

# COMMITTEE NEWS

## Toxic Torts and Environmental Law

### Chair Message

We did it again! This past April the Toxic Torts & Environmental Law Committee hosted its 27th Annual Spring CLE Conference at the iconic Arizona Biltmore Resort & Spa in Phoenix, Arizona. The conference was outstandingly successful by every measure. It highlighted the diversity of the TTEL Committee in all respects. The conference faculty included distinguished trial counsel from around the country, as well as in-house counsel, insurance professionals, experts, professors, and government decision-makers. The presentations addressed cutting-edge issues in the areas of **vaping**; the **use and abuse of science in the courtroom**; **alternative power generation**; a **frank discussion by in-house counsel** about expectations of outside lawyers; a **view from the plaintiff lawyer's perspective**; **asbestos and talc litigation**; emerging issues in **insurance coverage**; how recent **advancement in science, medicine, and genetics impact our understanding of causation**; the **anatomy of a jury deliberation in a toxic tort case**; and **ethical pitfalls** and how to avoid them.

**Edward Casmere**

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Highlights from the conference included an extremely lively in-house counsel panel discussion (moderated by TTEL Committee Diversity Subcommittee Chair **Barbara Bourgeois Ormsby**) on “how to get hired, and how to get fired” by in-house counsel; a presentation of a jury deliberation in a toxic tort trial (moderated by **Jeff Pypcznski**) featuring an in-depth analysis by the jury consultants from **DecisionQuest**; an invaluable discussion of ethical traps and pitfalls (moderated by **Rachel Tallon Reynolds**); a fascinating discussion on emerging issues in disputes in insurance coverage litigation (featuring **Kevin Clonts** and **Seth Lamden**); insights from the plaintiffs’ bar (moderated by **Phyra McCandless**); a mind-bending look at how recent advancements in science and genetics are changing or understanding of causation in toxic tort cases (moderated by **Joshua D. Lee**, and featuring **Andrew Maynard** of “Risk Bites” fame, **Len Van Zyl**, and **Gary Marchant**); and a riveting panel on the use and abuse of science in the courtroom (moderated by TTEL Newsletter Subcommittee Chair **Ann O’Connor McCready**).

Our highlighted public service project - - **Chicago’s Legal Prep Academy** ([www.legalprep.org](http://www.legalprep.org)) - - was overwhelmed with support following the presentation at our conference. The Academy’s COO and Co-Founder, Rather A. Stanton ([rstanton@legalprep.org](mailto:rstanton@legalprep.org)), asked me to extend his heartfelt thanks and appreciation for the support the conference attendees provided.

We owe a huge thank you to our conference sponsors: **Robson Forensic**; **Exponent, Inc.**; **Cardno ChemRisk**; **Center for Toxicology and Environmental Health**; **Ramboll Environ**; **RHP Risk Management, Inc.**; **Sandler Occupational Medical Associates**; and **DecisionQuest**. The 2018 Spring Conference Chair, **Leland Kellner**, deserves high praise for the brilliant program he put together. A very special thank you is owed to ABA Tort Trial & Insurance Practice Section Chair, **Holly M. Polglase**, whose leadership and guidance was invaluable this past year. **Janet Hummons** and **Felicia Stewart** made the entire conference a success, and did so with awe-inspiring grace, poise, and professionalism. There is one more individual to whom we owe the greatest debt of gratitude, **Debra Dotson**. Unfortunately, Debbie unexpectedly passed away days before the conference began this year. Words cannot adequately express how profound our loss, or how great Heaven’s gain, is with Debbie’s passing. The stars were brighter over the Arizona desert this year. Debbie will forever be in our hearts.

My term as TTEL Committee Chair is winding down, and soon **Jonathan Lively** will lead our committee onto bigger and better things. The Toxic Torts & Environmental Law Committee includes some of the most talented professionals - - plaintiff lawyers, defense lawyers, in-house lawyers, insurance professionals, consultants, and experts - - from across the country. I am grateful to count you as my friends and

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colleagues. Over the course of the last year, the TTEL Committee set out to focus on deepening the value, and broadening the benefit, we provide to our members, our profession, and our communities. Five goals guided us:

1. Provide meaningful networking, leadership, and professional development opportunities for our membership;
2. Be the primary source of education and knowledge for tort, trial, and insurance practice focused on toxic torts and environmental law issues, and elevate the quality of the discourse across the entire TTEL Bar;
3. Be a national voice for the advancement of the civil justice system;
4. Advance and support diversity in the profession; and
5. Highlight the importance of public service through leading by example.

I am happy to report that our committee delivered on all fronts, and I look forward to our continued success. Thank you for the opportunity to serve as Chair of the Toxic Torts and Environmental Law Committee for 2017 – 2018. It has been an honor and privilege working with, and for, you all. Cheers! ➤



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**Editors Message**

It is our pleasure to present the TIPS TTEL Summer Newsletter. This edition contains six articles covering a range of topics that we think will be of great interest to our readers. We are featuring articles addressing the best ways to present a good story to a jury, and the role and reliability of “peer-reviewed” literature in toxic tort and environmental litigation. We are also including an article on litigation over diabetes treatment drugs and the plaintiffs’ allegations that those incretin-based therapies created an increased risk of pancreatic cancer. This newsletter also contains an article addressing recent trends in climate change litigation and the alternative paths to addressing costs associated with climate change, and an article tackling the jurisdictional questions associated with the Clean Water Act. Finally, we have included a summary of a book recently published by a member of our committee, which provides a history and overview of environmental class actions in Canada.

We hope that you enjoy these articles and find them useful to your practice. We encourage committee members and nonmembers to submit article proposals for upcoming newsletters. Our next newsletter is set to come out next fall, but feel free to submit articles this summer for consideration for the fall newsletter. Articles must be between 1,000 and 3,000 words and must be relevant to recent legal, environmental, and/or medical developments that would be of interest to those practicing toxic tort or environmental law. Please submit any proposed articles to us via email, in Word format: [amccready@taftlaw.com](mailto:amccready@taftlaw.com) and [jbotticelli@goldbergsegalla.com](mailto:jbotticelli@goldbergsegalla.com).

We would like to thank the authors that have contributed to this edition, as well as the section members for their efforts in supporting this publication. We would also like to offer a special thanks to Committee chair, Edward Casmere, for his outstanding leadership this past year. ➤

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## Environmental Class Actions in Canada

There have been environmental class actions in Canada now for 30 years. The first class environmental class action was filed in Québec in 1988, and it involved 1,200 citizens complaining about dust that was emitted from a quarry. The case went to the merits, and the class members were awarded \$177,000 in damages after almost ten years of litigation. I recently published a book entitled *Environmental Class Actions in Canada*, in which I explored the history and outcomes of environmental class actions in this country. The following is a brief synopsis of some of the topics covered in that book, which is available from Thomson Reuters.

### Class Actions Laws in Canada

Québec was the first province to have a class action statute in 1979. Ontario followed in 1992 and British Columbia in 1996. By the early 2000, almost all the Canadian provinces had a class action law in their statute books, with the exception of the Prince Edward Island, Canada's smallest province.

### What I Aimed to Achieve in my Book

I have tried to provide the readers with an exhaustive review of all the environmental class actions in my country. I have written not only about the cases that led to a court ruling but also about the cases that were settled before or after certification.

I have organized the book by industry or by environmental issues.

### Noise

For example, I have devoted four chapters on noise class actions. There is a chapter on airport noise where I discuss past and current cases involving international and local airports, flight schools and water aerodromes.

There is one chapter on wind farm noise, another about highway noise and finally one about snowmobile noise (We are in Canada, after all!). The snowmobile noise class action is quite special. Each class member won damages in the amount of \$8,400 (\$1,200 per year for seven years) after a trial that lasted 31 days. There were between 1,000 and 1,500 persons in the class. After the court ruling, the Québec legislature adopted a law banning similar class proceedings to protect the tourist industry.

[Read more on page 19](#)

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## Incretin-Based Therapies Litigation

### I. Background on the Incretin Mimetics MDL in the U.S. District Court for the Southern District of California (San Diego), CASE#: 3:13-md-02452-AJB-MDD

The Judicial Panel on Multi-District Litigation created the MDL Incretin-Based Therapies Products Liability Litigation in 2013. The Panel selected Judge Anthony J. Battaglia, of the Southern District of California (San Diego) to preside over the consolidated litigation.<sup>1</sup>

The litigation involves four diabetes treatment drugs: Januvia, Janumet, Byetta, and Victoza. The Defendants in the litigation are the manufacturers and marketers of these four drugs and include:

- Merck Sharp & Dohme Corp.
- Amylin Pharmaceuticals
- Eli Lilly and Company
- Novo Nordisk Inc.
- H.D. Smith Wholesale Drug Co.
- Wolters Kluwer Health, Inc.

Plaintiffs claim that the Defendants failed to warn that these four prescription drugs used to treat Type 2 Diabetes cause or create an increased risk of pancreatic cancer. Their Complaint details the basis of their allegations.<sup>2</sup>

According to the American Diabetes Association, Type 2 diabetes is the most common form of diabetes. Millions of Americans have been diagnosed with Type 2 Diabetes. In Type 2 Diabetes, either the body does not produce enough insulin or the cells ignore the insulin. Insulin is necessary for the body to be able to use glucose for energy. When you eat food, the body breaks down all of the sugars and starches into glucose, which is the basic fuel for the cells in the body. Insulin takes the sugar from the blood into the cells. When glucose builds up in the blood instead of going into cells, it can lead to diabetes complications.<sup>3</sup> Type 2 diabetes mellitus is a chronic disease, characterized by insulin resistance and deficient insulin secretion leading to high blood sugar levels or “hyperglycemia,” which is the hallmark of the condition. Diabetes remains the most frequent cause of blindness, amputations and dialysis worldwide.<sup>4</sup> Current estimates are that more than 350 million patients worldwide suffer from Type 2 Diabetes<sup>5</sup> and it is considered to be one of the major health challenges of the twenty-first century.

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## Telling Good Tales

It happens too frequently.

After receiving a trial verdict or while watching mock jurors deliberate, trial counsel says, “It’s so frustrating to see this. It’s like they didn’t hear a word we said. They just don’t get it.”

Like parents struggling with teenagers (or, to be fair, teenagers looking out at the adult world), the difficult question becomes, “Why do they act that way?”

**Paul Jepsen**

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## Four Ways to Explain Why

In his book *Why?* Columbia University sociologist Charles Tilly describes four ways people explain why things happen. The four categories of reasons he identifies are: conventions (socially accepted clichés such as “I was stuck in traffic,” or “If you sign a contract you have to live with the terms of that contract”); stories (simplified cause and effect narratives); codes (legal, religious, and the like); and technical accounts (the presentation of specialized knowledge, such as a summary judgment brief).

Jurors use all four categories of reasons to decide cases.

### **Conventions**

As widely-accepted truisms, conventions can influence jury decision making. Sometimes they serve as an important first reaction to a case. Often, they are used in deliberations to dispute an opposing viewpoint. For example, many times the testimony of an expert witness is derailed in deliberations by a juror’s observation, “If you really want to, you can get statistics to say anything.”

The persuasiveness of conventions is often limited in trial by their inherent generality. “Lawyers are sneaky and dishonest” is a widely accepted convention in many places. But after a trial, most jurors favorably rate each side’s attorneys. Trial conduct, case evidence and more detailed arguments often trump simple conventions.

