UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., ACTAVIS LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC,
Petitioner

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

Case IPR2016-01332[1]
Patent 8,822,438 B2

REPLY DECLARATION OF IAN MCKEAGUE, Ph.D. IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,822,438

[1] Case IPR2017-00853 has been joined with this proceeding.

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I, Ian McKeague, Ph.D., do hereby declare:

I. INTRODUCTION

1. I am making this declaration at the request of Petitioners, in the matter of the *Inter Partes* Review ("IPR") of U.S. Patent No. 8,822,438 (the "'438 patent"), as set forth in the above caption.

II. EDUCATION AND PROFESSIONAL BACKGROUND

2. I received a B.A./M.A. and M.Math in Mathematics from the University of Cambridge in 1975 and 1976, respectively. I received a Ph.D. from the University of North Carolina at Chapel Hill in 1980, authoring a Ph.D. thesis titled *Covariance Operators and Their Applications in Probability and Information Theory*. My *curriculum vitae* is attached as Exhibit A.

3. After completing my Ph.D., I took a position as an Assistant Professor in the Department of Statistics at Florida State University. I held that position from 1980 to 1986, when I was promoted to Associate Professor, a title I held until 1991, when I was promoted to Professor. In 1996, I was promoted to Chairman of the Department of Statistics and I held that position until 1999. From 2000 to 2004, I was the Ralph A. Bradley Professor of Statistics at Florida State University. In 2004, I left that university and took a position as Professor of Biostatistics at Columbia University, a position I hold to this day. In addition, I have been a visiting professor at University of Padua, Italy (1985), University

Joseph Fourier, Grenoble, France (1992, 2001), and the University of California, Berkeley (1991).

4. I have received numerous professional honors, served as an editor on various journals, and have served on a number of professional committees. For example, I am a Fellow of the Institute of Mathematical Studies and a Fellow of the American Statistical Association. I am also an Associate Editor of the Journal of the American Statistical Association (1993–96, 2011–present), the International Journal of Biostatistics (2005–present), and Statistical Inference for Stochastic Processes (1998–present), and a former Associate Editor of the Annals of Statistics (1989–1995) and ESAIM: Probability and Statistics (2000–2005). At Florida State University, I received the Named Professorship Award (2000), the Graduate Teaching Award (1998), and the Professorial Excellence Program Award (1999). I have served on the Institute of Mathematical Statistics Fellows Committee (2008–2010); the ASA Section on Nonparametric Statistics Awards Committee (2010–2011); the NSF Statistics and Probability Program Panel (1997, 1999, 2000, 2002, 2003, 2007, 2009, 2010, 2016), Special Meetings Panel (2005), Biocomplexity in the Environment Panel (2004), and Knowledge and Distributed Intelligence Program Panel (1998).

5. As a biostatistician, I have more than twenty years of experience in clinical trial design and statistical analysis. I have consulted for a variety of

entities regarding clinical trial design and analysis, including biopharmaceutical companies and nonprofit research centers. In particular, I have been involved in the design and analysis of numerous clinical trials, with special expertise in designing cohort studies. I have published dozens of papers analyzing clinical trial data, often including analysis regarding study methodology. I have also spoken widely at conferences, symposia, and seminars on clinical trials. For example, I was the Keynote Speaker at the Fourth Annual International Symposium on the Evaluation of Clinical Trial Methodologies and Applications in Beijing, China in 2011, and I also was an invited speaker on clinical trials at the ICSA Applied Statistics Symposium in 2011.

6. My research interests include functional data analysis, empirical likelihood, and non-standard asymptotics, to name a few. I am a named author on 111 peer-reviewed articles, I have supervised eighteen doctoral students, and I have received grants from a number of organizations including the NIH and the NSF.

7. In the past four years, I have testified in the following cases:

- *Casas v. Consolidated Edison Co. of New York, Inc.*, Index No. 115106/04 (N.Y. Sup. Ct.);
- *In re Copaxone 40 mg Consolidated Cases*, No. 1:14-cv-01171-GMS (consolidated) (D. Del.);

- *In re Certain Consolidated Zoledronic Acid Cases*, No. 2:12-cv-03967-SDW-SCM (D.N.J.);
- *Gomez v. New York City Transit Authority*, Index No. 33888/01 (N.Y. Sup. Ct.); and
- *The Medicines Company v. Mylan Inc.*, No. 1:11-CV-01285 (N.D. Ill.).

8. I am being compensated at an hourly rate of $550/hour and am available to appear live for testimony in support of my opinions. My compensation in no way depends on the outcome of this proceeding. The opinions to which I will testify are based on the education, experience, training, and skill that I have accumulated in the course of my career as a biostatistician and researcher, as well as materials I have reviewed in connection with this case.

III. MATERIALS CONSIDERED

9. The list of materials I considered in forming the opinions set forth in this declaration is set forth in Exhibit B.

IV. LEGAL STANDARDS

10. I understand that this IPR involves U.S. Patent No. 8,822,438 (the "'438 patent"). Ex. 1001. I have been asked by Petitioners to review portions of the Declaration of Matthew B. Rettig, M.D. in Support of Janssen Oncology's Patent Owner Response (the "Rettig Declaration").

11. I have been informed of the relevant legal principles as part of preparing and forming my opinions set forth in this declaration. I have applied my understanding of those principles in forming my opinions. My understanding of those principles is summarized below.

12. I have been told that one of the four factual predicates in an obviousness inquiry is "secondary considerations." I understand that one such secondary consideration is unexpected results. I further understand that, to show unexpected results, Patent Owner Janssen Oncology Inc. ("Patent Owner" or "Janssen") must prove that the alleged invention produced benefits that were unexpected in light of the prior art, from the viewpoint of a person having ordinary skill in the field of technology of the patent at the patent's priority date.

13. I understand that evidence of secondary considerations such as unexpected results is only relevant to the obviousness analysis if the patentee can show a direct link, or nexus, between the secondary consideration and the claims of the patent, and that the evidence must be commensurate in scope with the asserted claims. I also understand that for results to be considered unexpected for these purposes, there must be a substantial difference from the prior art. In other words, a difference of kind, and not merely of degree.

14. I have been asked to apply the definition of the person of ordinary skill in the art offered by Dr. Garnick:

> A person of ordinary skill in the art at the time of filing of this patent is someone who is a physician specializing in urology, endocrinology or oncology, or holds a Ph.D. in pharmacology, biochemistry or a related discipline. A related discipline may include, for example, pharmaceutical sciences. Additional experience could substitute for the advanced degree. To the extent necessary, a person of ordinary skill in the art may collaborate with one or more other persons of skill in the art for one or more aspects in which the other person may have expertise, experience and/or knowledge that was obtained through his or her education, industrial or academic experiences. A person of ordinary skill in the art may consult with an endocrinologist, oncologist or medical biochemist and thus may rely on the opinions of such specialists in evaluating the claims.

15. I have also reviewed Patent Owner's definition of the person of ordinary skill in the art. Ex. 2038 (Rettig Decl.) ¶ 78. My opinions are the same regardless of which definition is applied.

V. SUMMARY OF OPINIONS

16. It is my opinion that Janssen has not offered evidence of any unexpected results of the combination of abiraterone acetate and prednisone to treat metastatic castration-resistant prostate cancer ("mCRPC"). On the contrary, no reliable conclusions can be drawn regarding the combined anti-cancer effect of prednisone administered with abiraterone acetate based on the data presented in Dr. Rettig's declaration. The data presented, and comparisons made, by Dr. Rettig in his declaration do not demonstrate unexpected results.

VI. BACKGROUND

A. Prostate Cancer And Abiraterone Acetate

17. I understand that prostate cancer is an androgen-dependent disease driven by testosterone and its derivatives.[2] Metastatic prostate cancer is cancer that is no longer localized and has spread beyond the prostate into other parts of the body.[3] One strategy to treat metastatic prostate cancer is to lower testosterone levels, but patients frequently develop metastatic castration-resistant prostate cancer ("mCRPC") when patients no longer respond to a reduction in testicular testosterone levels.[4] mCRPC can be treated with "second-line" hormonal therapies, one of which is abiraterone acetate.[5]

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[2] I am not an oncologist or urologist. My understanding of prostate cancer and its treatment comes from the references cited herein. Ex. 1092, Cancer.org (ACS), "Hormone Therapy for Prostate Cancer," found at https://www.cancer.org/content/cancer/en/cancer/prostate-cancer/treating/hormone-therapy.html (accessed April 10, 2017).

[3] Ex. 1093, Cancer.gov (NIH), "Metastatic cancer," found at https://www.cancer.gov/types/metastatic-cancer (accessed April 14, 2017).

[4] Ex. 1092.

[5] *Id.*

18. Prostate specific antigen ("PSA") is a protein produced by the prostate gland.[6] PSA levels can be measured and used to calculate time to PSA progression ("TTPP").

B. Cougar's[7] Clinical Trials Investigating Abiraterone Acetate

19. Dr. Rettig's unexpected results opinions rely on the results of disparate clinical trials conducted by Janssen's predecessor, Cougar Biotechnology, Inc. ("Cougar"). These clinical trials include COU-AA-001, COU-AA-002, COU-AA-301, and COU-AA-302.

20. COU-AA-001 was a single arm, open label, single center phase I/II study conducted in the United Kingdom to assess the safety, tolerability, and recommended abiraterone acetate dose for treating mCRPC patients. Ex. 2014 (Attard 2008); Ex. 2015 (Attard 2009); *see also* Ex. 2038 (Rettig Decl.) ¶¶ 194–97, 205 (representing that Attard 2008 and Attard 2009 describe the COU-AA-001 study). The study administered single agent abiraterone acetate to chemotherapy-naïve patients. *Id.* The phase I portion included dose escalation, and 1000 mg abiraterone acetate was administered daily in the phase II portion. Ex. 2014

[6] Ex. 1094, Cancer.gov (NIH NCI), "Prostate-Specific Antigen (PSA) Test," found at https://www.cancer.gov/types/prostate/psa-fact-sheet (accessed April 11, 2017).

[7] I understand that Johnson & Johnson, Janssen's parent company, acquired Cougar Biotechnology, Inc. in 2009. Ex. 2101.

(Attard 2008) at 4563, 4565; Ex. 2015 (Attard 2009) at 3743.[8] Mineralocorticoid excess toxicities were managed with a mineralocorticoid receptor antagonist or dexamethasone 0.5 mg daily. Ex. 2014 (Attard 2008) at 4565; Ex. 2015 (Attard 2009) at 3743. COU-AA-001 included an extension study in which 0.5 mg/day dexamethasone was added to patients who progressed on abiraterone acetate therapy. *Id.*

21. COU-AA-002 was a single arm, open label, multicenter phase II study conducted at 5 sites in the United States. Ex. 2017 (Ryan 2011); *see also* Ex. 2038 (Rettig Decl.) ¶ 205 (representing that Ryan 2011 describes the COU-AA-002 study). The purpose of the COU-AA-002 study was to assess the efficacy of abiraterone acetate in treating mCRPC patients and investigate the frequency of bone scan results inconsistent with PSA and clinical response. *Id.* at 4854. Patients without previous chemotherapy or ketoconazole treatment were given 1000 mg abiraterone acetate and 10 mg prednisone daily. *Id.*

22. COU-AA-301 was a two arm, double-blind, randomized, multicenter phase III clinical trial in 1195 chemotherapy-refractory patients. Ex. 1034 (de Bono). The treatment arm administered 1000 mg abiraterone acetate and 10 mg

[8] Because there are no page numbers branded on the Janssen exhibits (all exhibits numbered Ex. 2001 and higher), I have cited to the internal page numbers of these exhibits.

prednisone daily, and the placebo arm administered placebo and 10 mg prednisone daily. *Id.* at 1.

