

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF NEVADA  
3 BEFORE THE HONORABLE MIRANDA DU, DISTRICT JUDGE  
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4 AMARIN PHARMA, INC., and :  
5 AMARIN PHARMACEUTICALS :  
6 IRELAND LIMITED, :  
7 : No. 2:16-cv-02525-MMD-NJK  
8 Plaintiffs, :  
9 : January 14, 2020  
10 -vs- :  
11 : Reno, Nevada  
12 HIKMA PHARMACEUTICALS USA :  
13 INC., et al., : Volume 2  
14 Defendants. :  
15 \_\_\_\_\_ :  
16 :

17 TRANSCRIPT OF BENCH TRIAL

18 APPEARANCES:

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20 SIPES, MICHAEL KENNEDY, JEFFREY  
21 ELIKAN, JOSEPH KENNEDY, ELAINA M.  
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Reported by: Kathryn M. French, CCR #392, RPR  
Official Reporter  
U.S. District Court  
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(Appearances continue on next page.)

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1 RENO, NEVADA, TUESDAY, JANUARY 14, 2020, 8:30 A.M.

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4 THE COURT: Good morning. Please be seated.

5 All right. Counsel, did you resolve the issue  
6 with respect to Mr. Klein's demonstrative exhibits yesterday?  
7 Is there any objection to the Court attaching them as minutes  
8 to yesterday's hearing -- yesterday's trial, I mean?

9 MS. KEANE: Good morning, Your Honor. Meagan  
10 Keane.

11 Your Honor, we did have a chance to review the  
12 demonstrative. In our view, there is an error that's in the  
13 demonstrative with respect to a couple of patents that are  
14 actually listed both for the REDUCE-IT indication as well as  
15 for MARINE. So we don't think the slide is accurate as it's  
16 depicted.

17 What we would propose is that we are willing to  
18 work with defendants' counsel to come up with a compromise  
19 version that we can agree on and attach that as a  
20 demonstrative.

21 THE COURT: You're referring to DX 2699.

22 MS. KEANE: To the summary slide with respect to  
23 the list of patents, yes, Your Honor.

24 THE COURT: And that approach sounds agreeable  
25 to me. What I was asking, though, is that with the entire set

1 of exhibits that I admitted into evidence but that Mr. Klein  
2 had referenced during his cross-examination where he would  
3 show the exhibit and then highlight certain portions of the  
4 actual exhibit and reference DDX and then the number. That's  
5 what I was concerned about.

6 MR. SIPES: We apologize, Your Honor. This is  
7 Christopher Sipes.

8 What we thought might make sense, since  
9 demonstratives usually wouldn't be attached, would be for  
10 defendants to prepare just a chart that correlates the DDX  
11 number to the DX number and page. So it would be a simple  
12 chart, and that would make the record clear without having the  
13 argumentative parts of the demonstrative in, and we could just  
14 review that to make sure that it was accurate.

15 THE COURT: I think that would address my  
16 concern. All I want is to make sure that there's notation in  
17 the record as to whatever the reference is to DDX and then the  
18 specific slide number.

19 MR. SIPES: And the advantage of that, that  
20 would be a short compact thing that we just would provide the  
21 reference, Your Honor.

22 THE COURT: Mr. Klein?

23 MR KLEIN: Your Honor, we can put together that  
24 chart if you would like, but there was no argument in any of  
25 the demonstratives. You might be thinking of the opening

1 statement. But it was just call-outs.

2 THE COURT: I think the chart serves my purpose.  
3 All I want is to make sure that -- there were times when I  
4 thought that you didn't note the actual page of the exhibit  
5 but you noted the DDX number for certain exhibits that you  
6 were showing, that it's clear for the record which page of the  
7 actual exhibit you were referring to.

8 So the chart will suffice, and the chart will  
9 then be attached to yesterday's trial minutes.

10 MR KLEIN: Okay. Thank you.

11 THE COURT: All right.

12 And then on Exhibit 2299, I'm pretty sure that's  
13 the one that's left that I need to resolve; is that right?

14 THE CLERK: Yes.

15 THE COURT: That the parties will confer and let  
16 me know if you are able to reach a resolution.

17 MS. KEANE: Okay. Thank you, Your Honor.

18 THE COURT: All right. Let's proceed with  
19 Amarin's next witness.

20 MR. M. KENNEDY: Your Honor, this is Michael  
21 Kennedy for Amarin. Amarin calls Dr. Matthew Budoff.

22 THE COURT: Thank you.

23 MR. M. KENNEDY: Your Honor, we have some  
24 demonstratives with this witness as well as a witness binder.  
25 Permission to approach to distribute the binder, and if Your

1 Honor would like a copy of the slides as well.

2 THE COURT: I do not, but I don't want to have  
3 the same problem with reference to the page number of the  
4 slides. So if the slide is referenced as an exhibit, then you  
5 need to reference the actual page number of that exhibit.

6 MR. M. KENNEDY: Understood, Your Honor.

7 THE COURT: Thank you.

8 MATTHEW BUDOFF, M.D.,  
9 called as a witness on behalf of the Government,  
was sworn and testified as follows:

10 THE CLERK: Please be seated.

11 State for the record your full name and spell  
12 both your first name and your last name.

13 THE WITNESS: Matthew Budoff; M-a-t-t-h-e-w,  
14 B-u-d-o-f-f.

15 MR. M. KENNEDY: Good morning, Dr. Budoff.

16 THE WITNESS: Good morning.

17 DIRECT EXAMINATION

18 BY MR. M. KENNEDY:

19 Q Are you currently employed?

20 A Yes.

21 Q Where are you employed?

22 (Discussion held off the record.)

23 BY MR. M. KENNEDY:

24 Q Dr. Budoff, where are you employed?

25 A I'm employed at the David Geffen School of Medicine at

1 UCLA, formerly known as the UCLA School of Medicine, as well  
2 as the Lundquist Institute which is a research institute at my  
3 home institution.

4 Q At a very high level, please describe your job  
5 responsibilities in those roles.

6 A Yes. So my primary responsibility is teaching. I am the  
7 program director for the Division of Cardiology, which means I  
8 teach all of the cardiology fellows, those people who are  
9 doing three years of advanced training in cardiology, on how  
10 to practice cardiology.

11 I also have the opportunity to teach residents,  
12 medical students, and other clinicians.

13 And then, when I'm not teaching, I'm either doing  
14 clinical work, seeing patients directly, or doing clinical  
15 research.

16 Q Were you retained as an expert by a party in this case?

17 A Yes.

18 Q Which party?

19 A Amarin.

20 Q So at a very high level what were you asked to do in this  
21 case as an expert?

22 A Yes, I was asked to opine on the patents and understand  
23 if there would be infringement in this case if a generic  
24 version of a product was brought to market.

25 Q Do you specialize in a particular area of medicine?

1 A Yes.

2 Q What area?

3 A It's called cardiovascular medicine or commonly known as  
4 cardiology.

5 Q What is cardiology?

6 A Cardiology is the practice of evaluating the heart.

7 Q Do you have a subspecialty within cardiology?

8 A Yes, I'm a preventive cardiologist.

9 Q What is a preventive cardiologist?

10 A So a preventive cardiologist works to try to prevent  
11 either the first heart attack in those patients at high risk  
12 of heart disease, or the second heart attack, what we call  
13 secondary prevention, in those patients who have already  
14 suffered a cardiovascular event.

15 Q Are there other subspecialties within cardiology that  
16 you're familiar with?

17 A Yes.

18 Q Such as?

19 A There's imaging, there's invasive cardiology, those  
20 people who spend most of their time putting in stints and  
21 bypass and other devices, and then there's general cardiology  
22 as well.

23 Q How long have you characterized yourself as specialist in  
24 preventive cardiology?

25 A About 20 years.



1 Q How long has the field of cardiology recognized  
2 preventive cardiology as a subspecialty?

3 A It's been about ten years since it was formalized as a  
4 subspecialty.

5 Q So what did you call yourself before preventive  
6 cardiology was formalized as a subspecialty?

7 A So if there was no check box that said preventive  
8 cardiologist, then I generally -- I would have to refer to  
9 myself as a general cardiologist.

10 MR. M. KENNEDY: Mr. Brooks, can we have  
11 Plaintiffs' Exhibit 1161, please.

12 BY MR. M. KENNEDY:

13 Q And, Dr. Budoff, you should have this document on your  
14 screen as well.

15 A Yes.

16 Q Do you recognize this document?

17 A Yes.

18 Q What is it?

19 A It's my curriculum vitae or CV.

20 Q What does your curriculum vitae contain in general?

21 A It goes through my education, training, my current work  
22 and prior work opportunities, and then it lists all of my  
23 manuscripts and abstracts.

24 Q Does Plaintiffs' Exhibit 1161 accurately summarize your  
25 professional and educational background?

1 A Yes.

2 MR. M. KENNEDY: Your Honor, we would like to  
3 admit Plaintiffs' Exhibit 1161 into evidence.

4 MR KLEIN: No objection.

5 THE COURT: 1161 is admitted.

6 (Plaintiffs' Exhibit 1161 received in  
7 evidence.)

8 BY MR. M. KENNEDY

9 Q Dr. Budoff, have you worked with us to prepare slides to  
10 aid your testimony today?

11 A Yes.

12 Q Or I should say to illustrate your testimony today?

13 Have you prepared one such slide that summarizes  
14 your educational qualifications?

15 A Yes.

16 MR. M. KENNEDY: Mr. Brooks, if we could have  
17 PDX 2-2.

18 BY MR. M. KENNEDY:

19 Q And, Dr. Budoff, is this that slide?

20 A Yes.

21 Q Could we focus on the last two items on this slide  
22 starting with the internship and residency in internal  
23 medicine. Could you describe what that involved.

24 A Yes. So, my internship and residency is three years of  
25 training to become an internist or a primary care physician.

So I spent three years at Harbor UCLA Medical Center

1 affiliated with UCLA School of Medicine under that training.

2 Q What does it mean -- what does doing an internship in  
3 this context involve?

4 A So it's basically on-call every third or fourth night,  
5 taking care of patients in the hospital, seeing patients in  
6 clinic, just basically learning how to practice general  
7 medicine.

8 Q I would like to move to the cardiology fellowship at  
9 Harbor UCLA Medical Center. What it did that involve?

10 A So that's another three years of commitment. This is  
11 just focused on learning how to be a cardiologist, so I'm  
12 specializing in cardiovascular medicine and learning all of  
13 the aspects, including imaging and how to treat patients and  
14 how to do the invasive procedures.

15 Q And so am I correct that starting in 1997 or so you were  
16 a full-fledged cardiologist?

17 A Yes.

18 Q So you testified that you're a professor of medicine.  
19 What are your responsibilities in that role?

20 A So my primary responsibilities as a professor of medicine  
21 is to teach and do research. There's still an adage of  
22 publish or perish, so I still publish quite a bit as far as my  
23 academic career.

24 But I spend most of my time teaching, and I'll teach  
25 everybody from the primary care specialists, family medicine

1 doctors, and internal medicine doctors, the cardiology  
2 fellows, the interns and residents, and then the medical  
3 students who are also rotating through different rotations  
4 with me.

5 Q How long have you been teaching?

6 A Oh, I became a -- I started my professorship series in  
7 1997 so I've been teaching full time since July 1997.

8 Q And am I correct that you teach practicing physicians?

9 A Yes.

10 Q Could you go into a little more detail about what you  
11 teach them.

12 A Yeah. So I spend a lot of time -- I get invited to a lot  
13 of different academic meetings, so I'll present at large scale  
14 meetings where there will be anywhere from dozens to hundreds  
15 of practicing physicians, and I will give lectures on --  
16 usually on things related to lipids or things related to  
17 cardiovascular imaging to these different groups.

18 Q Do you have an understanding of why people ask you to do  
19 these lectures?

20 A Well, I've been told that I'm fairly clear when I  
21 lecture, and they find it educational so they invite me back.  
22 So I usually end up doing these on a regular basis.

23 Q Are you involved in any other physician education  
24 activities we haven't already covered?

25 A Well, I do a lot of publishing, and some of that is in

1 the form of guidelines. So I'll publish medical guidelines  
2 I'll write on behalf of different societies, different  
3 guidelines to help educate physicians in the field on how to  
4 practice cardiology or how to use certain tools in their  
5 practice.

6 Q What drew you to preventive cardiology?

7 A Yeah, so, I mean, the long-standing relationships with  
8 the patient, the ability to try to help them, enable them to  
9 prevent a catastrophic event was very rewarding for me, and  
10 I've enjoyed it in my clinical practice, so I've stayed with  
11 it over the many years since I started.

12 Q You mentioned you conduct research. What kind of  
13 research do you conduct?

14 A Yeah, so most of my research revolves around looking at  
15 the effect of different therapies on atherosclerosis, plaque  
16 build-up in the arteries, to see if drug X improves the  
17 arteries or if drug Y causes more problems in the arteries.

18 I also do a lot of research on clinical trials so  
19 I'll work with other investigators to perform clinical studies  
20 to see if a drug has its desired affect, be it anything from  
21 lowering the blood pressure to improving the cholesterol  
22 panel, to improving the triglycerides.

23 Q What is an investigator in the context of clinical  
24 trials?

25 A Yeah, so an investigator is the person who is principally

1 responsible for the local site, and the primary investigator  
2 or the principal investigator is responsible for the overall  
3 performance of the trial, everything from making sure the  
4 patients stay in the study and are appropriately treated, to  
5 ensuring their safety, and then to make sure that we capture  
6 all of the desired endpoints so that the trial can be  
7 published and hopefully advance science.

8 Q How long have you -- or how many times have you been a  
9 principal investigator at the national level?

10 A Probably around a dozen or so.

11 Q How many times have you been the principal investigator  
12 on a clinical trial at a local site?

13 A Oh, probably about a hundred times.

14 Q Can you give a few examples of clinical studies you've  
15 been involved in recently?

16 A Yes, I'm currently performing a multicenter trial that  
17 I'm the overall principal investigator on called EVAPORATE.  
18 That's actually using the product in question here, Vascepa,  
19 to look at plaque over time.

20 So I'm in charge of all of the sites in the trial  
21 and the overall performance of the trial, and I recently  
22 presented some of the interim data at the largest meeting of  
23 cardiology in the United States called the American Heart  
24 Association Meeting on a very large scale.

25 Q What do you hope to show in the EVAPORATE trial?

1       A     So EVAPORATE is -- the target of EVAPORATE is to  
2 demonstrate whether Vascepa reduces plaque in the coronary  
3 arteries as compared to placebo, so to see if some of its  
4 cardiovascular benefits that we've seen in the REDUCE-IT trial  
5 actually translate into plaque reduction at the coronary  
6 level.

7       Q     Can you tell us how EVAPORATE is going so far?

8       A     Yeah. It concludes in February. Hopefully by the end of  
9 the February we'll have our last patient, last visit.

10                So hopefully we'll be -- we plan on presenting this  
11 at the European Society of Cardiology Meeting in July or  
12 August which is the largest meeting in the world of  
13 cardiologists.

14       Q     Why do you do so many clinical trials?

15       A     Well, clinical trials have, I feel, a great purpose. We  
16 have to remember that about half of what we discover in -- at  
17 least in fields like cardiology, are based on these clinical  
18 trials.

19                These clinical trials show us whether a drug works  
20 and in whom they work. So, for example, if we just go back to  
21 the REDUCE-IT trial, it affords us a great opportunity to  
22 understand that we can reduce cardiovascular events in  
23 patients who have certain clinical criteria. So participating  
24 in those studies help us treat patients better.

25       Q     You mentioned REDUCE-IT. Did you have a role in the

1 REDUCE-IT clinical trials?

2 A Yeah, I was local principal investigator so I was  
3 responsible for my local site, and then I was a co-author on  
4 one of the recent papers describing the results in the United  
5 States population of REDUCE-IT.

6 Q So I think you mentioned earlier that you publish so that  
7 you don't perish. Have you prepared a slide that lists some  
8 of your publications?

9 A Yes.

10 MR. M. KENNEDY: Mr. Brooks, can we please have  
11 PDX 2-3.

12 BY MR. M. KENNEDY:

13 Q And are these some selected publications from your  
14 curriculum vitae, PX 11671?

15 A Yes.

16 Q Could you tell us a little bit more about number 1103.  
17 Is that the paper about REDUCE-IT that you just mentioned?

18 A Yes. So it's very important to understand how the U.S.  
19 population behaves in a clinical trial. Sometimes it's a  
20 little bit different than the overall clinical trials that are  
21 done with a worldwide influence.

22 So Dr. Bhatt and I put together this paper to look  
23 at the results of the -- of the 3,000 plus patients who were  
24 United States participants in the trial to see how they  
25 performed.



1 Q And if you could tell us a little bit more about 783. Is  
2 that also related to EPA?

3 A Yes. This was a review article. As I was preparing my  
4 research and preparing for the EVAPORATE trial to see how we  
5 wanted to perform that study and writing it up, we came across  
6 a lot of information related to the effects of both EPA and  
7 DHA on lipoproteins on lipids. So we wrote a little review  
8 article to help clarify that part of the science.

9 Q Who is the intended audience for these publications that  
10 you author?

11 A Yeah, so, generally, it depends on where we publish it.  
12 For example, the first publication that we discussed was  
13 published in *Circulation*. That's the Journal of the American  
14 Heart Association, so it generally goes out to all  
15 cardiologists in the United States and obviously has a bigger  
16 circulation than just the U.S. It goes around to  
17 cardiologists in the world. So that paper was more focused on  
18 getting the word out to cardiology.

19 Q So I would like to ask you a few more questions about  
20 your clinical practice. How long have you been seeing  
21 patients?

22 A I've been seeing patients since 1990 when I started my  
23 internship. We had what's called a continuity clinic, and I  
24 would see patients in my clinic starting in 1990, and I've  
25 continued since then.

1 Q How many patients do you see in a typical month?

2 A So I see approximately 200 patients in different venues.

3 Q Are there -- do you have different -- do you have  
4 different places where you practice?

5 A Yes, and it depends on my rotations at the time. For  
6 example, right now I'm supposed to be in the intensive care  
7 unit, in the cardiac care unit. So tomorrow morning I will be  
8 rounding in the CCU and taking care of more acute patients.

9 I also have a private clinic where I see my own  
10 patients. And I supervise fellows as well in the cardiology  
11 clinic where they will see a patient, and then I will go  
12 discuss the patient with them, go in and discuss the case with  
13 the patient, and see the patient as -- in a more supervisory  
14 role.

15 Q Now, in your own practice how do those patients find you?

16 A Yeah, I have a pretty typical preventive cardiology  
17 practice. My practice entails getting referrals from primary  
18 care physicians.

19 So a doctor may see somebody with high  
20 triglycerides, or may see somebody with very high LDL  
21 cholesterol, or a bad family history of heart disease and  
22 refer them directly to me, or I get patients directly from  
23 word of mouth. Some patients, some of my patients refer me,  
24 and their colleagues or friends or family members will come to  
25 see me as well.

1 Q What are the common medical problems that patients face  
2 in your practice?

3 A Yeah. So my private practice, it's fairly focused on  
4 preventive cardiology. So, in other words, I try to take  
5 patients who are high risk and try to work with them on risk  
6 reduction. So that could be anything from diet and exercise  
7 to drug therapy, to other types of interventions to help  
8 prevent them from ever suffering a cardiovascular event.

9 Q Do you see patients with elevated triglyceride levels?

10 A Yes.

11 Q How often?

12 A Very frequently. Elevated triglyceride levels are part  
13 of a mixed dyslipidemia, so they're part of -- people come in  
14 with high cholesterol and high triglycerides, and then I also  
15 see patients with isolated high triglycerides.

16 Q Do you see patients with severe hypertriglyceridemia?

17 A Yes.

18 Q How often?

19 A So it's a less common disease. I don't have a lipid  
20 clinic, I have a general preventive cardiology clinic, but I  
21 do see patients regularly with severe hypertriglyceridemia.

22 Q Do you see patients with elevated LDL-C levels?

23 A Yes.

24 Q How often?

25 A So that's most the common disorder that I see and the

1 most common disorder that I treat.

2 And, again, those patients with elevated LDL, or bad  
3 cholesterol, oftentimes have abnormal triglycerides as well.  
4 So we call that a mixed dyslipidemia.

5 Q Beyond your teaching, research, and clinical obligations,  
6 do you engage in other professional activities?

7 A Yes.

8 MR. M. KENNEDY: Mr. Brooks, could we please  
9 have slide PDX 2-4.

10 BY MR. M. KENNEDY:

11 Q And can you just briefly explain what you've depicted on  
12 this slide.

13 A Yeah, so these is just some of my recent memberships or,  
14 rather, affiliations with large organizations, national or  
15 international organizations, where my expertise was -- I was  
16 asked to be on the executive committee or be the chair of the  
17 steering committee for different groups.

18 Q Have you ever received any awards from your peers?

19 A Yes.

20 MR. M. KENNEDY: Mr. Brooks, can we please have  
21 PDX 2-5.

22 BY MR. M. KENNEDY:

23 Q Are these some of the awards that you've received that  
24 are reflected in your curriculum vitae?

25 A Yes.

1 Q Could you tell us about one of these awards that may be  
2 particularly meaningful to you.

3 A Yeah, the one that's bolded is, I think, the most  
4 prestigious is to be named an Endowed Chair.

5 That comes with some financial support because  
6 there's an endowment that supports your position, but, also,  
7 more importantly, you're recognized among your peers as being  
8 at the highest level of that field.

9 So this is the Endowed Chair of Preventive  
10 Cardiology that I was awarded in 2015.

11 MR. M. KENNEDY: Your Honor, at this time Amarin  
12 offers Dr. Budoff as an expert in the clinical treatment of  
13 patients with lipid disorders, including severe  
14 hypertriglyceridemia, and as an expert in cardiology.

15 MR KLEIN: No objection.

16 THE COURT: The request to certify Dr. Budoff in  
17 the clinical treatment of lipid disorders, including severe  
18 TG, and just preventive cardiology?

19 MR. M. KENNEDY: Cardiology in general.

20 THE COURT: Cardiology in general. That request  
21 is granted.

22 MR. M. KENNEDY: Thank you, Your Honor.

23 BY MR. M. KENNEDY:

24 Q So, Dr. Budoff, just to orient ourselves, I would like to  
25 go over a little bit of scientific background. I know some of

1 this was covered yesterday.

2 MR. M. KENNEDY: Mr. Brooks, if we could pull up  
3 slide PDX 2-6.

4 BY MR. M. KENNEDY:

5 Q So, Dr. Budoff, what have you shown on this slide?

6 A Yeah, so this is a lipoprotein. A lipoprotein -- I know  
7 Dr. Ketchum touched on this yesterday, but a lipoprotein is a  
8 kind of a way that we transport both cholesterol and  
9 triglycerides around the body.

10 If they are heavily containing both cholesterol  
11 and/or triglycerides, the bad lipoproteins, they're designated  
12 as apolipoprotein B, so you can see that in purple. And you  
13 can see within the content of that lipoprotein, that bad  
14 lipoprotein, that has both cholesterol in yellow and  
15 triglycerides depicted in red.

16 Q What are triglycerides?

17 A So triglycerides are basically how we store energy and  
18 how we then given energy to different organs when needed.

19 Q Are more triglycerides better?

20 A Well, up to a point. We need triglycerides, they are an  
21 energy source, but most commonly, especially in the United  
22 States, we have excess. We -- we have too many -- we eat too  
23 many calories, we store that as triglycerides, and  
24 triglycerides then build-up in the bloodstream which can cause  
25 plaque build-up, blockages in the arteries that then

1 subsequently cause heart attacks and death.

2 Q What purpose does cholesterol serve?

3 A Cholesterol is very important. It's a precursor for  
4 vitamins as well as for hormones, so it's a very important  
5 precursor.

6 But, again, in the United States we tend to run an  
7 excess of cholesterol, and that can, again, start to block up  
8 the arteries, gets converted into malignant cells that can  
9 then cause plaque buildup and heart attacks and strokes.

10 Q And what purpose does apolipoprotein B serve?

11 A So the apolipoproteins are divided into the good, those  
12 apo A, and bad lipoproteins, the ones that contain lot of  
13 cholesterol and triglyceride, are designated apo B.

14 So apo B -- I think of B as bad, so apo B is the bad  
15 lipoprotein that, when in excess, carries around too many  
16 triglycerides and cholesterol and can cause excess heart  
17 attacks, strokes, and death.

18 MR. M. KENNEDY: Mr. Brooks, can we have  
19 PDX 2-7.

20 BY MR. M. KENNEDY:

21 Q Dr. Budoff, what have you shown on this slide?

22 A Yeah, so this is just showing the natural -- the natural  
23 progression of what happens to the lipoproteins in our body.

24 When the liver first processes the food and creates  
25 these very low-density lipoproteins, they are very rich in

1 triglycerides. Then, via lipoprotein lipase and other  
2 enzymes, we deliver some of the triglycerides to organs.

3 And the lipoprotein gets smaller and denser, so it  
4 goes from very low-density to intermediate density. It's now  
5 a smaller lipoprotein, has less triglycerides and relatively  
6 more cholesterol, because the cholesterol is still there, and  
7 then further delivered to LDL cholesterol.

8 LDL cholesterol is what we commonly call bad  
9 cholesterol. This is a cholesterol-rich particle that is most  
10 associated with heart attacks and strokes and of great concern  
11 when we think about a patient's cardiovascular risk if they  
12 have too much LDL cholesterol.

13 Q Again, something we covered a little bit yesterday, but  
14 what is hypertriglyceridemia?

15 A So hypertriglyceridemia is simply hyper, too much,  
16 triglycerides, and then emia is in the blood. So too many  
17 triglycerides in the blood, and, again, that's what we call  
18 atherogenic. It causes atherosclerosis, and it causes  
19 cardiovascular events.

20 Q And what is severe hypertriglyceridemia, which I may also  
21 refer to STG?

22 A So severe hypertriglyceridemia is a less common disorder.  
23 It's an extreme state of hypertriglyceridemia mostly caused by  
24 genetics, so we know it as a chronic condition that is  
25 lifelong.



1           And when the triglycerides are very high, there are  
2 different risks as compared to when the triglycerides are only  
3 moderately elevated.

4       Q    Is severe hypertriglyceridemia a condition recognized in  
5 medical literature?

6       A    Yes.

7       Q    Could you give me example of the type of medical  
8 literature in which it's recognized?

9       A    Yes, so it's been discussed in the cholesterol  
10 guidelines, guidelines that talk about lipids and how to treat  
11 lipids, for decades.

12       Q    Now, you've mentioned guidelines a couple times. What  
13 are guidelines in this context?

14       A    So guidelines are very simply the -- to establish the  
15 medical standard of care. So they instruct clinicians who are  
16 practicing in the field on the best practices and what they  
17 should do when encompassing a certain condition.

18       Q    Do you use medical guidelines in your own practice?

19       A    Yes, every day.

20       Q    Do you have experience writing guidelines?

21       A    Yes. I've been involved in probably around 13 or 14  
22 guidelines, sometimes as the first author, sometimes as a  
23 member of the writing group.

24                   MR. M. KENNEDY: Mr. Brooks, could we have  
25 Plaintiffs' Exhibit 989.

1                   And, Your Honor, I believe this is one the  
2 exhibits that has already been preadmitted in this case.

3 BY MR. M. KENNEDY:

4       Q     Dr. Budoff, do you recognize this document?

5       A     Yes.

6       Q     What is it?

7       A     So this is a cholesterol guideline. We commonly refer to  
8 it as the Adult Treatment Panel III or ATP III report.

9       Q     What role does the American Heart Association have in  
10 these guidelines? I see that this document has its logo on  
11 it.

12       A     Yes, so this is -- this is a primary -- they are one the  
13 primary writers of the guidelines and sponsors of the  
14 guidelines. They are signed off by many organizations, but  
15 they are co-led by the American Heart Association and often  
16 the American College of Cardiology.

17       Q     What role does the ATP III guideline play in medical  
18 practice?

19       A     Yeah, so this was a very widely used and established  
20 guideline in the field. It really helped us -- directed  
21 physicians to be very aggressive with LDL or bad cholesterol  
22 control, and it also helped define some of the treatments and  
23 definitions of hypertriglyceridemia.

24                   MR. M. KENNEDY: Mr. Brooks, could we go to  
25 page 190 of this exhibit, PX 989. Also try page 33 -- yep,

1 there we go. If we could look at the table on the left-hand  
2 side.

3 BY MR. M. KENNEDY:

4 Q So, Dr. Budoff, what does this table show?

5 A So this table demonstrates the guidelines,  
6 recommendations for how we would categorize triglycerides.  
7 These are still used today and have been republished in many  
8 guidelines since 2002 when the ATP III came out.

9 You can see normal triglycerides is considered less  
10 than 150 milligrams per deciliter, so we are looking at  
11 concentrations of triglycerides in the blood, and these are  
12 always taken in the fasting state.

13 And then you can see borderline high triglycerides  
14 goes up to 199, high triglycerides are over 200 up to 499, and  
15 then very high triglycerides, which we also now call severe  
16 hypertriglyceridemia, is defined as greater than or equal to  
17 500 milligrams per deciliter.

18 Q You mentioned something about the fasting state. Why is  
19 it important to test triglyceride levels in the fasting state?

20 A Yeah, so triglycerides can vary throughout the day and  
21 can vary based on our diet. So there are small changes from  
22 hour to hour. And if we had a fatty meal or a high  
23 carbohydrate meal, our triglycerides may go up a little bit,  
24 so there are variabilities.

25 So to accurately assess a patient's baseline, where

1 they're starting with their triglyceride, we do it in the  
2 fasting state so after I treat a patient, be it with diet and  
3 exercise, or be it with a drug, I can then follow that value  
4 in the fasting state to see what the net effect was of my  
5 treatment.

6 Q Are these classifications still used by clinicians today  
7 in 2020?

8 A Yes, these are the -- to my knowledge, the only commonly  
9 used classifications for hypertriglyceridemia.

10 Q Now, do you treat patients differently depending on which  
11 category of triglyceride level they fall into?

12 A Yes.

13 MR. M. KENNEDY: Mr. Brooks, could we please  
14 have PDX 2-8.

15 BY MR. M. KENNEDY:

16 Q Dr. Budoff, what does this slide depict?

17 A Yes, so this is based on -- you can see the ATP III are  
18 recommendations, that's the reference at the bottom or the  
19 source at the bottom.

20 And it basically breaks up the groups into high  
21 triglycerides, what are described here as 200 to 499, and then  
22 very high or severe hypertriglyceridemia, which is greater  
23 than 500 milligrams per deciliter at the top.

24 Q So a patient has a baseline fasting triglyceride level  
25 over 500, am I correct your primary concern at that point is

1    pancreatitis?

2       A    Yes.

3       Q    What is pancreatitis?

4       A    So pancreatitis, as was described yesterday, is a severe  
5    life-threatening condition where the pancreatic enzymes -- the  
6    pancreas creates enzymes that are supposed to digest food.

7                If they have too many triglycerides, and the  
8    triglycerides block up the ducts, and the pancreas can't  
9    perform properly, those enzymes can leak out, dissolve the  
10   pancreas itself, that's inflammation of the pancreas, thus the  
11   term pancreatitis, and can also actually get into the  
12   abdominal cavity and cause much more problems.

13      Q    Does the patient's LDL-C level affect their treatment?

14      A    Yes.

15      Q    How so?

16      A    Well, so our first concern when the triglycerides are  
17    above 500 is pancreatitis because this is an acute, short-term  
18    life threatening illness. So pancreatitis can kill somebody  
19    fairly quickly, so we want to get the triglycerides below and  
20    maintain them below 500.

21               Once we've done that and brought them down from  
22    severe hypertriglyceridemia to -- to high triglycerides, 200  
23    to 499, we can then further assess them to decide whether or  
24    not they're at cardiovascular risk.

25               If their LDL cholesterol is elevated, if they have

1 diabetes, if they have other risk factors, we would then  
2 consider further therapy such as a statin.

3 Q What causes severe hypertriglyceridemia?

4 A So hypertriglyceridemia is primarily a genetic disorder,  
5 so we're born with it. We don't have -- we don't process --  
6 we don't have certain enzymes, or we have deficiencies in  
7 certain enzymes.

8 So when -- that original picture that I showed, when  
9 there's the VLDL, that VLDL, that very low-density  
10 lipoprotein, that big one, can't get brought down towards LDL  
11 cholesterol, so it stays in the bloodstream carrying too many  
12 triglyceride around the body, and that increases our risk of  
13 pancreatitis.

14 MR. M. KENNEDY: Mr. Brooks, could we have  
15 Plaintiffs' Exhibit 269.

16 BY MR. M. KENNEDY:

17 Q Dr. Budoff, do you recognize this document?

18 A Yes.

19 Q What is it?

20 A So this is another guideline by the American Heart  
21 Association published in the same journal as ATP III,  
22 *Circulation*, and this is a guideline specifically focusing on  
23 triglycerides and cardiovascular disease.

24 Q Is this a guideline that you've used in your own  
25 practice?

1 A Yes.

2 Q Is this a document you relied on in forming your opinions  
3 in this case?

4 A Yes.

5 MR. M. KENNEDY: Your Honor, I would like to  
6 enter PX 269 into evidence.

7 MR KLEIN: No objection.

8 THE COURT: 269 is admitted.

9 (Plaintiffs' Exhibit 269 received in  
evidence.)

10 MR. M. KENNEDY: Mr. Brooks, could we go to the  
11 table on page 12 of this document.

12 BY MR. M. KENNEDY:

13 Q Dr. Budoff, what does this table depict?

14 A So this is demonstrating the -- as the table is titled,  
15 Causes of Very High Triglycerides That May Be Associated With  
16 Pancreatitis.

17 Q And the first category appears to say Genetic. Can you  
18 tell us a little bit more about that category.

19 A Yeah, so that's the largest and most common cause of very  
20 high triglyceride, thus it's listed first.

21 They list the six most common genetic disorders --  
22 seven most common genetic disorders here, but there are others  
23 as well that are listed in the document.

24 There are many genetic causes of severe  
25 hypertriglyceridemia. These are again the most common ones

1 that are listed in this table.

2 Q What's the second category on the list, Acquired  
3 Disorders of Metabolism? What does that involve?

4 A Yeah, so, you know, genetic causes are lifelong, we're  
5 born with them, they stay with us forever and require  
6 long-term therapy.

7 Acquired disorders of metabolism are short-term  
8 causes, what we call secondary causes of high triglyceride.

9 So, for example, one of the -- one of the things  
10 listed here is poorly controlled diabetes. So if a person  
11 with diabetes goes into a very high diabetic state where their  
12 blood sugar runs really high, the triglycerides can  
13 transiently, temporarily go high.

14 So we would eliminate this prior to medical therapy  
15 for high triglycerides because the cause of their high  
16 triglycerides is not genetics. The cause of their  
17 triglyceride problem is diabetes. So you treat the root  
18 cause. You would treat the diabetes and not treat the high  
19 triglycerides first.

20 MR. M. KENNEDY: Your Honor, I'm advised that  
21 there's a technical issue with defendants' screens. I was  
22 wondering if we might take a brief break to try to fix it, if  
23 they want to take a break.

24 MR KLEIN: Yes.

25 MR. M. KENNEDY: Okay.



1 THE COURT: Yes, and Miss Clerk will alert our  
2 IT staff and see if he can help. We'll take a brief recess.

3 (A recess was taken.)

4 THE COURT: Please be seated.

5 How did we resolve the issue of the monitors?  
6 Are the monitors working now?

7 THE CLERK: No.

8 MR KLEIN: They are not, but we are able to  
9 review it on the big screen.

10 THE COURT: Do you have hardcopies of the  
11 demonstratives?

12 MR KLEIN: We do, but the issue really is the  
13 call-outs from the hot seat person.

14 MR. M. KENNEDY: Your Honor, may I proceed?

15 THE COURT: Yes.

16 BY MR. M. KENNEDY:

17 Q So, Dr. Budoff, let's go back to Plaintiffs' Exhibit 269,  
18 table 5 which was on the screen when we --

19 THE COURT: I'm sorry, now my screen is not on.

20 (Discussion held off the record.)

21 THE COURT: Do you have an extra copy?

22 MR. M. KENNEDY: Of the slides, your Honor?

23 THE COURT: Yes.

24 MR. M. KENNEDY: We do.

25 THE COURT: Or I can my staff make a copy.

1 MR. M. KENNEDY: No -- although, Your Honor, I  
2 would say we are going to be going to particular portions of  
3 exhibits, and that's what we don't have hardcopies of is like  
4 exactly --

5 THE COURT: I have the exhibits. If you  
6 reference the exhibit number, I can pull up the exhibit  
7 number.

8 MR. M. KENNEDY: I can reference exactly where  
9 we are. I'll make sure to do that.

10 THE COURT: If we -- I'm not able to get the  
11 monitor to work over the noon break, we may need to move to  
12 the courtroom across the hall until we can get outside vendors  
13 to come in and fix the monitors, but that's going to require  
14 lot of changes.

15 MR. SIPES: Your Honor, we do have an extra copy  
16 available of the exhibits.

17 THE COURT: I have the exhibits. Thank you.

18 MR. M. KENNEDY: Your Honor, I'll make sure to  
19 identify precisely where we are in each exhibit.

20 THE COURT: Thank you.

21 MR. M. KENNEDY: So we're currently at  
22 Plaintiffs' Exhibit 269, table 5. Your Honor, that's in PX  
23 269, that's page 2302.

24 THE COURT: 2302. If you'll give me one minute,  
25 let me pull up the exhibit. So, it's Exhibit 269.

1 THE CLERK: Your Honor, I'm going to try a small  
2 experiment and hopefully everything won't crash.

3 THE COURT: All right, 269.

4 MR. M. KENNEDY: Yeah, the pagination on the top  
5 left is 2302. There's also pagination associated with the  
6 exhibit number, and that's 12.

7 THE COURT: Thank you. You just need to give me  
8 the pagination associated with the exhibit number.

9 MR. M. KENNEDY: Understood, Your Honor.

10 THE COURT: I have it. Thank you.

11 BY MR. M. KENNEDY:

12 Q So, Dr. Budoff, we've been discussing the causes of very  
13 high triglycerides that are listed on PX 269, the guidelines.

14 Let's turn to the third category listed here which  
15 is Drugs (medications). How can medications cause severe  
16 hypertriglyceridemia?

17 A Yeah, so patients who already have a predisposition,  
18 already have high triglycerides, they're in the high  
19 triglycerides category, if they go on certain drugs, could  
20 push them up into the very high triglyceride category.

21 So it would be what we would say exacerbates or  
22 makes worse their underlying condition. So these are -- these  
23 are a list of the most common drugs that are associated with  
24 elevations in triglycerides.

25 Q And then the fourth category here it says Diet. How does

1 diet cause very high triglycerides?

2 A Yeah, so diet, very similar to drugs, can make worse an  
3 underlying disorder.

4 So patients who already have a problem with  
5 triglyceride metabolism, if they have too much alcohol, if  
6 they have a very bad diet, imagine somebody may be going from  
7 buffet to buffet eating too much, drinking too much, that  
8 could make worse an underlying condition.

9 But I just want to make it clear that if we were to  
10 do blood draws of most of the people who are eating too much  
11 and drinking too much at any given moment, very, very few of  
12 them would have severe hypertriglyceridemia.

13 This is not a common cause of severe  
14 hypertriglyceridemia, and, certainly, if you don't have an  
15 underlying problem, you don't get to that level. This is a  
16 very unusual state to see in clinical medicine.

17 Q So in your years of treating patients with lipid  
18 disorders, how often would you say that you see a patient who  
19 has very high triglycerides solely because of diet?

20 A Yeah, so that would be extremely rare. That would  
21 invoke -- once I corrected their diet, their triglycerides  
22 came down to 150 or below, came back down to normal, and I've  
23 never seen that happen.

24 I've seen patients who have gone from very high to  
25 high, so they've come down by 10 or 20 percent, but I've not

1 seen a three or four-fold reduction in triglycerides just by  
2 improving diet.

3 Q So a new patient walks into your office, has very high  
4 triglycerides, what's your first step in trying to treat them?

5 A Yeah, so my first step is always to assess what their  
6 current state of health is. So I would start with just simple  
7 questions about their current diet, how much alcohol they're  
8 drinking, do they exercise.

9 Then I would find out about some of these reversible  
10 causes of high triglycerides such as thyroid disease and  
11 diabetes.

12 And when I've eliminated all of those, let's say I  
13 have somebody who is already a good healthy patient, they're  
14 already eating well, then I would consider starting a lipid  
15 lowering therapy.

16 Q So if you've eliminated what you call reversible causes,  
17 and you've determined that the patient has very high  
18 triglycerides, what -- what's the next step?

19 A Right. So I counsel them on diet.

20 Unfortunately, most of us in clinical practice do  
21 not have dieticians associated with our practice. The  
22 healthcare system just does not support that. We just don't  
23 have the resources, and we don't get reimbursed for those  
24 visits. So I don't have a dietitian in my office.

25 I see the patient. I counsel them on diet and

1 exercise. I send them to resources to help them achieve a  
2 good diet and exercise assuming that they're already not doing  
3 something well.

4 And then, if they're not on a good diet and  
5 exercise, I would see them back in a few months to assess how  
6 well diet and exercise worked.

7 If they're already on an exceptional diet, which a  
8 lot of my patients who come to see me are already on a good  
9 diet, then I might start therapy at that time.

10 Q By therapy you mean medication.

11 A Yes.

12 Q What kind -- what medications have you used in your  
13 career to treat very high triglycerides?

14 A Yeah, so there are a few that -- that we've used  
15 commonly. Fibrates were the most commonly used historically,  
16 then Lovaza came out, and then finally now Vascepa is  
17 available.

18 Q So let's take these one at the time. What are fibrates?

19 A So fibrates are a therapy that specifically were designed  
20 to lower triglycerides so they've been around for decades. To  
21 my knowledge, all of them are now generic although there's a  
22 new one in development.

23 But they basically lower triglycerides dramatically.  
24 We get about a 50 percent reduction in triglycerides. So 600  
25 will go to 300 when you institute an fibrate on average.

1 Q So do fibrates have downsides?

2 A Yes. Unfortunately, the downside of fibrates is while  
3 the triglycerides come down dramatically, the bad cholesterol,  
4 the LDL cholesterol, goes up dramatically.

5 So literally we get a 50 percent drop in  
6 triglycerides, and on average in that population we get a  
7 50 percent rise in bad cholesterol. So you're basically  
8 trading one problem for another.

9 Q So do you have medications available that could address  
10 the LDL-C rise?

11 A Yes.

12 Q Like what?

13 A So, at least up until 2016, if I put somebody on a  
14 fibrate, let's say, and their triglycerides came down but  
15 their LDL went up, let's say from 100 to 150, so now they're  
16 at a very high risk of having a heart attack because their bad  
17 cholesterol is high, I would then have to institute a statin  
18 to lower that LDL by 50 percent back down to a hundred.

19 So I would have to use a high potency statin to  
20 counteract a side effect of fibrates, which is something that  
21 we always try to avoid in medicine, because now I'm putting  
22 them on two drugs instead of one.

23 Q Can you characterize how often you describe fibrates to  
24 STG patients earlier in your career compared to now.

25 A Yeah, so earlier in my career they were the primary

1 treatment of severe hypertriglyceridemia in my practice. They  
2 were widely used, and they were, again, generally -- there  
3 were generic versions of them so they were low cost, so I used  
4 them quite widely.

5 After 2016, the Food and Drug Administration opined  
6 that you cannot use a fibrate and a statin together.

7 So now I can't use fibrates in most cases of severe  
8 hypertriglyceridemia because, if I get that 50 percent rise in  
9 LDL, I then lose my primary way of reducing it.

10 Q But when you do prescribe fibrates to a patient with STG,  
11 for how long did you prescribe them?

12 A So I would put them on a therapy for life, and with all  
13 of our chronic conditions, high cholesterol, high blood  
14 pressure, high triglycerides, those are chronic conditions,  
15 those are lifetime treatment.

16 Q So I think you mentioned Lovaza. What is Lovaza?

17 A Lovaza is a fish oil derivative. We heard a little bit  
18 about it yesterday. It is a mixture of EPA and DHA.

19 Q What -- does it lower triglycerides, and to what extent?

20 A Yeah. So it's another dramatic reduction of  
21 triglycerides. Triglycerides come down by 50 percent. So  
22 literally we see a 50 percent drop in triglycerides on average  
23 when we put a patient with severe hypertriglyceridemia on  
24 Lovaza therapy.

25 Q Is there anything wrong with Lovaza?



1 A Yeah, Lovaza has the exact same problem as fibrates in  
2 that the average LDL rise, bad cholesterol rise, is  
3 approximately 50 percent.

