
write [3] - 1912:15,
 1913:13, 1968:5
writing [1] - 1967:6
written [4] - 1914:16,
 1965:8, 1965:9,
 1965:16
wrote [5] - 1805:1,
 1807:5, 1838:5,
 1912:12, 1968:4
          Υ
year [7] - 1776:2,
 1891:11, 1900:14,
 1907:21, 1932:17,
 1933:5, 1936:16
years [8] - 1793:18,
 1926:5, 1926:18,
 1928:3, 1930:13,
```