23. COU-AA-302 was a two arm, double-blind, randomized, multicenter phase III clinical trial in 1088 chemotherapy-naïve patients. Ex. 1009 (Ryan 2013); Ex. 2071 (Ryan 2015). The treatment arm administered 1000 mg abiraterone acetate and 10 mg prednisone daily, and the placebo arm administered placebo and 10 mg prednisone daily. Ex. 1009 (Ryan 2013) at 3; Ex. 2071 (Ryan 2015) at 152.

C. Statistical Principles

24. Statistical analysis can be used to test hypotheses to assess whether they are supported by data. More generally, statistics can be used to interpret and draw inferences from data sets. Hypothesis testing is the process of using data and statistical tests to assess the weight of the evidence in support of a hypothesis.

25. Statistically-based studies attempt to make inferences about a population from a representative sample of that population. Statistical power is a measurement of a study's ability to accurately test a hypothesis. Power is affected by the sample size and the variance of the study population.

26. A confidence interval indicates the precision available from a data set for estimating a quantity of interest. Particularly, if a point estimate (i.e., a median PSA value) is accompanied by a 95% confidence interval, there is a 95% chance

that the true value falls within the reported confidence interval. A finding of non-overlapping confidence intervals provides evidence that the two population values are significantly different. However, in the case of overlapping confidence intervals, no statistically significant difference can be claimed.

27. In the clinical trial context, studies can be designed to compare treatments. Phase III clinical trials typically have two arms—a treatment arm and a comparator arm. The comparator arm can comprise a placebo comparator or an active comparator, which allows the treatment arm to be compared with another effective intervention. A well-designed clinical trial allows the investigator to measure the effectiveness of a treatment over the placebo or active comparator.

28. Ideally, researchers can obtain robust information about a treatment from a well-designed clinical trial. In limited circumstances, researchers may also make inferences from cross-study comparisons. One requirement for any reliable cross-study comparison is that the compared studies must be similar in patient populations and study procedures.

VII. JANSSEN HAS NOT DEMONSTRATED UNEXPECTED RESULTS

29. Dr. Rettig has advanced two arguments that the combination claimed in the '438 patent produces unexpected results. ***First***, Dr. Rettig compared point estimates across multiple phase I/II studies to argue that the abiraterone acetate and prednisone combination produces an anti-cancer effect more than twice as great as

that produced by abiraterone acetate alone. Ex. 2038 (Rettig Decl.) ¶¶ 203–13. ***Second***, Dr. Rettig reported data from certain individual patients participating in a phase I/II extension study involving dexamethasone to advance the argument that glucocorticoids reverse the resistance that patients develop to abiraterone acetate treatment. *Id.* ¶¶ 194–202.

30. Upon investigation, both of Dr. Rettig's arguments contain fatal flaws and do not support any conclusion of unexpected results. Dr. Rettig did not demonstrate that abiraterone acetate and prednisone combination therapy has a longer time to PSA progression ("TTPP") than abiraterone acetate monotherapy for four independent reasons:

(1) The confidence intervals surrounding the compared point estimates overlap;

(2) Other reported data conflicts with the data used to support Dr. Rettig's conclusions;

(3) Dr. Rettig improperly compares point estimates across different clinical studies; and

(4) The phase III studies cannot ascertain any effect of prednisone.

31. The data from the phase I/II extension study also do not support a conclusion of unexpected results because the results are anecdotal and do not give a full picture of the COU-AA-001 extension study's results.

A. Dr. Rettig's Median TTPP Data Point Comparisons Do Not Demonstrate Any Unexpected Clinical Efficacy Of The Abiraterone Acetate And Prednisone Combination

32. Dr. Rettig's comparison table does not establish that the combination of abiraterone acetate and prednisone has a median TTPP more than twice as long as abiraterone acetate alone, as Dr. Rettig asserts in paragraph 205 of his declaration. In fact, Dr. Rettig has not shown *any* statistically significant difference in median TTPP between the combination of abiraterone acetate and prednisone and abiraterone acetate treatment alone.

1. *The Confidence Intervals In Dr. Rettig's Comparison Table Overlap*

33. Table 1 of Dr. Rettig's declaration reports a median TTPP point estimate for four patient groups: (1) abiraterone acetate monotherapy ("AA"), (2) abiraterone acetate + dexamethasone at progression in dexamethasone naïve patients ("AA+dex – dex naïve"), (3) abiraterone acetate + dexamethasone at progression in patients who previously failed dexamethasone monotherapy ("AA+dex – previous dex treatment"), and (4) abiraterone acetate + prednisone from the start ("AA+pred"). *Id.* ¶ 205.

34. Dr. Rettig failed to report the confidence intervals around the point estimates listed in Table 1, even though these confidence intervals are readily reported in the publications he cites in the very same table. Ex. 2015 (Attard 2009)

at 3745–46; Ex. 2017 (Ryan 2011) at 4856–57. In fact, Dr. Rettig never even mentions these confidence intervals in his declaration.

35. Dr. Rettig's omission of the confidence intervals is particularly troubling because the reported confidence intervals actually overlap, meaning that Dr. Rettig has not shown there is a statistically significant difference between the median TTPPs for any of the four groups in his comparison table:

Table 1: Adaptation of Rettig Table 1, With Confidence Intervals

Treatment	Median Time to PSA Progression (TTPP)	95% Confidence Interval[9]
AA	7.5 months (225 days)	5.4–9.6 months (162–287 days)
AA + dex – dex-naïve	12 months (361 days)	8.0–16.0 months (241–480 days)
AA + dex – previous dex treatment	12.4 months (372 days)	1.8–22.9 months (55–688 days)
AA + pred	16.3 months[10]	9.2 months–upper limit not estimable

Ex. 2015 (Attard 2009) at 3745–46; Ex. 2017 (Ryan 2011) at 4856–57.

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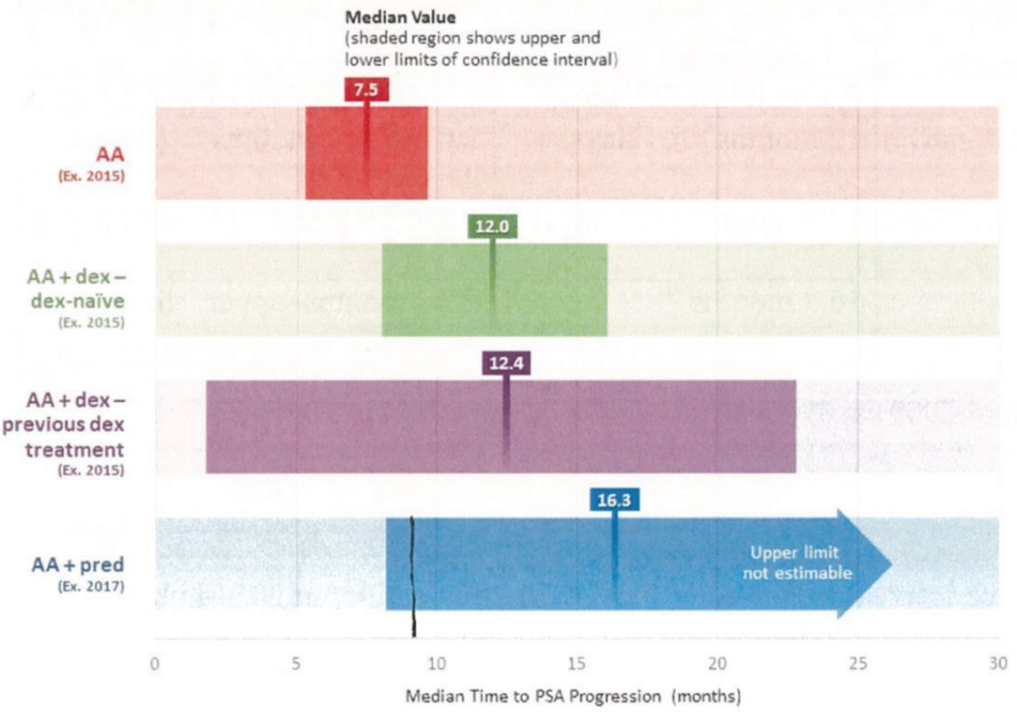
[9] The confidence intervals reported in the Attard 2009 and Ryan 2011 publications are 95% confidence intervals surrounding a single point estimate. If Dr. Rettig wanted to demonstrate a statistically significant difference between two medians based on such confidence intervals, it would be necessary to use a higher level of confidence (namely 97.5%) for each interval to ensure an overall confidence level of 95%.

[10] I note that both of Janssen's higher-powered phase III trials reported a lower median TTPP for patients treated with abiraterone acetate and prednisone. In COU-AA-301, the median TTPP in chemo-refractory patients treated with AA + pred was **10.2 months**, and in COU-AA-302, the median TTPP in chemo-naïve patients treated with AA + pred was **11.1 months**. Ex. 1034 (de Bono 2011) at 5; Ex. 1009 (Ryan 2013) at 7.

Figure 1: Representation of Rettig Table 1 Data, With Confidence Intervals

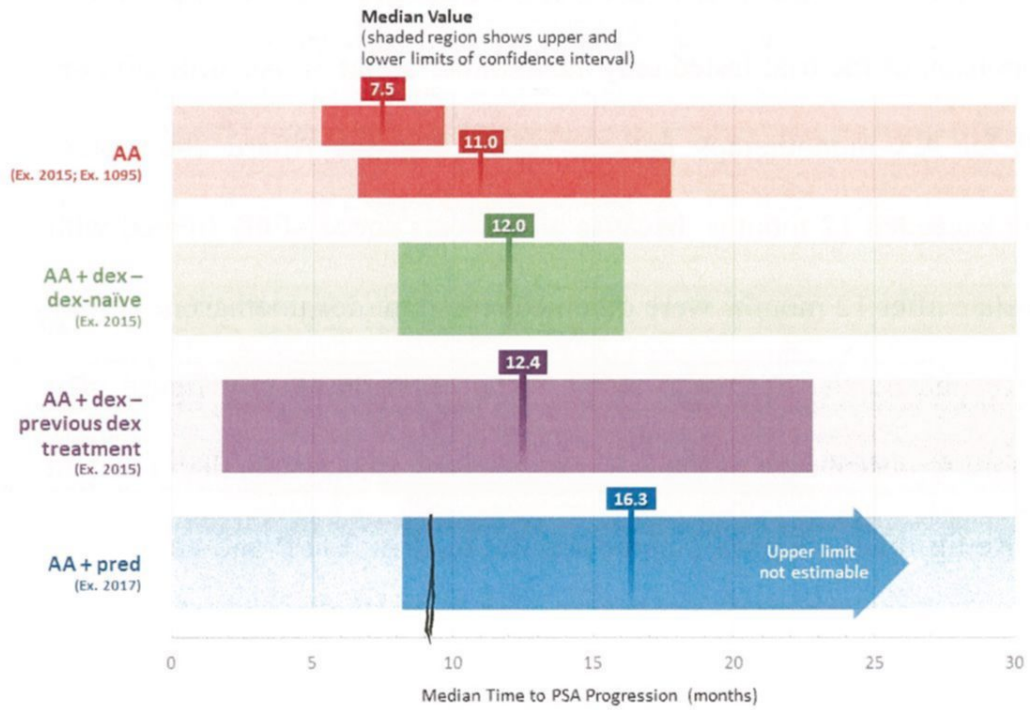


The overlap between confidence intervals is crucial because it indicates that there may be no statistically significant difference between any of the median TTPP point estimates listed above.