4 MR. M. KENNEDY: I would like to call up PX 566,  
5 and, Your Honor --

6 THE COURT: I'm able to see it on my screen now.

7 MR. M. KENNEDY: Of, terrific.

8 BY MR. M. KENNEDY:

9 Q So, Dr. Budoff, what is PX 566?

10 A This is the package insert for Lovaza.

11 Q Does the package insert go by other names?

12 A Yes, label or package insert or prescribing information.

13 Q Can we use those three terms interchangeably today?

14 A Yes.

15 Q Is this label for Lovaza a document you rely on in your  
16 own clinical practice?

17 A Yes.

18 Q Is this a document you relied on in forming your opinions  
19 in this case?

20 A Yes.

21 MR. M. KENNEDY: Your Honor, I would like to  
22 move PX 566 into evidence.

23 MR KLEIN: No objection.

24 THE COURT: PX 566 is admitted.

25

(Plaintiffs' Exhibit 566 received in evidence.)

BY MR. M. KENNEDY

Q We talked about this a little bit yesterday, but can you just explain at a high level what is the purpose of a prescribing information for an FDA approved drug?

A Yes, so this informs and instructs physicians on when to use the drug, when it's indicated, how to use the drug, and then, if you choose to use the drug, what you would expect to happen both from the positive side of things, what benefits you will get, and also what side effects or warnings you might -- you might need to be careful of when using that drug.

Q Do you use prescribing information in your own clinical practice?

A Yes.

Q How do you use it?

A So when I'm new to a drug and I'm not very, very familiar with it, I always refer to the prescribing information, and I read the prescribing information to understand the context of that drug, when I should be using it, how I should be using it, and what to look for if I choose to use it.

MR. M. KENNEDY: Mr. Brooks, could we pull up table 2 of PX 566.

BY MR. M. KENNEDY:

Q Dr. Budoff, what is the function of this portion of the Lovaza label?

1 A Yeah, so here you can see the randomized clinical trial.

2 These are how we establish what we call  
3 evidence-based medicine. We basically do these randomized,  
4 placebo-controlled trials. These are the highest level of  
5 trials that can be done in clinical medicine.

6 And this is the trial that demonstrated the effects  
7 of Lovaza in patients with very high triglycerides or what we  
8 call severe hypertriglyceridemia.

9 Q What is Lovaza's indication?

10 A Lovaza is indicated to reduce triglycerides in the  
11 setting of severe hypertriglyceridemia.

12 Q You mentioned the term evidence-based medicine. What is  
13 evidence-based medicine?

14 A Yeah, so evidence-based medicine is basically how we look  
15 at evidence to understand what the best science is, and then  
16 we formulate them into manuscripts, those get incorporated  
17 into guidelines, and those get percolated and taught to  
18 practicing physicians.

19 Q Do practicing physicians practice evidence-based  
20 medicine?

21 A They are supposed to.

22 Q Now, looking at table 2, what's your take away from the  
23 clinical data that's shown here for Lovaza?

24 A Yeah, if you just look at the top line data, literally  
25 the triglyceride results, that's our primary thing that we're

1 using it for, so that's the primary interest.

2 And you can see on the far right what the net effect  
3 is if I were to put somebody on Lovaza with severe  
4 hypertriglyceridemia as compared to somebody who got put on a  
5 matching placebo, and you can see a 51 percent reduction in  
6 their triglyceride levels.

7 Q Is there any other data here that is of particular  
8 interest to you as a cardiologist?

9 A Yes, I think the most important thing -- there was two  
10 things. One, if you look at the placebo category for  
11 triglycerides, you see a plus 6 percent rise in triglycerides.

12 And this is very common that over time, if you don't  
13 treat severe hypertriglyceridemia with a therapy, and you just  
14 use diet and exercise, you do not get a net benefit, and the  
15 triglycerides remain elevated. In this case, they went up by  
16 7 percent.

17 Also, looking at the LDL-C at the bottom, what  
18 happens to the LDL cholesterol, I mentioned that it goes up by  
19 approximately 50 percent, on the far right you can see the  
20 average increase was 49.3 percent.

21 So LDL went up from a baseline here in Lovaza of  
22 about 90 to about 130, so they went from low risk, from a  
23 cardiac perspective, to high risk because I put them on Lovaza  
24 therapy.

25 Q Does that data affect your -- does that affect your

1 analysis in terms of whether to prescribe Lovaza to your  
2 patients?

3 A Yes. I mean, this is a very serious problem.

4 Our number one cause of death in men and women in  
5 the United States is heart attacks. So while pancreatitis is  
6 a life-threatening condition that we need to treat more  
7 acutely, heart disease is something that's more likely to  
8 claim lives.

9 And if I raise somebody's LDL bad cholesterol by  
10 50 percent, I am literally doing harm and now have to figure  
11 out a way of counteracting that harm.

12 Q Is there anywhere else in the Lovaza label that discusses  
13 the effects Lovaza has on LDL-C of a severely  
14 hypertriglyceridemic patient?

15 A Yes, so it's mentioned in the table and in the text below  
16 the table. It's also mentioned in the warnings and  
17 precautions section of the label.

18 MR. M. KENNEDY: Mr. Brooks, could we go to the  
19 bottom of the right-hand column on table -- sorry, bottom of  
20 the right-hand column on table -- sorry, that's right. I  
21 apologize, this is the correct place.

22 BY MR. M. KENNEDY:

23 Q So, Dr. Budoff, is this the area of the Lovaza label you  
24 were just referring to?

25 A Yes.

1 Q In particular, the discussion at the bottom that begins  
2 "in some patients," is that the warning you were referring to?

3 A Yes. So literally here it says,

4 "Lovaza increased low-density lipoprotein...  
5 levels in some patients. LDL levels should be  
6 monitored periodically during Lovaza therapy."

7 Q Now, could you characterize how often you prescribe  
8 Lovaza to your STG patients earlier in your career compared to  
9 now.

10 A Yeah, so before Vascepa became available, I used this a  
11 fair amount. The -- it was increasingly being used.

12 Again, there was a competition between should I use  
13 a fibrate or should I use Lovaza. They both had robust  
14 reductions in triglycerides, 50 percent. They both had that  
15 adverse or negative side effect of raising LDL cholesterol.

16 So depending on the patient and their coverage, I  
17 would use one of these two therapies quite frequently.

18 Q So when you did use Lovaza, for how long would you  
19 prescribe it?

20 A So, again, it was always prescribed -- I always  
21 prescribed things as a one year initial prescription because  
22 that's the longest I can legally prescribe it, but my intent  
23 was always, once I deemed that they needed the Lovaza, it was  
24 for lifetime treatment.

25 Q Now, in the period before Vascepa was available, were

1 clinicians concerned about the LDL-C effects of fibrates and  
2 Lovaza?

3 A Yes.

4 Q Did clinicians nonetheless prescribe fibrates and Lovaza?

5 A Yes. They were the only drugs available, basically,  
6 widely available. There is niacin as well, but niacin came  
7 with a lot of flushing, and that would usually limit its use.

8 So I would say a vast majority of clinicians -- we  
9 had to get the triglycerides out of the severe range. Diet  
10 and exercise already failed by definition before we would  
11 start a therapy, so now these patients have a genetic cause, a  
12 lifetime problem, and need to be treated long-term with either  
13 Lovaza or fibrate therapy.

14 MR. M. KENNEDY: Sir, I would like to turn to  
15 Vascepa now. And, Mr. Brooks, could I have PX 1186 which has  
16 already been admitted into evidence.

17 BY MR. M. KENNEDY:

18 Q And, Dr. Budoff, do you recognize this document?

19 A Yes.

20 Q What is it?

21 A This is the prescribing information or label for Vascepa  
22 as of December 2019.

23 Q Is this a document you relied on in forming your opinions  
24 in this case?

25 A Yes.

1 Q So I would like to turn to page 11 of this document,  
2 which should be table 2. I think we looked at this yesterday.

3 But, Dr. Budoff, do you have an understanding of  
4 where the data in table 2 of the Vascepa label came from?

5 A Yes, the MARINE study.

6 Q So before we go on, were you in the courtroom yesterday  
7 when Dr. Ketchum testified?

8 A Yes.

9 Q So I would like to turn to a question that the Court  
10 asked and have you address it, and I believe the question was  
11 how do you know that the effects shown in table 2 are  
12 attributable to Vascepa and not to diet and lifestyle  
13 improvement.

14 Do you remember that question from yesterday  
15 morning?

16 A Yes.

17 Q So are the effects shown in table 2 attributable to  
18 Vascepa and not diet and lifestyle?

19 A Yes. So the way that the MARINE trial was done is  
20 concordant with how the prescribing information is written  
21 that first you try and you implement diet and lifestyle, and  
22 in the MARINE trial that's how it was done.

23 For six to nine weeks before they started -- got  
24 randomized, they were put on diet and lifestyle treatment, so  
25 the effect of diet and lifestyle already came into play.



1           Then we measured their baseline variables, and you  
2 can see the word baseline here. That's after the effect of  
3 diet and lifestyle.

4           So the first way we know this is not due solely to  
5 diet and lifestyle is that that has already been implemented  
6 and continued throughout the trial.

7           So these baseline variables are then, if they still  
8 had severe hypertriglyceridemia -- so it's very important to  
9 understand because we've eliminated all of those patients, as  
10 we are supposed to before prescribing Vascepa, we've  
11 eliminated all of those patients where diet and lifestyle  
12 fixed the problem.

13           In other words, I put them on diet and lifestyle if  
14 I was investigator in MARINE, their triglycerides dropped to  
15 450, they're no longer able to get randomized in the trial  
16 because they do not have severe hypertriglyceridemia at the  
17 time of the randomization.

18           So the other way we know that this is not due to  
19 diet and lifestyle is that both the Vascepa group and the  
20 placebo group both are getting diet and lifestyle throughout  
21 the trial. So the effect on diet and lifestyle would be  
22 neutral because it's -- it's reflected in both groups.

23           And the only difference between group A, Vascepa,  
24 and group B, placebo, is the drug itself. So the effects are  
25 only from the drug and not due to the diet and lifestyle

1 influence.

2 Q So at a high level, how does the data in table 2 for  
3 Vascepa compare to the data we just looked at for Lovaza?

4 A Yeah, so, again, the primary reason, the indication for  
5 Vascepa is to lower triglycerides in the setting of severe  
6 hypertriglyceridemia.

7 So we look at the triglyceride results at the top,  
8 and at the far right you can see the difference. The net  
9 effect is minus 33 percent, so not quite as robust as Lovaza,  
10 not quite as robust as fibrates, but it does nicely reduce  
11 triglycerides by about a third.

12 If we look at the placebo group, and look at the  
13 percent change, it's plus ten percent. Just like we saw with  
14 the Lovaza group, Lovaza was plus seven percent, that the net  
15 effect of continuing diet and exercise once you've employed  
16 it, does not generally reduce triglycerides in most patients.

17 The average increase was -- there was an actual  
18 average increase over time if they were just maintained on  
19 diet and exercise. Remember, placebo is placebo plus diet and  
20 exercise. Vascepa, is Vascepa plus diet and exercise.

21 Q So moving to the LDL-C row, how does the LDL-C data shown  
22 here compare to the data we saw with Lovaza?

23 A Yeah, so the LDL-C -- and this is dramatically different  
24 than both fibrates and Lovaza. Now, instead of plus  
25 49 percent, it's minus two percent.

1           The net effect of putting somebody on Vascepa is  
2 that LDL-C does not go up. So this is much different with  
3 much different cardiovascular implications for a patient  
4 because their LDL is not going up by 50 percent.

5       Q    So how did this clinical data affect your treatment  
6 decisions for your patients with severe hypertriglyceridemia?

7       A    So now this became the preferred agent when it was  
8 available.

9           Remember, there are still formulary issues. There  
10 are still cost issues because this is not generic, and Lovaza  
11 had a generic alternative at this time. But this would be a  
12 very compelling reason for clinicians to use Vascepa.

13           And I would argue in the setting of severe  
14 hypertriglyceridemia, the only reason to use it, because it's  
15 not as good a triglyceride lowering agent as Lovaza, so the  
16 reason you would pick a branded drug over Lovaza is going to  
17 be almost solely due to the LDL-C drop.

18       Q    But how do you know what other clinicians are doing in  
19 response to the Vascepa data?

20       A    Well, I spend quite a bit of time lecturing. Literally  
21 this afternoon I was supposed to be lecturing to the family  
22 medicine doctors at my institution on hypertriglyceridemia and  
23 hyperlipidemia. I had to move that lecture.

24           But I literally interact with primary care doctors  
25 on a daily basis. I educate them on this, and I know what

1 they're doing in practice, and try to direct them to guideline  
2 evidence-based medicine of what the best practices are at this  
3 point in time because obviously that continues to change over  
4 time.

5 Q When you do prescribe Vascepa to your STG patients, for  
6 how long do you typically prescribe it?

7 A So, again, once I've already eliminated the short-term  
8 causes, I've made sure they're not a diabetes person out of  
9 control, I make sure that their thyroid disease is controlled,  
10 I've put them on good lifestyle and diet, and all of that has  
11 failed, as per the label, I then institute Vascepa, and I  
12 institute Vascepa for life, because the only people left are  
13 people with genetic abnormalities that cause permanent  
14 elevations in their triglycerides. So it's always a lifetime  
15 treatment.

16 Q Sir, are you familiar with the proposed labels that will  
17 accompany defendants' ANDAs in this case?

18 A Yes.

19 MR. M. KENNEDY: Mr. Brooks, could we please  
20 have Plaintiffs' Exhibit 1203 which I believe has been  
21 pre-admitted in this case.

22 BY MR. M. KENNEDY:

23 Q Dr. Budoff, do you recognize this document?

24 A Yes.

25 Q What is it?

1 A So this is the package insert or label for the generic  
2 proposed alternative to Vascepa. I believe this is the Hikma  
3 version.

4 MR. M. KENNEDY: Okay. Could we pull up  
5 Plaintiffs' Exhibit 1209 -- I'm sorry.

6 BY MR. M. KENNEDY:

7 Q Dr. Budoff, did you rely on Plaintiffs' Exhibit 1203 in  
8 forming your opinions in this case?

9 A Yes.

10 Q Okay. So let me ask you about Plaintiffs' Exhibit 1209.  
11 Do you recognize this document?

12 A Yes.

13 Q What is it?

14 A So this is the label, or proposed label, for the generic  
15 alternative to Vascepa. I believe this is the Dr. Reddy's  
16 Labs' version.

17 Q Is this a document you relied on in forming your opinions  
18 in this case?

19 A Yes.

20 MR. M. KENNEDY: Your Honor, we would like to  
21 admit PX 1209 into evidence.

22 MR KLEIN: No objection.

23 THE COURT: 1209 is admitted.

24 (Plaintiffs' Exhibit 1209 received in  
25 evidence.)

1 BY MR. M. KENNEDY:

2 Q Dr. Budoff, how do the proposed labels for Hikma's ANDA  
3 product and DRL's ANDA product compare to one another?

4 A They are very, very similar.

5 Q Are there any differences between those two labels that  
6 are material to your infringement opinions in this case?

7 A No. The only difference is I think one is proposing a .5  
8 gram dose and one is not.

9 Q Is that difference material to any of your opinions you  
10 will be giving today?

11 A No.

12 Q How do the Hikma and DRL labels as of today compare to  
13 the Vascepa label PX 1186 that we looked at earlier?

14 A It is very, very similar. I think the only material  
15 difference is every time the word Vascepa appeared in the  
16 Vascepa label, the word icosapent ethyl appeared in the  
17 icosapent ethyl in these generic proposed labels.

18 Q Does that word substitution affect any of your  
19 infringement opinions in this case?

20 A No.

21 Q Does the Vascepa label as it exists today have the same  
22 indications as the DRL and Hikma labels as they exist today?

23 A The indications here are only for severe  
24 hypertriglyceridemia. They do not appear to have the  
25 REDUCE-IT indications listed in the generics, but my opinions

1 are based on the infringement of severe hypertriglyceridemia  
2 so the indications read word for word the same between the  
3 three labels.

4 Q So if I asked for your opinions today regarding the  
5 Vascepa label, PX 1186, would your opinion be the same if I  
6 had asked you about the Hikma label, PX 1203, or the DRL  
7 label, PX 1209?

8 A Yes.

9 MR. M. KENNEDY: So, Mr. Brooks, could we go  
10 back to PX 1186, the current Vascepa label.

11 BY MR. M. KENNEDY:

12 Q And let me just kind of go through some of the key  
13 portions we will be looking at today, starting with the  
14 indications and usage section.

15 And, generally, what's the purpose of the  
16 indications and usage section?

17 A You know, so this is, I think, you know, a very important  
18 part of the label.

19 This is where we decide whether or not my patient  
20 fits into the type of patients that are indicated. In other  
21 words, does this go along with the approved use of the drug,  
22 is my patient indicated to be on this therapy.

23 Q And let's go to the dosage and administration section.

24 At a high level, what's the purpose of the dosage  
25 and administration section in the label?

1       A     Yeah, so once I've established that the patient is  
2 indicated to be on the drug, I then have to read about how to  
3 initiate or prescribe the therapy. So this tells me what to  
4 do prior to initiation of Vascepa and then how to prescribe  
5 Vascepa specifically.

6                     MR. M. KENNEDY: Let's go, Mr. Brooks, to the  
7 warnings and precautions section which cuts across pages 2 and  
8 3.

9 BY MR. M. KENNEDY:

10       Q     What do you get as a physician from the warnings and  
11 precautions section?

12       A     So this is another very important section of the label.  
13 This warns me about things I need to be aware of, things I  
14 might need to inform my patients about when prescribing this  
15 therapy.

16                     MR. M. KENNEDY: Mr. Brooks, we already looked  
17 at the clinical study section which is 14, so let's go to the  
18 patient counseling information, section 17.

19 BY MR. M. KENNEDY:

20       Q     And, Dr. Budoff, what is the purpose of the patient  
21 counseling and information section?

22       A     As you can see here, and this is pages 11 and 12 of this  
23 label, that it basically tells us what we should inform our  
24 patients when prescribing this therapy.

25                     So it gives us a list of things that we should do,



1 things that we should inform our patients about, things that  
2 we should advise our patients about when starting Vascepa  
3 therapy.

4 Q So when you talk to your STG patients, is the advice that  
5 you give them consistent with what's in section 17 of the  
6 Vascepa label?

7 A Yes.

8 MR. M. KENNEDY: Mr. Brooks, if we could go to  
9 the patient information portion.

10 BY MR. M. KENNEDY:

11 Q Now, Dr. Budoff, what is the purpose of the patient  
12 information section?

13 A Yeah, so this is literally a handout that you can give  
14 patients. I do sometimes, depending on the patient. But when  
15 I prescribe a new therapy, the pharmacist may give this out to  
16 the patient when they first give them a new treatment.

17 This is information for the patient. It's written  
18 in lay language, and it goes through a lot of the same  
19 sections, but it's all lay language on what should the patient  
20 do, how should the patient take the medicine, how should the  
21 patient store the medicine.

22 So it has slightly different information. It's all  
23 based on the patient's -- what the patient needs to know when  
24 starting Vascepa.

25 Q Now, we've looked at several sections of the Vascepa

1 label, PX 1186. I think you testified that the generics are  
2 not seeking the new Vascepa indication.

3           Aside from that, are there any differences in any of  
4 the sections we've just looked at between the Vascepa label on  
5 the one hand and the proposed Hikma and DRL labels on the  
6 other hand?

7       A     There are no material differences that affected my  
8 opinion in this case.

9       Q     Were you instructed about the legal standard to be used  
10 in evaluating whether a patent claim has been infringed?

11      A     Yes.

12      Q     Have we prepared a slide summarizing your understanding  
13 of that standard?

14      A     Yes.

15                   MR. M. KENNEDY: Mr. Brooks, if we could have PX  
16 2-9.

17 BY MR. M. KENNEDY:

18      Q     Dr. Budoff, does this slide, PX 2-9, represent the legal  
19 standard that you've been given?

20      A     Yes.

21      Q     And so what is the first step in determining  
22 infringement?

23      A     So, that a -- what a person of ordinary skill in the art  
24 would understand or from the claims at the time of the  
25 invention.

1 Q And you understand the Court's already performed step one  
2 of this analysis.

3 A Yes.

4 Q And then what's step two of the infringement analysis?

5 A So step two is to compare the claims and then determine  
6 whether, if you followed the label, would you infringe on the  
7 patent itself.

8 Q And have you been instructed about the legal standard to  
9 be used in evaluating whether a defendant is inducing  
10 infringement of a patent claim?

11 A Yes.

12 MR. M. KENNEDY: Mr. Brooks, could we please  
13 have PDX 2-10.

14 BY MR. M. KENNEDY:

15 Q I'm sorry, one more question about the previous standard.  
16 Did you apply the standard for infringement that we just  
17 looked at in forming your opinions in this case?

18 A Yes.

19 Q So let's look at PDX 2-10.

20 Could you just give your understanding of induced  
21 infringement.

22 A Yes. So, this is -- inducement is when the label  
23 encourages or recommends or instructs a clinician to meet the  
24 limitations or elements, each of the elements in the claim.

25 Q And from what point of view are the labels interpreted?

1 A So the labels are interpreted from a practicing clinician  
2 in the field or a person of ordinary skill in the art.

3 Q And which portions of the label do you look at in this  
4 analysis?

5 A So the label is taken in its entirety.

6 Q I would like to move on to the infringement issues in  
7 this case. Are you familiar with the patents-in-suit?

8 A Yes.

9 Q Oh, sorry one more question about PDX 2-10.

10 What is your understanding of .2 here under the  
11 induced infringement standard?

12 A That it would be at least some clinicians would  
13 inevitably infringe on the label if they -- if they -- if they  
14 followed the methods or if they were encouraged by the label  
15 to meet all of the elements.

16 Q Okay. Now let's move on to the patents-in-suit in this  
17 case, and I would like to start with PDX 21, which is on the  
18 list of pre-admitted exhibits.

19 Dr. Budoff, do you recognize this document?

20 A Yes.

21 Q What is it?

22 A This is patent '728.

23 Q And the full number being patent 8293728?

24 A Yes.

25 Q Is this a patent you relied on in forming your opinions

1 in this case?

2 A Yes.

3 Q Now, again, in performing your infringement analysis,  
4 were there any relevant differences between the Vascepa label  
5 and either of the defendants' label?

6 A No.

7 Q So that being the case, if I asked you about the Vascepa  
8 label, would you have the same opinion if I had asked you  
9 about the Hikma or DRL labels?

10 A Yes.

11 Q So have you prepared a slide reproducing each element of  
12 claim 1 of the '728 patent?

13 A Yes.

14 MR. M. KENNEDY: So, Mr. Brooks, can we have  
15 PDX 2-11.

16 BY MR. M. KENNEDY:

17 Q Is this the slide I just referred to?

18 A Yes.

19 Q And there is a notation here that says stipulated. What  
20 does that mean?

21 A So my understanding is that the -- both sides have  
22 already agreed that this claim element would be met by the --  
23 by the labels.

24 MR. M. KENNEDY: So, Your Honor, let me just  
25 note for the record the stipulated facts associated with this

1 particular stipulation are paragraphs 204 to 209 for Amarin's  
2 Vascepa product and label, 216 to 221 for Hikma's product and  
3 proposed label, and 228 to 234 for DRL's proposed label.

4 THE COURT: Thank you.

5 BY MR. M. KENNEDY:

6 Q So, Dr. Budoff, reviewing the claim elements for claim 1  
7 of the '728 patent, do you follow the steps here when you use  
8 or when you administer Vascepa to treat patients with severe  
9 hypertriglyceridemia?

10 A Yes.

11 Q In your view, would other clinicians do the same thing?

12 A Yes.

13 Q Would somebody following the labeling of the Vascepa  
14 product follow every element of claim 1 of the '728 patent?

15 A Yes. The label encourages these steps to be taken and  
16 all of these elements to be met when prescribing these  
17 therapies.

18 Q So let's take these elements one at a time.

19 Have you formed an opinion concerning whether the  
20 contents of the Vascepa label encourages clinicians to  
21 prescribe Vascepa to a subject having a baseline  
22 triglyceride -- a fasting baseline triglyceride level of 500  
23 milligrams per deciliter to about 1500 milligrams per  
24 deciliter as required by claim 1 of the '728 patent?

25 A Yes.

1 Q What is that opinion?

2 A So the indication for these therapies is for severe  
3 hypertriglyceridemia, to lower triglycerides, so literally  
4 this is the indication, the literal indication of the drug to  
5 reduce severe -- to reduce triglycerides in a subject with  
6 severe hypertriglyceridemia, and that's greater or equal to  
7 500 milligrams per deciliter.

8 MR. M. KENNEDY: Mr. Brooks, could we have PX  
9 1186, the indications and usage section, and I would like to  
10 look at the second bullet point.

11 BY MR. M. KENNEDY:

12 Q Dr. Budoff, is this the indication you just referred to?

13 A Yes. Yesterday, I think they called this the MARINE  
14 indication, and this is the literally almost word for word of  
15 that first element.

16 Q And does each defendants' proposed label have the same  
17 indication?

18 A Yes.

19 MR. M. KENNEDY: Could we go to the clinical  
20 study section, table 2.

21 BY MR. M. KENNEDY:

22 Q Is there anything in the clinical study section relevant  
23 to your opinion that the first element of claim 1 of the '728  
24 patent is met?

25 A Yes. I mean, this, again, is in patients with severe

1 hypertriglyceridemia, and it demonstrates that use of the drug  
2 will reduce triglycerides here by an average of 33 percent.

3 Q Do you understand that the other asserted claims in this  
4 case have the same or very similar claim language to the  
5 element we just looked at concerning the 500 to  
6 1500 milligrams per deciliter patient?

7 A Yes.

8 MR. M. KENNEDY: Mr. Brooks, could we have PX  
9 2-12.

10 BY MR. M. KENNEDY:

11 Q And, Dr. Budoff, what does this slide depict?

12 A So this basically just shows two slightly different claim  
13 languages and which claims use those specific claim languages.

14 Q And the opinion you just expressed with respect to the  
15 version of this element that appears in claim 1 of the '728  
16 patent, would those opinions apply with equal force with the  
17 same or similar claim language that appears in the other  
18 asserted claims?

19 A Yes.

20 Q So let's move on to PDX 2-13, and this is the claim  
21 limitation requiring administration of the drug for a period  
22 of 12 weeks.

23 Have you formed any opinions concerning whether the  
24 contents of the Vascepa label encourage clinicians to  
25 prescribe Vascepa to their severely hypertriglyceridemic



1 patients for a period of 12 weeks as required by claim 1 of  
2 the '728 patent?

3 A Yes.

4 Q What is that opinion?

5 A That physicians, the average clinician practicing in the  
6 field will prescribe Vascepa for long-term therapy which will  
7 encompass a period of 12 weeks.

8 Q And would you have the same opinion if I'd ask you about  
9 the Hikma label, PX 1203, or the DRL label, PX 1209?

10 A Yes.

11 Q So let's go to the indications and usage section of the  
12 Vascepa label.

13 And, again, I would like to look at what we're  
14 calling the MARINE indication, which reads,

15 "As an adjunct to diet to reduce TG levels in  
16 adult patients with severe, over 500 milligrams per  
17 deciliter, hypertriglyceridemia."

18 Does the indications and usage by itself tell  
19 you anything or tell a clinician anything about the duration  
20 for which you should prescribe Vascepa?

21 A Yes.

22 Q What does it tell you?

23 A Well, clinicians in the field will know that severe  
24 hypertriglyceridemia is largely a genetic problem, a lifelong  
25 problem, and requires lifelong therapy. So when the

1 indication lists a chronic disease, then the treatment is  
2 long-term.

3 Q Is there anything in the indications and usage of the  
4 Vascepa label that tells you a maximum length of time for  
5 prescribing Vascepa?

6 A No, there's no limit put here as there would be if this  
7 was a short-term treatment for an acute condition.

8 Q Are the words adjunct to diet relevant to the length of  
9 time for which a clinician should prescribe Vascepa according  
10 to the label?

11 A Yes, and it's brought out again in the dosage and  
12 administration section talking about lifestyle and nutritional  
13 intake and physical activity, that it's maintaining this --  
14 maintaining this therapy over the long run because you've  
15 already eliminated the short-term problems of a bad life style  
16 or a bad diet or too much alcohol use.

17 So after diet, you then -- and they still have high  
18 triglycerides, then Vascepa is indicated. So you've  
19 eliminated short-term and now you're left with only the  
20 chronic genetic patients.

21 Q So let's go to the dosage and administration section  
22 which is immediately below. I would like to ask you about  
23 section 2.1 prior to initiation of Vascepa. What does it mean  
24 to initiate Vascepa?

25 A So prior to starting or prescribing Vascepa, they give

1 you some steps that you should take and accomplish prior to  
2 implementing treatment.

3 Q Let me just back up just for a second. What does the  
4 word initiation mean in this context?

5 A Oh, to start the therapy or to prescribe the therapy.

6 Q So let's talk about the first bullet point under the  
7 words "Prior to Initiation of Vascepa." What is this first  
8 bullet point of the label telling you to do?

9 A So it specifically tells you to identify other causes,  
10 and we talked about the short-term or the secondary causes  
11 that can cause transient elevations in triglycerides, such as  
12 poorly controlled diabetes or low thyroid disease, and manage  
13 those as appropriate first.

14 And if there's still a problem where the  
15 triglycerides are still above 500 and they still have severe  
16 hypertriglyceridemia, then you can go on to the next step.

17 Q So you mentioned transient causes. Is that the same  
18 thing as -- I think you mentioned reversible causes earlier?

19 A Yes.

20 Q So let's say you follow the first bullet point under 2.1,  
21 you identify these other reversible causes such as diabetes,  
22 hyperthyroidism, and medications, and you manage them as  
23 appropriate, and let's say you successfully manage them. At  
24 that point would those patients get Vascepa?

25 A No. Just like the MARINE trial, if they don't still have

1 severe hypertriglyceridemia, they would never be implemented  
2 on treatment.

3 Q And then let's go the second bullet point under  
4 section 2.1 which reads, quote,

5 "Patients should engage in appropriate  
6 nutritional intake and physical activity before  
7 receiving Vascepa which should continue during  
8 treatment with Vascepa."

9 So what -- you've probably touched on this  
10 earlier, but what does this involve?

11 A So, again, this is what I talked about earlier. The way  
12 the MARINE trial was literally done, you first counsel them  
13 and get them to engage in a good diet and exercise.

14 If good diet and exercise fail, then you would  
15 initiate Vascepa. If good diet and exercise is successful,  
16 you don't use Vascepa. It would be off-label use to use  
17 Vascepa before implementing diet and exercise.

18 Q So if it's one of those patients who you can counsel them  
19 on diet and lifestyle, and that gets them under 500 and keeps  
20 them there, would that patient get prescribed Vascepa if the  
21 clinician were following the label?

22 A No.

23 Q So would -- so if you back out the patients who have what  
24 you are calling reversible causes, and you're backing out the  
25 patients who have diet and lifestyle related issues that get

1 them over 500, who is left?

2 A So left -- as we saw in that table from the scientific  
3 statement from the American Heart Association, the only  
4 category that's left is genetic causes.

5 Q And do those people get Vascepa if a clinician is  
6 following the labeling, the people with genetic causes?

7 A Yes. They have a lifetime problem, and they're going to  
8 develop pancreatitis, their risk of developing pancreatitis is  
9 high, so they would get Vascepa as encouraged by the label  
10 here in dosage and administration.

11 Q Would a clinician following the label prescribe Vascepa  
12 to somebody whose cause of STG was addressed by something  
13 mentioned in section 2.1 of the label?

14 A I'm sorry, can you repeat that?

15 Q Would somebody whose STG was adequately addressed by one  
16 of the issues mentioned in 2.1 of the label be prescribed  
17 Vascepa by a clinician following the label as a whole?

18 A No, they would be eliminated from being a candidate for  
19 Vascepa.

20 Q So let's turn to the clinical study section of the  
21 Vascepa label. And, Dr. Budoff, does the clinical study --

22 MR. M. KENNEDY: Mr. Brooks, can we have the  
23 verbiage above table 2 as well this time? Sorry.

24 BY MR. M. KENNEDY:

25 Q Dr. Budoff, does the clinical study section of the

1 Vascepa label tell you anything about the duration of  
2 treatment that the label is calling for, for Vascepa?

3 A Well, yes. I mean, the study designed specifically calls  
4 out that patients were enrolled in this study for 12 weeks.

5 Q Why is that meaningful?

6 A Well, because, in clinical practice, we -- we try to  
7 follow the prescribing information, and if the prescribing  
8 information was done at 12 weeks, then that informs the  
9 physician, that instructs the physician that you should wait  
10 12 weeks to reassess lipids to see what the full effect of  
11 your treatment is, because my goal, when putting them on  
12 Vascepa, is to achieve the results in table 2.

13 In other words, I want to see a 33 percent drop on  
14 average in triglycerides. I want to see no rise in LDL  
15 cholesterol.

16 So those become really important, and the only way I  
17 can compare my patient to the label and what's being  
18 encouraged is to follow the instructions that are given, and  
19 the instructions here are to treat for 12 weeks.

20 Q Does the Vascepa label contain any clinical data  
21 concerning treatment of Vascepa for any duration other than  
22 12 weeks, like, for example, four weeks?

23 A No, there's no other mention of any other duration of  
24 treatment other than 12 weeks.

25 Q So if you, for some reason, decided to prescribe Vascepa

1 for four weeks to a severe hypertriglyceridemic patient, what  
2 would the label tell you about what lipid effects you would  
3 expect to achieve?

4 A So there are none listed here, so the label would not  
5 inform you at all on what to expect at four weeks.

6 Q And, again, just to -- the clinical studies data in  
7 table 2 of the Vascepa label, does the same data appear in the  
8 DRL and Hikma labels?

9 A Yes, the same exact language for 12 weeks exists.

10 Q The same data as well?

11 A Yes.

12 Q Dr. Budoff, is there any background information a  
13 clinician in this field would bring to bear when reading the  
14 Vascepa label?

15 A Yes. I mean, physicians who are treating patients with  
16 severe hypertriglyceridemia are generally either going to be  
17 primary care physicians, largely, may be endocrinology or  
18 cardiology, and they will be familiar with other therapies in  
19 the class. They're supposed to be familiar with the  
20 guidelines, and they are supposed to follow the label when  
21 prescribing these therapies.

22 Q So the clinicians who would be reading the Vascepa label,  
23 they would already know what severe hypertriglyceridemia is?

24 A Yes, I would hope so. Usually the physician who starts  
25 therapy understands the disease well enough to implement

1 treatment for that disease.

2 MR. M. KENNEDY: Mr. Brooks, could we have PX  
3 288.

4 BY MR. M. KENNEDY:

5 Q Dr. Budoff, do you recognize this document?

6 A Yes.

7 Q What is it?

8 A So, this is a review article written by Dr. Karalis, he's  
9 a professor and cardiologist in Pennsylvania.

10 Q Generally what's the subject matter of this article?

11 A So this is a review of all of the clinical guidelines for  
12 how to manage hypertriglyceridemia, and in this paper he  
13 focuses more on the treatment with the 4-gram doses of omega-3  
14 fatty acids, the high dose treatments that are available.

15 Q And the omega-3 fatty acids, that refers collectively to  
16 Vascepa and Lovaza?

17 A Yes.

18 Q Is this a document you relied on in forming your opinions  
19 in this case?

20 A Yes.

21 MR. M. KENNEDY: Your Honor, Amarin moves PX 288  
22 into evidence.

23 MR KLEIN: No objection.

24 MR. M. KENNEDY: Or seek to move 288 --

25 THE COURT: 288 is admitted.



1 (Plaintiffs' Exhibit 288 received in  
2 evidence.)

3 MR. M. KENNEDY: Mr. Brooks, could we go to  
4 page 309 of this article, the right-hand column, the section  
5 that starts "Patients with very high TG levels."

6 BY MR. M. KENNEDY:

7 Q And in particular, Dr. Budoff, I would like to ask you  
8 about the sentence that begins "If an individual with very  
9 high TG."

10 Dr. Budoff, what is this sentence telling you about  
11 what to do with somebody who falls into one of the very high  
12 TG groups?

13 A Yes, so this describes what we call step-wise care. So,  
14 and that's how every physician that I'm familiar with  
15 practices.

16 In other words, you do step one. In this case,  
17 let's say we put them on Vascepa therapy. That's step one.  
18 Then you see what happens after step one, and you decide if  
19 you're going to go to step two.

20 So this is describing the considerations of going to  
21 step two, "consideration should be given to adding a statin to  
22 their triglyceride-lowering therapy."

23 So it's not saying stop step one and start over,  
24 it's saying you've already put them on Vascepa, should I add a  
25 statin to further reduce their cardiovascular risk.

Q So this passage is talking about somebody who had very

1 high TGs, was put on an omega-3 fatty acid, and now they fall  
2 into a lower category of TG level?

3 A So now they're at lower level of TG level, but now  
4 they're at an enhanced level of cardiac risk so now my focus  
5 shifts.

6 I've treated -- I've successfully treated their high  
7 triglycerides. I maintain that, I continue that as outlined  
8 here, I continue the Vascepa, and now I say, oh, I've gotten  
9 you out of the risk of pancreatitis, but now you're at risk of  
10 a heart attack, I better do something else.

11 In this recommendation the something else, based on  
12 the 2013 cholesterol guidelines, is to add a statin to their  
13 regimen.

14 Q And just to be clear, Dr. Budoff, we're still talking  
15 about a patient with severe hypertriglyceridemia?

16 A Yes, the paragraph starts with "patients with very high  
17 triglyceride levels."

18 Q So --

19 A So that's literally the population that they're  
20 describing in this article.

21 Q And I --

22 THE COURT: Mr. Kennedy, may I interrupt for a  
23 moment?

24 MR. M. KENNEDY: Sure.

25 THE COURT: Earlier, Dr. Budoff, there was a

1 chart shown showing a patient with TG equal to or above 500 mg  
2 per deciliter, and then you -- I think the chart says the goal  
3 was to reduce their TG, and then the next category is between  
4 two something, 200 to 499.

5 THE WITNESS: Yes.

6 THE COURT: There's cardiovascular risk. Are  
7 you referring to that category of patient?

8 THE WITNESS: Yes. So now we've basically  
9 lowered their pancreatitis risk so now we now assess their  
10 cardiovascular risk.

11 THE COURT: Thank you.

12 BY MR. M. KENNEDY:

13 Q And, Dr. Budoff, I would like to turn to the last passage  
14 in this section here that starts, "If the TG levels fall to a  
15 normal or borderline level," and what is this passage saying  
16 about how to treat patients who started with severe  
17 hypertriglyceridemia?

18 A Yeah, so this is now the scenario that the patient who  
19 had very high triglyceride, above 500, severe  
20 hypertriglyceridemia, we've implemented lifestyle changes,  
21 we've implemented Vascepa or another drug and a statin, and  
22 they say if their triglycerides fall to normal or borderline,  
23 consideration can be given to discontinue the nonstatin,  
24 triglyceride-lowering medication.

25 Q And what is normal or borderline?

1 A So that would be less than -- so normal is less than 150,  
2 borderline is less than 200.

3 So implementation in this scenario, when using  
4 Vascepa, as an example, if you started above 500, so let's say  
5 they're about 600, which is even less than the average in the  
6 MARINE trial, to get to 600 to less than 200 would be a 66 --  
7 a two-thirds reduction in their -- in their triglyceride  
8 levels which would be double what we saw in the trials.

9 So I think this is an unlikely scenario. But if you  
10 do happen to achieve reversal of their triglycerides, and they  
11 come down to completely normal, then it says consideration can  
12 be given to stopping the triglyceride-lowering medication.

13 Q Now, in your own practice how often do you see that kind  
14 of magnitude of a reduction from someone who is at very high  
15 triglycerides to normal or borderline?

16 A Yes, I could say that -- I can say that I've never seen  
17 that in my practice.

18 In the EVAPORATE trial, which was a prospective  
19 randomized trial using Vascepa, no patients had a 66 percent  
20 drop in their triglycerides using Vascepa therapy.

21 Q Now, if you have a patient with very high triglycerides  
22 who achieves a triglyceride reduction with Vascepa short of  
23 that kind of 60 -- you know, 70 percent reduction, do you  
24 consider taking them off of Vascepa at that point?

25 A No. So if their triglyceride levels are still in the

1 high range, then I know if I stop Vascepa their triglycerides  
2 will go back up to baseline.

3 Remember, we've eliminated all of the short-term,  
4 all of the bad diets, all of the alcohol bingers, all of the  
5 diabetics out of control. What we're left with are the  
6 genetic patients, and if I stop the active treatment,  
7 triglycerides are going to go back up to where they started,  
8 and they're going to be back at risk of pancreatitis.

9 Q So the patients who we're talking about still have --  
10 patients we're talking about who have very high triglycerides,  
11 and you're able to lower their triglycerides with  
12 lipid-lowering therapy, those patients are considered to have  
13 the condition of severe hypertriglyceridemia, correct?

14 A Yes, a chronic condition -- you don't take away the  
15 diagnosis once you've controlled it. If somebody has high  
16 blood pressure, and I treat them, and now their blood pressure  
17 is reading normal, I don't tell the patient, oh, you no longer  
18 have high blood pressure, the patient has high blood pressure  
19 still, they just are treated or have successfully controlled  
20 high blood pressure.

21 I just want to point out the last sentence of this  
22 paragraph, it says,

23 "Triglyceride levels will need to be  
24 monitored closely for any rise in triglycerides."

25 So even Dr. Karalis in their review of the

1 guidelines are reminding you that if you stop the therapy, you  
2 best keep an eye on them because they're likely to go back up.

3 Q Would you -- if you put some patient with STG on Vascepa,  
4 have you ever seen them have their triglycerides lowered  
5 before 500 in less than 12 weeks?

6 A No. I don't measure less than 12 weeks. That's not only  
7 a practice with Vascepa, that's a general practice with all  
8 lipid-lowering therapies.

9 The statins, for example, the most common practice,  
10 the advocated practice, the way the trials were done, is to  
11 put them on a new therapy. Let's say I put them on Lipitor, a  
12 statin, I would follow them up at three months.

13 I don't get a lipid level at four weeks or  
14 six weeks, so I would not know what happens in the short run,  
15 I want to see what happens in the long run because this is a  
16 chronic disease that's going to be needed to treat long-term.

17 MR. M. KENNEDY: Mr. Brooks, can we go back to  
18 PX 989 which we put into evidence earlier today.

19 BY MR. M. KENNEDY:

20 Q And, Dr. Budoff, this is the ATP III we discussed  
21 earlier.

22 A Yes.

23 MR. M. KENNEDY: Mr. Brooks, could you please go  
24 to page 195, and there's a passage concerning very high  
25 triglycerides.

1 BY MR. M. KENNEDY:

2 Q And, Dr. Budoff, what is this passage attempting to  
3 convey?

4 A So, again, this goes through -- basically these are the  
5 guidelines, but they basically go through the same steps as  
6 the label.

7 You start with looking for drugs that could increase  
8 triglycerides and preferentially discontinue those drugs. You  
9 eliminate alcohol. You make sure that their diabetes is under  
10 good control.

11 And then it starts talking about diet and lifestyle  
12 changes, and then ultimately what triglyceride-lowering  
13 therapies you could institute if all of those first steps are  
14 not successful.

15 Q I would like to ask you about towards the end of this  
16 passage where it says,

17 "For most persons with extremely high  
18 triglycerides, therapy can be considered successful  
19 if it reduces serum triglycerides below 500."

20 Do you see that?

21 A Yes.

22 Q What does it mean -- what does the ATP III mean by  
23 successful in this context?

24 A Yeah, so all chronic diseases have goals. We always have  
25 a goal when we're implementing therapy. Our blood pressure

1 goal is to get the blood pressure down to below 130 or even  
2 down to below 120 millimeters of mercury. Our diabetes goals  
3 are to achieve a hemoglobin A1C of 6.5.

4 When we achieve those goals, we're considered to be  
5 successful. That doesn't mean that we stop therapy, that just  
6 means we've achieved our goal, and now we continue therapy, we  
7 maintain therapy, to keep the patient at that goal.

8 This is saying the same thing about severe  
9 hypertriglyceridemia, that when you get the triglycerides  
10 below 500, you've achieved your goal, you've lowered their  
11 pancreatitis risk.

12 It says they're often not possible to normalize  
13 triglycerides. Going back to what Dr. Karalis talked about,  
14 you can -- most of the time you're not getting them down to  
15 150 and can stop therapy, you're just getting them under 500,  
16 and now you maintain that drug to maintain your goal, so you  
17 maintain success over time.

18 Q And in this -- just to clarify, in this context extremely  
19 high triglyceride, that means severe hypertriglyceridemia?

20 A Yes.

21 Q And, again, just to clarify, somebody with severe  
22 hypertriglyceridemia who is on medication and gets below 500,  
23 those patients are still considered to have the condition  
24 severe hypertriglyceridemia?

25 A Yes, they have the disease, they're just being



1 controlled. They're controlled for -- with severe  
2 hypertriglyceridemia.

