

## RECENT DEVELOPMENTS IN TOXIC TORT AND ENVIRONMENTAL LAW

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## I. INTRODUCTION

Another dynamic year has passed in the world of toxic torts and environmental law. This article will address some of those interesting developments in court decisions and regulations. Specifically, this survey will span toxic tort subject matters, including the Food and Drug Administration’s regulation of e-cigarettes, the current tort liability dangers to the marijuana industry, and recent high number litigation verdicts in talc-

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related ovarian cancer lawsuits. With respect to updates in environmental law, this article will examine recent changes related to the enforcement and interpretation of CERCLA, the Clean Air Act, and the Clean Water Act, among other developments.

## II. FEDERAL REGULATION OF E-CIGARETTES

On May 10, 2016, the Food and Drug Administration (FDA) issued a final rule bringing electronic cigarettes and similar products, including e-hookahs, e-cigars, vape pens, personal vaporizers, and electronic pipes (collectively known as electronic nicotine delivery systems or ENDS) under the agency's regulatory authority. The FDA asserted authority to regulate ENDS under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act. The FDCA empowers the FDA to regulate "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and [ ] any other tobacco products" that the agency deems subject to the law.<sup>1</sup>

Section 321(rr) of the FDCA defines the term "tobacco product" to include "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."<sup>2</sup>

The new rule renders all ENDS subject to the regulations that already govern traditional tobacco products, e.g., cigarettes, cigars, loose tobacco, and smokeless tobacco. ENDS manufacturers and distributors will be required to register their manufacturing plants and products and submit product ingredients and harmful and potentially harmful constituents (HPHCs).<sup>3</sup> ENDS manufacturers and distributors are also subject to enforcement action and premarket review and prohibited from labeling their products with "modified risk descriptors," e.g., "mild," "light," or "low," and from distributing free samples of their products.<sup>4</sup>

The FDA has also invoked its authority under Section 906(d) of the FDCA to require health warnings for product packages and advertisements and prohibit the sale of ENDS to minors, as well as through vending machine sales, unless the vending machine is located in an adult-only facility.<sup>5</sup>

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1. 21 U.S.C. § 387a (2009).

2. 21 U.S.C. § 321 (2009).

3. Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28973 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143).

4. *Id.*

5. *Id.*

The FDA takes an expansive view of its regulatory authority over ENDS. The rule applies to any product that is derived from tobacco and to any component part that alters or affects the tobacco product's performance, composition, constituents, or characteristics, or is to be used for the consumption of a tobacco product.<sup>6</sup>

Since publishing the new rule, the FDA has faced a flurry of lawsuits filed by members of the ENDS industry. The complaints allege that the new rule fails to consider that ENDS products are a safer alternative to conventional tobacco products and therefore places an "arbitrary and capricious" burden on ENDS manufacturers.<sup>7</sup> The plaintiffs argue that the cost-prohibitive pre-market application process will force many ENDS producers out of the market.<sup>8</sup> According to the American Vaping Association, a single application is estimated to take more than 1,700 hours and cost more than \$1 million.<sup>9</sup> A lawyer for three Alabama-based plaintiffs has accused the FDA of overreaching its constitutional authority to "regulate the industry out of existence."<sup>10</sup> If that happens, the plaintiffs charge, many ENDS consumers will be driven back to cigarettes and other traditional tobacco products.<sup>11</sup>

According to the American Lung Association, however, much is still unknown about the health effects of ENDS.<sup>12</sup> In 2009, the FDA found detectable levels of carcinogens in two leading brands of e-cigarettes and eighteen varieties of liquid.<sup>13</sup> Some e-cigarette flavors contain diacetyl, a chemical that has been linked to a serious and irreversible lung disease.<sup>14</sup> There are also concerns about nicotine abuse and accidental poisoning from both ingestion and, in some cases, inhalation of the e-cigarette liquid.<sup>15</sup> It remains to be seen how much weight the courts will give these concerns in determining whether the FDA's new rule is in fact "arbitrary and capricious."

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6. *Id.*

7. Shayna Posses, *FDA Overreaching with Tobacco Rule Expansion: E-Cig Cos.*, LAW360, July 13, 2016, <http://www.law360.com/articles/816819/fda-overreaching-with-tobacco-rule-expansion-e-cig-cos>.