36. I note that on clinicaltrials.gov, Janssen reports a higher AA median TTPP point estimate of **11 months** (330 days), with a much broader 95% confidence interval of **6.6–17.7 months** (197–530 days). Ex. 1095 (COU-AA-001 synopsis) at 5. It is unclear why a longer median TTPP value appears on clinicaltrials.gov, but it may be because some COU-AA-001 patients were still being successfully treated on abiraterone acetate alone at the data cutoff. *See* Ex.

2015 (Attard 2009) at 3745 ("[S]ix patients continued on single-agent abiraterone acetate at the date of data cutoff."). Moreover, the abiraterone acetate monotherapy portion of the trial lasted only 12 months. *Id.* at 3. Accordingly, the median TTPP for AA monotherapy patients reported in the Attard 2009 paper could not have exceeded 12 months, because all patients successfully treated with abiraterone acetate after 12 months were given concomitant dexamethasone if they wanted to participate in the extension study. The clinicaltrials.gov figure may therefore be more representative of the AA monotherapy trial results than the data on which Dr. Rettig relies. Figure 2 compares the median TTPP and confidence interval reported on clinicaltrials.gov with the data presented in Dr. Rettig's Table 1:

Figure 2: Comparison of Conflicting Janssen-Reported AA Data With Rettig Table 1 Data



37. Simply comparing point estimates (here, the median TTPP) is not sufficient to demonstrate a meaningful difference between parameters. Indeed, where confidence intervals overlap, as here, comparing point estimates alone can be highly misleading. Dr. Rettig failed to perform the necessary statistical analysis to ensure that his comparison between point estimates is scientifically robust—namely, that there is a statistically significant difference between abiraterone acetate treatment alone and abiraterone acetate combined with a glucocorticoid. Any differences between the median TTPP estimates themselves, without more, cannot support any conclusion of unexpected results.

38. It is not surprising to me that the confidence intervals surrounding the point estimates in Dr. Rettig's Table 1 overlap. Confidence interval width is related to study power—in general, the higher a study's power, the narrower the confidence intervals. Dr. Rettig chose to present data from a selection of small phase I/II studies, and the broad confidence intervals are largely due to the small sample sizes used in those trials. Ex. 2015 (Attard 2009) at 3745–46 (the AA point estimate was obtained from a sample of **42** patients, and the AA + dex point estimates were obtained from samples of **19** patients (dex-naïve group) and **11** patients (previous dex treatment group)); Ex. 2017 (Ryan 2011) at 4856–57 (the AA + pred point estimate was obtained from a sample of **33** patients).

39. Because the confidence intervals surrounding the median TTPP point estimates in Dr. Rettig's comparison table overlap, Dr. Rettig's conclusions were improper. Dr. Rettig presented no evidence of any difference—much less a doubling—in TTPP between treatment with abiraterone acetate alone and treatment with abiraterone acetate and prednisone. Therefore, the data in Dr. Rettig's comparison table fail to support his conclusion that the claimed invention exhibited unexpected results.

2. *Other Data Reported By Janssen And Its Predecessor Conflict With The Data Reported In Dr. Rettig's Declaration*

40. Dr. Rettig's Table 1 compares median TTPP point estimates in two studies conducted in chemotherapy-naïve patient populations. However, Dr. Rettig

omits median TTPP estimates from other Janssen-sponsored studies of abiraterone acetate that do not support his conclusion of unexpected results.

41. For example, Janssen conducted phase II studies in patients who had previously been treated with chemotherapy ("chemo-refractory"). Ex. 1096 (Reid 2010); Ex. 2016 (Danila 2010). Reid 2010 describes a multicenter phase II study (COU-AA-003) in which 1000 mg abiraterone acetate monotherapy was administered daily to 47 patients, and TTPP was a secondary endpoint. Ex. 1096 (Reid 2010) at 1–2. Danila 2010 describes a multicenter phase II study (COU-AA-004) in which 1000 mg abiraterone acetate was administered daily to 58 patients along with 10 mg prednisone. Ex. 2016 (Danila 2010) at 1496–97; *see also* Ex. 2038 (Rettig Decl.) ¶ 202 (representing that Danila 2010 describes the COU-AA-004 study). TTPP was also a secondary endpoint in the Danila 2010 study. Ex. 2016 (Danila 2010) at 1498.

42. Below, I compare the median TTPP results from the COU-AA-003 and COU-AA-004 studies with the median TTPP results reported in Table 1 of the Rettig declaration:

Table 2: Median TTPP for Omitted COU-AA-003 and -004 Trials

Clinical Trial	Patient Group	Treatment	Median TTPP	Source
COU-AA-003	Chemo-refractory	Abiraterone acetate monotherapy	5.6 months (169 days)	Ex. 1096 (Reid 2010) at 4.
COU-AA-004	Chemo-refractory	Abiraterone acetate + prednisone from the start	5.6 months (169 days)	Ex. 2016 (Danila 2010) at 1499.

Rettig Table 1 (Ex. 2038 (Rettig Decl.) ¶ 205)

Clinical Trial	Patient Group	Treatment	Median TTPP	Source
COU-AA-001	Chemo-naïve	Abiraterone acetate monotherapy	7.5 months (225 days)	Ex. 2015 Attard *et al.* (2009), at 3745.
COU-AA-002, Amendment 5	Chemo-naïve	Abiraterone acetate + prednisone from the start	16.3 months	Ex. 2017, Ryan *et al.* (2011), at 4856–4857.

43. Unlike the median TTPP point estimates Dr. Rettig presented to support his unexpected results argument, the median TTPP point estimates from Cougar's chemo-refractory phase II trials are **identical** for abiraterone acetate alone and combination therapy with prednisone (both 5.6 months/169 days). Accordingly, the data from the COU-AA-003 and -004 trials do not support the existence of a difference in median TTPP between abiraterone acetate alone and combination therapy with prednisone.

3. *Dr. Rettig's Analysis Engages in an Improper Cross-Study Comparison*

44. Dr. Rettig relies on data points from two separate clinical studies, COU-AA-001 and COU-AA-002, to compare median TTPP point estimates between AA and AA+pred treatment groups. While Dr. Rettig points out a few choice similarities between these studies, he ignores a vast number of meaningful differences in patients, location, and study procedure that prevent any comparison between the two studies.

45. The best way to assess a potential difference between two treatments is to test them together in a randomized, double blinded, controlled trial. *See*, *e.g.*, Ex. 2038 (Rettig Decl.) ¶ 206. Cross-study comparisons are possible in specific, limited circumstances, but the comparison must control for differences in the compared studies. Otherwise, one cannot ensure that the compared treatments, instead of a difference in the compared studies, is responsible for the finding of a difference.

46. Dr. Rettig attempts to justify his improper cross-study comparison by selectively disclosing three similarities in patient populations and study design. Ex. 2038 (Rettig Decl.) ¶ 207. Dr. Rettig paints an incomplete picture by failing to disclose numerous differences in the two studies' patients, endpoints, and study procedures.

47. Following is a non-exhaustive list of the differences in the COU-AA-001 and COU-AA-002 patients:[11]

Table 3: Differences Between COU-AA-001 and -002 Patients

	COU-AA-001	COU-AA-002
Median baseline PSA level	110 ng/mL	23 ng/mL
Baseline PSA level range	9.7–964 ng/mL	5.9–1100.0 ng/mL
Baseline disease state	Progressive disease as defined by Prostate-Specific Antigen Working Group (PSAWG) I	Histologically confirmed adenocarcinoma of the prostate progressing on androgen deprivation therapy
Number of prior hormonal treatments	3 (median)	88% had 2
Location of patients	United Kingdom	United States
Number of patients	54; 42 treated at 1000 mg AA	33
Recruitment time period	December 13, 2005–November 28, 2007	October 2007–May 2008
Prior ketoconazole treatment allowed?	Yes	No

Ex. 2015 (Attard 2009) at 3743–44; Ex. 2017 (Ryan 2011) at 4855–56.

48. Following is a non-exhaustive list of the differences between the COU-AA-001 and COU-AA-002 study procedures:[12]

[11] Because I do not have access to any internal Janssen documents, I have compiled this list solely from publicly available documents. Accordingly, there may be more differences between the COU-AA-001 and COU-AA-002 patients than those I have listed in this declaration.

Table 4: Differences Between COU-AA-001 and -002 Study Procedures

	COU-AA-001	COU-AA-002
Clinical trial stage	Phase I/II	Phase II
Number of study centers	1	5
Location	United Kingdom	United States
Dose	12 patients received 250, 500, 750, or 2000 mg AA (3 at each dose level); 42 patients received 1000 mg AA	1000 mg AA + 10 mg prednisone
Secondary endpoints	Rate of PSA declines ≥30%	Durability of response as determined by TTPP
	Measurable target lesions monitored by CT scans using RECIST and reported by blinded radiologist	Objective radiographic response rate according to RECIST guidelines
	Changes in circulating tumor cell (CTC) counts	Radiographic progression-free survival time
	Radiologic assessments	Overall survival time
		Clinical benefit as determined by disease stabilization
		Change in ECOG performance status
		Overall treatment safety
Management of mineralocorticoid excess	Eplerenone; glucocorticoids if eplerenone did not reverse	5 mg prednisone bid

[12] Because I do not have access to any internal Janssen documents, I have compiled this list solely from publicly available documents. Accordingly, there may be more differences between the COU-AA-001 and COU-AA-002 study procedures than those I have listed in this declaration.

	toxicities	
Steroid used to manage mineralocorticoid excess	Dexamethasone	Prednisone

Ex. 2015 (Attard 2009) at 3743–44; Ex. 2017 (Ryan 2011) at 4855–56.

