Exhibit 142

Comments on Camp Lejeune Defendants' Reports
David Madigan, PhD

1. Background

1. I am Provost and Senior Vice-President for Academic Affairs at Northeastern University. From 2007 to 2020 I was Professor of Statistics at Columbia University in New York City. I was also chair of the Columbia Department of Statistics from 2008 to 2013 and I served as Executive Vice-President of Arts of Sciences and Dean of the Faculty of Arts and Sciences from 2013 to 2018. I received my bachelor's degree in mathematics from Trinity College Dublin in 1984 and was awarded the College's gold medal. In 1990, I received a Ph.D. in Statistics, also from Trinity College. I have worked in the past for KPMG, SkillSoft, University of Washington, AT&T Labs, and Soliloquy Inc. From 2005 to 2007 I was Professor of Statistics and Dean of Physical and Mathematical Sciences at Rutgers University. Prior to serving as Dean, I was Director of the Rutgers University Institute of Biostatistics. I am an elected Fellow of both the Institute of Mathematical Statistics and the American Statistical Association, as well as the American Association for the Advancement of Science, and was the 36th most cited mathematician worldwide from 1995-2005. I was an Institute of Mathematical Statistics Medallion Lecturer in 2009. I served a term as the Editor of *Statistical Science* from 2008 to 2010, the highest impact journal in Statistics.

2. I have published more than 200 technical papers on Bayesian statistics, biostatistics, epidemiology, pharmacovigilance, statistical graphics, Monte Carlo methods, computer-assisted learning, information retrieval, and text mining. Within the last few years, I have consulted for Clarus Therapeutics, Jarvik Heart, Lilly, Merck, Novartis, and Pfizer on a variety of statistical and epidemiological issues. In the past, I advised Boehringer Ingelheim on issues related to pharmacovigilance. I have considerable statistical experience with clinical trials including the design and analysis of pain studies at the University of Washington and the Fred Hutchinson Cancer Research Center, and more generally as a statistical consultant to multiple internal and external clients, particularly while I was director of the Institute of Biostatistics at Rutgers University.

3. Much of my research concerns statistical and epidemiological methods for assessing the effects of exposures such as drugs, medical devices, and chemicals. I have published my work in *Drug Safety*, *Pharmacoepidemiology and Drug Safety*, *Therapeutic Advances in Drug Safety*, *Epidemiology*, the *American Journal of Epidemiology*, and other journals. I have also served as an investigator in the Mini-Sentinel project. Mini-Sentinel was a pilot project sponsored by the FDA to inform and facilitate development of a fully operational active surveillance system, the Sentinel System, for monitoring the safety of FDA-regulated medical products. In 2010-11, I led the Mini-Sentinel Working Group on case-based methods in active surveillance. In addition, from 2010 to 2013 I was a Principal Investigator for the Observational Medical Outcomes Partnership (OMOP), a public-private partnership between the FDA and the pharmaceutical industry. The partnership conducted a multi-year initiative to research methods that are feasible and useful to analyze existing healthcare databases to identify and evaluate safety and benefit issues of drugs already on the market. The OMOP work now continues in the Observational

Health Data Sciences and Informatics (OHDSI) collaborative where I co-direct the Northeastern-based OHDSI lab. I was a member of the FDA's Drug Safety and Risk Management Advisory Committee (DSaRM) from 2011 to 2014 and then served the FDA as a consultant through 2017. DSaRM advises the FDA Commissioner on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the FDA has regulatory responsibility. From 2010 to 2011 I was a member of a sub-committee of the FDA Science Board charged with reviewing the Center for Drug Evaluation and Research's pharmacovigilance program.

4. Further information concerning my background, training, and experience, including a complete list of my publications, is reflected in my curriculum vitae, a copy of which is attached as Appendix 1. A list of the deposition and trial testimony I have provided in the last four years is attached as Appendix 2.

5. For my services, I am being compensated at the rate of $800 per hour. My compensation is not contingent on the outcome of this matter.

2. Scope and Summary of Opinions

6. I have been asked to provide my opinion, to a reasonable degree of scientific certainty, regarding the purpose of and methodological soundness of using meta-analyses in an assessment of the health outcomes from exposure to chemicals.

7. A meta-analysis is a statistical approach to summarizing the results of multiple independent studies. Meta-analyses are a means to study an effect (or lack of effect) by combining multiple independent, and potentially underpowered, studies into an analysis that will or may provide sufficient statistical power to demonstrate an effect more clearly. Greater statistical power means that a meta-analysis is generally more likely to yield a statistically significant finding, when a true effect actually exists. Meta-analyses also facilitate investigations of the consistency of evidence across studies, and the exploration of differences across studies. A meta-analysis is a critically important tool in interpreting results of sets of studies and understanding the health outcomes from exposure to chemicals.

3. Background for Opinion

a. Observational Studies

8. Randomized controlled trials (RCTs) are the gold standard for estimating the clinical effects of medical interventions.[1] However, RCTs may prove more challenging or impractical for certain medical interventions or effects. In the context of understanding the effects of chemical exposure on human beings, randomized controlled trials are not

[1] Friedman, L. M., Furberg, C. D., & DeMets, D. L. (2010). *Fundamentals of Clinical Trials*. Springer.

possible as it would be unethical for such a study to be done on human subjects for non-therapeutic chemicals such as TCE, PCE, benzene and other chemicals. Consequently, medical researchers often turn to non-interventional studies where the researchers observe the treatment assignment rather than control it. In a randomized controlled trial, a toss of a coin decides treatment assignment, and statistically one can be confident that the resulting estimate of the treatment effect is not biased. In an observational study, myriad factors can influence treatment choice, making it challenging to estimate the effect of the treatment. Nonetheless, nearly 80,000 observational studies were published in the decade 1990-2000.[2] In the following decade, the number of studies grew to more than 260,000.

9. The principal concern for all observational studies is the potential for bias. An observational study may be subject to bias if the treated and control groups differ prior to treatment in ways that can influence the outcome under study.[3] Several strategies exist for reducing the effects of bias within observational database studies. These include design-level considerations and analysis approaches. Multiple study design approaches have been proposed for observational investigations, including cohort, case control, and self-controlled case series (SCCS), each with its own approach to address confounding.

10. Cohort studies allow many possible approaches to address confounding. One design strategy is to impose restrictions on the selected sample to increase validity, potentially at the expense of precision. These restrictions may be analogous to clinical trials and include ensuring that only incident drug users are studied; the restrictions also aim to ensure similar comparison groups, patients without contraindications, and comparable adherence, as demonstrated by Schneeweiss et al.[4], who showed how bias was reduced at each stage of restriction using statin and 1-year mortality as an example.

11. The case–control method[5] is another widely used method in observational studies of the effects of drugs and chemicals. Case–control studies consider the question "are persons with a specific condition exposed more frequently to a specific drug or chemical(s) than those without the condition?" Thus, the central idea is to compare "cases," i.e., individuals that experience the outcome of interest with (possibly) matched "controls," i.e., individuals that did not experience the outcome of interest. The comparison focuses on differential exposure to the drug or chemical(s) of interest in the two groups; greater exposure amongst the cases than amongst the controls suggests a possible positive association.

---

[2] Naik G. 2012. Analytical trend troubles scientists. Wall Street Journal, May 4

[3] Rosenbaum PR. 2002. *Observational Studies*. New York: Springer. 2nd ed.;

[4] Schneeweiss S, Patrick AR, Sturmer T, Brookhart MA, Avorn J, et al. 2007. Increasing levels of restriction in pharmacoepidemiologic database studies of elderly and comparison with randomized trial results. *Med. Care* 45:S131—42.

[5] Woodward M. *Epidemiology Study Design and Data Analysis*. Chapman & Hall/CRC; 1999; Agresti A. *Categorical Data Analysis*. Hoboken, New Jersey: Wiley-Interscience; 2002; Breslow NE, Day NE. *Statistical Methods in Cancer Research: Volume I — The Analysis of Case–Control Studies*. International Agency for Research on Cancer; 1993.

12. For certain prescription drugs, a previous study of mine suggests that in some contexts case-control studies in administrative claims databases and electronic health record (HER) systems can be positively biased.[6] However, even in that study, upwards of 20% of the case control analyses were *negatively* biased. In a recent JAMA commentary, an FDA analyst suggested that case-control studies "can provide valuable empirical evidence to complement RCTs" and that "case-control studies may be able to address questions for which an RCT is either not feasible or not ethical."[7]

b. Relevant Statistical Principles

13. Observational studies commonly report "***point estimates***" of the effects of interventions such as drugs or chemical exposures in the form of relative risks or odds ratios. These "rate ratios" typically represent the value for the effect that is best supported by the data under study according to the methods and adjustments employed. For example, a rate-ratio estimate of 1.51, reports a 51% increase of the effect being studied. This value is an estimate.

14. Often researchers report a point estimate along with a related ***"95% confidence interval."*** The 95% confidence interval represents the range of hypothesized effects that are not rejected by the data, given a stated significance level. More informally, a 95% confidence interval represents a range of plausible values for the true risk ratio. When the confidence interval includes 1, it is a mistake for researchers to conclude definitively that there is *no* true effect. In fact, the data in such circumstances may be far more compatible with the existence of an effect than with an absence of an effect. For example,[8] a point estimate of 1.2 with a 95% confidence interval that ranges from 0.87 to 1.66 indeed includes 1 as a plausible true value for the rate ratio. However, a 70% confidence interval in this example goes from 1.01 to 1.42. In other words, even though the rate ratio is not statistically significant, with 70% confidence the true risk ratio exceeds 1 (more specifically, with 70% confidence the true rate ratio is between 1.01 and 1.42).

15. The ***"p-value"*** provides further insight into the true risk ratio. For instance, in the example above, a risk ratio point estimate of 1.2, with a p-value of 0.27 indicates a 27% probability of observing such a deviation from 1 by chance alone if in fact the true risk ratio is indeed 1. In many scientific contexts, an effect with a p-value at or below 0.05 is considered to be strong evidence that the true risk ratio is different from 1. However, this threshold of p=0.05 is one of policy and the current scientific methodology of analyzing studies for causation reject adherence to traditional statistical significance of

[6] Madigan, D., Schuemie, M. J., & Ryan, P. B. (2013). Empirical performance of the case–control method: lessons for developing a risk identification and analysis system. *Drug Safety*, *36*(1), 73-82.
[7] Irony, T. Z. (2018). Case-Control Studies: Using "Real-world" Evidence to Assess Association. *JAMA*, *320*(10), 1027-1028.
[8] 72/600 versus 60/600

95%.[9] As Gardner and Altman point out, "clinically important effects may be statistically non-significant."[10]

16. **"*Type II error,*"** also called a ***"false negative,"*** occurs when an analysis fails to detect an effect that is actually present, leading to the incorrect conclusion that there is no effect when an effect is really there. Statisticians may also describe Type II error as an erroneous failure to reject the "null hypothesis." An experiment's Type II error rate, denoted by the Greek letter β (beta), is a function of a variety of factors including the magnitude of the effect size being measured, the size of the data sample available, and the criterion for statistical significance used in the experiment.

17. **"*Power*"** refers to the ability of a study (observational or randomized) to detect a difference in effect between intervention and control (e.g., kidney cancer following TCE exposure) when one is truly present. Studies with small numbers of subjects and/or a small number of events often have very little power. Thus, in general, absence of a traditional statistically significant result (i.e., a small p-value) in any given study should be interpreted cautiously and not automatically deemed a negative finding, or in the case of a chemical exposure a "protective effect". Such an absence could be due to a lack of true effect, but it could also be the case that there is a true effect that the study did not or could not detect (i.e. a "Type II error"). Power is equal to 1 - β. Thus, if the Type II error rate in a study is 10%, the study is said to have 90% power. As the size of the effect you are trying to measure decreases, so does the trial's power and, thus, your confidence that the failure to observe an effect actually means it is not there (as opposed to being a case of Type II error). The same is true of the sample size (the number of data points collected): as it decreases, so does power.

18. Power can be used in advance of a study to determine how many subjects one will have to enroll to detect the results of interest. If no traditionally statistically significant result was observed in the study, power can also be used after the study has concluded to evaluate the possibility that the study simply failed to detect the result of interest (e.g., because the study was too small) for different candidate levels of the true effect size. In other words, power can be used to determine the Type II error rate in a study showing no difference between comparators, thus indicating how much weight one ought to place on the failure to observe the clinically meaningful effect in question. Many standard biostatistics textbooks provide power calculations pursuant to a non-significant result.[11]

---

[9] See, for example, Vinceti, S. R., & Filippini, T. (2021). Towards the dismissal of null hypothesis/statistical significance testing in public health, public law and toxicology. *Public Health and Toxicology*, 1(2), 1-6.

[10] Gardner, M.J. & Altman, D.G., *Confidence intervals rather than P values: estimation rather than hypothesis testing*, 292 *British Medical Journal* 746-750 (1986).

[11] Rosner, B., Fundamentals of Biostatistics, at 381-82, 625 (7th ed.); DeVeaux, et al., Stats, Data, and Models, at 513 (3d ed. 2011); Winer, B.J., et al., Statistical Principles in Experimental Design, at 20 (3d ed.); Chalmers T.C., et al., *A method for assessing the quality of a randomized control trial*, 2 Controlled Clin Trials. 31-49 (1981).

c. Meta-Analyses

19. Meta-analysis is the use of statistical methods to summarize the results of multiple independent studies. Per the Cochrane Handbook,[12] by combining information from *all* relevant studies, meta-analyses can provide more precise estimates of the effects of health effects from chemical exposure than those derived from the individual studies included within a review. They also facilitate investigations of the consistency of evidence across studies, and the exploration of differences across studies.[13] By combining multiple independent, and potentially underpowered, studies into an analysis that will or may provide sufficient statistical power to demonstrate an effect more clearly. Greater statistical power means that a meta-analysis is generally more likely to yield a statistically significant finding, when a true effect actually exists. In summary, meta-analyses play a crucial role in synthesizing evidence, enhancing statistical power, and resolving conflicts among studies, making them a cornerstone of evidence-based medicine and scientific research.[14]

20. Meta-analyses are a critically important tool in interpreting results of individual studies and understanding the health outcomes from exposure to chemicals.[15]

21. Researchers increasingly turn to meta-analyses of observational studies in an attempt to add power over individual studies.[16] Doing so was considered somewhat controversial in the distant past,[17] but meta-analyses have emerged as a key tool in the analyst's armamentarium. In many contexts, a properly conducted meta-analysis of observational studies can provide the highest level of evidence that is practically feasible.

---

[12] The "Cochrane Collaboration" (https://www.cochrane.org) is a global, independent network of researchers, professionals, patients, carers, and individuals interested in health. It was established in 1993 with the primary goal of helping people make well-informed decisions about healthcare by preparing, maintaining, and promoting systematic reviews of healthcare interventions. It plays a crucial role in promoting evidence-based medicine and public health practices worldwide (see, for example, Jadad, A. R., Cook, D. J., Jones, A., Klassen, T. P., Tugwell, P., Moher, M., & Moher, D. (1998). Methodology and reports of systematic reviews and meta-analyses: a comparison of Cochrane reviews with articles published in paper-based journals. *JAMA*, 280(3), 278-280).

[13] Cochrane Handbook, v5.1, emphasis added.

[14] Borenstein, M., Hedges, L. V., Higgins, J. P., & Rothstein, H. R. (2021). *Introduction to meta-analysis*. Wiley, p.xxix-xxxi; Schwarzer, G., Carpenter, J.R., and Rucker, G. (2015), *Meta-analysis with R*. Springer, p.v; Cochrane Handbook, v5.

[15] See, for example, Sheehan, M. C., & Lam, J. (2015). Use of systematic review and meta-analysis in environmental health epidemiology: a systematic review and comparison with guidelines. *Current Environmental Health Reports*, 2, 272-283.

[16] Stroup, D. F., Berlin, J. A., Morton, S. C., Olkin, I., Williamson, G. D., Rennie, D., ... & Thacker, S. B. (2000). Meta-analysis of observational studies in epidemiology. *JAMA: the Journal of the American Medical Association*, *283*(15), 2008-2012.

[17] Egger, M., Schneider, M., & Davey Smith, G. (1998). Spurious precision? Meta-analysis of observational studies. *Bmj*, *316*(7125), 140-144.

22. Statistical methods for meta-analysis fall into two broad categories, so called "random effects" and "fixed effects." Standard diagnostics accompany both.[18] Random effects analyses assume a high level of inter-study homogeneity than fixed effects.

23. The standard meta-analysis toolkit includes tools for heterogeneity assessment (the I^2 statistic or Cochran's Q test are typically used to quantify the extent of variation across studies) and assessment of potential publication bias (standard practice considers "funnel plots," along with statistical tests like Begg's and Egger's tests.

5. Comments on the Defendants' Reports Relating to Meta-Analysis

24. Dr. Shields raises a series of general concerns about meta-analyses that are entirely non-specific and in fact could be raised about essentially *any* statistical analysis. While it *could* be the case that a particular analysis is flawed, centuries of statistical research and practice coupled with a rigorous peer-review process have led scientists and policy makers to rely extensively on statistical analyses in general, and meta-analyses in particular.[19] Here are some examples of Dr. Shield's non-specific criticisms of well-established scientific methodology, and my comments in rebuttal:

Shields: "[meta-analyses] are thought to increase statistical power and precision, although this does not necessarily make the results reliable."
Madigan: Meta-analyses *always* increase statistical power over the individual component studies. They often increase precision as well. Indeed, while meta-analyses do not *necessarily* make the results more reliable, top-flight research journals and members of the scientific community publish thousands of meta-analyses each year, and these same analyses are the basis for regulatory and evidence-based decision making.[20]

Shields: "It can be argued that using studies from different populations makes the results more generalizable, but this cannot be assumed"
Madigan: While it may not be "assumed," it is recognized that in general using studies from different populations *does* make the results more generalizable. This is a recognized benefit of meta-analyses that leads to improved understanding of health effects from chemical exposure.

Shields: "the diversity of study populations and methods might increase cautious interpretation"
Madigan: This is a meaningless non-sequitur. Interpretation of study results should always be cautious.

Shields: "In some cases, these types of studies are mixing 'apples and oranges.' "

---

[18] Schwarzer, G., Carpenter, J.R., and Rucker, G. (2015). *Meta-analysis with R*. Springer; Borenstein, M., Hedges, L.V., Higgins, J.P.T., and Rothstein, H.R. (2021). *Introduction to Meta-Analysis (2nd edition)*, Wiley.
[19] Murad, M. H., Montori, V. M., Ioannidis, J. P., Jaeschke, R., Devereaux, P. J., Prasad, K., ... & Guyatt, G. (2014). How to read a systematic review and meta-analysis and apply the results to patient care: users' guides to the medical literature. *JAMA*, 312(2), 171-179.
[20] Per Google Scholar, 59,700 articles were published in 2024 alone with "meta-analysis" in the title.

Madigan: "[A]pples and oranges" is vague and undefined. Meta-analyses by definition combine different studies – this is not intrinsically problematic and is in fact a known strength of meta-analyses. *Examining* heterogeneity of studies in a meta-analysis context is of course standard practice. For example, meta-analysts often compute an "I-squared" (I^2) statistic as part of their work. The I^2 statistic quantifies the degree of heterogeneity among study results. It represents the percentage of variation across studies that is due to heterogeneity rather than sampling error or chance. I^2 ranges from 0% to 100%. Rubrics for interpreting I^2 exist and provide ranges that correspond to low, moderate and high heterogeneity.[21] Again, meta-analyses are recognized and widely used tools for scientific study.