3 MR KLEIN: Objection real quickly. I've given  
4 counsel a lot of latitude, but there's a fair amount of  
5 leading going on.

6 THE COURT: I consider the last few questions  
7 summarizing what Dr. Budoff already testified, so to the  
8 extent there's an objection, that objection is overruled.

9 BY MR. M. KENNEDY:

10 Q Has FDA expressed a view on whether triglyceride-lowering  
11 medication is needed after the patient's TG levels are reduced  
12 below 500?

13 A I'm sorry, can you we repeat that?

14 Q I'm sorry. Has FDA expressed a view as to whether  
15 TG-lowering medication is needed after a severely  
16 hypertriglyceridemic patient is reduced below 500 milligrams  
17 per deciliter?

18 A Yes.

19 MR. M. KENNEDY: Let's look at PX 289 which I  
20 think is on the list of pre-admitted exhibits.

21 BY MR. M. KENNEDY:

22 Q Dr. Budoff, do you recognize this document?

23 A Yes.

24 Q What is it?

25 A So this was very nicely described by Dr. Ketchum

1 yesterday. This is the medical review, what the FDA publishes  
2 to go along with their decision with the -- with the product  
3 for, in this case, Vascepa.

4 Q And I would like to go to page 40 of this document.  
5 There's a heading called Efficacy Summary.

6 And, Dr. Budoff, does this passage have any  
7 significance to your opinion concerning the duration of  
8 treatment indicated by the Vascepa label?

9 A Yes. They talk about the indication, and then the second  
10 sentence is,

11 "Patients with very high triglycerides have a  
12 strong genetic component to their disease and have an  
13 increased risk for acute pancreatitis."

14 So, again, genetic implies lifelong problem,  
15 implies lifelong treatment.

16 Q Does FDA speak elsewhere in this document to the need to  
17 maintain TG-lowering therapy in patients with SHT?

18 A Yes.

19 MR. M. KENNEDY: Mr. Brooks, could we go to  
20 page 67.

21 BY MR. M. KENNEDY:

22 Q And directing your attention to the heading 6.1.9, does  
23 this passage from the FDA review bear on your opinion  
24 concerning the duration of treatment for SHT patients  
25 indicated by the Vascepa label?

1 A Yes.

2 Q How so?

3 A So, I mean, this talks about the four-week and the  
4 additional 40 weeks, the one year data that was available as  
5 described by Dr. Ketchum yesterday, and they just say that the  
6 effect of Vascepa 4 grams occurred by week four and the  
7 effects were maintained throughout the study.

8 And then the label only talks about the 12-week data  
9 because that's the primary target of the trial and our most  
10 common practice when we follow-up patients.

11 Q I think you've mentioned this earlier in your testimony,  
12 but do you prescribe other lipid-lowering medications other  
13 than TG-lowering agents?

14 A Yes.

15 Q Could you give some examples.

16 A In what context?

17 Q Like other than -- you know, anything you prescribe to  
18 your patients other than Vascepa, fibrates, or Lovaza.

19 A Yeah, now we use statins, blood pressure medications,  
20 many therapies.

21 Q Do some of those other therapies call for indefinite  
22 treatment?

23 A Yes. I mean, the label never says treat indefinitely,  
24 but the label talks about a chronic condition, and the chronic  
25 condition therefore is treated long-term.

1 I think I spoke earlier to when I start a statin,  
2 I -- the intent when I put a patient on a statin is that  
3 they're going to take it for the rest of their life.

4 MR. M. KENNEDY: Mr. Brooks, could we have PX  
5 277.

6 BY MR. M. KENNEDY:

7 Q Dr. Budoff, do you recognize this document?

8 A Yes.

9 Q What is it?

10 A This is the National Lipid Association guidelines  
11 published in 2015.

12 Q What is the National Lipid Association?

13 A So the NLA, or the National Lipid Association, is the  
14 largest body of physicians who are primarily interested in  
15 controlling lipids, so lipids being bad cholesterol, LDL  
16 predominantly, and triglycerides, as the two most common that  
17 are measured and treated.

18 Q Are these NLA guidelines considered authoritative in your  
19 field?

20 A Yes.

21 Q Is this a document you relied on in forming your opinions  
22 in this case?

23 A Yes.

24 MR. M. KENNEDY: Your Honor, we would like to  
25 enter PX 277.

1 MR KLEIN: No objection.

2 THE COURT: PX 277 is admitted.

3 (Plaintiffs' Exhibit 277 received in  
4 evidence.)

5 MR. M. KENNEDY: And, Mr. Brooks, could we turn  
6 to the page marked 154 at the top, and I would like to direct  
7 you to the paragraph Follow-Up Visits that cuts across two  
8 columns.

9 BY MR. M. KENNEDY:

10 Q Dr. Budoff, does this passage bear on your opinion  
11 concerning the duration of treatment indicated by the Vascepa  
12 labeling?

13 A Yes. I mean, this -- this starting with the word -- with  
14 the very last sentence, once goal levels have been achieved,  
15 so this just speaks to you've now achieved your goal or your  
16 target, you've been successful as we've described before.

17 "...response to therapy should be  
18 monitored...to confirm continued success in  
19 maintenance of goal levels and patient adherence."

20 In other words, you don't stop the therapy, you  
21 start monitoring them at longer intervals. You don't need to  
22 monitor them every three months anymore, but you continue to  
23 monitor them over time to make sure that they stay at goal,  
24 that you can maintain the success with your therapy, and that  
25 they remain -- the patients stay on therapy and they remain  
adherent.

1 Q Adherent means that the patients are taking the  
2 medication as prescribed?

3 A Exactly.

4 Q When you write a prescription, do you intend that  
5 patients adhere to that prescription?

6 A Yes, I anticipate that they will follow my instructions,  
7 although we all know that not all patients are perfect in  
8 following the exact recommendations of their physician.

9 Q Now, are there drugs you encounter in your practice that  
10 do have a set limited duration of administration?

11 A Yes.

12 Q Can you think of some examples?

13 A Yes. I mean, the most common example are things like  
14 blood thinners like Lovenox or antibiotics. When we prescribe  
15 antibiotics, we give a course of antibiotics, we don't give a  
16 lifetime of antibiotics.

17 MR. M. KENNEDY: So, Mr. Brooks, could we have  
18 PX 285.

19 BY MR. M. KENNEDY:

20 Q And, Dr. Budoff, do you recognize this document?

21 A Yes.

22 Q What is it?

23 A This is the Lovenox package insert or the label for  
24 Lovenox.

25 Q And what is Lovenox used for?

1       A     So Lovenox is a blood thinner.  It's used for acute or  
2 short-term conditions surrounding surgery or for acute clots.  
3 So we always prescribe a drug that's prescribed for acute or  
4 short-term uses for a prescribed length of time.

5       Q     Is the Lovenox label a document you relied on in forming  
6 your opinions in this case?

7       A     Yes.

8                       MR. M. KENNEDY:  Your Honor, we would like to  
9 enter PX 285 into evidence.

10                      MR. KLEIN:  No objection.

11                      THE COURT:  285 is admitted.

12                                       (Plaintiffs' Exhibit 285 received in  
13                                       evidence.)

14                      MR. M. KENNEDY:  Mr. Brooks, could we have  
15 section 282 of the Lovenox labeling.

16       BY MR. M. KENNEDY:

17       Q     So, Dr. Budoff, is this an example of a drug with a  
18 limited duration?

19       A     Yes.  So this is the dosage section of the label, and it  
20 specifically tells you the duration of administration in every  
21 single scenario.

22                      So it gives you six different indications that  
23 Lovenox is indicated for, and in every single circumstance it  
24 talks about duration of administration because this is an  
25 acute drug that's not used long-term, so you are given this  
information in the dosage and usage section of the label.

1 Q So I would like to talk to you a little bit about your  
2 prescribing practices for Vascepa. Is administering Vascepa  
3 for at least 12 weeks consistent with your own practice?

4 A Yes.

5 Q So when you write a new prescription to a patient with  
6 severe hypertriglyceridemia for Vascepa, when is the next time  
7 you schedule an appointment with them?

8 A Yeah, so the most common practice, the practice that I've  
9 been taught, the practice that I teach, is that you follow  
10 them up at a three-month interval.

11 You get a lipid value at the end of three months  
12 which is, again, approximately 12 weeks, and then you see them  
13 a few days after their blood draw so you can review with the  
14 patient what the effect of that therapy was over the first  
15 12 weeks of treatment.

16 Q Theoretically would you find it useful if you could see  
17 them more quickly than 12 weeks?

18 A No. A lot of drugs don't hit their maximum potency or  
19 the patients may not be adherent. Remember, I'm trying to get  
20 them to stay on therapy long-term.

21 So whether or not they're successful at four weeks  
22 or six weeks is totally irrelevant to the long game, and as  
23 the guidelines talk about, you need to monitor them every 4 to  
24 12 months for lifetime to make sure that they stay on therapy.

25 So I'm interested more in a long-term follow-up than



1 an acute follow-up for my patients who have chronic diseases.

2 Q When you prescribe Vascepa, how much of a supply do you  
3 write the prescription for?

4 A Yeah, so most commonly I prescribe a 3-month supply at  
5 once. So I will give them 360 tablets, and then I will give  
6 them three refills so that will cover one year of treatment  
7 with Vascepa. That's how I implement Vascepa most commonly  
8 when I first start it for a patient.

9 Q Do you intend for the patients to take the entire supply  
10 as directed?

11 A Yes. It's always my hope that they comply or are  
12 adherent with my recommendations.

13 Q Do you ever tell a patient to stop taking Vascepa before  
14 the end of their supply?

15 A The only time I would ever stop it, and it would never be  
16 my intent to not have them take a long-term treatment for a  
17 chronic disease, but the only time I would sell them to stop  
18 it is if they had an adverse event from that therapy.

19 So, for example, with Vascepa, if they developed a  
20 bleeding problem, where they developed atrial fibrillation or  
21 some other problem that we know could be related to Vascepa, I  
22 might have them stop the therapy and come in and see me to  
23 make sure that they're not suffering an adverse event from  
24 taking that therapy.

25 Q Do you understand that the other asserted claims in this

1 case have the same or similar language concerning  
2 administration for at least 12 weeks?

3 A Yes.

4 MR. M. KENNEDY: Mr. Brooks, could we pull up  
5 PDX 2-14.

6 BY MR. M. KENNEDY:

7 Q And are these the other variations of the 12 weeks term  
8 in the other asserted claims?

9 A Yes.

10 Q Do the opinions you've expressed today concerning the  
11 claim element for a period of 12 weeks in the '728 patent  
12 claim 1 apply with equal force to the same or similar elements  
13 in the other asserted claims in this case?

14 A Yes.

15 Q And we've generally been asking -- I've generally been  
16 asking you about the Vascepa label today. Do the opinions  
17 you've expressed concerning the 12-week claim elements apply  
18 with equal force to the Hikma and DRL proposed labels?

19 A Yes.

20 MR. M. KENNEDY: So, Your Honor, I'm moving on  
21 to the next limitation. I'm happy to keep going, but I don't  
22 know if it's about time for the morning break.

23 THE COURT: I think we already took the morning  
24 break. I planned for us to go -- never mind. I guess it's  
25 time for our morning break.

1 MR. M. KENNEDY: Yeah.

2 THE COURT: All right. We'll take our morning  
3 break at this time.

4 MR. M. KENNEDY: Thank you, Your Honor.

5 (A recess was taken.)

6 THE COURT: Please be seated.

7 MR. M. KENNEDY: Your Honor, may I proceed?

8 THE COURT: Yes.

9 BY MR. M. KENNEDY:

10 Q Dr. Budoff, I actually do have one last question about  
11 the 12-weeks claim elements.

12 So, if you typically prescribe a multimonth or even  
13 a year supply to your patients -- strike that.

14 Why do you prescribe a multimonth or year-long  
15 supply of Vascepa to your patients if the clinical study in  
16 the label only has data for 12 weeks?

17 A Yes. So my intent is that they're going to stay on it  
18 for life. The maximum I'm allowed to prescribe, at least in  
19 the State of California, is for one year at a time so I give  
20 them a full year, and then, as I'm seeing them back, I can  
21 give them refills or give them new prescriptions after that.

22 Q Okay. Let's go -- Mr. Brooks, let's go PDX 2-15.

23 Moving on to the next claim element, the claim  
24 element requiring administration to effect a reduction in  
25 triglycerides.

1           Dr. Budoff, have you formed an opinion as to whether  
2 the contents in the Vascepa label encourages clinicians to  
3 administer Vascepa to effect a reduction in triglycerides as  
4 required by claim 1 of the '728 Patent?

5       A    Yes.

6       Q    What is that opinion?

7       A    That if physicians follow the label, that they will  
8 effect a reduction in triglycerides and this limitation will  
9 be met.

10      Q    Have you been informed that the Court has construed the  
11 claim language "to effect"?

12      A    Yes.

13      Q    Have prepared a slide reciting the Court's construction?

14      A    Yes.

15                   MR. M. KENNEDY:  Mr. Brooks, let's half  
16 PDX 2-16.

17 BY MR. M. KENNEDY:

18      Q    And, Dr. Budoff, does this slide, PDX 2-16, state the  
19 Court's construction?

20      A    Yes.

21      Q    And what's your understanding of this construction?

22      A    That it's not only the intent, but that it actually has  
23 to occur for the effect, the word effect.

24      Q    And have you been informed the Court's also construed the  
25 related language "compared to"?

1 A Yes.

2 Q And have you prepared a slide reciting that construction?

3 A Yes.

4 MR. M. KENNEDY: Mr. Brooks, could we please  
5 have PDX 2-17.

6 BY MR. M. KENNEDY:

7 Q Does PDX 2-17 recite the Court's construction?

8 A Yes.

9 Q And what's your understanding of the Court's construction  
10 of "compared to"?

11 A So it just means that the change will occur -- that the  
12 change will occur and the magnitude of the change that will  
13 occur.

14 Q Did you apply the constructions of "to effect" and  
15 "compared to" in forming your opinions in this case?

16 A Yes.

17 MR. M. KENNEDY: So, Mr. Brooks, let's go back  
18 to PDX 2-15.

19 BY MR. M. KENNEDY:

20 Q And how does the claim element regarding effecting a  
21 reduction in triglycerides relate to the claim element  
22 requiring.

23 "...compared to a second subject having a  
24 fasting baseline triglyceride level of 500 milligrams  
25 per deciliter to about 1500 milligrams per deciliter

1           who has not received the pharmaceutical composition  
2           and a concurrent lipid-altering therapy,"  
3 what's your understanding of how those two elements relate to  
4 each other?

5       A     So this is basically describing what -- the clinical  
6 trial section showing that there was a second subject, and we  
7 have a comparison in how well the Vascepa worked relative to a  
8 second subject.

9                       MR. M. KENNEDY:  So, Mr. Brooks, can we put this  
10 slide alongside the clinical study section in the Vascepa  
11 label that we've looked at today.

12                      And, Mr. Brooks, if you could go to section 14  
13 of the Vascepa label, and if we could get the whole --

14 BY MR. M. KENNEDY:

15       Q     So, Dr. Budoff, does the clinical study section of the  
16 Vascepa label relate to your opinions concerning the "to  
17 effect a reduction in triglycerides" claim element?

18       A     Yes.

19       Q     How so?

20       A     Oh, the primary results that are presented here in label  
21 two is the difference column, and the difference is comparing  
22 Vascepa 4 grams with a second subject who is not being  
23 treated, so, in this case, placebo therapy.

24       Q     Does the clinical study section of the Vascepa label  
25 reflect a reduction in triglycerides compared to a second

1 subject within the meaning of claim 1 of the '728 Patent?

2 A Yes. That difference of 33 percent is the reduction in  
3 triglycerides compared to a second subject who is receiving  
4 placebo, which is not receiving the pharmaceutical  
5 composition.

6 MR. M. KENNEDY: Mr. Brooks, can we go to the  
7 indications and usage section of the label, and you might as  
8 well keep it alongside the slide.

9 BY MR. M. KENNEDY:

10 Q And, Dr. Budoff, does the second indication in the  
11 Vascepa label relate to your opinions concerning the effect of  
12 reduction in triglycerides claim element?

13 A Yes.

14 Q How so?

15 A So it says here as an adjunct to diet, so it's not  
16 receiving concurrent lipid-altering therapy, just receiving  
17 diet, so monotherapy in patients with severe  
18 hypertriglyceridemia. In other words, patients who are --  
19 have triglycerides above 500 milligrams per deciliter as  
20 required in that element.

21 Q Do you prescribe Vascepa to your patients in accordance  
22 with the label -- with the indication?

23 A Largely, yes.

24 Q Does the clinical study section of the label inform your  
25 expectation of the lipid effects you achieve when you

1 prescribe Vascepa to your patients?

2 A Yes.

3 Q Why is that?

4 A So the -- I look towards the results that I'm expected to  
5 get with therapy, so I use the clinical trial section to say  
6 what would be my expected result, and then I see if my patient  
7 achieved that average result that was seen in the trial, and,  
8 if not, then I have to make changes in their regimen.

9 Q What percentage of your patients who you prescribe  
10 Vascepa experience lipid effects such as TG reduction in line  
11 with the results recited in the labeling?

12 A Yes, so about three quarters of patients will be at or  
13 around that number. So it's not going to be exactly minus  
14 33.0 percent, but they will have generally about a one-third  
15 reduction.

16 Of the remaining 25 percent, half of those patients  
17 will have even more dramatic effects, and half of those  
18 patients will have less dramatic effects. That's just what we  
19 call the normal distribution of results when we treat enough  
20 patients.

21 Q When you write a prescription to a patient with severe  
22 hypertriglyceridemia for Vascepa, do you have any way of  
23 knowing whether they're going to achieve lipid effects in line  
24 with the MARINE label as opposed to being one the people who  
25 don't?



1 A No, there's no good way to know in advance. That's why  
2 we repeat the lipid value at 12 weeks to see did they -- did  
3 they achieve or did they not achieve those desired results.

4 Q What lipid effects do you expect from a given SHT patient  
5 when you write the prescription?

6 A So I hope, I anticipate, I plan that they will achieve a  
7 33 percent reduction in triglycerides and that their LDL will  
8 not go up. So, that is my goal and intent when I'm  
9 prescribing this therapy.

10 I anticipate that the apo B will go down. I know  
11 we'll talk about that later. But I think that those are my  
12 goals and intent.

13 And then -- but some patients don't -- don't fall  
14 into that category, and they have to be -- I have to adjust my  
15 treatment based on the actual results in that individual  
16 patient.

17 Q Are you aware that the other asserted claims in this case  
18 also have claim elements relating to effecting a reduction in  
19 triglycerides?

20 A Yes.

21 Q Have you prepared a slide reciting those same or similar  
22 limitations in the other asserted claims?

23 A Yes.

24 MR. M. KENNEDY: Mr. Brooks, could we have  
25 PDX 2-18.

1 BY MR. M. KENNEDY:

2 Q Does PDX 2-18 recite the other claim elements relating to  
3 effecting a reduction in triglycerides?

4 A Yes.

5 Q And you also have some notations on the right-hand side  
6 concerning comparisons of various types. What does that  
7 denote?

8 A So those are the different languages that are used in  
9 each of the different claims.

10 So sometimes the language is "to effect a reduction  
11 in triglycerides compared to a second subject," we just  
12 described that, that's the placebo-controlled arm of the  
13 MARINE trial.

14 Sometimes it says "compared to placebo control,"  
15 that's another way of saying a second subject not receiving  
16 active compound.

17 Sometimes it says "compared to baseline" or "in the  
18 subject," and those would imply just looking at the reductions  
19 in line with the -- per the individual and not comparing it to  
20 a second subject or a placebo control.

21 MR. M. KENNEDY: Mr. Brooks, can we put table 2  
22 back up alongside this slide, and maybe blow up the table?

23 BY MR. M. KENNEDY:

24 Q So, Dr. Budoff, does table 2 of the Vascepa label reflect  
25 that administration of Vascepa effects a reduction in fasting

1 triglycerides of at least about ten percent in the subject?

2 A Yes, the average reduction is 33 percent. For compared  
3 to a second subject or placebo control, the average drop is  
4 27 percent in the same subject or compared to baseline, and  
5 both minus 27 and minus 33 are more than a 10 percent drop.

6 Q And let me ask you the same question with respect to the  
7 limitation effects reduction in fasting triglycerides of at  
8 least about 20 percent compared to placebo control as required  
9 by the '560 patent claim 17.

10 A Yes. Both minus 27 percent and minus 33 percent are at  
11 least 20 percent, so that claim element would also be met.

12 Q And then, finally, does table 2 of the Vascepa label  
13 reflect that administration of Vascepa according to the label  
14 would achieve a statistically significant reduction in  
15 triglycerides in the subject as required by claim 4 of the  
16 '715 Patent?

17 A Yes, if you see where it says minus 33 percent, and you  
18 see the asterisk that says the P value is less than .001, so  
19 that is highly statistically significant change, so that would  
20 achieve an effect that is a statistically significant  
21 reduction in triglycerides.

22 MR. M. KENNEDY: Mr. Brooks, could we go to  
23 PDX 2-19.

24 BY MR. M. KENNEDY:

25 Q Now we're back on claim 1 of the '728 Patent, and I would

1 like to turn to the element regarding avoiding a reduction in  
2 LDL-C.

3 Have you formed an opinion concerning whether the  
4 Vascepa label encourages clinicians to prescribe the product  
5 described in the label to effect a reduction in triglycerides  
6 without substantially increasing LDL-C compared to a second  
7 subject within the meaning of claim 1 of the '728 patent?

8 A Yes.

9 Q What is that opinion?

10 A That we have seen from the MARINE trial, and we have  
11 discussed already, that the LDL cholesterol does not go up, it  
12 goes down by minus 2 percent, so that is not substantially  
13 increasing LDL, that is neutral or slightly decreasing LDL.

14 Q And to recap, when claim 1 of the '728 refers to a  
15 comparison to a second subject, what does that comparison  
16 correspond to in table 2 of the Vascepa label?

17 A So that would be the placebo column. So that would be  
18 looking at the difference between the active Vascepa minus the  
19 placebo column to get the net difference which, in the MARINE  
20 trial, was minus 2 percent change in LDL cholesterol.

21 Q So you understand the Court's construed the language  
22 "without substantially increasing LDL-C"?

23 A Yes.

24 Q Do you have a slide showing that construction?

25 A Yes.

1 MR. M. KENNEDY: And, Mr. Brooks, can we have  
2 PDX 2-20.

3 BY MR. M. KENNEDY:

4 Q Dr. Budoff, does this slide, PDX 2-20, recite the Court's  
5 construction of "without substantially increasing LDL-C"?

6 A Yes.

7 Q And you see the construction is "without a meaningful  
8 increase in LDL-C." What does clinically meaningful mean in  
9 this context?

10 A So clinically meaningful in clinical practice, and this  
11 was brought out yesterday as well, is a 6 percent rise.  
12 That's typically considered a meaningful increase in LDL  
13 cholesterol whereby we might have to react to it, and that  
14 makes it a clinical event that I have to then react to that 6  
15 percent rise by changing my underlying management.

16 Q Did you apply the construction, the Court's construction  
17 of "without substantially increasing LDL-C" in forming your  
18 opinions?

19 A Yes.

20 Q And then there's the related construction that appears in  
21 different asserted claims, "without effecting a statistically  
22 significant increase in LDL-C." What's your understanding of  
23 that construction that's recited on the slide?

24 A Yes. So that, again, is -- basically, our definition of  
25 statistically significant is that it's not -- it's unlikely to

1 have occurred due to chance and that it's a real change.

2 MR. M. KENNEDY: Mr. Brooks, can we go to the  
3 dosage and administration section of the Vascepa label.

4 BY MR. M. KENNEDY:

5 Q And, Dr. Budoff, I would like to direct you in particular  
6 to 2.1 where it says, "assess lipid levels before initiating  
7 therapy." Do you see that?

8 A Yes.

9 Q Does this relate to whether Vascepa avoids an LDL-C  
10 increase?

11 A Well, yes. So, I mean, it doesn't say to address the  
12 triglyceride levels, or assess triglyceride levels before  
13 initiating therapy, it says lipid levels, and that tells the  
14 clinician to get a full lipid panel, and a full lipid panel  
15 includes LDL cholesterol as well as triglycerides.

16 So it's reminding the physician to get the full  
17 panel so that you can see what the effect is, not only on  
18 triglycerides, but also on LDL cholesterol.

19 Q Do clinicians treating STG patients typically get these  
20 lipid panels?

21 A Yes. It's very standard to get a standard lipid panel in  
22 all of your patients. I don't know how you would prescribe  
23 any cholesterol-lowering medicine without assessing a lipid  
24 panel before initiating therapies.

25 So I think this is fairly standard language for any

1 drug in this general class of lipid metabolism.

2 MR. M. KENNEDY: So, Mr. Brooks, can we pull up  
3 PDX 2-19 and put it alongside table 2.

4 BY MR. M. KENNEDY:

5 Q And is there anything in the clinical study section of  
6 the Vascepa label that speaks to whether the label encourages  
7 administration of Vascepa to effect a reduction in  
8 triglycerides without substantially increasing LDL-C compared  
9 to a second subject?

10 A Yes, so in the LDL-C column on the far right is compared  
11 to a second subject or compared to placebo control, and that's  
12 minus two percent.

13 So you can see LDL-C went down by 2 percent, which  
14 is not a substantial increase or meaningful increase because  
15 it's a decrease.

16 Q And the second -- the -- where, in the clinical study  
17 section, does it reflect a comparison to a second subject in  
18 the way required by claim 1 of the '728 Patent?

19 A I mean, literally, right under the table there it says  
20 difference, and it says the median of Vascepa minus placebo.  
21 So it literally defines that it's comparing it to the second  
22 subject.

23 It also says it in the last sentence of the  
24 paragraph, the reduction in triglycerides observed with  
25 Vascepa was not associated with elevations in LDL-C levels

1 relative to placebo.

2 Q Why is that relevant?

3 A Well, they're calling that out to the clinician. This is  
4 an emphasis to the clinician that this is an important  
5 finding, and thus it's put in the table -- it's put in the  
6 text below the table to further emphasize that result.

7 Q Do the effects on LDL-C shown in table 2 influence your  
8 treatment decisions for SH -- STG patients?

9 A Yes, I think as we talked about before, the other agents  
10 in the class that are indicated to reduce severe  
11 hypertriglyceridemia, niacin, fibrates, and Lovaza, are all  
12 associated with significant increases in LDL cholesterol.

13 This drug is not associated with elevations in LDL  
14 cholesterol making it a unique opportunity to treat patients  
15 for their triglycerides without increasing their cardiac risk  
16 of having a heart attack downstream.

17 Q So let me ask a slightly broader question not limited to  
18 LDL-C effects, but also for the other lipid effects shown in  
19 table 2.

20 Do they -- the clinical data on table 2 influence  
21 clinicians' treatment decisions for their severely  
22 hypertriglyceridemic patients?

23 A Yes.

24 Q How -- why is that?

25 A So, again, triglycerides go down significantly, LDL does



1 not go up.

2 And what we haven't yet talked about, but I think is  
3 also important, is that apo B -- remember apolipoprotein B is  
4 the bad lipoprotein, actually goes down significantly.

5 So it has three affects that are all deemed positive  
6 for our patients with severe hypertriglyceridemia.

7 MR. M. KENNEDY: Mr. Brooks, can we go to the  
8 warnings and precautions section of the Vascepa label.

9 BY MR. M. KENNEDY:

10 Q And, Dr. Budoff, is there anything in the warnings and  
11 precautions section of the Vascepa label that is relevant to  
12 your opinion that the label encourages administration to  
13 effect a reduction in triglycerides without substantially  
14 raising LDL-C?

15 A Yes.

16 Q What about this section supports that opinion?

17 A So, in all the other therapies, the fibrates, Lovaza,  
18 there is a warning about LDL rise in the warnings and  
19 precautions sections of those labels.

20 Here there is no such warning, and a doctor who is  
21 treating severe hypertriglyceridemia would know that. This  
22 would be a common knowledge of the effects of the other agents  
23 and the warnings that go with the other agents, and so the  
24 absence of that warning is important for physicians to  
25 understand.

1 Q Do you understand that the other asserted -- some of the  
2 other asserted claims in this case have limitations drawn to  
3 avoiding LDL-C effects?

4 A Yes.

5 MR. M. KENNEDY: Mr. Brooks, could we have  
6 PDX 2-21.

7 BY MR. M. KENNEDY:

8 Q Dr. Budoff, does this slide depict the other claim  
9 elements and other asserted claims regarding LDL-C effects?

10 A Yes.

11 Q And, again, the different claims have different  
12 comparators such as second subject, placebo control, and  
13 baseline?

14 A Yes.

15 Q Do the opinions you've expressed today concerning the  
16 claim element, "without substantially increasing LDL-C" in  
17 claim 1 of the '728 Patent, apply with equal force to the same  
18 or similar terms in the other asserted claims?

19 A Yes.

20 Q For example, does -- does the Vascepa label reflect  
21 avoidance of a statistically significant increase in LDL-C in  
22 the subject as required by '715 patent, claim 14 patent?

23 A Yes, there was a decrease in LDL-C so there was not a  
24 statistically significant increase by definition.

25 Q So does that entail that the terms about avoiding an

1 increase this LDL-C in claims 4 and 17 of the '560 patent are  
2 also met?

3 A Yes. Again, a decrease is without an increase by  
4 definition. So I think that those claims are all met by the  
5 results of the clinical trials section that's put forth in all  
6 of the labels.

7 MR. M. KENNEDY: Could we go to the slide  
8 PDX 2-22.

9 BY MR. M. KENNEDY:

10 Q Dr. Budoff, do you have an opinion as to whether the  
11 Vascepa label encourages physicians to prescribe Vascepa to  
12 severely hypertriglyceridemic patients who are not receiving a  
13 concurrent lipid-altering therapy as required by claim 1 of  
14 the '728 Patent?

15 A Yes.

16 Q What is that opinion?

17 A That the majority of patients treated in the MARINE trial  
18 and the indication itself both advocate for monotherapy.  
19 Monotherapy by definition is without receiving concurrent  
20 lipid-altering therapy.

21 Q Do you understand that the Court previously construed the  
22 phrase "concurrent lipid-altering therapy"?

23 A Yes.

24 MR. M. KENNEDY: Mr. Brooks, could we have  
25 PDX 2-23.

1 BY MR. M. KENNEDY:

2 Q And, Dr. Budoff, is this the Court's construction?

3 A Yes.

4 Q Did you apply the Court's construction of "concurrent  
5 lipid-altering therapy" in forming your opinions in this case?

6 A Yes.

7 MR. M. KENNEDY: Mr. Brooks, can we go to trial  
8 Exhibit 1186, the Vascepa label, the indications and usage  
9 section.

10 BY MR. M. KENNEDY:

11 Q And, Dr. Budoff, is there anything about the indications  
12 and usage that is relevant to your opinion that the label  
13 encourages administration to severely hypertriglyceridemic  
14 patients who aren't receiving concurrent lipid-altering  
15 therapy?

16 A Yes.

17 Q What -- what about the indications and usage section  
18 supports your opinion?

19 A So you can see the MARINE indication literally says as an  
20 adjunct to diet to reduce triglyceride levels. So diet is not  
21 considered concurrent lipid-altering therapy. The Court  
22 construed that that's a medication.

23 So this is literally advocating for Vascepa to be  
24 used as monotherapy without concurrent -- it's not requiring  
25 concurrent lipid-altering therapy.

1 Q Do you -- so with respect to your severe  
2 hypertriglyceridemic patients, do you sometimes prescribe  
3 concurrent lipid-altering therapy and sometimes not?

4 A Yes.

5 Q Could you describe the type of patient who has severe  
6 hypertriglyceridemia to whom you would prescribe Vascepa as a  
7 monotherapy?

8 A Yeah. So a very common scenario is -- and triglycerides  
9 tend to affect women more than men, hypertriglyceridemia.

10 So a very common scenario would be a young,  
11 otherwise healthy woman gets referred to me because their  
12 triglycerides are very high.

13 When I meet her, I ask her questions about her diet  
14 and exercise. She's already adhering to a good diet, she's  
15 already exercising regularly. I can see that she's not very  
16 overweight so I know she's an over -- overwhelmingly healthy  
17 person.

18 I check for diabetes and thyroid disease, and if she  
19 doesn't have any of those things, then my primary therapy is  
20 going to be Vascepa. She's on it, it's an adjunct to diet and  
21 exercise.

22 Now I'm going to prescribe Vascepa monotherapy.  
23 After I prescribe monotherapy, I'll see her back, and I'll  
24 assess her lipid profile in three months.

25 But a lot of these young, healthy people only have

1 triglyceride abnormalities. Her LDL cholesterol could be nice  
2 and low, and if her LDL cholesterol is nice and low, and she's  
3 otherwise healthy, then she doesn't qualify for concurrent  
4 lipid-altering therapy. I don't need to put her on a statin,  
5 she wouldn't benefit from such therapy, and I would just  
6 continue Vascepa monotherapy in that patient.

7 Q Is there anything about the Vascepa labeling that gives  
8 you comfort that Vascepa would be appropriate as a monotherapy  
9 in the patient you just described?

10 A Yes.

11 Q What -- what part of the label?

12 A So the clinical trial section also speaks to the utility  
13 of this therapy as monotherapy.

14 Q Could you describe the type of severely  
15 hypertriglyceridemic patient that you might prescribe Vascepa  
16 along with a concurrent lipid-altering therapy?

17 A Yes. So take another patient walks into my office, this  
18 time they have underlying heart disease so they might have  
19 already suffered a heart attack or maybe have a stint. Their  
20 triglycerides are over 500.

21 I implement diet and exercise, have them come back.  
22 They're still above 500. I now need to use Vascepa therapy in  
23 that person.

24 They might already be on a statin, so that would be  
25 concurrent lipid-altering therapy or, after I put them on

1 Vascepa and see that their LDL, their bad cholesterol, is  
2 still too high, I would then implement statin therapy.

3 We discussed the guidelines advocate for that  
4 step-wise care that is so important when we assess patients  
5 with high triglycerides.

6 MR. M. KENNEDY: Mr. Brooks, could we go to  
7 table 2.

8 BY MR. M. KENNEDY:

9 Q So is there anything about the labeling that encourages  
10 you as a clinician to administer Vascepa -- I'll start -- I'll  
11 just start without concurrent lipid-altering therapy, the  
12 young woman, for example.

13 A Yes. Mr. Brooks, could you expand it to the top  
14 paragraph real quickly? Sorry.

15 So this is the full clinical trial section, and you  
16 can see there's a sentence fairly far down in the first  
17 paragraph starting with 25 percent of patients were on  
18 concomitant statin therapy.

19 So that literally tells you that this -- this trial,  
20 one fourth of the patients were on a statin plus Vascepa, or  
21 statin plus placebo, and 75 percent were not.

22 So the vast majority of the patient results in table  
23 2 reflects Vascepa monotherapy. That literally reflects  
24 75 percent of the results of the patients randomized in this  
25 trial.

1           So the study definitely encourages physicians to  
2 prescribe Vascepa as monotherapy, and because 25 percent of  
3 patients were on statin, concomitant statin therapy, it also  
4 encourages patients to use it with concurrent lipid-altering  
5 therapy when appropriate.

6       Q    I'd like to look at the verbiage underneath table 2. Is  
7 there anything about that portion of the clinical study  
8 section that encourages clinicians to administer Vascepa  
9 without concurrent lipid-altering therapy?

10       A   Well, again, so two-thirds, three-quarters of the  
11 patients achieve these results without statin therapy. So  
12 this largely reflects Vascepa reduced triglycerides with  
13 without elevating LDL-C, that largely reflects the placebo,  
14 the statin -- I mean, the Vascepa monotherapy arm rather than  
15 patients who are on concomitant therapy.

16       Q    Do you understand that some the other asserted claims  
17 have the same or similar claim language concerning  
18 administering Vascepa to STG patients without concurrent  
19 lipid-altering therapy?

20       A    Yes.

21                       MR. M. KENNEDY: Let's look at PDX 2-24.

22 BY MR. M. KENNEDY:

23       Q    Dr. Budoff, does this slide, PDX 2-24, recite the other  
24 similar claim language?

25       A    Yes.



1 Q Do the opinions you've expressed today concerning the  
2 claim language "who does not receive concurrent lipid-altering  
3 therapy" in claim 1 of the '728 Patent apply with equal force  
4 to the same or similar claim elements in the other asserted  
5 claims that have these limitations?

6 A Yes.

7 Q And, again, the opinions -- when you've answered  
8 questions about the Vascepa label, do your opinions concerning  
9 the concurrent lipid-altering therapy claim elements apply  
10 with equal force to the Hikma and DRL labels?

11 A Yes.

12 MR. M. KENNEDY: So, Mr. Brooks, can we go to  
13 PDX 2-26.

14 BY MR. M. KENNEDY:

15 Q And I would like to do the last two elements of this  
16 patent together. These require administering orally to the  
17 subject about 4 grams per-day of a pharmaceutical composition.

18 Have you formed any opinions concerning whether the  
19 Vascepa label encourages clinicians to administer orally to  
20 the subject about 4 grams per day of a pharmaceutical  
21 composition as required in claim 1 of the '728 Patent?

22 A Yes.

23 Q What is that opinion?

24 A Multiple times throughout the patent physicians are  
25 encouraged to administer this medicine. The only way it can

1 be administered is orally, and the only dose is 4 grams per  
2 day, so these two are automatically met by using the  
3 prescription the way it has to be prescribed.

4 Q So I think in your last answer you said the patent  
5 requires, did you mean the prescribing --

6 A The label requires.

7 Q So do you understand the Court previously construed the  
8 orally -- the "administering orally" claim language?

9 A Yes.

10 MR. M. KENNEDY: And, Mr. Brooks, can we go to  
11 PDX 2-27.

12 BY MR. M. KENNEDY:

13 Q And, Dr. Budoff, is this the construction you applied in  
14 forming your opinions?

15 A Yes.

16 Q And so what's your understanding of the Court's  
17 construction of "orally administered" or "administering"?

18 A That the doctor is the one prescribing the medicine, and  
19 the medication is being taken by the patient at the doctor's  
20 direction. So this is a doctor-directed oral administration.

21 Q So writing the prescription constitutes administering?

22 A Yes.

23 Q And do you understand the parties also reached an  
24 agreement about the construction the claim term  
25 "pharmaceutical composition"?

1 A Yes.

2 MR. M. KENNEDY: And, Mr. Brooks, can we have  
3 2-30.

4 BY MR. M. KENNEDY:

5 Q And, Dr. Budoff, do you see the stipulated construction  
6 of "pharmaceutical composition"?

7 A Yes.

8 Q Is this the construction you applied in forming your  
9 opinions?

10 A Yes.

11 MR. M. KENNEDY: Mr. Brooks, could we go back to  
12 slide 2-26 and put it alongside the description section of the  
13 prescribing information, section 11.

14 BY MR. M. KENNEDY:

15 Q And, Dr. Budoff, I don't think we've seen this section of  
16 the labeling today. In general, what's the purpose of the  
17 description section of a label?

18 A This describes the medication so that the physician knows  
19 and the patient knows what it's going to look like and how --  
20 what it constitutes.

21 Q And do the Hikma and DRL labels contain identical  
22 descriptions?

23 A Yes.

24 Q Except they're not called Vascepa, they're called  
25 icosapent ethyl.

1 A Yes.

2 Q So what in the description section informs your opinion  
3 that the label encourages administration orally to the subject  
4 about 4 grams per-day of a pharmaceutical composition?

5 A Well, the description says it's for oral use.

6 Q And what does it say about 4 grams?

7 A I don't think it says 4 grams here. I think in the  
8 dosage and administration section it speaks to 4 grams as the  
9 dose that's to be given.

10 MR. M. KENNEDY: So let's go to the dosage and  
11 administration section.

12 BY MR. M. KENNEDY:

13 Q And what about the dosage and administration section of  
14 the Vascepa label informs your opinion that the label  
15 encourages administering about 4 grams per day of a  
16 pharmaceutical composition?

17 A Under 2.2, dosage and administration, the daily dose of  
18 Vascepa is 4 grams per day, and then advise patients to  
19 swallow whole and take it with food.

20 Both of those imply -- the only way you can swallow  
21 it or take it with food is an oral administration. So this  
22 covers both oral and 4 grams.

23 Q And what does the dosage and administration section say  
24 about the dosage form in which Vascepa is delivered?

25 A So it's a capsule, so, again, given orally.

1 Q And are you aware that other claims at issue in this case  
2 have language similar to about 4 grams per day that appears in  
3 claim 1 of the '728 Patent?

4 A Yes.

5 MR. M. KENNEDY: And can we go to slide  
6 two-dash, PDX 2-31? PDX 2-31? Oh, sorry.

7 BY MR. M. KENNEDY:

8 Q And, Dr. Budoff, do the opinions you've expressed today  
9 concerning the about 4 grams per day claim element in claim 1  
10 of the '728 Patent apply with equal force to the same or  
11 similar claim elements in the other asserted claims?

12 A Yes.

13 MR. M. KENNEDY: And then, Mr. Brooks, if we  
14 could go to PDX 2-28.

15 BY MR. M. KENNEDY:

16 Q And do you understand that other claims at issue in this  
17 case have the same or similar language concerning  
18 administering orally to the subject?

19 A Yes.

20 Q And do the opinions you've expressed today concerning  
21 whether the Vascepa label encourages administering orally to  
22 the subject as required of claim 1 of the '728 Patent apply  
23 with equal force to the other asserted claims with the same or  
24 similar claim language?

25 A Yes.

1                   MR. M. KENNEDY: So, Mr. Brooks, can we go to  
2 PDX 2-32. And you can take down the label for right now.  
3 Thank you.

4 BY MR. M. KENNEDY:

5       Q     And just so sum up, Dr. Budoff, what is your opinion  
6 concerning whether the Vascepa label taken as a whole will  
7 encourage clinicians to admit to follow each step in the  
8 method claimed by claim 1 of the '728 Patent?

9       A     Yes. So as I've just outlined, every element will be  
10 met, every limitation will be met, if physicians follow the  
11 label, they will be encouraged to do all of these steps that  
12 are listed here on the slide.

13       Q     In your opinion, would physicians follow the label?

14       A     Yes, physicians are supposed to follow the label.

15       Q     And, again, if I had asked you about the Hikma or DRL  
16 label instead of the Vascepa label, would your opinions be the  
17 same?

18       A     Yes.

19                   MR. M. KENNEDY: So let's move on to claim 16 of  
20 the '728 Patent, and that's PDX 2-33.

21 BY MR. M. KENNEDY:

22       Q     And, Dr. Budoff, what are you depicting on this slide?

23       A     So this is just the other claim that's -- that's being  
24 contested, and it just shows that all the claim elements are  
25 met in claim 1.

1           So that refers to the previous slide that we just  
2 went through, all the limitations are already met, and then it  
3 describes another -- the pharmaceutical composition again  
4 which has already been stipulated or agreed upon by the  
5 parties. So all the elements for claim 16 of the '728 Patent  
6 are met.

7       Q    So just to sum up, would the labeling -- Vascepa labeling  
8 encouraging -- encourage clinicians to follow each step of the  
9 method claimed by claim 16 of the '728 Patent?

10       A    Yes. For all the reasons I've previously stated,  
11 physicians will -- following the label will meet all of these  
12 elements.

13       Q    And you would have the same opinion with respect to the  
14 Hikma and DRL labels?

15       A    Yes.

16                       MR. M. KENNEDY: So let's move on to trial  
17 Exhibit 26.

18 BY MR. M. KENNEDY:

19       Q    And, Dr. Budoff, do you recognize that document?

20       A    Yes.

21       Q    What is it?

22       A    This is the '652 Patent.

23       Q    And so that's U.S. patent 8,367,652?

24       A    Yes.

25       Q    Is this one of the patents you've analyzed in forming

1 your opinions in this case?

2 A Yes.

3 MR. M. KENNEDY: Your Honor, I believe PX 26 is  
4 on the pre-admitted exhibit list.

5 THE CLERK: It is.

6 THE COURT: Thank you.

7 BY MR. M. KENNEDY:

8 Q And you understand that Amarin is asserting infringement  
9 of claim 1 of the '652 Patent?

10 A Yes.

11 MR. M. KENNEDY: So, Mr. Brooks, let's just go  
12 to PDX 2-34.

13 BY MR. M. KENNEDY:

14 Q And, Dr. Budoff, what are you attempting to state here  
15 where you have the notation "See Claim 1 ('728 Patent)"?

16 A So these are the same or similar languages that we've  
17 already discussed and demonstrated, that a physician following  
18 the label will meet all of these limitations. So the same  
19 analysis that I applied to claim 1 of the '728 Patent applies  
20 to claim 1 of the '652 Patent.

21 Q Now, there's one element that's not filled in here,  
22 "compared to baseline." Do you see that?

23 A Yes.

24 Q Have you formed any opinions concerning whether the  
25 Vascepa label encourages clinicians to prescribe Vascepa to a



1 subject to effect a reduction in triglycerides without  
2 substantially increasing LDL-C compared to baseline as  
3 required by claim 1 of the '652 Patent?