Conventions are also often susceptible to being turned against their original users. For example, nearly everyone agrees with conventions such as “Better safe than sorry.” But in a product-liability case, it is difficult to know which side will benefit most from such a general sentiment. Was the defendant insufficiently concerned with safety? Or, was the plaintiff too careless to benefit from the existing warning?

*[Read more on page 30](#)*



## Climate Change Lawsuits – New Theories and Old Defenses

An interesting battle currently is unfolding across the country as various parties take to the courts, ever more concerned about the mounting costs of responding to climate change-related damages and the increasingly dire predictions made by scientists as atmospheric greenhouse gas concentrations continue to increase.<sup>1</sup> Further motivating this concern is the backdrop of obvious reluctance on the part of major fossil fuel producers and the United States government to seriously address climate change. These current legal efforts have taken two separate tracks, with one set of lawsuits being filed by government entities, and another set being advanced by various groups of young Americans alleging, through various means, violations of their fundamental rights to be free of government actions that harm “life, liberty, and property” of current and future generations.<sup>2</sup>

John A. Lee  
Gregory M. McNamee

### Government Entity Climate-Change Suits

On May 9, 2018, King County in Washington State, which includes the city of Seattle, became the 13<sup>th</sup> government entity to file suit against some of the world’s largest oil and gas companies, seeking compensation for the costs of adapting to climate change in their communities, joining the City of Boulder, Boulder County, and San Miguel County, all in Colorado, along with the cities of San Francisco, Oakland, Richmond, Imperial Beach, and Santa Cruz, and the counties of San Francisco, San Mateo, and Santa Cruz, all in California, along with the City of New York. Essentially, these suits can be considered “second generation” climate change suits, which seek to hold producers of greenhouse gases responsible, based on their *production* rather than their *emissions*, for the costs that government entities are forced to expend in adapting to climate change.

Collectively, these suits take a different approach to climate change litigation, being based solely on state law claims, rather than on federal common law as in the “first generation” of previously unsuccessful suits such as *Am. Elec. Power Co., Inc. v. Connecticut*, 564 U.S. 410 (2011) (“AEP”) and *Native Village of Kivalina v. ExxonMobile Corp.*, 696 F.3d 849 (9th Cir. 2012) (“Kivalina”). Common to both of these earlier cases, plaintiffs had sought a remedy based on the defendants’ direct *emissions* of carbon dioxide, but the courts held that the Clean Air Act preempted federal common law in regards to carbon dioxide emissions (AEP) and damages caused by global warming (Kivalina). Specifically, in AEP, the Supreme Court stated that, “because the plaintiffs could petition EPA to set the power-plant emission standards that the plaintiffs’ federal common-law claims sought (and in fact had

[Read more on page 34](#)



## The Continuing Saga of the Obama- Era Waters of the United States Rule under the Clean Water Act: Proper Jurisdiction for Review

Although the Clean Water Act (CWA) has been in force since 1972, courts are still struggling with interpreting parts of the Statute. One part of the statute that has been extensively litigated is what is commonly known as a Section 404 Permit ([33 U.S.C. § 1344](#)). Section 404 regulates the discharge of dredged and fill material into “navigable waters.” The CWA defines the term “navigable waters” as “waters of the United States.” [33 U.S.C. § 1362\(7\)](#). The phrase “waters of the United States,” (WOTUS) however, was not defined. Thus, defining the phrase has been done by the agencies designated by Congress to write regulations implementing the CWA -- the Environmental Protection Agency (EPA) and the Army Corps of Engineers (ACE). While this article provides general historical and statutory information for perspective, the article focuses on the litigation regarding [33 U.S.C. § 1369\(b\)\(1\)](#), which enumerates seven categories of action by the Administrator of EPA that must be appealed directly and exclusively to federal courts of appeals. Ultimately, the issue of jurisdiction was decided by the Supreme Court in [National Association of Manufacturers v. Department of Defense et al.](#), 138 S.Ct. 617, 553 U.S. \_\_\_\_ (2018).

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*The views expressed in this article are solely those of the author and do not reflect the position of the Department of Energy.*

### The Pathway through the District and Appellate Courts

As required, EPA and ACE issued regulations shortly after the CWA was enacted. However, the current regulatory definition of WOTUS has essentially been the same since the late 1970s. Although the agencies have enacted regulations and provided guidance, there has been much litigation over the years as to the scope of WOTUS for purposes of federal jurisdiction. In fact, the Supreme Court has weighed in on multiple occasions and its rulings have been relied on by the agencies in further defining the scope of WOTUS. EPA/ACE guidance has basically tried to articulate what types of waters are considered jurisdictional based on Supreme Court precedent set out in *Rapanos v. ACE*, [547 U.S. 715 \(2006\)](#) which articulated two tests for the EPA/ACE to use in making WOTUS jurisdictional determinations. As this article focuses on interpretation of [§ 1369\(b\)\(1\)](#), a description of the *Rapanos* decision is beyond the scope of the discussion.

Most recently, under the Obama Administration In 2015, the agencies issued a new proposed rule with the intent of clarifying the scope of WOTUS subject to federal jurisdiction, as court rulings had muddled the waters regarding the public's

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## Peer-Reviewed Articles Are Facially Reliable. Not?

### I Introduction

Peer-reviewed literature can play an important role in environmental and toxic tort litigation. Such literature can be used to support causation and injury claims. Peer-reviewed studies also can influence regulatory decisions, impacting ecological and human health risk advisories, and can form the basis for establishing remediation goals. But what does it mean to be “peer-reviewed?” Are peer-reviewed papers any more reliable than non-peer-reviewed studies?

Twenty-five years ago, the *Daubert* Court found that “peer review” was one of several factors courts should consider in evaluating the admissibility of expert testimony.<sup>1</sup> This finding was based on the presumption that because peer-reviewed work is subject to scientific scrutiny, there is an increased likelihood that errors or flaws will be detected.<sup>2</sup> The problem is that “peer review” is an amorphous, unregulated label without basis in any generally-accepted set of standards. The peer review process does not guarantee the underlying research is robust or based upon sound science.<sup>3</sup> As discussed immediately below and further illustrated in the case study that follows, counsel should not assume peer-reviewed studies are conducted using sound science or are without significant flaws.

### II The Peer Review Process and Limitations

“True peer review” occurs when a scientist can replicate a test, study, or experiment and reach the same results as the proponent of the research.<sup>4</sup> Editorial peer review is a process where manuscripts undergo some level of inspection by third-parties before they are accepted for publication in a journal. The idea is to subject articles to scrutiny by others who are experts in the same field before they are published.<sup>5</sup> Peer review is intended to advance two goals—screen out poor-quality research so that it does not get published and improve the quality of manuscripts before they do get published.<sup>6</sup> Accordingly, editorial peer-reviewers are generally asked by journals to examine the validity, significance, and originality of the manuscripts submitted for publication.<sup>7</sup>

Even though editorial peer review is common practice, there is no universal standard that espouses what the process should entail. In fact, scholarly journals have different procedures dictating what peer review means.<sup>8</sup> For instance, different journals have varying requirements governing what materials must be submitted

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along with a manuscript, how many third-parties will review a manuscript, and how long the third-parties will have for that review. As a result, the quality of peer review may differ dramatically from one journal to the next,<sup>9</sup> and fall far short of “true peer review.” There is a growing body of scholarship highlighting significant flaws with the quality of the peer review process in general. For instance, The BMJ, a leading medical journal, performed several studies where “major errors” were inserted into papers that were sent out for peer review.<sup>10</sup> The experiment revealed that no reviewer identified all the errors, some reviewers did not uncover any of the errors, and most reviewers recognized only a small fraction of the errors.<sup>11</sup>

A similar experiment was performed by Harvard University science journalist John Bohannon in 2013. Dr. Bohannon submitted 304 versions of a paper he wrote under the name of a made up individual, associated with a fictitious research institution, and submitted the paper to open access journals touting themselves as “peer-reviewed journals.”<sup>12</sup> Interjected into the paper were what Dr. Bohannon described as “shortcomings” and “fatal flaws” that should have been discovered by “[a]ny reviewer with more than a high-school knowledge of chemistry and the ability to understand a basic data plot.”<sup>13</sup> Nevertheless, the paper was accepted by more than half of the journals it was submitted to, and peer review comments were only prepared relative to 36 of the 304 submissions.<sup>14</sup> Shockingly, 16 of those papers were accepted for publication notwithstanding the negative reviews.<sup>15</sup>

Further, in 2015, a cancer researcher associated with the University of Sydney, Jennifer Byrne, began to discover that numerous peer-reviewed papers describing experiments involving a gene associated with breast cancer referred to the incorrect nucleotide sequence.<sup>16</sup> Because Byrne was part of a team that cloned the gene two decades earlier, she recognized that the experiments described in the papers either did not examine what they claimed to examine, or had not been performed as described.<sup>17</sup> Byrne was troubled by this because “papers potentially reinforce each other,” and “[t]he arguments start to look more convincing because there are more and more papers that say the same thing.”<sup>18</sup>

### III. Case Study: The Jackson et al. Carolina Wren Study

In 2011, an article entitled *Mercury Exposure Affects the Reproductive Success of a Free-Living Terrestrial Songbird, The Carolina Wren (Thryothorus Ludovicianus)* (the “Carolina Wren Study” or “Study”) was published in *The Auk*, the journal of the American Ornithologists’ Union.<sup>19</sup> The authors represented that it was the first field study to document the effect of specific songbird blood mercury concentrations on breeding performance, and to make specific estimates of nesting success based upon blood mercury concentrations.



To do this, the Study reportedly monitored breeding Carolina Wrens upstream and downstream of two mercury contaminated rivers in Virginia from 2007 to 2010. The authors monitored the birds using nest boxes and natural nests. The Study did not find any significant differences in the number of fledglings between the upstream and downstream sites, but did observe a difference in nesting success due to birds abandoning more nests in the downstream aspect of the Study area. The Carolina Wren Study then used an “information-theoretic approach” with MCESTIMATE software to predict nesting success based upon specific blood mercury concentrations. For example, the authors concluded that a 10% reduction in nest success would be associated with 0.7 micrograms per gram (ug/g) of mercury in bird blood. The dose-response relationship presented in the paper has been utilized by scientists to set target acceptable risk based levels for mercury in bird blood.<sup>20</sup>

The Auk, an international peer-reviewed journal, specifies that at the time of article submission authors must upload certain information, including original and derived datasets.<sup>21</sup> Further, the journal encourages authors to deposit data in public repositories when appropriate, and to include data deposit information in the acknowledgments section of the manuscript.<sup>22</sup> The source of all data must be cited, and for author datasets, information must be provided about how the data can be accessed.<sup>23</sup>

Notwithstanding these requirements, the Carolina Wren Study model, its application to the actual data, and the analytically derived data apparently were not independently reviewed or validated prior to publication. Other scientists who have evaluated the paper have concluded that it did not provide sufficient information to replicate the modeling effort or independently assess the results, did not report complete field and laboratory data, and did not report numerical approaches selected during the modeling process.<sup>24</sup> The Study has also been critiqued on the grounds that its modeled predictions do not agree with the actual reference area nest success rates.<sup>25</sup> For example, the model predicted reference area nest success of 75-80 percent based on bird mercury blood levels between 0.2 and 0.5 mg/kg, but the actual reference area nest success was 60 percent.<sup>26</sup> In estimating success, the model used a baseline bird blood concentration of 0.0 mg/kg instead of actual baseline mercury blood concentrations of 0.2 to 0.5 mg/kg.<sup>27</sup>