49. As shown by the differences listed in the tables above, while Dr. Rettig was able to name three similarities between the COU-AA-001 and COU-AA-002 studies, there are a far greater number of differences that could have affected the results of the compared studies. Ex. 2038 (Rettig Decl.) ¶ 207. Dr. Rettig did not account for any of these differences in his declaration.

50. Dr. Rettig dismisses the difference between the patients' baseline PSA levels in the COU-AA-001 and COU-AA-002 studies, stating without explanation that he would not expect these differences to account for the differences in TTPP. Ex. 2038 (Rettig Decl.) ¶ 208. As a biostatistician, I find the substantially different baseline values in the primary variable to be alarming. For a study's conclusions to be reliable, the study groups must begin at approximately the same point. Dr. Rettig should have provided evidence that there is no statistically significant or clinically meaningful difference between baseline variables, especially those used as outcomes. There is no such evidence here. At minimum, Dr. Rettig was required to disclose the confidence intervals surrounding the two baseline PSA point estimates and show that there is no significant difference between the baseline PSA levels of the COU-AA-001 and COU-AA-002 patient groups.

Simply stating that he would not expect the differences in baseline PSA levels to account for TTPP differences is not sufficient.

51. In addition, one of the publications cited by Dr. Rettig indicates that different baseline PSA levels *are* significant. Ex. 2017 (Ryan 2011) at 4860 ("The PSA response proportion of 67% in this study is slightly higher than that observed in previous phase II studies with abiraterone acetate . . . . Potential explanations for this observation are many and include the fact that this was a population with less extensive disease than in past studies (e.g., median PSA level was 23 in this study)."). It was therefore improper for Dr. Rettig to compare the COU-AA-001 and COU-AA-002 median TTPP results without explaining or adjusting for the different baseline PSA levels.

52. Based on the numerous differences between the COU-AA-001 and COU-AA-002 patients and study procedures alone, I conclude that it is necessary to control for these differences if the TTPP data from these two studies is to be compared. Janssen could have easily conducted a true comparison trial or taken other measures to control for the differences in the compared studies, yet it did not. Therefore, the comparison between the median TTPP values in the COU-AA-001 and COU-AA-002 studies does not support any conclusion of unexpected results.

4. *The Phase III Studies Are Not Designed To Ascertain Any Effect Of Prednisone*

53. After comparing the median TTPP point estimates from select phase I and II trials, Dr. Rettig generally discusses overall survival results from Cougar's larger phase III studies, COU-AA-301 and COU-AA-302. Ex. 2038 (Rettig Decl.) ¶¶ 210–13. However, these phase III trials were not designed to estimate any effect of prednisone, anti-cancer or otherwise, because prednisone appears in both the placebo and treatment arms of each phase III study. Ex. 1034 (de Bono 2011) at 1; Ex. 1009 (Ryan 2013) at 3; Ex. 2071 (Ryan 2015) at 152.

54. Notably, Dr. Rettig admits that "head-to-head comparisons in a randomized, adequately powered placebo-controlled Phase III clinical trial are the highest standard in evaluating comparative efficacy of two prostate cancer therapies[.]" Ex. 2038 (Rettig Decl.) ¶ 206. The phase III studies Dr. Rettig asserts support his unexpected results conclusion were head-to-head comparisons of AA + prednisone versus placebo + prednisone. This study design controls for any potential confounding anti-cancer effect of prednisone, and it is therefore impossible to draw any conclusions about the independent anti-cancer effect of prednisone from these studies.

55. This two arm study design suggests that Janssen was not interested in investigating whether prednisone has an anti-cancer effect separate from that of abiraterone acetate. Janssen could have, for example, designed a three arm study

to ascertain the survival benefit of both abiraterone acetate monotherapy and AA + prednisone. Instead, the COU-AA-301 and COU-AA-302 studies were designed to measure the impact of ***abiraterone acetate*** on overall survival. These study designs are at odds with Dr. Rettig's conclusion that Janssen found novel, anti-tumor benefits of prednisone in its phase I/II studies—Janssen did not even attempt to test this theory in following studies. Because the phase III study designs cannot measure any anti-cancer effect of prednisone, the phase III study results are therefore irrelevant to any purported anti-cancer effect of prednisone in combination with abiraterone acetate.

B. Janssen's Selective Disclosure Of Four Instances Of Supposed "Reversal Of Resistance" Does Not Demonstrate Unexpected Clinical Efficacy

56. Dr. Rettig presents certain data from individual patients participating in the COU-AA-001 extension study to advance the argument that glucocorticoids reverse the resistance patients develop to abiraterone acetate treatment. Ex. 2038 (Rettig Decl.) ¶¶ 194–202.

57. Upon review of the publications describing the COU-AA-001 study, Dr. Rettig seemingly selects the results that support his desired conclusion. There is no indication that he even considered the majority of patients who did not respond favorably to treatment with dexamethasone in the study he cites. At best,

these results are anecdotal and do not support a conclusion of unexpected results of treatment with abiraterone acetate and prednisone.

58. The COU-AA-001 extension treated patients who progressed on abiraterone acetate alone with a combination of abiraterone acetate and dexamethasone. Ex. 2014 (Attard 2008) at 4565; Ex. 2015 (Attard 2009) at 3743. The COU-AA-001 extension included 15 patients in the phase I portion and 39 patients in the phase II portion. Ex. 2014 (Attard 2008) at 4568; Ex. 2015 (Attard 2009) at 3745. Individual patients received dexamethasone after progressing on abiraterone acetate.

59. Dr. Rettig appears to suggest that the results discussed in his declaration exemplify the entirety of the extension study results. Ex. 2038 (Rettig Decl.) ¶¶ 198–200. That implication is incorrect. On the contrary, the publications cited by Dr. Rettig reveal that he discloses only certain "positive" results from the extension study. Ex. 2014 (Attard 2008) at 4568 ("The addition of dexamethasone 0.5 mg/d resulted in successful salvage in four of 15 patients"); Ex. 2015 (Attard 2009) at 3742 ("[T]he addition of dexamethasone at disease progression reversed resistance in 33% of patients"). In other words, while Dr. Rettig presents two graphs from two individual dexamethasone-naïve patients and generally discusses that an unspecified number of patients previously treated with dexamethasone also experienced drops in PSA levels (Ex. 2038 (Rettig Decl.) ¶¶ 198–200), only 27%

of phase I patients and 33% of phase II patients experienced this alleged reversal of resistance. Ex. 2014 (Attard 2008) at 4568; Ex. 2015 (Attard 2009) at 3742. Dr. Rettig does not present any statistical analysis demonstrating the significance of these results.

60. The data from the COU-AA-001 extension present additional problems. The sample size is small, indicating an under-powered study. Ex. 2014 (Attard 2008) at 4568; Ex. 2015 (Attard 2009) at 3745. While Dr. Rettig did not include any statistical analysis in his declaration, the low power of the study restricts the inferences that can be drawn from the study results. Furthermore, this study design was never replicated in a larger study or in a different patient population, and hence Dr. Rettig's anecdotal results were never confirmed in a manner sufficient to demonstrate unexpected results.

61. While meaningful information can be garnered from certain individual patient experiences in limited circumstances, a much more sophisticated analysis is required to demonstrate unexpected results. Dr. Rettig simply observes plots from a select number of patients in the extension study without performing any analysis. The COU-AA-001 extension phase clearly obtained more than one data point for each patient (*see*, *e.g.*, Ex. 2038 (Rettig Decl.) ¶ 198), and Dr. Rettig therefore could have analyzed the whole data set and obtained a p-value to demonstrate, for example, whether these patients experienced a statistically significant reversal of

resistance, or whether the alleged "reversal" seen graphically is merely random variation (i.e., noise). As it stands, the data Dr. Rettig presented in his declaration do not show that the addition of dexamethasone at PSA progression on abiraterone acetate alone causes—or is even correlated with—a statistically significant drop in PSA levels. This anecdotal data therefore does not demonstrate any unexpected results of the combination of abiraterone acetate and prednisone.

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: April 17, 2017

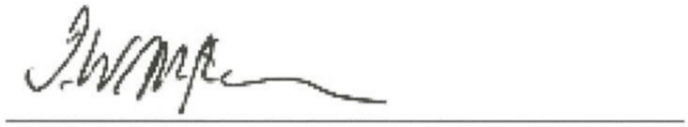


EXHIBIT A

CURRICULUM VITÆ

(updated April14, 2017)

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EDUCATION

University of North Carolina at Chapel Hill	1977–1980	Ph.D.	Statistics
University of Cambridge	1975–1976	M.Math.	Mathematics
University of Cambridge	1972–1975	B.A. (1st class hons.), M.A.	Mathematics

Ph.D. thesis: *Covariance Operators and their Applications in Probability and Information Theory.*
Advisor: C. R. Baker.

PROFESSIONAL EXPERIENCE

2004–present	Professor of Biostatistics, Columbia University
2000–2004	Ralph A. Bradley Professor of Statistics, Florida State University
1996–1999	Chairman, Department of Statistics, Florida State University
1991–2000	Professor, Department of Statistics, Florida State University
1986–1991	Associate Professor, Dept. of Statistics, Florida State University
1980–1986	Assistant Professor, Dept. of Statistics, Florida State University
Nov–Dec 1991	Visiting MSRI, University of California, Berkeley
Feb–May 1992	Visiting Université Joseph Fourier, Grenoble, France
June–July 2001	Visiting Université Joseph Fourier, Grenoble, France
May–June 1985	Visiting University of Padua, Italy

RESEARCH INTERESTS

Post-selection inference, functional data analysis, empirical likelihood, non-standard asymptotics, statistical methods for trajectory analysis in life course epidemiology, survival analysis, Bayesian inverse problems in physical oceanography, statistical aspects of quantum physics and relativity, Markov chain Monte Carlo, competing risks models for HIV/AIDS data, inference for stochastic processes, simultaneous inference, efficient estimation for semiparametric models, counting process and martingale methods in survival analysis.

PROFESSIONAL HONORS AND ACTIVITIES

Fellow of the Institute of Mathematical Statistics
Fellow of the American Statistical Association
Annals of Statistics, Associate Editor, 1989–1995
Journal of the American Statistical Association, Associate Editor, 1993–1996, 2011–
International Journal of Biostatistics, Associate Editor, 2005–
Statistical Inference for Stochastic Processes, Associate Editor, 1998–
ESAIM: Probability and Statistics, Associate Editor, 2000–2005
G. W. Snedecor Lecture, Iowa State University, 2007
Florida State University Named Professorship Award, 2000
Florida State University Graduate Teaching Award, 1998
Florida State University Professorial Excellence Program Award, 1999

Institute of Mathematical Statistics Fellows Committee, 2008–2010
ASA Section on Nonparametric Statistics, JNPS Awards Committee, 2010–2011
NIH and NIAID Review Panel for "International Centers of Excellence for Malaria Research (U19)", 2016.
NSF *Statistics and Probability Program* Panel, 1997, 1999, 2000, 2002, 2003, 2007, 2009, 2010, 2016.
NSF *Special Meetings* Panel, 2005.
NSF *Biocomplexity in the Environment* Panel, 2004.
NSF *Knowledge and Distributed Intelligence Program* Panel, 1998.
Chair of Organizing Committee, IMS mini-meeting "Statistical Approaches to the Ocean Circulation Inverse Problem," Florida State University, November 2001.
SAMSI program *Data Assimilation in Geophysical Systems*, Scientific Committee member, 2004–2005.
Chair of Organizing Committee, AMS-IMS-SIAM Summer Research Conference "Stochastic Inference, Monte Carlo and Empirical Methods," Mt. Holyoke College, 1996.
Member of the American Statistical Association, and the Institute of Mathematical Statistics.
New Zealand University Scholarship, 1971.
Duke of Edinburgh Gold Award, 1972.
Postgraduate Fellowship (declined), Australian National University, 1976.
Selwyn College Scholarship, University of Cambridge, 1975.
First Class Honors (Wrangler), Mathematical Tripos, University of Cambridge, 1975.