4 A Yes.

5 Q And what is that opinion?

6 A That they would be encouraged to lower triglycerides, and  
7 LDL will not go up when you compare that person to their own  
8 baseline, and that was done in the clinical studies section of  
9 the labels.

10 MR. M. KENNEDY: And let's just very quickly put  
11 this slide alongside table 2 of the Vascepa label.

12 BY MR. M. KENNEDY:

13 Q And, Dr. Budoff, if you could just point out, does the  
14 MARINE data stated in the Vascepa label contain a comparison  
15 to baseline?

16 A Yes. So in the table 2, can you see under Vascepa it  
17 says the word baseline. These are the changes that are seen  
18 compared to baseline.

19 So to effect a reduction in triglycerides, the  
20 change was 27 percent compared to baseline. Two, without  
21 increasing LDL-C, there was a minus five percent, there was  
22 decrease in LDL-C compared to baseline. So these elements  
23 will be met when physicians follow the label.

24 Q And when you administer Vascepa to a subject, what kinds  
25 of lipid effects do you expect to see in that patient? I

1 should say a subject with severe hypertriglyceridemia.

2 A Right. So, again, our intent is, in our vast majority of  
3 patients, that our patients will behave similarly to the  
4 clinical trial, and these are the types of results that we  
5 will see.

6 So we will see a significant reduction in  
7 triglycerides with a small decrease or no change in LDL-C.

8 Q So, in your opinion, will the Vascepa labeling encourage  
9 clinicians to follow each step in the method claimed in claim  
10 1 of the '652 Patent?

11 A Yes.

12 MR. M. KENNEDY: So let's move on to Plaintiffs'  
13 Exhibit 25?

14 BY MR. M. KENNEDY:

15 Q And, Dr. Budoff, do you recognize this document?

16 A Yes, this is U.S. patent 8,357,677.

17 Q Is this one of the patents you've analyzed in this case?

18 A Yes.

19 Q And have you been informed that Amarin is asserting  
20 infringement of claims 1 and 8 of the '677 Patent?

21 A Yes.

22 MR. M. KENNEDY: Mr. Brooks, can we please go to  
23 slide PDX 2-36.

24 BY MR. M. KENNEDY:

25 Q And, Dr. Budoff, again, can you just very briefly explain

1 what this slide shows.

2 A Yes. So for all the analyses that we've already  
3 described for each of these claim elements, these are the same  
4 or similar language to claim 1 of the '728 Patent, that these  
5 elements will be met in claim 1 of the '677 Patent.

6 The only claim -- or, excuse me, the only element  
7 that's not yet met in this is "compared to placebo control."

8 Q And have you formed any opinions concerning whether the  
9 Vascepa label encourages clinicians to prescribe Vascepa to  
10 effect a reduction in triglycerides without substantially  
11 increasing LDL-C compared to placebo control as required by  
12 claim 1 of the '677 Patent?

13 A Yes.

14 Q What is that opinion?

15 A So as we've talked about before, probably now a few  
16 times, the net effect of following these elements or following  
17 the label and prescribing Vascepa the way that the label  
18 encourages, will effect a reduction in triglycerides on  
19 average by 33 percent compared to placebo control, and will  
20 lower LDL-C by 2 percent, so not without substantially  
21 increasing LDL-C compared to placebo control.

22 So this element will also be met based on the data  
23 in table 2 and in the paragraphs below, the paragraph below  
24 table 2, which re-emphasizes all of those findings.

25 Q So just to be clear, the data you just recited is from

1 table 2 in the clinical study section of the Vascepa label  
2 that we've looked at a couple times today?

3 A Yes, and then two sentences below the table that  
4 reemphasized these exact findings.

5 Q Do you prescribe Vascepa with the intent to achieve in  
6 your STG patient the effects recited in claim 1 of the '677  
7 patent?

8 A Yes.

9 Q To the best of your knowledge, do other clinicians  
10 prescribe with the attempt to achieve those lipid effects?

11 A Yes.

12 Q Do patients that you treat actually exhibit lipid effects  
13 in line with what's recited in table 2?

14 A Yes.

15 Q And with what's recited in claim 1 of the '677 Patent?

16 A Yes.

17 Q In your opinion, will the labeling encourage clinicians  
18 to follow each step in the method claimed in claim 1 of the  
19 '652 patent?

20 A Of the '677 Patent?

21 Q That's what I meant, yes, I'm sorry.

22 A Yes.

23 MR. M. KENNEDY: So, Mr. Brooks, let's go to  
24 PDX 2-38.

25

1 BY MR. M. KENNEDY:

2 Q And this is the other asserted claim of the '677 Patent,  
3 and what are you attempting to show in the notation "(See  
4 Claim 1)"?

5 A So, again, based on all of the previous descriptions that  
6 we've already given and the elements that we've already  
7 addressed, that those elements will be met by the previous  
8 claim 1 of the '677 Patent.

9 Q Have you formed any opinions concerning whether the  
10 Vascepa label encourages clinicians to prescribe Vascepa to a  
11 subject to effect a reduction in apolipoprotein B compared to  
12 placebo control as required by claim 8 of the '677 patent?

13 A Yes.

14 Q What is that opinion?

15 A That physicians who are reading the label will be  
16 encouraged to reduce apo B. It occurred in the clinical trial  
17 section, it's reemphasized in the paragraph below the clinical  
18 trial section, that compared to placebo control, Vascepa will  
19 effect a reduction in apolipoprotein B.

20 Q What was the magnitude of the reduction compared to  
21 placebo control in apo B recited in the label?

22 A Minus 9 percent, and that was statistically significant.

23 Q Dr. Budoff, do clinicians prescribe Vascepa with the  
24 intent to achieve the apo B reductions compared to placebo  
25 control reflected in claim 8 of the '677 Patent?

1 A Yes.

2 Q In your experience, does the data show that patients  
3 experience those effects?

4 A Yes, and we have ample experience that this occurs in  
5 clinical practice.

6 Q So will the labeling -- the Vascepa labeling encourage  
7 clinicians to follow each step claimed in claim 8 of the '677  
8 Patent?

9 A Yes.

10 MR. M. KENNEDY: Let's go to PX 22.

11 BY MR. M. KENNEDY:

12 Q Dr. Budoff, do you recognize that document?

13 A Yes, it is U.S. patent 8,318,715.

14 Q Is this one of the patents you've analyzed in this case?

15 A Yes.

16 MR. M. KENNEDY: And this is on the pre-admitted  
17 exhibit list?

18 THE COURT: Yes. It's Exhibit 40?

19 MR. M. KENNEDY: Twenty-two.

20 THE COURT: Is this the '715 patent?

21 MR. M. KENNEDY: Yeah, I have PX 22.

22 THE COURT: On the stipulated exhibit list --  
23 oh, sorry, I'm looking at the file history. You're incorrect.

24 BY MR. M. KENNEDY:

25 Q Do you understand that Amarin is asserting claim 14 from

1 the '715 Patent?

2 A Yes.

3 MR. M. KENNEDY: And, Mr. Brooks, let's have  
4 PDX 2-40.

5 BY MR. M. KENNEDY:

6 Q And could you just describe what the notations on the  
7 right-hand side mean of this slide, PDX 2-40?

8 A And, again, for the same reasons that we've already  
9 discussed, the language is exactly the same or similar to  
10 those elements that we've already discussed in the claim 1 of  
11 the '728 Patent, so for the same reasons the elements will be  
12 met for claim 14 of the '715 patent.

13 Q Have you formed any opinions concerning whether the  
14 Vascepa label encourages clinicians prescribe Vascepa to  
15 effect a statistically significant reduction in triglycerides  
16 and apo B without effecting a statistically significant  
17 increase of LDL-C in the subject as required by claim 14 of  
18 the '715 patent?

19 A Yes.

20 Q And what is that opinion?

21 A That based on a lot of the discussion we've already had,  
22 that they will be encouraged to have these effects occur when  
23 they use -- when they follow the label for Vascepa or its  
24 generic proposed alternatives.

25 Q And, Dr. Budoff, do you understand the Court has

1 previously construed the term "without it effecting a  
2 statistically significant increase in LDL-C"?

3 A Yes.

4 MR. M. KENNEDY: And I think we've touched on  
5 this before, but, Mr. Brooks, if you could quickly pull up  
6 PDX 2-20.

7 BY MR. M. KENNEDY:

8 Q And directing you to the bottom claim term and  
9 construction, is this the construction of "without affecting a  
10 statistically significant increase in LDL-C" that you applied  
11 in forming your opinions?

12 A Yes.

13 MR. M. KENNEDY: Mr. Brooks if you could pull up  
14 PDX 2-40 again and put it alongside trial Exhibit 1186,  
15 page 2, the dosage and administration section.

16 BY MR. M. KENNEDY:

17 Q And directing your attention to 2.1, where the label  
18 instructs to assess lipid levels before initiating therapy, is  
19 this relevant to your opinions concerning the claim elements  
20 in claim 14 of the '715 Patent?

21 A Yes.

22 Q How so?

23 A We've already discussed this, but, again, it's not just  
24 telling you to assess triglyceride levels, it's telling you to  
25 assess the lipid panel before initiating therapy because



1 changes may occur in the lipid panel.

2 Q And if we could go to the clinical study section, and  
3 I -- you know, obviously we've looked at this a few times, but  
4 let me start with the claim language in this claim "in the  
5 subject."

6 Where in the clinical study section does the Vascepa  
7 label address levels in the subject?

8 A Again, that's in the baseline category that we discussed  
9 earlier under the word Vascepa.

10 Q And does the clinical study section reflect a  
11 statistically significant reduction in TGs and apo B compared  
12 to baseline?

13 A Yes.

14 Q How do you know it's a statistically significant  
15 reduction?

16 A The P values are listed there. You see the asterisks. P  
17 value for a single asterisk, which is the minus 33 percent for  
18 triglycerides, the P value is minus .001, and for the apo B,  
19 the double asterisk, minus 9 percent reflects a P value of  
20 .05. Both of those are considered statistically significant.

21 Q And does the clinical study section disclose an increase,  
22 statistically significant or otherwise, in LDL-C levels of the  
23 subject, or in the subject?

24 A No, LDL-C goes down by 2 percent or by 5 percent from  
25 baseline. Both of those are decreases. So a decrease is not

1 a statistically significant increase by definition.

2 Q And, to the best of your knowledge, do clinicians  
3 prescribe Vascepa with the intent to achieve the lipid effects  
4 and avoidance of the lipid effects recited in claim 14 of the  
5 '715 patent?

6 A Yes.

7 Q In your own experience, do your severely  
8 hypertriglyceridemic patients actually achieve effects of the  
9 type recited in claim 14 of the '715 patent?

10 A Yes.

11 Q And what is your expectation when you administer Vascepa  
12 to a severely hypertriglyceridemic patient in terms of the  
13 lipid effects those patients will experience?

14 A That the average patient, majority of my patients will  
15 achieve these lipid effects when I prescribe Vascepa.

16 Q So will the Vascepa labeling encourage clinicians to  
17 follow each step in the method claimed in claim 14 of the '715  
18 Patent?

19 A Yes, for all the reasons that we've discussed.

20 Q Let's go to PX 30. And, Dr. Budoff, do you recognize  
21 this document?

22 A Yes. This is U.S. patent 8,431,560.

23 Q And is this one of the patents you analyzed in forming  
24 your opinions in this case?

25 A Yes.

1 MR. M. KENNEDY: Your Honor, plaintiffs  
2 Exhibit 30 is on the preadmitted list.

3 THE COURT: Yes.

4 BY MR. M. KENNEDY:

5 Q Have you been informed that Amarin is asserting  
6 infringement of claims 4 and 17 from the '560 Patent?

7 A Yes.

8 MR. M. KENNEDY: And, Mr. Brooks, if we could  
9 have PDX 2-42.

10 BY MR. M. KENNEDY:

11 Q And, again, what does the notations in the Element Met  
12 column mean?

13 A So, again, just to reiterate, these are all -- all these  
14 elements have already been met based on our analysis of claim  
15 1 of the '728 Patent.

16 Q Have you formed any opinions concerning whether the  
17 Vascepa label encourages clinicians to prescribe Vascepa to  
18 patients with severe hypertriglyceridemia wherein the  
19 administering effects a reduction in fasting triglycerides of  
20 at least about 10 percent without increasing LDL-C by more  
21 than 5 percent in the subject?

22 A Yes.

23 Q And what is that opinion?

24 A As we've discussed already, the effects in the subject,  
25 the triglyceride reductions, will be fasting triglyceride

1 reductions, which is how the trials are done and how the  
2 methods are done, in practice, the fasting triglyceride levels  
3 will drop by 27 percent. So that's at least 10 percent.

4 LDL-C will go down by 5 percent in the subject,  
5 which is not a 5 percent increase, but rather a 5 percent  
6 decrease.

7 So all three of these elements will be met when  
8 physicians follow the label.

9 Q And, again, these are -- you're referring to the data in  
10 the clinical study section of the Vascepa label that we've  
11 looked at?

12 A Yes.

13 Q When you administer Vascepa to a severely  
14 hypertriglyceridemic patient, do you expect to achieve results  
15 of the type claimed by claim 4 of the '560 patent?

16 A Yes.

17 Q When you administer Vascepa to a patient, do you achieve  
18 effects of the type claimed by claim 4 of the '560 Patent?

19 A Yes.

20 Q To the best of your knowledge, do clinicians prescribe  
21 with the intent to achieve the results -- the lipid effects --  
22 the results of lipid effects claimed by claim 4 of the '560  
23 patent?

24 A Yes.

25 Q So will the labeling encourage clinicians to follow each

1 step in the method claimed in claim 4 of the '560 patent?

2 A Yes.

3 MR. M. KENNEDY: Okay. Then let's please look  
4 at PDX 244.

5 BY MR. M. KENNEDY:

6 Q And, again, is this asserted claim 17 of the '560 patent?

7 A Yes.

8 Q And what are you denoting with the notations in the  
9 Element Met column?

10 A Similar to the last few claims, again, these are the same  
11 language that was used and elements that were met based on the  
12 same analysis for claim 1 of the '728 Patent.

13 Q Have you formed any opinions concerning whether the  
14 Vascepa label encourages clinicians to prescribe Vascepa and  
15 expect to achieve effecting a reduction in fasting  
16 triglycerides of at least about 20 percent without increasing  
17 LDL-C in the subject compared to placebo control as required  
18 by claim 17 of the '560 Patent?

19 A Yes.

20 Q What is that opinion?

21 A That physicians following the label will see more than a  
22 20 percent drop in fasting triglycerides, it dropped by  
23 33 percent compared to control.

24 So that element will be met when they follow the  
25 label and look at the clinical trials section, they will see

1 that there is no increase in LDL-C compared to placebo  
2 control. So all of these elements will be met as physicians  
3 follow the label.

4 Q Dr. Budoff, do you administer Vascepa with the intent to  
5 effect reductions in fasting triglycerides of about 20 percent  
6 without increasing LDL-C in the subject compared to placebo  
7 control as required by claim 17 of the '560 patent?

8 A Yes.

9 Q When you administer Vascepa to patients with STG, do they  
10 achieve results in line with those required by claim 17 of the  
11 '560 patent?

12 A Yes.

13 Q Do other physicians prescribe Vascepa with the intent to  
14 achieve the lipid results claimed in claim 17 of the '560  
15 patent?

16 A Yes.

17 Q So, in your opinion, will the Vascepa labeling encourage  
18 clinicians to follow each step in the method claimed by claim  
19 17 of the '560 patent?

20 A Yes.

21 Q And then let's go to the PX 31, and this is -- Dr.  
22 Budoff, do you recognize this document?

23 A Yes, this is U.S. patent 8,518,929.

24 Q And is this one the patents you analyzed in forming your  
25 opinions in this case?

1 A Yes.

2 Q You understand that Amarin is asserting claims 1 and 5  
3 from this patent?

4 A Yes.

5 MR. M. KENNEDY: And, Mr. Brooks, can we go to  
6 slide PDX 2-46.

7 BY MR. M. KENNEDY:

8 Q And, Dr. Budoff, what have you shown on this slide?

9 A So, again, as previously stated, all of the elements will  
10 be met using the same analysis as claim 1 of the '728 Patent.

11 Q Does the Vascepa label instruct daily administration of  
12 Vascepa?

13 A Yes.

14 Q Daily administration of 4 grams of a pharmaceutical  
15 composition?

16 A Yes.

17 Q And will the labeling -- will the Vascepa labeling  
18 encourage clinicians to follow each step in the method of  
19 claim 1 of the '929 patent?

20 A Yes.

21 Q And then slide 2-47, this is claim -- asserted claim 5 of  
22 the '929 patent.

23 And, again, Dr. Budoff, can you just very briefly  
24 explain what this slide shows.

25 A Yes. So, again, the elements we just discussed in claim

1 are met by the analysis of claim 1 on the previous slide,  
2 and now there's two new elements here, "effective to reduce  
3 apolipoprotein B in subjects."

4 Q Have you formed any opinions concerning whether the  
5 Vascepa label encourages clinicians to administer Vascepa to  
6 patients with severe hypertriglyceridemia effective to reduce  
7 apolipoprotein B in subjects?

8 A Yes.

9 Q And what is that opinion?

10 A That the apolipoprotein B goes down in subjects as seen  
11 in table 2 of the label, and physicians will be encouraged to  
12 use Vascepa to reduce apolipoprotein B in their subjects.

13 MR. M. KENNEDY: And since we haven't looked at  
14 apolipoprotein B quite as much today, Mr. Brooks, can we pull  
15 up table 2 alongside this slide.

16 BY MR. M. KENNEDY:

17 Q And, Dr. Budoff, does table 2, the clinical study section  
18 of the Vascepa label, support your opinion that the label will  
19 encourage clinicians to administer Vascepa to reduce  
20 apolipoprotein B in subjects?

21 A Yes, you can see that. Compared to baseline there was a  
22 minus 4 percent reduction in apo B, and the overall difference  
23 compared to placebo control is minus 9 percent, and it's  
24 called out again in the sentence below the table, Vascepa 4  
25 grams per day reduced median TG, VLDL-C, and apo B levels from



1 baseline relative to placebo.

2 Q Dr. Budoff, do you prescribe Vascepa with the intent to  
3 reduce apolipoprotein B?

4 A Yes.

5 Q When you prescribe Vascepa, do you observe reductions in  
6 apolipoprotein B in your patients?

7 A Yes.

8 Q To your knowledge, do other clinicians prescribe Vascepa  
9 with the intent to reduce apolipoprotein B in the expectation  
10 that those reductions will be achieved?

11 A Yes.

12 Q So will the Vascepa labeling encourage clinicians to  
13 follow each step in the method claimed by claim 5 of the '929  
14 patent?

15 A Yes.

16 Q And as with all the other Vascepa label related  
17 questions, if I ask you with respect to the Hikma and DRL  
18 labels, would your answer be the same?

19 A Yes.

20 MR. M. KENNEDY: So I have no further questions  
21 for the witness at this time.

22 THE COURT: Thank you, Mr. Kennedy.

23 MR KLEIN: Your Honor, do you want to break or  
24 keep going?

25 THE COURT: Well, if I had my preference, we

1 would keep going, but I think we should take a lunch break at  
2 this time, so let's take a 30-minute lunch break. Thank you.

3 (The noon recess was taken.)

4 --o0o--

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1 RENO, NEVADA, TUESDAY, JANUARY 14, 2020, 1:04 P.M.

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3  
4 THE COURT: Please be seated.

5 Mr. Klein?

6 MR KLEIN: Thank you, Your Honor.

7 Good afternoon, Dr. Budoff.

8 THE WITNESS: Afternoon.

9 MR. KLEIN: We obviously met at your deposition,  
10 but, for the record, I'm Charles Klein, and I will be asking  
11 you some questions on behalf of the defendants.

12 CROSS-EXAMINATION

13 BY MR. KLEIN:

14 Q Each asserted patent in this case requires using  
15 icosapent for at least 12 weeks. You understand that, right?

16 A Yes.

17 Q Okay. And defendants' product labels do not specifically  
18 encourage using icosapent for at least 12 weeks, correct?

19 A No, they do.

20 Q They specifically encourage using icosapent for at least  
21 12 weeks?

22 A Yes.

23 Q Okay. Let's take a look at the indication. And for the  
24 record, you recognize the top snapshot as DX 2248? That's the  
25 Vascepa MARINE indication?

1 A Yes.

2 Q Okay. And we're not going to talk about -- you  
3 understand there's a new indication, right?

4 A Yes.

5 Q Okay. We're not going to talk about that other  
6 indication today so if I refer simply to the Vascepa  
7 indication, can we understand that we're talking about the  
8 MARINE indication?

9 A Yes.

10 Q Okay. And then we have the Hikma indication, which is  
11 DX 2256, and the DRL indication which is DX 2266, and I  
12 believe on direct you testified that these three indications  
13 are materially identical, correct?

14 A Yes.

15 Q All right. Neither the Vascepa indication nor  
16 defendants' indications is actually telling doctors to use the  
17 drug for at least 12 weeks, right?

18 A It does not state 12 weeks, that's correct.

19 Q Right. Right. And if we look at the dosage and  
20 administration section, and here I've got the Hikma label,  
21 DX 2256, on the screen, but do you understand that the DRL  
22 label is materially identical?

23 A Yes.

24 Q Okay. And the dosage and administration section in  
25 defendants' labels doesn't specify any duration of treatment,

1 correct?

2 A Correct.

3 Q And so defendants' dosage and administration section  
4 doesn't specifically encourage using icosapent for at least  
5 12 weeks, right?

6 A Correct.

7 Q In fact, there's no explicit instruction in the Vascepa  
8 label or in defendants' labels to use icosapent for at least  
9 12 weeks, right?

10 A No, there is explicit language.

11 Q There -- listen carefully to the question, please.

12 Is there -- there is no explicit instruction  
13 anywhere in the Vascepa label or in defendants' labels telling  
14 doctors to use icosapent for at least 12 weeks.

15 A There is explicit language in the Hikma and DRL labels  
16 instructing physicians to use Vascepa or icosapent ethyl for  
17 12 weeks.

18 Q So what language are you referring to?

19 A The clinical trials section.

20 Q Okay. We'll get to that later, but the clinical trials  
21 section is describing a 12-week study, the MARINE study,  
22 right?

23 A Well, I was just trying to answer your question.

24 My understanding of the infringement is the label  
25 taken in its entirety. So when you ask me does the label

1 state 12 weeks, and I say yes, I believe I'm correct.

2 Q And we'll get to the clinical trial section later in the  
3 examination, but just to make sure we're on the same page, the  
4 clinical trial section of defendants' labels does not say,  
5 doctors, you should give the drug for at least 12 weeks. Can  
6 we agree on that?

7 A It does not say those words, that's correct.

8 Q And instead, the Vascepa label, as well as defendants'  
9 labels, leave it entirely up to the physician's discretion to  
10 determine the duration of treatment, correct?

11 A Yes.

12 Q Now, so, what that means is defendants' labels will allow  
13 doctors to tailor treatment duration to the individual  
14 patients, correct?

15 A Yes, but they have to be concordant with the disease  
16 that's indicated.

17 Q Right. Of course. But doctors can follow defendants'  
18 labels and prescribe icosapent indefinitely if they want.  
19 That's your opinion, right?

20 A Yes.

21 Q But a doctor could also prescribe icosapent for only ten  
22 weeks, if that's what's called for, for the particular patient  
23 and the patient concerns, correct?

24 A I can't imagine that scenario, but if that scenario  
25 existed, then yes, I agree.

1 Q Okay. Then we'll come back to that.

2 Either way, the labeling gives this decision, the  
3 treatment duration, to the doctor to make, right?

4 A Yes.

5 Q And so it would be entirely consistent with defendants'  
6 labels for a doctor to prescribe icosapent for less than  
7 12 weeks, right?

8 A Yes.

9 Q Now, we talked about how there's no explicit instruction  
10 in the labels that actually tells doctors you should use  
11 icosapent for at least 12 weeks. Do you remember that?

12 A Yes. I believe I feel there is explicit language, and  
13 you feel there is not. But, yes, I remember that previous  
14 discussion we just had.

15 Q Okay. But I think you said there's no explicit language  
16 that actually tells doctors you should use this product for at  
17 least 12 weeks, correct?

18 A Your quote is not in the label, I agree with that.

19 Q Right. You're referring to the 12 weeks term in the  
20 clinical studies section, right?

21 A Yes, which I believe instructs physicians to use it for  
22 12 weeks.

23 Q Okay. So your opinion really is, when doctors read the  
24 label as a whole, including the 12 weeks statement in the  
25 clinical studies section, that will apply to doctors that they

1 should go ahead and use the drug for at least 12 weeks, right?

2 A Yes.

3 Q On the screen is DX 2256 and, for the record, it's  
4 DDX 3.3. This is -- you recognize this as the indications and  
5 usage section of Hikma's proposed label, right?

6 A Yes.

7 Q And, obviously, as -- the indication is for severe  
8 hypertriglyceridemia, right?

9 A Yes.

10 Q And your opinion is that doctors know that this is a  
11 chronic condition?

12 A Yes.

13 Q Okay. And your opinion is that the condition, severe  
14 hypertriglyceridemia, requires indefinite drug therapy, right?

15 A Yes.

16 Q Okay. I want to make sure I understand what you're  
17 saying. Are you saying that doctors will read defendants'  
18 indication as necessarily, in all circumstances, requiring  
19 indefinite treatment?

20 A No.

21 Q And why do you say no?

22 A Well, not everybody can tolerate therapy forever so we  
23 never use absolutes, but I would say doctors will read this  
24 label and say, oh, severe hypertriglyceridemia, that's a  
25 chronic condition, I'm going to treat this chronically.



1           To say that in every case they use it indefinitely  
2 is, obviously, not possible. Some patients don't tolerate  
3 therapy, some patients can't get therapy, so we can't use  
4 absolutes when we talk about what a person of ordinary skill  
5 in the art will do in a given situation.

6       Q    Okay. And we'll come back to that concept.

7           I want to direct you to paragraph 357 of plaintiffs'  
8 proposed findings of fact, and this is ECF number 331.

9           You probably haven't seen this, but I will represent  
10 to you that this is a statement from plaintiffs' to the Court  
11 last week, and in this proposed findings of fact, plaintiffs  
12 propose that the Court find that clinicians will read  
13 defendants' labeling with the understanding that severe  
14 hypertriglyceridemia is almost invariably a chronic condition.

15           Do you see that?

16       A    Yes.

17       Q    And as a matter of linguistics, almost invariably isn't  
18 always, right?

19       A    Correct.

20       Q    Okay. And so is this consistent with your testimony that  
21 it's almost invariably a chronic condition?

22       A    Yes.

23       Q    Okay. And so you're not testifying that severe  
24 hypertriglyceridemia is always a chronic condition, correct?

25       A    Correct.

1 Q And do you understand that defendants' labels never  
2 actually say that severe hypertriglyceridemia is a chronic  
3 condition, right?

4 A Yes. I think Dr. Ketchum went through that yesterday.

5 Q Yeah, I was just going to bring that up. You were here,  
6 right?

7 A Yes.

8 Q And you understood that there was a proposal to the FDA  
9 from Amarin to characterize the Vascepa patient population as  
10 requiring chronic care, but FDA rejected that, right?

11 A Yes.

12 Q But your opinion is that a doctor would see the  
13 indication and understand that severe hypertriglyceridemia is  
14 very often a chronic condition, right?

15 A Yes.

16 Q Okay. And so what you're really saying is that a doctor  
17 knows that severe hypertriglyceridemia can be a chronic  
18 condition, not that it always is a chronic condition, right?

19 A I think we keep changing the adjectives, but why don't we  
20 stick with almost invariably just to be concise because we've  
21 gone from almost invariably now to can.

22 Q Okay.

23 A Which I think is a pretty broad change in terminology.  
24 So I'll stick with this language as language that I'm  
25 comfortable with.

1 Q Okay. Well, you agree it's not always a chronic  
2 condition, right?

3 A That's correct.

4 Q So just as a matter of logic, what you're saying is it  
5 can be. Now, in your view, it is almost invariably, but  
6 you're really saying it can be a chronic condition, correct?

7 A It is a chronic condition in almost all cases, but not  
8 all cases.

9 I described the reversible causes earlier, diabetes  
10 out of control, binge drinking, hypothyroidism, as other  
11 causes that can push people up into the severe  
12 hypertriglyceridemic range that would not be considered a  
13 chronic condition.

14 Q Okay. Thanks. You're getting to my next point.

15 So you were here for opening statements as well,  
16 right?

17 A Yes.

18 Q And did you see this testimony from Dr. Toth during the  
19 opening statements?

20 A Yes.

21 Q And you know who Dr. Toth is, right?

22 A Yes.

23 Q You understand he's one of Amarin's experts in this case.

24 A Yes, I know Dr. Toth.

25 Q Yeah, you actually know him otherwise as --

1 A Yes, we are -- we are on different guidelines and  
2 committees together.

3 Q And so you saw that Dr. Toth testified in his deposition  
4 that there would be circumstances where very high  
5 triglycerides was an acute phenomenon, right?

6 A Yes.

7 Q And you agree with that?

8 A Yes, for the reasons I've already stated.

9 Q Right. And that's what you meant by the reversible  
10 causes?

11 A Yes.

12 Q Okay. And doctors would know from reading defendants'  
13 indications that sometimes severe hypertriglyceridemia can be  
14 an acute phenomenon, right?

15 A Yes.

16 Q Did you also see this testimony from Dr. Peck?

17 A Yes.

18 Q Do you know Dr. Peck?

19 A No, not outside of this context.

20 Q Okay. But you understand that Dr. Peck is Amarin's  
21 regulatory expert in this case?

22 A Yes.

23 Q And so you saw that Dr. Peck said he doesn't think that  
24 the indicated use of Vascepa is limited to chronic use, right?

25 A Yes.

1 Q Okay. And you're not an expert in FDA regulations,  
2 correct?

3 A Correct.

4 Q So you agree with Dr. Peck's testimony when he says, "I  
5 don't think the indicated use of Vascepa is limited to chronic  
6 use." Correct?

7 A I disagree with that.

8 Q You disagree with what -- so you think Dr. Peck is not  
9 accurately characterizing the indication from an FDA  
10 regulatory perspective?

11 A I didn't have a chance to discuss with Dr. Peck. It  
12 would be -- I don't know, I think you guys throw around the  
13 word hearsay -- for me to take this at face value without any  
14 context.

15 But I believe, if you're asking my opinion, that the  
16 current indicated use of Vascepa, you're supposed to  
17 systematically eliminate all of the acute causes, that's  
18 clearly listed in the label, and then the resultant treatment,  
19 the resulted indication for Vascepa is, after you've removed  
20 all of the acute indications, you use Vascepa which would  
21 leave only chronic use.

22 So my reading of the label -- and I'm not arguing  
23 with Dr. Peck, but my reading of the label is that the current  
24 indicated use of Vascepa is for the resultant people who have  
25 genetic problems, and thus it is a chronic condition.

1 Q Okay.

2 A So it's only indicated to -- for chronic use.

3 Q And we'll unpack that a bit.

4 But what I'm getting at here is you're offering that  
5 opinion from the perspective of a physician who will apply the  
6 label, correct?

7 A Yes.

8 Q Okay. And do you understand that Dr. Peck is offering an  
9 opinion from the perspective of what FDA approved?

10 A Yes. Again, I wasn't there. I didn't read Dr. Peck's  
11 full deposition transcript. I see it referenced here, so I  
12 really don't think I can speak to this one sentence.

13 But my opinion is I agree with Dr. Peck on this one  
14 question. I would answer it differently.

15 Q Okay. But you are not an FDA regulatory expert, right?

16 A That's been established.

17 Q And you're not expert in FDA labeling, right?

18 A That's been established.

19 Q So if Dr. Peck testifies from the FDA perspective that  
20 FDA did not limit the indication to chronic use, you would  
21 have no basis to dispute that, correct?

22 A I would not argue with Dr. Peck on the FDA, but I believe  
23 we already heard about the FDA, and it said should it be used  
24 for acute use, and the answer was not applicable.

25 So, again, my reading from yesterday, and my

1 understanding of what the FDA already opined on, is that it's  
2 not appropriate for acute use because they said not  
3 applicable. That was in the questions in the FDA documents  
4 that were presented yesterday.

5 But, again, I'm not going to get into an FDA  
6 argument with Dr. Peck.

7 Q And just to be clear, you're referring to the form that  
8 was used in Dr. Ketchum's testimony?

9 A Yes.

10 Q You did not offer any opinions on that form in your  
11 report, correct?

12 A No.

13 Q And you're not offering any opinions on that form today,  
14 correct?

15 A I'm only trying to answer your question as best I can.

16 Q Okay. But -- so you say you disagree with Dr. Peck at  
17 least from a physician perspective, but you do agree it would  
18 be consistent with the Vascepa labeling for a doctor to  
19 prescribe Vascepa for fewer than 12 weeks, correct?

20 A Yes.

21 Q Let's go back to the indication, and, again, I'm using  
22 Hikma's indication for simplicity, but you understand DRL's  
23 indication is the same, right?

24 A Yes.

25 Q And we talked about this a moment ago.

1           You are relying on the term severe  
2 hypertriglyceridemia in the indication as signaling to doctors  
3 that they should use the drug long-term, correct?

4     A    Yes.

5     Q    Okay. Now, let's focus on that term.

6           The term severe hypertriglyceridemia has a  
7 well-known meaning to doctors who treat the condition, right?

8     A    Yes.

9     Q    And the meaning of severe hypertriglyceridemia is  
10 actually in the indication. It means greater than or equal to  
11 500 milligrams per deciliter, right?

12    A    Yes.

13    Q    And that's it. That's -- that's the definition of severe  
14 hypertriglyceridemia, right?

15    A    Well, no. I mean, there's definitions of diseases. This  
16 is not a definition. This is just stating the term, severe  
17 hypertriglyceridemia.

18           But, yes, it's characterized by triglycerides  
19 greater than 500 milligrams per deciliter in the blood in the  
20 fasting state. But, yes, that's -- that's what I construe to  
21 be severe hypertriglyceridemia.

22    Q    Right. And that is how doctors diagnose severe  
23 hypertriglyceridemia. They have a blood test taken, and if  
24 the triglycerides are above 500, then the doctors conclude the  
25 patient has severe hypertriglyceridemia, right?



1 A Yes.

2 Q Okay. And severe hypertriglyceridemia has various  
3 causes, right?

4 A Yes.

5 Q And the diagnosis of severe hypertriglyceridemia does not  
6 turn on the cause, right?

7 A That's correct.

8 Q So as long as the patients have triglyceride levels above  
9 500, regardless of why, they have severe hypertriglyceridemia.

10 A Just to be concise, I would say fasting triglycerides  
11 greater than 500, that's the definition.

12 Q And that's a fair point. And let's just assume, when we  
13 talk about the triglyceride levels, that we're talking about  
14 fasting levels. I think that's a fair characterization.

15 And doctors know that when patients have  
16 triglycerides above 500, the goal is to prevent an acute  
17 pancreatitis attack, right?

18 A Yes.

19 Q Okay. And so the indication is signaling to doctors that  
20 if the patient has triglycerides above 500, no matter the  
21 cause, that icosapent can be used in that patient, right?

22 A No, that's not how I read the label. I read the label as  
23 you must exclude acute causes, and then you would use Vascepa.  
24 That's how I read the label, and that's how I believe  
25 physicians read the label.

1 Q Okay. And you're referring to the dosage and  
2 administration section, right?

3 A Yes. But when you say the label, I'm taking the label --  
4 again, my understanding of infringement is the label taken in  
5 its entirety.

6 So I don't think it would be fair to say, "Doctor,  
7 you're only allowed to read the first line. Now what do you  
8 want to do with your patient?"

9 Q Okay. No. And that's a fair point, Doctor, and we'll  
10 get to the dosage and administration section, but for now  
11 let's focus on the indication itself.

12 A doctor looking at the indication would understand  
13 that if the patient presents with triglycerides over 500, then  
14 icosapent can be used in that patient subject to, you know,  
15 other instructions in the label, correct?

16 A Yes.

17 Q And a doctor would understand that if icosapent is being  
18 used, it will be used as an adjunct to diet, right?

19 A Yes.

20 Q And the hope is that using icosapent as an adjunct to  
21 diet will avoid pancreatitis.

22 A Yes.

23 Q All doctors who treat severe hypertriglyceridemia  
24 understand when they read the indication of Vascepa or  
25 defendants' labels, that that's the goal of using the drug,

1 right?

2 A That is at least the primary goal, yes.

3 Q Yes. Well, okay.

4 Let's go to the ATP III guidelines, and you talked  
5 about this on direct, right?

6 A Yes.

7 MR. KLEIN: And, for the record, this is  
8 DX 1526, page 28, and the document has been admitted into  
9 evidence.

10 BY MR. KLEIN:

11 Q Now, the ATP guidelines explain that when triglycerides  
12 are very high, greater than or equal to 500, the initial aim  
13 of therapy is to prevent acute pancreatitis through  
14 triglyceride lowering, and you agree with that, right?

15 A Yes.

16 Q Okay. And that's the primary treatment aim regardless of  
17 why the patient has triglycerides above 500, right?

18 A Yes.

19 Q If we go to the next slide, which is DDX 3.9, we're on  
20 DX 1526, page 28, the guidelines go on to say this approach --  
21 in other words, the aim of preventing acute pancreatitis  
22 through triglyceride lowering -- requires very low fat diets,  
23 weight reduction, increased physical activity, and usually a  
24 triglyceride-lowering drug, and I omitted the parentheticals,  
25 right?

1 A Yes.

2 Q And this approach is consistent with your own practice,  
3 right?

4 A Yes, except they don't stipulate -- they don't -- this is  
5 pre-2002, this was pre-Vascepa, so the only two choices given  
6 here are fibrate and nicotinic acid, and now we have two other  
7 drugs that are for this indication. But, yes.

8 Q Okay. Yeah. Putting aside the specific drugs, this  
9 statement in the ATP III guidelines is consistent with your  
10 practice, right?

11 A Yes.

12 Q And to be clear, the guidelines here say the approach  
13 focuses on diet, weight reduction, increased physical  
14 activity, and usually a triglyceride-lowering drug, right?

15 A Yes.

16 Q Okay. And the guidelines don't tell doctors if patients  
17 present with severe hypertriglyceridemia, you should always  
18 use drug therapy, correct?

19 A That's correct.

20 Q And that, too, is consistent with your own practice,  
21 right?

22 A Yes.

23 Q Okay. Let's go to the next slide, and I'm just  
24 highlighting a different sentence on the same page.

25 The guidelines then say only after triglyceride

1 levels have been lowered to less than 500 milligrams per  
2 deciliter should attention turn to LDL lowering to reduce risk  
3 for CHD, right?

4 A Yes.

5 Q And, in other words, once the triglyceride -- once the  
6 triglyceride levels in a patient dip below 500, you become  
7 less concerned about pancreatitis and your focus turns to  
8 cardiovascular treatment, correct?

9 A Yes, and I've tried to outline that today in the direct  
10 testimony as well.

11 Q Okay. And I think you talked about this as well, this is  
12 how the ATP III characterizes the different levels of  
13 triglycerides, right?

14 A Yes.

15 Q Okay. And high triglycerides are 200 to 499, right?

16 A Yes.

17 Q Okay. And some patients are in this range, the high  
18 triglyceride range, because of generic -- genetic factors,  
19 correct?

20 A Yes.

21 Q And -- but even if a patient has triglycerides over 500,  
22 and you're able to reduce the pancreatitis risk by getting the  
23 triglycerides into the very high -- into the high triglyceride  
24 range, you still want to get those levels lower, right?

25 A I think we know a lot more now also given the results of

1 the REDUCE-IT trial. But, yes, I think that is -- still I  
2 would still like to get the triglycerides lower than 499.

3 Q You would like to get them lower than 200, right?

4 A Yes.

5 Q But that goal, that desire, is based on cardiovascular  
6 risk, not pancreatitis risk, correct?

7 A That's correct.

8 Q And you understand that the goal with regard to severe  
9 hypertriglyceridemia is not -- the primary goal is not to  
10 reduce cardiovascular risk but to reduce the acute  
11 pancreatitis risk, right?

12 A Yes.

13 Q Okay. And defendants' products are not indicated to  
14 reduce triglycerides in patients who have baseline levels  
15 below 500, right?

16 A Correct.

17 Q And so a doctor using Vascepa or defendants' products,  
18 should they come to market, solely to reduce cardiovascular  
19 risk would be using icosapent off label, again, ignoring the  
20 new REDUCE-IT indication.

21 A Yes.

22 Q And so you understand defendants' products are not  
23 indicated to improve cardiovascular outcomes, right?

24 A Correct.

25 Q And you also understand -- although I don't think it came

1 up during your direct, but you understand that defendants are  
2 carving out this second REDUCE-IT indication from their  
3 proposed labels, right?

4 A Yes.

5 Q Now, we talked about how there can be various causes of  
6 very high triglycerides, right?

7 A Yes.

8 Q And most commonly severe hypertriglyceridemia is caused  
9 by unhealthy diet and poor lifestyle choices, right?

10 A No, most commonly it's caused by genetics. We've  
11 reviewed that, I think, a few times.

12 Q Now, when you say genetics, there are really two  
13 different types of genetic -- genetic causes of severe  
14 hypertriglyceridemia. For example, there are some genetic  
15 causes that, no matter what you do with diet and exercise, you  
16 are absolutely going to need drugs, correct?

17 A Yes.

18 Q And these patients generally have triglycerides well  
19 above 500, right?

20 A The more severe the genetic abnormality, the higher the  
21 triglyceride levels will go, yes.

22 Q I mean, we're talking sometime 1,000 or even 2,000,  
23 correct?

24 A Yes.

25 Q Okay. And the -- these conditions include familial

1 hypertriglyceridemia; is that right?

2 A Yes.

3 Q And familial combined hyperlipidemia; is that right?

4 A That's usually represented by -- combined implies that  
5 multiple di -- there's multiple problems and usually the  
6 triglycerides are not as high and their LDL, their bad  
7 cholesterol is also high.

8 So there are, again -- I mean, I listed some of  
9 the -- I think scientific statement from the American Heart  
10 Association talked about the seven most common genetic  
11 abnormalities.

12 Q Okay. And another one is defects in lipoprotein lipase  
13 or apo C-2, right?

14 A Yes.

15 Q Okay. But these types of genetic disorders where the  
16 patients have triglycerides at the 1,000, 2,000 level, these  
17 are pretty rare, right?

18 A Some of those specific ones are pretty rare, but some of  
19 them are what we call incomplete transmissions.

20 So, for example, somebody could have a triglyceride  
21 level 550 or 600, and if we were to do genetic testing, we  
22 might find that they have a partial -- partial expression of  
23 that problem.

24 In other words, they don't have to be pure -- kind  
25 of like not be purebreds per se in the regard to that



1 disorder. But the patients who have pure genetic disorders,  
2 they tend to have very high triglycerides as you're  
3 describing.

4 Q And that is rare.

5 A That is rare.

6 Q Okay. Now, with regard to the patient population who has  
7 very high triglycerides, it's less rare for patients to have a  
8 genetic predisposition to high triglycerides, and then there  
9 are other factors that cause them to go above 500. Is that  
10 fair?

11 A Yes.

12 Q Okay. And that's where diet and lifestyle can come into  
13 play.

14 A Yes.

15 Q All right. Okay. Let's go to slide DX 3.13, which is  
16 DX 1982, and I don't believe this is in evidence, so I would  
17 move -- do you recognize this as Amarin's website for Vascepa?

18 A I don't know if I've seen this, but I would take your  
19 word for it that it is. It looks like it.

20 MR KLEIN: I move to admit DX 1982.

21 MR. M. KENNEDY: No objection, Your Honor.

22 THE COURT: That request is granted.

23 (Defendants' Exhibit 1982 received in  
24 evidence.)

24 BY MR. KLEIN:

25 Q Now, here you can see that -- and I'll represent to you

1 that we took this from Vascepa.com, and you'll see that the  
2 title of this portion of the web page says what are the  
3 causes?

4 A Yes.

5 Q And according to Amarin's Vascepa website, there are five  
6 causes listed, right?

7 A There are five listed here, yes.

8 Q And the first one is diet. Do you see that?

9 A Yes.

10 Q And I circled "especially alcohol." You agree that diet,  
11 especially alcohol, with be a cause of severe  
12 hypertriglyceridemia, right?

13 A Yes.

14 Q Okay. And the second one is lack of exercise, that's  
15 also a common cause of severe hypertriglyceridemia?

16 A It tends to be a contributing factor. I think -- I don't  
17 think lack of exercise by itself is considered a primary  
18 cause, but I think it would contribute so we recommend  
19 exercise to help lower triglycerides.