Shields: "The inclusion and exclusion criteria are critical to evaluate and can be subject to great subjectiveness"
Madigan: Obviously careful consideration of inclusion and exclusion criteria is important, but this is often straightforward and uncontroversial. For example, the recent Seyyedsalehi meta-analysis of benzene and kidney and bladder cancers[22] states the following: "First, we included all studies that were reported in the most recent IARC Monograph on benzene exposure published in 2018 (IARC, 2018). Next, we conducted a search in the MEDLINE (PubMed), SCOPUS, and EMBASE (Ovid) databases for studies reported after that publication. Two authors (M.S.S. and M.B.) performed the search independently. The final search was updated in May 2024 for English-, French-, Italian-, German-, and Spanish-language cohort and case-control peer-reviewed publications published on the association of occupational exposure to benzene and risk (incidence and mortality) of any type of solid cancer." Dr. Shields discusses this meta-analysis but offers no criticism whatsoever of these criteria other than the following: "the Seyyedsalehi paper … [fails] to consider the high-quality benzene cohort studies that demonstrate an increased risk of AML and so omit critical data." This of course misses the point that that Seyyedsalehi does not focus on AML. Indeed, Dr. Shields acknowledges this: "For example, with benzene and kidney cancer, the major cohorts by NCI and Pliofilm published their solid tumor results without mentioning kidney." He then adds an entirely speculative and unfounded comment that the authors likely recorded kidney cancer but failed to report it: "However, it is highly likely they assessed this based on their methodology, but did not include it in tables." So, he is criticizing the authors for failing to include studies that did not report kidney cancer effects on the basis that he has a hunch that they had it and didn't report it. That is unfounded and pure speculation.

Shields: "[Meta-analyses] are also subject to publication bias"
Madigan: Dr. Shields fails to identify publication bias as an actual concern in *any* of the meta-analyses he actually discussed.

Shields: "Different meta-analyses for the same research question might have different results because, for example, the inclusion and exclusion criteria differ which leads to inclusion of different studies, different models, and combining disparate types of studies."
Shields: "It is not uncommon that different computer models provide different results, weakening the usefulness of the meta-analysis process."

---

[21] See, for example, Higgins, J. P., Thompson, S. G., Deeks, J. J., & Altman, D. G. (2003). Measuring inconsistency in meta-analyses. *BMJ*, 327(7414), 557-560.
[22] Seyyedsalehi, M. S., Bonetti, M., Shah, D., DeStefano, V., & Boffetta, P. (2024). Occupational benzene exposure and risk of kidney and bladder cancers: a systematic review and meta-analysis. European Journal of Cancer Prevention, 10-1097.

Madigan: "[M]ight have," "not uncommon." Once more, nothing specific just a vague general concern with no specific examples relevant to the current context.

Shields: "Different models can be applied, with strengths and weaknesses, but the highest level of evidence is when multiple methods corroborate each other."
Madigan: The relevance to the present context is unclear.

Shields: "The process does not reduce bias and confounding of individual studies, and all of the studies may be subject to the same bias and/or confounding."
Madigan: Certainly, meta-analyses do not alter the results of the component studies, but Dr. Shields cites *no* examples where "all of the studies" are "subject to the same bias and/or confounding."

Shields: States without citation: "it is problematic to combine case-control and cohort studies."
Madigan: Many published, peer-reviewed meta-analyses include both cohort studies and case-control studies. Here are healthcare examples:

> Du H, Zhang T, Lu X, Chen M, Li X, Li Z (2022) Glycemic index, glycemic load, and lung cancer risk: A meta-analysis of cohort and case-control studies. *PLoS ONE* 17(9): e0273943.
>
> Aune, D., Sen, A., & Vatten, L. J. (2017). Hypertension and the risk of endometrial cancer: a systematic review and meta-analysis of case-control and cohort studies. *Scientific Reports*, 7(1), 44808.
>
> Huxley, R. R., Filion, K. B., Konety, S., & Alonso, A. (2011). Meta-analysis of cohort and case-control studies of type 2 diabetes mellitus and risk of atrial fibrillation. *The American Journal of Cardiology*, 108(1), 56-62.

Shields: States without citation: "Including many small and/or low-quality studies does not necessarily provide a more reliable risk estimate, and the results may not be any better than the lower quality studies it represents."
Madigan: Performing meta-analyses to address the limited power of smaller studies is one of the primary motivations for doing meta-analyses in the first place. For example, underpowered studies make up the entirety of the evidence in most Cochrane reviews.[23] Concerning low quality studies, this is a general and vague comment and Dr. Shields does not point at any specific problematic meta-analysis.

Shields: "But, in the real-world application, for example the clinical setting, meta-analyses can be done but decision-making is based on context, for example relying more heavily on the highest quality study(ies) such as randomized studies or large cohort studies with biomarkers."
Madigan: Dr. Shields provides no citations for this proposition. Indeed, randomized studies can provide higher quality evidence but, as mentioned above, this is not relevant to the present context.

Shields: "The most useful information is the overview and how the study results vary (e.g., as in the Forest Plot)."

[23] Turner, R. M., Bird, S. M., & Higgins, J. P. (2013). The impact of study size on meta-analyses: examination of underpowered studies in Cochrane reviews. *PloS One*, 8(3), e59202.

Madigan: I disagree. The most useful information is the actual summary estimate of the effect and a corresponding confidence interval.

Shields: "Forest plots may reveal a consistency of no effect, even though the summary estimate might be statistically increased."
Madigan: This is tantamount to saying that even if a meta-analysis shows a "statistical increase" (presumably Dr. Shields means statistically significant although I can't be certain), he would reject it if his subjective, ill-defined ("a consistency of no effect") review of the forest plot revealed something he didn't like. This is hardly good scientific practice.

Shields: He refers to many meta-analyses as "null." For example, he states: "Odutola and coworkers (2021) conducted a meta-analysis for painters and follicular lymphoma (FL) with null results for an overall summary estimate or by exposure-response."
Madigan: Odutola et al.'s FL estimate for painters is actually 1.34 (i.e., 34% increased risk) with a 95% confidence interval of (0.95 , 1.89). Odutola et al. do not characterize this as "null:" "Associations between FL and other specific occupational groups were null *except for* an elevated risk for medical doctors and spray painters, and decreased risk for bakers and higher education teachers" (emphasis added). While the Odutola et al. estimate for spray painters is not statistically significant, the authors characterize it as an "elevated risk."

It is a grave error to equate lack of statistical significance with an absence of evidence:

- Statistical significance does not indicate importance: A statistically significant result doesn't necessarily imply a scientifically or practically important effect, and vice versa.[24]

- Arbitrary cutoffs: The common p-value threshold of 0.05 for statistical significance is arbitrary. Results above and below this cutoff may well provide useful information about causation.[25]

- Sample size matters: In small studies, even large effects may not reach statistical significance due to lack of power. Conversely, in very large studies, even trivial effects can be statistically significant.

- Misinterpretation of results: Non-significant results are often misinterpreted as evidence of no effect, when in reality they may in fact provide evidence of an effect.[26]

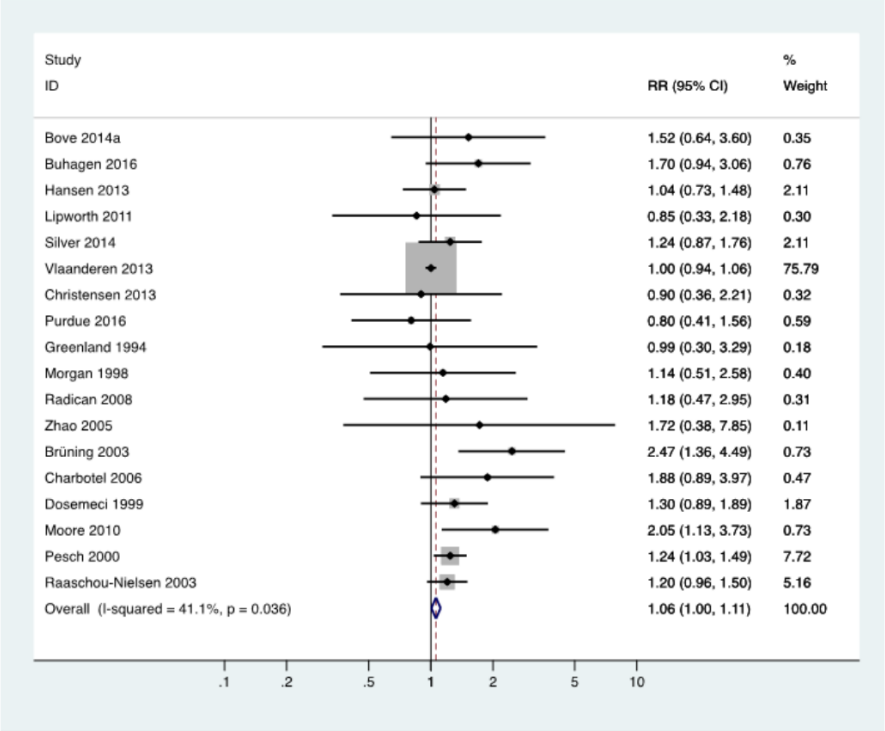
- Confidence intervals are crucial: Looking at confidence intervals provides more information about the range of plausible effect sizes than p-values alone.[27]

[24] See, for example, Ranganathan, P., Pramesh, C. S., & Buyse, M. (2015). Common pitfalls in statistical analysis: Clinical versus statistical significance. *Perspectives in Clinical Research*, 6(3), 169-170.
[25] See, for example, Aguinis, H., Vassar, M., & Wayant, C. (2021). On reporting and interpreting statistical significance and p values in medical research. *BMJ Evidence-Based Medicine*, 26(2), 39-42.
[26] See, for example, https://cccrg.cochrane.org/sites/cccrg.cochrane.org/files/uploads/Common%20mistakes.pdf
[27] See, for example, Stang, A., & Schmidt, B. (2022). Reporting of statistical inference in abstracts of major cancer journals, 1990 to 2020. *JAMA Network Open*, 5(6), e2218337-e2218337.

Shields: Concerning an EPA meta-analysis for kidney cancer, Dr. Shields states "Thus, there was low risks with either model, one of which was only borderline significant. Their Forest Plot was very unconvincing for consistency with only 2 studies being statistically significant. They did a sensitivity analysis by removing Vlaanderen (2013) where the results now become positive, but that is not the informative analysis. While they conducted an analysis for high exposure studies in their NHL analysis, this was not done for kidney cancer."

Madigan: The risks that Dr. Shields classifies as "low" were a relative risk point estimate of 1.06 for a fixed effects model and 1.22 for a random effects model. Both were statistically significant at the 5% level. I don't know what scientific basis Dr. Shields is using to call increases of 6% and 22% in the risk of an outcome associated with significant morbidity and mortality[28] "low." Dr. Shields touts the importance of statistical significance in other parts of his report but here seems dismissive of a finding that *is* statistically significant. He describes the forest plot as "unconvincing." He reproduces the forest plot for the fixed effects meta-analysis (see below) – I fail to see why this is "unconvincing."

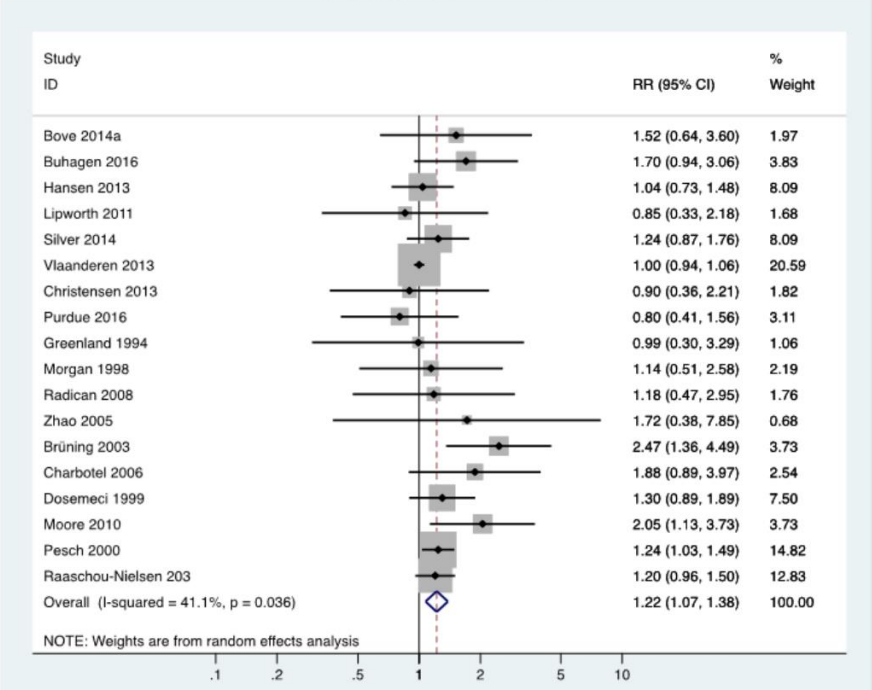
Figure_Apx K-5. Fixed-effects model, overall association of kidney cancer and exposure to TCE.



[28] See, for example, Pajunen, H., Veitonmäki, T., Huhtala, H., Nikkola, J., Pöyhönen, A., & Murtola, T. (2024). Prognostic factors of renal cell cancer in elderly patients: a population-based cohort study. *Scientific Reports*, 14(1), 6295.

Shields: Notably, he declines to reproduce the corresponding plot for the random effects meta-analysis.
Madigan: I reproduce the corresponding plot for the random effects meta-analysis below. This is certainly not "borderline" statistical significance, and I fail to see how any scientist could describe it as "unconvincing."

Figure_Apx K-6. Random-effects model, overall association of kidney cancer and exposure to TCE.



Dr. Shields appears to equate "unconvincing" with having only 2 component studies being statistically significant. I know of no authoritative source for the proposition that 2 component studies need to be statistically significant to pass *any* scientific threshold. Similarly, later in his report, Dr. Shields dismisses a "positive" meta-analysis by Yan et al. because "no single paper in the analysis was statistically significantly positive." Again, I know of no authoritative source for the proposition that any component study in a meta-analysis needs to be statistically significant to pass *any* scientific threshold.

Shields: Notes the EPA performed a sensitivity analysis excluding the Vlaanderen 2013 study remarking that the results then "become positive."
Madigan: The results were already "positive" at least in the sense of showing statistically significant estimates exceeding 1. Dr. Shields dismisses the analysis excluding Vlaanderen as "not the informative analysis." That analysis yielded a fixed effect estimate of 1.26 with a corresponding 95% confidence interval of (1.14 , 1.40), up from 1.06 and (1.00 , 1.11). I know of no scientific basis to conclude this is not informative. The fixed and random effects approaches now essentially converge but Dr. Shields does not comment on this.

25. In each of her reports Dr. Goodman raises similar non-specific concerns (emphases added).

Goodman: "One issue with meta-analyses is that they *may* result in "over-conclusiveness," or the appearance that results are more precise and conclusive than they actually are (Lash et al., 2021). Also, because meta-analysis methods cannot correct the biases in the underlying study-specific results, these biases carry over to the meta-analysis results. When pooling studies with similar biases, individual study CIs and p-values "tighten" to yield even stronger pooled values, resulting in this over-conclusiveness."

Goodman: "In addition, all systematic reviews and meta-analyses are subject to *potential* publication bias."

Goodman: "Underrepresentation of null findings *can* bias the results of a systematic review or meta-analysis away from the null."

Madigan: These are hypothetical concerns that may or may not have *any* relevance to a specific meta-analysis. Dr. Goodman. For the most part, Dr. Goodman fails to raise any of these concerns in the context of any specific meta-analysis discussed. In some instances, she repeats some of these generic concerns without explaining at any level of detail how they apply in the specific meta-analyses she cites:

Nonspecific concerns about study quality: "Two meta-analyses did not stratify by study quality," "ATSDR (2017a) did not consider impacts of study quality on the interpretation of meta-analysis results," "The impact of study quality on the interpretation of individual study results and meta-analysis results was not fully considered by US EPA (2020b).,"and "US EPA (2011) did not fully consider these and other study quality limitations in its interpretation of meta-analysis results."

Nonspecific concerns about exposure misclassification and confounding: "but this meta-analysis could not overcome the critical limitations of non-specific and indirect exposure characterization and uncontrolled and residual confounding, which is present in most of these studies," "In addition, because all the studies used in these analyses relied on indirect exposure assessments in primary studies, the meta- and pooled analyses cannot overcome the critical limitation of the potential for exposure misclassification."

Nonspecific limitations of meta-analysis in general: "All of the pooled and meta-analyses incorporated some of the cohort and case-control studies reviewed here and were limited by the underlying limitations of the analyzed studies," "All these meta-analyses are limited by the underlying limitations in the individual studies they included. Averaging results across studies cannot overcome the critical limitations of non-specific and indirect exposure characterization and uncontrolled and residual confounding, which is present in most of these studies," "The meta- and pooled analyses cannot overcome limitations in the original research studies, particularly exposure misclassification, and did not include several studies published after they were conducted."

26. Concerning the various non-specific concerns that Drs. Shields and Goodman raise, the peer review process is meant and is presumed to take such general concerns into account when iterating with authors and deciding to publish or not publish a given paper.

Clinical, regulatory and legislative action relies on this process. In my view, neither Dr. Shields nor Dr. Goodman identified that any specific criticisms of the meta-analyses relied upon by Plaintiffs' experts that would render such analyses non-informative.

David Madigan, PhD
March 16th, 2025

Exhibit 1

David Madigan

davidbennettmadigan@gmail.com

Tel: (862) 812-3690

Curriculum Vitae

1 January 2025

Education

Trinity College Dublin, Ph.D., Statistics, 1990. Dissertation "An investigation of weights of evidence in the context of probabilistic expert systems." K. R. Mosurski, Advisor.

Trinity College Dublin, B.A. (Mod.), Mathematics, 1984, First Class Honours.

Employment History

2020 - : Northeastern University

- 2020 - : Professor of Statistics
- 2020 - 2025 : Provost & Senior Vice-President for Academic Affairs

2007 - 2020 : Columbia University

- 2007 - 2020 : Professor of Statistics
- 2013 - 2018 : Executive Vice-President for Arts and Sciences
- 2013 - 2018 : Dean of the Faculty of Arts and Sciences
- 2007 - 2013 : Chair, Department of Statistics

2001 - 2007 : Rutgers University

- 2001 - 2007 : Professor of Statistics and Biostatistics
- 2005 - 2007 : Dean, Physical and Mathematical Sciences
- 2003 - 2004 : Director, Institute of Biostatistics

2000 - 2001 : Vice President, Data Mining, Soliloquy, Inc.

1999 - 2000 : Principal Technical Staff Member, AT&T Labs-Research

1990 - 1999 : University of Washington/ Fred Hutchinson Cancer Research Center

- 1995 - 1999 : Associate Professor of Statistics, UW
- 1992 - 1999 : Assistant/Associate Member, FHCRC
- 1990 - 1995 : Assistant Professor of Statistics, UW

1989 - 1990 : Information Technology Consultant, KPMG, Ireland

1986 - 1989 : Technology Manager, Peregrine Expert Systems Ltd., Ireland

1985 - 1986 : Expert System Consultant, SkillSoft, Ireland

1984 - 1985 : Actuarial Associate, Hibernian Life Assurance, Ireland

Honors

2014: Elected Member of the International Statistical Institute

2012: Elected Fellow of the American Association for the Advancement of Science.

2009: Institute of Mathematical Statistics Medallion Lecturer.

2006: Elected Fellow of the Institute of Mathematical Statistics.

2005: 36th Most Cited Mathematician in the World, 1995-2005, ISI Thomson.

1999: Elected Fellow of the American Statistical Association.

1995: University of Washington Distinguished Teaching Award.

1984: Gold medal awarded by the board of Trinity College Dublin.

1980: Trinity College Dublin, Entrance Scholarship in Mathematics.