8. *Id.*

9. Sabrina Tacernise, *F.D.A. Imposes Rules for E-Cigarettes in a Landmark Move*, N.Y. TIMES, May 5, 2015, [http://www.nytimes.com/2016/05/06/science/fda-rules-electronic-cigarettes.html?\\_r=0](http://www.nytimes.com/2016/05/06/science/fda-rules-electronic-cigarettes.html?_r=0).

10. See Posses, *supra* note 7.

11. *See id.*

12. *E-cigarettes and Lung Health*, AMERICAN LUNG ASS'N (June 2, 2016), <http://www.lung.org/stop-smoking/smoking-facts/e-cigarettes-and-lung-health.html>.

13. *See id.*

14. *See id.*

15. *See id.*

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### III. FEDERAL GENETICALLY MODIFIED INGREDIENTS LABELING LEGISLATION

On July 29, 2016, President Obama signed a bill that will require all food labels to display whether the item contains genetically modified ingredients (GMOs).<sup>16</sup> The U.S. Department of Agriculture (USDA) has two years to establish a national mandatory labeling standard—the law will not go into effect until that time.

The federal standard does not require manufacturers to include a labeling statement. Instead, the statute lays out three GMO disclosure options: a text label, symbol, or an electronic code or digital link, which should be readable by smartphone. The legislation also specifies that the food manufacturer can select the disclosure option.

The new legislation amends the Agricultural Marketing Act of 1946<sup>17</sup> and applies to all “bioengineered food,” including food containing genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (DNA) techniques and food for which the modification could not otherwise be obtained through conventional breeding or found in nature.<sup>18</sup>

The absence of federal standards paired with the citizenry’s growing concerns inspired a number of state legislatures to pass their own GMO labeling laws.<sup>19</sup> For example, Vermont’s labeling law required that all GMO food labels include the phrase “produced with genetic engineering.”<sup>20</sup> Members of the food industry challenged the Vermont law on First Amendment, Commerce Clause, and preemption grounds.<sup>21</sup> The battle over the Vermont statute came to an abrupt halt when President Obama signed the federal GMO labeling bill into law. The federal law immediately preempted all state GMO labeling laws and bars state and local governments from enacting future laws addressing the labeling or disclosure of bioengineered food.

The new legislation prohibits a food manufacturer’s knowing violation of the statute. Entities and individuals subject to the mandatory disclosure requirement must keep “reasonable” records in order to comply. However, the law does *not* grant the USDA Secretary the authority to recall

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16. National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (2016).

17. 7 U.S.C. § 1621 (2016).

18. National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, § 291(1), 130 Stat. 834 (2016) (codified as amended at 7 U.S.C. § 1639(1)).

19. See CONN. GEN. STAT. § 21a-92c; ME. REV. STAT. tit. 22, § 2593; VT. STAT. ANN. tit. 9, § 3043.

20. VT. STAT. ANN. tit. 9, § 3043.

21. See *Grocery Mfrs. Ass’n v. Sorrell*, 102 F. Supp. 3d 583, 594 (D. Vt. 2015).

a food that does not disclose GMO information.<sup>22</sup> The details of the law's enforcement remain open.

On November 19, 2015, the FDA approved AquAdvantage salmon, a genetically engineered salmon produced by the Massachusetts-based biotechnology company AquaBounty Technologies.<sup>23</sup> AquAdvantage salmon is the first genetically modified animal approved by the FDA for human consumption.

The engineered salmon contain an added growth hormone from the Pacific Chinook salmon and a gene from an eel-like fish called an ocean pout that allow salmon to produce growth hormone all year long.<sup>24</sup> As a result, the engineered salmon grow twice as fast as natural salmon and reach market size more quickly.<sup>25</sup> The November FDA approval permitted the AquAdvantage salmon to be raised in "land-based, contained hatchery tanks" in only two specific facilities, one in Canada and the other in Panama.<sup>26</sup> The agency determined that the salmon would not have a negative environmental impact due to the "multiple and redundant" physical barriers required at the facilities to keep the engineered eggs and fish from escaping into ocean waters.<sup>27</sup> The fish are also engineered so that they cannot reproduce on their own or interbreed with wild salmon; they are bred female and sterile.<sup>28</sup>

The approval of the genetically engineered salmon immediately caused a wave of backlash against the FDA.<sup>29</sup> Environmental groups and the salmon fishing industry opposed the approval of the fish and expressed concerns about the impacts on the environment and native salmon populations if the engineered salmon escape the designated production facilities.