Mercury scientists who reviewed the Study’s underlying data have also exposed the fact that the results were supported by a small number of samples. Sample sizes for abandoned nests in the Study area were 6 abandoned nests versus 2 in the reference area.<sup>28</sup> Further, an analysis of the data showed that the nest success rates did not differ between the Study area and reference areas in 2007 through 2009, and that nest type was a potential confounding factor.<sup>29</sup>



#### IV. Discovery of Research Data and Excluding Expert Testimony

In the future there may be software that can be used to verify accuracy of papers in certain fields of science.<sup>30</sup> In the meantime, as the Carolina Wren Study highlights, peer-reviewed studies should be approached with a discriminating eye. Counsel should familiarize themselves with the journal a piece was published in and the field of research. Reputable journals may have larger pools of potential reviewers, whereas lesser known journals may have a harder time finding qualified peer-reviewers. If the field of research is new or cutting edge, there may not be a third-party who has experience with the methodology or is able to provide a robust review of a manuscript.<sup>31</sup> It is also wise to consider what materials the peer-reviewer had access to. Some journals require that authors make underlying data available to peer-reviewers.<sup>32</sup> Reviewing data, however, is “difficult, expensive, and time consuming.”<sup>33</sup> Further, studies show that peer-reviewers spend an average of just six hours reviewing manuscripts, suggesting that they are not taking time to thoroughly evaluate underlying data.<sup>34</sup> Journals also prescribe time limits for peer review. For example, *Science* requests that peer-reviewers return comments within one to two weeks for most papers.<sup>35</sup> These tight deadlines may not be conducive to in-depth review, especially since reviewers are likely engaged full time in their own research or other institutional responsibilities.

Twenty-five years ago, the Court in *Daubert* stated that “whether a theory or technique has been subjected to peer review and publication” is a “pertinent consideration” in determining admissibility of expert testimony.<sup>36</sup> Nevertheless, the Court cautioned that publication (one component of peer review) “is not a *sine qua non* of admissibility,” “does not necessarily correlate with reliability,”<sup>37</sup> and further acknowledged that while “submission to scrutiny of the scientific community” may increase the likelihood that methodological flaws will be detected, publication in a peer review journal is “not dispositive” regarding the “scientific validity of a particular technique or methodology on which an opinion is premised.”<sup>38</sup> Thus, counsel should obtain the data underlying any studies critical to the issues presented in their case and have that data reviewed and conclusions verified by competent experts in the appropriate field—all with the goal of verifying the reliability (or exposing the unreliability) of the studies.

Underlying data can be obtained informally or through the discovery process. For instance, journals may require researchers to make data available to readers as a condition of publication.<sup>39</sup> Another avenue for obtaining these materials is through a Freedom of Information Act (FOIA) request. Federal regulations require that research data generated relating to federally-funded studies must be made available

through the FOIA.<sup>40</sup> Further, federal agencies sponsoring research may make data-sharing a condition of research funding awards.<sup>41</sup>

Demands for research data also may be made via discovery requests directed towards researchers involved in the litigation or subpoenas to third party researchers whose work has informed the opinions of expert witnesses. Researchers may try to avoid turning over data by arguing that disclosure would violate their First Amendment rights, or that disclosure would have a chilling effect on scientific research. There is limited support, however, for application of such privilege based on academic freedom under the First Amendment.<sup>42</sup> Generally, courts engage in a balancing test under [Federal Rule of Civil Procedure 26\(b\)\(2\)\(C\)](#), and consider the interest of the party requesting the research data against the researcher's interest in withholding the data, as well as the impact on the public.<sup>43</sup> When confidentiality considerations come into play, courts may order disclosure of research data under a protective order to safeguard confidential information.<sup>44</sup> Further, parties seeking to discover "pre-publication information compiled by an academic researcher must first make a *prima facie* showing that [their] 'claim of need and relevance is not frivolous.'"<sup>45</sup>

In addition to document subpoenas for research data, parties can also seek testimony of third party researchers if they can establish that there is a need for the testimony under [Federal Rule of Civil Procedure 26\(b\)\(1\)](#).<sup>46</sup> As the Supreme Court has pronounced:

[I]t has now been recognized as a fundamental maxim that the public ... has a right to every man's evidence. When we come to examine the various claims of exemption, we start with the primary assumption that there is a general duty to give what testimony one is capable of giving, and that any exemptions which may exist are distinctly exceptional, being so many derogations from a positive general rule.<sup>47</sup>

Efforts to obtain discovery of other information related to the peer review process itself (*i.e.*, a peer-reviewer's notes and analysis), however, likely fall into the category of information that will be protected from discovery.<sup>48</sup>

## V. Conclusion

Peer-reviewed literature often plays a critical role in environmental and toxic tort litigation. Because of the lack of consistent enforceable standards associated with the peer review process, not all peer-reviewed papers are scientifically reliable. Thus, counsel are well served by obtaining and evaluating underlying data for any critical studies, including "peer-reviewed" papers. ➤



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Endnotes

1 *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592-593 (1993).

2 *Id.*

3 See Nature, *Quality and value: The true purpose of peer review* (2006), available at <https://www.nature.com/nature/peerreview/debate/nature05032.html> (“[S]cientists understand that peer review per se provides only a minimal assurance of quality, and that the public conception of peer review as a stamp of authentication is far from the truth.”).

4 Effie J. Chan, *The “Brave New World” of Daubert: True Peer Review, Editorial Peer Review, and Scientific Validity*, 70 N.Y.U.L. REV. 100, 113 (1995).

5 Jacalyn Kelly, et al., *Peer review in scientific publications: benefits, critiques, & a survival guide*, 25 JOURNAL OF THE INT’L FED’N OF CLINICAL CHEMISTRY AND LAB. MEDICINE 227 (2014).

6 *Id.* at 228.

7 *Id.*

8 See Chan, *supra* note 5, at 117 (“[E]ditorial peer review remains an entirely discretionary practice of the journals”; “The practice was never universally adopted by the journals; rather, individual journals resorted to it on an ad hoc basis”; “In addition to being wholly voluntary, editorial peer review also is completely unregulated. It is not a monolith but a variegated collection of different practices”; “Members of the scientific community are well aware that the types of editorial peer review at the different scientific publications vary greatly.”). See also Richard Smith, *Peer Review: a flawed process at the heart of science and journals*, 99 JOURNAL OF THE ROYAL SOC’Y OF MEDICINE 178 (2006) (“[P]eer review is impossible to define in operational terms (an operational definition is one whereby if 50 of us looked at the same process we could all agree most of the time whether or not it was peer review).”).

9 Chan, *supra* note 4, at 117 (“[T]here is a general correlation between a journal’s prestige and the quality of its editorial peer review.”). See also Charles G. Jennings, *Quality and value: The true purpose of peer review*, NATURE (2006), available at <https://www.nature.com/nature/peerreview/debate/nature05032.html> (“It is generally understood among scientists that there is a hierarchy of journals. At the apex of the . . . pyramid stand the most prestigious multidisciplinary journals; below them is a middle tier of good discipline-specific journals with varying degrees of selectivity and specialization; and propping up the base lies a large and heterogenous collection of journals whose purviews are narrow, regional or merely unselective.”); and Steven Novella, *The Importance and Limitations of Peer-Review*, SCIENCE-BASED MEDICINE (Sept. 3, 2008), available at <https://sciencebasedmedicine.org/the-importance-and-limitations-of-peer-review/> (“Small or obscure journals may follow the rules and gain recognized peer-reviewed status, but be desperate for submissions and have a low bar for acceptance. They also have a harder time getting world-class experts to review their submissions, and have to find reviewers that are also farther down the food chain. The bottom line is that when a study is touted as ‘peer-reviewed’ you have to consider where it was reviewed and published.”).

10 Smith, *supra* note 9, at 179.

11 *Id.*

12 John Bohannon, *Who’s Afraid of Peer Review*, 342 SCIENCE 60 (2013), available at [science.sciencemag.org/content/342/6154/60.full](http://science.sciencemag.org/content/342/6154/60.full).

13 *Id.*

14 *Id.*

15 *Id.*

16 John Power, *The Cancer Researcher Catching Scientific Fraud at Rapid Speed*, THE ATLANTIC (Apr. 3, 2018), available at <https://www.theatlantic.com/science/archive/2018/04/jennifer-byrne-science-fraud/557096>; see also Kate Aubusson, *Sydney cancer scientist Jennifer Byrne named as one of 10 people who matter in science by Nature*, THE SYDNEY MORNING HERALD (Jan. 25, 2017), available at <https://www.smh.com.au/healthcare/sydney-cancer-scientist-jennifer-byrne-named-as-one-of-10-people-who-matter-in-science-by-nature-20171219-h075ma.html>.

17 Power, *supra* note 16.

18 *Id.* (internal quotation marks omitted). After making this discovery, Byrne began working with a colleague to identify additional flawed papers. This led to the creation of a software program, currently in its test phase, to extract DNA sequences referenced in papers, run them through a database, and verify that they do what the paper claims.

19 Allyson K. Jackson, et al., *Mercury Exposure Affects the Reproductive Success of a Free-Living Terrestrial Songbird, the Carolina Wren (Thryothorus Ludovicianus)*, 128 THE AUK 759 (2011).

20 See, e.g., Phyllis C. Fuchsman, et al., *Toxicity Reference Values for Methylmercury Effects on Avian Reproduction: Critical Review and Analysis*, 37 ENVTL. TOXICOLOGY AND CHEMISTRY, 294, 305 (2017) (“Several researchers have adopted the [nest success] estimates from [the Carolina Wren Study] dose-response analysis as a means of interpreting both eggs and blood Hg concentrations in a variety of bird species.”).

21 American Ornithological Society Publications, Journals Mission and Scope, [http://americanornithologypubs.org/page/mission\\_scope?code=coop-site](http://americanornithologypubs.org/page/mission_scope?code=coop-site) (last accessed May 4, 2018); American Ornithological Society Publications, Instructions for Authors, <http://americanornithologypubs.org/page/instructions> (May 4, 2018).

22 *Id.*

23 American Ornithological Society Publications, Instructions for Authors, <http://www.editorialmanager.com/auk/default.aspx> (Jan. 2018).

24 See Fuchsman, et al., *supra* note 23, at 305 (“Although it is apparent that nest success in 2010 differed between the reference and downstream areas in the [Carolina Wren Study], there are important limitations in the dose-response relationship developed from the data set. Specifically, the article does not provide sufficient detail to allow the dose-response modeling exercise to be reproduced, and the limited data presented do not agree with the model as presented.”).

25 *Id.* at 305-306.

26 *Id.*

27 *Id.*

28 *Id.* at 306.



29 Elizabeth A. Henry and Josh Murauskas, *Carolina Wren Revisited: The Challenges of Field Study*, presented at the International Conference on Mercury as a Global Pollutant (July 16-21, 2017).

30 *Supra* notes 17 – 19.

31 See Smith, *supra* note 9, at 178.

32 *Id.* at 182.

33 *Id.*

34 Kelly, et al., *supra* note 6, at 231.

35 Science, Peer Review at Science Publications, <http://www.sciencemag.org/authors/peer-review-science-publications> (last accessed May 4, 2018).