Refereed Publications

1. Mulgrave, J.J., Madigan, D., and Hripcsak, G. (2024). Bayesian Posterior Interval Calibration to Improve the Interpretability of Observational Studies. *Statistical Analysis and Data Mining*, https://doi.org/10.1002/sam.11715
2. Selzman, C.H., Feller, E.D., Walker, J.C., Sheridan, B.C., Silvestry, S.C., Daly, R.C., Anyanwu, A.C., Madigan, D., Liu, P-Y., Frazier, O.H., and Griffith, B.P. (2023). The Jarvik 2000 Left Ventricular Assist Device: Results of the United States Bridge to Transplant Trial. *ASAIO Journal*, *69*(2), 174-182.
3. Schuemie, M.J., Chen, Y., Madigan, D., and Suchard M. (2021). Combining Cox Regressions Across a Heterogeneous Distributed Research Network Facing Small and Zero Counts. *Statistical Methods in Medical Research*, https://doi.org/10.1177/09622802211060518.
4. Zagar, A., Kadziola, Z., Lipkovich, I., Madigan, D., and Faries, D. (2021). Evaluating Bias Control Strategies in Observational Studies Using Frequentist Model Averaging. *Journal of Biopharmaceutical Statistics*, DOI: 10.1080/10543406.2021.1998095.
5. Chen, R., Suchard, M.A., Krumholz, H.M., Schuemie, M.J., Shea, S., Duke, J., Pratt, N., Reich, C.G., Madigan, D., You, S.C., Ryan, P.B., and Hripcsak, G., (2021). Comparative first-line effectiveness and safety of angiotensin converting enzyme inhibitors and angiotensin receptor blockers: a multinational cohort study. *Hypertension*, https://doi.org/10.1161/HYPERTENSIONAHA.120.16667.
6. Hripcsak, G., Schuemie, M.J., Madigan, D., Ryan, P.B., and Suchard, M. (2021). Drawing reproducible conclusions from observational clinical data with OHDSI. *Yearbook of Medical Informatics*, DOI: 10.1055/s-0041-1726481.
7. Park, S., You, S.C., Krumholz, H.M., Suchard, M.A., Schuemie, M., Hripcsak, G., Chen, R., Shea, S., Duke, J., Pratt, N., Reich, C., Madigan, D., Ryan, P., and Park, R.W. (2021). Comprehensive comparative effectiveness and safety of first-line beta-blocker monotherapy in hypertensive patients: a large-scale multi-center observational study. *Hypertension*, to appear.

8. Dwivedi, R., Tan, Y. S., Park, B., Wei, M., Horgan, K., Madigan, D., & Yu, B. (2020). Stable discovery of interpretable subgroups via calibration in causal studies. *International Statistical Review*, 88, S1, S135-S178 doi:10.1111/insr.12427.

9. You, S.C., Rho, Y., Bikdeli, B., Kim, J., Siapos, A., Weaver, J., Londhe, A., Cho, J.,Park, J., Schuemie, M., Suchard, M.A., Madigan, D., Hripcsak, G., Gupta, A., Reich, C. G., Ryan, P.B., Park, R.W., and Krumholz, H.M. (2020). Association of ticagrelor versus clopidogrel with net adverse clinical events in patients with acute coronary syndrome undergoing percutaneous coronary intervention. *JAMA*. 2020;324(16):1640-1650. doi:10.1001/jama.2020.16167.

10. Kim, Y., Tian, Y., Yang, J., Huser, V., Jin, P., Lambert, C., Park, H., You, S.C., Park, R.W., Rijnbeek, P., Zandt, M., Reich, C., Vashisht, R., Wu, Y., Duke, J., Hripcsak, G., Madigan, D., Shah, N., Ryan, P., Schuemie, M., Suchard, M. (2020). Comparative safety and effectiveness of alendronate versus raloxifene in women with osteoporosis. *Scientific Reports*, 10.1 (2020): 1-10.

11. Schuemie, M.J., Ryan, P.B., Pratt, N., You, S.C., Krumholz, H.M., Madigan, D., Hripcsak, G. and Suchard, M.A. (2020). Principles of Large-Scale Evidence Generation and Evaluation across a Network of Databases (LEGEND). *Journal of the American Medical Informatics Association,* https://doi.org/10.1093/jamia/ocaa103

12. Schuemie, M.J., Ryan, P.B., Pratt, N., You, S.C., Krumholz, H.M., Madigan, D., Hripcsak, G. and Suchard, M.A. (2020). Large-Scale Evidence Generation and Evaluation across a Network of Databases (LEGEND): Assessing Validity Using Hypertension as a Case Study. *Journal of the American Medical Informatics Association,* https://doi.org/10.1093/jamia/ocaa124.

13. Schuemie, M.J., Cepeda, M.S., Suchard, M.A., Yang, J., Tian, Y., Schuler, A., Ryan, P.B., Madigan, D., and Hripcsak, G. (2020). How Confident Are We About Observational Findings in Healthcare: A Benchmark Study. *Harvard Data Science Review,* 2.1, DOI: 10.1162/99608f92.147cc28e.

14. Hripcsak, G., Suchard, M.A., Shea, S., Chen, R., Pratt, N., Madigan, D., Krumholz, H.M., Ryan, P.B., and Schuemie, M.J. (2019). Real-World Evidence on the Effectiveness and Safety of Chlorthalidone and Hydrochlorothiazide. *JAMA Internal Medicine*, doi:10.1001/jamainternmed.2019.7454.

15. Suchard, M.A., Schuemie, M.J., Krumholz, H.M., You, S., Chen, R., Pratt, N., Reich, C.G., Duke, J., Madigan, D., Hripcsak, G., and Ryan, P.B. (2019). Comprehensive comparative effectiveness and safety of first-line antihypertensive drug classes. *The Lancet*, DOI:https://doi.org/10.1016/S0140-6736(19)32317-7. *International Medical Informatics Association Best Paper 2019 - Bioinformatics and Translational Informatics.*

16. Lu, F., Zheng, Y., Cleveland, H., Burton, C., and Madigan, D. (2018). Bayesian hierarchical vector autoregressive models for patient-level predictive modeling. *PLoS ONE*, https://doi.org/10.1371/journal.pone.0208082.

17. Schuemie, M., Ryan, P., Hripcsak, G., Madigan, D., and Suchard, M. (2018). Improving reproducibility by using high-throughput observational studies with empirical calibration. *Philosophical Transactions A*, **376**:20170356. http://dx.doi.org/10.1098/rsta.2017.0356.

18. Madigan, D. and Shin, J. (2018). Drospirenone-Containing Oral Conraceptives and Venous Thromboembolism: An Analysis of the FAERS Database. *Open Access Journal of Contraception*, **9**:29-32.

19. Schuemie, M.J., Ryan, P., Hripcsak, G., Madigan, D., and Suchard, M. (2018). Empirical confidence interval calibration for population-level effect estimation studies in observational healthcare data. *Proceedings of the National Academy of Science*, https://doi.org/10.1073/pnas.1708282114.
20. Berger, M., Sox, H., Willke, R., Brixner, D., Eichler, H-G., Madigan, D., Makady, A., Schneeweiss, S., Tarricone, R., Wang, S., Mullins, D., Watkins, J. (2017). Recommendations for Good Procedural Practices for Real-World Data Studies of Treatment Effectiveness and/or Comparative Effectiveness: Report of the Joint ISPOR-ISPE Special Task Force on Real-World Evidence in Health Care Decision Making. *Pharmacoepidemiology and Drug Safety*, DOI: 10.1002/pds.4297.
21. Zannad, F., Michael S. Lauer, Robert Temple, Marc A. Pfeffer, Deepak L. Bhatt, Denise E. Bonds, Jeffrey S. Borer, Gonzalo Calvo, Louis Fiore, Lars H. Lund, David Madigan, Aldo P. Maggioni, Jerry A. Menikoff, Catherine M. Meyers, Yves Rosenberg, Tabassome Simon, Wendy Gattis Stough, Andrew Zalewski, Nevine Zariffa, Robert M. Califf (2017). Streamlining Cardiovascular Clinical Trials to Achieve Improved Efficiency and Generalizability: Current Progress and Future Steps. *Heart*, 103 (15) 1156-1162.
22. Sobel, M., Madigan, D., and Wang, W. (2017). Meta-analysis: A causal framework, with application to randomized studies of Vioxx. *Psychometrika*. 82: 459, 10.1007/s11336-016-9507-z
23. Shahn, Z. and Madigan, D. (2016). Latent Class Mixture Models of Treatment Effect Heterogeneity. *Bayesian Analysis*, DOI: 10.1214/16-BA1022.
24. Shaddox, T.R., Ryan, P.B., Schuemie, M.J., Madigan, D., and Suchard, M.A. (2016). Hierarchical models for multiple rare outcomes using massive observational heathcare databases. *Statistical Analysis and Data Mining*, *9*(4), 260-268.
25. Selzman, C. H., Felker, E., Sheridan, B. C., Silvestry, S., Daly, R. C., Anyanwu, A., Madigan, D., Frazier, O. & Griffith, B. P. (2016). The Jarvik 2000: Results of the United States Bridge to Transplant Trial. *The Journal of Heart and Lung Transplantation*, *35*(4), S38.
26. Webman, R. B., Carter, E. A., Mittal, S., Wang, J., Sathya, C., Nathens, A. B., Nance, M.L., Madigan, D. & Burd, R. S. (2016). Association between trauma center type and mortality among injured adolescent patients. *JAMA Pediatrics*, *170*(8), 780-786.
27. Hripcsak, G., Patrick Ryan, Jon Duke, Nigam H. Shah, Rae Woong Park, Vojtech Huserh, Marc A. Suchard, Martijn Schuemie, Frank DeFalco, Adler Perotte, Juan Banda, Christian Reich, Lisa Schilling, Michael Matheny, Daniella Meeker, Nicole Pratt, and Madigan, D. (2016). Addressing Clinical Questions at Scale: OHDSI Characterization of Treatment Pathways. *Proceedings of the National Academy of Sciences*, vol. 113 no. 277329–7336, doi: 10.1073/pnas.1510502113.
28. Moghaddass, R., Rudin, C., and Madigan, D. (2016). The Factorized Self-Controlled Case Series Method: An Approach for Estimating the Effects of Many Drugs on Many Outcomes. *Journal of Machine Learning Research,* 17(185):1−24, 2016.
29. Beck, H.E., Mittal, S., Madigan, D., and Burd, R.S. (2015). Reassessing mechanism as a predictor of pediatric injury mortality. *Journal of Surgical Research* 199 (2), 641-646.
30. Boland, M.R., Z Shahn, D Madigan, G Hripcsak, NP Tatonetti (2015). Birth Month Affects Lifetime Disease Risk: A Phenome-Wide Method. *Journal of the American Medical Informatics Association*, DOI: http://dx.doi.org/10.1093/jamia/ocv046.

31. Shahn, Z., Ryan, P., and Madigan, D. (2015). Predicting Health Outcomes from High Dimensional Longitudinal Health Histories Using Relational Random Forests. *Statistical Analysis and Data Mining*, 8:128-136, DOI: 10.1002/sam.11268.
32. Berger, M.L., Lipset, C., Gutteridge, A., Axelsen, K., Subedi, P., and Madigan, D. (2015). Optimizing the Leveraging of Real World Data: How It Can Improve the Development and Use of Medicines? *Value in Health*, http://dx.doi.org/10.1016/j.jval.2014.10.009.
33. Hripcsak, G., Jon D Duke, Nigam H Shah, Christian G Reich, Vojtech Huser, Martijn J Schuemie, Marc A Suchard, Rae Woong Park, Ian Chi Kei Wong, Peter R Rijnbeek, Johan van der Lei, Nicole Pratt, G Niklas Norén, Yu-Chuan Li, Paul E Stang, David Madigan, and Patrick B Ryan (2015). Observational Health Data Sciences and Informatics (OHDSI): Opportunities for Observational Researchers. MedInfo, Stud Health Technol Inform. 2015; 216: 574–578.
34. Letham, B., Rudin, C., McCormick, T.H., and Madigan, D. (2014). Interpretable classifiers using rules and Bayesian analysis: Building a better stroke prediction model. *Annals of Applied Statistics*, 9, 1350-1371, DOI: 10.1214/15-AOAS848.
35. Hripcsak, G., Varela, S.V., Ryan, P.B., Madigan, D., Stang, P., Schuemie, M., Friedman, C., and Tatonetti, N. (2014). Similarity-based Modeling applied to Signal Detection in Pharmacovigilance. *CPT: Pharmacometrics & Systems Pharmacology*, *3*(9), 1-9.
36. Schuemie, M.J., Trifirò, G., Coloma, P.M., Ryan, P.B. and Madigan, D. (2014). Detecting adverse drug reactions following long-term exposure in longitudinal observational data. *Statistical Methods in Medical Research*, doi:10.1177/0962280214527531.
37. Price, K. L., Xia, H.A., Lakshminarayanan, M., Madigan, D., Manner, D., Scott, J., Stamey, J., Thompson, L. (2014). Bayesian Methods for Design and Analysis of Safety Trials. *Pharmaceutical Statistics*, 13, 13-24.
38. Simpson, S., Madigan, D., Zorych, I., Schuemie, M.J., Ryan, P.B., and Suchard, M. (2013). Multiple self-controlled case series for large-scale longitudinal observational databases. *Biometrics*, DOI: 10.1111/biom.12078.
39. Ryan, P.B., Schuemie, M.J., Gruber, S., Zorych, I., and Madigan, D. (2013). Empirical Performance of a New User Cohort Method: Lessons for Developing a Risk Identification and Analysis System. *Drug Safety*, **36** (Suppl 1):S59-S72.
40. Madigan, D., Schuemie, M.J., and Ryan, P.B. (2013). Empirical Performance of the Case-Control Method: Lessons for Developing a Risk Identification and Analysis System. *Drug Safety*, **36** (Suppl 1):S73-S82.
41. Suchard, M.A., Zorych, I., Simpson, S.E., Schuemie, M.J., Ryan, P.B., and Madigan, D. (2013). Empirical Performance of the Self-Controlled Case Series Design: Lessons for Developing a Risk Identification and Analysis System. *Drug Safety*, **36** (Suppl 1):S83-S93.
42. Ryan, P.B., Schuemie, M.J., and Madigan, D. (2013). Empirical Performance of a Self-Controlled Cohort Method: Lessons for Developing a Risk Identification and Analysis System. *Drug Safety*, **36** (Suppl 1):S95-S106.
43. Schuemie, M.J., Madigan, D., and Ryan, P.B. (2013). Empirical Performance of LGPS and LEOPARD: Lessons for Developing a Risk Identification and Analysis System. *Drug Safety*, **36** (Suppl 1):S133-S142.
44. Noren, G.N., Bergvall, T., Ryan, P.B., Juhlin, K., Schuemie, M.J., and Madigan, D. (2013). Empirical performance of the calibrated self-controlled cohort analysis within Temporal Pattern

Discovery: Lessons for developing a risk identification and analysis system. *Drug Safety*, 36 (Suppl 1):S107-S121.

45. Ryan, P.B., Stang, P.E., Overhage, J.M., Suchard, M.A., Hartzema, A.G., DuMouchel, W., Reich, C.G., Schuemie, M.J., and Madigan, D. (2013). A Comparison of the Empirical Performance of Methods for a Risk Identification System. *Drug Safety*, **36** (Suppl 1):S143-S158.
46. DuMouchel, W., Ryan, P.B., Schuemie, M.J., and Madigan, D. (2013). Evaluation of disproportionality safety signalling applied to healthcare databases. *Drug Safety*, **36** (Suppl 1):S123-S132.
47. Hartzema, A.G., Reich, C.G., Ryan, P.B., Stang, P.E., Madigan, D., Welebob, E., Overhage, J.M. (2013). Managing data quality for a drug safety surveillance system. *Drug Safety*, **36** (Suppl 1):S49-S58.
48. Ryan, P.B., Madigan, D., Stang, P.E., Schuemie, M.J., and Hripcsak, G. (2013). Medication-wide association studies. *CPT: Pharmacometrics & Systems Pharmacology* **2**, e76; doi:10.1038/psp.2013.52.
49. Mittal, S., Madigan, D., Suchard, M., and Burd, R. (2013). High-Dimensional, Massive Sample-Size Cox Proportional Hazards Regression for Survival Analysis. *Biostatistics*, doi: 10.1093/biostatistics/kxt043.
50. Rudin, C., Letham, B., and Madigan, D. (2013). Learning theory analysis for association rules and sequential event prediction. *Journal of Machine Learning Research*, **14**, 3441-3492.
51. Madigan, D., Stang, P.E., Berlin, J.A., Schuemie, M.J., Overhage, J.M., Suchard, M.A., DuMouchel, W., Hartzema, A.G., and Ryan P.B. (2013). A Systematic Statistical Approach to Integrating Information from Observational Studies. *Annual Review of Statistics and Its Application*, 1, 11-39.
52. Schuemie, M., Ryan, P., DuMouchel, W., Suchard, M.A., and Madigan, D. (2013). Interpreting observational studies - why empirical calibration is needed to correct p-values. *Statistics in Medicine*, DOI: 10.1002/sim.5925.
53. Simpson, S., Madigan, D., Zorych, I., Schuemie, M.J., Ryan, P.B., and Suchard, M. (2013). Multiple self-controlled case series for large-scale longitudinal observational databases. *Biometrics*, 69, 893-902.
54. Letham, B., Rudin, C., McCormick, T.H., and Madigan, D. (2013). An interpretable stroke prediction model with using rules using Bayesian analysis. *Twenty-Seventh AAAI Conference on Artificial Intelligence (AAAI-13) Late Breaking Paper*.
55. Letham, B., Rudin, C., and Madigan, D. (2013). A supervised ranking approach to sequential event prediction. *Machine Learning*, 10.1007/s10994-013-5356-5.
56. Ryan, P., Suchard, M.A., Schuemie, M., and Madigan, D. (2013). Learning from epidemiology: Interpreting observational studies for the effects of medical products. *Statistics in Biopharmaceutical Research*, DOI:10.1080/19466315.2013.791638.
57. Mittal, S., Madigan, D., Cheng, J., and Burd, R. (2013). Large-scale Bayesian parametric survival analysis. *Statistics in Medicine*, DOI: 10.1002/sim.5817.
58. Emir, B., Amaratunga, D., Beltangady, M., Cabrera, J., Freeman, R., Madigan, D., Nguyen, H., and Whalen, E. (2013). Generating productive dialogue between consulting statisticians and their clients ion the pharmaceutical and medical research settings. *Open Access Medical Statistics*, **3**, 51-56.

59. Madigan, D., Ryan, P., Schuemie, M., Stang, P., Overhage, M., Hartzema, A., Suchard, M.A., DuMouchel, W., and Berlin, J. (2013). Evaluating the impact of database heterogeneity on observational studies. *American Journal of Epidemiology*, DOI: 10.1093/aje/kwt010.

60. Suchard, M., Simpson, S.E., Zorych, I., Ryan, P., and Madigan, D. (2013). Massive parallelization of serial inference algorithms for generalized linear models. *ACM Transactions on Modeling and Computer Simulation*, 23:1-17.

61. Madigan, D., Ryan, P.B., and Schuemie, M.J. (2012). Does design matter? Systematic evaluation of the impact of analytical choices on effect estimates in observational studies. *Therapeutic Advances in Drug Safety*, 4, 53-62.

62. Ryan, P.B., Madigan, D., Stang, P.E., Overhage, J.M., Racoosin, J.A., Hartzema, A.G. (2012). Empirical Assessment of Analytic Methods for Risk Identification in Observational Healthcare Data: Results from the Experiments of the Observational Medical Outcomes Partnership. *Statistics in Medicine*, **30**, 4401-4415.

63. Madigan, D., Sigelman, D., Mayer, J.W., Furberg, C.D., Avorn, J. (2012). Under-reporting of cardiovascular events in the rofecoxib Alzheimer studies. *American Heart Journal*, doi:10.1016/j.ahj.2012.05.002.

64. Harpaz, R., DuMouchel, W., Shah, N.H., Madigan, D., Ryan, P., and Friedman, C. (2012). Novel data mining methodologies for adverse drug event discovery and analysis. *Clinical Pharmacology & Therapeutics*, doi:10.1038/clpt.2012.50.