20 Q It's normally discussed in combination with diet. Is  
21 that fair?

22 A Yes.

23 Q And then the third cause is medical conditions, right?

24 A Yes.

25 Q And I think you talked about that, for example, a patient

1 could have diabetes and that might cause severe  
2 hypertriglyceridemia?

3 A Yes.

4 Q But if the diabetes is controlled, that might address the  
5 severe hypertriglyceridemia.

6 A That is the guidelines and my recommendation, yes.

7 Q Okay. And then there's specific drugs. I think talked  
8 about that as well, right?

9 A Yes.

10 Q And we'll get back to that.

11 And then genetics is the fifth cause listed on  
12 Vascepa.com, right?

13 A Right.

14 Q Now, the defendants' indication and labels are not  
15 limited to addressing the genetic issues that we talked about  
16 that can cause triglycerides to be way up in the 1,000, 2,000  
17 area, right?

18 A That's correct.

19 Q Yeah. Defendants' labels would include very high  
20 triglycerides caused by any of these five factors, diet,  
21 exercise, medical condition, specific drugs, or genetics,  
22 correct?

23 A No.

24 Q Okay. So you're saying that the Vascepa.com website is  
25 incorrect?

1 A No. Vascepa -- this is saying what are causes of very  
2 high triglycerides, and they list five different causes.

3 The label, and, again, the label taken in its  
4 entirety, tells you to address diet and exercise first and  
5 eliminate those causes, to address medical conditions and  
6 eliminate those causes, to look for specific drugs and  
7 eliminate those causes; and then, if their triglycerides are  
8 still high, to treat.

9 So if you looked at your chart and you crossed out  
10 those other four, the only thing left to use Vascepa on label  
11 would be genetics.

12 Q Okay. I want to make sure I understand this testimony.

13 You're saying that the indication requires doctors  
14 to eliminate the first four causes on Vascepa.com, diet,  
15 exercise, medical conditions, specific drugs, and use the drug  
16 only if genetics is the sole cause. Is that your testimony?

17 A No, I'm saying that the label eliminates those other 4,  
18 and then says if severe hypertriglyceridemia still exists, you  
19 then prescribe Vascepa.

20 Q Are you saying, Doctor, that if -- if a patient presents  
21 to a physician, and has triglycerides of 550, and the doctor  
22 says, "I -- I want you to go on a diet, and I want you to  
23 exercise, and I want you to start Vascepa right away," you're  
24 saying that's an off-label use?

25 A No. You're supposed to institute diet and exercise first

1 and then Vascepa.

2 Q Okay. But it's not an off-label use if the doctor at  
3 that first visit says, "I want you to change your diet, I want  
4 you to exercise, and I want you to fill this prescription,"  
5 right, sir?

6 A I mean, you can interpret that as saying, well, I said  
7 the word diet and exercise first so it preceded it, but that's  
8 not the intent of the FDA nor the guidelines. The guidelines  
9 say institute diet and exercise and then prescribe Vascepa.

10 So instituting, to me, is not saying, "Mr. Johnson,  
11 you should really eat better. Here's a prescription."

12 I don't believe that meets the term institute, and  
13 it's not how the guidelines are written. We just went through  
14 the ATP III guidelines. They say to address diet first and  
15 then prescribe Vascepa.

16 And I think the label is pretty clear in that  
17 language that you should institute diet and exercise first  
18 before initiating Vascepa.

19 There's literally a section, 2.1, that says what to  
20 do before initiating Vascepa. So it's telling you to do that  
21 specifically. That's not my interpretation. That's got to be  
22 the exact way that the label is encouraging physician's use.

23 Q Okay. Well, let's start with this. The Vascepa labeling  
24 is not limited to reducing triglycerides in patients who have  
25 a genetic predisposition to high triglycerides, right?

1 A That's true.

2 Q Okay. And nothing in the Vascepa label discusses genetic  
3 causes of severe hypertriglyceridemia?

4 A That's true.

5 Q And the cause of severe hypertriglyceridemia in most  
6 patients is not solely genetics, right?

7 A Well, again, by the time we get to -- we're talking about  
8 on-label use, I believe it is largely genetics. If we're  
9 talking just about anybody who has ever had a fasting  
10 triglyceride of 501 more, or 500 or more, that could be a  
11 combination of factors, I agree with you.

12 Q Okay. Let's put aside whether it's on-label or off-label  
13 now, and we'll talk turn that next.

14 A Sure.

15 Q Just doctors understand that when patient -- the patient  
16 population that has very high triglycerides, a large portion  
17 of that population has very high triglycerides for reasons not  
18 solely related to genetics. Fair?

19 A Yes.

20 Q Okay. In fact, at least a third of the patient  
21 population with severe hypertriglyceridemia has the condition  
22 for reasons not solely related to genetics, right?

23 A I think that would probably be correct. Yes.

24 Q And the other causes would include things like diet and  
25 exercise are not ideal, correct?

1 A Yes.

2 Q Okay. Let's go to -- let's fast forward and go to the  
3 dosage and administration section because that's what you were  
4 focusing on.

5 Okay. And this is DX 2256 for the record.

6 Do you recognize this as the dosage and  
7 administration section from Hikma's proposed label?

8 A Yes.

9 Q And you testified that the dosage and administration  
10 section instructs doctors to eliminate other causes of high  
11 triglycerides before prescribing icosapent, right?

12 A Yes.

13 Q Okay. Let's walk through what each section says. The  
14 title -- and I'm focusing on 2.1. That's what you're focusing  
15 on, right?

16 A Yes.

17 Q The title says Prior to Initiation of Icosapent Ethyl,  
18 right?

19 A Yes.

20 Q And then the first thing it says to do is assess lipid  
21 levels before initiating therapy, and I think you testified  
22 that, you know, that's -- that just makes sense, it's  
23 standard, you have to take a test, right?

24 A Yes.

25 Q Okay. Then it says identify other causes, e.g.,

1 diabetes, hypothyroidism, or medications of high triglyceride  
2 levels, and manage as appropriate, right?

3 A Yes.

4 Q So this is telling doctors look to see if there are other  
5 causes, right?

6 A Yes.

7 Q And if the doctors identify other causes, the label  
8 leaves it up to the discretion of the doctor to manage as the  
9 doctor feels is appropriate, right?

10 A Yes.

11 Q Okay. The label is not telling, in this first bullet,  
12 the label is not telling doctors don't give icosapent yet,  
13 address those other factors first. Agreed?

14 A Correct.

15 Q Okay. And that bullet certainly isn't saying only give  
16 icosapent if absolutely necessary and the only causes are  
17 genetics, right?

18 A That's correct.

19 Q And when the label, 2.1, first bullet says manage as  
20 appropriate, that is giving doctors wide discretion to do what  
21 the doctor sees fit for the individual patient.

22 A Yes.

23 Q Okay. Let's go to the second bullet.

24 The second bullet says patients should engage in  
25 appropriate nutritional intake and physical activity before



1 receiving icosapent ethyl which should continue during  
2 treatment with icosapent ethyl, right?

3 A Yes.

4 Q And what this bullet is saying is that doctors should  
5 make sure they don't use icosapent as a substitute for diet  
6 and exercise, right?

7 A No, they're saying that patients should try a trial of  
8 nutritional intake and physical activity before receiving  
9 icosapent ethyl.

10 It says they should engage in appropriate  
11 nutritional intake and physical activity before receiving the  
12 drug.

13 So saying eat well, exercise, and here's a  
14 prescription, would not be following Hikma's proposed label  
15 because they wouldn't be engaging in any of those things  
16 before receiving icosapent ethyl.

17 Q Okay.

18 A So I believe that if you don't give the patients a trial  
19 of diet and exercise before receiving icosapent ethyl, that  
20 that would be perceived as an off-label use of the drug.

21 Q Okay. So your opinion is that doctors should never  
22 prescribe icosapent without first making sure that the  
23 patients engage in diet and exercise?

24 A You can vary from the label. Doctors have discretion.  
25 But the label specifically tells you that they should engage

1 first.

2 So if you are following the label, an on-label use  
3 would be a trial of diet and exercise, we've discussed that a  
4 few times today, and then if they fail appropriate diet and  
5 exercise, then you prescribe icosapent ethyl.

6 Q That's not how you practice, right?

7 A That's how I largely practice.

8 Q When a patient comes to see you and presents with very  
9 high triglycerides, you hold off on prescribing Vascepa until  
10 the next visit?

11 A If their triglyceride are 550, like in your example, and  
12 they have a terrible diet, yes. I would say let's clean up  
13 your diet and exercise and see if we don't get there without  
14 therapy, and if we don't get there without therapy, then I'm  
15 going to need to prescribe a medication.

16 That's how we all prescribe therapy. That's the  
17 common use of all treatments. Blood pressure pills are the  
18 same. When I see somebody with high blood pressure, and they  
19 have a high salt diet, I say let's try diet and exercise and  
20 see if your blood pressure comes down, and if that fails, I'm  
21 going to have to write you a prescription for a blood pressure  
22 pill.

23 Q Okay.

24 A That's the way the FDA literally says -- there's no -- I  
25 don't think there's any interpretation here. Patients should

1 engage in appropriate nutritional intake and physical activity  
2 before receiving icosapent ethyl. Your company wrote a --  
3 very clear instructions for doctors to follow.

4 Q Okay. Doctor, you prescribe icosapent the first time you  
5 see a patient who presents with very high triglycerides,  
6 right? That happens?

7 A Sometimes, sure.

8 Q Probably most of the time, right?

9 A I don't know. I haven't looked back exactly. But some  
10 of my patients are already engaged in appropriate nutritional  
11 activity and nutritional intake when they first see me.

12 I described a scenario today of a young woman who is  
13 already doing all the right things, and her triglycerides are  
14 too high. So she already engaged in appropriate nutritional  
15 intake and physical activity before receiving icosapent ethyl,  
16 and then I prescribed it. That's my first visit, but the  
17 patient is already doing what the label instructs me to do.

18 Q Okay. And pancreatitis can be a life-threatening  
19 condition, right?

20 A Yes.

21 Q And if a patient presents to you with 650, for example,  
22 you're not going to hold off on giving that patient Vascepa  
23 for -- until you see the patient a second time, you're going  
24 to prescribe Vascepa right away, correct?

25 A In most cases, yes.

1 Q Yes. And are you really telling the Court that the  
2 Vascepa label and defendants' label will make it an off-label  
3 use if a doctor prescribes Vascepa at the same time as the  
4 doctor instructs the patients to improve their exercise and  
5 diet?

6 A I believe, and I think the label is explicitly clear  
7 here, that if you think diet and exercise is all they need,  
8 then you should not be prescribing Vascepa.

9 So in your first example where the triglycerides are  
10 550, and they have a terrible diet, I would not, and the label  
11 would not advocate to put them on Vascepa because it is highly  
12 likely that diet and exercise intervention alone will not  
13 achieve the target.

14 Now, if somebody has triglycerides of 2,000, and  
15 their blood is turning white from fats, then I do not wait.  
16 But I think that that could be perceived as an off-label use.

17 Regardless, the vast majority of patients we see,  
18 we're supposed to first address nutritional intake and  
19 physical activity before receiving icosapent ethyl, and then,  
20 if they don't get under 500, we then prescribe them the  
21 therapy.

22 That's also how the MARINE trial was done which I  
23 testified to this morning on how we did the MARINE trial, how  
24 the trial was performed by having a 6-to 9-week trial of diet  
25 and exercise before prescribing therapy.

1 Q Okay. Let's take another look at the language in the  
2 second bullet.

3 So would you -- your entire opinion here is based on  
4 one term, the term "before," right?

5 A No, my entire opinion is based on my experience,  
6 treatment, and training. The word "before" --

7 Q No, no, hold on. Just to be clear --

8 A -- is contributory towards that. My opinion is never  
9 based on a single word.

10 Q No, no, just --

11 A I want to be clear for the court.

12 Q Okay. All right. But your opinion with regard to what's  
13 on-label and off-label in view of 2.1 -- bullet 2, turns on  
14 the word before, right?

15 A In this one scenario, yes.

16 Q I mean, if that said "with," you would have a different  
17 opinion, right?

18 A I think the implication would be different, yes.

19 Q And when 2.1 bullet two uses the term before, it doesn't  
20 specify any time frame, right?

21 A That's true.

22 Q It doesn't say, doctors, make sure that the patients  
23 actually improve their diet and exercise for 12 weeks, come  
24 back, and then if it's clear that the causes are genetic, then  
25 you may prescribe icosapent. That's not what the label is

1 saying, right?

2 A It doesn't give a time period, that's correct.

3 Q And, in fact, and I think you mentioned something like  
4 this earlier, if the doctor told the patients I want you to --  
5 here's a diet, I want you to follow it, here's exercise,  
6 regimen I want you to follow it, here's a prescription, fill  
7 it when you can get to a pharmacy, that would be following the  
8 dosage and administration section 2.1, bullet 2, correct?

9 A No.

10 Q And why is that?

11 A Another word in the label it says engage, so they should  
12 engage in appropriate nutritional intake and physical  
13 activity. It doesn't say a doctor should advise that you go  
14 on diet and exercise, and here's a prescription. It says that  
15 they should engage in appropriate nutritional intake and  
16 physical activity before receiving icosapent ethyl.

17 I don't think you can change the meaning of that. I  
18 think doctors would read that and understand that you should  
19 give them a trial. It doesn't have to be exactly 12 weeks as  
20 you outlined in your previous example, but you need to give  
21 them a trial of diet and exercise, and if they fail that, then  
22 they can receive icosapent ethyl if their triglycerides are  
23 still above 500.

24 Q Now, Dr. Budoff, the most common practice is for doctors  
25 to prescribe icosapent as a first step for patients with

1 triglycerides above 500, correct?

2 A I don't know that.

3 Q Okay. Actually you do. Let's go to DX 1554, paragraph  
4 56. Let's go first to the first page so we can identify the  
5 document.

6 Okay. You recognize DX 1554 as your opening report?

7 A Yes.

8 Q Okay. Now let's go to page 17, paragraph 56.

9 A I'm sorry, what paragraph?

10 Q Paragraph 56.

11 A Okay. It's not on the screen?

12 Q It will be there in a second.

13 A Sure.

14 MR KLEIN: This is the reply? Do I have the  
15 wrong document?

16 No, this is right.

17 BY MR. KLEIN:

18 Q Okay. Here, in your opening report, you said,

19 "For elevated lipids, therapy guidelines,  
20 including ATP III, recommend diet and lifestyle  
21 modification, and for patients with triglycerides of  
22 500 milligrams per deciliter or higher, given the  
23 serious risk of pancreatitis and a recognition that  
24 lifestyle counseling alone is often insufficient for  
25 these patients, physicians most commonly recommend a

1 triglyceride-lowering medication, along with  
2 lifestyle counseling, as the first step."

3 Was that in your report, sir?

4 A No, that's citing ATP III, that's correct. That's 2002.  
5 I don't believe that's an on-label use.

6 Q Okay. So you're saying this statement in your opening  
7 report is inaccurate?

8 A No, I'm not saying that it's inaccurate at all. I'm  
9 saying that it's -- I don't perceive it to be an on-label use  
10 if you prescribe the drug at the same time as diet and  
11 exercise and you don't have them engage in nutritional intake  
12 and appropriate physical activity before receiving icosapent  
13 ethyl.

14 Q Okay. Let's take a look at your reply report, and you  
15 submitted a reply expert report after Dr. Sheinberg responded  
16 to your report, right?

17 A Yes.

18 Q So this is after Dr. Sheinberg raised the 12-week  
19 noninfringement defense, right?

20 A Yes.

21 Q Okay. And you recognize DX 1556 is your reply report?

22 A Yes.

23 Q Okay. Let's first take a look at paragraph 54.

24 In paragraph 54 of your reply report you said, "I  
25 disagree that clinicians would read the indications and usage



1 section as encouraging clinicians to treat  
2 hypertriglyceridemia by providing the patients with a  
3 prescription for Vascepa or one of defendants' proposed ANDA  
4 products but instruct the patient not to begin taking the  
5 medication until after improving their diet and exercise  
6 regimen over the course of 4 to 6 weeks."

7 Right? Is that something you said in your reply  
8 report in response to Dr. Sheinberg's report?

9 A Yes.

10 Q Okay. Let's also take a look at paragraph 57 of your  
11 reply report.

12 All right. In paragraph 57, you start off by  
13 talking about the treatment guidelines, and in the second  
14 sentence you say,

15 "The treatment guidelines therefore advise  
16 that clinicians immediately treat severely  
17 hypertriglyceridemic patients with triglyceride-  
18 lowering pharmacotherapies."

19 Right? Is that what you said?

20 A Yes.

21 Q Immediately treat, right?

22 A Yes.

23 Q Okay. And if we go to paragraph 209 of your reply  
24 report, here you say that,

25 "Statements in the label acknowledge that

1 clinicians will generally recommend to their severely  
2 hypertriglyceridemic patients that they improve their  
3 diet or improve or begin an exercise regimen.

4 However, in cases where the risk of pancreatitis is  
5 judged sufficiently immediate, pharmacotherapy will  
6 begin immediately."

7 This was in your reply report as well?

8 A Yes, that's exactly the scenario I just gave you. I said  
9 if the triglyceride are superhigh --

10 Q Sir, I -- Doctor, I just asked you whether that was in  
11 your report.

12 A Okay. I was just trying to put it in context, but, yes.

13 Q Okay. And according to ATP III, if patients have  
14 triglycerides above 500, they're at risk for pancreatitis,  
15 correct?

16 A Yes, they are at risk for pancreatitis.

17 Q And putting aside all of your testimony with regard to  
18 the dosage and administration section that we were talking  
19 about, a clinician -- it would be consistent with the Vascepa  
20 labeling, and thus defendants' labels, for a doctor to  
21 prescribe icosapent ethyl for fewer than 12 weeks, correct?

22 A Yes.

23 MR. KLEIN: Now, we were talking about the  
24 various causes -- can you go back to the PowerPoint and  
25 DDX 3.14.

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BY MR. KLEIN:

Q We were talking about various causes of severe hypertriglyceridemia, and we looked at the Vascepa.com website. Do you remember that?

A Yes.

Q Okay. I want to now turn to the Miller article which you talked about on direct. Do you remember that?

A Yes.

MR. KLEIN: Okay. And for the record, I'm referring to DX 1632, and I believe the same document PX 269 has already been admitted, but for the -- to avoid any confusion we'll move to admit DX 1632.

MR. M. KENNEDY: No objection.

THE COURT: 1632 is admitted.

(Defendants' Exhibit 1632 received in evidence.)

BY MR. KLEIN:

Q And we're at 1632, page 11. Do you remember talking about this?

A Yes.

Q Okay. And you understand -- do you understand that Dr. Miller was actually Amarin's claim construction expert in this case?

A I'm not aware of that, but I'll take your word for it.

Q Okay. So looking at table 5, this lists causes of very

1 high triglycerides that may be associated with pancreatitis,  
2 right?

3 A Yes.

4 Q Okay. And I highlighted a couple of these causes:  
5 Pregnancy, especially in the third trimester. Do you see  
6 that?

7 A Yes.

8 Q Can we agree that pregnancy in the third trimester is not  
9 a chronic condition?

10 A That's correct.

11 Q And certain drugs cause very high triglycerides, right?

12 A Yes.

13 Q And some of these drugs can be taken for less than 12  
14 weeks, right?

15 A Yes.

16 Q For example, steroids?

17 A Yes.

18 Q Anything else?

19 A Steroids are probably the best example on this list of a  
20 drug that's often used for short term therapy, maybe  
21 Interferon as well.

22 Q And then diet, including alcohol, excess, we talked about  
23 that, right?

24 A Yes.

25 Q And then a high saturated fat diet?

1 A Yes.

2 Q And eating high saturated fat food is not a chronic  
3 condition, right?

4 A It often is in the United States, but -- yes, it's not.

5 Q You would like to think that --

6 A It doesn't have to be.

7 Q If you tell people they'll die if they don't stop eating  
8 MacDonald's, they'll listen to you?

9 A Unfortunately not all the time, but, yes.

10 Q Okay. And diseases is up there too. As we talked about  
11 some diseases can cause severe hypertriglyceridemia if they're  
12 not controlled, right?

13 A That's correct.

14 Q And triglycerides can fluctuate based on factors such as  
15 diet and exercise, right?

16 A Yes.

17 Q And in fact a patient's triglyceride levels can vary  
18 significantly based on lifestyle and medication changes,  
19 right?

20 A Yes.

21 Q Continuing through this article, we're at DDX 3.15, and  
22 we're on page 20 of DX 1632, this slide says a weight loss of  
23 5 to 10 percent results in a 20 percent decrease in  
24 triglycerides. That's a true statement, right, sir?

25 A Yes.

1 Q Okay. Then moving to DX 1632, page 22, DDX 3.16, the  
2 Miller reference says Mediterranean style diet versus a low  
3 fat diet is more commonly associated with an approximately 10  
4 to 15 percent lowering of triglycerides and a reduced  
5 prevalence of hypertriglyceridemia, right?

6 A Yes.

7 Q That's true as well?

8 A Yes.

9 Q And if we go to DX 1632, pages 23 and 24, DDX 3.17,  
10 Dr. Miller says,

11 "Ingestion of one ounce per day would  
12 correspond to a 5 to 10 percent higher triglyceride  
13 concentration than found in nondrinkers."

14 Is that correct?

15 A That's an average, but, yes.

16 Q Okay. On page 24 of DX 1632, DDX 3.18, Dr. Miller says,

17 ""Optimization of nutrition-related practices  
18 can result in a marked triglyceride-lowering effect  
19 that ranges between 20 and 50 percent," right?

20 A Yes.

21 Q And on page 27 of DX 1632, which is DDX 3.19, Dr. Miller  
22 says,

23 ""Reductions of 50 percent or more in  
24 triglyceride levels may be attained through intensive  
25 therapeutic lifestyle change."

1 Do you agree with that?

2 A I have not seen that, but, yes, I agree.

3 Q Okay. But you understand that what Dr. Miller is saying  
4 is, he's saying no drug therapy can get you this, right? You  
5 can get this result without drugs.

6 A Yes.

7 Q And so a patient who presents with triglyceride levels of  
8 550, for example, could eventually reduce the triglyceride  
9 levels down to 275, roughly, through intensive therapeutic  
10 lifestyle changes alone. Right?

11 A If you took a terrible patient and made them a perfect  
12 patient, yes.

13 Q Okay. But, I mean, that's going to take some time,  
14 right?

15 A But it's also not always the scenario. In your scenario  
16 to do all of these things, they have to be overweight,  
17 nonexercising, drinking person who has a terrible diet to be  
18 able to make all of those lifestyle changes, and then, in that  
19 scenario, you go from very high to high. But, yes, that is  
20 possible.

21 Q Okay. And so the mere fact that a patient presents to  
22 the doctor with triglycerides over 500 does not necessarily  
23 mean the patient requires drug therapy, right?

24 A Absolutely.

25 Q Now, Doctor, half of your patients with severe

1 hypertriglyceridemia have the condition due to poor lifestyle  
2 choices, correct?

3 A Let's say poor lifestyle choices contribute to the  
4 condition.

5 Q Okay. Because -- and you say that because the patients  
6 may be genetically predisposed to high triglycerides.

7 A Yes.

8 Q And, again, these lifestyle causes are not necessarily  
9 chronic, right?

10 A And I think to be accurate and consistent, I think we  
11 said a third earlier, so I would like to stay with that number  
12 if we could.

13 So I don't want my -- my testimony to be changing  
14 during this transcript. We said a third of patients earlier.  
15 I think we'll stick with that number if that's okay with you.

16 Q Right. We don't want your testimony to change.

17 A Right.

18 Q So you would say maybe half of your patients have poor  
19 lifestyle that has pushed the patient's triglycerides the  
20 wrong way, right?

21 A Yeah, of the people I see, probably half of them are not  
22 eating optimally when I see them, that's correct.

23 Q And that's contributing to the very high triglyceride  
24 level?

25 A Yes.



1 Q And we talked -- you talked about binge drinking, right?

2 A Yes.

3 Q Binge drinking can cause spikes in some patients above  
4 550.

5 A Above 500, yes.

6 Q I'm sorry, above 500.

7 And to be clear, and I think you made this point,  
8 you're not saying, and I think you used the example in the  
9 deposition, you're not saying at Mardi Gras everyone walking  
10 around is going to have very high triglycerides, right?

11 A Very few will.

12 Q Yeah, you're saying that there are patients that are  
13 predisposed to high triglycerides, have never had very high  
14 triglycerides, but they engage in binge drinking and their  
15 triglycerides spike above 500, correct?

16 A Yes.

17 Q Okay. And these types of patients can get their  
18 triglyceride levels below 500 by cutting out the alcohol,  
19 right?

20 A If they're sufficiently close to 500, yes.

21 Q And doctors know this, right?

22 A Yes.

23 Q And so a doctor -- I mean, so a patient who presents with  
24 triglycerides let's say close to 600, and you identify at  
25 least one contributing cause as alcohol, could potentially

1 benefit from taking icosapent for a short time while the  
2 patient goes off alcohol, and then could stop the treatment if  
3 it turns out the patient is now below 500 after taking out the  
4 alcohol, correct?

5 A I think that's completely unknown, that hypothetical. We  
6 have no idea what the short term benefits of icosapent ethyl  
7 are in terms of pancreatitis, and I think the label  
8 specifically calls that out, that the effect on pancreatitis  
9 is not known.

10 Q Okay. And so a doctor who sees a patient with  
11 triglycerides above 500 due to binge drinking could tell the  
12 patient stop drinking but also take Vascepa to help avoid  
13 pancreatitis, right?

14 A I doubt anybody would ever do that in practice, but that  
15 is a hypothetical situation.

16 Q And that hypothetical would be on-label, right?

17 A No, it would be off-label because they're not engaging in  
18 proper nutritional activity before initiating Vascepa therapy  
19 unless you think that the words saying stop drinking means  
20 that they stopped drinking.

21 And I can tell you that the words stop smoking do  
22 not imply that the patient has stopped smoking. So they need  
23 to engage, your label, engage in appropriate nutritional  
24 activity before initiating icosapent ethyl. I'm -- it's not  
25 my terminology. This is what you're putting forth.

1 Q Okay. It would not be off-label if a patient who had  
2 triglycerides above 500 because of binge drinking, for the  
3 doctor to say, "Stop drinking, but also take Vascepa because  
4 you have a risk of pancreatitis, and we want to get your  
5 triglycerides down immediately," correct?

6 A I think that's a probably a borderline off-label use, but  
7 I would say it's appropriate to do that if their triglycerides  
8 are very, very high and the risk of acute pancreatitis is  
9 eminent.

10 Q Doctor you were deposed in it case, right?

11 A Yes.

12 MR. KLEIN: You should have a copy of your  
13 deposition, but we'll play a video clip. Mr. Gross, can you  
14 play page 196, page 10 -- I'm sorry, page 196, lines 10 to 25.

15 (Deposition video played.)

16 BY MR. KLEIN:

17 Q Sir, was that your testimony?

18 A Yes.

19 Q Okay. And can we agree that a patient with severe  
20 hypertriglyceridemia does not necessarily require indefinite  
21 drug therapy?

22 A Yes.

23 Q Okay. And many patients with severe hypertriglyceridemia  
24 don't require any drug therapy at all, right?

25 A That's correct.

1 Q And that's in part because weight reduction and exercise  
2 can reduce triglycerides in many patients, right?

3 A In some patients, yes.

4 Q Some patients. Okay.

5 Let's take another look at the indication. We're on  
6 DX 2256, and it's DDX 3.20.

7 We talked about this a little bit before, but the  
8 indication is for use as an adjunct to diet, right?

9 A Yes.

10 Q And adjunct in this context means in addition to diet?

11 A Yes.

12 Q And so it's pretty clear that FDA did not approve Vascepa  
13 to replace diet, right?

14 A Yes.

15 Q And the label is telling doctors that diet is the primary  
16 way to treat severe hypertriglyceridemia, right?

17 A I think that's overstating the label. Diet and Vascepa  
18 reduces triglyceride levels. I don't think it says diet alone  
19 in the label, at least I'm not aware of diet alone being the  
20 primary way to treat severe hypertriglyceridemia appearing  
21 anywhere in the label.

22 Q Doctor, I thought your testimony is that when a patient  
23 presents, you're supposed to put them on a diet first.

24 A Yes, but it doesn't usually work.

25 Q Okay.

1 A So it's not predominant way of doing it. It works in  
2 20 percent of patients, and in 80 percent of patients it  
3 fails. So the predominant way is to use drug therapy just to  
4 go back to the your initial question.

5 Q Right. But if you look at the indication, the indication  
6 is clearly telling doctors that they can use Vascepa as an  
7 adjunct to diet according to the doctor's discretion, right?

8 A Yes.

9 Q And in your personal practice you have seen diet and  
10 exercise alone without any drugs decrease triglyceride levels  
11 by about 25 percent, right?

12 A Yes.

13 Q And you're familiar, you talked about the MARINE study on  
14 direct, right?

15 A Yes.

16 Q Let's talk about the MARINE study, and this is DX 1694,  
17 page 24, DDX 3.21. This is already admitted.

18 In MARINE, patients were given diet and exercise for  
19 a period of four to six weeks as a lead-in before the 12-week  
20 study began, right?

21 A Yes.

22 Q And then, if we go to DDX 3.22 on the same page, there  
23 was then a two- to three-week qualifying period, right?

24 A Yes.

25 Q And this was to make sure that the patients who were

1 going to enter the 12-week MARINE study had severe  
2 hypertriglyceridemia, right?

3 A Yes.

4 Q And had severe hypertriglyceridemia that was not  
5 addressed by diet and exercise in the four- to six-week  
6 lead-in, right?

7 A Yes.

8 Q And so in this scenario, in the MARINE study, Amarin  
9 tried diet and exercise in a number of patients, and then a  
10 number of those patients didn't qualify, right?

11 A Right.

12 Q And that's because diet and exercise worked for them,  
13 correct?

14 A Yes. That's one reason. There's other reasons why  
15 people don't qualify, but, yes, that's the primary exclusion.

16 Q Okay. Fair enough.

17 And then during these two to three weeks Amarin is  
18 looking at the remaining population and saying these patients  
19 qualify for the 12-week trial, right?

20 A Yes.

21 Q And then we're on DDX 3.23. It's the same document,  
22 page 27, I just changed the highlighting.

23 Only patients with triglycerides above 500 after  
24 this four to six-week lead-in and the two to three-week  
25 qualifying period entered into the 12-week safety and efficacy

1 **MARINE** trial, right?

2 A Yes.

3 Q And, in your view, Vascepa is indicated for those  
4 patients who qualified for the **MARINE** study, right?

5 A Yes.

6 Q These are patients that went through some diet and  
7 exercise and still didn't get their triglycerides below 500 in  
8 that period of time, right?

9 A Exactly.

10 Q And you agree that Vascepa is indicated for those  
11 patients who qualified for the **MARINE** trial, right?

12 A Yes.

13 Q And defendants' labels will be directed to this patient  
14 population as well?

15 A Yes.

16 Q And all of the patients who qualified for the **MARINE**  
17 study could benefit from icosapent treatment, right?

18 A Potentially, yes.

19 Q And your position is that all patients who qualified for  
20 the 12-week **MARINE** study had severe hypertriglyceridemia,  
21 right?

22 A Yes, at baseline visit.

23 Q Now, Doctor, some of the patients that qualified for the  
24 **MARINE** study were put into a placebo group, right?

25 A Yes.

1 Q Okay. And all of the patients in the placebo group had  
2 triglycerides above 500.

3 A Yes.

4 Q Okay. And let me change documents. This is DX 1701,  
5 page 51. This is from the medical review. Do you remember  
6 looking at that?

7 A I've seen it. I didn't review it in great detail, but,  
8 yes, I've seen this document.

9 Q You used this on your direct examination, right, the FDA  
10 medical review?

11 A I think I referenced one section of it, but, yes.

12 Q Okay. And for the record this is DDX 3.24.

13 The subjects in the placebo group in MARINE were  
14 instructed to maintain the diet and exercise regimen  
15 throughout the entire 12-week period, right?

16 A Yes.

17 Q And those -- so those patients in the placebo group  
18 didn't get any Vascepa.

19 A That's correct.

20 Q And after 12 weeks of continuing a diet and exercise  
21 regimen, 21 percent of those subjects in the placebo group, 16  
22 out of 75, were able to achieve and maintain triglyceride  
23 levels below 500 milligrams per deciliter by the study  
24 endpoint, correct?

25 A Yes.



1 Q And that's the green bar on DDX 3.24, right?

2 A Yes.

3 Q And so according to MARINE, about 21 percent of patients  
4 falling within the scope of defendants' indication can achieve  
5 and maintain triglyceride levels below 500 with diet and  
6 exercise alone, correct?

7 A Yes.

8 Q And these patients didn't need any Vascepa to get below  
9 500, right?

10 A That's correct.

11 Q And these patients could benefit from a short course of  
12 icosapent given that they qualified for the MARINE study, but  
13 long-term they wouldn't require Vascepa to maintain levels  
14 below 500, right?

15 A How would they benefit? I don't understand the question.

16 Q Well, these are patients who, in the first four to  
17 six weeks tried diet and exercise alone and it didn't work,  
18 right?

19 A Right.

20 Q Okay. And so if these patients in the placebo group were  
21 given Vascepa immediately, their triglyceride levels would  
22 drop more quickly, right?

23 A Probably, yes.

24 Q And by the time you get into the 12-week period, they  
25 wouldn't even need Vascepa, according to MARINE, to maintain

1 levels above 500, right?

2 A You're talking about those 21 percent.

3 Q Correct.

4 A Yes.

5 Q And consistent with MARINE, about 20 percent of your  
6 patients with severe hypertriglyceridemia are able to reduce  
7 their triglyceride levels below 500 with diet and exercise  
8 alone, right?

9 A Yes.

10 Q And so about one-fifth or 20 percent of patients with  
11 very high triglyceride levels don't necessarily need any drug  
12 therapy to get their levels below 500, right?

13 A That's correct.

14 Q Now, even in those patients who don't necessarily need  
15 Vascepa, you still sometimes prescribe Vascepa, right?

16 A I would never prescribe a drug that I don't perceive they  
17 need, no.

18 Q Well, you -- well, let's come back to that.

19 Now, some of your patients who were able to reduce  
20 triglycerides below 500 with diet and exercise alone say no  
21 thanks when you suggest Vascepa, right?

22 A Right. They can't get it or they don't want to take it.  
23 That's correct.

24 Q And this happens with some frequency because you have a  
25 lot of patients who don't like taking drugs unless they need

1 to, right?

2 A Yes.

3 Q You practice in California so you may see that more often  
4 than others.

5 A Yes.

6 Q Okay. And the dosing regimen for Vascepa is four pills a  
7 day twice a day.

8 A Four pills a day total; two twice a day.

9 Q That's what I meant. I'm sorry. Two pills in the  
10 morning and two in the evening, right?

11 A Yes.

12 Q That's an inconvenient dosing regimen for many patients,  
13 right?

14 A Yes.

15 Q And so you have patients who start on Vascepa therapy and  
16 then stop.

17 A Yes.

18 Q About ten percent of your patients stop taking Vascepa  
19 for various reasons, right?

20 A Yes.

21 Q And you agree that patients could follow the Vascepa  
22 labeling and effectively treat patients with severe  
23 hypertriglyceridemia for less than 12 weeks, right?

24 A Can you say that again? I'm sorry.

25 Q Okay. You agree that physicians could follow the Vascepa

1 labeling and treat severely hypertriglyceridemic patients with  
2 Vascepa 4 grams per day for fewer than 12 weeks and achieve an  
3 effect, correct?

4 A Yes.

5 Q Okay. In other words, Vascepa is suitable to reduce  
6 triglyceride levels in patients suffering from severe  
7 hypertriglyceridemia in less than 12 weeks, right?

8 A Yes.

9 Q And, in fact, some patients with severe  
10 hypertriglyceridemia taking icosapent because they don't  
11 need to -- let me stop and rephrase.

12 Some patients with severe hypertriglyceridemia  
13 stopped taking icosapent because they don't need to take the  
14 drug long-term to keep triglycerides below 500, correct?

15 A I think that's a minority, but, yes.

16 Q Okay. And after all, icosapent can significantly reduce  
17 triglycerides in as few as four weeks, maybe even sooner,  
18 right?

19 A Yeah, I don't think anybody knows sooner, but we have  
20 data at four weeks.

21 Q Right. The first data point was four weeks, it could be  
22 sooner, we don't know, right?

23 A Yeah, I don't think anybody knows that.

24 Q And let's go to DX 3.26 which is DX 1694, page 214. You  
25 recognize this as the MARINE study?

1 A Yes.

2 Q And MARINE reported the most significant reduction in  
3 triglyceride levels at just four weeks, right?

4 A Yes.

5 Q And on the screen, just so, you know, everyone is  
6 oriented, the baseline median triglyceride was about 680,  
7 right?

8 A Yes.

9 Q And then by week four, the median triglyceride dropped to  
10 471, right?

11 A Yes.

12 Q And so by week four, the median patient had a  
13 triglyceride level below 500, right?

14 A Yes.

15 Q Let's go to the next document which is DX 1816, page 70,  
16 and it's DDX 3.27. I will represent to you that this is a  
17 document that's already been admitted from Amarin to the FDA.

18 And it says -- this portion of the document says,

19 "Time course of effects: In studies in which  
20 serial measurements were performed and/or reported,  
21 the maximum effect was seen at four to w 8 weeks,  
22 after which time the reduction was maintained."

23 Are you familiar with that?

24 A Yes.

25 Q Okay. And that's an accurate statement, right?

1 A Yes.

2 Q And so icosapent works well if a doctor wants a drug to  
3 get triglyceride levels below 500 quickly to eliminate the  
4 risk of pancreatitis, right?

5 A To reduce the risk of pancreatitis, yes.

6 Q Fair. Fair point.

7 Okay. So if you assume a patient who has just  
8 barely above 500, let's say 510, and the patient can reduce  
9 their triglyceride level by 25 percent with diet and exercise  
10 eventually, like the -- like the placebo patients in MARINE, a  
11 doctor reasonably could prescribe icosapent for short-term use  
12 to reduce the pancreatitis risk as soon as possible, right?

13 A So -- yes, they could do that.

14 Q And some of your patients start Vascepa after testing  
15 above 500, and then think they don't need the drug anymore  
16 once their levels drop below 500, right?

17 A There are some patients who do that, yes.

18 Q In fact, about 5 percent of your patients stopped taking  
19 Vascepa after they see their triglycerides drop below 500,  
20 right?

21 A Yes.

22 Q And this drop below 500 can happen in less than 12 weeks  
23 on icosapent, right?

24 A Theoretically, yes. I don't measure it at less than  
25 12 weeks, but, yes.

1 Q Okay. And in your personal practice, some of your  
2 patients do take -- strike that.

3 In your -- in your practice, some of your patients  
4 with very high triglycerides take Vascepa for less than  
5 12 weeks, right?

6 A Yes.

7 Q And when they stop Vascepa, you don't feel that their  
8 lives are being put at risk given the pancreatitis risk,  
9 right?

10 A The moment they stop? No.

11 Q Okay. And about 5 percent of your patients with severe  
12 hypertriglyceridemia take Vascepa for less than 12 weeks,  
13 correct?

14 A Yes, for various reasons.

15 Q Now, we've touched on this earlier, but certain drugs can  
16 cause triglyceride levels to spike, right?

17 A Yes.

18 Q And we talk about -- we talked about steroids or  
19 corticosteroids as an example, right?

20 A Yes.

21 Q And I believe you said corticosteroids can be used short  
22 term, right?

23 A They most often are.

24 Q Yeah, less than 12 weeks?

25 A Yes.

1 Q Okay. And a patient who needs a short-term  
2 corticosteroid treatment could take Vascepa to counteract the  
3 side effect of the triglyceride level spike if necessary to  
4 address, right?

5 A Again, a very unusual hypothetical, but I guess that's  
6 theoretically possible.

7 Q Now, let's go to DX 2256, page 7, which is DDX 3.28 and  
8 you recognize this as the clinical study section of -- this is  
9 Hikma's label, but the identical language is in DRL's label,  
10 right?

11 A Yes.

12 Q And the clinical study section summarizes the study that  
13 justified the FDA approved indication, right?

14 A Yes.

15 Q We know that it's a MARINE study, but the label doesn't  
16 actually identify the study name, right?

17 A Correct.

18 Q And the clinical study section provides data beyond the  
19 scope of the indication, right?

20 A Yes.

21 Q And some of the data may be relevant to a prescribing  
22 physician, right?

23 A Yes.

24 Q But some of the data may be completely irrelevant to a  
25 prescribing physician, right?



1 A Yes.

2 Q In other words, some physicians will find some of the  
3 clinical study information helpful, but others will find it  
4 irrelevant to their practices, right?

5 A Yes.

6 Q And the clinical study section says the study supporting  
7 the indication lasted 12 weeks. We talked about earlier,  
8 right?

9 A Yes.

10 Q The study certainly didn't last more than a year, right?

11 A That's correct.

12 Q The study ended at 12 weeks, right?

13 A There was the -- the carry-on up to a year.

14 Q For -- right, for some patients.

15 A Yes.

16 Q Okay. And this section -- and we talked about this  
17 earlier. This section, the clinical study section, does not  
18 specifically instruct doctors that in view of the 12-week  
19 clinical study, doctors should go ahead and make sure they  
20 give icosapent for at least 12 weeks, right?

21 A Encourages them to use it for at least 12 weeks to see  
22 what the effects will be, to see if they achieve the effects  
23 in table 2.

24 Q Okay. You're talking about some kind of implied  
25 encouragement, right?

1 A I don't want to get into legal terms. I think it  
2 encourages physicians to try to follow the clinical study to  
3 see if it happens in their patients.

4 Q And just to be clear, I wasn't asking you a legal  
5 question. The only time the term 12 weeks is used in  
6 defendants' label is to describe the underlying clinical  
7 trial, right?

8 A Yes.

9 Q In other words, defendants' labels don't otherwise  
10 comment on the 12-week duration such as saying because these  
11 effects were achieved in 12 weeks, make sure you give the drug  
12 for at least 12 weeks. There's nothing like that, right?

13 A It doesn't say that explicitly, that's correct.

14 Q Let's take a look at the patient information, DX 2256,  
15 page 9, which is DDX 3.29. You talked about this on direct,  
16 right?

17 A Yes.

18 Q Okay. And the second bullet says,  
19 "Do not change your dose or stop taking  
20 icosapent ethyl without talking to your doctor,"  
21 right?

22 A Yep.

23 Q This statement is it not instructing doctors and patients  
24 so use icosapent for at least 12 weeks, right?

25 A Correct.

1 Q In fact, this statement doesn't speak to whether the  
2 label is encouraging any particular duration, right?

3 A Right. The statement just warns them if you're going to  
4 stop it, talk to your doctor.

5 Q Now, even if one of your patients does not necessarily  
6 need icosapent long-term, you still often prescribe it  
7 long-term, right?

8 Let me rephrase the question because now there are  
9 two indications.

10 Even if your patient with severe  
11 hypertriglyceridemia does not necessarily need icosapent long  
12 term to address the severe hypertriglyceridemia, you still  
13 prescribe the drug long-term, right?

14 A My intent is, when I'm treating people with Vascepa for  
15 severe hypertriglyceridemia, that they're going to need the  
16 drug long-term, and my intent is to give it to them long-term.

17 Q But you also give your patients Vascepa long-term for  
18 reasons unrelated to severe hypertriglyceridemia, right?

19 A Can you say that again? I'm sorry.

20 Q You prescribe Vascepa to your patients for reasons  
21 unrelated to controlling severe hypertriglyceridemia.

22 A You're talking about the other indication.

23 Q Right.

24 A I thought we weren't going to talk about the REDUCE-IT  
25 indication.

1 Q Well, I'm not going to talk about the specific  
2 indication, I'm talking about your practice.

3 A Which addresses the second indication, yes. I use it for  
4 the REDUCE-IT indication.

5 Q Okay. And before the new indication was approved, you  
6 often prescribed Vascepa for reasons unrelated to controlling  
7 severe hypertriglyceridemia, right?

8 A I used it for that same purpose, for the REDUCE-IT type  
9 indication, for the REDUCE-IT study results, to try to emulate  
10 that in my practice, yes.

11 Q And you also used it because you're not satisfied when  
12 your patients have high triglyceride levels. You want it  
13 lower, right?

14 A So I would sometimes use it when they were close to 500  
15 and not exactly 500, but that would probably be considered an  
16 off-label use.

17 Q Right. And before the new indication was approved, you  
18 often prescribed Vascepa for off-label uses, right?

19 A Yes.

20 Q And did you do that because you thought that could help  
21 address cardiovascular issues, right?

22 A Because I knew the results of REDUCE-IT, the study, I was  
23 an investigator, and I wanted to emulate that in my patients.