36 *Daubert*, 509 U.S. at 592-593.

37 *Id.*

38 *Id.* at 594.

39 For example, *Nature* specifies as a condition of publication that “authors are required to make materials, data and associated protocols promptly available to readers without undue qualifications” and readers who encounter refusal by authors may contact the journal. This is based on the “inherent principle of publication ... that others should be able to replicate and build upon the authors’ published claims.” Palgrave Communications, Editorial and Publishing Policies, <https://www.nature.com/palcomms/about/editorial-policies> (last accessed May 3, 2018).

40 Office of Management and Budget Circular A-110 §.36(d)(1) provides, relative to grants and agreements with institutions of high education, hospitals, and other non-profit organization, that: “[I]n response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA.” Note, however, that exemptions may apply under FOIA (i.e., confidential business information, trade secrets, privacy) as well as state public records laws, including a “balancing test” exemption (discussed at note 45 and associated text, below).

41 See National Institutes of Health, NIH Data Sharing Policy, [https://grants.nih.gov/grants/policy/data\\_sharing/](https://grants.nih.gov/grants/policy/data_sharing/) (Apr. 17, 2007) (sets forth policies for data sharing); National Science Foundation, Dissemination and Sharing of Research Results, <https://www.nsf.gov/bfa/dias/policy/dmp.jsp> (last accessed May 3, 2018) (states that “Investigators are expected to share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections and other supporting materials created or gathered in the course of work under NSF grants. Grantees are expected to encourage and facilitate such sharing.”).

42 See *In Re NCAA Student-Athlete Name & Likeness Licensing Litigation*, No. 4:12-mc-00508 JAR, 2012 WL 4856968, at \*2 (E.D. Miss. Oct. 12, 2012) (“[T]he Eight Circuit has not addressed the existence of an academic or scholar’s privilege as a defense to subpoenas calling for research data, and the majority of courts outside this Circuit that have considered this issue have declined to recognize it.”); *Smith v. Dow Chemical Co.*, 173 F.R.D. 54, 56 (W.D.N.Y. 1997) (noting that two cases from the Seventh Circuit, *Deitchman v. E.R. Squibb & Sons, Inc.* and *Dow Chemical Co. v. Allen*, recognize a qualified researcher’s privilege, principally to protect the interest of the researcher in not having the results of his or her research disclosed prematurely, but that other courts “have been less sympathetic to the recognition of the privilege.”).

43 See, e.g., *Dow Chemical Co. v. Allen*, 672 F.2d 1262 (7th Cir. 1982) (upholding denial of manufacturers administrative subpoena of notes, reports, working papers, and raw data relating to ongoing animal toxicity study in herbicide cancellation proceeding based on findings that the material was of little probative value, there was no convincing showing of need, the risk of inadvertent premature disclosure outweighed the probative value of a need for the information and constituted an unreasonable burden on the researchers, academic freedom was an appropriate consideration, and denying disclosure rather than granting a protective order was appropriate where inadvertent disclosure could jeopardize the careers and reputations of the researchers); cf. *Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556 (7th Cir. 1984) (holding that defendant drug company was entitled to some discovery of data gathered by third party researcher and requiring the district court to fashion a discovery order balancing the defendant’s need for information to present a defense against the privacy rights of the researcher; stating that when a court is confronted with motions to quash subpoenas, “its duty is not to deny any discovery, but to reduce the demand to what is reasonable, considering the discoverer’s needs and the discoverer’s problems.”).

44 See, e.g., *Deitchman*, 740 F.2d at 558-59 (requiring district court to fashion an appropriate protective order where, to establish a registry, the researcher promised to “keep confidential all information submitted to it”); *Cusumano v. Microsoft Corp.*, 162 F.3d 708 (1st Cir. 1998) (affirming that the sought-after interviews fell “along the continuum of confidentiality at a point sufficient to justify significant protection,” where certain assurances of confidentiality had been made to interviewees).

45 *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 249 F.R.D. 8, 12 (D. Mass. 2008) (quoting *Cusumano*, 162 F.3d at 714).

46 “Non-retained or involuntary experts or researchers do not have any federal statutory, case law or common law privilege which protects against their having to involuntarily share their expertise with parties in litigation.” *Anker v. G.D. Searle & Co.*, 126 F.R.D. 515, 519 (M.D.N.C. 1989) (citing *Kaufman v. Edelstein*, 539 F.2d 811, 820 (2d Cir. 1976); *Wright v. Jeep Corp.*, 547 F. Supp. 871 (E.D. Mich. 1982); *In re Snyder*, 115 F.R.D. 211 (D. Ariz. 1987)).

47 *U.S. v. Bryan*, 339 U.S. 323, 331 (1950).

48 *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 249 F.R.D. 8 (denying drug manufacturer’s motion to compel discovery of peer review comments because the probative value was limited and the journal had a significant interest in maintaining confidentiality of the peer review process, especially in light of its non-party status); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. 08 C 402, 2008 WL 4345158 (N.D. Ill. Mar. 14, 2008) (denying motion to compel production of peer review comments, analyses, and evaluations based on the lack of probative value and burden on the journals).





*Environmental... Continued from page 7*

### **Mines, Quarries, and Sandpits**

In another chapter, I talk about mines, quarries, and sandpits. In two of these cases, the mining accidents that led to the class action filing did not even take place in Canada. In one case, the accident took place in Guyana, and the local residents attempted to sue in Québec because the head office of the parent company was situated in Montréal.

In the other case, a securities class action, the spill occurred in Spain, and the lawsuit was filed in British Columbia because the head office of the parent company was in Vancouver.

### **Railroads**

I devote two chapters about railroads, one about the nuisances resulting from the operation of a marshalling yard or a suburban train, and the other about spills that have resulted from a train derailment.

### **Waste Management Operations**

Nuisances of all kinds associated with waste management operations form a considerable chapter of the book. Rendering plants and odour problems are discussed. Noise and dust resulting from truck traffic and ordinary landfill operations are reviewed.

One Québec case about a landfill that was supposed to receive only construction debris but accepted putrescible substances led the court to create the concept of “laxness” or “complacency” to find the regulators liable for poor enforcement of environmental standards.

The most well-known Canadian environmental class action, *Hollick v. City of Toronto*, began with a class action filed by John Hollick in the Superior Court of Justice of Ontario. Hollick’s action was first certified, but the City of Toronto appealed the certification order with success. The Supreme Court of Canada granted leave to appeal, and the court upheld the dismissal of the certification order on the basis that the certificate of compliance issued by the Minister of the Environment of Ontario provided for a trust fund to address small nuisance claims. This was considered a “preferable procedure,” one of the five requirements to certify a class action in Ontario and in other common law provinces, that is, all the Canadian provinces with the exception of Québec, which has a civil law system based on the laws of France (like Louisiana), and where the Code of Civil Procedure does not include a “preferable procedure” requirement.



All the common law provinces share the same basic requirements for certification:

- a) The pleadings disclose a cause of action.
- b) There is an identifiable class of two or more persons.
- c) The claims of the members raise common issues.
- d) A class proceeding would be the preferable procedure for the resolution of the common issues.
- e) There is a representative plaintiff who can represent fairly and adequately the interest of the class members.

The fact that *Hollick* did not succeed in the Supreme Court of Canada is generally considered as having had a chilling impact on the development of class actions, at least in English Canada.

### Harbors and Wharves

By contrast, in Québec, the most important environmental case, the *Alcan* case, was successful and the decision of the Court of Appeal of Québec is widely credited with having made environmental class actions a viable avenue of redress for environmental wrongs, at least in Québec.

In that case, the neighbours of the wharf owned by Alcan complained about the dust that was blown from its property onto the houses and gardens of the class members.

The authorization (the words used in the Code of Civil Procedure of Québec for certification) was not granted by the Superior Court, in accordance with the jurisprudence then in force. In a ground-breaking ruling, the Court of Appel gave a wide and liberal interpretation of the requirements that “the facts alleged must appear to satisfy the conclusions sought by the petitioner” and that “the claims of the members raise identical, similar or related questions of law or fact.” Justice Rothman, who wrote the decision of the Court, went on to say that: “[t]he class action (...) seems an obvious means for dealing with claims for compensation for the harm done when compared to numerous individual law suits, each raising many of the same issues of fact and law”. The case was eventually settled for \$2,000,000.

### Air Pollution and Depositions of Particulate Matters

The most famous Canadian environmental class action after *Hollick* is the case of *Smith v. Inco*. Neighbours of a nickel refinery complained that nickel particles had



deposited onto their houses and gardens over the course of several decades and had the effect of reducing the value of their property. The class action was certified, and the trial judge awarded \$36,000,000 to the class. Inco appealed and the Court of Appeal quashed the award. This case was, to use the famous adverb, “robustly” litigated over 12 years.

### The Moose-Vehicle Collision Class Action in Newfoundland and Labrador

Another case that went to the merits in a common law province is *George v. Newfoundland and Labrador*. The class action was certified by consent of the parties, a very rare phenomenon, and that case went to trial. The plaintiffs complained that the Province of Newfoundland and Labrador was not doing enough, signage or barriers, to prevent or reduce moose-vehicle collisions. They lost.

### Drinking Water Contamination

The Walkerton water contamination class action did not go to trial and ended with a settlement of \$17,000,000. The E.coli bacteria found its way into the drinking water system of Walkerton, in Ontario, 2300 residents became ill and caused the death of seven people.

### Cases That Went To the Merits in Québec

In Québec, nine cases went to the merits. The plaintiffs won in five cases and lost in four cases.

The biggest award for the plaintiffs was in the case *Barrette v. St. Lawrence Cement*, the only environmental class action case that went to the merits and to the Supreme Court of Canada.

The court granted an award of \$15,000,000 to the approximately 3,000 class members. The residents complained about cement dust essentially but also about odours and noise from the cement plant. Although this case was based on the civil law doctrine known as “neighbourhood annoyance doctrine,” the court held that this doctrine of neighbourhood annoyances and the tort of nuisance at common law were “analogous schemes.” Whether this means that the analysis of nuisance in the common law provinces will borrow from the Québec cases on abnormal neighbourhood disturbances is something to watch in the future.



## Catastrophic Dam Failures

There have been four cases of catastrophic dam failures. Three in Québec 25 years ago and one recently in Manitoba. The Manitoba case was settled in 2017 for the sum of \$83,281,000, and the Court approved the settlement in January 2018.

## Conclusions and Takeaways

The Supreme Court of Canada is a very liberal court, and it has repeatedly stressed the importance of environmental protection laws. It is only a matter of time before the court sends a pro-class action message to the lower courts in environmental cases.

My book has 29 chapters and it has more than 1,000 pages; I have meticulously attempted to describe the facts and procedural twists and turns of the cases as they move forward because, as every practitioner knows, facts drive the outcome in environmental cases. ➤



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*Incretin... Continued from page 8*

Januvia, Janumet, Byetta, and Victoza are supposed to help prevent complications related to this disease. The two most recently approved classes of therapeutic agents for the treatment of type 2 diabetes, glucagon-like peptide-1 (GLP-1) receptor agonists (such as Byetta and Victoza) and dipeptidyl peptidase-4 (DPP-4) inhibitors (such as Janumet and Januvia), exert their actions through potentiation of incretin receptor signaling. Incretins are gut-derived hormones, principally GLP-1 and glucose dependent insulin tropic peptide (GIP), that are secreted at low basal levels in the fasting state.