65. Maclure, M., Fireman, B., Nelson, J.C., Hua, W., Shoaibi, A., Paredes, A., and Madigan, D. (2012). When should a distributed system for active medical product surveillance use case-based designs for safety monitoring?. *Pharmacoepidemiology and Drug Safety*, **21**, 50-61.

66. McCormick, T., Madigan, D., Raftery, A.E., and Burd, R.S. (2012). Dynamic model averaging for logistic regression. *Biometrics*, **68**:23-30.

67. McCormick, T., Rudin, C., and Madigan, D. (2012). A hierarchical model for association rule mining of sequential events: an approach to automated medical symptom prediction. *Annals of Applied Statistics*, **6**, 652-658.

68. Oquendo, M.A., Baca-Garcia, E., Artes, A., Perez-Cruz, F, Galfalvy H.C., Blasco-Fontecilla, H., Madigan, D., Duan, N. (2011). Hypothesis Generation in the 21st Century. *Molecular Psychiatry*, to appear.

69. Smith, R.T., Merriam, J.E., Sohrab, M.A., Pumariega, N.M., Barile, G., Blonska, A.M., Haans, R, Madigan, D., and Allikmets, R. (2011). Complement Factor H 402H Variant and Reticular Macular Disease. *Archives of Ophthalmology* 129(8):1061-1066.

70. Madigan, D., Mittal, S., and Roberts, F. (2011). Efficient sequential decision making algorithms for container inspection operations. *Naval Research Logistics,* **58**, 637-654.

71. Zorych, I., Madigan, D., Ryan, P., and Bate, A. (2011). Disproportionality methods for pharmacovigilance in longitudinal observational databases. *Statistical Methods in Medical Research*, doi: 10.1177/0962280211403602.

72. Rudin, C., Salleb-Aouissi, A., Kogan, E. and Madigan, D. (2011). Sequential Event Prediction with Association Rules. *Proceedings of the 2011 Conference on Learning Theory (COLT)* (30%). Also JMLR: Workshop and Conference Proceedings 19 (2011) 615-634.

73. Madigan, D. and Ryan, P. (2011). What can we really learn from observational studies? The need for empirical assessment of methodology for active drug safety surveillance and comparative effectiveness research. *Epidemiology*, 22 (5), 629-631.
74. Madigan, D., Ryan, P., Simpson, S.E., and Zorych, I. (2010). Bayesian methods in pharmacovigilance (with discussion). In: J. M. Bernardo, M. J. Bayarri, J. O. Berger, A. P. Dawid, D. Heckerman, A. F. M. Smith and M. West (eds), Bayesian Statistics 9, Oxford University Press, 421-438.
75. Balakrishnan, S. and Madigan, D. (2010). Priors on the variance in sparse Bayesian learning: the demi-Bayesian lasso. In: *Frontiers of Statistical Decision Making and Bayesian Analysis: In Honor of James O. Berger* by Ming-Hui Chen, Peter Müller, Dongchu Sun, and Keying Ye.
76. Caster, O., Noren, G.N., Madigan, D., and Bate, A. (2010). Large-Scale Regression-Based Pattern Discovery: The Example of Screening the WHO Global Drug Safety Database. *Statistical Analysis and Data Mining,* **3**, 197-208.
77. Ross, J.S., Madigan, D., Konstam, M.A., Egilman, D.S., and Krumholz, H.M. (2010). Does Rofecoxib cardiovascular risk persist after discontinuation? *Archives of Internal Medicine*, **170**, 2035-2036.
78. Cheng, J. and Madigan, D. (2010). Bayesian Approaches to Aspects of the Vioxx Trials: Non-ignorable Dropout and Sequential Meta-Analysis. In: *Handbook of Applied Bayesian Analysis*, Oxford University Press, 51-68.
79. Ross, J.S., Madigan, D., Hill, K.P., Egilman, D.S., Wang, Y., Krumholz, H.M. (2009). Pooled analysis of Rofecoxib placebo-controlled clinical trial data: Lessons for post-market pharmaceutical safety surveillance. *Archives of Internal Medicine*, **169**, 1976-1985.
80. Burd, R. and Madigan, D. (2009). An evaluation of the impact of injury coding schemes on mortality prediction in pediatric trauma. *Academic Emergency Medicine*, **16**, 639-645.
81. Pearson, R.K., Hauben, M., Goldsmith, D., Gould, A.L., Madigan, D., O'Hara, D.J., Reisinger, S., and Hochberg, A. (2009). Influence of the MEDDRA hierarchy on pharmacovigilance data mining results. *International Journal of Medical Informatics*, 78, e97-e103.
82. Hochberg, A., Hauben, M., Pearson, R.K., O'Hara, D., Reisinger, S., Goldsmith, D.I., Gould, A.L., and Madigan, D. (2009). An Evaluation of Three Signal Detection Algorithms Using a Highly Inclusive Reference Event Database. *Drug Safety*, 32, 509-525.
83. Burd, R.S., Ouyang, M., and Madigan, D. (2008). Bayesian logistic injury severity score (BLISS): A method for predicting mortality using ICD-9 codes. *Academic Emergency Medicine*, 15(5), 466-475.
84. Caster, O., Noren, G.N., Madigan, D., and Bate, A. (2008). Large-scale regression-based pattern discovery: The example of the WHO drug safety database. *KDD Workshop on Mining Medical Data,* to appear.
85. Naik, P., Wedel, M., Bacon, L., Bodapati, A., Bradlow, E., Kamakura, W., Kreulen, J., Lenk, P., Madigan, D., and Montgomery, A. (2008). Challenges and Opportunities in High-Dimensional Choice Data Analysis." *Marketing Letters*, 19 (3), 201-213.
86. Balakrishnan, S. and Madigan, D. (2007). Algorithms for Sparse Linear Classifiers in the Massive Data Setting. *Journal of Machine Learning Research,* **9**, 313-337, 2007.

87. Balakrishnan, S. and Madigan, D. (2007). LAPS: Lasso with Partition Search. *Proceedings of the IEEE International Conference on Data Mining,* 415-420, 19% acceptance rate.

88. Hauben, M., Madigan, D., Reisinger, S., Hochberg, A., and O'Hara, D. (2007). Data Mining in Pharmacovigilence: Computational Cost as a Neglected Performance Parameter. *International Journal of Pharmaceutical Medicine*, **21**, 319-323.

89. Hauben, M., Reich, L., Gerrits, C.M., and Madigan, D. (2007). Spontaneous Reporting of Hyperkalemia and The Randomized Aldactone Evaluation Study. *Drug Safety*, **30**, 1143-1149.

90. Eyheramendy, D. and Madigan, D. (2007). A Bayesian feature selection score based on Naive Bayes models. In: *Computational Methods of Feature Selection*, H. Liu and H. Motoda, Editors, 277-294.

91. Madigan, D., Mittal, S., and Roberts, F. (2007). Sequential decision making algorithms for port of entry inspection: overcoming computational challenges. *Proceedings of 2007 Intelligence and Security Informatics Conference*, 1-7.

92. Eyheramendy, S. and Madigan, D. (2007). A Flexible Bayesian Generalized Linear Model for Dichotomous Response Data with an Application to Text Categorization. In: IMS Lecture Notes - Monograph Series, Volume 54, *Complex datasets and inverse problems: tomography, networks and beyond*. Regina Liu, William Strawderman & Cun-Hui Zhang, Editors, 76-91.

93. Genkin, A., Lewis, D.D., and Madigan, D. (2007). Large-scale Bayesian logistic regression for text categorization. *Technometrics*, **49**, 291-304.

94. Rolka, H., Burkom, H., Cooper, G.F., Kulldorff, M., Madigan, D., and Wong, W-K. (2006). Issues in Applied Statistics for Public Health Bioterrorism Surveillance using Multiple Data Streams: Research needs. *Statistics in Medicine*, **26**, 1834-1856.

95. Balakrishnan, S. and Madigan, D. (2006). Decision Trees for Functional Variables. *Proceedings of the IEEE International Conference on Data Mining,* 798-802, 20% acceptance rate.

96. Dayanik, A., Lewis, D.D., Madigan, D., Menkov, V., and Genkin, A. (2006). Constructing Informative Prior Distributions from Domain Knowledge in Text Classification, *Proceedings of the 29th Annual International ACM SIGIR conference*, 493-500 (18.5% acceptance rate).

97. Anand, S., Madigan, D., Mammone, R., Pathak, S. and Roberts, F. (2006). Experimental Analysis of Sequential Decision Making Algorithms for Port of Entry Inspection Procedures. In S. Mehrotra, D. Zeng, H. Chen, B. Thuraisingham, and F-X Wang (eds.), Intelligence and Security Informatics, *Proceedings of ISI-2006, Lecture Notes in Computer Science #3975,* Springer-Verlag, New York, 2006.

98. Balakrishnan, S. and Madigan, D. (2006). A One-Pass Sequential Monte Carlo Method for Bayesian Analysis of Massive Datasets. *Bayesian Analysis*. **1**, 345-362.

99. Madigan, D., Ju, W., Krishnan, P., and Krishnakumar, A.S. (2006). Location estimation in wireless networks: A Bayesian approach. *Statistica Sinica*, 16, 495-522.

100. Madigan, D., Vardi, Y., and Weissman, I. (2006). Extreme value theory applied to document retrieval from large collections. *Information Retrieval*, **9**, 273-294.

101. Hauben, M., Madigan, D., Gerrits, C.M., Walsh, L., and Van Puijenbroek, E.P. (2005). The role of data mining in pharmacovigilance. *Expert Opinion in Drug Safety*., **4**(5), 929-948.

102. Madigan, D., Genkin, A., Lewis, D.D., and Fradkin, D. (2005). Bayesian multinomial logistic regression for author identification. *Proceedings of the 25th International Workshop on Bayesian inference and Maximum Entropy Methods in Science and Engineering (MaxEnt 05)*, 509-516.

103. Madigan, D., Genkin, A., Argamon, S., Fradkin, D., and Ye, L. (2005). Author identification. *Proceedings of CSNA/Interface 05*.

104. Eyheramendy, S. and Madigan, D. (2005). A Novel Feature Selection Score for Text Categorization. *International Workshop on Feature Selection for Data Mining*, 1-8, 24% acceptance rate.

105. Madigan, D. (2005). Statistics and Data Mining. In: *AMS-DIMACS Discrete Methods in Epidemiology*, James Abello and Graham Cormode (Editors), 21-24.

106. Hanks, S. and Madigan, D. (2005). Probabilistic temporal reasoning. In: *Handbook of Temporal Reasoning in Artificial Intelligence*, M. Fisher, D. Gabbay, and L. Vila, Editors, Elsevier B.V., 315-342.

107. Madigan, D. (2005). Bayesian data mining for surveillance. In: *Spatial and Syndromic Surveillance for Public Health* (Andrew Lawson and Ken Kleinman, Editors), 203-221.

108. Madigan, D., Elnahrawy, E., Martin, R.P., Ju, W., Krishnan, P. and Krishnakumar, A.S. (2004). Bayesian Indoor Positioning Systems. *Proceedings of IEEE Infocom*, 1217-1227 (17% acceptance rate)

109. Madigan, D. (2004). Statistics and the war on spam. In: *Statistics: A Guide to the Unknown*, Deb Nolan (Editor), 135-147.

110. Fradkin, D. and Madigan, D.. (2003). Experiments with random projections for machine learning. In *Proceedings of KDD-03, The Ninth International Conference on Knowledge Discovery and Data Mining*, 517-522.

111. Ridgeway, G. and Madigan, D. (2003). A sequential Monte Carlo Method for Bayesian analysis of massive datasets. *Journal of Knowledge Discovery and Data Mining*, **7**, 301-319.

112. Eyheramendy, S., Lewis, David D., and Madigan, David (2003). On the naïve bayes model for text classification. In *Proceedings of The Ninth International Workshop on Artificial Intelligence and Statistics*, C.M. Bishop and B.J. Frey (Editors), 332-339.

113. Madigan, D., Vardi, Y., and Weissman, I. (2003). On retrieval properties of samples of large collections. In *Proceedings of The Ninth International Workshop on Artificial Intelligence and Statistics*, C.M. Bishop and B.J. Frey (Editors), 265-270.

114. Madigan, D. and Ridgeway, G. (2003). Bayesian data analysis for data mining. In *Handbook of Data Mining*, N. Ye (Ed.), 103-132..

115. Cohen, A., Madigan, D., and Sackrowitz, H.B. (2003). Effective directed tests for models with ordered categorical data. *Australian and New Zealand Journal of Statistics*, **45**, 285-200. 2003 Best Paper Award.

116. Mangione, S., Yuen, E., and Madigan, D. (2003). Asthma in Philadelphia schools. *Chest*, **124** (4): 141S.

117. Mangione, S., Yuen, E., and Madigan, D. (2003). Asthma and tobacco: A survey of 65 Philadelphia middle schools. *Chest*, **124** (4): 141S-142S.

118. Dunbar, P.J., Madigan, D., Grohskopf, L.A., Revere, D., Woodward, J., Minstrell, J., Frick, P.A., Simoni, J.M., and Hooton, T.M. (2003). A two-way messaging system to enhance antiretroviral adherence. *Journal of The American Medical Informatics Association*, **10**, 11-15.

119. Ridgeway, G. and Madigan, D. (2002). Bayesian analysis of massive datasets via particle filters In *Proceedings of KDD-02, The Eighth International Conference on Knowledge Discovery and Data Mining*, 5-13.

120. Madigan, D., Raghavan, N., DuMouchel, W., Nason, M., Posse, C., and Ridgeway, G. (2002). Likelihood-based data squashing: A modeling approach to instance construction. *Journal of Data Mining and Knowledge Discovery*, **6**, 173-190.

121. Tanimoto, S., Carlson, A., Husted, J., Hunt, E.B., Larsson, J., Madigan, D., and Minstrell, J. (2002). Text Forum Features for Small Group Discussions with Facet-Based Pedagogy. *Proceedings of CSCL2002, Computer Supported Cooperative Learning.*

122. Hoeting, J., Raftery, A.E., and Madigan, D. (2002). A method for simultaneous variable and transformation selection in linear regression. *Journal of Computational and Graphical Statistics*, **11**, 485-507.

123. Liu, R., Madigan, D., and Eyheramendy, S. (2002). Text classification for mining aviation inspection reports. In: *Statistical Data Analysis based on the L1-norm and Related methods*. Birkhauser Statistics for Industry and technology, Y. Dodge editor, 379-392.

124. da Silva, C.Q., Zeh, J., Madigan, D., Laake, J., Rugh, D., Baraff, L., Koski, W., and Miller, G. (2001). Capture-recapture estimation of bowhead whale population size estimation using photo-identification data. *Journal of Cetacean Research and Management*, **2**, 45-61.

125. Levitz, M., Perlman, M.D., and Madigan, D. (2001). Separation and Completeness Properties for AMP Chain Graph Markov Models. *Annals of Statistics*, **29**, 1751–1784.

126. Church, L., Oliver, L., Dobie, S., Madigan, D., and Ellsworth, A. (2001). Analgesia for colposcopy: A double-blind, randomized comparison of ibuprofen and benzocaine gel for colposcopic analgesia. *Obstetrics and Gynecology*,**97**, 5-10.

127. Andersson, S.A., Madigan, D., and Perlman, M.D. (2001). An alternative Markov property for chain graphs. *Scandinavian Journal of Statistics*, **28**, 33-85.

128. Glusker, A.I., Dobie, S.A., Madigan, D., Rosenblatt, R.A., Larson, E.H. (2000). Differences in fertility patterns between urban and rural women in Washington state, 1983-1984 to 1993-1994. *Women and Health,* **31**, 55-70.

129. Kanungo, T., Haralick, R. M., Baird, H. Stuetzle, W., and Madigan, D. (2000). A statistical, nonparametric methodology for document degradation models validation. *IEEE Transactions on Pattern Analysis and Machine Intelligence*, **22**, 1209-1223.

130. Dobie, S.A., Hart, G., Glusker, A., Rosenblatt, R., and Madigan, D. (2000). Reproductive health services in rural Washington state: Scope of practice and the potential of medical abortions. *American Journal of Public Health*., **90**, 624-626.

131. Madigan, D. and Nason, M. (2000). Statistics perspectives on data and knowledge. *Handbook of Knowledge Discovery and Data Mining*, Oxford University Press.

132. Nason, M. and Madigan, D. (2000). Sampling. *Handbook of Knowledge Discovery and Data Mining*, Oxford University Press.

133. Madigan, D., Raghavan, N., DuMouchel, W., Nason, M., Posse, C., and Ridgeway, G. (2000). Instance construction via likelihood-based data squashing. *Instance Selection and Construction, A Data Mining Perspective*, H. Motoda and H. Liu (Eds.), Kluwer, 209-226.

134. Hoeting, J.A., Madigan, D., Raftery, A.E., and Volinsky, C.T. (1999). Bayesian model averaging – a tutorial. *Statistical Science*, **14**, 382-401.

135. Dobie, S.A., Hart, G., Glusker, A., Madigan, D., Larsen, E.B., and Rosenblatt, R. (1999). Abortion services in rural Washington State, 1983-1984 to 1993-1994: availability and outcomes. *Family Planning Perspectives*, **31**, 241-245.

136. Condliff, M.K., Lewis, D.D., Madigan, D., and Posse, C. (1999). Bayesian mixed-effects models for recommender systems. *Proceedings of SIGIR-99 Workshop on Recommender Systems.*

137. Madigan, D. (1999). Bayesian Graphical Models, Intention-to-Treat, and the Rubin Causal Model. In *Proceedings of Uncertainty-99, The Seventh International Workshop on Artificial Intelligence and Statistics*, 123-132.

138. Golinelli, D., Madigan, D., and Consonni, G. (1999). Relaxing the local independence assumption for quantitative learning in acyclic directed graphical models through hierarchical partition models. In *Proceedings of Uncertainty-99, The Seventh International Workshop on Artificial Intelligence and Statistics*, 203-208.

139. Ridgeway, G., Madigan, D., and Richardson, T. (1999). Boosting Methodology for Regression Problems. In *Proceedings of Uncertainty-99, The Seventh International Workshop on Artificial Intelligence and Statistics*, 152-161.

140. Ridgeway, G., Madigan, D., Richardson, T., and O'Kane, K. (1998). Interpretable Boosted Naïve Bayes Classification In *Proceedings of KDD-98, The Fourth International Conference on Knowledge Discovery and Data Mining*, 101-104.

141. Andersson, S.A., Madigan, D., Perlman, M.D., and Richardson, T. (1998). Graphical Markov Models in multivariate analysis. In *Multivariate Analysis, Design of Experiments, and Survey Sampling*, Subir Ghosh (Ed.), Marcel Dekker Inc.

142. Draper, D. and Madigan, D. (1997). The scientific value of Bayesian statistical methods. *IEEE Intelligent Systems and their Applications*, **12**, 18-21.

143. Madigan, D. and York, J. (1997). Bayesian methods for estimating the size of a closed population. *Biometrika*, **84**, 19-31.

144. Glymour, C., Madigan, D., Pregibon, D., and Smyth, P. (1997). Statistical themes and lessons for data mining. *Journal of Data Mining and Knowledge Discovery*, **1**, 11-28.

145. Volinsky, C.T., Madigan, D., Raftery, A.E., and Kronmal, R.A. (1997). Bayesian Model Averaging in Proportional Hazard Models: Predicting Strokes. *Applied Statistics* **46**, 433-448.

146. Andersson, S.A., Madigan, D., Perlman, M.D., and Triggs, C.M. (1997). A graphical characterization of lattice conditional independence models. *Annals of Mathematics and Artificial Intelligence*, **21**, 27-50.

147. Madigan, D., Mosurski, K., and Almond, R.G. (1997). Explanation in belief networks. *Journal of Computational and Graphical Statistics*, **6**, 160-181.

148. Andersson, S.A., Madigan, D., and Perlman, M.D., (1997). A characterization of Markov equivalence classes for acyclic digraphs. *Annals of Statistics*, **25**, 505-541.