Food-safety activists also expressed concerns, particularly because the salmon will not have mandatory labels identifying them as genetically engineered. According to long-standing FDA policy, manufacturers are not required to label food products as genetically engineered unless there is a material difference between the genetically engineered and non-genetically

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22. National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, § 293(g)(4), 130 Stat. 834 (2016) (codified as amended at U.S.C. § 1639b).

23. Press Release, U.S. Food & Drug Admin., FDA Takes Several Actions Involving Genetically Engineered Plants and Animals for Food (Nov. 19, 2015), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473249.htm>.

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

29. See Andrew Pollack, *Genetically Engineered Salmon Approved for Consumption*, N.Y. TIMES, Nov. 19, 2015, [https://www.nytimes.com/2015/11/20/business/genetically-engineered-salmon-approved-for-consumption.html?\\_r=0](https://www.nytimes.com/2015/11/20/business/genetically-engineered-salmon-approved-for-consumption.html?_r=0).

engineered versions of the product.<sup>30</sup> The FDA found that “there are no biologically relevant differences in the nutritional profile of AquAdvantage Salmon compared to that of other farm-raised Atlantic salmon.”<sup>31</sup>

The FDA also faced backlash from members of Congress. In December 2015, Alaska Senator Lisa Murkowski inserted a provision into the 2016 Omnibus Appropriations Act that blocked the FDA from allowing the introduction of any food that contains genetically engineered salmon until the agency publishes final labeling guidelines for consumers.<sup>32</sup> On January 29, 2016, the FDA complied by issuing a temporary ban on imports of genetically engineered salmon.<sup>33</sup>

The backlash continued on March 30, 2016, when consumer, environmental, and fishing groups filed a lawsuit in the U.S. District Court for the Northern District of California against the FDA and related agencies.<sup>34</sup> The suit challenges the agency’s claimed statutory authority to regulate genetically modified animals as “animal drugs” under the 1938 FDCA and seeks to overturn the FDA’s approval of the genetically engineered salmon for human consumption.<sup>35</sup> The lawsuit also alleges that the FDA failed to fulfill its federal statutory duty to consider all of the environmental and ecological risks associated with the fish during its review process.<sup>36</sup> As required by the National Environmental Policy Act, the FDA conducted an environmental assessment and determined that the engineered salmon would have no significant environmental impact.<sup>37</sup> The plaintiffs claim, however, that the FDA’s assessment was “extremely limited” and did not properly assess the risk that the genetically engineered

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30. U.S. Food & Drug Admin., *Guidance for Industry, Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon* (Nov. 19, 2015), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm469802.htm>.

31. FDA Press Release, *supra* note 23.

32. Press Release, Sen. Lisa Murkowski, Murkowski Works to Support Alaska’s Fisheries and Protect Consumers Through Omnibus Bill (Dec. 17, 2015), <https://www.murkowski.senate.gov/press/release/murkowski-works-to-support-alaskas-fisheries-and-protect-consumers-through-omnibus-bill>.

33. U.S. Food & Drug Admin., Import Alert 99-40, FDA, Genetically Engineered (GE) Salmon (Jan. 29, 2016), [http://www.accessdata.fda.gov/CMS\\_IA/importalert\\_1152.html](http://www.accessdata.fda.gov/CMS_IA/importalert_1152.html).

34. Complaint, *Inst. for Fisheries Res. v. Burwell*, 4:16cv1574 (N.D. Cal. filed Mar. 30, 2016), ECF No. 1. The suit was filed against DHHS Secretary Burwell, FDA Commissioner Robert M. Califf, the FDA, and the U.S. Fish and Wildlife Service (although claims against FWS were later dismissed). The plaintiffs include the Institute for Fisheries Resources, Pacific Coast Federation of Fishermen’s Associations, Golden Gate Salmon Association, Kennebec Reborn, Friends of Merrymeeting Bay, Cascadia Wildlands, Center for Biological Diversity, Ecology Action Centre, Friends of the Earth, Food and Water Watch, and Center for Food Safety. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

salmon would escape from the facilities where they are manufactured and breed with wild salmon or spread diseases.<sup>38</sup>

On June 14, 2016, AquaBounty moved to intervene in the suit, arguing that it is “directly threatened” by the relief the plaintiffs seek.<sup>39</sup> The company estimates that it spent \$80 million during the FDA approval process, giving it a significant protectable interest in the suit.<sup>40</sup> The court agreed and allowed the company to intervene. In July, the Quinalt Indian Nation, a Washington State Native American tribe, also joined the suit against the FDA, as a plaintiff.<sup>41</sup> The outcome of this lawsuit could determine the fate of genetically engineered animals in the years to come.