24 So, yes, there was a window where before REDUCE-IT  
25 indication came out, but after the REDUCE-IT trial came out,

1 that I was informed that that's a really good idea to treat  
2 those patients to reduce their cardiovascular risk, and I  
3 started doing that, and the guidelines encouraged me, but the  
4 FDA did not opine on that until December 2019.

5 So there was a window where I was using it for  
6 REDUCE-IT, but the indication was not yet in the label.

7 Q Right. And just to be clear, doctors are allowed to  
8 prescribe drugs off-label, correct?

9 A Yes.

10 Q So I'm certainly not suggesting you're doing anything  
11 wrong. You understand that.

12 A No, I just want to explain why my off-label use.

13 Q Yeah. And so you had patients who had -- who may have  
14 presented with triglycerides at, say, 550, who you thought  
15 maybe were overweight and weren't in shape and could probably  
16 maintain levels below 500 without Vascepa, you told them  
17 continue taking the drug because it might have additional  
18 benefits, right?

19 A Yeah. Especially after the REDUCE-IT trial, yes.

20 Q Okay. And icosapent is fairly well tolerated, right?

21 A Yes.

22 Q So there's not too much of a downside if your patient is  
23 tolerating the medication, and they don't necessarily need it  
24 for severe hypertriglyceridemia, to tell them to continue the  
25 medication because there may be cardiovascular benefits,

1 right?

2 A That's a given indication now as well, yes.

3 Q Right. And even -- you have -- even before the new  
4 indication, you used Vascepa to treat triglyceride levels to  
5 get them down as low as 135, right?

6 A I never targeted 135, but some patients might have gotten  
7 to 135.

8 135 is the entry criteria for the REDUCE-IT trial.  
9 That's not a goal or target. That was -- that just happened  
10 to be a random number that was -- that was started at with the  
11 study, but the targets are less than 150, not 135.

12 Q I see. But you routinely, before and now after the new  
13 indication, have been prescribing Vascepa often to address  
14 triglyceride levels that are not above 500 but are still too  
15 high, fair?

16 A Yes, the REDUCE-IT indication.

17 Q And you understand that defendants' products will not be  
18 indicated for cardiovascular effects, right?

19 A Yes.

20 Q And so even before the new Vascepa indication, about  
21 85 percent of your prescriptions were off-label, right?

22 A Again, I just explained why. But, yes, that was the  
23 window between the REDUCE-IT results being published and the  
24 REDUCE-IT indication being changed by the FDA. At that point  
25 I was using it for the REDUCE-IT indication that was not yet

1 part of the label.

2 Q Okay. And just to be more clear, that 85 percent of your  
3 patients did not ever have triglycerides above 500, correct?

4 A That -- right, correct.

5 Q Okay. And now that there's a new indication, do you  
6 expect the percentage of prescriptions that would be off-label  
7 to defendants' labels to be higher than 85 percent?

8 A I think it would be very high. I don't know if it will  
9 be higher or lower than 85 percent.

10 MR. KLEIN: Mr. Gross, can you turn to PX 277.

11 BY MR. KLEIN:

12 Q Let's start with the first page. Do you remember this  
13 exhibit from the Jacobson reference that you discussed on  
14 direct examination?

15 A Yes.

16 Q Okay. I just a couple questions about this.

17 Let's go to page 26, and do you remember discussing  
18 this section of the article on follow-up visits?

19 A Yes.

20 Q Okay. And just to be clear, this article in the  
21 discussion you were focusing on was talking about statins,  
22 right?

23 A This paragraph was talking about statins, yes.

24 Q Right. And if we back out of this and go the page  
25 before, which is PX 277, page 25, that section that you were

1 discussing is under a larger header -- heading called  
2 Cholesterol Lowering Drug Therapies, right?

3 A Yes.

4 Q Not very high triglycerides, right?

5 A Yes.

6 MR. KLEIN: All right. Let's go back -- can you  
7 go back to the PowerPoint.

8 BY MR. KLEIN:

9 Q Let's go back to DDX 3.30. This is again back to the  
10 indication. And now you're aware of certain asserted patent  
11 claims, and you just discussed them on direct, that focused on  
12 lipids other than triglycerides, right?

13 A Yes.

14 Q Now, defendants' labels will be indicated solely to  
15 reduce triglycerides in the specific population, right?

16 A Yes.

17 Q And you understand that defendants' labels will not be  
18 indicated to reduce any lipid parameter other than  
19 triglycerides, right?

20 A Correct.

21 Q And so a doctor could follow the indication in  
22 defendants' labels and prescribe their products, once they're  
23 introduced, to reduce triglycerides and not focus on any other  
24 lipid parameters, right?

25 A They don't have to focus on other parameters, that's



1 correct.

2 Q Let's go to DDX 3.31, we're in DX 2256, pages seven to  
3 eight. This is table 2 of defendants' label.

4 I assume this is familiar, right?

5 A Yes.

6 Q And there's a statement underneath the table that you  
7 talked about on direct, right?

8 A Yep.

9 Q And that statement is reporting on observations  
10 concerning the clinical trial that's being reported in table  
11 2, right?

12 A Yes.

13 Q And these are not instructions on how to use icosapent,  
14 right?

15 A Correct.

16 Q They're mere descriptions of the clinical study results.

17 A No, they're to show you what to expect if you use the  
18 drug.

19 Q Okay. And they're describing the clinical study results,  
20 right?

21 A Yes.

22 Q Okay. And, in your opinion, doctors will see the phrase  
23 icosapent 4 grams per day, reduce median triglyceride, VLDL-C  
24 and apo B levels from baseline relative to placebo and infer  
25 an instruction that doctors can expect similar results in a

1 majority of individual patients, right?

2 A Yes.

3 Q And that inference goes beyond the scope of the  
4 indication, right?

5 A Of the specific indication? Yes.

6 Q Yes. And median data from a clinical trial may or may  
7 not relate to an individual patient depending on, for example,  
8 the specific patient population that was being tested, right?

9 A Yes.

10 Q And, for example, the information in the clinical study  
11 section says that the median triglyceride level was 684,  
12 right?

13 A Yes.

14 Q Okay. And a doctor would understand that the effects  
15 listed in table 2 may not be the same if the patient's  
16 triglyceride levels were, for example, only 500, right?

17 A As long as they're above 500, they should have these  
18 general results.

19 Q Okay. Or a patient with 2,000, with triglycerides of  
20 2,000, may or may not receive these -- obtaining those same  
21 results, right?

22 A I think patients in this trial with triglycerides above  
23 750 did a little better.

24 Q Now, the label, defendants' labels are not encouraging  
25 doctors to use Vascepa to obtain effects unrelated to

1 triglycerides, right?

2 A I'm sorry, could you say that again?

3 Q Let me rephrase. Defendants' products are not indicated  
4 to control LDL-C, right?

5 A That's correct.

6 Q Okay. And you don't prescribe Vascepa to avoid raising  
7 LDL-C, right?

8 A No, that is one of the considerations of why I choose  
9 Vascepa over other generics.

10 Q Fair enough. But your intent in prescribing icosapent is  
11 to lower triglyceride levels, not to effect LDL-C levels,  
12 right?

13 A It's to lower triglyceride levels without raising LDL-C.

14 Q Well, defendants' labels are not encouraging doctors to  
15 use the drug because it controls LDL-C, right?

16 A That's correct.

17 Q Let's take another look at table 2 again, it's DX 2256,  
18 pages 7 to 8, DDX 3.32, and I want to focus now on the LDL-C  
19 results, do you see that?

20 A Yes.

21 Q Now, the doctor would understand from table 2 and the  
22 statement below it that we looked at, that there was no LDL-C  
23 increase for an average patient, right?

24 A That's true.

25 Q Okay. And there are footnotes that denote the

1 statistical significance, you talked about that, right?

2 A Yes.

3 Q And the LDL-C data does not reference either of the two  
4 footnotes, right?

5 A Correct.

6 Q And so a doctor reading defendants' label would  
7 understand that the LDL-C data in table 2 is not statistically  
8 significant, right?

9 A Correct.

10 Q And there's a column marked Difference (95 Percent  
11 Confidence Level), do you see that?

12 A Yes.

13 Q There are two numbers in the parenthesis for the LDL-C,  
14 minus 13 and plus eight, right?

15 A Yes.

16 Q And the plus eight means that within the group  
17 representing 95 percent of the patients in the study, LDL-C  
18 increased as high as eight percent, right?

19 A Yes.

20 Q And that would be a clinically meaningful increase,  
21 right?

22 A Yes.

23 Q And the doctor -- so the doctor reading defendants' label  
24 would understand that some percentage of patients in this  
25 study actually had an LDL-C increase, right?

1 A There will be some, yes. There are outliers to any  
2 effect.

3 Q And based on this information in defendants' labels, a  
4 doctor would understand that some patients taking icosapent  
5 will actually experience a clinically significant LDL-C  
6 increase, right?

7 A That is possible, and that's why we repeat the lab values  
8 at 12 weeks to see if anything has happened.

9 Q Okay. Let's go to the next slide which is DDX 3.33.  
10 We're looking at DX 2256, page 8, which is Hikma's proposed  
11 label, and DX 1578 which is the Lovaza label. Both documents  
12 are in evidence.

13 You recognize these two documents, right?

14 A Yes.

15 Q And you talked about the Lovaza warning, right?

16 A Yes.

17 Q Okay. And your opinion is that doctors will compare the  
18 top snapshot from defendants' labels to the Lovaza warning  
19 about LDL-C, right?

20 A Yes.

21 MR. KLEIN: Okay. Actually, it's the Lovaza  
22 warning -- that's in evidence, right?

23 Let me move just in case, the Lovaza label may  
24 be a PX so let me move to admit DX 1578 just in case it's not  
25 in evidence.

1 MR. M. KENNEDY: No objection, Your Honor.

2 THE COURT: It hasn't been admitted. DX 1578 is  
3 admitted.

4 (Defendants' Exhibit 1578 received in  
5 evidence.)

6 BY MR. KLEIN:

7 Q And so your opinion with regard to the LDL-C limitation  
8 assumes that the doctor reading defendants' label would be  
9 aware of this warning in the Lovaza label, right?

10 A Yes.

11 Q And it's your opinion that -- and your opinion assumes  
12 that the doctor would compare the adverse reactions from the  
13 Lovaza study to the -- Hikma's proposed label and the study in  
14 Hikma's label, right?

15 A Yes.

16 Q Okay. And this LDL-C statement in Hikma's label would  
17 carry significance to a doctor only because and if the doctor  
18 understood that Lovaza had this side effect, right?

19 A Yes.

20 Q Otherwise, it wouldn't mean much to the doctor to say  
21 there was no LDL-C increase, right?

22 A Correct.

23 Q Defendants' labels never tell doctors to compare the  
24 icosapent clinical trial to the Lovaza clinical trial, right?

25 A Correct.

Q And, in fact, defendants' labels don't refer to the

1 Lovaza label at all, right?

2 A Correct.

3 Q Let's go to DDX 3.34 which is DX 2256, page 3. This is  
4 section 6.1 of Hikma's propose label. You've seen this,  
5 right?

6 A Yes.

7 Q And this section is called Clinical Trials Experience,  
8 and it says,

9 "Because clinical trials are conducted under  
10 widely varying conditions, adverse reaction rates  
11 observed in the clinical trials of a drug cannot be  
12 directly compared to rates in the clinical trials of  
13 another drug and may not reflect the rates observed  
14 in practice," right?

15 A Yes.

16 Q In other words, defendants' labels is telling doctors and  
17 warning them against comparing adverse reactions from two  
18 clinical trials involving 2 different drugs, right?

19 A Yes.

20 Q So this warning section, 6.1 in defendants' labels, would  
21 cover comparing the Vascepa LDL-C adverse reaction rates with  
22 the Lovaza LDL-C adverse reaction rates which was obviously a  
23 separate trial, right?

24 A Well, the LDL rates are part of the primary study.  
25 Adverse reactions are usually side effects like bleeding or

1 joint pain or back pain or rash. So these are a little bit  
2 different.

3 Q But a doctor would understand reading -- a doctor reading  
4 defendants' labels would understand that two clinical trials  
5 involving two different drugs are conducted under different  
6 situations, and they may or may not be comparable, right?

7 A Yes.

8 Q And a doctor reading defendants' labels as a whole would  
9 obviously see section 6.1, right?

10 A Yes.

11 Q Now, you -- on direct you talked about how some asserted  
12 claims require reductions in apo B. Do you remember that?

13 A Yes.

14 Q Let's take another look at Hikma's label DX 2256, page 8,  
15 DDX 3.35. And this -- you talked about this statement on  
16 direct, "icosapent ethyl 4 grams per day reduced," and I'm  
17 just going to focus on "apo B levels from baseline relative to  
18 placebo." Do you remember that?

19 A Yes.

20 Q Now, this statement would not necessarily affect  
21 prescription decisions, right?

22 A It could because apo B going down would lower  
23 cardiovascular risk, and, again, that's an indication for  
24 Vascepa.

25 I realize it's not in your label, but we already



1 talked about people potentially using your product off-label  
2 to get that benefit. So I think is this the benefit  
3 REDUCE-IT, is that Vascepa or icosapent ethyl lowers apo B,  
4 therefore lowers cardiovascular risk.

5 So I think this is a very important point that  
6 doctors would use the drug for to achieve cardiovascular  
7 benefit.

8 Q Okay. And those cardiovascular benefits would be beyond  
9 the scope of defendants' labels, right?

10 A Yes.

11 Q Now, on direct you told the Court that you prescribed  
12 Vascepa with the intent to reduce apo B; is that right?

13 A Yes.

14 Q But you don't focus on apo B in your practice, right?

15 A I don't often measure it, no.

16 Q You often don't even look at apo B, right?

17 A If it's available, I look at it, but I don't send  
18 patients to the lab for apo B measurements routinely.

19 Q And so when you prescribed Vascepa, reducing apo B is not  
20 an intended result with regard to treating severe  
21 hypertriglyceridemia, right?

22 A No, it's more for cardiovascular risk as I stated.

23 Q And defendants' products are not indicated specifically  
24 to reduce triglycerides by any particular amount, right?

25 A That's correct.

1 Q And it would be consistent with the Vascepa labeling to  
2 prescribe the drug to patients with severe  
3 hypertriglyceridemia even if you only wanted to have a 5  
4 percent reduction, right?

5 A I don't think that would be the intent of the physician,  
6 but if that occurred, that would still be an on-label use.

7 Q Now, let's take a look at DDX 3.36, and this is DX 2256,  
8 page 21. Do you recognize this as claim 1 of the '728 Patent?

9 A Yes.

10 Q And I highlighted the limitation "who does not receive  
11 concurrent lipid-altering therapy." Do you see that?

12 A Yes.

13 Q And on direct you testified that a statin is an example  
14 of a lipid-altering therapy, right?

15 A Yes.

16 Q Probably the most common example, right?

17 A Yes.

18 Q But there are other lipid-altering therapies, right?

19 A Yes.

20 Q For example, fibrates, niacin, right?

21 A Yes.

22 Q And also Zetia; is that right?

23 A Yes.

24 Q And the chemical name is Ezetimibe?

25 A Yes.

1 Q And in your practice, your patients very commonly take  
2 Vascepa with a statin, right?

3 A Yes.

4 Q And you don't read the Vascepa labeling as requiring  
5 doctors and yourself to give the drug without a statin, right?

6 A It's -- right. You have the option as a physician to use  
7 it with or without a statin.

8 Q For example, you don't -- in your practice, you wouldn't  
9 start Vascepa with no statin, wait for the triglycerides to  
10 decline below 500, and then add a statin later, right?

11 A I may. I gave an example of that during my direct.

12 Q Okay. But that's not the common way you would use  
13 Vascepa, right?

14 A It's more commonly patients are already on a statin and  
15 their triglycerides are above 500, so I might implement  
16 Vascepa.

17 Q And maintain the statin therapy, right?

18 A Yes.

19 Q And if we go to DDX 3.37, this is DX 2256, page 7, this  
20 is the portion of defendants' label that says 25 percent of  
21 patients were on concomitant statin therapy, right?

22 A Yes.

23 Q And this is just letting doctors know that 25 percent of  
24 patients in the clinical study discussed in the labeling were  
25 taking a statin, right?

1 A Yes.

2 Q In other words, this sentence is just -- or this phrase  
3 is just discussing the study protocol, right?

4 A Yes.

5 Q This sentence is not an instruction to doctors to make  
6 sure they use a statin, right?

7 A It's not a mandate to use a statin in this indication.

8 Q And it's not mandating not to use a statin either.

9 A Right.

10 Q Okay. And this statement doesn't say anything about  
11 other lipid-altering therapies, right?

12 A Correct.

13 Q And so the statement is not requiring doctors and  
14 patients to take icosapent without any concurrent  
15 lipid-altering therapy, right?

16 A It's not forcing them, right. They can use it as  
17 monotherapy, it's indicated as monotherapy, but it's not  
18 mandated as monotherapy.

19 Q And when you read this phrase, you inferred that  
20 75 percent were not on a statin, right?

21 A Yes.

22 Q Okay. But the labeling doesn't say anything about  
23 whether this 75 percent of patients were taking a different  
24 lipid-altering therapy, right?

25 A Right. We know most of them were not.

1 Q But you know from the MARINE study.

2 A Well, that's what this is referring to, yes.

3 Q No, but if a doctor were just reading the label, the  
4 doctor couldn't tell whether those 75 percent of patients were  
5 on a different lipid-altering therapy correct?

6 A Right.

7 Q And even if we just focus on statins, there's nothing in  
8 the clinical trial section or the label as a whole suggesting  
9 any preference for using icosapent with or without a statin,  
10 right?

11 A I think it encourages the option of either, but it  
12 doesn't say you have to use it one way or the other for that  
13 indication.

14 Q And, in fact, a doctor would not even be able to infer a  
15 preference with or without a statin from what's in the label,  
16 right?

17 A Well, I think, again, it's up to the clinical judgment of  
18 the physician and the clinical scenario of patient, and that  
19 is left to the doctor, the treating doctor, as we described  
20 before.

21 Q Right. So the defendants' labeling leaves it entirely up  
22 to the physician's discretion as to whether to add a  
23 concurrent lipid-altering therapy to icosapent, correct?

24 A Right. If it's needed you add it, if it's not needed,  
25 you don't have to add it.

1 Q All right. Now --

2 THE COURT: Mr. Klein, are you transitioning --

3 MR. KLEIN: I am.

4 THE COURT: -- to another exhibit?

5 I think it would make sense to take our  
6 afternoon recess at this time.

7 We'll take a 15-minute recess.

8 (A recess was taken.)

9 THE COURT: Please be seated.

10 Mr. Klein, are you ready?

11 MR. KLEIN: Thank you.

12 BY MR. KLEIN:

13 Q Dr. Budoff, you're not a lawyer, right?

14 A No.

15 Q And you're not an expert in patent law, right?

16 A No.

17 Q And I noticed, for the large part, you avoided any type  
18 of legal conclusions, right?

19 A I tried.

20 Q Okay. You're certainly not offering any opinions as to  
21 the legal standards for patent infringement, right?

22 A Correct.

23 Q And you're not testifying about whether any language in  
24 defendants' proposed labeling actually meets specific legal  
25 standards, correct?

1 A Correct.

2 Q You weren't familiar with the legal standards for patent  
3 infringement before this case, right?

4 A No.

5 Q And the legal standards for induced infringement can be a  
6 bit confusing? Did you find them confusing?

7 A Yes.

8 Q Okay. You're not the only one.

9 But do you understand that you might consider a  
10 particular statement in the labeling to encourage  
11 infringement, but the case law might require more specific  
12 statements to induce, right?

13 A Yes.

14 Q And your understanding when preparing your reports was  
15 that a product label induces infringement if the doctor  
16 follows the label and ends up using the drug on-label for an  
17 infringing use, right?

18 A Yes.

19 Q And on your direct, let's go to DDX 3.38, which is a copy  
20 of PDX 2-10, you talked about the legal standards that you  
21 applied, right?

22 A Yes.

23 Q And in the second bullet, you said,

24 "Evidence that defendants' labels would  
25 inevitably lead some clinicians to infringe

1           establishes defendants' intent to induce  
2           infringement," right?

3       A     Yes.

4       Q     And that came from the lawyers, presumably, right?

5       A     Yes.

6       Q     And -- but your view in preparing your reports was that  
7     at least -- if at least some physicians will prescribe Vascepa  
8     or its generic equivalent for severe hypertriglyceridemia to  
9     lower triglycerides, that means the label inevitably induces  
10    infringement, right?

11    A     Yes.

12    Q     And you understand that that phrase actually comes from  
13    case law?

14    A     Yes.

15    Q     And you're not offering an opinion on whether that  
16    particular phrase as construed by the courts has been  
17    satisfied by the labels, right?

18    A     Leave that to the Court.

19    Q     Exactly.

20                 Now, Dr. Budoff, you have a long consulting history  
21    with Amarin outside the context of this case, right?

22    A     Yes.

23    Q     And, for example, Amarin has retained you as a Thought  
24    Leader to discuss the Vascepa product?

25    A     Yes.



1 Q And you also served on Amarin's Speakers Bureau for  
2 Vascepa, right?

3 A Yes.

4 Q Let's go to the next slide, which is DX 2003, and it's  
5 DDX 1.39. Did you see this document during opening  
6 statements?

7 A Yes.

8 Q Is this a document you've seen before?

9 A No.

10 MR. KLEIN: Okay. I move into evidence DX 2003  
11 as an Amarin document.

12 MR. M. KENNEDY: No objection, Your Honor.

13 THE COURT: 2003 is admitted.

14 (Defendants' Exhibit 2003 received in  
15 evidence.)

16 BY MR. KLEIN:

17 Q This -- you were on, and still are, actually, on Amarin's  
18 Speakers Bureau, right?

19 A Yes.

20 Q Okay. And this -- this document says, "Dear VITAL  
21 Speakers." Do you understand VITAL is an abbreviation for  
22 advanced -- to Advance Interventions and Total Assessment of

23 A Yes.

24 Q Do you know what that is?

25 A That's just the name of their Speakers Bureau.

1 Q I see. Okay.

2 And that's -- the Dr. Matthew Budoff is you on this  
3 page, right?

4 A Yes.

5 Q And you recognize Dr. Toth as well?

6 A Yes.

7 Q And you recognize Dr. Mason?

8 A Yes.

9 Q Do you understand he, along with yourself and Dr. Toth,  
10 are all experts for Amarin in this case?

11 A Yes.

12 Q And if we go to DDX 3.40, there's a picture of Dr.  
13 Miller, right?

14 A Yes.

15 Q Is that the doctor who wrote the publication we looked at  
16 earlier?

17 A Yes.

18 Q Okay. And you understand now that he was actually  
19 retained as another Amarin expert earlier in the case?

20 A You told me that, yes.

21 Q Yeah.

22 And you began consulting for Amarin about eight  
23 years ago, in 2012?

24 A Yeah. I'd have -- I don't know exactly, but somewhere  
25 around that time.

1 Q Okay. And with regard to Amarin's Speakers Bureau, you  
2 encourage clinicians to use Vascepa, right?

3 A No, I try to educate them on the science and the  
4 guidelines. It's not my job, nor would I ever encourage them  
5 to use a specific product outside of what would be appropriate  
6 and best for the patient's care.

7 Q Okay. Understood. But Amarin was paying you to go out  
8 and speak to doctors about Vascepa, right?

9 A Yes. I get paid by a lot of different groups to give  
10 lectures. It's on my own time. I have to travel. So I do  
11 get compensated when I have to lecture most of the time.

12 Q You served as an Amarin speaker for Vascepa about a 100  
13 times; is that right?

14 A I wouldn't know exactly, but it's possible over the seven  
15 years.

16 Q You estimate maybe 100 in your deposition. Does that  
17 sound right?

18 A Yeah.

19 Q And I think you've said this earlier, you're still a  
20 speaker for Vascepa today, right?

21 A Yes.

22 Q And as an Amarin Thought Leader, you gave Amarin advice  
23 on how to help market Vascepa to physicians, right?

24 A Not generally. I usually give them advice on what  
25 science to do or what next study to do.

1 I've met with them about the EVAPORATE trial and  
2 tried to encourage them to do other studies. I'm not a  
3 marketing expert, so I don't give them marketing advice.

4 Q You gave Amarin general advice or direction on what  
5 things about Amarin's clinical study may resonate with  
6 clinicians or what things should be emphasized or  
7 de-emphasized; is this right?

8 A Yes.

9 Q And you also consulted with Amarin on the REDUCE-IT  
10 trial? You talked about that, right?

11 A Yeah. I wasn't directly involved in the REDUCE-IT trial,  
12 outside of being a principal investigator. I wasn't on the  
13 steering committee or anything. So, I wasn't really involved  
14 in that other than recruiting some patients locally at my own  
15 site.

16 Q Okay. And just to be clear, REDUCE-IT focused on a  
17 different patient population than the patient population we're  
18 talking about in defendants' labels, right?

19 A Yes.

20 Q And you also sent proposals to Amarin with regard to the  
21 EVAPORATE trial, right?

22 A Yes.

23 Q And since 2016, about half of your income comes from  
24 pharmaceutical companies, including Amarin, right?

25 A All lectures combined, but, yes.

1 Q And about 10 percent of your income comes from Amarin,  
2 right?

3 A Yeah.

4 Q And you also testified for Amarin at the FDA Advisory  
5 Committee meeting held last November for the new REDUCE-IT  
6 indication, right?

7 A I was just a public speaker. That was on my own behalf.

8 MR. KLEIN: Okay. Let's go to DX 2246, pages 1  
9 and 62, and it's DDX 3.41. This is Amarin's supplemental NDA  
10 financial disclosure.

11 We'll move this into evidence.

12 MR. M. KENNEDY: No objection, Your Honor.

13 THE COURT: 2246 is admitted.

14 (Defendants' Exhibit 2246 received in  
15 evidence.)

16 BY MR. KLEIN:

17 Q I don't know, have you seen Amarin's financial disclosure  
18 with regard to its supplemental NDA?

19 A No.

20 Q Okay. I'll represent to you that that's what this is.

21 You know what the financial disclosure is, right?

22 A Yes.

23 Q And Amarin had to make financial disclosures to the FDA  
24 for you and other investigators, right?

25 A Yes.

Q Okay. And Amarin submitted this document on March -- in

1 March 2019, right? You see that at the bottom?

2 A Yes.

3 Q Okay. If we turn to Section 3, it's DX 2246, page 3,  
4 DDX 3.42, the document -- you see the title, Clinical  
5 Investigators With Disclosable Interests?

6 A Yes.

7 Q And the document explains that,

8 "Clinical investigators with disclosable  
9 financial interests including a significant equity  
10 interest in the sponsor of the covered study as  
11 defined in" the regulations "and/or significant  
12 payments of other sorts (SPOOS)," S-P-O-O-S, "as  
13 defined" in the regulations, "are provided in Table  
14 1. Details of their disclosed financial interests  
15 and arrangements are included in Table 2."

16 Do you see that?

17 A Yes.

18 Q All right. Now, let's go to the next slide DX 2246,  
19 pages 3 to 4. This is DDX 3.43. You see this is Table 1?

20 A Yes.

21 Q And can you see that you are one of the doctors who was  
22 disclosed by Amarin?

23 A Yes.

24 Q And if my count's right, there were 12 in total.

25 A Okay.

1 Q All right. Now, turning to the next page, DX 2246,  
2 page 7, this is DDX 3.44, Table 2 lists the details of the  
3 disclosed financial interests and arrangements for the 12  
4 people we just looked at. Do you understand that?

5 A Yes.

6 Q Okay. And, again, this -- you are the Matthew Budoff on  
7 the left there?

8 A Yes.

9 Q And Table 2 lists SPOOS, which was defined earlier as  
10 Significant Payments of Other Source -- Sorts, for you of  
11 close to \$1.3 million. Do you see that?

12 A Yes.

13 Q And then the table breaks this down. Do you see that?

14 A Yes.

15 Q And so Amarin has provided you with a research grant of  
16 \$900,000 related to the EVAPORATE study, right?

17 A That goes to my institution, not to me, but, yes.

18 Q And just so you know, my next question was, to be fair,  
19 you didn't receive the money personally.

20 A Right.

21 Q Okay. But it does help a study that you proposed to  
22 Amarin, right?

23 A Yes.

24 Q And you're the principal investigator for that study.

25 A Yes.

1 Q And your name will be associated with the results of the  
2 study if it's successful, right?

3 A It already is. I've been publishing on that trial.

4 Q We go to the next slide, it's the same page, different  
5 highlighting, DDX 3.45, you received a higher research grant  
6 than any of the other 11 individuals listed in the table,  
7 right?

8 A Yes.

9 Q Now, if we go to the next slide, which is DDX 3.46,  
10 again, it's the same slide, I just changed the highlighting.  
11 If we take out the \$900,000 grant, the rest of the  
12 \$1.3 million was paid by Amarin to you personally, right?

13 A No. The honorarium and consulting fees goes to me  
14 personally. A lot of the compensation might go to my  
15 institution. For example, I do educational programs at my  
16 institution, and they support that. That money would go to  
17 the institution and not to me.

18 Q Okay. But it's your institution, correct?

19 A No, I don't own it. It's named the Lundquist Institute.  
20 I'm one of 1,000 investigators there, and the money that goes  
21 to the institute supports all of our services there; research,  
22 pharmacies, the statistics, a lot of different things.

23 Q Okay.

24 A It doesn't benefit me personally in any way.

25 Q Well, it benefits you personally indirectly to the extent



1 it's benefitting an institution to which you belong, correct?

2 A Well, yes, but they just received a \$70 million grant to  
3 name the institution, so my contribution of a total of 300,000  
4 is probably not very significant, and that money doesn't go to  
5 me as well.

6 So I would say that I'm definitely responsible for  
7 receiving the consulting fees of 33,000 and the honorarium of  
8 27,000. I don't know what education of \$42 represents, but  
9 let's -- I'll take credit for that as well, maybe I received  
10 that payment.

11 Q Okay. Over the years, for your consulting work,  
12 unrelated to this case, you would guess you have received  
13 probably \$300,000, or something over, spanning the last eight  
14 years, right?

15 A No, nowhere near that number.

16 Q Okay.

17 A That would be listed here if that were the case.

18 MR. KLEIN: Mr. Gross, can you play the 272 --  
19 page 272 of his deposition, line 24, to 273, line 6.

20 (Deposition video played.)

21 BY MR. KLEIN:

22 Q Doctor, was that your testimony?

23 A Yes, but that includes money that goes to my institution,  
24 not to me personally.

25 Q The question -- okay.

1 A I apologize. I didn't understand your question.

2 Yes. It says right here, 302,000. I think that  
3 number is probably very accurate.

4 MR KLEIN: No further questions.

5 MR. M. KENNEDY: Your Honor, I do have a little  
6 bit of redirect.

7 Your Honor, may I proceed?

8 THE COURT: Yes.

9 REDIRECT EXAMINATION

10 BY MR. KENNEDY:

11 Q So, Dr. Budoff, I'm going to jump around a few topics you  
12 covered with Mr. Klein just now.

13 Mr. Klein asked you about whether Vascepa was  
14 suitable to reduce triglycerides in severely  
15 hypertriglyceridemic patients in less than 12 weeks.

16 Do you remember that discussion?

17 A Yes.

18 Q And you do you remember the related discussion with  
19 Mr. Klein about whether triglyceride levels are reduced in  
20 less than 12 weeks? Do you remember that testimony?

21 A Yes.

22 Q Now, once a severely hypertriglyceridemic patient's  
23 triglyceride levels have been reduced, is therapy complete?

24 A No.

25 Q Why not?

1 A Well, again, if you stop the therapy, in most cases it  
2 will go back up. We've seen that in the MARINE trial. We see  
3 that in clinical practice, that in a vast majority of patients  
4 triglycerides will not stay below 500 without additional  
5 medical therapy.

6 Q What is the therapeutic goal for a patient with severe  
7 hypertriglyceridemia?

8 A The goals and the guidelines are to reduce and maintain  
9 their triglycerides below 500 milligrams per deciliter.

10 Q Now, for a severely hypertriglyceridemic patient who  
11 doesn't have what we've been calling one of the reversible  
12 causes of severe hypertriglyceridemia, how do you maintain a  
13 reduction in triglyceride levels?

14 A So in almost all cases I continue the therapy long-term,  
15 as I've described this morning and this afternoon.

16 Q With your typical patients who have very high  
17 triglycerides or severe hypertriglyceridemia, would you know  
18 if they had reduced their triglycerides below 500 in fewer  
19 than 12 weeks?

20 A No. I don't usually bring them in for lab testing at a  
21 shorter interval.

22 Q Do you know of any clinicians who do, as a habit?

23 A No. I think the vast majority, if not all physicians  
24 that I'm aware of, their practice patterns revolve around what  
25 we would call a typical practice, and a typical practice would

1 be to repeat the results at three months, to bring them back  
2 at three months for a follow-up visit.

3 Q Now, Mr. Klein also asked you on cross about whether your  
4 patients ever take Vascepa for less than 12 weeks.

5 Do you remember that testimony?

6 A Yes.

7 Q And I think you said that some of your patients do take  
8 Vascepa for less than 12 weeks. Do you remember that?

9 A Yes.

10 Q Now, have you ever prescribed Vascepa to a patient with  
11 severe hypertriglyceridemia for fewer than 12 weeks?

12 A No. The shortest prescription I've ever written would be  
13 a one month prescription with three refills. So that would be  
14 four months, at a minimum, to get them to the three-month  
15 follow-up, where I can reassess their lipids.

16 Q So I think you alluded to some reasons why one of your  
17 patients might, nonetheless, take Vascepa for fewer than 12  
18 weeks. Can you explain what those reasons are.

19 A Yeah. So most commonly they go to the pharmacy, and the  
20 price is too high, and they say, "I can't afford it," and so  
21 they don't want to take it, and they call me and they say,  
22 "Can I take something else?"

23 Second most commonly would be side effects.  
24 Patients perceive side effects, even though Vascepa I consider  
25 generally safe. I would say that Vascepa is -- has some side

1 effects and some issues with tolerability. So some people  
2 would say, "Oh, I feel joint aches," or, "I'm getting some  
3 other problem. I'm going to stop the therapy before 12  
4 weeks."

5 Q Now, you had a discussion with Mr. Klein about whether  
6 there are patients with very high triglycerides who can have  
7 their condition addressed solely with diet and lifestyle.

8 Do you remember that discussion?

9 A Yes.

10 MR. M. KENNEDY: Mr. Brooks, can we have PX 989.  
11 This is ATP III guidelines we a looked at earlier today.

12 COMPUTER TECHNICIAN: Madam clerk, can you  
13 switch me?

14 MR. M. KENNEDY: And, Mr. Brooks, if you'd go to  
15 page 195 of the document and blowup the left-hand column.

16 BY MR. M. KENNEDY:

17 Q So, Dr. Budoff, do you recognize this passage?

18 A Yes.

19 Q I think we discussed portions of this earlier today.

20 A Yes.

21 Q I would like to direct you a few lines down, and the  
22 heading of this passage is Very High Triglycerides. What is  
23 your understanding of why this passage is headed that way?

24 A This is the part of the document that addresses severe  
25 hypertriglyceridemia.

1                   MR. M. KENNEDY: So, Mr. Brooks, I would like to  
2 go about ten lines down and highlight the sentences beginning  
3 with "weight reduction and increased physical activity," and  
4 go through the word "pancreatitis," about five lines down.

5 BY MR. M. KENNEDY:

6       Q     And, Dr. Budoff, if you could review this passage and let  
7 me know what, if anything, does this passage tell you about  
8 the clinical needs of patients with severe  
9 hypertriglyceridemia?

10     A     Well, it's just saying that after lifestyle modifications  
11 are emphasized, triglyceride-lowering drugs are usually  
12 required. So, it just tells you that most patients -- as we  
13 discussed this afternoon, most patients fail diet and exercise  
14 as a primary treatment strategy.

15     Q     And what if a patient succeeds with diet and lifestyle  
16 changes?

17     A     Well, if they were successful, then they would not be  
18 indicated to start Vascepa, and I would just continue  
19 lifestyle changes, as least for the MARINE indication purposes  
20 of discussion.

21     Q     So you also had some discussion with Mr. Klein about  
22 LDL-C. Do you remember that testimony?

23     A     Yes.

24     Q     What would a clinician in your field know about LDL-C,  
25 just whether it's good or bad, what its function is?

1 A I would hope that every person who is practicing in the  
2 field of lipids understands that LDL cholesterol is bad.

3 Q And they would understand that, all things being equal,  
4 it would be better to have low LDL-C rather than high LDL-C?

5 A Yes.

6 Q Is this knowledge that clinicians in your field would  
7 have in their minds when reviewing the Vascepa labeling and  
8 particularly the clinical data?

9 A Yes.

10 Q Is this background knowledge -- would that affect your  
11 treatment decisions for patients with severe  
12 hypertriglyceridemia?

13 A That would really be the only reason, short of the  
14 REDUCE-IT indication, to use Vascepa preferentially over the  
15 less expensive fibrates or Lovaza which has a generic  
16 alternative.

17 So, we go through great steps to get patients on  
18 Vascepa right now. I have to often call the insurance  
19 company. I have to convince them that my patient meets the  
20 criteria. I have to then sometimes get a formal prior  
21 authorization approved.

22 So I go through steps. The patient has to pay extra  
23 money at the pharmacy, all of that. The primary reason is not  
24 because it's the best triglyceride-lowering drug, but because  
25 it's the best drug at not -- that lowering triglycerides will

1 not affect that LDL cholesterol.

2 So, I think that becomes paramount in the  
3 clinician's decision to use Vascepa over generic alternatives.

4 Q So just to be clear, these considerations that you just  
5 mentioned, do they affect your decision about which medication  
6 to prescribe with patients with severe hypertriglyceridemia?

7 A Absolutely.

8 Q So Mr. Klein asked you some questions about the clinical  
9 effects experienced by patients who take Vascepa, and  
10 particularly whether some patients may not achieve the  
11 clinical effects touted in the clinical trial section of the  
12 label. Do you remember that testimony?

13 A Yes.

14 Q Now, when you administer Vascepa to a patient by writing  
15 a prescription, and a patient with severe  
16 hypertriglyceridemia, what clinical effects do you expect to  
17 achieve at the moment you write that prescription?

18 A So my intent is that they will follow the general results  
19 of the MARINE trial, that they will get a triglyceride  
20 reduction of about a third, that their LDL cholesterol will  
21 not go up, that their apo B will go down.

22 Obviously there are patient-to-patient differences.  
23 That's why I have to retest them at 12 weeks to see what  
24 really happened in my patient.

25 Q So what percentage of your patients end up achieving the



1 effects touted in Table 2 of the labeling, that is, severely  
2 hypertriglyceridemic patients to whom you prescribe Vascepa  
3 according to the labeling?

4 A Yeah. So we know it's about three-quarters of patients  
5 will achieve that general result, and there will be some  
6 people on the outsides of that, the extremes.

7 Q I think you called them outliers in your discussion with  
8 Mr. Klein?

9 A Yes.

10 Q So at the moment you write the prescription to a patient  
11 with very high triglycerides, do you have any way of knowing  
12 whether that patient is going to be an outlier?

13 A No.

14 Q So, I would like to ask you couple questions about apo B.  
15 So am I -- is treating very high triglycerides with  
16 Vascepa in order to reduce triglycerides and lower apo B, is  
17 that on-label?

18 A Yes.

19 Q Is that part of your prescribing practice to patients  
20 with very high triglycerides?

21 A Yes.

22 Q And, finally, I would like to go to a document that  
23 Mr. Klein used with you, it's your reply expert report, and  
24 this is PX 177.

25 MR. M. KENNEDY: And, Mr. Brooks, if you could

1 turn to page 23 of this document.

2 BY MR. M. KENNEDY:

3 Q Now, Mr. Klein showed you paragraph 54 of your expert  
4 report, and 57, but I would like to show you a couple  
5 surrounding paragraphs that he didn't show you, and starting  
6 with paragraph 53.

7 MR. M. KENNEDY: And, Mr. Brooks, can you blow  
8 that up, please. And maybe put 53 along with 54, if you're  
9 able to do that.

10 BY MR. M. KENNEDY:

11 Q Now, Dr. Budoff, again, Mr. Klein showed you 54. He  
12 didn't show you 53. Could you just review 53 and then tell us  
13 what was the context in which you were giving the opinions  
14 that Mr. Klein showed you in 54?

15 A (Witness reviews document.)

16 Yeah. So this is suggesting that even though  
17 Dr. Sheinberg has given them the medication, that he's  
18 instructed them to wait six weeks before filling the  
19 prescription and then coming back at 12 weeks. Therefore,  
20 when they return, they've only received six weeks of therapy  
21 and not 12 weeks of therapy.

22 Q Do you agree with Dr. Sheinberg's theory as stated in  
23 paragraph 53?

24 A This has, to my knowledge, never been practiced this way,  
25 and this would not be how any physician that I've ever

1 encountered would prescribe medication.

2 We give them the prescription and say start this  
3 medicine. And if we don't want them to start the medicine, we  
4 wouldn't give them the prescription.

5 I don't give them a prescription and say put in your  
6 calendar for six weeks from now to go to the pharmacy and fill  
7 this. That would not work in clinical practice, and it's not  
8 recommended approach to treatment.

9 Q Now, at the time you wrote this reply expert report, you  
10 gave a number of reasons why you disagree with Dr. Sheinberg;  
11 is that right?

12 A Yes.

13 Q And Mr. Klein did show you a couple of those reasons in  
14 paragraphs 54 and 57; is that right?

15 A Yes.

16 Q Now, he didn't show you paragraph 55, which Mr. Brooks  
17 has kindly put on the screen. And I'll read it into the  
18 record.

19 "To begin with, the Prescribing Information  
20 counsels that the drug should be given to patients  
21 for whom efforts to reduce their triglycerides below  
22 500 milligrams per deciliter, using only diet and  
23 lifestyle modifications, have been unsuccessful."

24 Do you see that?

25 A Yes.

1 Q Now, you reference the Prescribing Information. Are  
2 there particular portions of the Prescribing Information that  
3 counsel that drug should only be given to patients who can't  
4 reduce their triglycerides below 500 without -- through just  
5 diet and lifestyle?

6 A Yes.

7 Q Which portions do you have in mind?

8 A Well, we talked about Section 2, the dosing and  
9 administration. I think that explicitly states that you  
10 should use diet and lifestyle. The patient should engage in  
11 diet and lifestyle before using therapy, and then, obviously,  
12 if they're still not at goal, you would put them on therapy.

13 Also, the Section 14, the clinical trial section, we  
14 know and we reviewed that this afternoon as well, the MARINE  
15 trial was done with that six- to nine-week washout period  
16 where they documented that after diet and lifestyle failed, if  
17 their triglycerides were still above 500, were then they  
18 enrolled in the study.

19 Q Now, people who are able to reduce their triglycerides  
20 below 500 with diet and lifestyle, is Vascepa indicated for  
21 those patients?

22 A Well, now it is. The REDUCE-IT indication may play a  
23 role depending on their underlying cardiovascular risk. But  
24 for severe hypertriglyceridemia, the MARINE indication, it  
25 would not be indicated.

1 MR. M. KENNEDY: Your Honor, I have no further  
2 questions.

3 THE COURT: Mr. Klein?

4 MR KLEIN: No further questions.

5 THE COURT: All right. Thank you, Dr. Budoff.  
6 You may step down.

7 THE WITNESS: Thank you very much.

8 MR. SIPES: Your Honor, Christopher Sipes for  
9 Amarin. With that, plaintiffs close their opening case.

10 MR KLEIN: Your Honor, Ms. Fundakowski is going  
11 to address the fact that plaintiffs have closed their case,  
12 and Ms. Fundakowski will make a motion.

13 MS. FUNDAKOWSKI: Claire Fundakowski on behalf  
14 of the defendants Hikma.

15 Your Honor, we understand that this is a bench  
16 trial, but if Your Honor is so inclined, defendants would like  
17 to move for a judgment on partial findings under Rule 52(c).

18 Plaintiff's sole infringement theory is that  
19 defendants --

20 THE COURT: Now, you need -- I don't know if  
21 you're reading from something. You need to slow down if you  
22 are reading because, otherwise, the court reporter will remind  
23 you to slow down. I also want to take some notes, so you need  
24 to indulge me.

25 MS. FUNDAKOWSKI: Thank you, Your Honor.

1           Plaintiff's sole infringement theory is that  
2 defendants' proposed labels will actively induce doctors to  
3 infringe the claims. To prevail, plaintiff's must show by  
4 preponderance of the evidence that defendants have the  
5 specific intent, based on the contents of their proposed  
6 labels, to encourage physicians to prescribe defendants' ANDA  
7 products in an infringing manner. Plaintiffs have failed to  
8 meet this burden.

9           Among other limitations, each of the asserted  
10 claims requires at least 12 weeks of treatment. As recognized  
11 in the Court's summary judgment order and confirmed by today's  
12 testimony, defendants' proposed labels do not explicitly tell  
13 doctors they should prescribe the drug for at least 12 weeks.