**Januvia** was approved by the Food and Drug Administration (“FDA”) on October 16, 2006 “as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus as monotherapy and in combination with metformin or a PPAR $\gamma$  agonist (e.g., thiazolidinedione) when diet and exercise plus the single agent do not provide adequate glycemic control.”<sup>6</sup>

**Janumet** was approved by the FDA on March 30, 2007 “as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin.”<sup>7</sup> Janumet is the successor of Januvia.<sup>8</sup>

**Byetta** was approved by the FDA in April of 2005 and was marketed to the medical community and general public shortly thereafter. Byetta is a member of the new class of drugs known as GLP-1 receptor agonists.

**Victoza** is manufactured by Novo Nordisk of Bagsvaerd, Denmark and was approved by the FDA on January 25, 2010. Novo Nordisk, Inc. is responsible in all respects for Victoza in the United States. Victoza is also a member of the new class of drug known as GLP-1 receptor agonists. Victoza was approved with several post-marketing requirements under the Food and Drug Administration Amendments Act (FDAAA) to ensure that the company will conduct studies to provide additional information on the safety of this product.

The FDA acknowledged the need for these post-marketing requirements after five clinical trials involving more than 3,900 people found that pancreatitis occurred more often in patients who took Victoza than in patients taking other diabetes medicines. In February 2010, concerns were published regarding the GLP-1 drugs, including Victoza and Byetta, and the DPP-4 inhibitors, including Januvia and Janumet, and their potential link with pancreatic cancer.





Writing in *DIABETES CARE*, Butler *et al.* published *GLP-1–Based Therapy for Diabetes: What You Do Not Know Can Hurt You*<sup>9</sup> stating, “History has taught us that enthusiasm for new classes of drugs, heavily promoted by the pharmaceutical companies that market them, can obscure the caution that should be exercised when the long-term consequences are unknown. Of perhaps greatest concern in the case of the GLP-1–based drugs, including GLP-1 agonists and dipeptidyl peptidase-4 (DPP-4) inhibitors, is preliminary evidence to suggest the potential risks of asymptomatic chronic pancreatitis and, with time, pancreatic cancer.”

In addition, these researchers wrote, “However, in the context of a new class of medical therapy, we feel that enough preliminary evidence has accumulated to suggest that there is a plausible risk that long-term recipients of GLP-1–based therapy may develop asymptomatic chronic pancreatitis..., and worse, subsequently a minority of individuals treated by this class of drug may develop pancreatic cancer.”

In February 2011, the journal *Gastroenterology* published on-line the work of Elashoff *et al.*<sup>10</sup> titled, *Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies*. These researchers used the FDA Adverse Event Reporting System (AERS) to assess the association between treatment with Victoza and Januvia and an adverse event report of pancreatitis, where the drugs were listed as the primary suspect associated with a pancreatitis report in the database. A secondary goal was to examine the FDA AERS database for reported pancreatic or thyroid cancer associated with use of Victoza and Januvia, with various other anti-diabetic drugs used as controls. Metformin was not used as a control drug because it has been reported to decrease the risk of pancreatic cancer.

These researchers reported that pancreatitis, inflammation of the pancreas, was >10-fold more frequently reported as an adverse event for patients administered GLP-1 class of drugs (which includes Victoza and Byetta) and >6-fold more frequently reported in patients prescribed Januvia (and other DPP-4 inhibitors, which includes Janumet). Both these associations were statistically significant.

Because pancreatitis is a known risk factor for pancreatic cancer,<sup>11</sup> Elashoff *et al.* evaluated the reported rates of pancreatic cancer with Januvia (and similar drugs) compared to control events relative to Avandia (rosiglitazone). The reported event rate for pancreatic cancer was 2.9-fold greater in patients treated with Byetta (and similar drugs in the GLP-1 class, like Victoza) compared to other therapies. The reported event rate for pancreatic cancer was 2.7- fold greater with Januvia (and similar DPP-4 drugs, like Janumet) than other therapies.



It is foreseeable that there is a progressive increased risk of pancreatic cancer with prolonged exposure to the Drugs because pancreatitis acts as a risk factor for subsequent pancreatic cancer through the mechanisms of chronic inflammation and increased cell turnover.<sup>12</sup> These researchers noted that the potential to increase the risk of cancer might be expected to occur by “permitting declaration of tumors previously held in check by an intact immune system” as has been published by others within the world’s medical literature.

On May 13, 2011, (Drug Commission of the German Medical Association - AkdÄ) published *Pancreatic cancers associated with exenatide (Byetta®)* on its website.<sup>13</sup> In the German adverse event database, reporting of pancreatic cancer was also unusually high in association with Byetta.<sup>14</sup> The period between the start of treatment with Byetta and a diagnosis of pancreatic cancer was on average 12.2 months (within a range of 2-33 months).

Some of the manufacturers of the Drugs have suggested that the most likely reason for the apparent association between the use of these Drugs and acute pancreatitis is the increased risk of pancreatitis in patients with type 2 diabetes.<sup>15</sup> However, animal studies showing pancreatitis as a consequence of GLP-1 mimetic therapy (and other incretin-based therapies) challenge that assumption and lead to the conclusion that asymptomatic chronic pancreatitis is an adverse effect of GLP-1-based treatment, which is further confirmed by specific studies as applied to sitagliptin (active ingredient in Janumet and Januvia)<sup>16</sup> and Exenatide (Byetta).<sup>17</sup> Butler *et al.*<sup>18</sup> also reported that human and rodent pancreases contain numerous GLP-1 receptors in areas in which cancer is thought to originate, and mice that are genetically predisposed to pancreatic cancer develop the disease more quickly than usual in response to Byetta.

In April 2012, Public Citizen, a non-profit consumer-advocacy organization based in Washington DC, sent a petition to the FDA to withdraw Victoza (liraglutide), a drug in the GLP-1 class, from the market. Dr. Sidney Wolfe, director of the health and research group at Public Citizen, said at that time, “We don’t just go after drugs casually...(W)e only go after drugs when there is clear evidence of unique dangers or risks, and when there is no evidence of a unique clinical advantage.”

Dr. Wolfe said at the time that his concern extends to other diabetes drugs that alter the GLP-1 pathway, which would include Januvia, Janumet and Victoza. The petition to withdraw Victoza was based on information pulled from the FDA’s adverse-event reporting database. Public Citizen counted 28 cases of pancreatic cancer reported between February 2010 and September 2011 among patients on Victoza, compared



with just one case in a patient taking a diabetes drug that does not manipulate the GLP-1 pathway.

In February 2013, the results of the first case-controlled epidemiological study looking at the Drugs and their effects upon the pancreas were published by Singh et. al out of the Johns Hopkins School of Medicine and School of Public Health.<sup>19</sup> Singh et. al used administrative claims data from the BlueCross Blue Shield Association plans of Tennessee, Hawaii, Michigan, and North Carolina; Highmark, Inc. and Independence Blue Cross of Pennsylvania; and Wellmark, Inc. of Iowa and South Dakota. They evaluated 1,269 hospitalized cases with acute pancreatitis using a validated algorithm and 1,269 control subjects matched for age category, sex, enrollment pattern, and diabetes complications. The strengths of this study include the large size of the sample, the ability to adjust for confounders, and the independence of the authors from the companies marketing the Drugs. Current use of GLP-1–based therapies within 30 days demonstrated the existence of a statistically significant adjusted Odds Ratio (OR) of 2.24 in relation to the development of acute pancreatitis. For those patients who had used the GLP-1-based therapies in the recent past 30 days, and less than 2 years, the statistically significant OR was 2.01 for the development of acute pancreatitis as compared to the odds of ‘nonusers’ of these drugs.

The results from the case-controlled epidemiological study “...support findings from the previously mechanistic studies and spontaneous reports submitted to the US Food and Drug Association that such an association may be causal.”<sup>20</sup> The import of this language - “...*such an association may be causal*” - by these epidemiologists and physicians as peer-reviewed and published in the *Journal of the American Medical Association - Internal Medicine*, one of the finest medical journals in the world, cannot be understated.

It is easy to appreciate that the increased risk of pancreatitis associated with the Drugs is of critical importance. Antecedent pancreatitis is the most common risk factor for subsequent pancreatic cancer. Analysis of the FDA adverse event reporting system, discussed *supra*, already showed a signal for pancreatic cancer with exenatide and sitagliptin by 2009, and likely, much earlier. Pancreatic cancer develops after progressive accumulation of somatic mutations leads to the formation of pancreatic intraepithelial neoplasia (PanIN) of increasing grade that, in a subset of individuals, transforms to malignant neoplasms.<sup>21</sup>



## II. Procedural history of Incretin Mimetics MDL litigation

In November 2015, the MDL Court granted Summary Judgment on preemption grounds:

Defendants have demonstrated by clear evidence that the FDA would have rejected a reference to pancreatic cancer in the product labeling during the time in which Plaintiffs' claims accrued. Plaintiffs' challenges to the FDA's conclusions regarding pancreatic cancer risk are insufficient to overcome preemption in light of the extensive regulatory history of the drugs at issue. The evidence establishes the FDA has reviewed the risk specific to Plaintiffs' claims and, after considering the totality of available scientific data, concluded a warning or other reference to that risk is unsubstantiated. Accordingly, the Court GRANTS Defendants' motion for summary judgment and DENIES Plaintiffs' cross-motion for summary judgment.

*In re Incretin-Based Therapies Prod. Liab. Litig.*, [142 F. Supp. 3d 1108, 1132 \(S.D. Cal. 2015\)](#), vacated, No. 15-56997, 2017 WL 6030735 (9th Cir. Dec. 6, 2017)

In December 2017, the Ninth Circuit vacated the Summary Judgment:

We do not decide whether the defendants met their burden under *Levine's* "clear evidence" test because we hold the district court misapplied *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012, 148 L.Ed.2d 854 (2001), in two ways: first, the district court relied on *Buckman* to impermissibly circumscribe discovery; and second, the district court relied on *Buckman* to deem the plaintiffs' newly discovered evidence "irrelevant" to the court's preemption analysis at the summary judgment stage. Either of these errors would independently warrant reversal.

*In re Incretin-Based Therapies Prod. Liab. Litig.*, No. 15-56997, [2017 WL 6030735](#), at \*1 (9th Cir. Dec. 6, 2017).

## III. Status of litigation post December 2017 Ninth Circuit decision vacating summary judgment and remanding

Cases have now returned to the MDL for discovery. At a hearing on February 27, 2018, Judge Battaglia ordered the Parties to brief, limited to 15 pages, how to proceed. Defendants want to revisit general causation and renew more appeals;



plaintiffs have argued that the court should select bellwether cases and proceed as with any other case. Discovery is continuing at the time of publication.

#### IV. Recent medical research developments since the Southern District of California's summary judgment ruling.

This class of drugs works on a particular pathway in one or both of two ways: By stimulation of target cells (and off target cells) in the pancreas to increase production of insulin and the other hormone cascades that fail in diabetes, and/or slowing the breakdown of the same stimulants, causing them to outlive their expected half-lives.