#### IV. EMERGING PRODUCT LIABILITY CONCERNS FOR THE MARIJUANA INDUSTRY

As marijuana’s legal status changes, those in the industry face product liability challenges. In the past year, two high-profile product liability cases were brought against marijuana businesses in Colorado, which may be potential harbingers of things to come.

In *Flores v. LivWell, Inc.*, the plaintiffs brought a putative class action against a medical marijuana supplier alleging it used the pesticide Eagle 20 on its plants.<sup>42</sup> Colorado had previously issued a list of approved pesticides for use on cannabis, which did not include Eagle 20.<sup>43</sup> The complaint alleged that Eagle 20 was harmful when inhaled, but the judge dismissed the lawsuit because the plaintiffs had not shown that smoking marijuana contaminated with the pesticide had harmed them.<sup>44</sup> While the *Flores* case is over, use of banned pesticides on marijuana plants remains a problem. In the first ten months of 2016, marijuana manufacturers and distributors issued over forty separate product recalls for unsafe pesticide contamination.<sup>45</sup>

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38. *Id.*

39. J.R. Pegg, *GE Salmon Maker Seeks to Defend FDA Approval*, FOOD CHEM. NEWS (June 20, 2016, 2:30 P.M.), <https://www.agra-net.com/agra/food-chemical-news/agriculture/biotechnology/ge-salmon-maker-seeks-to-defend-fda-approval-518590.htm>.

40. *Id.*

41. Adam Lidgett, *Washington Tribe Joins Suit Over FDA’s Modified Salmon Approval*, LAW360 (July 19, 2016, 6:23 P.M.), <http://www.law360.com/articles/819233/wash-tribe-joins-suit-over-fda-s-modified-salmon-approval>.

42. Complaint, *Flores v. LivWell, Inc.*, Case No. 2015-cv-33528 (Colo. Dist. Ct. Oct. 5, 2015).

43. Colo. Dep’t of Agric., *Pesticide Use in Cannabis Production Information*, <https://www.colorado.gov/pacific/agplants/pesticide-use-cannabis-production-information>.

44. David Migoya, *Denver Judge Tosses Consumer Lawsuit Filed over Pesticides on Pot*, DENVER POST (Feb. 11, 2016), <http://www.denverpost.com/2016/02/11/denver-judge-tosses-consumer-lawsuit-filed-over-pesticides-on-pot/>.

45. Ricardo Baca, *Full Recall List*, CANNABIST (Oct. 25, 2016), <http://www.thecannabist.co/2015/12/04/pesticide-pot-recall-list-marijuana/44711/>.

Another product liability case involving marijuana this year was the wrongful death action filed by the children of Kristine Kirk against her killer, Richard Kirk.<sup>46</sup> Four months after Colorado law made recreational marijuana use legal under state law, Richard Kirk shot and killed his wife. His defense has centered around an insanity plea based on the large amount of edible marijuana he consumed just before the killing. In May 2016, Kristine Kirk's heirs brought a civil suit against both Richard Kirk and the manufacturer and retailer of the edible marijuana. The suit alleged that the manufacturer and retailer failed to provide labels instructing on proper dosages and the possibility of side effects, including hallucinations and psychosis.<sup>47</sup> While the viability of such claims remains uncertain, the Kirk case signals that plaintiffs and plaintiffs' lawyers are actively seeking new ways to hold those in the marijuana industry liable.

Government regulation is also affecting those in the marijuana industry. For instance, California's Proposition 65 categorizes marijuana smoke as a substance requiring special labeling as a carcinogen.<sup>48</sup> In 2016, the FDA began warning a number of medical marijuana dispensaries not to make unproven claims about the medical benefits of marijuana use.<sup>49</sup>

## V. TALC LITIGATION 2016: AN EVOLVING LANDSCAPE

While products liability cases against talc manufacturers have been brought since the mid-2000s, the early cases typically involved asbestos-contaminated talc. Plaintiffs claimed to have inhaled asbestos fibers from the asbestos-contaminated talc products, which allegedly caused certain asbestos-related diseases. The recent wave of litigation involves plaintiffs who claim their ovarian cancer was caused by their use of feminine talc products.