14           Plaintiffs therefore argue that the Court should  
15 infer that defendants induce infringement because defendants'  
16 proposed labels instruct doctors to treat severe  
17 hypertriglyceridemia as an adjunct to diet.

18           Plaintiffs' evidence fails to show that  
19 defendants' proposed labels induce physicians to prescribe  
20 icosapent for at least 12 weeks.

21           Under *Grunenthal*, 919 F.3d 1333 at 1339, even if  
22 the indicated use includes the patented use, there is no  
23 inducement if the proposed labels do not specifically  
24 encourage the patented use.

25           The rationale for the Federal Circuit's

1 *Grunenthal* decision is rooted in plaintiff's burden to prove  
2 that defendants possessed specific intent to induce  
3 infringement.

4 Because the plaintiff in that case could not  
5 show that the indicated use was coextensive with or required  
6 the patented use, the Court could not infer that defendants  
7 had a specific intent to induce infringement.

8 The Federal Circuit reached this conclusion in  
9 *Grunenthal* even though plaintiff presented evidence that, I  
10 quote, "most of the uses of their proposed ANDA products would  
11 be directed to," end quote, the claimed use. And that was at  
12 1340.

13 Here, for the same reason, plaintiffs have  
14 failed to show that defendants' proposed labels will induce  
15 prescribers to treat patients for at least 12 weeks. The  
16 undisputed evidence that defendant proposed -- show that the  
17 defendants' proposed labels are indicated for conditions that  
18 do not require treatment --

19 THE COURT: Where is the undisputed evidence?

20 MS. FUNDAKOWSI: I believe we heard Dr. Budoff  
21 testify today that severe hypertriglyceridemia has, I quote,  
22 reversible causes, which according to Dr. Budoff would, I  
23 quote, not be considered a chronic condition.

24 Dr. Budoff agreed with plaintiffs' invalidity  
25 expert, Dr. Toth, that severe hypertriglyceridemia, I quote,

1 can be acute -- an acute phenomenon.

2 Dr. Budoff testified that weight loss of 5  
3 percent to 10 percent can result in a 20 percent decrease in  
4 triglycerides. He testified that it is possible to see  
5 reductions in triglycerides of up to 50 percent without any  
6 medication.

7 And even in the MARINE study, in the patient  
8 population that received four to six weeks of diet and  
9 exercise, they were unable to reduce their triglycerides.  
10 Dr. Budoff testified, and as shown in DX 1701-51, that about  
11 21 percent of patients falling within the scope of defendants'  
12 proposed indication can reduce and maintain their  
13 triglycerides down to below 500 milligrams per deciliter with  
14 diet and exercise alone, or, in other words, without the need  
15 for continued drug treatment for at least 12 weeks.

16 Plaintiffs' evidence therefore fails to show  
17 that the Court can infer that defendants' proposed labels  
18 induce doctors to prescribe icosapent for a period of at least  
19 12 weeks.

20 Plaintiffs argue that specific intent to induce  
21 infringement can be inferred because, according to plaintiffs,  
22 defendants' proposed labels would inevitably lead some  
23 physicians to prescribe icosapent for at least 12 weeks, but  
24 plaintiff's misstate the legal standard.

25 The Federal Circuit has never held that



1 inducement can be inferred if only some physicians will  
2 eventually infringe. Rather, the law merely holds that an  
3 instruction to infringe need not be directed to all physicians  
4 in order for there to be inducement.

5 This case law does not apply here because there  
6 is no such instruction inducing infringement. For example, in  
7 *Eli Lilly*, 845 F.3d 1357 at 1369, the Court found that  
8 repeated instructions and warnings throughout defendants'  
9 proposed labeling demonstrated specific intent to induce  
10 infringement.

11 As explained at 1368, the Court explained that  
12 the instructions teach an infringing use such that we are  
13 willing to infer from those instructions an infirmative intent  
14 to infringe the patent.

15 The Federal Circuit there did not require  
16 evidence that all physicians would follow those repeated  
17 instructions and warnings, but in light of the unambiguous,  
18 repeated instructions and warnings, the Court explained at  
19 1369 that it was sufficient that those instructions, I quote,  
20 would inevitably lead some physicians to infringe.

21 Likewise in *Vanda*, 887 F.3d 1117 at 1131, the  
22 court found that there was a recommendation to perform the  
23 claimed genotyping test. The label did not require all  
24 physicians to perform the genotyping test, so it was again  
25 sufficient that defendants' labels would inevitably lead some

1 physicians to infringe.

2 Here defendants' proposed labels do not contain  
3 an explicit instruction that defendants' products should be  
4 administered for at least 12 weeks. As in *Grunenthal*,  
5 defendants' proposed labels likewise do not implicitly require  
6 a 12-week treatment.

7 Plaintiffs have thus failed to meet their burden  
8 to show induced infringement, and defendants respectfully  
9 request judgment in their favor.

10 THE COURT: Thank you.

11 MS. FUNDAKOWSI: Thank you, Your Honor.

12 THE COURT: Mr. Sipes, will you be responding?

13 MR. SIPES: If the Court would like, I can  
14 respond, Your Honor.

15 THE COURT: Well, I would like some response.

16 MR. SIPES: That was my question. I wasn't  
17 asking to choose. I wanted to make sure the Court did not  
18 just want to just take it under submission.

19 THE COURT: I'm going to give you a ruling, so I  
20 want a response.

21 MR. SIPES: Okay.

22 I understand them to be moving principally on  
23 the 12-week limitation, so I will respond on that.

24 The issue here is one of whether or not the  
25 labeling induces administration of the drug for at least

1 12 weeks. First, let me go through the evidence that shows  
2 that it does, and then I will address the legal standard  
3 question.

4 Dr. Steve Ketchum testified about FDA's review  
5 and negotiation over the labeling, and pointed to a number of  
6 documents both public that would help explain to physicians  
7 what the scope of the approval was, and otherwise that showed  
8 that the indication for which the drug was approved, treatment  
9 of severe hypertriglyceridemia, is chronic, and that treatment  
10 is to reduce and maintain triglyceride levels below 500 which  
11 requires treatment more than 12 weeks.

12 And, in fact, then Dr. Budoff went on and  
13 explained how physicians understand the labeling, and that the  
14 labeling is understood to require clinicians to maintain  
15 triglyceride levels in these patients under 500, and that as a  
16 chronic condition that requires indefinite treatment. He went  
17 through all the other elements of the claims as well and  
18 showed that they were met too.

19 There's no question that the labeling is  
20 instructing physicians that the drug may be used to treat the  
21 chronic condition of severe hypertriglyceridemia, to maintain  
22 triglycerides below 500, and that that will go on for 12 or  
23 more weeks.

24 In fact, Dr. Budoff went on and said that the  
25 dosage and administration section instructs doctors rule out

1 the reversible causes. So it in fact specifically directs  
2 physicians towards chronic patients, towards 12 or more weeks  
3 treatment.

4 In terms of the case law, for example, in  
5 *Astrazeneca v. Apotex*, 633 F.3d 1042, Federal Circuit 2010,  
6 the Federal Circuit addressed a case in which the (inaudible)  
7 had actually carved out an indication for once daily  
8 administration that the claim was directed to, their labeling  
9 instructed for twice daily administration, but also included  
10 titration language, that physicians should seek to use the  
11 lowest possible dose, and Federal Circuit found there that  
12 that would inevitably lead some physicians to treat once a  
13 day, that that was sufficient for induced infringement.

14 That case was actually endorsed by the *Vanda v.*  
15 *West-Ward* case, 887 F.3d 1117, Federal Circuit 2018, which  
16 rejected the line of argument, I believe, that the defendants  
17 are making now, that we need to show that all physicians would  
18 be led.

19 In this case, we have clear instructions in the  
20 labeling to rule out reversible causes. We have clear  
21 instructions to treat patients for a chronic condition. We  
22 have descriptions of the clinical study section, which shows  
23 as well that the drug is safe and effective for 12 or more  
24 weeks. There was no instructions to treat any shorter period  
25 of time.

1                   And, we have accompanying FDA review documents  
2 available to the public that would further inform physicians  
3 as to the meaning of the labeling the defendants are  
4 proposing, and we think that more than meets the standard for  
5 induced infringement in this case.

6                   Thank you, Your Honor.

7                   THE COURT: Thank you.

8                   MR. SIPES: If there are no questions.

9                   THE COURT: Any rebuttal?

10                  MS. FUNDAKOWSI: If I may, Your Honor.

11                  Your Honor, I would like to make two points.

12                  Claire Fundakowski again.

13                         We believe *Grunenthal*, 919 F.3d 1333 at 1340, is  
14 completely on point here. Mr. Sipes mentioned a case, I  
15 believe it was the *Astrazeneca v. Apotex* case, in which the  
16 dosage and administration section included express  
17 instructions for patients to titrate down the medication.

18                         *Grunenthal* distinguished that case explaining --  
19 and, again, this is at 1340 -- that *Astrazeneca* is in apposite  
20 to our facts. There was specific intent that could be  
21 inferred, I quote, because the defendant proceeded with a plan  
22 to distribute the generic drug knowing that its label imposed  
23 infringement problems.

24                         In addition, the instructions in the Dosage and  
25 Administration Section of the label would inevitably lead some

1 consumers to practice the claimed method of once daily dosing  
2 by encouraging users to taper downward to the lower -- lowest  
3 effective dose.

4 The language in that Court's decision that "some  
5 users" would be led to infringe is because not all physicians  
6 would be required to use the lowest effective dose. Not all  
7 physicians would be required to taper down to that dose. But  
8 there was an express instruction in that case, and that --  
9 such an instruction is absent here.

10 I would also like to point out Mr. Sipes  
11 referenced the FDA forms that mention chronic use. But as  
12 noted -- just a moment, please -- as noted in *Horizon*, 940  
13 F.3d 680 at 702, knowing of the possibility of infringement  
14 will not suffice.

15 Of course, Vascepa can be used long-term. It  
16 can also be used short-term. The label is indifferent to the  
17 length of treatment and leaves it entirely up to physician  
18 discretion. This does not show active intent to induce  
19 infringement and therefore defendants believe judgment should  
20 be granted in their favor.

21 That's all, Your Honor.

22 THE COURT: Thank you.

23 I want to take some time to formulate my ruling.  
24 I want to continue with the defendants' rebuttal portion.

25 Are you ready to proceed?

1 MR. REIG-PLESSIS: Yes, Your Honor.

2 Your Honor, my name is Eimeric Reig, I'm counsel  
3 for the defendants here, and as defendants' first witness, we  
4 call Dr. Jonathan Sheinberg.

5 THE COURT: Thank you.

6 THE CLERK: Would counsel like to please have  
7 someone come up and retrieve these exhibit binders?

8 MR. REIG-PLESSIS: And we would also ask  
9 permission to approach. We have some witness binders, as  
10 well, for Dr. Sheinberg.

11 THE COURT: Yes.

12 JONATHAN I. SHEINBERG, M.D.,  
13 called as a witness on behalf of the Defendants,  
was sworn and testified as follows:

14 THE CLERK: Please be seated.

15 Please state for the record your full name and  
16 spell your last name.

17 THE WITNESS: Jonathan Sheinberg,  
18 S-h-e-i-n-b-e-r-g. Jonathan, J-o-n-a-t-h-a-n.

19 MR. REIG-PLESSIS: Good afternoon,  
20 Dr. Sheinberg.

21 THE WITNESS: Good afternoon.

22 DIRECT EXAMINATION

23 BY MR. REIG-PLESSIS:

24 Q Where are you currently employed?

25 A I'm currently employed in Austin, Texas, for Baylor Scott

1 & White Cardiology.

2 Q And what is your current position at Baylor Scott & White  
3 Cardiology?

4 A I am a senior staff cardiologist. I am an invasive  
5 cardiologist with an interest in preventive cardiology as  
6 well.

7 Q Did the defendants retain you to testify as an expert in  
8 this case?

9 A Yes, they have.

10 Q Now, apart from this case, do you have any affiliation  
11 with the defendants?

12 A I do not.

13 Q And you mentioned that you are a general cardiologist  
14 with an interest in preventive cardiology. Could you just  
15 explain what preventive cardiology is.

16 A Yes, sir. So I have general cardiology experience, in  
17 other words, I practice the full gamut of cardiology from  
18 initial evaluation of a patient with intent to prevent that  
19 patient from developing coronary disease, taking a patient who  
20 already has developed coronary disease and preventing that  
21 patient from having a secondary event.

22 I also treat general cardiology patients.

23 I'm also proficient in the catheterization  
24 laboratory in which we perform invasive procedures to evaluate  
25 problems.



1 THE COURT: Also, would you make sure you speak  
2 into the microphone. I want to make sure everyone is able to  
3 hear you. Thank you.

4 THE WITNESS: Yes, ma'am.

5 BY MR. REIG-PLESSIS:

6 Q So turning first to DDX 4.1, there is a snapshot on the  
7 screen of DX 2225, page 1, which is in your binder as well.

8 Could you identify this document, please.

9 A Yes, this is my CV.

10 Q Does your CV accurately summarize your educational  
11 background, work experience, and research?

12 A Yes, it does.

13 MR. REIG-PLESSIS: And, Your Honor, we would  
14 move into evidence DX 2225.

15 MS. KEANE: No objection, Your Honor.

16 THE COURT: 2225 is admitted.

17 (Defendants' Exhibit 2225 received in  
18 evidence.)

18 BY MR. REIG-PLESSIS:

19 Q So turning to DDX 4.2, there's another snapshot on the  
20 screen of the same exhibit DX 2225.

21 Could you summarize your educational background for  
22 the Court, please.

23 A Yes, I can. I graduated with a bachelor's degree from  
24 Washington and Lee University. I attended Georgetown  
25 University School of Medicine where I received my medical

1 degree.

2 At that time I entered active duty with the United  
3 States Air Force and did my internship at Georgetown and  
4 Fairfax Hospital and my residency at Keesler Air Force Base in  
5 internal medicine, that's in Biloxi, Mississippi.

6 After completion of my internal medicine residency,  
7 I went to Wilford Hall Air Force Base -- I'm sorry -- Wilford  
8 Hall Medical Center at Lackland Air Force Base, Texas, to  
9 finish my fellowship in cardiovascular disease.

10 After completing that, I continued to serve in the  
11 Air Force for an additional four years with a combat  
12 deployment overseas before settling in Austin, Texas, in 2004,  
13 which is where I am living now.

14 Q Do you have any board certifications currently?

15 A I'm Board Certified in cardiovascular disease.

16 Q And how long have you been a cardiologist?

17 A This is my 20th year.

18 Q How many patients do you see per month, approximately, in  
19 your cardiology practice?

20 A I see roughly a 100 patients or more per month -- I'm  
21 sorry, per week, which averages about 400 or so, plus or  
22 minus, per month.

23 Q Do you treat patients with elevated triglycerides?

24 A Every day.

25 Q Do you treat patients with triglyceride levels above 500?

1 A Yes, I do.

2 Q How often?

3 A Relatively frequently, on the order of approximately 20  
4 to 30 per month.

5 Q Have you prescribed Vascepa before?

6 A Yes, I have.

7 Q And have you taught courses relating to cardiology?

8 A Yes, I have. I have been an instructor and a professor  
9 of medicine both at the University Uniform Health Science  
10 Center in Bethesda, Maryland, as well as Wright State  
11 University in Dayton, Ohio.

12 COURT REPORTER: Slow down, please.

13 THE WITNESS: Sorry. So the Uniform Services  
14 University in Bethesda, Maryland, as a Clinical Professor, as  
15 well as an Assistant Professor at Wright State University in  
16 Dayton, Ohio. I'm currently an Assistant Professor of  
17 Medicine at the University of Texas Medical Branch in  
18 Galveston.

19 BY MR. REIG-PLESSIS:

20 Q And do you conduct any other activities related to  
21 cardiology?

22 A Yes, I do. As the first page of my CV pointed out, not  
23 only am I a cardiologist, but I'm also one of the few  
24 physicians in the United States who is a sworn police officer.

25 I serve in that capacity, not only as an officer,

1 but I work within the Department of Justice to develop and  
2 create wellness programs which we institute throughout the  
3 United States and Canada to keep police officers and other  
4 first responders healthy as well.

5 Q Now, do you have any publications on your CV?

6 A I do not.

7 Q And why not?

8 A I am a practicing, busy, what we like to refer to as,  
9 quote, in the trenches, cardiologist. With a very busy  
10 clinical practice, there's really no time left to devote to  
11 research.

12 In fact, we often in -- those of us who practice in  
13 busy, clinical practices often say that we are penalized if we  
14 spend time doing research because at that time we are not  
15 actively seeing patients and we are not generating volume  
16 through the clinic.

17 So I do not have any research publications in that  
18 regard.

19 Q Now, we've heard some testimony already today about  
20 approved drug labels. Are those labels generally directed to  
21 researchers or to clinicians?

22 A They're directed towards clinicians.

23 Q And are you a clinician?

24 A Yes, sir, I am.

25 MR. REIG-PLESSIS: Defendants now tender

1 Dr. Sheinberg as an expert in the field of cardiology.

2 MS. KEANE: No objection, Your Honor.

3 MR. REIG-PLESSIS:

4 Q Dr. Sheinberg, do you have slides --

5 THE COURT: Is this just a general field of  
6 cardiology?

7 MR. REIG-PLESSIS: Yes, Your Honor.

8 THE COURT: Is that the motion?

9 You have to wait for me to rule. So, is that  
10 the motion?

11 MR. REIG-PLESSIS: Yes, Your Honor, in the  
12 general field of cardiology.

13 THE COURT: There's no objection, so the request  
14 is granted.

15 BY MR. REIG-PLESSIS:

16 Q Dr. Sheinberg, do you have slides to assist the Court  
17 with your testimony today?

18 A Yes, I do.

19 Q And are the documents cited in those slides documents you  
20 relied on in forming your opinions?

21 A Yes, they are.

22 Q So turning now to DDX 4.3, could you summarize the  
23 opinions you'll be presenting in your testimony today.

24 A Yes, I will.

25 I will -- it will be my opinion this afternoon that

1 severe hypertriglyceridemia is not necessarily a chronic  
2 condition which requires indefinite drug treatment, and I also  
3 will opine that severe hypertriglyceridemia can be treated  
4 with a short course of drug therapy followed by diet and  
5 exercise to maintain the triglyceride reductions that we  
6 have seen.

7 Q And, Doctor, are you offering those opinions today in the  
8 context of the indicated use for Vascepa and defendants'  
9 products to treat, quote, severe hypertriglyceridemia?

10 A Yes, I am.

11 Q So turning to DDX 4.4, do you also have specific opinions  
12 on defendants' product labels?

13 A Yes, I do. It is the opinion that I will share today  
14 that defendants' labels do not encourage, recommend, promote,  
15 or require administration -- administering their product for  
16 any duration, let alone at least 12 weeks, to achieve specific  
17 effect on the lipids, including a minimum percent reduction in  
18 triglycerides, to avoid an increase in LDL, and to cause a  
19 reduction of apolipoprotein B levels.

20 I will also show this can be done without concurrent  
21 lipid-altering therapy.

22 Q Turning to DDX 4.5, in forming your opinions did you  
23 analyze the claims that are asserted by Amarin in this case  
24 against the defendants?

25 A Yes, I have. '929 patent claims 1 and 5; '728 patent

1 claims 1 and 16; '715 patent claim 14; '677 patent claims 1  
2 and 8; '652 patent claim 1; and '560 patent claims 4 and 17.

3 Q And are you familiar with those claims which are in the  
4 patents that are in your binder?

5 A Yes, I am.

6 Q Turning to DDX 4.6, which limitations of the asserted  
7 claims did you specifically analyze?

8 A In regarding the at least 12 weeks duration of drug  
9 treatment limitation, that is in all 10 asserted claims.

10 In regards to the specific effects on lipid levels  
11 limitation, which includes the minimum triglyceride  
12 reductions;

13 The no increase in LDL; and

14 The reduction in apolipoprotein B that is seen in  
15 nine claims which are all asserted claims except '929 patent  
16 claim 1; and

17 The limitation of no concurrent lipid-altering  
18 therapy, which we will discuss, which includes statins, but  
19 not limited to that drug class is in three claims;

20 '728 patent claims 1 and 16; as well as '715 patent  
21 claim 14.

22 Q And are you addressing any other limitations of the  
23 claims in your testimony besides the limitations described in  
24 DDX 4.6?

25 A No, sir, I am not.

1 Q So turning to DDX 4.7, there is a snapshot from DX 1500,  
2 which I understand is on the admitted exhibits list, could you  
3 point out the three categories of limitations that you  
4 analyzed in an exemplary asserted claim.

5 A Yes. In this example, which is '728 patent claim, you  
6 can see that it does have all three of the limitations.  
7 Starting with the yellow highlighted section number 1 for a  
8 12-week duration, as you can see it describes that acid or  
9 esters for a period of 12 weeks.

10 In regards to the specific lipid effects, the  
11 example here which is seen in nine claims, to effect a  
12 reduction in triglycerides without substantially increasing  
13 LDL.

14 And the third example, which is highlighted in  
15 orange, is seen under the section after 1500 milligrams per  
16 deciliter, talking about individuals who do not receive  
17 concurrent lipid-altering therapy as this is one of the claims  
18 that has all three components associated with it.

19 Q So turning now to DDX 4.8, there are snapshots on the  
20 screen of the Court's claim construction order, and the  
21 parties' stipulation on agreed upon constructions which are  
22 ECF numbers 135 and 83. Did you apply the constructions in  
23 these documents in forming your opinions in this case?

24 A Yes, I have.

25 Q So turning to DDX 4.9, what are the topics you intend to



1 address in your testimony?

2 A There will be two specific topics. The first I will give  
3 background regarding the concept of severe  
4 hypertriglyceridemia, and we will -- I will also talk about  
5 how Vascepa is used, and then we will discuss the  
6 noninfringing analysis that I performed.

7 Q So turning to DDX 4.10, there is a snapshot on the screen  
8 of DX 1876, page 99. We understand this exhibit has also been  
9 admitted. Could you identify this document.

10 A Yes, I can. This is the National Cholesterol Education  
11 Program, the NCEP expert panel on detection, evaluation, and  
12 treatment of high blood cholesterol levels in adults,  
13 otherwise known as the Adult Treatment Panel, or ATP III final  
14 report. It was published in circulation in 2002.

15 And, as this document goes on to describe in the  
16 highlighted area below, it states that if triglycerides are  
17 very high, which is greater than or equal to 500 milligrams  
18 per deciliter, attention turns first to the prevention of  
19 acute pancreatitis.

20 Q And what is severe hypertriglyceridemia or very high  
21 triglycerides?

22 A In terms of the definition here, greater than  
23 500 milligrams per deciliter, is that the --

24 Q Yes. Just in general what is it?

25 A It's a situation in which hyper means too many.

1 Triglyceridemia means triglycerides in the blood, and so it's  
2 too many triglycerides in the blood.

3 Q Now, is severe hypertriglyceridemia a discrete disease?

4 A It is not actually a discrete disease. It is more of a  
5 downstream consequence of multiple potential etiologies or  
6 causes.

7 Q Why does severe hypertriglyceridemia require treatment?

8 A Because if it is not treated, we know it can cause two  
9 different issues, the first which is described here as  
10 pancreatitis. Pancreatitis, which has already been described  
11 as a very painful, horrible condition in which the pancreas  
12 becomes inflamed and essentially begins to digest itself.

13 Not only is it painful, but it carries with it a  
14 rather high mortality rate. In other words, it can cause  
15 death in a relatively frequent amount of people who suffer  
16 from it.

17 And we also know that there is an association with  
18 elevated triglycerides in cardiovascular risk.

19 Q Now, if a patient is at risk for pancreatitis, do you  
20 delay treating that patient with triglyceride-lowering drugs?

21 A Absolutely not. If I have a patient that is at risk for  
22 this potential life-threatening complication, we treat that  
23 person aggressively from day one.

24 Q Do you necessarily treat patients differently depending  
25 on whether their triglycerides are above or below 500?

1 A There is no magic thing that happens at 500. If I have  
2 someone who has triglycerides of 400, someone who has  
3 triglycerides of 550 or 600, I will look at that person  
4 relatively equivalently and treat those people aggressively to  
5 prevent the sequelae or the consequences that those  
6 triglycerides would potentially result in.

7 Q So turning to DDX 4.11, there is a snapshot on the screen  
8 of DX 1982, page 2 which is already in evidence. Could you  
9 identify this document.

10 A Yes, I can.

11 This is the website for Vascepa, and the website  
12 goes on to describe what are the causes for  
13 hypertriglyceridemia, and it lists five specific issues. The  
14 first two are highlighted in yellow here.

15 Oftentimes, as the testimony has shown throughout  
16 the day, these two things run hand-in-hand, but according to  
17 the website here it quotes, "Here are some ways that  
18 triglyceride levels may become very high."

19 The first is diet and lack of exercise. This  
20 combination of poor diet and a sedentary lifestyle is the  
21 cause of most of what we see. I would imagine that's why they  
22 are the two items that are listed first. And after practicing  
23 for 20 years with 25,000 patients in my population that I see,  
24 it is no question in my mind that these are the primary causes  
25 of hypertriglyceridemia.

1 Under the diet section, it says what you eat and  
2 drink, especially alcohol and processed carbohydrates. Quite  
3 frankly, the concept, at least where I practice in Texas,  
4 sugared sodas should be listed on that list because it is a  
5 considerable problem that we see. We also know that our  
6 patients are likely not getting the exercise that they need.

7 Besides diet and exercise, we see certain medical  
8 conditions which can cause hypertriglyceridemia such as  
9 diabetes.

10 And I would go on to also say, in regards to  
11 diabetes, most of the diabetes that we treat in cardiology is  
12 Type II diabetes, it's diabetes that results from what we call  
13 insulin resistance which is a diabetes not from a genetic,  
14 discrete problem in which the pancreas doesn't produce enough  
15 insulin, it's from a metabolic problem which is basically a  
16 diet and exercise issue.

17 The fourth thing on the list are specific drugs,  
18 which includes hormones and certain blood pressure  
19 medications.

20 And the last thing on this list, it says genetics,  
21 and that's a rather broad term, which if I may define it a  
22 little bit at this moment.

23 There are two -- we can think of the genetic issue  
24 as basically two different discrete issues. There is a  
25 definitive, genetic abnormality in a very small minority of

1 our patients that are missing the genetic ability, or missing  
2 the ability to code for certain enzymes or proteins, which,  
3 for example, cause triglycerides to be broken out of certain  
4 cholesterol particles.

5 For example, there's an enzyme called lipoprotein  
6 lipase, and if there is an individual who does not have that  
7 enzyme, that individual will have severely elevated  
8 triglycerides which are what we call refractory or very  
9 difficult to treat.

10 There are other genetic abnormalities. They've  
11 already been mentioned here this morning and this afternoon.  
12 But, 98 or more of our patients -- 98 percent or more of our  
13 patients do not have those discrete genetic abnormalities.

14 What they may have is what we like to call a genetic  
15 predisposition. In medicine we understand that there are  
16 genetic predispositions for everything, for how tall people  
17 are, for how people respond to certain diets and exercise.

18 We all know people who -- the layman's term is they  
19 look at a pizza and they gain weight. We know people who are  
20 able to eat very little and still not achieve optimal body  
21 mass, and the other side of the spectrum is true as well. We  
22 know people who can eat everything on their plate and they  
23 never gain weight.

24 We have genetic proclivities that influence how we  
25 respond to everything in our lives, and there are people who

1 have a genetic proclivity to have elevated triglycerides  
2 without having the specific genetic abnormality which relates  
3 in exceedingly elevated triglyceride levels.

4 Q So can a patient be genetically predisposed to  
5 hypertriglyceridemia that is not severe?

6 A Absolutely.

7 Q Now, apart from those listed on Amarin's website, are  
8 there other cases of severe hypertriglyceridemia?

9 A There are. Under medical conditions we have -- we see  
10 renal failure. We see people who smoke have an increased  
11 risk. We know in pregnancy, especially in the last trimester,  
12 women can have hypertriglyceridemia which sometimes becomes  
13 severe.

14 So there are certainly other things that this list  
15 is exclusive of.

16 Q Are there short-term causes of severe  
17 hypertriglyceridemia?

18 A Absolutely. We know it for a fact that when people  
19 overindulge in certain diets, a diet which is very high in  
20 simple sugars or alcohol, and potentially reduce their  
21 activity -- the best example of this I can think of is you  
22 take someone who goes on a cruise, who is potentially  
23 genetically predisposed to have elevated triglycerides.  
24 They're on the cruise for the week. They are eating at the  
25 buffet, having as many desserts as they want, they're not

1 exercising. They're consuming considerable amounts of  
2 alcohol.

3 That individual, who is genetically predisposed for  
4 an elevation of triglycerides, even severe elevation of  
5 triglycerides, after that cruise there's a very good chance  
6 that individual will be over 500.

7 So there are acute conditions. You remove those  
8 acute insults, you take the person off the cruise, they go  
9 back on their lifestyle, and that situation of  
10 hypertriglyceridemia can potentially resolve. So there are  
11 certainly other acute reasons.

12 Q Now, does Amarin's website indicate anywhere that the use  
13 of Vascepa is limited to patients with genetic abnormalities  
14 causing severe hypertriglyceridemia?

15 A No, sir, it does not.

16 Q And what are the typical triglyceride levels of patients  
17 with those types of genetic abnormalities?

18 A The genetic abnormalities that I mentioned, the ones that  
19 have already been mentioned earlier in testimony, are  
20 typically well over 1000 to 2000.

21 Again, there's a considerable variability, but those  
22 people who have discrete genetic conditions typically have  
23 triglycerides which are multiples of 500.

24 Q So generally, in the triglyceride range of 500 to 1000,  
25 does that include patients with genetic abnormalities usually?

1 A It can, but usually it does not. As we get higher, up to  
2 that 1000 level range, the genetic abnormality will become  
3 more prevalent.

4 But when we talk between 500, as we get higher in  
5 that range, there are still plenty of people who will have  
6 severe hypertriglyceridemia which is not from a discrete  
7 genetic abnormality.

8 Q And when you say "plenty of people," can you estimate  
9 what percent of patients would have it?

10 A Ninety-seven plus percent, 98 percent.

11 Q And just to be clear, that's 98 percent without a genetic  
12 abnormality?

13 A The discrete -- excuse me. The discrete genetic  
14 abnormalities really occur in potentially 2 percent of the  
15 population that we see.

16 Q So turning now to DDX 4.12, there's a snapshot on the  
17 screen of DX 1953, page 29. Could you identify this document.

18 A Yes, I can. This is Amarin's validity contentions.

19 This document goes on to say that -- in the first  
20 paragraph here,

21 "Persons of ordinary skill in the art also  
22 understood that both diet and exercise level could  
23 have significant impacts on triglyceride levels.  
24 Heavy consumption of carbohydrates, certain kinds of  
25 fats and/or alcohol was understood to lead to



1           increased triglyceride levels."

2                       The document further goes on to say in the  
3 second paragraph,

4                       "In contrast, it was understood that regular  
5 exercise could offset the triglyceride effects of  
6 some dietary factors and decreased triglyceride  
7 levels. Accordingly, the lack of exercise and/or  
8 sedentary lifestyle are known to correlate with  
9 higher triglyceride levels."

10       Q    Do you agree with these statements in Amarin's validity  
11 contentions in this case?

12       A    Absolutely. This is what I would consider the absolute,  
13 primary reason many of our patients suffer from  
14 hypertriglyceridemia.

15                       MR. REIG-PLESSIS: And, Your Honor, we would  
16 move the admission of DX 1953.

17                       MS. KEANE: Your Honor, plaintiffs object to the  
18 admission --

19                       THE COURT: Would you make sure you speak into  
20 the microphone.

21                       MS. KEANE: Yes, Your Honor.

22                       Plaintiff's object to the admission of DX 1953.  
23 These are Amarin's preliminary validity contentions. It is a  
24 document containing attorney argument. It is not evidence of  
25 fact, and it, therefore, is not appropriate admissible

1 evidence.

2 We are aware of there is case law --

3 THE COURT: Isn't it already part of the record?

4 MS. KEANE: They have not been admitted, Your  
5 Honor.

6 THE COURT: Well, wasn't it a record in terms of  
7 it being filed with the Court on the docket?

8 MS. KEANE: No, Your Honor. It was not filed,  
9 it was just exchanged amongst the parties. It's a preliminary  
10 statement --

11 THE COURT: Oh, I see.

12 MS. KEANE: -- of positions of counsel.

13 THE COURT: I'm sorry to interrupt. But, you  
14 were saying --

15 MS. KEANE: Yes. We believe there's a case from  
16 the District of Hawaii that's directly on point, that  
17 preliminary contentions, one, are not evidence of fact, and,  
18 two, they are not party admission either. And the cite for  
19 that is 2015 WL 1117993, and the title is *Kowalski v. Anova*  
20 *Food*.

21 THE COURT: What's your response?

22 MR. REIG-PLESSIS: Well, Your Honor, a couple  
23 responses. I think we're a little puzzled by the objections  
24 since these are Amarin's own statements and contentions in  
25 this very case. We submit that they would be at least party

1 admissions under Federal Rule of Evidence 801(d) (2) .

2 We're aware of the *Kowalski* case which  
3 plaintiffs have cited to us. It's an unpublished case from  
4 the District of Hawaii which was not applying this court's  
5 patent rules.

6 Obviously these contentions were served under  
7 this court's patent rules on defendants. It is far too late  
8 for plaintiffs to amend the contentions. These statements  
9 were never amended.

10 We tried to avoid having to move these into  
11 evidence by simply adding Amarin's own statements of fact  
12 verbatim, a stipulated fact into the Pretrial Order. Amarin  
13 refused. It seems they are backing away from these statements  
14 that, again, were their own contentions of fact.

15 Now, you know, we're not arguing they're bound  
16 by these contentions as judicial admissions, we would just say  
17 that they are at least evidentiary admissions that should come  
18 in and FRE 801.

19 I should just add there are also cases going the  
20 other way. We cited one such case from the Eastern District  
21 of Texas which hears almost -- many, many patent cases, and  
22 that found the other way.

23 THE COURT: Well, regardless of how other  
24 district courts have ruled, I overrule the objection. I find  
25 that because the validity contentions were exchanged as part

1 of the Court's Local Rule, the party that offered the  
2 contentions are bound by their contentions and now cannot try  
3 to seek to exclude them, therefore, the objection is  
4 overruled.

5 Exhibit 1953 is admitted.

6 (Defendants' Exhibit 953 received in  
7 evidence.)

8 MR. REIG-PLESSIS: Thank you, Your Honor.

9 BY MR. REIG-PLESSIS:

10 Q So turning now to DDX 4.13, there's a snapshot on the  
11 screen of DX 1957, page 6. Could you identify this document,  
12 please.

13 A Yes, I can. This is an excerpt from the Karalis paper, *A*  
14 *Review of Clinical Practice Guidelines For the Management of*  
15 *Hypertriglyceridemia*. It was published in *Advanced*  
16 *Therapeutics* in 2017 out of the University of Pennsylvania.

17 Dr. Karalis goes on to describe in this paper,

18 "The cornerstone for the treatment of  
19 hypertriglyceridemia is lifestyle intervention with  
20 diet and exercise."

21 He goes on further to describe,

22 "However, pharmacologic therapy to lower  
23 triglycerides may be considered based on an  
24 individual's cardiovascular risk and how high the  
25 level of triglycerides are."

Q So based on Karalis, is pharmacologic therapy to lower

1 triglycerides in patients with severe -- excuse me -- with  
2 hypertriglyceridemia always required?

3 A No, they are not always required.

4 MR. REIG-PLESSIS: And, Your Honor, we would  
5 move into evidence DX 1957.

6 MS. KEANE: No objection.

7 THE COURT: I'm sorry. I didn't hear. Did you  
8 say no objection?

9 MS. KEANE: No objection.

10 THE COURT: DX 1957 is admitted.

11 (Defendants' Exhibit 1957 received in  
12 evidence.)

13 MR. REIG-PLESSIS: Thank you, Your Honor.

14 BY MR. REIG-PLESSIS:

15 Q So turning to DDX 4.14, Dr. Sheinberg, were you in the  
16 courtroom were Mr. Klein presented the testimony on the screen  
17 from Dr. Budoff during opening statements?

18 A Yes, I was.

19 Q And were you in the courtroom when Dr. Budoff confirmed  
20 this testimony during his examination?

21 A Yes, I was.

22 Q And how does Dr. Budoff's clinical -- excuse me. How  
23 does Dr. Budoff's testimony on DDX 4.14 compare with your own  
24 clinical experience?

25 A Let me first describe what Dr. Budoff is saying here.  
His -- the question was,

1                   "And so is it consistent with your experience  
2                   that roughly one-fifth of patients with severe  
3                   hypertriglyceridemia are able to reduce their  
4                   triglyceride levels below 500 through diet and  
5                   exercise alone?"

6                   To which Dr. Budoff replies yes.

7                   And to answer your question after reading that,  
8                   it is consistent, however, my experience is even more so.  
9                   Dr. Budoff will say one-fifth of his patients, my experience  
10                  is it's more closely with -- closer to 70 percent to  
11                  75 percent of my patients can reduce their triglycerides below  
12                  500 through diet and exercise alone.

13                 Q    And why do you believe your experience differs from  
14                 Dr. Budoff's?

15                 A    I can simply tell you that in my practice I see -- there  
16                 may be several reasons. Number one, we're in different parts  
17                 of the country so I can only comment on what the dietary  
18                 makeup for the local central Texas patient population is,  
19                 which, unfortunately, Texas has a significantly high rate of  
20                 obesity which is one of the highest in the country.

21                 Also, the type of patients that I see, I am in a  
22                 primary setting. In other words, I have -- most of my  
23                 patients are referred to me by either word-of-mouth, they come  
24                 in directly, or they come from a primary care physician. I do  
25                 not have secondary, tertiary referrals.

1           In other words, I don't work at a large center which  
2 specializes or is known to be a research center that would  
3 receive more difficult cases.

4           So I think the combination of my initial patient  
5 population -- and, again, I cannot speculate on Dr. Budoff's  
6 population or how his practice runs, but I do see quite a bit  
7 of individual referrals, patients who do not go through other  
8 individuals who are treating their lipids before they come to  
9 me.

10       Q    And is the indicated use of Vascepa to treat severe  
11 hypertriglyceridemia limited to patients for secondary or  
12 tertiary referrals?

13       A    It is not.

14       Q    So turning now to DDX 4.15. There's a snapshot on the  
15 screen of DX 1960, page 38. Could you identify this document,  
16 please.

17       A    Yes, I can. This is an excerpt from a textbook on  
18 dyslipidemia by Pete Kwiterovich. It is written out of Johns  
19 Hopkins, and the chapter 7 which I am quoting here is  
20 *Disorders of Hypertriglyceridemia*, written by Dr. Michael  
21 Miller.

22           It goes on to say that, "in addition to" -- and this  
23 abbreviation of HFCS stands for high fructose corn syrup --

24           "A diet high in carbohydrates may lead to an  
25 elevation of triglycerides."

1                   It goes on further towards the bottom and it  
2                   says, "Regardless of macronutrient intake," which  
3                   means whether it's protein or fat or carbohydrate,  
4                   "the most potent manner for reducing triglycerides is  
5                   through weight reduction,"  
6                   which is absolutely consistent with what I see in my clinical  
7                   practice daily.

8           Q     And do you understand from the testimony earlier today  
9           that Michael A. Miller was Amarin's claim construction expert  
10          in this case?

11          A     Yes, I do.

12          Q     So turning now to DDX 4.16, there's a snapshot on the  
13          screen of DX 1957, page 10.

14                   Now, once a patient starts a triglyceride lowering  
15          drug, can it be discontinued?

16          A     Yes, it can.

17          Q     And could you explain.

18          A     Yes, I can. This is an excerpt from that Karalis article  
19          that we discussed. The excerpt says,

20                   "If the triglyceride levels fall to normal or  
21                   borderline level with lifestyle changes and a  
22                   combination of lipid-lowering therapy, consideration  
23                   may be given to discontinuing the nonstatin  
24                   triglyceride-lowering medication."

25                   And then if you look at the bottom of the slide,



1 there's a simple graphic which represents the initiation of an  
2 individual's visit with a physician in which a short course of  
3 drug therapy is initiated, along with a lifestyle  
4 modification, which again is a diet, reconstruct -- diet  
5 construction and an exercise prescription.

6 That is continued for a brief amount of time,  
7 and then the drug can be discontinued when the triglycerides  
8 are less than 500 milligrams per deciliter, and we can  
9 maintain that with diet and exercise alone.

10 Q And is the treatment depicted on DDX 4.16 a medically  
11 reasonable way to treat a patient with a triglyceride-lowering  
12 drug?

13 A Absolutely.

14 Q So turning to DDX 4.17, I'll represent to you that this  
15 is a snapshot from Amarin's trial brief in this matter which  
16 was filed as ECF number 327, at pages 12 and 13, and could you  
17 just let us know whether you agree with the statements in this  
18 paragraph?

19 A So in order to give you that answer, I actually have to  
20 dissect this paragraph a little bit. That's a little bit more  
21 complicated than just answering yes or no because certain  
22 things I do agree with, and other things I would like to make  
23 a clarification because I do not agree with.

24 It goes on to say that,

25 "Severe hypertriglyceridemia is

1           life-threatening because it puts patients at acute  
2           risk of pancreatitis."

3                       I think there's no question. We all agree on  
4           that.

5                       It goes on to say,

6                       "It is chronic because it is typically caused  
7           by genetic factors."

8                       Well, if we take that portion of this document  
9           here, I would argue that it is not chronic and that it is not  
10          typically caused by genetic factors. I think my testimony so  
11          far has really been evident that the chronicity of this is not  
12          something that is definitive. We -- and I've given examples  
13          of individuals who can have acute elevations of triglycerides.

14                      When we talk about genetic factors, again, I  
15          like to make sure that we delineate the two different types of  
16          genetic factors that we're talking about, the absolute  
17          discrete genetic abnormality, which is a very small percentage  
18          of our patients, versus a genetic predisposition or  
19          predilection to develop a problem.

20                      So to say that it is chronic, which is typically  
21          caused by genetic factors, I do not believe the way it's  
22          written here is correct.

23                      It goes on to say that this cannot be cured  
24          through medication, and, again, that sentence or that  
25          statement here, we will agree that this type of problem can't

1 be -- there's no cure.

2           It's a treatment, not a cure, which is very  
3 different than someone who has a pneumonia. In that case, we  
4 give medication to cure a pneumonia. Here, we use a  
5 treatment.

6           The problem is the treatment is not necessarily  
7 through medication. The treatment, and like I've testified,  
8 is really lifestyle limiting.

9           So, for example -- it's a silly example, but if  
10 you have a rowboat that has a hole in it that is filling with  
11 water and you keep scooping out the water, you aren't going to  
12 get anywhere. You have to fix the underlying problem. You  
13 have to patch that hole.

14           In that example, patching the hole is fixing the  
15 underlying lifestyle problem. Unless you fix that problem,  
16 you can bail water all day long, and you're never going to  
17 have this problem fixed.

18           The document goes on further to say,

19           "If triglyceride-lowering medications are  
20 ceased, the severely hypertriglyceridemic patient  
21 will have triglyceride levels which will typically  
22 rise again to dangerous premedication levels."

23           And, again, to go back to the example that I  
24 said earlier, it's not if the medications are ceased but if  
25 the lifestyle modifications are not sustained and prolonged.

1 This is also manifested in individual patients who yo-yo on  
2 their weight.

3 We take someone who has what we call metabolic  
4 syndrome, they're overweight, they're sedentary, they're  
5 diabetic or pre-diabetic, we get those individuals well  
6 treated, we get them on a diet and exercise program, they lose  
7 weight, they are no longer diabetic or pre-diabetic, their  
8 blood pressure issues resolve.

9 If they maintain that, they're great. If they  
10 don't, they gain their weight back, they go right back to the  
11 same risks they had.

12 In this case, if they don't maintain the dietary  
13 and lifestyle changes that were prescribed, their  
14 triglycerides will, again, typically rise to the dangerous  
15 levels. But I would argue that it's not the medication that's  
16 doing it, it's the lifestyle.

17 This document further goes on to say,

18 "To prevent triglyceride levels from  
19 returning to dangerous pretreatment levels, standard  
20 medical practice is to administer triglyceride-  
21 lowering medications to severely hypertriglyceridemic  
22 patients chronically, not on a short-term,  
23 intermittent basis."

24 And, again, throughout this example I've laid  
25 out several scenarios in which the triglyceride medicine does

1 not need to be given chronically. It can be given on a  
2 short-term basis, and it can be given on an intermittent  
3 basis.

4 To go back to the example that I just mentioned,  
5 if I have an individual who was able to effect a good diet and  
6 exercise shift, they turn the leaf over, they're exercising,  
7 they're not smoking, they're not consuming carbohydrate-rich  
8 and sugar-rich foods, that person will have a reduction in  
9 their triglycerides.