When cells are already diseased in the pancreas, as is usually the case in diabetes, that overstimulation also results in proliferation of those diseased cells which can have the first series of transcription errors leading to cancer. In the case of pancreatitis, the proliferation simply leads to blockages of the ducts.<sup>22</sup>

Cases that are likely to have the strongest chance of prevailing at trial include those who used one of the drugs at issue for a year or more. The period of time between drug use and the onset of the cancer is also an important consideration and the where the time was relatively short, the causation case is stronger. Similarly, where the plaintiff is a non-smoker the causation case is greater. Those who developed cancer following use of the drug at a younger age also strengthens the causation argument. Finally, the type of cancer must be one believed to be caused by these drugs, such as Adenocarcinoma. ➤

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#### Endnotes

- 1 MDL website: <https://www.casd.uscourts.gov/SitePages/13md2452.aspx>
- 2 The portion of the article describing the background giving rise to the litigation was taken directly from the Complaint pending in the *In re: Incretin –Based Therapies Product Liability Litigation* MDL.
- 3 <http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-type2>
- 4 *Id.*
- 5 IDF Diabetes atlas, <http://www.idf.org/diabetesatlas/5e/diabetes>.
- 6 [http://www.accessdata.fda.gov/Drugatfda\\_docs/applletter/2006/021995s000ltr.pdf](http://www.accessdata.fda.gov/Drugatfda_docs/applletter/2006/021995s000ltr.pdf)
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- 8 Drucker D, Easley Continuing, Kirkpatrick P. Sitagliptin. *Nature Reviews Drug Discovery*. Feb. 2007; 6:109-10.
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13 <http://www.akdae.de/Arzneimittelsicherheit/Bekanntgaben/Archiv/2011/20110513.html>

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15 Monami M, Lamanna C, Marchionni N, and Mannucci E. Rosiglitazone, *Risk of cancer: a metaanalysis*

16 Matveyenko AV, Dry S, Cox HI, et al. *Beneficial endocrine but adverse exocrine effects of sitagliptin in the HIP rat model of type 2 diabetes, interactions with metformin*. Diabetes 2009;58: 1604–1615.

17 Nachnani JS, Bulchandani DG, Nookala A, et al. *Biochemical and histological effects of exendin-4 (exenatide) on the rat pancreas*. Diabetologia 2009; 58:1604–1615.

18 Gier B, Matveyenko AV, Kirakossian D, et al. *Chronic GLP-1 Receptor Activation by Exendin-4 Induces Expansion of Pancreatic Duct Glands in Rats and Accelerates Formation of Dysplastic Lesions and Chronic Pancreatitis in the KrasG12D Mouse Model*. Diabetes May 2012vol. 61 no. 5 1250-1262

19 Singh S et al. *Glucagonlike Peptide 1–Based Therapies and Risk of Hospitalization for Acute Pancreatitis in Type 2 Diabetes Mellitus*. JAMA Intern Med. 2013 Feb 25;1-6. [Epub ahead of print].

20 *Id.*

21 Gier B, Butler PC. *Glucagonlike Peptide 1-Based Drugs and Pancreatitis: Clarity at Last, but what about Pancreatic Cancer?: Comment on "Glucagonlike Peptide 1-Based Therapies and Risk of Hospitalization for Acute Pancreatitis in Type 2 Diabetes Mellitus"*. JAMA Intern Med. 2013 Mar 5;1-3. doi: 10.1001/jamainternmed.2013.3374. [Epub ahead of print]

22 Michael Elashoff et al, *Pancreatitis, Pancreatic, and Thyroid Cancer With Glucagon-Like Peptide-1–Based Therapies*, GASTROENTEROLOGY 2011;141:150–156 (2011); Véronique Gigoux and Daniel Fourmy, *Acting on hormone receptors with minimal side effect on cell proliferation: a timely challenge illustrated with GLP-1R and GPER*, FRONTIERS IN ENDOCRINOLOGY (2013).

*Telling... Continued from page 9*

Conventions can be powerful persuaders, but on their own, they can be like an isolated, exposed queen on a chessboard. They are probably going to cause more problems than they solve.

### **Codes**

Used alone, codes rarely persuade jurors. For example, jurors often expect more from corporate defendants than simply meeting government standards. Sometimes, it is not necessary to exceed the speed limit to prove reckless driving. Often, jurors have formed strong verdict opinions long before the judge instructs them on the law.

Some codes are more persuasive than others. For example, getting a patent is often seen as strong evidence of validity.

But codes usually do little to change opinion; a scripture passage is rarely very persuasive to someone outside the religion. On their own, codes are more likely to reinforce than persuade.

### **Technical Accounts**

These abound in litigation, but they are rarely effective as the sole means of persuading jurors.

Often, for trial lawyers who have spent years preparing for trial — and who have come to know more about the case than anyone else on the planet — technical accounts are the primary means they use to understand and describe a case. Litigators are convinced that jurors will find technical accounts persuasive once they have assimilated them, and when they don't assimilate them at all, lawyers complain that jurors "just don't get it." In response, trial counsel sometimes makes the mistake of trying to simplify or "dumb-down." However, this strategy rarely succeeds.

Technical accounts can provide anchors for jurors to bolster their position during deliberations and can reinforce a juror's favorable opinion. But, they are rarely effective on their own in persuading jurors to adopt an argument.

For one, although most jurors are capable of understanding and using technical accounts to make and support their decisions, they simply choose not to do so. This is consistent with how people make many major life decisions. If people routinely used technical accounts to make important decisions, automakers would use radically different advertising strategies to sell cars.

Secondly, by the time jurors come to understand enough about a case to comprehend and appreciate technical accounts, they have usually already formed strong verdict-



related opinions. Cause must precede effect; under-standing of technical accounts rarely precedes opinion formation.

### **Stories**

Stories are the most common tool jurors use to perceive and explain why things have happened.

Jurors construct stories based on their predispositions and perceptions of the evidence at trial. These stories serve as powerful filters and influence how jurors experience the case and the verdict decisions they reach. For jurors deciding cases, using a story to explain why things happen is the decision-making tool most use, most of the time.

Developing a straightforward, persuasive case story is one of the most effective ways to foster a successful trial effort.

### **What Makes A Good Case Story**

It may be easier to describe what is not a story. A story is not a list of key points. It is not a summary of the important facts and evidence in a case. A recital of key case themes is not a story. Adding emotion and active words does not make a case presentation into a story. Illustrations, analogies, similes and examples, on their own, do not make a presentation into a story.

What is it that makes a presentation of information into a story? Stories have several necessary components.

- **Case stories have a beginning, a middle and an end.**

Stories start at a certain time and place. Something happens. Then, during the middle of the story, various other things happen. Decisions are made. Actions are taken. Then, a story comes to its end. Based on what has happened in the beginning and middle, a story comes to its logical, inevitable finish.

- **Case stories have a point of view.**

A story can be told in the first person, second person, or third person. It can be told in the past or present tense. But, a story must always have a discernable point of view.



- **Case Stories are scalable.**

A story can be short and simple – I came, I saw, I conquered. The story can be expanded and told over several minutes. The story can be expanded further and told for several hours. The basic story structure stays the same; the amount of information added varies.

- **Case story must involve people.**

A story must involve people who act, think, believe and move the story forward. Although, trial counsel often say so, documents cannot tell the story of a case.

- **Case stories involve conflict.**

Case stories generally involve one or more of the following three types of conflict. One is Man vs. Man — the “he said/she said” conflict of a harassment or discrimination lawsuit. Another is Man vs. Circumstances — a self-defense argument in a murder trial. The third is Man vs. Society — a class-action lawsuit against environmental damage.

Charles Tilly, in describing how stories are used to provide explanations, notes that stories are used to circumscribe time and space, limit the number of actions and actors involved, elevate the personal over the institutional and (most important for application to litigation) situate all causes “in the consciousness of the actors.”

Story creation is the primary means by which jurors understand and decide cases. Keep in mind the following “Litigator’s Miranda Warning: You have a right to a story for your case. If you do not have a story, one will be provided for you — by opposing counsel. If you present a case without a story, another story can and will be used against you.”

The more complex, dry and technical a case is, the greater the need for a simple story. It is relatively easy to posit a case story for an injured plaintiff in a product-liability case. It is more difficult — but even more important — to tell the simple case story for a complex litigation effort. Contract disputes, insurance coverage cases, patent litigation, and antitrust lawsuits are the types of cases that most need a simple case story.

Custom graphics can help tell your story. Visual images make stories more interesting. For eons, storytellers have used visual aides (“Oog and Thang are little sticks here, Mastodon is big rock there”) to add drama and clarity. Visual images also make stories more memorable; jurors recall much more of what they have seen and heard than what they only hear. Finally, visual images are

expected. Today's jurors have grown accustomed to visuals. They see them all the time, and to rephrase an old judicial ruling, "What the ear may hear, the eye now expects to see."

### The Difficult Craft of Creating a Good Story

It is difficult and time-consuming to draft, refine, and present a simple case story for a major litigation effort. The desire to present the jurors with every piece of favorable evidence and information is often a major bar to developing a simple case story. Finding sympathetic, attractive characters to populate a case story can be difficult. Accepting and revealing the dirty laundry of conflict is daunting. Consider how often direct witness examinations fail to effectively communicate a party's simple case story because all the potential conflict has been carefully edited out of the pre-planned question-and-answer script. In contrast, the conflict of cross-examination often has a memorable impact on the jurors.

Those responsible for managing litigation efforts must consistently and frequently push trial counsel, throughout the entire litigation lifecycle, to develop and refine a simple case story for every trial effort. In addition to schedules, budgets, case valuations, and risk (or opportunity) assessments, case status reports should also include recitals of your current simple case story, and the ones opponents are likely to use.

It is important to get expert help with drafting and refining the story. Few business-unit executives would ever consider launching a new product, making an acquisition, or reorganizing a unit without first conducting independent, empirical research. For similar reasons, with important litigation, counsel can use jury research to help create, refine, and test potential simple case stories. It is important to differentiate this type of story-development jury research effort from a mock trial designed to see what might happen if the case goes to trial.

Again, you have a right to a simple case story. Using a story to explain why things happened is the decision-making tool jurors use most often to decide a case.

Developing and refining a simple, persuasive case story is one of the most effective ways to help achieve courtroom success.

For jurors, it is the story that explains and helps them remember why. 



*Climate... Continued from page 10*

done so), “[t]he Act itself . . . provides a means to seek limits on the emissions of carbon dioxide from domestic powerplants—the same relief the plaintiffs seek by invoking federal common law.” See, *States’ Amicus Brief in Support of Plaintiffs’ Opposition to Motion to Dismiss, City of Oakland v. B.P. P.L.C., et al.*, 3:17-cv-6011, citing *AEP*, 564 U.S. at 425.

### Suits Filed by Young Americans

In addition to the government suits listed above, as noted above, without a lot of public awareness five law suits have been filed on behalf of various groups of young Americans alleging violations of their constitutional rights. The most well-known of these suits is *Juliana et al., v. The United States of America, et al.*, 6:15-cv-01517 (Dist. OR. 2015). In *Juliana*, 21 plaintiffs sued the President, various US Departments, the State Department, and the EPA, alleging violations of Due Process and Equal Protection enshrined in the Fifth Amendment, unenumerated rights preserved in the Ninth Amendment, and violations of the Public Trust Doctrine. As stated in relation to the Ninth Amendment, “protecting the vital natural systems of our nation for present and future generations is fundamental to our scheme of ordered liberty.” *Juliana First Amended Complaint*, ¶303.