PEER-REVIEWED ARTICLES

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[75] Z. Li and I. W. McKeague. Power under Local Alternatives for Generalized Estimating Equations. *Statistics and Information Forum* **26** 81–82 (2011).*

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[101] I. W. McKeague. Central Limit Theorems under Special Relativity. *Statistics and Probability Letters* **99** 149–155 (2015). PMID: 25798020.*

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[113] A. S. Brown, D. Gyllenberg, H. Malm, S. Hinkka-Yli-Salomäki, M. Artama, M. Gissler, K. Cheslack-Postava, M. M. Weissman, J. A. Gingrich, A. Sourander. Association of Selective Serotonin Reuptake Inhibitor Exposure During Pregnancy With Speech, Scholastic, and Motor Disorders in Offspring. *JAMA Psychiatry* 73(11): 1163–1170 (2016).

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PROCEEDINGS AND DISCUSSION ARTICLES

[118] I. W. McKeague and M.-J. Zhang. Nonlinear Time Series Analysis via Cumulative Regressograms. *Proceedings of the Thirty-Seventh Conference on Design of Experiments in Army Research Development and Testing* 217–224 (1992).*

[119] I. W. McKeague. Discussion of papers of P. Sasieni and E. Slud. In: *Survival Analysis: State of the Art* (J. P. Klein and P. K. Goel, eds.), 263–265, 367–368, Kluwer, (1992).*

[120] I. W. McKeague and P. Sasieni. Discussion of T. Hastie and R. Tibshirani's paper "Varying-coefficient models." *J. R. Statist. Soc. B* **55** 786–787 (1993).*

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[124] I. W. McKeague. Comments on "A Review on Empirical Likelihood Methods for Regression" by Ingrid Van Keilegom and Song Xi Chen. *TEST* **18** p. 461 (2009).*

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[126] L. L. Davidson, S. Kauchali, M. K. Chhagan, F. Bah, O.O.T. Uwemedimo, M.H. Craib and I. W. McKeague. The Use of a Wealth Index within an Impoverished Community: A Cohort Study in KwaZulu-Natal, South Africa. *J. Epidem. Com. Health* **66** [Supp 1], A59 (2012).

DOCTORAL STUDENTS

[1] Dr. Klaus Utikal, Institute for Economics and Social Sciences, University of Bonn, Germany. Inference for a Nonlinear Semimartingale Regression Model, 1987.

[2] Dr. Mei-Jie Zhang, International Bone Marrow Transplant Registry, Medical College of Wisconsin, Milwaukee. Cumulative Regression Function Methods in Survival Analysis and Time Series, 1991.

[3] Dr. Yanqing Sun, Department of Mathematics, University of North Carolina at Charlotte. Transformations of Gaussian Random Fields, with Applications in Survival Analysis, 1992.

[4] Dr. Jie Yang. Likelihood Ratio Based Confidence Bands in Survival Analysis, 1995. (co-advised with Myles Hollander)

[5] Dr. Sundarraman Subramanian, Department of Mathematics, New Jersey Institute of Technology. Estimation of Survival Functions with Missing Failure Indicators, 1995.

[6] Dr. Cyrus Amir. Testing for a Time-Dependent Covariate Effect in the Linear Risk Model, 1995.

[7] Dr. Mourad Tighiouart. Assistant Director of the Biostatistics and Bioinformatics Research Center, and Associate Professor, Division of Hematology and Oncology, Cedars Sinai Medical Center, Los Angeles. Nonparametric Bayesian Inference for Survival Data, 1998.

[8] Dr. Blake Whitten, Department of Statistics and Actuarial Science, University of Iowa. Formulations of Missing-Data Models and Likelihood-Based Inference, 2001.

[9] Dr. Marc Loizeaux, Department of Mathematics, University of Tennessee at Chattanooga. Bayesian Inference for a Spatial Cluster Model via Perfect Sampling, 2001.

[10] Dr. Yichuan Zhao, Department of Mathematics and Statistics, Georgia State University. Empirical Likelihood Methods for Comparison of Survival Functions, 2002.

[11] Dr. Gang Ye, Nemours Children's Clinic, Orlando, Florida. Inference for Semiparametric Time-Varying Covariate Effect Relative-Risk Regression Models, 2005.

[12] Dr. Radu Herbei, Department of Statistics, Ohio State University. Quasi-3D Statistical Inversion of Oceanographic Tracer Data, 2006.

[13] Dr. Shean-Sheng Wang, Associate Director of Biostatistics, Johnson & Johnson, New Brunswick, New Jersey. Analysis of the MTCT-Plus Initiative: An Application of a Piecewise Multilevel Latent Variable Regression Model, 2010.

[14] Dr. Zhigang Li, Section of Biostatistics and Epidemiology, Department of Community and Family Medicine, Dartmouth Medical School. Power under Local Alternatives for Generalized Estimating Equations with Applications to Sibling Studies, 2010.

[15] Dr. Wei Xiong, Sparse Functional Regression Models: Minimax Rates and Contamination, 2012. Currently at BlackRock, Inc.

[16] Dr. Yulei Zhang, Sparse Selection in Cox Models with Functional Predictors, 2012. Currently at J. P. Morgan.

[17] Dr. Hsin-Wen Chang, Statistical Institute, Academia Sinica, Taipei. Empirical Likelihood based Tests for Stochastic Ordering, 2014. A paper based on her dissertation won the 2014 ICSA student paper competition award.

[18] Dr. Tzu-Jung Huang, Adaptive Resampling Test for Survival Data, 2017.

GRANTS

NIH Grant 2R01 GM095722-05, "Post-selection Inference and Trajectory Analysis," Project Director and Principal Investigator, 2015–2019. Total support awarded: $197,000/year.

NSF Grant DMS-1307838, "Optimal Treatment Policies and Adaptive Screening for Functional Predictors," Project Director and Principal Investigator, 2013–2016. Direct support awarded: $113,000.

NIH Grant R01 GM095722-01, "Point Impact and Sparsity in Functional Data Analysis," Project Director and Principal Investigator, 2011–2015. Direct support awarded: $114,000/year.

NSF Grant DMS-0806088, "Sparse Predictors in Functional Data Analysis," Project Director and Principal Investigator, 2008–2012. Direct support awarded: $119,000.

NSF Grant DMS-0505201, "Hybrid Likelihood Methods," Project Director and Principal Investigator, 2005–2009. Direct support awarded: $114,000.

NSF Grant ATM-0222244, Opportunities for Research Collaborations between the Mathematical Sciences and the Geosciences Program, "Ocean Circulation Climatology and Dynamics Using Bayesian Hierarchical Methods," Project Director and Principal Investigator, 2002–2006. Direct support awarded: $178,000.

NSF Grant DMS-0204688, "Bayesian, Empirical Likelihood and Counting Process Methods for Semiparametric Models," Project Director and Principal Investigator, 2002–2005. Direct support awarded: $60,000.

NSF Grant DMS-0207139, Interdisciplinary Grants in the Mathematical Sciences Program, "Statistical Modeling in Oceanography," Project Director and Principal Investigator, 2002–2004. Direct support awarded: $55,000.

NSF Grant DMS-9971784, "Efficient Condensation of Spatial/Temporal Information," Project Director and Principal Investigator, 1999–2002. Direct support awarded: $57,000.

NSA Grant DMS-19984075, "Bayesian Signature Recognition," Project Director and Principal Investigator, 1999–2000. Direct support awarded: $57,000.

NSF Grant ATM-9417528, "Empirically Determined Climate Predictability using Nonlinear Time Series," Project Director and Principal Investigator, 1995–1998. Direct support awarded: $64,000.

Army Research Office Grant DAA03–90–G, 1990–1993. Co-Principal Investigator.

Army Research Office Grant DAAL03–86–K–0094, 1986–1990. Co-Principal Investigator.

Army Research Office Grant DAAG29–82–0168, 1982–1986. Co-Principal Investigator.

Florida State University Committee on Faculty Research Grants, 1981, 1985, 1988, 1994, 2001. Project Director and Principal Investigator. Direct support awarded: partial summer salary.

DEPARTMENTAL AND UNIVERSITY COMMITTEE EXPERIENCE

Member of the Columbia University Tenure Review Advisory Committee, 2011–2014. Co-chair of the Columbia University Medical Center Committee on Appointments and Promotions (CUMC COAP), 2010–2011. Extensive experience at Departmental, College and University levels since 1980, including a three-year term as Chair of Department; Colloquium Chair, Ph.D. Qualifying Exam Committee Chair, Academic Affairs Chair, Student Affairs Chair, Faculty Recruiting Chair; service on numerous Promotion and Tenure Committees, Science Area Committee service within the College of Arts and Sciences at FSU; Ad Hoc Committee Chair at Columbia; University Faculty Teaching Awards Committee Chair; Committee on Appointments and Promotions in the Mailman School of Public Health.

TEACHING EXPERIENCE

Selected course titles: Special Topics in Asymptotic Statistics, Analysis of Longitudinal Data, Introduction to Biostatistical Methods, Survival Analysis, Statistical Methods in Oceanography, Introduction to Applied Statistics, Probability and Measure, Distribution Theory and Inference, Probability Theory, Advanced Probability, Topics in Stochastic Processes, Counting Processes and Survival Analysis, Introduction to Mathematical Statistics, Empirical Likelihood, Markov Chain Monte Carlo, Information Theory.

PAPERS PRESENTED AT INTERNATIONAL MEETINGS

Invited speaker, IMS-China International Conference on Statistics and Probability, Guangxi University for Nationalities, Nanning, China, June 28 – July 2, 2017.

Invited speaker, The 1st International Conference on Econometrics and Statistics (EcoSta 2017), Hong Kong University of Science and Technology, Hong Kong, June 15–17 2017.

Invited speaker, Bangkok Workshop on Discrete Geometry and Statistics, Chulalongkorn University, Bangkok, Thailand, January 30 – February 3, 2017.

Invited speaker (Talk: "On the relativistic reconstruction of growth velocity curves"), The 22nd International Conference on Computational Statistics, Oviedo, Spain, 23–26 August, 2016.