149. Raftery, A.E., Madigan, D., and Hoeting, J. (1997). Accounting for model uncertainty in linear regression. *Journal of the American Statistical Association*, **92**, 179-191.

150. Madigan, D., Keim, M, and Lewis, D.D. (1997). Bayesian information retrieval. *Proceedings of the Sixth International Workshop on Artificial Intelligence and Statistics*, 303-310.

151. Andersson, S.A., Madigan, D., and Perlman, M.D. (1997). On the Markov equivalence of chain graphs, undirected graphs, and acyclic digraphs. *Scandinavian Journal of Statistics*, **24**, 81-102.

152. Madigan, D., Raftery, A.E., Volinsky, C.T., and Hoeting, J.A. (1996). Bayesian model averaging. In*: Integrating Mulitple Learned Models (IMLM-96)*, P. Chan, S. Stolfo, and D. Wolpert (Eds.), 77-83.

153. Raftery, A.E., Madigan, D., and Volinsky, C.T. (1996). Accounting for model uncertainty in survival analysis improves predictive performance. In: Bernardo, J. M., Berger, J. O., Dawid, A. P. and Smith A. F. M., (eds.), *Bayesian Statistics V*, Oxford University Press, 323-350.

154. Andersson, S.A., Madigan, D., and Perlman, M.D. (1996). An alternative Markov property for chain graphs. In *Proceedings of the Twelfth Annual Conference on Uncertainty in Artificial Intelligence*, Eric Horvitz and Finn Jensen (Eds.), Morgan Kaufmann Publishers, Inc., San Mateo.

155. Schaffner, A., Madigan, D., Hunt, E., Graf, E., Minstrell, J., and Nason, M. (1996). Benchmark lessons and the world wide web: Tools for teaching statistics. In: D. Edelson and E. Domeshek (Eds.) *Proceedings of ICLS 96. Association for the Advancement of Computing in Education,* 480-484.

156. Madigan, D. and Almond, R.G. (1996). On test selection strategies for belief networks. In *Learning from Data: Artificial Intelligence and Statistics V*, D. D. Fisher and H. Lenz (Eds.), Springer Verlag, 89-98 (20% acceptance rate for plenary papers).

157. Glymour, C., Madigan, D., Pregibon, D., and Smyth, P., and (1996). Statistical inference and data mining. *Communications of the ACM*, **39**, 35-41.

158. Madigan, D., Andersson, S.A., Perlman, M.D, and Volinsky, C.T. (1996). Bayesian model averaging and model selection for Markov equivalence classes of acyclic digraphs. *Communications in Statistics - Theory and Methods*, **25**, 2493-2519.

159. Hoeting, J.A., Madigan, D., and Raftery, A.E. (1996). A Method for Simultaneous Variable Selection and Outlier Identification in Linear Regression, *Journal of Computational Statistics and Data Analysis*, **22**, 251-270.

160. Madigan, D., Chapman, C.R., Gavrin, J., Villumsen, O., and Boose, J.H. (1995). Repertory hypergrids for large-scale hypermedia linking. *International Journal of Human-Computer Studies*, 43, 465-481.

161. Madigan, D., Gavrin, J., and Raftery, A.E. (1995). Eliciting prior information to enhance the predictive performance of Bayesian graphical models. *Communications in Statistics - Theory and Methods*, 24, 2271-2292.

162. Madigan, D. and York, J. (1995). Bayesian graphical models for discrete data. *International Statistical Review*, 63, 215-232.

163. Andersson, S.A., Madigan, D., Perlman, M.D., and Triggs, C.M., (1995). On the relation between conditional independence models determined by finite distributive lattices and by directed acyclic graphs. *Journal of Statistical Planning and Inference,* **46**, 25-46.

164. York, J., Madigan, D., Heuch, I., and Lie, R.T. (1995). Estimation of the proportion of congenital malformations using double sampling: Incorporating covariates and accounting for model uncertainty. *Applied Statistics*, **44**, 227–242.

165. Madigan, D., and Chapman, C.R. (1995). Multimedia tools for cancer pain education. In: *Medical Multimedia*, C. Ghaoui and R. Rada (Eds.), Intellect, Oxford, 121–136.

166. Haynor, D. and Madigan, D. (1995). Bayesian approach to differential diagnosis with use of Monte Carlo technique. *Radiology*, **197**, 425S.

167. Hanks, S., Madigan, D., and Gavrin, J. (1995). Temporal reasoning in probabilistic knowledge-based systems. In *Proceedings of the Eleventh Annual Conference on Uncertainty in Artificial Intelligence*, Philippe Besnard and Steve Hanks (Eds.), Morgan Kaufmann Publishers, Inc., San Mateo, 111-119.

168. Madigan, D., Chapman, C.R., Gavrin, J., Villumsen, O., and Boose, J.H. (1994). Repertory Hypergrids: An Application to Clinical Practice Guidelines. *Proceedings of the ACM European Conference on Hypermedia Technology*, 117–125.

169. Almond, R, Bradshaw, J.M., and Madigan, D. (1994). Reuse and sharing of graphical belief network components. In *Selecting Models from Data: Artificial Intelligence and Statistics IV*, P. Cheeseman and W. Oldford (Eds.), Springer Verlag, 113-122.

170. Madigan, D., York, J.C., Bradshaw, J.M., and Almond, R.G. (1994). Bayesian graphical models for predicting errors in databases. In *Selecting Models from Data: Artificial Intelligence and Statistics IV*, P. Cheeseman and W. Oldford (Eds.), Springer Verlag, 123-132.

171. Madigan, D., Raftery, A.E., York, J.C., Bradshaw, J.M., and Almond, R.G. (1994). Strategies for graphical model selection. In *Selecting Models from Data: Artificial Intelligence and Statistics IV*, P. Cheeseman and W. Oldford (Eds.), Springer Verlag, 91-100.

172. York, J.C. and Madigan, D. (1994). Markov chain Monte Carlo methods for hierarchical Bayesian expert systems. In *Selecting Models from Data: Artificial Intelligence and Statistics IV*, P. Cheeseman and W. Oldford (Eds.), Springer Verlag.

173. Madigan, D., Chapman, C.R., Gavrin, J., Villumsen, O., and Boose, J.H. (1994). Modularized Maintenance for Hyperlinking: An Application to Clinical Practice Guidelines. *Proceedings of the AAAI-94 Workshop on Indexing and Reuse in Multimedia Systems*, 126–140.

174. Kanungo, T., Haralick, R. M., Stuetzle, W., and Madigan, D. (1994). Document Degradation Models: Parameter Estimation and model validation. In *Proc. of Int. Workshop on Machine Vision Applications*, Kawasaki, Japan, 552-557.

175. Madigan, D. and Raftery, A.E. (1994). Model Selection and accounting for model uncertainty in graphical models using Occam's window. *Journal of the American Statistical Association*, **89**, 1535–1546.

176. Madigan, D. (1993). A note on equivalence classes of directed acyclic independence graphs. *Probability in the Engineering and Informational Sciences*, **7**: 409–412.

177. Bradshaw, J.M., Chapman, C.R., Sullivan, K.M., Almond, R.G., Madigan, D., Zarley, D., Gavrin, J., Nims, J., and Bush, N. (1993). KS-3000: Applying DDUCKS to bone-marrow transplant patient support. *Proceedings of the Sixth Annual Florida AI Research Symposium (FLAIRS '93)*, Ft. Lauderdale, FL, April, 78–83.

178. Bradshaw, J.M., Madigan, D., Richards, T., and Boy, G.A. (1993). Emerging technology and concepts for computer-based training. *Proceedings of the Sixth Annual Florida AI Research Symposium (FLAIRS '93)*, Ft. Lauderdale, FL, April, 89–95.

179. Bradshaw, J.M., Richards, T., Fairweather, P., Buchanan, C., Guay, R., Madigan, D.,and Boy, G.A. (1993). New directions in computer-based training in aerospace. *Proceedings of the Fourth International Conference on Human Machine Interactions and Artificial Intelligence in Aerospace*. Toulouse, France.

180. Bradshaw, J.M., Chapman, C.R., Sullivan, K.M., Boose, J.H., Almond, R.G., Madigan, D., Zarley, D., Gavrin, J., Nims, J. and Bush, N. (1993). KS-3000: An application of DDUCKS to bone-marrow transplant patient support. *Proceedings of the Seventh European Knowledge Acquisition for Knowledge-Based Systems Workshop (EKAW-93)*. Toulouse and Caylus, France, 57-74.

181. E.A. Kiely, Madigan, D., P.C. Ryan and M.R. Butler (1991). Ultrasonic imaging for extracorporeal shockwave lithotripsy: Analysis of factors in successful treatment. *British Journal of Urology*, **66**: 127–131.

182. Madigan, D. and Mosurski, K. (1991). An extension of the results of Asmussen and Edwards on collapsibility in contingency tables. *Biometrika*, **77**: 315–319.

Letters to the Editor/Commentaries

183. Madigan, D. (2021). Supra-disciplinary data science. *Harvard Data Science Review*, Issue 3.2.

184. Egilman, D., Madigan, D., Yimam, M., and Tran, T. (2020). Evidence that cosmetic talc is a cause of ovarian cancer. *Gynecology and Pelvic Medicine*, http://dx.doi.org/10.21037/gpm-20-28.

185. He, X., Madigan, D., Yu, B., and Wellner, J. (2019). Statistics at a crossroads: Who is for the challenge in *NSF Workshop report. National Science Foundation. https://www. nsf.* 1115 *gov/mps/dms/documents/Statistics at a Crossroads Workshop Report 2019. pdf.*

186. Egilman, D., Madigan, D., Yimam, M., and Tran, T. (2019). Letter to the Editor: Response to Vermont Talc-Miners Cohort Study Update. *Journal of Occupational and Environmental Medicine*, PMID: 31790061. DOI: 10.1097/JOM.0000000000001783.

187. Madigan, D., Egilman, D., Finkelstein, M., Yimam, M., and Tran, T. (2019). Response to Marsh, G. M., Ierardi, A. M., Benson, S. M., & Finley, B. L. (2019). Occupational exposures to cosmetic talc and risk of mesothelioma: an updated pooled cohort and statistical power analysis with consideration of latency period. *Inhalation Toxicology*, 31(6), 213–223.

188. Schuemie, M., Ryan, P., Hripcsak, G., Madigan, D., and Berlin, J. and Reich, C. (2019). Comment on "How pharmacoepidemiology networks can manage distributed analyses to improve replicability and transparency and minimize bias" *Pharmacoepidemiology and Drug Safety*, DOI: 10.1002/pds.4798

189. Schuemie, M., Ryan, P., Hripcsak, G., Madigan, D., and Suchard, M. (2016). Robust empirical calibration of p-values using observational data: Comment on 'Limitations of empirical calibration of p-values using observational data. *Statistics in Medicine*, DOI**:** 10.1002/sim.6977.

190. Schuemie, M.J., Ryan, P.B., Suchard, M., Shahn, Z., and Madigan, D. (2013). Discussion of "An estimate of the science-wise false discovery rate and application to the top medical literature" by Jager and Leek, *Biostatistics*.

191. Caster, O., Noren, N., Madigan, D., and Bate, A. (2013). Logistic regression in signal detection: another piece added to the puzzle (letter). *Clinical Pharmacology & Therapeutics*, 94, 312.

192. Ryan PB, Madigan D, Stang PE, Marc Overhage J, Racoosin JA, Hartzema AG. (2013) Response to Comment on 'Empirical assessment of methods for risk identification in healthcare data'. *Statistics in Medicine*, Mar 15;32(6):1075-7. doi: 10.1002/sim.5725.

193. Maclure, M., Fireman, B., Nelson, J., & Madigan, D. (2012). Mortality and the self-controlled case series method. Response to Letter to Editor. *Pharmacoepidemiology and Drug Safety*, *21*(8), 907-907.

194. Madigan, D. and Gelman, A. (2009). Comment on "What is Statistics," *American Statistician*, **63**, 114.

195. Bilker, W., Gogolak, V., Goldsmith, D., Hauben, M., Herrera, G., Hochberg, A., Jolley, S., Kulldorff, M., Madigan, D., Nelson, R., Shapiro, A., Shmueli, G. (2006). Accelerating Statistical Research in Drug Safety, Letter to the Editor, *Pharmacoepidemiology and Drug Safety*, **15**, 687-688.

196. Madigan, D. and Stuetzle, W. (2004). Statistics graduate education. Discussion of "The future of statistics" *Statistical Science*, **19**, 3, 408.

197. Madigan, D. and Ridgeway, G. (2003). Discussion of "Least Angle Regression" by Efron, Hastie, Johnstone, and Tibshirani. *Annals of Statistics*.

198. Madigan, D. and Ridgeway, G. (2002). Discussion of "Chain graph models and their causal interpretations" by Lauritzen and Richardson. *Journal of the Royal Statistical Society (Series B)*.

199. Madigan, D. (1999). Discussion of "Bayesian data mining in large frequency tables" by Bill DuMouchel. *The American Statistician*, **53**, 198-200.

200. Richardson, T., Ridgeway, G., and Madigan, D. (1999). Discussion of Bump Hunting in High-Dimensional Data by Jerome Friedman, *Statistics and Computing*, **9**, 150-152.

201. Higdon, D. and Madigan, D. (1998). Discussion of paper by Lavine in *Bayesian Statistics, VI*, 381-382.

202. York, J. and Madigan, D. (1993). Discussion of the paper by Smith and Roberts, *Journal of the Royal Statistical Society (Series B)*, **55**, 88.

203. Madigan, D. (1993). What's next? Contribution to *Statistical Science* discussion of two papers on graphical models, **8**:261–263.

204. Madigan, D. (1995). Discussion of the paper by Draper *Journal of the Royal Statistical Society (Series B)*, **57**, 85..

205. Madigan, D. (1995). Discussion of the paper by Chatfield *Journal of the Royal Statistical Society (Series A)*, **158**, 458-459.

Other Publications

206. Egilman, D., Madigan, D., Yimam, M., and Tran, T. (2020). Evidence that cosmetic talc is a cause of ovarian cancer. *Gynecology and Pelvic Medicine*. doi: 10.21037/gpm-20-28

207. Gelman, A. & Madigan, D. (2015). Ethics and Statistics: How is Ethics Like Logistic Regression? Ethics decisions, like statistical inferences, are informative only if they're not too easy or too hard. *CHANCE*, *28*(2), 31-33.

208. Ryan, P., Madigan, D., and Schuemie, M. (2014). The Emerging Role of Observational Healthcare Data in Pharmacovigilance. In: *Quantitative Evaluation of Safety in Drug Development: Design, Analysis and Reporting* edited by Qi Jiang and Amy Xia.

209. Stang, P., Patrick Ryan, Abraham G. Hartzema, David Madigan, J Marc Overhage, Emily Welebob, Christian G. Reich, Thomas Scarnecchia (2014). Development and Evaluation of Infrastructure and Analytic Methods for Systematic Drug Safety Surveillance: Lessons and Resources from the Observational Medical Outcomes Partnership. In: *Mann's Pharmacovigilance*, 3rd Edition Elizabeth B. Andrews and Nicholas Moore (Eds), Chapter 28.

210. McCormick, T.H., Rudin, C. and Madigan, D. (2011). Predicting medical conditions with Bayesian hierarchical rule modeling. Proceedings of the 6th INFORMS Workshop on Data Mining and Health Informatics (DM-HI 2011. P. Qian, Y. Zhou, C. Rudin, eds.

211. Hauben, M., Madigan, D., Patadia, V., Sakaguchi, M., van Puijenbroek, E. (2010). Quantitative signal detection for vaccines. *Human Vaccines*, 6, 1.

212. Madigan, D. (2007). Introduction to the LARS chapter. Volume celebrating Efron's 60th birthday, Springer.

213. Dayanik, A., Genkin, A., Kantor, P., Lewis, D.D., and Madigan, D. (2005). DIMACS at the TREC 2005 Genomics Track. TREC 2005.

214. Eyheramendy, S., Genkin, A., Ju, W-H., Lewis, D.D., and Madigan, D. (2003). Sparse Bayesian classifiers for text categorization. *JICRD*.

215. Madigan, D. (2003). Sparse Bayesian classifiers for text categorization. *Proceedings of the International Statistical Institute*.

216. Chaudhuri, S., Madigan, D., and Fayyad, U.M. (2000). KDD-99: The Fifth ACM SIGKDD International Conference on Knowledge Discovery and Data Mining. *SIGKDD Explorations*, 1, 49-51.

217. Nakamura, Y., Chabal, C., Chapman, C.R., Dunbar, P.J., Madigan, D., and Minstrell, J. (1997). FABLE: A computer-based tool for teaching geriatric pain management skills. In *Proceedings of the Annual Conference of the American Pain Socity*.

218. Madigan, D., Perlman, M.D, and Volisnky, C.T. (1995). Bayesian model averaging and model selection for Markov equivalence classes of acyclic digraphs. *Proceedings of Workshop on Model Robustness and Model Uncertainty*, Bath, England, http://www.isds.duke.edu:80/conferences/bath/abstracts.html.

219. Madigan, D. (1995). Editorial for special issue of the *International Journal of Human-Computer Studies* on Knowledge-Based Hypermedia, **43**, 279.

220. Clarkson, D.B., Donnell, D., Minstrell, J., Hunt, E., Madigan, D., and Traynor, C. (1994). Vital: An intelligent tutoring system for statistics. *American Statistical Association, Proceedings of Section on Statistical Education*, 88-93.

221. Dunbar, P.J., Madigan, D., Lam, A.M., and Matta, B.F. (1994). A hypermedia instruction tool for teaching retrograde jugular venous cannulation. Multimedia Scientific Exhibit at the 1994 Meeting of the American Society of Anesthesiologists, San Francisco, CA.

222. Madigan, D. (1989). Microcomputer research at the Meath hospital. *Irish Medical Times*, **21** (34), 14-15.

223. Madigan, D. (1989). Expert systems in government. *Irish Computer*, 22-24.

Book and Software Reviews

224. Madigan, D. (2002). A review of "Principles of Data Mining" by Hand, Mannila, and Smyth. *SIAM Review*, **44**, 501-502.

225. Madigan, D. (2001). A review of "Probabilistic Networks and Expert Systems" by Cowell, Dawid, Lauritzen, and Spiegelhalter. *Journal of the American Statistical Association,* **96**, 1524.

226. Madigan, D. (1994). A review of MIM: graphical modelling software. *Statistics and Computing*, **4**, 33–39.

227. Madigan, D. (1994). A review of "Graphical models in applied multivariate statistics" by Joe Whittaker. *Networks*, **24**,125.

Unpublished Technical Reports

228. Brookhart, M.A., Ryan, P., Madigan, D., Sturmer, T. (2011). An Empirical Comparison of Different Implementations of a Standardized New User Design For Drug Safety Surveillance.

229. Egilman, D., Madigan, D., and Druar, N.M. (2011). A Drug Trial Gone Wrong: Excess Death and Injury Among Study Volunteers in an Unmonitored Alzheimer's Drug Study.

230. Ryan, P.B., Reich, C., Welebob, E., Overhage, J.M., Stang, P.E., Hartzema, A.G., Racoosin, J.A., Scarnecchia, T., Madigan, D. (2011). Managing data quality for an active surveilance system.

231. Pickering, W.H., Madigan, D., McCarter, R.J., and Burd, R.S. (2009). Evaluating relative importance of injury groupings on in-hospital mortality.

232. Hauben, M., Madigan, D., Reisinger, S., Hochberg, A., and O'Hara, D. (2008). Effects of Stratification on Three Pharmacovigilance Data Mining Algorithms.

233. Ju, Wen-Hua, Madigan, David, and Scott, Steven (2002). On Bayesian learning of sparse classifiers.

234. J.W. O'Kane, G. Ridgeway, and D. Madigan (1999). Statistical Analysis of Clinical Variables to Predict the Outcome of Surgical Intervention in Patients with Knee Complaints.