### A. *Talc: Background*

Talc is a magnesium silicate material used in a variety of products, including cosmetics and ceramics.<sup>50</sup> While historically talc mines may have con-

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46. Jordan Steffen, *Lawsuit Against Marijuana Company, First-of-Its-Kind?*, DENVER POST (May 10, 2016), <http://www.denverpost.com/2016/05/10/lawsuit-against-marijuana-company-first-of-its-kind/>.

47. *Id.*

48. Cal. Office of Env'tl. Health Hazard Assessment, *The Proposition 65 List*, <http://oehha.ca.gov/proposition-65/proposition-65-list>.

49. Debra Borhardt, *FDA Sends Warning Letters to Cannabis Companies over False Claims*, FORBES (Mar. 9, 2016), <http://www.forbes.com/sites/debraborhardt/2016/03/09/fda-sends-warning-letters-to-cannabis-companies/#6851d869348b>. The FDA's actions came after years of private parties accusing drug companies of advocating off-label uses of marijuana and marijuana-like derivatives. See, e.g., *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1321 (11th Cir. 2009) (accusing defendant of advocating off-label uses of synthetic THC).

50. Nat'l Ctr. for Biotechnology Info., PubChem Compound Database, CID=16211421, <https://pubchem.ncbi.nlm.nih.gov/compound/16211421>.

tained talc contaminated with amphibole asbestos fibers, including tremolite and amosite, cosmetic talc products have been asbestos-free since the 1970s, according to the American Cancer Society.<sup>51</sup>

The FDA identifies published scientific literature dating back to the 1960s that has suggested a possible association between the use of powders containing talc and the incidence of ovarian cancer.<sup>52</sup> These studies, however, have not conclusively demonstrated any link, or if a link exists, what risk factors might be involved.<sup>53</sup> The International Agency for Research on Cancer listed cosmetic talc as a possible carcinogenic to humans (Group 2B, the same category as pickled vegetables).<sup>54</sup>

### B. *Talc Cases: A Legal Landscape*

The first talc case involving ovarian cancer was tried to verdict in 2013. Deane Berg claimed she had used Johnson & Johnson's feminine talc powder from 1975 until 2007, and as a result, developed ovarian cancer in 2006. The jury returned a verdict for Johnson & Johnson on strict liability failure to warn and for plaintiff on negligence; however, the jury awarded no damages.

#### 1. Multi-Million Dollar Verdicts

Three years later, in February 2016, the estate of Jacqueline Fox prevailed over Johnson & Johnson in Missouri state court with a widely publicized win.<sup>55</sup> Ms. Fox's case marks the first time monetary damages were awarded in a case involving talc-containing personal hygiene products and ovarian cancer. Ms. Fox used Johnson & Johnson's talc-based baby powder, Shower to Shower, for thirty-five years, which, she claimed, led to her ovarian cancer diagnosis and later death at the age of sixty-two.

At trial, defendant Johnson & Johnson pointed to the FDA's statement that there were no conclusive links between talc and ovarian cancer. The plaintiff cited to medical articles stating that women using talc products had a 30 percent increased risk for ovarian cancer. The plaintiff also introduced internal Johnson & Johnson documents indicating it knew of studies linking talc to ovarian cancer, but continued to market and sell the

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51. Am. Cancer Soc'y, *Talcum Powder and Cancer*, <http://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/talcum-powder-and-cancer>.

52. U.S Food & Drug Admin., *Talc*, <http://www.fda.gov/cosmetics/productsingredients/ingredients/ucm293184.htm>.

53. *Id.*

54. Int'l Agency for Research on Cancer, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, <http://monographs.iarc.fr/ENG/Classification/>.

55. Yanan Wang, *Johnson & Johnson Ordered to Pay \$72 Million in Suit Linking Talcum Powder to Ovarian Cancer*, WASH. POST, Feb. 24, 2016, [https://www.washingtonpost.com/news/morning-mix/wp/2016/02/24/johnson-johnson-ordered-to-pay-72m-in-suit-linking-talcum-powder-to-ovarian-cancer/?utm\\_term=.a58abe9a161a](https://www.washingtonpost.com/news/morning-mix/wp/2016/02/24/johnson-johnson-ordered-to-pay-72m-in-suit-linking-talcum-powder-to-ovarian-cancer/?utm_term=.a58abe9a161a).