Invited speaker (Talk: "Combining Parametric and Empirical Likelihoods"), Workshop on Empirical Likelihood Based Methods in Statistics, IMS, National University of Singapore, June 19–25, 2016.

Invited speaker (Talk: "Stein's method and convergence of empirical distributions in an interpretation of quantum mechanics"), International Society of Nonparametric Statistics Conference, Avignon, France, June 10–16, 2016.

Invited speaker (Talk: "Stein's Method and the Many-Worlds Interpretation of Quantum Mechanics"), Workshop on New Directions in Stein's Method, IMS, Singapore, May 18–29, 2015.

Invited speaker (Talk: "Marginal Screening for High-Dimensional and Functional Predictors"), 60th World Statistics Congress ISI 2015, Rio de Janeiro, Brazil, July 26–31, 2015.

Invited speaker (Talk: "Post-Selection Inference and High-Dimensional Screening"), The 13th Islamic Countries Conference on Statistical Sciences, Bogor, Indonesia, Dec 18–21, 2014.

Invited speaker, The 3rd Institute of Mathematical Statistics Asian Pacific Rim Meeting, Taipei, Taiwan, June 29–July 3, 2014.

Invited speaker in the Survival Analysis session, Second International Forum on Non/Semiparametric Statistics, Southwestern University of Finance and Economic, Chengdu, China, June 24–26, 2014.

Invited speaker, International Society of Nonparametric Statistics Conference, Cadiz, Spain, June 12–16, 2014.

Invited speaker in the session "New Methodologies in Individualized Treatment Policies," Joint Statistical Meetings, Montreal, Canada, Aug 4–8, 2013.

Invited speaker, IMS-China Meeting, Chengdu, China, July 1–5, 2013.

Plenary speaker, Australasian Applied Statistics Conference, Queenstown, New Zealand, Dec 3–7, 2012.

Invited speaker, IMS-China International Conference on Statistics and Probability, XiAn, China, July 8–11, 2011.

Keynote speaker, Fourth Annual International Symposium on the Evaluation of Clinical Trials Methodologies and Applications, Beijing, China, July 2–3, 2011.

Invited speaker, Second International Workshop on Functional and Operatorial Statistics, Santander, Spain, June 16–18, 2011.

Invited speaker, First Joint Biostatistics Symposium, Beijing, China, July 17–18, 2010.

Invited speaker, International Conference on Statistics and Society, Beijing, China, July 10–12, 2010.

Invited speaker, International Conference on Statistical Analysis of Complex Data, Kunming, China, July 1–3, 2010.

Invited speaker, Workshop on Statistical Frontiers, Institute of Statistics, Academia Sinica, Taiwan, December 15–17, 2009.

Invited speaker, The 57th International Statistical Institute (ISI) Conference, Durban, South Africa, August 16–22, 2009.

Invited speaker, The 1st IMS ASIA Pacific Rim Meeting, Seoul, South Korea, June 28–July 1, 2009.

Invited speaker, Workshop on Long Term Consequences of Exposure to Famine, Lorentz Center, University of Leiden, The Netherlands, November 3–6, 2008.

Invited speaker, First Workshop of the ERCIM Working Group on Computing & Statistics, 19–21 June 2008, Neuchatel, Switzerland. Talk: Principal components for gradients of sparse functional data.

Invited Lecturer, Advanced School and Conference on Statistics and Applied Probability in Life Sciences, International Center for Theoretical Physics, Trieste, Italy, September 24 – October 12, 2007.

Invited speaker, International Conference on Reliability and Survival Analysis, Indian Statistical Institute, New Delhi, India, December 20–22, 2005. Talk: Extending the Scope of Empirical Likelihood.

Invited speaker, The 5th IASC Asian Conference on Statistical Computing, Hong Kong University, December 15–17, 2005. Talk: Bayesian Computational Methods for Oceanographic Tracer Data.

Invited speaker and participant, Program on Semiparametric Methods for Survival and Longitudinal Data, Institute for Mathematical Sciences, National University of Singapore, March 2005.

Invited speaker (session on Functional Data Modeling), 6th World Congress of the Bernoulli Society, Barcelona, Spain, July 2004.

Invited speaker, XXXIVèmes Journées de Statistique, Brussels, Belgium, May 2002.

Invited speaker, Eighth Summer Workshop, New Zealand Mathematics Research Institute, Napier, New Zealand, January 2002.

Invited speaker, First European Conference on Spatial and Computational Statistics, Ambleside, England, September 2000.

Principal Lecturer, Workshop on Survival Analysis and MCMC, Tamkang University, Taiwan, December 1998.

Invited speaker, Second St. Petersburg Workshop on Simulation, St. Petersburg, Russia, June 1996.

Invited speaker, Meeting on Empirical Processes: Theory and Applications, Mathematical Institute, Oberwolfach, Germany, October 1995.

Invited speaker at the Conference to Celebrate the Tenth Anniversary of the Institute of Statistics, Academia Sinica, Taiwan, July 1992.

Contributed paper, 2nd World Congress of the Bernoulli Society and the 53rd Annual Meeting of the Institute of Mathematical Statistics, Uppsala, Sweden, August 1990.

Invited paper, Meeting on Martingale Methods in Statistics, Mathematical Institute, Oberwolfach, West Germany, December 1988.

Invited paper, Meeting on Mathematical Statistics and Probability for the 46th Session of the International Statistical Institute (ISI), Kyoto, Japan, September 1987.

PAPERS PRESENTED AT NATIONAL MEETINGS

Invited speaker, Conference on Lifetime Data Science, University of Connecticut, Storrs, May 25 – May 27, 2017.

Invited speaker, (Talk: "Estimation of optimal treatment policies and marginal screening"), Biometric Society (ENAR) Spring Meeting, Austin, Texas, March 6–10, 2016.

Invited speaker (Talk: "The many-interacting-worlds interpretation of quantum mechanics and Stein's method"), Fourth Rutgers Applied Probability Conference, Rutgers University, Oct 2–3, 2015.

JASA-Theory and Methods Special Invited Paper (with discussion), Joint Statistical Meetings, Seattle, Aug, 2015.

Invited speaker, Joint Statistical Meetings, Boston, Aug 2–7, 2014.

Invited speaker, Statistics of Time Warpings and Phase Variations, Mathematical Biosciences Institute, Columbus, Ohio, Nov 13–16, 2012.

Invited speaker, 3rd Princeton Day of Statistics Workshop, Oct 19, 2012.

Invited speaker, Joint Statistical Meetings, San Diego, July 29–Aug 2, 2012.

Keynote speaker, Workshop on Biostatistics and Bioinformatics, Department of Mathematics and Statistics, Georgia State University, Atlanta, May 4–6, 2012,

Invited speaker, session on "Recent Advances in Survival Analysis and Clinical Trials," ICSA Applied Statistics Symposium, New York, June 26–29, 2011.

Invited speaker (talk: "Optimal treatment policies based on high-dimensional gene expression profiles"), NSF Workshop on High Dimensional Data, Nantucket, MA, May 12–14, 2011.

Invited speaker, ENAR Spring meeting, Miami, Florida, March 20–23, 2011.

Invited speaker and discussant, Joint Statistical Meetings, Washington, D.C., August, 2009.

Invited speaker, Time Series Analysis in Neuroscience Workshop, Columbia University, April 14, 2009.

Invited speaker, 1st Princeton Day of Statistics Workshop, Princeton University, April 4, 2008.

Invited speaker, Joint Statistical Meetings, Salt Lake City, Utah, July, 2007. Talk: Trajectories as predictors of univariate responses.

Invited speaker, Conference on Frontiers in Applied and Computational Mathematics 2007, New Jersey Institute of Technology, May 2007.

Invited speaker, 15th annual ICSA Applied Statistics Symposium, University of Connecticut, Storrs, Connecticut, June 14–17, 2006.

Invited panelist and speaker, First Semi-Annual CDAS Statistics Conference, United States Military Academy, West Point, New York, October 27–28, 2005.

Invited speaker, Workshop on Data Assimilation for Geophysical Systems, Statistical and Applied Mathematical Sciences Institute, Research Triangle Park, North Carolina, January 2005.

Invited speaker (session on Dynamic Survival Modeling) and Discussant (session on Empirical Likelihood), Joint Statistical Meetings, Toronto, Canada, August, 2004.

Plenary speaker, Classification Society of North America, Annual Meeting (CSNA 2003), June 12–15, 2003, Tallahassee, FL.

Invited speaker and Session Organizer, International Conference in Reliability and Survival Analysis (ICRSA), May 21–24, 2003, Columbia, SC.

Invited speaker, AMS-ASA-MAA-SIAM Conference on NSF/DMS Funding Opportunities, May 9–10, 2003, Arlington, VA.

Invited speaker, Nonparametric Statistics Research Conference, January 17–18, 2003, Florida State University.

Invited speaker, University of Florida Fifth Annual Winter Workshop, An IMS Mini-Meeting on Functional Data Analysis, January 10–11, 2003, University of Florida.

Invited speaker, AMS Fall Southeastern Section Meeting, Orlando, FL, November 9–10, 2002.

Invited speaker, SAMSI Research Workshop "Challenges in Stochastic Computation," Research Triangle, North Carolina, September 28 – October 1, 2002.

Invited speaker, WNAR/IMS Meeting, University of California, Los Angeles, June 2002.

Invited speaker, Symposium on Monte Carlo for the New Millenium, University of Florida, Gainesville, January 2001.

Contributed paper, Annual Meeting of the American Statistical Association, Indianapolis, August 2000.

Invited speaker, Symposium on Inference for Stochastic Processes, Athens, Georgia, May 10–12, 2000.

Contributed paper, Annual Meeting of the American Statistical Association, Baltimore, August 1999.

Contributed paper, Annual Meeting of the American Statistical Association, Dallas, August 1998.

Contributed paper, 13th International Workshop on Statistical Modeling, New Orleans, July 1998.

Invited speaker, Annual Meeting of the Institute of Mathematical Statistics, Park City, Utah, July 1997.

Invited speaker, special session on Spatial Stochastic Models, American Mathematical Society Meeting, College Park, Maryland, April 1997.

Invited speaker, AMS-IMS-SIAM Summer Research Conference "Stochastic Inference, Monte Carlo and Empirical Methods," Mt. Holyoke College, July 1996.

Contributed paper, Annual Meeting of the American Statistical Association, Orlando, August 1995.

Invited speaker, Joint Biometric Society (ENAR) and Institute of Mathematical Statistics Spring Meeting, Cleveland, Ohio, April 1994.

Contributed paper, Joint Annual Meetings of the American Statistical Association (ASA) and IMS, San Francisco, August 1993.

Invited discussant, Nato Advanced Studies Workshop on Survival Analysis and Related Topics, Ohio State University, Columbus, June 23–28, 1991.

Invited speaker, The Thirty-Seventh Conference on Design of Experiments in Army Research, Development and Testing. U.S. Army Engineering Waterways Experiment Station, Vicksburg, Mississippi, October 1991.

Two contributed papers, Joint Annual Meetings of the American Statistical Association, the Biometric Society (ENAR/WNAR) and IMS, Atlanta, Georgia, August 1991.