235. Madigan, D. (1998). Combining probability distributions: A Review. Statistical Sciences Inc. Research Report.

236. Schaffner, A., Madigan, D., Clarkson, D.B., Donnell, D., Hunt, E.B., Keim, M., Minstrell, J., Nason, M., and Volinsky, C.T. (1996). Facet-based learning for statistics.

237. Schaffner, A., Madigan, D., Hunt, E.B., and Minstrell, J. (1996). Virtual benchmark instruction.

238. Madigan, D., Hunt, E., Levidow, B., and Donnell, D. (1995). Bayesian graphical models for intelligent tutoring systems.

239. Madigan, D. (1992). Temporal Reasoning with Probabilities: A Review. Statistical Sciences Inc. Research Report Number 7.

240. Madigan, D. (1992). Approaches to Explanation in Bayesian Networks. Statistical Sciences Inc. Research Report Number 8.

241. Carlsen, J.C., Madigan, D. and Bradshaw, D. (1992). Music expectancy and its measurement. UW Department of Music Technical Report.

Research Grants

Principal Investigator on sub-contract to Northeastern University from FDA Award 75F40120D0039 to Columbia University, 2020-2024, $601,673.

Principal Investigator on sub-contract from NSF Award IIS 1251151 to UCLA, "Patient-level predictive modeling from massive longitudinal databases." 2013-2017, $217,837.

Principal Investigator on FNIH/Observational Medical Outcomes Partnership grant to Columbia University, "Methods for Active Drug Safety Surveillance," 2009-2013.

Co-Principal Investigator on National Instutes of Health grant "Improving Pediatric Trauma Triage Using High Dimensional Data Analysis," R01 GM87600-01, 2010-2013.

Principal Investigator on sub-contract from FDA Award HHSF223200910006I to Harvard Pilgrim Healthcare, "Mini-sentinel," 2010-2011.

Investigator on Department of Homeland Security grant "Center for Dynamic Data Mining" to Center for Discrete Mathematics and Theoretical Computer Science (DIMACS), Rutgers University, 2006-2009, $2,400,000 total.

Principal Investigator on National Science Foundation grant "Bayesian Methods for Large-Scale Applications" to Columbia University, DMS-0505599, 2005-2009, $150,000 total.

Principal Investigator (with Shlomo Argamon) on National Science Foundation grant "Community resources for author identification" to Rutgers University, CNS-0454126, 2005, $56,019 total.

Principal Investigator on Knowledge Discovery and Dissemination (KD-D) grant to DIMACS "Author Identification," 2004, $250,000 total.

Co-Principal Investigator on National Science Foundation grant "Monitoring Message Streams" to DIMACS, Rutgers University, KDI-0087022, 2002-2008, $1,500,000 total (annual renewal).

Investigator on National Science Foundation grant "Computational and Mathematical Epidemiology" to DIMACS, Rutgers University, ITR-0205116, 2002-2007, $2,750,000 total.

Principal Investigator on National Science Foundation grant "Bayesian Data Analysis for Digital Traces" to Rutgers University, DMS-0113236, 2001-2004, $245,000 total.

Principal Investigator (with Steen Andersson and Michael Perlman) on National Science Foundation grant "Graphical Markov Models" to the University of Washington, DMS-9704573, 1997-2000, $313,722 total.

Principal Investigator (with Steven Tanimoto) on grant from National Science Foundation to University of Washington: "Use of Online Assessment in Forming and Coaching Learning Groups," 1996-1999, $600,501, CRLT-9616532.

Principal Investigator on National Science Foundation grant "Computing Environments for Graphical Models" to the University of Washington, DMS-92111629, 1992-1996, $65,000 total.

Principal Investigator on Subcontract to the University of Washington under National Institutes for Health Phase II SBIR grant "TALARIA: Multimedia tools for cancer pain education" to Mathsoft, Inc., 1995-1997, $750,000 total (UW Subcontract, $231,652).

Principal Investigator on Subcontract to the University of Washington under National Institutes for Health Phase I SBIR grant "An intelligent tutoring system for biostatistics" to Statistical Sciences, Inc., 1994-5, $80,853.

Principal Investigator on National Institutes for Heath SBIR Phase I grant "A Multimedia Teaching and Reference Tool for Cancer Pain" to Statistical Sciences, Inc., 1993-1994, $50,000 total.

Investigator (20%) on Quantum Health Resources Grant "Knowledge-based Systems for Bone Marrow Transplant Long Term Follow-up" to the Fred Hutchinson Cancer Research Center, 1993-94, $1m (C. Richard Chapman, P.I.).

Investigator (and author) on Department of Energy Phase I SBIR grant "An intelligent tutoring system for statistics" to Statistical Sciences, Inc., 1993-4, $75,000.

Investigator (10%) on Robert Wood Johnson Foundation grant to the Department of Family Medicine, University of Washington (Sharon Dobie, PI), 1995-1999.

Investigator (5%) on American College of Clinical Pharmacy grant to the Department of Family Medicine, University of Washington (Allan Ellsworth, PI), 1995-1996.

Patents

Ju, W., Krishnakumar, A.S., Krishnan, P., and Madigan, D. (2008). Method and apparatus for positioning a set of terminals in an indoor wireless environment. US PTO # 7403784.

Selected Invited Presentations

Judging Science, Columbia Science and Technology Law Review Symposium, November 2024.

Celebration for Adrian Raftery, University of Washington, Seattle, "The Role of a Consulting Statistician," August 2024.

Irish Statistics Association, Athlone, "The State of Academic Statistics," May 2024.

Penn State Medical School, "Real Real-World Evidence" November 2022.

International Biometrics Conference, Riga, Latvia (presidential keynote), "Real Real-World Evidence" July 2022.

UMass Flex Conference, Amherst, "Flexible Learning at Northeastern," April 2022.

ECOSTA (virtual), "Real Real-World Evidence" June 2021.

ISPOR 2021 (virtual), "We have the technology," April 2021.

Temple University, Data Science Meeting (virtual), "Real Real-World Evidence" November 2020.

Joint Statistical Meeting (virtual),"OHDSI Methods for Causal Inference" August 2020.

Advances in Precision Medicine Conference, Columbia University (virtual), "Real Real-World Evidence" April 2020.

EPFL, Switzerland (virtual), "Real Real-World Evidence" April 2020.

University at Buffalo, "Real Real-World Evidence" November 2019.

AMS Regionakl Meeting, Riverside, CA, "Real Real-World Evidence," November 2019.

ASA NJ Chapter / Bayer 7th Annual Workshop, Keynote Speaker, "Real Real-World Evidence," November 2019.

National Academy of Science, Applying Big Data to Address the Social Determinants of Health in Oncology, "Real Real-World Evidence," October 2019.

University of Florida Informatics Institute, Annual Symposium, Keynote, "Real Real-World Evidence," October 2019.

Harvard University Department of Healthcase Policy, "Real Real-World Evidence" September 2019.

U. Penn Big Data in Healthcare Meeting, Washington, DC, "Real-World Evidence" September 2019.

Duke-Margolis Meeting on Leveraging RCTs to Generate Real-World Evidence, Washington, DC, "Real-World Outcomes" July 2019.

NYC R Conference, New York, "Honest Inference from Observational Studies" May 2019.

Data Science Dean's Speaker Series, SUNY Binghamton, "Honest Inference from Observational Studies" April 2019.

Neyman Lecture, University of California, Berkeley, "Honest Inference from Observational Studies" March 2019.

Arizona State University, Phoenix, "Honest Inference from Observational Studies" November 2018.

Boston University, Boston, "Ethical Challenges in Drug Development" October 2018.

IQVIA Research Institute Forum, Boston, "Honest Inference from Observational Studies" July 2018.

Keynote Address, FDA Center for Biologics Evaluation Research Science Day, "Honest Inference from Observational Studies" June 2018.

ASA Conference on Statistical Learning and Data Science, Keynote Address, "Honest Inference from Observational Studies" June 2018.

Atlantic Causal Inference Conference, "A Bayesian approach to modeling negative controls in observational studies." CMU, May 2018.

University of Arizona, "Honest Inference from Observational Studies" April 2018.

Temple University, "Honest Inference from Observational Studies" April 2018.

CRM Montreal, Workshop on Risk Modeling, Management and Mitigation in Health Sciences, "A data-driven world: opportunities and challenges," December 2017.

Royal Society London, Workshop on the Ubiquity of Algorithms, "A data-driven world: opportunities and challenges," October 2017.

New York University, Center for Data Science, "A data-driven world: opportunities and challenges," October 2017.

Pfizer Analytics Summit, "Honest Inference from Observational Studies" October 2017.

American Express, New York, "A data-driven world: opportunities and challenges," September 2017.

IBM Watson Computational Health Summit, "Honest Inference from Observational Studies" May 2017.

IMS Spring Research Conference, Rutgers, Keynote Address, "Honest Inference from Observational Studies" May 2017.

New England Statistics Symposium, U Conn, Keynote Address, "Honest Inference from Observational Studies" April 2017.

IBM Watson, Yorktown Heights, NY, "Honest Inference from Observational Studies" March 2017.

National Academy of Sciences, Washington, DC, "Honest Inference from Observational Studies" March 2017.

University of Wisconsin, Department of Biostatistics, "Honest Inference from Observational Studies" November 2016.

Vanderbilt University, Department of Biostatistics, "Honest Inference from Observational Studies" October 2016.

Dana-Farber Reproducibility in Personalized Medicine Research Workshop, Boston, "Honest Inference from Observational Studies," September 2016.

EXPERT 2016: Trailblazers, "Large-scale Observational Healthcare Data: Promise and Peril," IUPUI, Indianapolis, September 2016.

International Society for Pharmacoepidemiology and Therapeutic Risk Management, Annual Meeting, Dublin, Ireland, August 2016.

International Chinese Statistical Association Applied Statistics Meeting, Keynote Address, Atlanta, "Honest Inference from Observational Studies" June 2016.

Trends and Innovations in Clinical Trial Statistics, Keynote Address, North Carolina, "Honest Inference from Observational Studies" May 2016.

Penn State University, Department of Statistics, "Honest Inference from Observational Studies" April 2016.

Theory of Big Data Conference, London, "Honest Inference from Observational Studies" January 2016.

University of Michigan, Department of Statistics, "Honest Inference from Observational Studies" October 2015.

ASA Connecticut Chapter, Farmington, CT, "Honest Inference from Observational Studies" April 2015.

National Academy of Sciences, Washington, DC, "Honest Inference from Observational Studies" March 2015.

NISS Affiliates Workshop, Miami FL, "Observational Studies: Lessons from OMOP and OHDSI" March 2015.

ENAR, Miami FL, "Observational Studies: Lessons from OMOP and OHDSI" March 2015.

U. Mass Medical School Grand Rounds, Worceter, MA, "Observational Studies: Lessons from OMOP and OHDSI" February 2015.

11th Global Cardiovascular Clinical Trials Forum, Washington, DC, "Honest Inference from Observational Studies" December 2014.

Duke University, Department of Statistical Science, "Honest Inference from Observational Studies" October 2014.

Good Medical Research Conference, Cooper Union, New York, "Honest Inference from Observational Studies" October 2014.

First Seattle Symposium on Healthcare Data Analytics, Group Health, Seattle, "Honest Inference from Observational Studies" September 2014.

Institute for Data Sciences and Engineering, Columbia University, "Are Observational Studies Any Good?" September 2014.

Joint Statistical Meetings, Boston, Lunch with the Speaker, "Are Observational Studies Any Good?" August 2014.

Rutgers Annual Statistics Symposium, "Are Observational Studies Any Good?" May 2014.

Keynote Address, SIAM International Conference on Data Mining, Philadelphia, "Are Observational Studies Any Good?" April 2014.

Rustagi Lecture, Ohio State University, "Calibrating Observational Studies" April 2014.

ENAR, Baltimore, "Calibrating Observational Studies" March 2014.

Stern School, New York University, "Are Observational Studies Any Good?" March 2014.

PaSiPhIC Conference, San Luis Obispo, "Are Observational Studies Any Good?" Keynote address, February 2014.

Robert Wood Johnson/Rutgers, "Are Observational Studies Any Good?" December 2013.

Pfizer Inc., New York, "The Bayesian List Machine" October 2013.

University at Buffalo, "Are Observational Studies Any Good?" October 2013.

Joint Statistical Meetings, Montreal, "The Bayesian List Machine," August 2013.

NYC R-Meetup, "Are Observational Studies Any Good?" July 2013.

IMA New Directions Summer School, University of Minnesota, June 2013.

McGill University, Department of Epidemiology, Biostatistics & Occupational Health, "Are Observational Studies Any Good?" February 2013.

Brown University, Department of Biostatistics, "Are Observational Studies Any Good?" November 2012.

Pfizer Inc., New York, "Are Observational Studies Any Good?" November 2012.

Yale University, Department of Biostatistics, "Are Observational Studies Any Good?" November 2012.

University of Montreal, Canada, "Are Observational Studies Any Good?" October 2012.

Rutgers University, Department of Statistics, "Are Observational Studies Any Good?" October 2012.

Carnegie Mellon University, Department of Statistics, "Are Observational Studies Any Good?" October 2012.

Yale University, Department of Statistics, "Are Observational Studies Any Good?" October 2012.

SAMSI Opening Workshop on Data-Driven Decisions in Healthcare, "A Predictivist Approach to Observational Analyses in Healthcare," SAMSI, August 2012.

Atlantic Causal Inference Conference, "Big-Data-Driven Medicine," Baltimore, May 2012.

Interface 2012, "Massive Parallelization of Serial Inference Algorithms for a Complex Generalized Linear Model," Houston, TX, May 2012.

IMA Meeting on User-Centered Modeling, "Big-Data-Driven Medicine," Minneapolis, May 2012.

New York City Center for Innovation Through Data Intelligence, "Big-Data-Driven Medicine," New York City, April 2012.

University of Texas at Austin, "High-Dimensional Pharmacoepidemiology," Austin TX, April 2012.

ENAR Spring Meeting, "High-Dimensional Pharmacoepidemiology," Washington DC, April 2012.

Institute of Medicine Meeting on Healthcare Data, "High-Dimensional Pharmacoepidemiology," Washington DC, March 2012.

Wharton Business School, "Statistical Methods for Drug Safety Surveillance: Big Data to the Rescue?" Philadelphia, December 2011.

New Paradigms in Clinical Trial Methodology Symposium, "Medicine meets Big Data," Research Triangle Park, NC, November 2011.

Drug Information Association Annual Meeting, "OMOP – A Summary of the Findings," Chicago, June 2011.

Drug Safety Research Unit 6th Biennial Conference - Signal Detection & Interpretation in Pharmacovigilance, London, "Signal Detection Methods," June 2011.

New York Machine Learning Meet-up, New York, "Bayesian model averaging – new tricks for an old dog," May 2011.

Café Science public lecture, New York, "How safe are your prescription drugs?" May 2011.

PhRMA/FDA Statistical Leaders Conference, Washington DC, "Bayesian methods in active surveillance," April 2011.

AcademyHealth, Electronic Data Methods Forum Symposium, Washington, DC, "OMOP Initial Findings," April 2011.

North Carolina State University, "Drug Safety", April 2011

DIA Computational Science Meeting, Washington DC, "Self-controlled methods for analyzing recurrent events in large-scale longitudinal data," March 2011.

Department of Mathematics and Statistics, Bowling Green State University, "Active Surveillane for Drug Safety," Bowling Green, OH, December 2010.

Second Annual Princeton Day of Statistics, "Active Surveillane for Drug Safety," Princeton, NJ, October 2010.

Workshop on Recent Advances in Bayesian Computation, "Big Bayesian Logistic Regression," Singapore, Septmeber 2010.

Joint Statistical Meetings, "The Observational Medical Outcomes Partnership," Vancouver, Canada, August 2010.

Sparsity Workshop, University of Bristol, "Sparse methods in drug safety," Bristol, U.K., June 2010.

Valencia 9 International Meeting on Bayesian Statistics, "Bayesian methods in pharmacovigilance," Benidorm, Spain, June 2010

CRiSM Workshop on Model Uncertainty, "Sequential Bayesian Model Averaging," Warwick, U.K., May 2010

Data Mining and Nonparametric Statistics conference, "Active Surveillane for Drug Safety," Columbus, OH, May 2010.

International Society for Pharmacoepidemiology, mid-year meeting, "Observational Medical Outcomes Partnership: Methods Update," Raleigh, NC, April 2010.

Department of Statistics, Harvard University, "Active Surveillane for Drug Safety," Cambridge, MA, March 2010.

Frontiers of Statistical Decision Making and Bayesian Analysis (in honor of Jim Berger), "Active Surveillance for Drug Safety," San Antonio, March, 2010.

American Society for Microbiology Biodefense Meeting, "A cross-species analysis of the CDC anthrax vaccine safety data," Baltimore, February, 2010.

DIMACS 20th Anniversary Conference, "Drug safety, port security, and anthrax: A DIMACS medley." New Jersey, November, 2009.

DIA 2nd Annual Conference on Signal Detection and Data Mining, "The OMOP Project." New York, November 2009.

Keynote Speaker at 11th Annual Johnson & Johnson Statistics Conference, "Post-marketing drug safety surveillance: new developments," New Jersey, October, 2009.

CDC Annual Anthrax Vaccine Research Meeting, "Correlates of protection, the bridge from animals to humans." September 2009.

Joint Statistical Meetings, "Sequential Bayesian Model Selection," Washington, DC, August 2009

IMS Medalion Lecture, WNAR Conferece, "High Dimensional Bayesian Classifiers," Portland, Oregon, June 2009.

Quality and Productivity Research Conferece, "High Dimensional Bayesian Classifiers," IBM Watson, June 2009.

Taft Competitive Lecture, University of Cincinnati, "How safe are your drugs?." May, 2009

Department of Biomedical Informatics, Columbia University, "Shrinkage methods for drug safety," New York, March 2009.

Roche Global Safety Science Meeting, "Logistic regression for drug safety," Vienna, Austria, February 2009.

Department of Statistics, Rice University, "Shrinkage methods for drug safety," Houston, TX, January 2009.

Department of Statistics, University of Illinois, "Shrinkage methods for drug safety," Champaign, IL, December 2008.

Drug Information Association Signal Detection and Data Mining workshop, "Shrinkage methods for drug safety," Washington DC, November 2008.

DIMACS Port Security Wokshop, "Efficient sequential decision making algorithms for container inspection operations," New Jersey, November 2008.

Psychiatry Institute, Columbia University, "Data mining and the drug development process: Safety," New York, September 2008.

Institute of Mathematical Statistics Annual Meeting, "High Dimensional Bayesian Classifiers," Singapore, July 2008.

International Conference on Machine Learning and Data Mining, half day tutorial, "Text Mining," Beijing, China, June 2008.

International Conference on Machine Learning and Data Mining, "Data mining and the drug development process: Safety," Beijing, China, June 2008.

International Indian Statistical Association Annual Meeting. "Data mining and the drug development process: Safety," University of Connecticut, May 2008.

10th Annual Symposium on Statistics in Psychiatry, "High-dimensional Bayesian classifiers," New York University, May 2008.

Brooklyn Law School, "Secrets of Vioxx: Lessons for Drug Safety," April 2008.

Columbia University, Department of Applied Mathematics, "High-dimensional Bayesian classifiers," April 2008.

NIH/NIAID, "Secrets of Vioxx: Lessons for Drug Safety," March 2008.

CDC Anthrax Vaccine Correlate of Protection Meeting, "Predictive modeling building for correlates of protection, " March 2008.

Tenth Annual Winter Workshop, Bayesian Model Selection and Objective Methods, University of Florida, "High-Dimensional Bayesian Classifiers," January 2008.

University of Pennsylvannia Wharton Business School, "Secrets of Vioxx: Lessons for Drug Safety in the Drug Development Process," December 2007.

University of Washington Department of Biostatistics, "Secrets of Vioxx: Lessons for Drug Safety in the Drug Development Process," November 2007.