product.<sup>56</sup> In closing, the plaintiff's counsel asked the jurors to award \$5 million in compensatory damages and \$10 million to \$15 million in punitive damages.<sup>57</sup> The jury exceeded this request and awarded \$10 million in compensatory damages and \$62 million in punitive damages.<sup>58</sup> Jurors identified Ms. Fox's age as the reason for their large punitive damages verdict.<sup>59</sup>

Some months later, another Missouri state court jury found for plaintiff Gloria Ristesund, a sixty-two-year-old woman who used Johnson & Johnson powder for forty years.<sup>60</sup> One of the three defendants, supplier Imerys Talc America, received a defense verdict but the other two, both Johnson & Johnson entities, were held liable and assessed \$5 million in compensatory damages and \$50 million in punitive damages.<sup>61</sup> The plaintiff also relied on a 1986 Johnson & Johnson internal document that connected talc use in the vaginal area with the incidence of ovarian cancer.<sup>62</sup> Johnson & Johnson stated that it plans to appeal both judgments.<sup>63</sup>

## 2. The Science

The science behind plaintiffs' claims is not conclusive. In 1971, W.J. Henderson, along with British researchers, identified talc embedded in tumor tissues after an examination of tumors from ovarian and cervical cancer patients.<sup>64</sup> In 1982, Dr. Daniel Cramer of Harvard's Cancer Center published the first study linking ovarian cancer and talc use in women. He later testified that he was visited by a Johnson & Johnson senior scientist, who tried to convince him that talc did not present the claimed risks.<sup>65</sup>

In addition to Dr. Cramer, experts who have testified for plaintiffs in these ovarian cancer cases include David C. Steinberg, a regulatory ex-

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56. Brandon Lowrey, *J&J's Talcum Trial Losses Create Litigation Powder Keg*, LAW360, May 4, 2016.

57. *Id.*

58. *Id.*

59. Wang, *supra* note 55.

60. Margaret Cronin Fisk, Tim Bross & Jef Feeley, *J&J Faces 1,000 More Talc-Cancer Suits After Verdict Loss*, BLOOMBERG, May 2, 2016, <https://www.bloomberg.com/news/articles/2016-05-02/j-j-ordered-to-pay-55-million-over-cancer-linked-to-talc>.

61. *Id.*

62. Brandon Lowrey, *J&J Baby Powder Cancer Suit Goes to Missouri Jury*, LAW360, Apr. 29, 2016, <https://www.law360.com/articles/790858/j-j-baby-powder-cancer-suit-goes-to-missouri-jury>.

63. Brian Amaral, *J&J Wants Talc Trial Moved Due to Plaintiffs' Atty Ads*, LAW360, Aug. 2, 2016, <https://www.law360.com/articles/824275/j-j-wants-talc-trial-moved-due-to-plaintiffs-atty-ads>.

64. W.J. Henderson, *Talc and Carcinoma of the Ovary and Cervix*, 78 BRIT. J. OF OBSTETRICS & GYNECOLOGY 266-72 (1971).

65. James A. Morris, Jr., *J&J Talc Verdict Is Product Liability Game-Changer*, LAW360, Feb. 25, 2016, <http://www.law360.com/articles/763875/j-j-talc-verdict-is-product-liability-game-changer>.

pert, and Graham A. Colditz, M.D., MPH, from Washington University's Institute of Public Health on general causation.<sup>66</sup>

In defense, the defendants present alternate potential causes of the plaintiffs' ovarian cancer, which include endometriosis, a known cause, and genetic predisposition.<sup>67</sup> Like BAP-1 with mesothelioma, experts have linked those exhibiting genetic defects in the BRCA1 gene as more susceptible to get ovarian cancer.<sup>68</sup> According to the American Cancer Society, for these patients, independent of any potential outside force or exposures, the lifetime risk of developing ovarian cancer is between 30 percent and 70 percent.<sup>69</sup> Further, women with the BRCA2 genetic mutation are between 10 percent and 30 percent more likely to develop ovarian cancer in their lifetimes.<sup>70</sup> Researchers continue to investigate whether other mutations may also increase susceptibility.