Invited speaker, Joint Annual Meetings of the American Statistical Association and the Biometric Society (ENAR/WNAR), Anaheim, California, August 1990.

Invited speaker, AMS/IMS/SIAM Joint Summer Research Conference on Inference from Stochastic Processes, Cornell University, Ithaca, August 1987.

Invited speaker, 200th Meeting of the Insitute of Mathematical Statistics, Blacksburg, Virginia, May 1987.

Invited speaker, 195th Meeting of the Institute of Mathematical Statistics, Atlanta, March 1986.

Invited participant at the NSF–CBMS Conference on Stochastic Processes in the Neurosciences (Principal Lecturer: Henry Tuckwell), North Carolina State University, Raleigh, June 1986. Contributed paper.

Invited participant at the Mathematical Sciences Lecture Series on Inference for Stochastic Processes of Semimartingale Type (Principal Lecturer: A. N. Shiryayev), Johns Hopkins University, July 1984. Contributed paper.

Contributed paper, 187th Meeting of the Institute of Mathematical Statistics, Orlando, March 1984.

Contributed paper, 45th Annual Meeting of the Institute of Mathematical Statistics, Toronto, August 1983.

OTHER PROFESSIONAL ACTIVITIES

Invited speaker, Department of Mathematics, De La Salle University, Manila, Philippines, Feb 16, 2017.

Invited speaker, School of Statistics, University of the Philippines Diliman, Quezon City, Philippines, Feb 15, 2017.

Invited speaker, Applied Probability and Risk seminar, Columbia University, October 20, 2016. Title of talk: Many Interacting Worlds, Quantum Mechanics and Stein's Method.

Invited seminar speaker, Department of Mathematics, Thammasat University, Bangkok, Thailand, June 30, 2016.

Member of Organizing Committee, Workshop on Empirical Likelihood Based Methods in Statistics, IMS, National University of Singapore, June 19–25, 2016.

Invited seminar speaker, Department of Biological Statistics, Cornell University, May 4, 2016.

Invited seminar speaker, Department of Statistics, University of Missouri, April 27, 2016.

Invited seminar speaker, Department of Statistics, Temple University, Philadelphia, April 1, 2016.

Invited seminar speaker, Institute of Mathematics, Federal University of Rio de Janeiro, Brazil, March 18,2016.

Invited seminar speaker, Department of Statistics, University of Sao Paulo, Brazil, March 15, 2016.

Invited seminar speaker (Talk: "Is there a needle in the haystack? Marginal screening and post-selection inference"), Centre for Quantitative Medicine, Duke-NUS Medical School, National University of Singapore, Dec 16, 2015.

Academic Program Reviewer for the Department of Statistics, Texas A&M University, site visit April 26–29, 2015.

Invited seminar speaker, Department of Statistics, George Washington University, Washington DC, Feb 13, 2015.

Invited seminar speaker, Department of Statistics and Applied Probability, National University of Singapore, Dec 12, 2014.

Invited seminar speaker, Statistical Institute, Academia Sinica, Taiwan, Dec 10, 2014.

Invited seminar speaker, Department of Mathematics, National Sun Yat-sen University, Kaohsiung, Taiwan, Dec 8, 2014.

Invited seminar speaker (Talk: "CLTs under special relativity"), Department of Statistics, University of Minnesota, Oct 23, 2014.

Invited visitor and seminar speaker, Department of Mathematics, University of Oslo, Norway, Sept 3–8, 2014.

Invited seminar speaker, Department of Mathematics, University of Maryland, College Park, Feb 27, 2014.

Invited seminar speaker, Department of Biostatistics, University of California, Berkeley, Jan 22, 2014.

Invited seminar speaker, Department of Biostatistics, Brown University, Jan 13, 2014.

Invited seminar speaker, Department of Mathematical Sciences, New Jersey Institute of Technology, Nov 21, 2013.

Invited seminar speaker, Department of Statistics, University of Buffalo, Sept 26, 2013.

Invited seminar speaker, Department of Mathematics, Thammasat University, Bangkok, Thailand, July 8, 2013.

Invited seminar speaker, Department of Statistics, Rutgers University, April 17, 2013.

Invited seminar speaker, Department of Statistics, Texas A&M University, Jan 18, 2013.

Invited seminar speaker, Department of Statistics and Operations Research, Victoria University, Wellington, New Zealand, Nov 23, 2012.

Invited seminar speaker, Department of Statistics, University of Auckland, New Zealand, Nov 19, 2012.

Invited seminar speaker, Department of Mathematics, University of Santiago de Compostela, Spain, July 3, 2012.

Invited seminar speaker, Department of Statistics, George Mason University, May 1, 2012.

Invited seminar speaker, Department of Biostatistics and Computational Biology, University of Rochester, April 19, 2012.

Invited seminar speaker, Institute of Statistics, Université Catholique de Louvain, Louvain-la-Neuve, Belgium, March 29, 2012.

Invited seminar speaker, Department of Statistics, North Carolina State University, Raleigh, March 16, 2012.

Invited seminar speaker, Department of Biostatistics, Yale University, October 25, 2011.

Invited participant and speaker, Finnish Prenatal Studies Meeting, University of Turku, Finland, October 3–6, 2011.

Invited seminar speaker, Department of Statistics, University of Connecticut, September 21, 2011.

Invited seminar speaker, Department of Statistics and Applied Probability, National University of Singapore, July 13, 2011.

Invited seminar speaker, Department of Statistics, Universidad Carlos III de Madrid, Spain, June 10, 2011.

Invited seminar speaker, Department of Biostatistics, University of Washington, Seattle, January 27, 2011.

Invited speaker, Finnish Prenatal Studies Meeting, University of Turku, Finland, September 13–17, 2010.

Invited seminar speaker, Department of Mathematical Sciences, University of Nevada Las Vegas, April 16, 2010.

Invited seminar speaker, Department of Biostatistics, University of North Carolina at Chapel Hill, March 17, 2010.

Invited seminar speaker, Biostatistics Core Facility, Sloan–Kettering Institute, New York, Feb 10, 2010.

Invited speaker, Department of Biostatistics, Harvard University, November 5, 2009. Talk: "Fractals with point impact in functional regression and an application to gene expression data."

Invited participant, Finnish Prenatal Study Workshop, University of Turku, Finland, September 14–16, 2009.

Invited participant in The 28th Leeds Annual Statistical Research Workshop — Statistical Tools for Challenges in Bioinformatics, Leeds, UK, July 7–9, 2009.

Invited visitor and seminar speaker, Department of Statistics, Shanghai University of Finance and Economics, Shanghai, China, July 2–5, 2009.

Invited visitor and seminar speaker, Institute of Applied Mathematics, Chinese Academy of Sciences, Beijing, China, June 26–28, 2009.

Invited visitor, Universidad Pablo de Olavide, Sevilla, Spain, May 19–26, 2009.

Invited seminar speaker, Department of Statistics, Yale University, April 6, 2009.

Invited visitor and seminar speaker, Universidad Pablo de Olavide, Sevilla, Spain, Feb 2–11, 2009.

Invited seminar speaker, Department of Statistical Sciences, Cornell University, 29 October, 2008.

Participant, Workshop on Future Directions in High-Dimensional Data Analysis, 23–27 June 2008, Isaac Newton Institute for Mathematical Sciences, Cambridge, UK.

Principal speaker, Growth Trajectories Workshop, Department of Epidemiology, Columbia University, 2 May 2008.

External reviewer for a proposed Masters Program in Biostatistics, Department of Mathematical Sciences, New Jersey Institute of Technology, December, 2007.

Invited seminar speaker, Department of Biostatistics, University of Pennsylvania, November 13, 2007.

Invited seminar speaker, Department of Statistics, Yale University, November 5, 2007.

Invited seminar speaker, Institute for Economics and Social Sciences, University of Bonn, Germany, September 2007.

External member, Ph.D. committee of Anouar El Ghouch, Institute of Statistics, Université Catholique de Louvain, Louvain-la-Neuve, Belgium, August 2007.

Invited speaker, Department of Biostatistics, University of Copenhagen, Denmark, May 2007.

Seminar speaker, Department of Biostatistics, Columbia University, April 2007.

G. W. Snedecor Lecture ("Analyzing trajectories: functional predictors of univariate responses"), Iowa State University, April 2007.

Invited colloquium speaker, Department of Mathematics and Statistics, Portland State University, Oregon, April 2007.

Invited colloquium speaker, Department of Mathematics and Statistics, University of North Carolina, Charlotte, April 2007.

Invited colloquium speaker, Department of Statistics and Computer Information Systems, Baruch College, City University of New York, October 25, 2006.

Invited visitor and seminar speaker, Department of Mathematics, University of Oslo, Norway, August 31, 2006.

Invited colloquium speaker, Department of Mathematics, University of Maine, May 1, 2006.

Invited colloquium speaker, Department of Mathematics and Statistics, Georgia State University, April 28, 2006.

Invited colloquium speaker, Department of Quantitative Health Sciences, Cleveland Clinic Foundation, April 7, 2006.

Invited colloquium speaker, Department of Statistics, University of Michigan, Ann Arbor, November 4, 2005.

Seminar talk ("Extending the Scope of Empirical Likelihood"), Department of Mathematics, University of Science and Technology, Hong Kong, December 14, 2005.

Seminar talk for the IGERT Joint Program in Applied Mathematics and Earth and Environmental Science, Columbia University, September 2005.

Invited visitor, Institute of Statistics, Université Catholique de Louvain, Louvain-la-Neuve, Belgium, August 2005.

Seminar talk on Bayesian Data Assimilation for Tracer Data, Program on Data Assimilation for Geophysical Systems, SAMSI, Research Triangle Park, North Carolina, February 2005.

Invited speaker, National Institutes of Health, Taiwan, March 2005.

Invited speaker, Rutgers University, Department of Statistics, February 2005.

Invited visitor, Fred Hutchinson Cancer Research Center, Seattle, December 2004.

Invited speaker, University of Central Florida, Department of Mathematics, January 2004.

Invited visitor, Fred Hutchinson Cancer Research Center, Seattle, December 2003.

Invited visitor, Department of Mathematics, University of Oslo, Norway, November 2003.

Invited speaker, University of North Carolina, Chapel Hill, Department of Mathematics, October 2003.

Invited speaker, Department of Biostatistics, Columbia University, October 2003.

Invited speaker, Department of Mathematics, Free University, Amsterdam, The Netherlands, June 2003.

Invited speaker, Joint Statistics and Biostatistics Colloquium, University of Wisconsin, Madison, April 2003.

Invited speaker, Department of Mathematics, University of Wisconsin, Milwaukee, April 2003.

Invited speaker, Department of Statistics and Applied Probability, University of California, Santa Barbara, February 2003.

Organized and chaired an IMS Invited Paper Session, "A Decade of Empirical Likelihood," Joint Statistical Meetings, New York City, August 2002.