10 If that person goes back to their previous  
11 lifestyle, their triglycerides will rise. They may now have a  
12 need, again, for hypertriglyceride-lowering medicines. They  
13 may also have a need again for anti-hypertensive medicines or  
14 diabetic medicine.

15 So all these medicines can be used on a  
16 short-term, intermittent basis.

17 Q Now, do you also have slides on how Vascepa is prescribed  
18 in clinical practice?

19 A Yes, sir, I do.

20 Q How often do you personally prescribe Vascepa?

21 A I prescribed Vascepa probably 15 to 20 times per month.

22 Q Are there similar products that you use more often than  
23 Vascepa?

24 A Yes, there are. I use the -- I use generic version of  
25 Lovaza, and I often use over-the-counter fish oil products as

1 well. There are some over-the-counter products that contain  
2 DHA, DPA, and EPA, and some that just contain EPA. So, I use  
3 a very similar products on a daily basis in my practice.

4 Q So turning now to DDX 4.19, there's a snapshot on the  
5 screen of DX 2248, page 2, and this exhibit is already in  
6 evidence.

7 When you do use Vascepa, Dr. Sheinberg, what are  
8 your main reasons for prescribing it?

9 A So I will start -- there are several reasons, and let me  
10 start with the indications that are listed here from the  
11 package insert.

12 The first indication, which throughout the last two  
13 days of testimony we've come to know as the REDUCE-IT  
14 indication, which is the indication to reduce the risk of  
15 heart attack, stroke, revascularization, which is bypass and  
16 stint, and unstable angina, really chest pain requiring  
17 hospitalization in the set population which are individuals  
18 who have cardiovascular disease or individuals who have  
19 diabetes and two more risk factors.

20 The second indication is an adjunct diet, which is  
21 what we've described here as the previous indication, which is  
22 to reduce -- or the MARINE indication, which is to reduce  
23 triglyceride levels in adults with triglycerides over 500.

24 But I will also point out there are other reasons  
25 which Vascepa is used in my practice, one of which is those of

1 us who use what we call advanced lipid testing, which is lipid  
2 testing or cholesterol testing which doesn't just focus on the  
3 amount of cholesterol, we actually focus on the quality of  
4 cholesterol.

5 So, for example, LDL, which is bad cholesterol,  
6 occurs in many different sizes. We know these products have  
7 an improvement in cholesterol quality.

8 We also know these products, which is icosapent  
9 ethyl, has an improvement in inflammation, and we now  
10 understand that when someone has a heart attack, it is  
11 actually resulting from an inflammatory change within that  
12 artery.

13 So our understanding of the pathogenesis of heart  
14 disease is based on our understanding of the inflammatory  
15 changes within the artery. Icosapent ethyl effectively  
16 reduces those inflammatory changes which may or may not lead  
17 to the benefits that we see here, that's been speculated over  
18 and over again.

19 So the reality is there are multiple reasons to use  
20 this medication.

21 Q Now, just focusing on the two on-label uses of Vascepa,  
22 does the REDUCE-IT indication, as the parties have been  
23 referring to it, have anything to do with the original MARINE  
24 indication?

25 A They are completely separate indications which affect

1 completely different patient populations.

2 I can tell you in my practice of over 400 and some  
3 odd patients per month, and, like I said earlier, a patient  
4 base of over 25,000 patients, I have rather -- maybe 10, 5 to  
5 10 percent of my patients that will have hypertriglyceridemia  
6 to the effect of greater than 500 milligrams per deciliter.

7 But I will have 70 some odd percent of my patient  
8 population which is characterized for the indication for  
9 REDUCE-IT. So, they do affect very different patient  
10 populations.

11 Q Now, do the defendants' labels in this case include both  
12 of the indications that are on the Vascepa label?

13 A No, they do not. The defendants' label is consisted only  
14 with what we have been categorizing as the MARINE indication,  
15 which is the adjunct to diet to reduce triglyceride levels in  
16 patients with severe hypertriglyceridemia.

17 Q And when you prescribe Vascepa for the MARINE indication,  
18 do you prescribe it together with diet and exercise?

19 A Absolutely.

20 Q And do you generally prescribe Vascepa long-term?

21 A Generally, I do.

22 Q And why is that?

23 A Even though the testimony to follow will show it, and I  
24 can tell you in my clinical practice we can see reductions in  
25 triglycerides rather rapidly for the effects that I mentioned



1 previously, which are the reduction of cardiovascular problems  
2 which is described above, the improvement in cholesterol  
3 quality and particle size and density, and in the  
4 anti-inflammatory properties.

5           If I'm able to get someone on this medication  
6 long-term, I would like to use it long term. But the minority  
7 of that is to reduce triglycerides in patients over  
8 500 milligrams per deciliter.

9       Q    So is the reason that you keep patients on Vascepa  
10 long-term to keep their triglycerides below 500 as required by  
11 the MARINE indication?

12       A    Absolutely not.

13       Q    So turning now to DDX 4.20, could you provide an example  
14 of how you're able to use Vascepa with a typical patient.

15       A    Yes. This is a slide I put together as an illustrative  
16 example. So what it describes here as a first patient visit  
17 after undergoing a lipid evaluation.

18           This individual has a triglycerides of  
19 550 milligrams per deciliter. At the time of the visit, the  
20 patient would undergo history, physical exam, other courses  
21 of -- or other etiologies that would potentially be  
22 contributing to hypertriglyceridemia would be discussed,  
23 whether this patient is a smoker, if they're taking medication  
24 that could potentially cause this, if they have diabetes, and  
25 if they have hypothyroidism. These would be potentially

1 addressed at that time.

2           The patient would also be given a specific  
3 nutritional plan and a specific exercise plan, either by  
4 myself, or I would bring in an exercise physiologist and a  
5 nutritionist who I have in my office.

6           And at the same time, that patient will be given  
7 Vascepa or icosapent ethyl specifically because the  
8 consequences of pancreatitis are so severe that I want to  
9 address those risks absolutely as aggressively and as  
10 thoroughly as I possibly can relatively immediately.

11           After the patient leaves the office, I will have he  
12 or she return within a two- to four-month time period. I will  
13 have a second set of labs drawn prior to the visit.

14           In this case the triglycerides have dropped to 300.  
15 I'd like to point out the medication and the lifestyle  
16 modification has successfully treated the severe  
17 hypertriglyceridemic component. Even though this individual  
18 is not yet at goal, where I want them, they are no longer in  
19 the severe hypertriglyceridemic range, and at that point, a  
20 decision is made.

21           More often than not, I will admit I do continue the  
22 Vascepa. It has long-term risk reduction. It has those  
23 tremendous benefits on advanced lipidology and advanced lipid  
24 testing, and it has a discrete, definitive, anti-inflammatory  
25 component.

1           But, there's a decent proportion of patients at that  
2 time that I will discontinue the medication for various  
3 reasons, and I will continue to instruct them -- in fact, it  
4 is absolutely vital that they continue to make their diet and  
5 exercise changes.

6           Most of the benefit we see in diet and exercise  
7 changes do not occur in two to four months, it occurs over a  
8 year. So we will continue to see that individual in the  
9 clinic, we will continue to measure parameters, but there are  
10 people who I will definitively stop this medication for and  
11 continue aggressive lifestyle risk reduction.

12       Q    Are there lifestyle interventions that can start  
13 benefitting a patient before 12 weeks?

14       A    Absolutely. So we can see discontinuation of smoking,  
15 discontinuation of high-sugared beverages, and, again, the  
16 reference we keep referring to is alcohol. But, again, where  
17 I practice is Dr. Peppers, it's Big Gulps of 64 ounces of a  
18 sugared soda, it is gummy bears.

19           So we can make those differences rather quickly by  
20 convincing the individuals to change their habits.

21       Q    Now, have you reviewed any data on how quickly Vascepa  
22 can reduce triglycerides below 500?

23       A    Yes, sir, I have.

24       Q    So turning to DDX 4.21. There's snapshot on the screen  
25 of DX 1694, page 214, and this is one of the exhibits on the

1 joint admitted list. Could you identify this document for the  
2 record.

3 A Yes, I can. This is a clinical study report from the  
4 MARINE study, and to take you through what we're looking at  
5 here, it's the study of icosapent ethyl, and this is a summary  
6 of the triglycerides in milligrams per deciliter. Circled is  
7 week four, which is the fifth visit of the patient.

8 You look at the baseline initial evaluation, the  
9 average -- I'm sorry, the median triglyceride level at  
10 baseline was 679.5 milligrams per deciliter.

11 If you go down to the week four value, the median  
12 has dropped to 471 milligrams per deciliter, and, again, that  
13 third drop occurred by week four.

14 Q So according to Amarin's MARINE study, how long does it  
15 take for Vascepa to lower triglycerides below 500?

16 A Four weeks, and I tell you this is also congruent with  
17 what I see in my clinical practice.

18 Q So turning now to DDX 4.22, there's snapshot on the  
19 screen DX 1701, page 68, which is also on the joint list of  
20 admitted exhibits.

21 We've heard some testimony about this document, but  
22 could you explain what you're showing on this slide for the  
23 record?

24 A This is the FDA medical review for Vascepa from the  
25 Center For Drug Evaluation and Research by the FDA.

1           This is a -- the paragraph below goes on to say that  
2 the open extension MARINE, which was data up to 40 weeks, was  
3 submitted as part of the 120-day update.

4           There is no figure described, but it describes that  
5 the maximum triglyceride-lowering effect of 4 grams of Vascepa  
6 occurred by week four, and the effects were maintained  
7 throughout the study, and, again, this is what we see in the  
8 clinical practice world.

9       Q    So turning to DDX 4.23. There's another snapshot of  
10 DX 1701, page 41.

11           Did you hear Dr. Budoff's testimony earlier about  
12 the sentence "patients with very high triglycerides have a  
13 strong genetic component to their decease," and it goes on?

14       A    Yes, I did.

15       Q    What does it mean for severe hypertriglyceridemia to have  
16 a strong genetic component?

17       A    Again, this is a -- it's a reiteration of what I  
18 mentioned little bit earlier, and, that is, there needs to be  
19 a definitive delineation here between a genetic abnormality  
20 which results in a specific genetic issue and which an  
21 individual has no other way around.

22           So, for example, if I have an individual who lacks  
23 the gene for liposomal protein lipase, lipoprotein lipase, and  
24 they have that genetic deficiency, that is a true genetic  
25 abnormality.

1           But even as Dr. Budoff said there are people who  
2 don't express think genetic abnormalities completely. There  
3 are people who have genetic predispositions or genetic  
4 proclivities to have things.

5           So patients with very high triglycerides levels  
6 likely have a genetic component in some way to have  
7 elevated -- elevated lipid issues whether it's triglycerides  
8 or whatnot.

9           But it doesn't mean that their genetic differences  
10 that we see within the patients make them unable to respond to  
11 other interventions such as discontinuation of smoking,  
12 engagement in proper exercise -- proper exercise regimens and  
13 appropriate diet.

14       Q    So are genetics the only component contributing to  
15 patient severe hypertriglyceridemia?

16       A    Absolutely not. Let me take this one step further and  
17 definitively argue.

18           If I have a patient who's genetically predisposed to  
19 be heavy, it may take us a little bit more dietary coaching or  
20 a little bit more exercise prescription to get that person  
21 where they need to be, but it doesn't mean it can't be done.  
22 In fact, we do every single day.

23       Q    So does everyone with a genetic predisposition for severe  
24 hypertriglyceridemia require drug treatment?

25       A    No, they do not.

1 Q So turning now to DDX 4.24, there's another snapshot of  
2 DX 1701, page 41, which is still on the screen, and before I  
3 get to the slide, what is your goal for triglycerides in terms  
4 of the patients you treat?

5 A Ultimately I like to try to shoot for a triglyceride  
6 level which is less than 150 milligrams per deciliter.

7 Q And are those normal triglycerides?

8 A That would be considered normal.

9 Q At what point does the FDA consider therapy with Vascepa  
10 successful?

11 A They consider therapy successful in this population if  
12 the triglycerides are lowered to less than 500 milligrams per  
13 deciliter.

14 Q And does it take 12 weeks to achieve that success for  
15 purposes of the indicated use?

16 A It does not.

17 Q Now, does Vascepa successfully reduce triglycerides in  
18 all patients?

19 A It does not.

20 Q So turning to DDX 4.25, there's snapshot on the screen of  
21 DX 1694, page 12, which we reviewed earlier.

22 According to the MARINE study report, are there  
23 patients on Vascepa who do not experience triglyceride  
24 reductions?

25 A Yes, that is correct. To look at this document, this is

1 an excerpt from the Amarin MARINE study, the Clinical Study  
2 Report.

3 What we're look at here which is highlighted is the  
4 percentage change from baseline to the 12-week evaluation.  
5 It's the endpoint in fasting triglycerides, and you can see at  
6 the bottom which highlighted, percent change from baseline,  
7 the median is 26.6 percent.

8 But if you look at what is described at Q1 and Q3,  
9 Q1 is the median in the first half of the group receiving this  
10 medication, the Q3 designation is the median of the second  
11 half of the group receiving this medication.

12 And you can see the median of that second half  
13 absolutely had a 0.0 percent change which means there are some  
14 people in this evaluation who actually had an increase in  
15 triglycerides, up to 25 percent of those people based on what  
16 we see here.

17 Q Does the MARINE Clinical Study Report also include data  
18 on LDL-C and apo B levels?

19 A Yes, it does.

20 Q So turning to DDX 4.26, there's a snapshot on the screen  
21 now DX 1694, page 268. According to the MARINE study  
22 report -- I'm sorry.

23 Are there patients taking Vascepa who's LDL-C  
24 increases according to the Clinical Study Report?

25 A Yes, this is the same type of data we just looked at on



1 the previous analysis. This is percent change in LDL from  
2 baseline to week 12.

3 And you can see, although there was median reduction  
4 of 4.5 percent, if you look at Q3, which is the median of the  
5 second half of the data group, there was an increase in LDL-C  
6 of 17.2, which means, again, that's the median, so there's a  
7 group of people in this evaluation who had an LDL increase  
8 above 17.2 percent.

9 Q And turning now to DDX 4.27, there's snapshot on the  
10 screen of DX 1694, page 239. Are there patients taking  
11 Vascepa whose apo B is not reduced?

12 A Yes, that is correct. Again, same document. It's laid  
13 out in the same way. This time we're looking apolipoprotein  
14 B.

15 Their percent change from baseline, the median was a  
16 reduction of 3.8 percent. But, again, if you look at that Q3  
17 evaluation highlighted in yellow, you can see in that second  
18 half of the group that there was an actual 3.8 percent rise in  
19 apolipoprotein B which again indicates that are certain  
20 individuals, up to 25 percent, who had a rise which was even  
21 higher than 3.8 percent.

22 Q So turning to DDX 4.28, there are snapshots on the screen  
23 of DX 2248, DX 2256, and DX 2266. Could you identify these  
24 documents for the record.

25 A These are the package inserts or the labels for Vascepa

1 for Hikma's icosapent ethyl and Dr. Reddy's Laboratories'  
2 icosapent ethyl.

3 MR. REIG-PLESSIS: And I believe DX 2248 and  
4 2256 are already admitted, but we would move into evidence  
5 DX 2266, which is the DRL label.

6 MS. KEANE: No objection, Your Honor.

7 THE COURT: 2248 is admitted.

8 MR. REIG-PLESSIS: And, I'm sorry, it was 2266.  
9 I believe 2248 --

10 THE COURT: I'm sorry -- I looked at the first  
11 one, 2248, 2256, 2266 are the three that are laid side by  
12 side?

13 MR. REIG-PLESSIS: Correct, Your Honor. I  
14 believe the first two --

15 THE COURT: I thought all of them were admitted  
16 already. All the labels are in, aren't they?

17 THE CLERK: One was not, two was, 2266, Your  
18 Honor.

19 THE COURT: The DRL label is not -- well, if it  
20 hasn't been, it will be admitted.

21 (Defendants' Exhibit 2266 received in  
22 evidence.)

23 MR. REIG-PLESSIS: Thank you, Your Honor.

24 I believe perhaps the PX version was previously  
25 admitted, so we're moving into evidence just the 2266 DX  
version.

1 THE COURT: Thank you.

2 MR. REIG-PLESSIS: Thank you.

3 BY MR. REIG-PLESSIS:

4 Q Dr. Sheinberg, are any differences between these three  
5 labels, the Vascepa label, the Hikma label, and the DRL label,  
6 material to any of your opinions relating to infringement of  
7 the asserted claims?

8 A There is no difference.

9 THE COURT: I'm sorry, what was the answer?

10 THE WITNESS: I'm sorry, would you ask the  
11 question again? I want to make sure I answer it properly.

12 MR. REIG-PLESSIS: Sure.

13 BY MR. REIG-PLESSIS:

14 Q Are there any material differences between the Vascepa  
15 label, the Hikma label, and the DRL label, and when I mean  
16 material, I mean differences that are material to your  
17 noninfringement opinions.

18 A There's no difference, no material difference.

19 Q Are any differences between the Vascepa product and  
20 defendants' generic products material to your opinions?

21 A No.

22 Q So let's move on to your noninfringement opinions. What  
23 topics do you tend to address in your analysis?

24 A Well, now that we've finished the background, my  
25 noninfringement analysis will effectively cover three

1 different topics, the 12 weeks duration topic, the lipid  
2 effects topic, and the no concurrent lipid-altering therapy  
3 topic.

4 Q What is the legal standard that you applied in analyzing  
5 defendants' labels?

6 A The legal standard that I used is, quote,

7 "In order to induce infringement, the label  
8 must encourage, recommend, or promote infringement.  
9 Merely describing an infringing mode is not the same  
10 as recommending, encouraging, or promoting an  
11 infringing use, or suggesting that an infringing use  
12 should be performed."

13 Q Now, just to be clear, Dr. Sheinberg, are you a lawyer?

14 A No, I am not.

15 Q Are you offering any legal opinions?

16 A No, sir, I am not.

17 Q Are you offering any opinions on FDA regulatory issues?

18 A No, sir, I am not.

19 Q Are you offering opinions from the perspective of a  
20 physician?

21 A Yes, I am.

22 Q Now, as a physician, what parts of a drug label do you  
23 generally expect to provide instructions on the duration of  
24 treatment for a drug?

25 A Typically the areas that provide instruction are the

1 indication and usage and the dosage and administration  
2 sections of the package insert.

3 Q So turning to DDX 4.31, there's snapshot on the screen  
4 from DX 2256, pages 1 and 2. What are you showing on this  
5 slide?

6 A This is the indication and usage section of the package  
7 insert of defendants' label, and it goes on to describe  
8 icosapent ethyl as indicated as an adjunct to diet to reduce  
9 triglyceride levels in patients with severe  
10 hypertriglyceridemia.

11 Q Now, to a physician, does the term severe  
12 hypertriglyceridemia in the indication imply that indefinite  
13 drug treatment is required?

14 A Absolutely not.

15 Q Is the indication for defendants' products limited to  
16 patients with a genetic abnormality?

17 A It is not limited to any patient of any type.

18 Q So are the indicated uses for defendants' products  
19 limited to chronic use?

20 A No, they are not.

21 Q And according to the indication, are defendants' products  
22 a primary treatment for severe hypertriglyceridemia?

23 A They are not. They're adjunctive therapy which means  
24 they need to be used in combination with diet.

25 Q So does the indications and usage section encourage

1 recommend or promote administering defendants' products for at  
2 least 12 weeks?

3 A No, it does not.

4 Q Now, turning to DDX 4.32, were you in the courtroom when  
5 Mr. Klein presented the testimony on this demonstrative from  
6 Dr. Budoff during opening statements?

7 A Yes, I was.

8 Q And were you in the courtroom when Dr. Budoff confirmed  
9 that testimony?

10 A Yes, I was.

11 Q And is your opinion consistent with Dr. Budoff's  
12 testimony on this point?

13 A Yes, and to describe it, Dr. Budoff was asked and do you  
14 agree it would still be consistent with the Vascepa labeling  
15 for a doctor to prescribe Vascepa for fewer than 12 weeks, to  
16 which Dr. Budoff replied yes.

17 Q Turning now to DDX 4.33. There's snapshot on the screen  
18 of DX 2256, page 2. What are you showing on this slide?

19 A This is the dosage and administration section of the  
20 package insert of defendants' drug, and under section 2.1 it  
21 really goes on to describe what we've been talking about which  
22 is obviously prior to initiation of icosapent ethyl assess  
23 lipid levels which it's obvious, identify other causes which  
24 we have talked about, and manage as appropriate, which I  
25 testified earlier that would include treatment of those other

1 issues concomitantly with the use of lifestyle therapy and  
2 medication.

3 It goes on as second bullet to say patients should  
4 engage in appropriate nutritional intake and physical activity  
5 before receiving icosapent ethyl which should continue during  
6 treatment with icosapent ethyl.

7 Q Does the instruction to identify and manage other causes  
8 imply that medication should be delayed until those causes are  
9 addressed?

10 A Absolutely not. It's giving me sort of a direction that  
11 we need to fix underlying causes as appropriate, but it does  
12 not state that that should be done specifically prior.

13 And I would argue specifically against doing that  
14 because we understand the severe consequences in morbidity and  
15 mortality for pancreatitis, that we want to treat that as  
16 aggressively as we possibly can.

17 Q So focusing now on the second bullet under section 2.1,  
18 does the statement to engage in nutritional intake and  
19 physical activity before receiving icosapent ethyl mean that a  
20 patient should wait for diet and exercise to take effect  
21 before icosapent is administered?

22 A It's my interpretation of this that that is not the case.  
23 Again, ultimately, a goal for the prescribing physician is to  
24 make sure we keep our patients healthy and out of the  
25 hospital. In order to do so in this case, we have to keep

1 those people from developing pancreatitis.

2 So in terms of engaging in appropriate nutritional  
3 intake and physical activity, it does not specifically  
4 describe how long that should be, what it should be, and  
5 that's really up to the discretion of the prescribing  
6 physician.

7 I interpret this unequivocally to mean I have to  
8 make the appropriate nutritional and physical activity  
9 assessment and recommendations and then, in the same visit,  
10 prescribe the medication.

11 For example, if I have an individual who is a  
12 smoker, and I tell that individual after sitting with them and  
13 counseling them and showing them the risks, and I said to that  
14 individual, "I need you to stop smoking," and they say, "Okay,  
15 Doc, I understand, I'm going to stop smoking," well, that was  
16 a successful intervention right there. He immediately is  
17 engaged in appropriate smoking cessation.

18 The same thing holds true with alcohol consumption,  
19 or the example that I've been using this afternoon was the  
20 Dr. Pepper, and this is Texas where I grew up so Dr. Peppers  
21 are the thing out there, but it could be substituted for  
22 anything else.

23 But I can tell an individual, you know what, those  
24 Big Gulps of Dr. Pepper that you're drinking every day, it's  
25 not helping, in fact, that's causing your problem. The



1 patient can turn around say, "Okay, I understand, I'm done  
2 with Dr. Peppers." Well, we just -- that patient just engaged  
3 in appropriate nutritional effect.

4 Same thing goes physical with activity. It's  
5 January 1st, the gyms are filled with people who, on  
6 January 1st, are starting a physical activity program. They  
7 may join a gym, they've engaged in physical activity.

8 So it's really at the discretion and interpretation  
9 of the physician and how this sentence is actively utilized.

10 Q In your practice, do you delay administering drug therapy  
11 when a patient presents with severe hypertriglyceridemia?

12 A I don't. I can't. In fact, I would argue along those  
13 lines that if I have a patient that comes to my office with  
14 severe hypertriglyceridemia, and I don't treat it aggressively  
15 to the best of my ability, and that individual leaves my  
16 office just to come back in four to six weeks for  
17 reassessment, and they develop acute pancreatitis within those  
18 four to six weeks, I feel that I have violated the standard of  
19 care, that my colleagues would look at that and say why didn't  
20 you treat this person when he was in your office.

21 Because the consequences are so severe, every  
22 possible avenue of therapy needs to be addressed immediately  
23 at that first visit.

24 Q So, in your opinion, is it an off-label use of Vascepa to  
25 start Vascepa and diet and exercise at the same time?

1 A It is not.

2 Q So turning now to DDX 4.34, were you in the courtroom  
3 when Mr. Klein presented this deposition testimony from  
4 Dr. Budoff during opening statements?

5 A Yes, I was.

6 Q And were you in the courtroom when Dr. Budoff confirmed  
7 this testimony?

8 A Yes, I was.

9 Q Is your opinion consistent with Dr. Budoff's testimony on  
10 this point?

11 A Yes. And, actually, again, let me read it into the  
12 record.

13 Dr. Budoff was asked,  
14 "The dosage and administration section in the  
15 Vascepa label leaves it entirely up to the  
16 physician's discretion to determine the duration of  
17 treatment. Do you agree?"

18 To which Dr. Budoff replied yes.

19 And, again, that is my understanding, and I do  
20 agree that it is entirely up to the physician's discretion.

21 Q And just to turn back to DDX 4.33 for a moment, does the  
22 reference to engaging in appropriate nutritional intake  
23 require the patient to eat specific foods, or would it also  
24 include restraining from eating certain foods?

25 A It really is a combination of both, and it has to be

1 addressed on a specific individual level, which takes into  
2 consideration where that person is in terms of their  
3 lifestyle, if there's any predisposing ethnic issues which  
4 would predispose that individual to eat in certain different  
5 food groups, if that person is a vegetarian, if they have  
6 other dietary restrictions.

7           So it does not describe in any way, shape, or form  
8 what that nutritional intake change should be here. It simply  
9 tells me it needs to be what is described as, quote,  
10 appropriate, unquote.

11       Q    So in your example would ceasing to consume Big Gulps of  
12 Dr. Pepper be engaging in appropriate nutritional intake or be  
13 one component of that?

14       A    Absolutely.

15       Q    Now, have you compared defendants' labels to labels for  
16 other drugs that actually specify duration of treatment?

17       A    Yes, I have.

18       Q    So turning first to DDX 4.35, there's a snapshot on the  
19 screen of DX 1984, page 2. Could you identify this document.

20       A    Yes, I can. This is the Lamisil label. Lamisil is an  
21 antifungal tablet which we use for fingernail and toenail  
22 infections, fungal infections.

23                   MR. REIG-PLESSIS: And defendants would move in  
24 the admission DX 1984.

25                   MS. KEANE: No objection, your Honor.

1 THE COURT: DX 1984 is admitted.

2 (Defendants' Exhibit 1984 received in  
3 evidence.)

4 BY MR. REIG-PLESSIS:

5 Q How does the dosage and administration section of the  
6 Lamisil label compare to the same section in defendants'  
7 labels?

8 A It's discretely different.

9 The Lamisil label goes on to specifically prescribe  
10 a duration of therapy which is in complete contradistinction  
11 to what is seen in the defendants' label, for example, for  
12 fingernail onychomycosis which is a fingernail infection.

13 It specifically directs me to have the individual  
14 use one tablet once daily for six weeks. For toenail  
15 infections, it specifically instructs me to have an individual  
16 take one tablet once daily for 12 weeks.

17 Q Have you ever prescribe Lamisil?

18 A Yes, I have.

19 Q So turning to DDX 4.36, there is a snapshot on the screen  
20 of DX 1679 at page 5. Could you identify this document,  
21 please.

22 A Yes, this is the dosage and administration section for  
23 the package insert of what's called Lovenox which is  
24 enoxaparin. It's an injectable low molecular heparin or an  
25 injectable blood thinner.

In this case, they're describing the use of this

1 drug in the treatment of deep venous -- deep vein thrombosis  
2 which is a clot with or without pulmonary embolism which is a  
3 clot in the lungs.

4 The label goes on to specifically describe and  
5 instruct the physician to initiate Warfarin which is Coumadin,  
6 it's an oral blood thinner, when appropriate, and then  
7 continue Lovenox for a minimum of five days and until a  
8 therapeutic anticoagulant effect has been reach on the  
9 Coumadin.

10 So, again, in complete contradistinction to  
11 defendants' label, this label instructs a providing physician  
12 to use this medication for a minimum duration of time that's  
13 specifically spelled out.

14 MR. REIG-PLESSIS: Defendants' move the  
15 admission DX 1679.

16 THE COURT: Isn't there already the Lovenox  
17 label admitted earlier?

18 MR. REIG-PLESSIS: Your Honor --

19 THE COURT: Regardless, is there objection?

20 MS. KEANE: No objection.

21 THE COURT: All right. DX 1679 is admitted.

22 (Defendants' Exhibit 1679 received in  
23 evidence.)

23 MR. REIG-PLESSIS: Thank you, your Honor.

24 And I believe some of the PX exhibits and DX  
25 exhibits refer to the same documents because these

1 demonstratives were prepared before we knew what they would  
2 admit.

3 THE COURT: All right. I remember Dr. Budoff  
4 testifying as to the Lovenox label I think.

5 MR. REIG-PLESSIS: Thank you, your Honor.

6 BY MR. REIG-PLESSIS:

7 Q Turning now to DDX 4.37, there's snapshot on the screen  
8 of DX 2256, page 7. What are you showing on this slide?

9 A This is the clinical study section of the defendants'  
10 package insert or label in the clinical study section which is  
11 described in 14.2 severe hypertriglyceridemia.

12 There's a reference to what we've described today as  
13 the MARINE study, and I have highlighted here,

14 "Patients whose baseline triglyceride levels  
15 were between 500 and 2,000 were enrolled in the study  
16 which went on for 12 weeks in duration."

17 Q So does the clinical study section describe the use of  
18 EPA for 12 weeks?

19 A It describes the use of EPA in this study for 12 weeks.

20 Q In your practice as a physician, do you look to the  
21 clinical study section of a drug label for instructions on how  
22 long to administer that drug?

23 A I do not. I look at the clinical studies section so I  
24 can understand the rationale for using this.

25 It's simply -- what is described here is a simply a

1 discussion and a synopsis of what was seen in the reference  
2 trial.

3 Q To a physician, does the statement that the clinical  
4 trial lasted 12 weeks indicate that patients need to be  
5 treated for at least 12 weeks to reduce their triglycerides  
6 below 500?

7 A Absolutely not. It does not describe that or encourage  
8 that. It simply describes what was found in the study.

9 You can go further on to say, you know, if you look  
10 at the MARINE study, most of the individuals in the MARINE  
11 study were 53-year-old white males which doesn't correspond to  
12 the majority of my patient population anyway. So it's hard to  
13 extrapolate.

14 The only thing this description tells me is what was  
15 done in the MARINE trial.

16 Q So does the clinical study section encourage, recommend,  
17 or promote administering defendants' products for at least 12  
18 weeks?

19 A No, sir, it does not.

20 Q So turning now to DDX 4.38, there are snapshots on the  
21 screen again of DX 2256, but now at pages 3 and 5. Are there  
22 any other references to a 12-week duration in defendants' drug  
23 labels?

24 A Yes, there are.

25 In section 6, which is the adverse reaction section,

1 they describe two randomized, double-blind, placebo-controlled  
2 trials in patients with triglycerides between 200 and 2,000  
3 who were treated for 12 weeks, and it describes the adverse  
4 reactions that occur.

5 And in the second section, which is the clinical  
6 pharmacology section under the pharmacodynamic subheading, it  
7 describes a 12-week dose-ranging study in patients with severe  
8 hypertriglyceridemia, and it describes it that it reduced the  
9 triglycerides from baseline to placebo.

10 Q And, in your opinion, do these descriptions of a 12-week  
11 duration encourage, recommend, or promote administering  
12 defendants' products for at least 12 weeks?

13 A Again, absolutely not. This 12-week reference simply  
14 describes in the first case two randomized studies that were  
15 done looking at adverse reactions, and, in the second section,  
16 it describes a dose-ranging study to show that there was  
17 reduction in triglycerides relative to placebo.

18 But, again, these 12-week durations simply describe  
19 what was seen in these limited studies, it does not in any way  
20 indicate to me that that is how long I need to treat my  
21 patients for.

22 Q So turning now to DDX 4.39, there's a snapshot on the  
23 screen of DX 2256, page 9, and it's a snapshot from the  
24 patient information section of defendants' labels.

25 Do you see the statement, "Do not change your dose



1 or stop taking icosapent ethyl without talking to your  
2 doctor"?

3 A Yes, I do.

4 Q In your opinion, does that statement encourage,  
5 recommend, or promote administering defendants' products for  
6 at least 12 weeks?

7 A It does not. It simply instructs the patients to take  
8 the medication that has been prescribed in the way it's been  
9 given to you. Do not alter the medication without discussing  
10 it with your own physician.

11 Q When a patient talks to his or her doctor, could the  
12 doctor tell the patient to take the drug for less than  
13 12 weeks?

14 A Absolutely. I receive at least a dozen phone calls a day  
15 from patients, most of which are medication issues that need  
16 to be resolved.

17 Often times after talking to the patient, I will  
18 agree to stop that patient's medication well below the 12-week  
19 limit or 12-week prescription.

20 Q And you may have testified to this before, but after  
21 prescribing a drug like Vascepa to a patient, how long do you  
22 usually wait before seeing that patient again?

23 A Anywhere between two and four months would be very  
24 reasonable in my practice.

25 Q So do you sometimes see patients again before 12 weeks?

1 A Very frequently.

2 Q And have you told patients that it's okay to stop  
3 Vascepa?

4 A I have.

5 Q And what are some of the reasons why a patient may want  
6 to stop Vascepa?

7 A Well, if I have someone who has had a very successful  
8 change in lifestyle, in other words, they're adhering to the  
9 exercise prescription and nutritional recommendations that  
10 we've made, we will stop the Vascepa because at this point,  
11 they no longer need it.

12 There are also other reasons. Individuals can't  
13 afford it. Some individuals have side effects. My experience  
14 with this medication has been mostly GI or gastrointestinal  
15 side effects. There are people who are eager to get off all  
16 medications. So it is not infrequent that we stop medications  
17 for these patients.

18 Q Is the size or number of pills a contributing factor in  
19 patients' decisions?

20 A Without question. This is a difficult medicine to take  
21 because it's a large number of pills, it's four pills. If  
22 you've never seen these pills, patients joke and say they're  
23 horse capsules, they're very large capsules, and there's a lot  
24 of people that cannot swallow these capsules and simply  
25 because of that reason want to stop their medication.

1 Q Now, on the screen is DDX 4.40 with another highlighted  
2 snapshot of the same page, DX 2256, page 9.

3 Does the patient information section suggest any  
4 other treatments for reducing triglycerides?

5 A Yes, it does. It says, "Your doctor may start you on a  
6 diet." It specifies what potential type of diet that would  
7 be, and it specifically says "stay on this diet while taking  
8 this medication."

9 Q So turning now to DDX 4.41, there's a snapshot on the  
10 screen of DX 2256, page 10.

11 If a physician decides to administer defendants'  
12 products long-term, is that necessarily for the indicated  
13 MARINE use of treating patients with triglycerides of at least  
14 500?

15 A It's not. I testified earlier during this testimony that  
16 oftentimes we use this -- most often we use this medication  
17 for other reasons than the MARINE data, and in the patient  
18 information section it specifically tells the patients that we  
19 would potentially do that.

20 It describes a situation in which medicines are  
21 sometimes prescribed for purposes other than those listed in  
22 the patient information leaflet.

23 Now, as a prescribing physician I like to think we  
24 would talk to the patient and explain the reasons why, but  
25 this gives us full latitude in which in order to do so.

1 Q So taking defendants labels as a whole, do the labels  
2 encourage, recommend, or promote administering defendants' for  
3 at least 12 weeks?

4 A I'm sorry, can you repeat that one more time so I make  
5 sure I answer the question properly?

6 Q Sure. Taking defendants' labels as a whole, do the  
7 labels encourage, recommend, of promote administering  
8 defendants' products for at least 12 weeks?

9 A No, they do not.

10 Q Do they express any preference for short-term versus  
11 long-term use?

12 A The labels are completely silent in this regard, and  
13 therefore and it is left up the discretion of the prescribing  
14 physician.

15 Q What is the next set of claim limitations that you  
16 analyzed?

17 THE COURT: Mr. Reig, how much longer do you  
18 have for Dr. Sheinberg's direct examination?

19 MR. REIG-PLESSIS: Probably 15 more slides.  
20 We've covered obviously the 12 weeks duration, but there are  
21 two other categories of limitations.

22 THE COURT: I'm trying to assess whether it  
23 makes sense to recess the testimony portion for today.

24 If you had about five minutes or so, I would let  
25 you continue and then have plaintiffs start with the

1 cross-examination in the morning, but if you think you have  
2 longer than five to ten minutes, I would probably pause and  
3 recess for the day.

4 MR. REIG-PLESSIS: I would estimate that we have  
5 probably little more than that, so a recess might make sense,  
6 Your Honor.

7 THE COURT: We'll at least pause the testimony  
8 portion for today. I want to have enough time to give you my  
9 ruling on the Rule 52 motion earlier. So, at this time, let's  
10 do that.

11 I'm going to ask Dr. Sheinberg to step down from  
12 the witness stand.

13 THE WITNESS: Yes, your Honor.

14 THE COURT: And then we'll resume with your  
15 testimony in the morning. I understand you have patients to  
16 see, but, unfortunately, you have to return tomorrow.

17 THE WITNESS: That's okay.

18 MR. REIG-PLESSIS: Thank you, Your Honor.

19 THE COURT: All right. I will try to speak  
20 slowly lest I get an instruction to slow down.

21 Here's my ruling on the Rule 52 motion.

22 Defendants asked for judgment under Rule 52(c)  
23 as to plaintiff's induced infringement claim based on the  
24 claim limitation presented in all of the asserted claims that  
25 is requiring the administration of EPA for at least 12 weeks.

1                   However, I will not enter judgment in  
2 defendants' favor at this time because I find that plaintiffs  
3 present sufficient evidence to satisfy the preponderance of  
4 the evidence standard as to the 12-week limitation.

5                   The question of whether defendants may be held  
6 liable for inducing infringement turns on whether defendants  
7 have, and I quote from the *Grunenthal* decision, this is at 919  
8 F.3d 1333 at 1339, it's a Federal Circuit 2019 decision, and,  
9 that is, defendants have -- the issue turns on whether  
10 defendants have specific intent based on the contents of their  
11 proposed labels to encourage physicians to use their proposed  
12 ANDA products in a way that infringes the asserted claims.

13                   In other words, I have to find -- I have to ask  
14 whether the label, and I quote, encourages, recommends, or  
15 promotes infringement. These are the terms that counsel have  
16 used extensively throughout the examination and  
17 cross-examination, and the PIN cite for that is the same, it's  
18 at 1339.

19                   And because the asserted claims are method  
20 claims, I quote again, the pertinent question is whether the  
21 proposed label instructs users to perform the patent method,  
22 and the pin cite is the same at 1339.

23                   Defendants' primary argue that their proposed  
24 labels cannot be read to encourage, recommend, or promote  
25 infringement of the 12-week limitation. However, Dr. Budoff

1 testified that reading the label as a whole, physicians would  
2 be encourage to prescribe Vascepa or one of defendants' ANDA  
3 drugs, the labels that are materially the same, for at least  
4 12 weeks.

5 He testified that this is because a clinician  
6 working in the field would know that STG, severe  
7 hypertriglyceridemia, is largely a genetic problem requiring  
8 long-term therapy.

9 Moreover, on cross-examination, Dr. Budoff  
10 testified that STG is almost invariably a chronic condition.  
11 He also testified to his own treatment practices describing  
12 that he almost always prescribes Vascepa for more than  
13 12 weeks and checks in with his patients about every three  
14 months to monitor their lipid levels over the long term.

15 He also points to portions of the labeling  
16 supporting his testimony that the proposed labels encourage  
17 infringement of the 12-week limitation.

18 He specifically pointed to section 2.1 of the  
19 labeling, and I'll refer to PX 1186, as I say, the labels are  
20 the same, that is the December 2019 Amarin's label for  
21 Vascepa.

22 He points to section 2.1 regarding what a doctor  
23 needs do before initiating therapy with Vascepa. He testified  
24 that this section of the labeling supports his testimony that  
25 drug therapy using Vascepa is intended to be long-term. He

1 emphasized how the labeling tells doctors to first identify  
2 other causes of STG and manage them as appropriate before  
3 initiating therapy.

4           Therefore, a doctor would not begin Vascepa  
5 therapy if the doctor can identify and remediate those other  
6 causes such as diabetes.

7           Second, he testified that the labeling instructs  
8 doctors to encourage patients to change their diet and get  
9 more exercise before Initiating drug therapy. So he read the  
10 labeling to require elimination of acute causes before  
11 initiating Vascepa.

12           In other words, Dr. Budoff testified that the  
13 only people left after removing the groups of people suffering  
14 from acute causes of STG are people who have the genetic  
15 disorder causing their elevated STG levels, and that is a  
16 lifetime problem so doctors would initiate long-term therapy  
17 for this chronic condition.

18           Now, defendants point to excerpts from  
19 Dr. Budoff's testimony to argue that STG is not a chronic  
20 condition, and on cross-examination Dr. Budoff acknowledged  
21 that binge drinking, for example, can cause a spike in the TG  
22 levels to over 500 milligrams per deciliter in patients who  
23 are predisposed to high TG levels, and these patients can get  
24 their TG levels back below 500 by cutting out alcohol if their  
25 TG levels were sufficiently close to 500.



1           But he also explained that people who eat too  
2 much or drink too much without an underlying medical issue  
3 would not have STG, and, again, he explained that the label  
4 instructs physicians to eliminate these acute cases first.

5           For those reasons I find that plaintiffs have at  
6 least met their initial burden such that defendants are not  
7 entitled to judgment of noninfringement on plaintiff's induced  
8 infringement theory at this time, and the Rule 52(c) motion is  
9 denied.

10           All right. With that we'll resume in the  
11 morning at 8:30.

12           THE CLERK: Your Honor, may I ask clarification  
13 please? I have not filed the minutes of yesterday yet because  
14 of a question of a chart that may be produced by counsel with  
15 regard to Mr. Klein's cross-examination. Should I go ahead  
16 and submit my minutes as they are written?

17           THE COURT: Why don't you submit the minutes,  
18 and the chart that will be created, counsel can file that on  
19 the docket.

20           There is -- I probably should resolve the  
21 evidentiary issue raised at the end of yesterday about the 25  
22 additional exhibits. I don't know if counsel -- Mr. Rounds,  
23 if you have identified which expert or which documents will be  
24 used with which expert because I don't know if they'll up  
25 tomorrow.

1 MR. ROUNDS: Yes, we did that last night, your  
2 Honor, and, no, they're not up tomorrow.

3 THE COURT: Will they be up Friday?

4 MR. ROUNDS: No, not as far as I know.

5 THE COURT: Well, I've looked at the exhibits,  
6 and my preliminary reaction is I don't think that it supports  
7 the -- while I realize that there are -- well, let me describe  
8 what the exhibits are. Give me one moment.

9 So there were 25 exhibits and they're various  
10 categories and they are exhibits that were produced by Amarin.  
11 I think they're about 136 pages, although there were a few  
12 blank pages. They include the drafting labeling for the EPA  
13 capsules, there's an article by an Amarin employee about the  
14 MARINE and the ANCHOR studies, 1099 tax forms for a company,  
15 some e-mail exchanges, the CV of Edward A. Fisher, I assume  
16 he's one the witnesses.

17 My point is, while I agree with Amarin that  
18 deadlines are there for a reason, they're -- they're there to  
19 ensure fair play and that there's no ambushing of any of the  
20 attorneys or counsel at trial -- or the witnesses at trial, so  
21 I expect -- and I'm very rule-oriented person. I expect  
22 counsel to follow the rules.

23 But I do understand that given the voluminous  
24 nature of the exhibits in this case, and the complexities of  
25 the testimony of the witnesses, that -- such that I will

1 accept the explanation for the delay in identifying these  
2 additional exhibits.

3 And because of the volume, because of the fact  
4 that they were documents produced by Amarin, I don't -- I'm  
5 not persuaded by the argument that there's prejudice to Amarin  
6 if I don't exclude the additional exhibits, and that's the  
7 main reason why I'm going to permit the exhibits to be  
8 offered. Whether or not individually they will be admitted at  
9 trial is a different issue, but I'm not going to exclude them  
10 for their late disclosure.

11 Therefore the motion that was filed orally  
12 yesterday to exclude the additional 25 exhibits is denied.

13 I expect going forward that counsel will comply  
14 with the rules. I know that you're updating your exhibit  
15 lists constantly, and I understand that there's fluctuations  
16 during the trial. Peggie has probably already reminded you  
17 that when you do that, you need to give me the updated  
18 exhibits and the updated exhibit list.

19 Okay. With that we'll resume in the morning.

20 (The evening recess was taken.)

21 -o0o-

22  
23 I certify that the foregoing is a correct  
24 transcript from the record of proceedings in the  
above-entitled matter.

25 /s/ Kathryn M. French

1/25/2020

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**Kathyrn M. French, CCR #392, RPR**

**Date**

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