Although these disparate suits employ different legal strategies to reach relatively similar goals, both within the suits and in comparison to the *Kivalina* and *AEP* suits, i.e., fashioning some remedy and holding someone accountable for current and future damages related to the increasingly apparent effects of climate change, the legal arguments deployed in opposition by the sued entities, both private and public, are remarkably similar, being based on the arguments used in the *Kivalina* and *AEP* suits.

### Background: Kivalina and AEP

The small village of Kivalina, situated on a barrier reef on the northwest coast of Alaska, increasingly found itself during the 1990s and early 2000s subject to increasingly severe erosion as a result of rising seas and depletion of protective sea ice during the winter season. In response, in what is widely believed to be the first lawsuit relating to damage caused by global warming, the residents of Kivalina, Alaska filed suit against 24 energy companies in 2008 in the Northern District of California, seeking \$95 to \$400 million in damages to relocate their village.<sup>3</sup>

Kivalina’s theory of recovery was grounded in the fundamental science of global warming, that the increased production of carbon dioxide by energy companies had caused atmospheric temperatures to rise, the oceans to warm, sea ice to melt, and sea levels to rise due to thermal expansion of the water. Believing the





24 oil, power and utility companies were responsible for the increased amount of carbon dioxide in the atmosphere, Kivalina filed suit against them on a theory of public nuisance based in federal common law. Specifically, Kivalina alleged that the energy companies' contributions to global warming constituted a substantial and unreasonable interference with public rights, including the rights to use and enjoy public and private property in the Village of Kivalina.

The defendants successfully moved to dismiss the lawsuit on two separate grounds. First, the District Court held it lacked subject matter jurisdiction because the allegations constituted a non-justiciable political question: in order to resolve the claims, the District Court would have to determine the point at which greenhouse gas emissions become excessive, without any guidance from the executive or legislative branches. Second, the District Court held that Kivalina lacked standing due to Kivalina's inability to demonstrate either a "substantial likelihood" that defendants' conducted caused Kivalina's injury or that the "seed" of the injury could be traced to any of the defendants.

Kivalina appealed to the Ninth Circuit Court of Appeals, which affirmed the ruling, albeit on different grounds. While the District Court's ruling was on appeal, however, the Supreme Court in *AEP*, held that the Clean Air Act and the EPA's corresponding regulatory authority displaced plaintiff's ability to seek abatement of power plant emissions under a theory of federal common law. Referring to that decision, the Ninth Circuit stated that "[t]he Supreme Court has already determined that Congress has directly addressed the issue of domestic greenhouse gas emissions from stationary sources and therefore displaced federal common law." *Kivalina*, 696 F.3d at 856.

Even though the residents were not seeking *abatement* of emissions as in *AEP*, but rather damages for harm caused by *past* emissions, nevertheless, the Ninth Circuit relied on Supreme Court precedent in holding that the type of remedy asserted is not relevant to the applicability of the doctrine of displacement. The Ninth Circuit found that the field had been made the subject of comprehensive legislation by Congress, displacing any federal common law public nuisance action. The lawsuit's dismissal was therefore affirmed, with the Supreme Court eventually denying the writ of certiorari.

### Legal Arguments in the Government Suits

The San Francisco and Oakland suits assert causes of action that narrowly focus on public and private nuisance, first put forward under state law and then, in response to the February 28, 2017 ruling by the federal court judge currently overseeing the Oakland and San Francisco suits in response to the municipalities'



efforts to have the cases remanded to state court (the cases having previously been removed to federal court by the defendants), recast under both federal common law and state law.<sup>4</sup>

In support of its contention that federal common law might be the appropriate vehicle to address the merits of the Oakland and San Francisco suits, the court took a decidedly “big picture” view of climate change, noting that plaintiffs’ nuisance claims address the “national and international geophysical phenomenon of global warming.” *Order on Remand*, pg. 3. Specifically, the court stated that:

[t]aking the complaints at face value, the scope of the worldwide predicament demands the most comprehensive view available, which in our American court system means our federal courts and our federal common law. A patchwork of fifty different answers to the same fundamental global issue would be unworkable. *Id.*

The city of New York takes a similar approach, basing its causes of action on state claims of public and private nuisance, but adding a count alleging trespass.

In contrast, the suits filed by the cities of Richmond, San Mateo, and Boulder undertake a more interesting and expansive legal attack against the defendant industries by adding products liability-type claims in addition to the nuisance and trespass claims found in the San Francisco, Oakland, and New York suits. Specifically, in addition to public and private nuisance, and trespass claims on behalf of San Mateo County and the People of California, the complaint adds: strict liability – failure to warn; strict liability – design defect; and negligence – failure to warn. The liability claims are based on allegations that the defendants “heavily marketed, promoted, and advertised” fossil fuel products that “presented and still present a substantial risk of injury,” while “fail[ing] to adequately warn customers, consumers, elected officials and regulators of known and foreseeable risk of climate change and the consequences that inevitable follow from *the normal, intended use and foreseeable misuse of Defendants’ fossil fuel products.*” (emphasis added)<sup>5</sup> Boulder adds claims asserting unjust enrichment and violations of the Colorado Consumer Protection Act ([Col. Rev. Stat § 6-1-105\(1\)](#), *et. seq.*)

Given that all these actions are based on the energy producers’ fossil fuel *production*, adding product liability-type claims would appear to be a logical choice, both in support of the underlying argument – that the product when used as intended leads to changes in the global climate system that results in the damages experienced by the cities – as well as in refuting the legal arguments put forward by the corporate defendants in these suits.



In this context, all the suits, whether including explicit product liability arguments or not, essentially follow a similar path that naturally leads to these arguments. For example, all the suits first address the reality of climate change and how the altered weather patterns that are symptomatic of that change produce the local injury for which the specific city is seeking a remedy – for San Francisco, Oakland, and New York, coastal flooding of low-lying areas, increased shoreline erosion, and damaged coastal buildings and infrastructure, while for Boulder, increased drought, decreased snowpack, and an increase in wildfire danger. The suits then connect the production of fossil fuels with the producers' knowledge and actions. For example, all the suits allege some version of the following: (1) Defendants have produced massive amounts of fossil fuels for many years; (2) they have done so despite knowing since at least the late 1970s and early 1980s that massive fossil fuel usage would cause dangerous global warming; (3) Defendants continue to engage in massive fossil fuel production and execute long-term business plans to continue and even expand their fossil fuel production for decades into the future; and (4) Defendants engaged in large-scale, sophisticated advertising and communications campaigns to promote pervasive fossil fuel usage and to portray fossil fuels as environmentally responsible and essential to human well-being – even as they knew that their fossil fuels would contribute, and subsequently were contributing, to dangerous global warming.<sup>6</sup>

These allegations put the complaints fully in the nuisance camp, but also completely in the products liability camp (think asbestos and industrial talc – useful products with harmful results and industries that allegedly were aware of the danger.)

The fossil fuel producers' legal response, however, goes directly through *Kivalina* and *AEP*. For example, in the San Francisco and Oakland matters, defendants moved, both collectively and individually, to dismiss the suits, while amicus briefs were filed on their behalf by the United States and the Attorneys General of 15 states.<sup>7</sup> The arguments in all these briefs cite heavily to the *Kivalina* and *AEP* matters arguing, for example, that:

- “Congress has displaced Plaintiffs’ federal common law claims based on domestic activities by “speak[ing] directly to the question at issue,” (*citing to AEP* at 424,) and federal common law principles do not grant Plaintiffs a cause of action for foreign activities”;
- “Plaintiffs seek to evade *AEP* and *Kivalina* by “fixat[ing] on an earlier moment in the train of industry, the earlier moment of production and sale of fossil fuels, not their combustion”; and
- “Plaintiffs do not assert that the mere extraction or sale of fossil fuels created the alleged nuisance, but rather that the *combustion* of fossil fuels by third-



party users—such as Plaintiffs themselves—causes global warming and rising seas. (*citing AEP and Kivalina*).”<sup>8</sup>

Essentially, the Defendant fossil fuel producers brushed aside Plaintiffs’ attempts to reframe the climate change legal debate as one of *production* rather than *emission*, instead arguing that the issue really is one of *emission*, and that the courts already have decided this argument in their favor in *Kivalina* and *AEP*.

### The San Francisco and Oakland Suits are Dismissed

Despite the novel approach taken by San Francisco and Oakland, both suits were dismissed on June 25, 2018, falling victim to the same reasoning that governed the outcomes in the *AEP* and *Kivalina* suits – preemption - bringing an end, *at least temporarily*, to two of the fourteen second-generation climate change lawsuits, and essentially punting the issue back to a federal government that currently shows very little interest in addressing climate change. In reaching this decision, however, the judge made sure to point out that “the issue is not over science” but “is a legal one — whether these producers of fossil fuels should pay for anticipated harm that will eventually flow from a rise in sea level.” *Dismissal Order*, at 6.

To decide whether the suits should be dismissed, the court first examined whether the common law tort of nuisance could be applied in the climate change context, looking to Section 821B of the Restatement of Torts, which provides three tests to determine whether an interference with a public right is unreasonable. *Dismissal Order*, at 6. In this context, the court recast the issue as one of “fairness”:

Without those fuels, virtually all of our monumental progress would have been impossible. All of us have benefitted. Having reaped the benefit of that historic progress, would it really be fair to now ignore our own responsibility in the use of fossil fuels and place the blame for global warming on those who supplied what we demanded? Is it really fair, in light of those benefits, to say that the sale of fossil fuels was unreasonable?

*Id.* at 8.

The court next applied the *Kivalina* and *AEP* decisions, questioning whether the distinction between the *emission* and *production* of fossil fuels is “enough to avoid displacement under *AEP* and *Kivalina*?” *Id.* The court recognized, however, that the San Francisco and Oakland suits “added another dimension not addressed in *AEP* or *Kivalina*, namely that the conduct and emissions contributing to the nuisance arise *outside* the United States, although their ill effects reach *within* the United



States.” *Id.* Nevertheless, the court decided that, “[t]hese claims are foreclosed by the need for federal courts to defer to the legislative and executive branches when it comes to such international problems.” *Id.* Continuing, the judge invoked the “the presumption against extraterritoriality” in employing reasoning straight out of *AEP* and *Kivalina*, stating,

[q]uestions of how to appropriately balance [the] worldwide negatives against the worldwide positives of the energy itself, and of how to allocate the pluses and minuses among the nations of the world, demand the expertise of our environmental agencies, our diplomats, our Executive, and at least the Senate. Nuisance suits in various United States judicial districts regarding conduct worldwide are far less likely to solve the problem and, indeed, could interfere with reaching a worldwide consensus.

*Id.*, at 12.

The court is correct that the issues raised in the San Francisco and Oakland suits address issues international in their scope. His reliance, however, on the Executive and Legislative branches to provide the sole remedy, given the current makeup, essentially abdicates a needed engagement by the judiciary. As this decision likely will be appealed, the last word on these suits has yet to be written. If, however, the other climate change suits meet the same fate, climate change litigation might have to reinvent itself for a third time, or else follow the *Juliana* model. In any event, given the increasing effects and costs related to climate change, this issue is not going away. ➤

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## Endnotes

1 Latest CO<sub>2</sub> concentrations can be found at: <https://www.co2.earth/daily-co2>.

2 Rights-based climate law suits have been filed in Alaska, Colorado, Florida, Massachusetts, Oregon, and Washington.

3 *Kivalina*, 696 F.3d at 849 (9th Cir. 2012)

4 See, *First Amended Complaint for Public Nuisance*, filed by both the cities of Oakland and San Francisco on April 4, 2018.