Annual meeting of the International Society of Pharmacovigilance, Bournemouth, UK, "How to Shrink in Pharmacovigilance." October, 2007.

SIAM Conference on Mathematics for Industry, Philadelphia, PA, "Pharmacovigilance: new methods needed." October, 2007.

U. Penn Invitational Choice symposium, Philadelphia, PA, "Statistical Analysis: Bigger and Bigger," June 2007.

Midwest Biopharmaceutical Statistics Workshop, Muncie IN, "Bayesian post-marketing drug safety surveillance," May 2007.

Yale University, "Lasso Logistic Regression: Recent Developmentsm" April, 2007.

ENAR Annual Meeting, Atlanta GA, "Bayesian post-marketing drug safety surveillance," March 2007.

Duke University, "Lasso Logistic Regression: Recent Developments" November, 2006.

CDC Anthrax Vaccine Research Program Seventh Annual Investigator's Meeting, "Non-Human Primate Study," Atlanta, GA, October 2006.

UCLA Undergraduate Statistics Program, "Localization in Wireless Networks", two-day practicum, June 2006, Los Angeles.

Classification Society of North America Annual Meeting, "The Power of the Prior," May 2006, New Jersey.

Workshop on The Science of Learning and the Teaching of Math and Science, "Facet-Based Learning," May, 2006, Rutgers University.

Data Mining in Pharmacovigilence, April 2006, Pfizer, New York City

Data Mining in Pharmacovigilence, March 2006, DIA Meeting, Washington, DC

University of Chicago, "Sparse Bayesian Classification", February 2006.

Data Mining in Drug Safety, February 2006, DIMACS Workshop

Bayesian Statistics VIII, June 2006, Valencia, Invited talk. (declined due to conflict)

Drug Information Association Tutorial on Data Mining for Pharmacovigilence, Washington D.C., January 2006.

CDC Anthrax Vaccine Research Program Sixth Annual Investigator's Meeting, "Non-Human Primate Study: Interim Report," Atlanta, GA, October 2005.

NISS Workshop in Honor of Jon Kettenring, Better Data Analysis with Prior Knowledge, September 2005.

SAMSI Workshop on Homeland Scurity and National Defence, Statistical Methods for Authorship Attribution, SAMSI, September 2005.

Mitre Workshop on the Significance of Bioinformatics to National Security, Washington D.C., June 2005

Plenary Address, Graybill Conference, "Text Mining," Colorado, June 2005.

Google, New York, "Text mining," April 2005

Princeton University, "Online logistic regression," March 2005

American Statistical Association, Florida Chapter, Annual Meeting, "From Sewage to Guns: 20 Years of Statistical Consulting", February 2005.

Florida State Unversity, "The statistical analysis of text data", February 2005

MCMSki Workshop, Bormio, Italy, "Text categorization", January 2005.

M2004 SAS Data Mining Conference, "Text mining", October, 2004

Pacific Northwest National Laboratory, "Bayesian Model Selection", October, 2004

Bell Labs, "Bayesian Location Estimation", October, 2004

JSM, Toronto, "Bayesian Location Estimation", August, 2004

Bertinoro, Italy, Workshop on the Mathematics of Web Search, "Statistical Analysis of text Data", June 2004.

Wharton Business School, "Bayesian text categorization," April 2004.

DIMACS Workshop on Data Mining and Epidemiology, "Data Mining: An Overview", March 2004.

Columbia University, "Statistical methods for the analysis of textual data", September 2003.

University of Aalborg, Denmark, "Bayesian graphical models for location determination", September 2003

SAMSI, "Statistical methods for the analysis of textual data", September 2003.

ISI, Berlin, "Text Categorization", August 2003.

DIMACS Working Group on Data Mining and Epidemiology, "Analysis of Hospital Discharge Data", May 2003.

Johns Hopkins University, "Text categorization", May 2003

North Carolina State University, "Text Categorization", May 2003

Cleveland Clinic, "Graphical Markov Models", December, 2002.

IBM TJ Watson, "Text Categorization", November, 2002

Educational Testing Service, "Sequential Monte Carlo Methods for Massive Datasets", November, 2002

University of Connecticut, "Text Categorization", September, 2002

IMS Annual Meeting, Banff, Canada, "Retrieval properties of large collections," July, 2002.

IMS Annual Meeting, Banff, Canada, "Bayesian analysis of hidden Markov models," July, 2002.

Keynote Speaker, 22nd International Symposium on Forecasting, Dublin, "Bayesian analysis of hidden Markov models", June 2002.

Bayesian Statistics VII, June 2002, Valencia, Invited discussion.

Duke University, "Text Categorization", May 2002.

University of California, Irvine, "Text Categorization", April 2002.

University of Southern California, "Text Categorization", April 2002.

New York University, "Bayesian analysis of hidden Markov models", April 2002.

DIMACS Epidemiology Workshop, "Some aspects of adverse events detection." March 2002.

Temple University, "Text Categorization", April 2002.

Haifa Winter Workshop on Computer Science and Statistics, Technion, Haifa, Israel, "Bayesian Analysis of Hidden Markov Models." December, 2001.

Haifa Winter Workshop on Computer Science and Statistics, University of Haifa, Israel, "Likelihood-based Data Squashing." December, 2001.

Columbia University, Graphical Models and Bayesian Networks: A History. October, 2001.

SCILS, Rutgers University, Bayesian statistical methods for digital traces, April, 2001.

Bell Labs, Data warehousing and reporting: a case study, January, 2001.

Rutgers University, Graphical Markov Models, December, 2000.

University of Washington. Data squashing. November 2000.

Royal Statistical Society Annual Meeting, University of Reading. Graphical Models and Bayesian Networks: A History. September, 2000.

University of Chicago Business School. Data squashing. November 1999.

Joint Statistical Meetings, August 1999, Baltimore. "Bayesian data mining in large frequency tables."

UW Mathday Plenary Speaker. Data in-Garbage out: How to twist the truth with statistics. March 1999.

Bell Labs, Bayesian Model Selection. January 1999.

Seventh International Workshop on AI and Statistics, Florida. Bayesian Graphical Models, Intention-to-Treat, and the Rubin Causal Model. January, 1999.

Bayesian Statistics VI, June 1998, Valencia, Invited discussion.

Bellcore, "Bayesian Collaborative Filtering" June 1998.

Cambridge University, Statistical Laboratory, "Noncompliance in clinical trials," October 1997.

Isaac Newton Institute for Mathematical Sciences, Cambridge, UK "Bayesian model averaging," October 1997.

Trinity College Dublin, "Bayesian model averaging," October 1997.

UW/Microsoft Data Mining Institute, "Bayesian model averaging," July 1997.

KDD-97, "Graphical models," August 1997.

"The World-Wide Web as a Statistical Producer," Derry, Northern Ireland, "Statistical Analysis of Web-Generated Data," April 1997.

International Association for Statistical Computing, Pasadena, CA, "Graphical Markov Models for Chain Graphs," February 1997.

Sixth International Workshop on AI and Statistics, Florida, "Bayesian Information Retrieval," January, 1997.

Royal Statistical Society, Special Session sponsored by the Research Section, Invited Talk, "Dealing with model uncertainty," September, 1996.

ETS, Princeton, New Jersey, August 1996, "Bayesian model averaging."

Joint Statistical Meetings, August 1996, Chicago. "Bayesian information retrieval."

First European Conference on Highly Structured Stochastic Systems, Rebild, Denmark, May 1996.

INFORMS (formerly ORSA-TIMS) meeting, May 1996, Washington DC, "New developments in Bayesian model averaging."

Departments of Philosophy and Statistics, Carnegie-Mellon University, Invited talks, May 1996.

ENAR meetings, Richmond, VA, and ISDS, Duke University, "Model Selection and Averaging with Biostatistics applications," March 1996, invited.

Department of Mathematical Sciences, University of Alaska at Fairbanks, February 1996, invited.

NIPS Conference, Vail, Colerado December 1995, "Bayesian model averaging and model selection for Markov equivalence classes of acyclic digraphs"

Model Uncertainty Workshop, Bath, England, June 1995, "New developments in Bayesian model averaging."

Algebraic Methods in Multivariate Statistics, Oberwolfach, Germany, July 1995.

Workshop on Maximum Entropy and Bayesian Methods, Sante Fe, July 1995, "New developments in Bayesian model averaging."

Department of Psychology, UW, Facet-based Learning for Statistics, April, 1995

Fifth International Workshop on Artificial Intelligence and Statistics, Florida, Plenary Talk, "Test selection for graphical models," January 1995.

Department of Statistics, UW, Facet-based Learning for Statistics, December, 1994

European Conference on Hypermedia Technology, Edinburgh, Scotland, September 1994, "Repertory hypergrids: An application to clinical practice guidelines."

Bell Communications Research, August 1994, "Repertory hypergrids for hypermedia."

Bell Laboratories, August 1994, "Model Uncertainty" .

IMS Meeting, June 1994, Chapel Hill, "Computations for Bayesian graphical models."

Bayesian Statistics V, June 1994, Valencia, "Improving the predictive performance of Bayesian graphical models."

The Seventh Annual Florida Artificial Intelligence Research Symposium, May 1994. "Building Bayesian models for intelligent tutoring systems."

Joint Statistical Meetings, August 1993, San Francisco. "Accounting for Model Uncertainty."

First ACM Workshop on Multimedia in Medical Education, August 1993, Anaheim. "Multimedia tools for Cancer Pain Education."

Bayes Factors and Sensitivity Analysis Workshop, Febuary 1993, UCLA. "Bayesian graphical models."

Society for Medical Decision Making, October 1992, Portland, Oregon. "Bayesian Statistics."

Joint Statistical Meetings, August, 1992, Boston. "Model Selection and Accounting for Model Uncertainty in Graphical Models using Occam's Window."

The Second International Conference on Music Perception and Cognition, February, 1992, Los Angeles. "Development of a Data-based Expectancy Model."

Scholarly Service Activities

Scholarly Journals

Associate Editor, *International Statistical Review*, 2022-.

Associate Editor, *Harvard Data Science Review*, 2018-.

Editorial Board, *Journal of Scientific Practice and Integrity*, 2018-2023.

Member, Editorial Committee, *Annual Reviews of Statistics and its Application*, 2018-2021.

Editor-in-Chief, *Statistical Analysis and Data Mining – the ASA Data Science Journal*, 2013-2015.

Associate Editor, *Statistical Science*, 2011-2013.

Editor-in-Chief, *Statistical Science*, 2008-2010.

Editorial Board, *Therapeutic Innovation and Regulatory Science*, 2013-

Editorial Board, *International Journal of Occupational and Environmental Health*, 2012-2017

Advisory Board, Wiley Interscience Review Series (WIRES) On Data Mining And Knowledge Discovery, 2008-

Editorial Board, *Foundations and Trends in Machine Learning*, 2007-2021.

Senior Associate Editor, *Advances in Disease Surveillance*, 2005-2009.

Advisory Board, *Bayesian Analysis,* 2004-2006.

Action Editor, *Journal of Machine Learning Research*, 2003-2006.

Associate Editor, *Journal of Computational and Graphical Statistics*, 1997-2002.

Associate Editor, *Journal of the Royal Statistical Society (Series B)*, 1995-1999.

Editor of special issue of the *International Journal of Human-Computer Studies*: "Knowledge-based hypermedia," 1995.

Editorial Board for the *Handbook of Knowledge Discovery and Data Mining,* 1997-2000.

Editorial Board for the *Journal of Data Mining and Knowledge Discovery*, 1996-2004.

Professional Societies

Co-Chair, ACM-IMS Data Science Joint Venture, 2019-2021.

Chair, ASA Breiman Award Committee, 2019-2020.

Member, International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force in Enhancing the Utility of Real World Evidence for Decision Making, 2016-2017.

Charter Member, International Prize in Statistics Foundation, 2014-2017.

Publications Officer, Statistical Learning and Data Mining Section, American Statistical Association, 2014-2016.

Chair, Ad-Hoc IMS Committee to select the editor-in-chief of the *Statistical Science*, 2012.

IMS representative to the steering committee for the International Year of Statistics, 2013.

Program Chair, Statistical Learning and Data Mining Section, American Statistical Association, 2009-2010.

Chair, ISBA Constitution and Bylaws Committee, 2009-2014

Program Chair, Institute of Mathematical Statistics, 2005.

Member, Ad-Hoc IMS Committee to select the editor of the *Annals of Applied Statistics*, 2006.

Member, Ad-Hoc ISBA Committee to select the editor of *Bayesian Analysis*, 2006.

Elected Member of the ISBA Board (International Society Bayesian Analysis), 2005-2006.

Program Chair, Statistical Computing Section, American Statistical Association, 2003-2004.

Conferences

Program Chair, ACM-IMS Conference on the Foundations of Data Science (FODS-2020).

Co-Chair, Pfizer-ASA-Columbia Symposium on Risks and Opportunities of AI in Pharmaceutical Science, June 6, 2022, June 5, 2023, June 10-11, 2024, June 9-10, 2025.

Co-Chair, ACM-IMS Interdisciplinary Summit on the Foundations of Data Science, June 15, 2019, San Francisco.

Member, NAS Leveraging Randomized Designs to Generate Real World Evidence for Regulatory Purposes Planning Committee, 2019.

Member, NAS Real World Evidence Workshop Planning Committee, 2017.

Co-Organizer, Workshop on Transdisciplinary Foundations of Data Science, Institute of Mathematics and its Applications, Minnesota, September 2016.

Chair, Organizing Committee for International Year of Statistics Capstone Workshop, 2012-13.

Member, Senior Program Committee, KDD-2011.

Member, Program Committee, 2nd International Conference on Algorithmic Decision Theory, DIMACS, 2011

Co-Chair, BioSurveillance 2007: NSF BioSurveillance Workshop: Systems and Case Studies.

Student Awards Chair, KDD-2004, *The ACM SIGKDD International Conference on Knowledge Discovery and Data Mining.*

Member of the Organizing Committee for the National Syndromic Surveillance Conference, 2003, 2004.

Member of the KDD-2003, *The ACM SIGKDD International Conference on Knowledge Discovery and Data Mining,* Best Paper Award Committee, 2003.

Program Chair, KDD-1999, *The ACM SIGKDD International Conference on Knowledge Discovery and Data Mining.*

Program Chair, AISTATS-07, *Sixth International Workshop on Artificial Intelligence and Statistics*, 1997.

Member of the program committee for Association for Computing Machinery Special Interest Group on Infromation Retrieval Annual Conference (ACM SIGIR)-2002, 03, 04.

Member of the program committee for KDD-95, 96, 97, 98, 99, 00, 01, 02, & 2004 Knowledge Discovery in Databases.

Member of the program committee for UAI-95, 96, 97, 98, 99, 02, 03 & 04, the Annual Conference on Uncertainty in Artificial Intelligence.

Member of the program committee for AISTATS-95, 97, 99, 01, 03 & 05, the International Workshop on Artificial Intelligence and Statistics.

Member of the program committee for IDA-01, Intelligent Data Analysis.

Co-organizer, Worskhop on Learning in Graphical Models, NIPS, Colorado, December, 1995.

Co-Chair for Institute of Mathematical Statistics/National Science Foundation Graphical Models Summer Workshop, 1997.

Member of the program committee for Florida Artificial Intelligence Research Symposium (FLAIRS) 1996 & 1997 Uncertain Reasoning in Artificial Intelligence Track, Florida.

Government

Chair, Scientific Advisory Committee, Insight Data Science Ireland, 2020-

Member, Organizing Committee NSF Statistics at a Crossroads, 2018.

Member, NAS Committee on Applied and Theoretical Statistics, 2017-2020.

Consultant, FDA Advisory Committees, 2014-2017.

Member, FDA Advisory Committee on Drug Safety and Risk Management, 2011-2014.

NIH Panel member, Special Emphasis Panel/Scientific Review Group 2012/10 ZRG1 PSE-B (02) M, 2012.

Member, NAS-NRC Committee on Massive Data, 2010-2011.

Member, FDA Science Board – CDER sub-committee, 2010-2011.

Science Foundation Ireland Mathematics Review Panel, March, 2005, October 2005, February 2006, November 2006, March 2007.

National Science Foundation Artificial Intelligence and Cognitive Science Review Panel, 2004

National Science Foundation Statistics Review Panel, 2003, 2004, 2007

Member of the Institute of Medicine Committee to Review the CDC Anthrax Vaccine Safety and Efficacy Research Program, 2000-2002.

Other

Member, Research Committee, National Association of Sports Officials, 2019-

Member, International and Independent External Advisory Board of the Early Detection of Neurodegenerative Diseases (EDoN) initiative, 2019-2023

Member, Scientific Advisory Committee, Insight Centre for Data Analytics, 2019-

External Review Committee for the School of Computer Science and Statistics, Trinity College Dublin, February 2016.

External Review Committee for the Harvard Division of Continuing Education, February 2016.

External Review Committee for Statistics (Chair), Cornell, April 2015.

External Review Committee for Arts & Sciences (Chair), Emory University, April 2015.

External Review Committee for Statistics (Chair), Carnegie Mellon University, 2013.

Member, DIMACS Advisory Board, 2013-

Member, CCICADA Advisory Board, 2012-

Member, Advisory Board, University of Maryland "Development and Evaluation of Search Technology for Discovery of Evidence in Civil Litigation." 2011-2014.

Co-Organizer of Summer 2011 Undergraduate "Explorations in Statistics" camp, 30 students.

Member, Advisory Board, Command, Control, and Interoperability Center for Advanced Data Analysis, A Department of Homeland Security Center of Excellence, 2010-

External Review Committee for Biostatistics, Columbia University, May 2012.

External Review Committee for Statistics, Harvard University, April 2010.

External Review Committee for Statistics (Chair), Duke University, 2009.

External Review Committee for Statistics, University of North Carolina, 2008.

Editorial Board, ASA-SIAM Series on Statistics and Applied Probability, 2006-2008.

Series Editor, Chapman and Hall Computer Science and Data Analysis Series, 2002-2021.

External Examiner for PhD Dissertation of Susanne Bottcher, Aalborg University, Denmark, June 2004.

External Examiner for PhD Dissertation of Bo Thieson, Aalborg University, Denmark, September 1996.

Selected Consulting Activities

Consultant, Aris Global, 2012.

Consultant, Emergent Biosolutions, 2012-2013.

Consultant, Pharmaceutical Development Group, Inc., 2012-2020.

Consultant, DaVita Inc., 2010.

Consultant, Boehringer Ingelheim, 2010.

Consultant, Foundation for the NIH, OMOP, 2009-2013.

Consultant, CDC Anthrax Vaccine Research program, 2005-2010.

Consultant, Skarven Enterprises/Boeing, 2003-2012.

Consultant, Wyeth Pharmaceutical, 2006, 2008-09.

Consultant, Novartis Inc., 2006-2008.

Consultant, Takeda Inc., 2008, 2011, 2021-2023 (EMBOLDEN DSMB).

Consultant, Pfizer Inc., 2007-2008, 2013-14.

Advisory Board, mediGuard/Quintiles, 2007-2011.

Consultant, Adready Inc., 2008.

Consultant, Jarvik Heart Inc., 2009-2016,

Consultant, GSK Inc., 2009.

Consultant, Eli Lilly Inc., 2016-2018.

Consultant, Endo Pharmaceuticals Inc., 2016-2017.

Consultant, Merck, 2016.

Consultant, Heron Therapeutics Inc., 2018-2019.

Consultant, Shire Plc, 2018-2020.

Consultant, Bayer Inc., 2019-.

Consultant, Quest Partners, 2019-2020.

Consultant in litigation in the last four years related to Taxotere, Talc, Zostavax, Navient, Valsartan, Roundup, Lyft, and Avacopan.