### C. *A Change in the Tides: "Narrow and Shallow"*

Since the large jury verdicts, plaintiffs have lost in other talc cases. In August 2016, Atlantic County, New Jersey, Judge Nelson C. Johnson was not persuaded by the plaintiffs' experts that there was causal connection between talc and ovarian cancer and dismissed two cases. In the consolidated case of Brandi Carl and Diana Balderrama, defendants Johnson & Johnson and Imerys Talc America moved to exclude the plaintiffs' expert witnesses, Doctors Graham Colditz and Daniel Cramer, on the grounds that their theories were flawed and had no reliable scientific support.<sup>71</sup>

Judge Johnson agreed. He concluded in a detailed ruling that, although both experts were highly qualified, their testimony suffered from several defects, including the "narrowness and shallowness" of their inquiries, and the glaring fact that neither expert even attempted to explain how or why the presence of talc in the ovaries causes ovarian cancer.<sup>72</sup> Judge Johnson opined that the plaintiffs' experts were acting as advocates, rather than scientists.<sup>73</sup>

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66. Carl v. Johnson & Johnson, 2016 N.J. Super. Unpub. LEXIS 2102 (Law Div. Sept. 2, 2016).

67. Fisk et al., *supra* note 60.

68. Ovarian Cancer Research Fund Alliance, *Factors that may increase the risk of ovarian cancer: Genetics, BRCA1 and BRCA2*, <https://ocrfa.org/patients/about-ovarian-cancer/risk-factors>.

69. Am. Cancer Soc'y, *What Are the Risk Factors for Ovarian Cancer?*, <http://www.cancer.org/cancer/ovariancancer/detailedguide/ovarian-cancer-risk-factors> (hereditary breast and ovarian cancer syndrome).

70. *Id.*

71. See Carl v. Johnson & Johnson, 2016 N.J. Super. Unpub. LEXIS 2102 (Law Div. Sept. 2, 2016).

72. *Id.* at \*62.

73. *Id.*

The court cited several reasons for its holding. First, the experts confined their analysis to smaller studies and did not analyze the larger studies highlighted by Johnson & Johnson. Next, the experts failed to address other scientific fields, outside of their own, to support their claims. Third, they ignored significant risk factors for ovarian cancer that both plaintiffs exhibited, including obesity and intrauterine devices. Finally, the court noted that neither expert offered a logical explanation as to how talc in the tissue, and the resulting inflammation, led to cancer.<sup>74</sup>

To address the admissibility of expert witness opinion, New Jersey courts rely on the *Kemp* standard first articulated in *Kemp v. New Jersey*, not the *Daubert* standard recognized by many state and all federal courts. The *Kemp* standard requires the proponent of an expert to demonstrate that the expert's opinion or theory is generally accepted in the scientific community.<sup>75</sup> The court continued stating that such a standard may be relaxed, and the trial court judge may use New Jersey Rule of Evidence 104 to assess the soundness of an expert's proffered methodology when faced with a theory that is not yet generally accepted.<sup>76</sup>

Judge Johnson heard seven days of testimony and reviewed 100 documents before excluding the plaintiffs' experts' opinions and dismissing the lawsuits.<sup>77</sup>

#### D. Sink or Swim: What the Future Holds

On the heels of the *Fox* verdict, 17,000 women have contacted lawyers regarding their own potential suits.<sup>78</sup> Plaintiffs have filed well over a thousand cases nationwide, including 1,000 lawsuits in Missouri and 200 lawsuits in New Jersey.<sup>79</sup> Since the large verdicts this spring, the cases have received considerable attention, leading Johnson & Johnson to seek to move its upcoming St. Louis trial to avoid the targeted advertising that it believes could influence jurors.<sup>80</sup> Johnson & Johnson expert Rustin Silverstein argued in court that more talc litigation advertisements were broadcast in St. Louis than in any other U.S. media market and that

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74. *Id.*

75. *Kemp v. New Jersey*, 809 A.2d 77, 84–85 (N.J. 2002).

76. *Id.*

77. *Id.* at 89.

78. John Breslin, *Thousands of Prospective Plaintiffs Turn Up After Massive Talc Verdicts in St. Louis*, FORBES, Aug. 3, 2016, <http://www.forbes.com/sites/legalnewsline/2016/08/03/thousands-of-prospective-plaintiffs-turn-up-after-massive-talc-verdicts-in-st-louis/#5ff206ae458f>.

79. Jonathan Stempel, *J&J must pay \$72 million for cancer death linked to talcum powder: lawyers*, REUTERS BUS. NEWS (Feb. 25, 2016, 5:13 AM), <http://www.reuters.com/article/us-johnson-johnson-verdict-idUSKCN0VW20A>.