Invited lecturer for a 2 day workshop, "Empirical Likelihood Methods in Survival Analysis," as part of 3 week visit to Institute of Statistics, Université Catholique de Louvain, Louvain-la-Neuve, Belgium, May 2002.

Invited speaker, Department of Biostatistics, Harvard University, December 2001.

Invited speaker, Institut Henri Poincaré, Paris, France, June 2001.

Visitor, Laboratoire de Statistique et Modélisation Stochastique, Université Joseph Fourier, Grenoble, France, June–July 2001.

Invited speaker, Department of Biostatistics, University of Copenhagen, September 2000.

Invited speaker, Department of Biostatistics, University of California, Berkeley, March 1999.

Invited speaker, Department of Biostatistics, UCLA, March 1999.

Invited speaker, Statistical Institute, Academia Sinica, Taiwan, December 1998.

Invited speaker, Department of Mathematics, National Central University, Taiwan, December, 1998.

Invited speaker, Department of Mathematics, University of Helsinki, Helsinki, Finland, June 1996.

Invited talk, Department of Statistics, Columbia University, April 1996.

Invited talk, Division of Biostatistics, Medical College of Wisconsin, Milwaukee. April 1996.

Invited talk, Department of Statistics, Rutgers University, March 1996.

Invited talk, Department of Mathematics, UNC-Charlotte, October 1994.

Invited talk, Department of Statistics, Columbia University, March 1994.

Invited talk, Department of Statistics, Rutgers University, March 1994.

Invited talk, Department of Statistics, Penn State, December 1993.

Invited talk, Department of Mathematics, UNC-Charlotte, December 1993.

Invited talk, Institute of Statistics and Operations Research, Victoria University, Wellington, New Zealand, August 1993.

Invited talk, Department of Statistics, University College Dublin, May 1992.

Invited talk, Department of Statistics, University College Cork, May 1992.

Invited talk, Department of Mathematics, Statistics and Epidemiology, Imperial Cancer Research Fund Laboratory, London, May 1992.

Invited talk, Department of Statistics, Birkbeck College, University of London, May 1992.

Invited talk, Mathematical Institute, University of Cologne, May 1992.

Invited talk, Department of Statistics, University of Padua, Italy, May 1992.

On sabbatical leave at Laboratoire de Statistique et Modélisation Stochastique, Université Joseph Fourier, Grenoble, France, February–May 1992. Seminar talks in February and April.

Invited visitor and participant, Program on Non- and Semi-parametric Models and Survival Analysis, December 1991–January 1992, Mathematical Sciences Research Institute, University of California, Berkeley.

Session Chairman, Statistics Days at FSU; A Meeting to Celebrate the 30th Anniversary of the Department of Statistics, FSU. Tallahassee, March 1990.

Invited speaker, Department of Statistics, University of Padua, Italy, December 1988.

Invited speaker, Statistical Laboratory, Dept. of Pure Mathematics and Mathematical Statistics, University of Cambridge, England, December 1988.

Session Chairman, Meeting of the Florida Chapter of the American Statistical Association, Tallahassee, February 1988.

Invited speaker, University of Kentucky, Lexington, Department of Statistics Colloquium Series, April 1987.

Invited speaker, University of North Carolina, Chapel Hill, Department of Statistics Colloquium Series, February 1987.

Invited speaker and visitor, Matematiska Institutionen, Åbo Akademi, Turku, Finland, October 1986.

External examiner, Ph.D. dissertation of Timo Koski, Matematiska Institutionen, Åbo Akademi, Turku, Finland, October 1986.

Invited speaker, University of Oulu, Oulu, Finland, Applied Mathematics and Statistics Department Colloquium Series, October 1986.

Invited speaker, University of Helsinki, Helsinki, Finland, Department of Mathematics and the Department of Statistics Colloquium Series, October 1986.

Invited speaker, University of North Carolina, Chapel Hill, Departments of Statistics and Biostatistics joint Colloquium Series, August 1985.

Invited Lecturer and Visitor, University of Padua and Instituto per Ricerche di Dinamica dei Sistemi e di Bioingegneria, Consiglio Nazionale delle Ricerche, Padua, Italy, May–June 1985.

Invited participant at the NSF–CBMS Conference on Stochastic Differential Equations in Infinite Dimensional Spaces and their Applications (Principal Lecturer: K. Itô), Louisiana State University, Baton Rouge, May 1983.

CONSULTING

Consultant to a law firm representing Mylan Pharmaceuticals, Inc., in connection with abiraterone acetate litigation, 2017. Provided expert opinion in affidavits and a deposition.

Consultant to a law firm representing Consolidated Edison, Inc., in connection with litigation over a workplace accident, 2017. Provided expert opinion in affidavits and as a witness in court.

Consultant to a law firm representing a New York City construction company in connection with litigation over a crane collapse, 2016.

Consultant to a law firm representing Mylan Pharmaceuticals, Inc., in connection with copaxone litigation, 2015–2016. Provided expert opinion in affidavits, depositions and as a witness in court.

Consultant to law firms representing a group of pharmaceutical companies (Actavis, Akorn, Apotex, DRL, Emcure, Fresenius, Hikma, Hospira, Pii, Sagent, Strides, Sun, USV) for zoledronic acid litigation, 2015.

Consultant to a law firm representing various healthcare providers in connection with Medicaid audit reviews carried out by the State of Connecticut Department of Social Services, 2015–2017.

Consultant to a law firm representing a group of pharmaceutical companies (Apotex, Hetero, Lupin, Mylan, Amneal, Glenmark) in milnacipran litigation. Provided expert opinion in affidavits and depositions, 2015.

Consultant to the Metropolitan Transportation Authority (MTA), New York, 2014, in connection with litigation over a train derailment. Provided expert opinion in affidavits and as a witness in court.

Consultant to Mylan Pharmaceuticals, 2012–2014, in connection with Hatch–Waxman litigation over patent rights to bivalirudin (Angiomax). Provided expert opinion in affidavits, depositions and as a witness in court.

Consultant to Amgen on the analysis of clinical trials data, 2008–2009.

Consultant to a Los Angeles law firm on statistical aspects of a case involving the relative effectiveness of two competing drugs, 2007–2008.

Consultant to a New York law firm on statistical aspects of cases involving infringement of drug patents, 2004–2006.

One-day seminar for Aon Consulting on the development of an additive risk model to be used in software for valuing stock options, April 2006.

Consultant to the New York State Attorney's Office on statistical aspects of an investigation of out-of-network health insurance reimbursement, 2004–2008.

Consultant to the Florida Department of Environmental Protection on statistical aspects of the Everglades phosphorus criterion rule development process, 2002–2003. Provided expert testimony in depositions and court hearings.

Consultant to the Statistical Center for HIV/AIDS Research and Prevention, Fred Hutchinson Cancer Research Center, Seattle, 2003–2007. Developed statistical methods for HIV vaccine efficacy trials.

Reviewer of the statistical methods used by the Bureau of Medicaid Program Integrity, Florida Agency for Health Care Administration, 1999–2004. Three studies of the sampling methods used to assess overpayment of Medicaid claims. Provided expert testimony in depositions and court hearings.

Consultant to a Chicago law firm, 1999. Provided a statistical analysis of a problem raised by a major credit card company.

Consultant to a Miami law firm, 1990. Provided expert opinion on the statistical evidence in litigation involving an exam for the certification of foreign medical doctors.

Consultant to the Florida Department of Transportation, 1991. Designed an economic time series model to help in policy decisions concerning future road construction.

Consultant to publishers of various textbooks in Statistics, 1980–present.

EXHIBIT B

Exhibit No./ Paper No. [1]	Description
MYL 1001	U.S. Patent No. 8,822,438, Auerbach and Belldegrun, "Methods and Compositions for Treating Cancer" ("the '438 patent")
MYL 1009	Ryan, C.J. et al., "Abiraterone in metastatic prostate cancer without previous chemotherapy," New Eng. J. Med., 368:138–148 (2013)
MYL 1034	de Bono, J.S. et al., "Abiraterone and increased survival in metastatic prostate cancer," New Engl. J. Med., 364:1995–2005 (2011)
MYL 1092	Cancer.org (ACS), "Hormone therapy for prostate cancer," https://www.cancer.org/conten/cancer/en/cancer/prostate-cancer/treating/hormone-therapy.html (accessed 4/10/2017)
MYL 1093	Cancer.gov (NIH NCI), "Metastatic cancer," https://www.cancer.gov/types/metastatic-cancer.html (accessed 4/14/2017)
MYL 1094	Canger.gov (NIH NCI), "Prostate-specific antigen (PSA) test," https://www.cancer.gov/types/prostate/psa-fact-sheet (accessed 4/11/2017)
MYL 1095	Cougar Biotechnology, Inc., Clinical Study Report: COU-AA-001 and COU-AA-001 EXT (Nov. 17, 2010)
MYL 1096	Reid, A.H.M. et al., "Significant and sustained antitumor activity in post-docetaxel, castration-resistant prostate cancer with the CYP17 inhibitor abiraterone acetate," J. Clin. Onc., 28(9):1489-1495 (2010)
JSN 2014	Attard et al., "Phase I Clinical Trial of a Selective Inhibitor of CYP17, Abiraterone Acetate, Confirms That Castration-Resistant Prostate Cancer Commonly Remains Hormone Driven," *Journal of Clinical Oncology*, 26(28):4563-4571 (2008)
JSN 2015	Attard et al., "Selective Inhibition of CYP17 With Abiraterone Acetate Is Highly Active in the Treatment of Castration-Resistant Prostate Cancer," *Journal of Clinical Oncology*, 27(23):3742-3748 (2009)

[1] All references are to papers and exhibits in the above-captioned IPR unless otherwise specified.

Exhibit No./ Paper No. [1]	Description
JSN 2016	Danila et al., "Phase II Multicenter Study of Abiraterone Acetate Plus Prednisone Therapy in Patients With Docetaxel-Treated Castration-Resistant Prostate Cancer," *Journal of Clinical Oncology*, 28(9):1496-1501 (2010)
JSN 2017	Ryan et al., "Phase II Study of Abiraterone in Chemotherapy-Naïve Flare Discordant with Serologic Response Metastatic Castration-Resistant Prostate Cancer Displaying Bone," *Clinical Cancer Research*, 17:4854-4861 (2011)
JSN 2038	Declaration of Matthew Rettig, M.D.
JSN 2071	Ryan et al., "Abiraterone acetate plus prednisone versus placebo plus prednisone in chemotherapy-naive men with metastatic castration-resistant prostate cancer (COU-AA-302): final overall survival analysis of a randomised, double-blind, placebo-controlled phase 3 study," *Lancet Oncology*, 16:152-160 (2015)
JSN 2101	J&J May 21, 2009 Press Release
Paper No. 1	Petition for *Inter Partes* Review
Paper No. 21	Decision
Paper No. 35	Patent Owner's Response
Paper No. 33	*Amerigen v. Janssen*, IPR2016-00286, Patent Owner's Response
JSN 2119	*Amerigen v. Janssen*, IPR2016-00286, Declaration of Matthew B. Rettig, M.D.