PhD Committee Chairmanships

1. Jeremy C. York, Dissertation Title: " Bayesian Methods for the Analysis of Misclassified or Incomplete Multivariate Discrete Data." PhD Awarded 1992. Winner of the Savage Outstanding Dissertation Award. Currently employed at amazon.com, Seattle.
2. Jennifer Hoeting, Dissertation Title: "Accounting for Model Uncertainty in Linear Regression." PhD Awarded 1994 (joint with Adrian Raftery). Currently Professor at Colorado State University.
3. Chris Volinsky, Dissertation Title: " Bayesian Model Averaging in Censored Survival Models." PhD Awarded 1997 (joint with Adrian Raftery). Currently Professor at NYU.
4. Andrew Schaffner, Dissertation Title: "Tools for the Advancement of Undergraduate Statistics Education." PhD Awarded 1997. Currently Professor at California Polytechnic State University, San Luis Obispo.
5. Michelle Keim, Dissertation Title: "Bayesian Information Retrieval." PhD Awarded 1997. Currently employed at Detectent, San Diego.
6. Cibele daSilva, Capture-recapture methodology for bowhead whales. PhD Awarded 1999.
7. Greg Ridgeway, Learning Massive Bayesian Networks. PhD Awarded 1999. Currently Associate Professor, U. Penn.

8. Susana Eyheramendy, Text categorization. PhD Awarded 2003. Currently Professor, Department of Statistics, Pontificia Universidad Catolica de Chile.
9. Ivan Zorych, Location estimation in wireless networks, PhD Awarded 2005 (NJIT/Rutgers). Previously Research Scientist at Columbia University.
10. Aimin Feng, Bayesian methods for post-marketing drug safety surveillance, PhD Awarded 2006 Currently employed at Moderna, Inc.
11. Denise Chang, Individualized hospital report cards, PhD Awarded 2006. Currently employed at Sanofi-Aventis.
12. Suhrid Balakrishnan, Algorithms and Applications for Classifiers of Massive and Structured Data Problems, PhD Awarded 2007. Currently employed at Lionshare
13. Jerry Cheng, Bayesian Methods for Non-Standard Missing Data Probems, PhD Awarded 2010. Currently Assistant Professor at NYIT.
14. Shouhou Zhou, Bayesian Predictive Model Selection Criteria, PhD Awarded 2010. Assistant Professor, Penn State.
15. Shawn Simpson, Self-controlled methods for postmarketing drug safety surveillance in large-scale longitudinal data, PhD Awarded 2011. Currently data scientist at BlackRock Inc.
16. Zach Shahn, Methods for Personalized and Evidence Based Medicine, PhD Awarded 2015. Currently Professor at CUNY.
17. Ed Cheng, Applications of Bayesian Methods of Legal Problems, PhD Awarded 2018. Professor at Vanderbilt
18. Feihan Liu, PhD Awarded 2018. Data Scientist at Upstart Inc.

PhD Committee Memberships

UW PhD Reading Committees

Mayumi Adachi, Department of Music
Denise Draper, Department of Computer Science
Geof Givens, Department of Statistics
Steven Lewis, Department of Statistics
Heike Blossey, Department of Statistics
Jeremy York, Department of Statistics (Chair)
Jennifer Hoeting, Department of Statistics (Chair)
David Bradshaw, Department of Music
Craig Donovan, SIPhD
Dan Hershman, Department of Music
Tapas Kanungo, Department of Electrical Engineering

UW PhD Committees

Carlos Diaz Avalos, Department of Statistics
Lang Wu, Department of Statistics
Renato Assuncao, Department of Statistics
Dave Higdon, Department of Statistics
Brian Hopkins, Department of Mathematics

Shili Lin, Department of Statistics
Brian Lockyear, Department of Computer Science
Badr al Badr, Department of Electrical Engineering
Tapas Kanungo, Department of Electrical Engineering
Michael Heeley, Business School
Kyung-Im Sung, Department of Electrical Engineering

Rutgers PhD Committees

William McLoughlin, Department of Chemistry
Francis Mendez, Business School, RU Newark
Qi Xia, Department of Statistics
Pai-Hsi Huang, Department of Computer Science
Yihua Wu, Department of Computer Science
Aynur Dayanik, Department of Computer Science
Dmitriy Fradkin, Department of Computer Science
Ying Sun, School of Communication, Information and Library Studies
Jun Li, Department of Statistics
Yong Wang, Department of Genetics

Rutgers MS Committees

Saumitr Pathak, Department of Electrical and Computer Engineering

Columbia PhD Committees

Lucy Robinson, Department of Statistics
Jane Paik, Department of Statistics
Mladen Laudanovic, Department of Statistics
Ragna Haraldsdottir, Department of Statistics
Tyler McCormick, Department of Statistics
Kamiar Rahnama Rad, Department of Statistics
Pannaga Shivaswamy, Department of Computer Science
Xiaoyan Wang, Department of Biomedical Informatics
Anil Raj, Department of Applied Physics and Applied Mathematics
Ivor Cribben, Department of Statistics
Ying Liu, Department of Statistics
Maria de los Angeles Resa Juarez, Department of Statistics
Susanna Makela, Department of Statistics
David Hirschberg, Department of Statistics
Yixin Wang, Department of Statistics

Teaching

edX

Statistical Thinking for Data Science and Analytics (joint with 5 other instructors)

Columbia University

Research Design (APANKS5300), Fall 2017
Bayesian Data Analysis (ERM5580), Spring 2017
Applied Statistical Methods (W2025), Spring 2012, Spring 2013
Introduction to Statistical Methods (W3005), Fall 2012, Fall 2014, Fall 2015
Statistical Consulting, Fall 2008, Spring 2009, Fall 2009, Spring 2010, Fall 2010, Spring 2011
Data Mining, Fall 2008
Applied Statistics (G6101-2): Fall 2007 - Spring 2008.
Introduction to Statistical Reasoning (W1001): Spring 2010, Fall 2010.

Rutgers University

Bayesian Data Analysis: Fall 2002, Spring 2003, Spring 2004, Spring 2006
Data Mining: Spring 2001, Spring 2002, Fall 2003, Fall 2004.
Computing and Graphics in Applied Statistics (486): Fall 2001.
Mathematical Statistics (583): Spring 2003.
Mathematical Statistics (384): Spring 2007.

University of Washington

Introductory Statistics (311): Spring 1992, Fall 1992, Winter 1994, Spring 1995, Fall 1995, Spring 1997
Mathematical Statistics (341): Fall 1991, Winter 1991
Mathematical Statistics (342): Spring 1991
Introductory Statistics for Social Scientists (361-2): Fall-Winter 1998-9
Statistics for Engineers (390): Fall 1990, Spring 1993, Fall 1994, Winter 1995, Spring 1996
Stochastic Processes (396): Spring 1992
Mathematical Statistics (481): Fall 1993
Scientific Computing (535): Winter 1996, Winter 1997
Graphical Models (592): Fall 1991, Winter 1994, Spring 1995 (overload)
Statistical Consulting (598): Winter 1991, Fall 1992, Spring 1993

University Service

Columbia Service Activities

Member, Columbia University Institutional Conflict of Interest Committee , 2019-
Board Member, Columbia University Press, 2013-2016
Chair, Provost's Faculty Committee on Online Learning, 2012-2018
Chair, Columbia Shared Research Computing Policy Advisory Committee, 2011-2014
Executive Committee, Columbia Institute for Data Sciences and Engineering, 2012-
Member, Search Committee for Biostatistics Chair, 2012.
Member, Advisory Committee, Institute for Statistics and the Brain, 2012-
Member, Review Committee for Biostatistics Department, 2011.
Executive Committee, School of Continuing Education, 2011-2014.
Chair, Arts and Science Committee on Classroom Technology, 2011-2.
Member, Task Force on Benefits, 2010-2011.
Member, Provost's Committee on Retirement, 2011-2.
Member, Arts and Sciences Space Committee, 2009-2013.

Chair, Search Committee for Dean of the School of Continuing Education, 2008.
Ad-hoc promotion committees (2)

Rutgers Service Activities

Lecturer in workshop for high school teachers on Mathematics in Homeland Security, DIMACS, 2007.
Member of the Faculty of Arts and Sciences Transition Team, 2006.
Member of the Faculty of Arts and Sciences Budget Reduction Committee, 2005-06.
Member of the Faculty of Arts and Sciences Appointments and Promotions Committee, 2003-04.
Member of Organizing Committee for DIMACS Special Focus on Data Mining, 2001-.
Member of Organizing Committee for DIMACS Special Focus on Epidemiology, 2002-.
Co-Organizer of the DIMACS Working Group on Adverse Event and Disease Reporting, Surveillance, and Analysis.
Chair, DIMACS Associate Director Search Committee, 2005-06.
Member, Rutgers University Computer Coordinating Council, 2005-

UW Service Activities

Chair of the Department Computing Committee, 1994-1999.
MS Applied Exam Committee, 1991-1999 (chair in 1993)
PhD Applied Exam Committee, 1993 (reader in other years)
Graduate Program Director, 1998-1999
UW Advisory Board on Accountability, 1998-1999
Seminar Series on Graphical Models, 1990-1991 (with Russell Almond)
Multivariate Analysis and Graphical Models of Association (MAGMA) Seminar Series, 1993-1994, 1996 (with Michael Perlman)
Seminar Co-ordinator, 1991-1992 (including PNWSM)
Director of Consulting, 1993-1994
Mathday Lecture, 1994, 1995, 1997, & 1998
College of Arts and Sciences Distance Learning/Instructional Technology Task Force, 1996
College of Arts and Sciences Graduation Committee, 1996-1998.
UW Distinguished Teaching Award Committee, 1996 and 1997.
Chair, Review Committee for UW Math Science Computing, 1996.

Exhibit 2

David Madigan

27 Colchester Street, Brookline, MA 02446

davidbmadigan@gmail.com

Tel: (862) 812-3690

Deposition and Trial Testimony – Last Four Years

March 15, 2025

Taxotere

Taxotere Litigation, United States District Court, Eastern District of Louisiana, MDL No. 2740, Virtual, September 17th, 2021 (Deposition Testimony), New Orleans, November 16th, 2021 (Trial Testimony), New Orleans, November 14-15, 2022 (Deposition Testimony).

Talc

Plotkin v. Johnson & Johnson, Connecticut Superior Court, Bridgeport, No. CV-21-6109520-S, September 16, 2021 (Trial Testimony), June 15 & 22, 2023, May 9, 2024 (Deposition Testimony), October 4, 2024 (Trial Testimony).

Foster, March 25, 2021 (Deposition Testimony).

Casaretto v. Johnson & Johnson, Broward County, Florida, No. 18-028502, April 2, 2021 (Deposition Testimony).

McNeal v. Autozone Inc., California Superior Court, Los Angeles County, No. BC698965, April 6, 2021 (Trial Testimony).

Prudencio v. Johnson & Johnson, Superior Court of California, County of Alameda, No. RG20061303, April 19, 2021 (Deposition Testimony).

Hirschberg v. Colgate-Palmolive Co., District Court for Oklahoma County, Oklahoma, No. CJ-2018-4739, May 2, 2022 (Daubert Hearing).

Manz v. Brenntag North Am., United States District Court for the District of New Jersey, No. 18-cv-14083, June 2, 2021 (Deposition Testimony).

Pritchard, June 18, 2021 (Deposition Testimony).

Van Klive v. Johnson & Johnson, Superior Court of California, County of Alameda, No. RG 20062734, June 25, 2021 (Deposition Testimony).

Hurley v. Walgreens, Inc., Circuit Court of Illinois, Cook County, No. 2020-L-004159, June 29, 2021 (Deposition Testimony), February 16, 2023 (Trial Testimony).

Petas v. Avon Prods., Inc., Superior Court of California, County of Los Angeles, No. BC701655, August 10, 2021 (Deposition Testimony).

Doyle v. Imerys Talc America Inc., Santa Clara County Superior Court, No. 18CV333609, August 19, 2021 (Deposition Testimony).

Sandoval v. American Water Heater Company, Superior Court of California, County of Los Angeles, JCCP 4674 / BC592765, August 25, 2021 (Deposition Testimony).

Dobson v. Clark Industrial Insulation Co., Court of Common Pleas, Cuyahoga County, Ohio, No. 880333, September 8, 2021 (Deposition Testimony).

Gutierrez, October 8, 2021 (Deposition Testimony).

Moore v. Johnson & Johnson, Superior Court of California, Los Angeles County, No. 21STCV05513, November 11, 2021 (Deposition Testimony).

McLellan, April 26, 2022 (Deposition Testimony).

Hauser v. Johnson & Johnson, Superior Court of California, Los Angeles County, No. 20STCV24355, August 2, 2022 (Deposition Testimony).

Martin v. Aramis Inc., Superior Court of California, County of Los Angeles, No. 22STCV07322, October 3, 2022 (Deposition Testimony).

Egli v. Johnson & Johnson, Superior Court of California, County of Alameda, No. RG20Q75272, October 20, 2022 (Deposition Testimony).

Chapman v. Avon Prods., Inc., Superior Court of California, County of Los Angeles, No. 22STCV05968, October 31, 2022 (Trial Testimony).

Coit v. Avon Prods., Inc., Delaware Superior Court, New Castle County, No. 22M-08-202, November 11, 2022 (Deposition Testimony).

Weiss v. Albertsons Cos., Superior Court of Arizona, Maricopa County, No. CV 2021-090946, January 5, 2023 (Deposition Testimony).

Childers v. American Cast Iron Pipe Company, Circuit Court of Jefferson County, Alabama, No. CV-2020-900060, January 9, 2023 (Deposition Testimony).

Graham v. Avon Prods., Inc., Circuit Court of Oregon, County of Multnomah, No. 21CV40522, January 27, 2023 (Trial Testimony).

Regan v. Barretts Minerals, Superior Court of California, County of Los Angeles, No. 22STCV18841, January 30, 2023 (Deposition Testimony).

Anderson v. Avon Prods., Inc., Washington Superior Court, King County, No. 21-2-14042-1, February 5, 2023 (Deposition Testimony).

Dotson/Carlson v. Barretts Minerals Inc., Superior Court for the State of Washington, County of King, No. 22-2-03149-2 KNT, February 20, 2023 (Deposition Testimony).

Plant v. Avon Prods., Inc., Richland County Court of Common Pleas, South Carolina, No. 2022CP4001265, February 27, 2023 (Trial Testimony).

Dunn v. Arkema Inc., Missouri Circuit Court, No. 2122-CC09045, March 27, 2023 (Deposition Testimony).

Roby v. 3M Company, *Superior Court of the State of California, County of Los Angeles,* No. 21STCV24675, April 14, 2023 (Deposition Testimony).

Metcalf, May 17, 2023 (Deposition Testimony).

Davis v. Albertsons LLC, Alameda Superior Court, No. RG21112811, June 7, 2023 (Deposition Testimony).

Alloway v. Almay Inc. et al., Superior Court for the State of California, County of Los Angeles, No. 22STCV14241, August 28, 2023 (Deposition Testimony).

Lanzo v. Cyprus Amax Minerals Co., Superior Court of New Jersey Law Division, Middlesex County, No. Mid-L-7385-16AS, October 16, 2023 (Deposition Testimony).

Zundel v. Amerilure, Inc., Massachusetts Superior Court, Middlesex County, No. 2281CV02145, November 10, 2023 (Deposition Testimony), September 11, 2024 (Trial Testimony).

Yerkes v. Avon Prods. Inc., California Superior Court, Alameda County, No. 23CV032102; *Hofmaister v. Johnson & Johnson*, California Superior Court, Alameda County, No. 23CV033743, January 15, 2024 (Deposition Testimony).

Barkley v. Johnson & Johnson, California Superior Court, Alameda County, No. RG20066950, February 14, 2024 (Deposition Testimony).

Young v. Aventis Inc., Supreme Court of the State of New York, County of Erie, No. 815818/2020, February 22, 2024 (Deposition Testimony).

Krich v. Johnson & Johnson, California Superior Court, Los Angeles County, No. 21 STCV22952, February 25, 2024 (Deposition Testimony).

Salcedo, v. Cyprus Amax Minerals Co., Illinois Circuit Court, Cook County, No. 2020 L 004505, March 27, 2024 (Trial Testimony).

Wolfe v. Avon Prods., Inc., California Superior Court, Los Angeles County, No. 22STCV35680, April 10, 2024 (Deposition Testimony).

Clark, April 25, 2024 (Deposition Testimony), July 10, 2024 (104 Hearing).

Newton v. Johnson & Johnson, District Court, Harris County, Texas, No, 2019-67903, May 6, 2024 (Deposition Testimony).

Kyung Lee v. Johnson & Johnson, Multnomah County Courthouse, Oregon, No. 23CV400369, May 14, 2024 (Trial Testimony).

Hodge v. Avon Products Inc., Iowa District Court for Polk County, LACL 151100, May 29, 2024 (Deposition Testimony).

Perry v. American International Industries, Richland County Court of Common Pleas, South Carolina, No. 2023-CP-40-04072, July 15, 2024 (Deposition Testimony), August 7, 2024 (Trial Testimony).

Sorum v. Albertsons Cos., Superior Court of California, Alameda County, No. 23CV031203, July 29, 2024 (Deposition Testimony).

Ward v. General Electric Co., Superior Court of California, County of Alameda, No. 22CV016505, August 7, 2024 (Deposition Testimony).

Sneider v. Avon Prods., Inc., Superior Court of California, County of Los Angeles, No. 23STCV25951, August 14, 2024 (Deposition Testimony).

Cooper, August 15, 2024 (Deposition Testimony).

McBrayer v. Acme Markets, Charleston County Court of Common Pleas, South Carolina, No. 2020-CP-10-03946 September 9, 2024 (Deposition Testimony).

Doomey v. Albertsons Companies Inc., Superior Court of the State of California, County of Los Angeles, No. 21STCV47286, October 7, 2024 (Deposition Testimony).

Michaeleen Lee, November 27, 2024 (Trial Testimony).

Richards v. Johnson & Johnson, Superior Court of the State of Washington for the County of Spokane, No. 22-2-00902-32, December 23, 2024 (Deposition Testimony).

Dubois v. 3M Company, *Marion County Superior Court, Indiana,* No. 49D13-2404-CT-015028, January 7, 2025 (Deposition Testimony).

Patterson v. 4520 Corp., Inc., Court of Common Pleas for the Fifth Judicial Circuit, South Carolina, 2024-CP-40-02293, February 17, 2025 (Deposition Testimony).

Phelan v. Arkema Inc., Superior Court of Fairfield at Bridgeport, Connecticut, FBT-CV-23-6124450-S, February 21, 2025 (Deposition Testimony).

Haney v. Advance Stores Company Inc., State of Indiana, Marion County Superior Court, 49D13-2404-CT-019200, March 7, 2025 (Deposition Testimony).

Zostavax

In re Zostavax (Zoster Vaccine Live) Products Liability Litigation, United States District Court for the Eastern District of Pennsylvania, MDL No. 18-2848, Civil Action No. 2:18-md-02848, June 11th, 2021 (Deposition Testimony).

Navient

Lord Abbett Affiliated Fund, Inc. v. Navient Corp., et al., United States District Court for the District of Delaware, No. 16-112-MN, June 15th, 2021 (Deposition Testimony).

Valsartan

In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig., United States District Court for the District of New Jersey, No. 19-MD-2875, August 5th, 2021 (Deposition Testimony).

Roundup

Albanese v. Monsanto Co., St. Louis Circuit Court, Missouri, No. 1922-CC11226, October 6th, 2022 (Deposition Testimony).

Lyft

Doe, Jane v. Lyft, Inc., et al., United States District Court for the District of Kansas, No. 23-2548-JWB-TJJ, March 17th, 2023 (Deposition Testimony).

Avacopan

Homyk v. ChemoCentryx, United States District Court for the Northern District of California, No. 21-cv-03343, December 20th, 2024 (Deposition Testimony).

Exhibit 3

Fee Schedule

David B. Madigan, PhD
Statistician

(862) 812-3690
davidbennettmadigan@gmail.com

Brookline, MA 02446

- My consulting rate is $800 per hour for all activities, preparing reports, deposition, and testimony in court