5 See, e.g., *San Mateo Complaint*, ¶¶ 206-208, 211.

6 See, *First Amended Complaint for Public Nuisance*, filed by San Francisco, ¶¶ 1-5.

7 See, *Amicus Brief of Indiana and Fourteen Other States in Support of Dismissal*; *Amicus Curiae Brief of United States of America in Support of Dismissal*. In response, the Attorneys General of California, New Jersey, and Washington filed an Amicus Brief in support of the Cities’ arguments – See, *States’ Amicus Brief in Support of Plaintiffs’ Opposition to Motion to Dismiss*.

8 See, *Defendants’ Motion to Dismiss*, filed March 20, 2018, pp. 1-3.



*Continuing Saga... Continued from page 11*

understanding of what types of water sources were federally regulated. This proposed rule, however, differed from prior rules because the agencies drafted the rule relying on a comprehensive report prepared by the EPA's Office of Research and Development entitled "Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence." This publication evaluated the best available peer-reviewed science on water connectivity, such as to meet the definition of WOTUS after the Supreme Court cases. After receiving over a million comments, the rule became final on June 29, 2015, and was effective on August 28, 2015. See [80 Fed. Reg. 37053-37127](#).

At this point, multiple plaintiffs brought suit against the agencies arguing that the scope of the new WOTUS rule was beyond what was allowed under the CWA through interpretation by the Supreme Court. In order to promote efficiency, the Government requested that all of the cases be consolidated and transferred to a single district court. The Judicial Panel on Multidistrict (JPML) denied this motion. As a preemptive measure, several plaintiffs also filed "protective" petitions for review at various courts of appeals to preserve their challenges in the event that the district court cases were dismissed. The JPML subsequently consolidated these cases and transferred them to the Sixth Circuit Court of Appeals. Thereafter, the Sixth Circuit issued a nationwide stay of the WOTUS rule.

Parallel litigation at the district court level continued; several courts dismissed the cases concluding that federal appellate courts had exclusive jurisdiction over challenges to the WOTUS Rule. One district court ruled that it had jurisdiction. Meanwhile, in the Sixth Circuit, several parties, including the National Association of Manufacturers moved to dismiss for lack of jurisdiction. The Sixth Circuit denied the motions to dismiss, issuing three separate opinions. *In re Department of Defense*, [817 F.3d 261 \(2016\)](#). Rehearing en banc was denied. Due to the confusion as to proper jurisdiction for challenging the WOTUS Rule, the Supreme Court granted certiorari and in a unanimous opinion written by Justice Sotomayor, reversed the Sixth Circuit's holding.

During the course of the aforementioned litigation, a significant change occurred. The American people elected Donald J. Trump as President of the United States. One of the early initiatives of the Trump administration was regulatory reform. On February 28, 2017, the President issued [Executive Order 13778](#) directing the agencies to propose a rule rescinding or revising the WOTUS Rule. [82 Fed. Reg. 12497](#). On July 27, 2017, the agencies issued a proposed rule rescinding the Obama WOTUS rule and reviving the regulatory definition of WOTUS pre-2015. [82 Fed. Reg. 34899](#). In November of 2017, however, the agencies issued a second proposed





rule establishing a new effective date for the 2015 WOTUS rule, which originally had an effective date of August 28, 2015, as noted above. The agencies noted that the text of the CFR did not include an applicability date, so the agencies proposed to modify the text to add a new applicability date. Until the new applicability date, the agencies could continue to operate at the status quo, as they had been operating as of the Sixth Circuit's stay of the [2015 Rule](#). [82 Fed. Reg. 55542](#). Thus, the Supreme Court found that the issue of jurisdiction was not moot because the "WOTUS Rule remain[ed] on the books for now." *NAM*, 553 US \_\_\_\_, n.5.

### Final Stop: The US Supreme Court

As described previously, [§ 1369\(b\)\(1\)](#) enumerates seven categories of action by the Administrator of EPA that must be appealed directly and exclusively to federal courts of appeal. However, only two subparagraphs of [§ 1369\(b\)\(1\)](#) were at issue in this case, those being Subparagraphs E and F. Subparagraph E states that review of an administrator's action "in approving or promulgating any effluent limitation or other limitation under section 1311, 1312, 1316, or 1345" of Title 33 takes place in federal courts of appeals. Subparagraph F states that review "in issuing or denying any permit under section 1342 of Title 33 (National Pollutant Discharge Elimination System Permit) likewise also confers original and exclusive jurisdiction in a federal court of appeal. Throughout the course of the litigation, the Government took the position that litigation pertaining to the WOTUS Rule should be heard at the federal court of appeal level.

With respect to Subparagraph E, the Government argued that the agencies' action in issuing the WOTUS Rule qualifies as an action promulgating or approving an "other limitation" under Section 1311 because the WOTUS Rule establishes the geographic scope of limitations promulgated under Section 1311. In analyzing the argument, the Court first noted that the WOTUS Rule is not an "effluent limitation," as defined by the CWA as "any restriction . . . on quantities, rates, and concentrations of pollutants that are "discharged from point sources into navigable waters." [33 U.S.C § 1362\(11\)](#). The Court found that the WOTUS Rule was not such a limitation, but rather a regulatory definition for a statutory term that establishes the "geographic scope of limitations promulgated under § 1311."

The Government further asserted that Subparagraph E covers any "any effluent limitation or other limitation." The Court noted that the Government's interpretation word "any" cannot expand the phrase "other limitation" because to do so would effectively read out of the Statute the words "effluent limitation or other."



Failing to convince the Court that Subparagraph E confers original jurisdiction at courts of appeals on challenges to the WOTUS Rule, the Government next asserted that [Subparagraph F of § 1369 \(b\)\(1\)](#) requires original and exclusive jurisdiction for challenges to the WOTUS Rule. As noted above, Subparagraph F confers original and exclusive jurisdiction to appellate courts on issuing or denying NPDES permits. The Court dismissed the argument, stating that because the language of the Statute was unambiguous, the inquiry ends. (citing [Bedroc Limited LLC v. US](#), 541 US 176, 183 (2004) plurality opinion).

The Government then urged the Court to follow [Crown Simpson Pulp Co., v. Costle](#), 445 U.S. 193 (1980) (per curium), which allows a statutory inquiry to be broadened by applying the “functional interpretive approach” in finding that jurisdiction lies with courts of appeal. The “functional interpretive approach” directs courts to ask whether agency actions are “functionally similar” to permit issuances or denials. The Government argued that the WOTUS Rule is “functionally similar” to issuing or denying a permit because it establishes the geographical boundaries of EPA’s permitting authority and thereby dictates whether a permit is or is not issued.

The Court rejected this argument, finding that while the WOTUS Rule may define a jurisdictional prerequisite to the issuance of a permit, the Rule itself makes no decision on individual permit applications. Thus, the [Crown Simpson](#) case was not applicable to the facts of this case because [Crown Simpson](#) addressed jurisdiction with respect to an EPA rejection of a state-issued permit, which essentially was the denial of a NPDES permit, and thus that case was appropriately heard at the court of appeal.

Failing to persuade the Court based on statutory construction, the Government resorted to making policy arguments in convincing the court to rule in its favor. First, it asserted allowing original and exclusive jurisdiction for challenges to Administrator actions such as challenges to rules would avoid an irrational, bifurcated system of review because courts of appeals would review actions denying or issuing permits, whereas district courts would review regulations governing those actions. The Court held that the statutory language was clear and that the judicial review scheme is no more irrational than Congressional intent to require circuit courts to review individual NPDES permitting decisions and require district courts to hear challenges to [§ 1344](#) permits (permits for dredging and filling).

Next, the Government asserted that immediate appellate court review would facilitate quick and orderly resolution to issues regarding the WOTUS Rule. Acknowledging that review at the appellate court level would be more efficient, the Court noted that if efficiency was the greatest concern of Congress, it could have all authorized direct



circuit court review of all nationally applicable regulations, as was done in the Clean Air Act ([42 U.S.C. § 7607 \(b\)\(1\)](#)).

Third, the Government argued that allowing original jurisdiction for challenges to the WOTUS Rule at courts of appeals establishes national uniformity. Once again, the Court found that the clear language of [§ 1369\(b\)](#) makes clear that Congress intended review at the court of appeals level for only those the seven areas articulated.

In a final attempt to convince the Court that challenges to the WOTUS Rule must be heard at courts of appeal, the Government argued that the Court should take heed of the presumption favoring court of appeals review of administrative actions. In response to that argument, the Court again found that that consideration did not outweigh the statutory language of Subparagraphs E and F which clearly indicated Congress' intent that original jurisdiction for review of the WOTUS Rule was to be at the district court level.

### Conclusion:

Although the Government made many interesting arguments regarding interpretation of [§ 1369\(b\)\(1\)\(E\)](#) and [\(b\)\(1\)\(F\)](#), the Court did not stray from the clear language providing seven cases where Congress determined what agency actions would require original jurisdiction at the courts of appeal level. The same was true regarding the Government's arguments that efficiency and consistency in interpreting the statute should outweigh the clear language. While the Court agreed that there was merit to those arguments, it still found that the clear language articulated by Congress controlled the interpretation. Although this case resolved a question regarding a scheme established by the CWA, it is not limited in scope. The case also provides insight into how other cases may be decided because the Court's adherence to statutory language when the language is unambiguous clearly outweighs prudential considerations. ➤

## Calendar

August 2-5, 2018	<b>ABA Annual Meeting</b> Contact: Janet Hummons – 312-988-5656 Speaker Contact: TBD	Swissotel Chicago Chicago, IL
October 10-14, 2018	<b>TIPS Fall Leadership Meeting</b> Contact: Janet Hummons – 312-988-5656	Ritz Carlton Amelian Island Amelia Island, FL
October 18-19, 2018	<b>Aviation Litigation Conference</b> Contact: Janet Hummons – 312-988-5656	Ritz Carlton Washington DC Washington, DC
November 7-9, 2018	<b>Fidelity &amp; Surety Law Fall Conference</b> Contact: Janet Hummons – 312-988-5656	Ritz Carlton Philadelphia Philadelphia, PA
January 16-18, 2019	<b>Fidelity &amp; Surety Law Midwinter Conference</b> Contact: Janet Hummons – 312-988-5656	Hilton San Diego Bayfront San Diego, CA
January 17-19, 2019	<b>Midwinter Symposium on Insurance and Employee Benefits</b> Contact: Janet Hummons – 312-988-5656	Hyatt Regency Coral Gables, FL
January 23-27, 2019	<b>ABA Midyear Meeting</b> Contact: Janet Hummons – 312-988-5656	Las Vegas, NV
February 21-23, 2019	<b>Insurance Coverage Litigation Midyear Conference</b> Contact: Janet Hummons – 312-988-5656	Arizona Biltmore Resort & Spa Phoenix, AZ
March 20-22, 2019	<b>Transportation MegaConference XIV</b> Contact: Janet Hummons – 312-988-5656	Sheraton New Orleans New Orleans, LA
March 22-23, 2019	<b>Admiralty and Maritime Law National Program</b> Contact: Janet Hummons – 312-988-5656	Sheraton New Orleans New Orleans, LA
April 4-5, 2019	<b>Motor Vehicle Products Liability Conference</b> Contact: Janet Hummons – 312-988-5656	Hotel Del Coronado Coronado, CA

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