80. Breslin, *supra* note 78.

over half of those interviewed who had viewed the ads had an unfavorable view of talc powder.<sup>81</sup>

## VI. INCONSISTENT OUTCOMES IN BENZENE LITIGATION

Two recent benzene cases suggest that plaintiffs must develop better causation theories in the future. On May 23, 2016, the Fifth Circuit upheld a trial court's decision to exclude general causation testimony that exposure to gasoline can cause acute myeloid leukemia (AML) under *Daubert*.<sup>82</sup> The court found the expert testimony unreliable because it relied on studies that did not support causation.<sup>83</sup> In *Burst v. Shell Oil Co.*, the plaintiff alleged that her husband's exposure to gasoline containing benzene while working as a gas station attendant and mechanic caused his AML. She relied on a general causation opinion that benzene, including benzene containing material such as gasoline, can cause AML. The Fifth Circuit held that the expert had failed to evaluate studies specific to gasoline—the particular substance at issue—and instead relied only on studies of pure benzene, making his opinion unreliable to prove that gasoline can cause AML.<sup>84</sup>

The First Circuit also affirmed a trial court's decision to exclude causation testimony under *Daubert*, ruling that the expert did not analyze conflicting epidemiological studies.<sup>85</sup> In that case, the plaintiff worked for over thirty years as a pipefitter and refrigerator technician.<sup>86</sup> He claimed that exposure to benzene from paints, among other things, caused his acute promyelocytic leukemia (APL).<sup>87</sup> The plaintiff's expert relied on a relative-risk causation theory that (1) workers exposed to certain benzene levels were more likely than control groups to develop APL, (2) the plaintiff's exposure was above those exposure levels, and (3) therefore the plaintiff's APL was caused by benzene exposure.<sup>88</sup> When confronted with an epidemiological study finding no increased risk of APL at the exposure levels experienced by the plaintiff, however, the expert could not explain how she had weighed the competing studies or why she chose to rely on one study rather than another.<sup>89</sup> The First Circuit made clear in affirming the district court that where "an expert's medical

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81. Defendants' Motion to Change Venue for Upcoming September Trial, *Hogans v. Johnson & Johnson*, Case No. 1422-CC09012-01 (Mo. Cir. Ct. July 28, 2016); see also Amaral, *supra* note 63.

82. *Burst v. Shell Oil Co.*, 650 F. App'x 170 (5th Cir.), cert. denied, 137 S. Ct. 312 (2016).

83. *Id.* at 173.

84. *Id.* at 172.

85. *Milward v. Rust-Oleum Corp.*, 820 F.3d 469 (1st Cir. 2016).

86. *Id.* at 471.

87. *Id.*

88. *Id.* at 477–78.

89. *Id.*

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opinion is grounded exclusively on scientific literature, a district court acts within its discretion to require the expert to explain why she relied on the studies that she did and, similarly, why she disregarded other, incompatible research.”<sup>90</sup>

## VII. CERCLA

### A. *Air Emissions Are Not “Disposal” for Purposes of CERCLA*

The Ninth Circuit ruled that an operator of a smelter is not liable under CERCLA for emissions of hazardous substances from a smoke stack that contaminated land and water downwind from the smoke stack.<sup>91</sup> The court held that the operator had not “disposed” of the compounds according to the definition of disposal incorporated into CERCLA.<sup>92</sup> The court explained that it was bound by the Ninth Circuit’s previous interpretation of “disposal” that had concluded that the definition did not include “the gradual spread of contaminants without human intervention.”<sup>93</sup> The court, therefore, reversed the district court’s holding and granted the defendant’s motion to dismiss the CERCLA claim.<sup>94</sup>

### B. *Preliminary or Investigative Activities Do Not Trigger the Six-Year Statute of Limitations for a Remedial Action*

CERCLA requires that a claim for costs related to a remedial action be brought within six years after “initiation of physical on-site construction” of the remedial action.<sup>95</sup> In two cases this year, courts have held that preliminary or investigative activities to determine the magnitude of contamination do not constitute the initiation of physical on-site construction.<sup>96</sup> In *Dave Drilling*, the U.S. District Court for the Northern District of California denied the defendant’s motion to dismiss based on the statute of limitations because investigation work done to develop a remedy and work plan was not per se the initiation of construction.<sup>97</sup>

Similarly, in *California River Watch*, the court held that activities occurring before the remedial action plan was finalized did not constitute the initiation of construction.<sup>98</sup> In the Ninth Circuit, “the initiation of phys-

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90. *Id.* at 474 (citation omitted).

91. *Pakootas v. Teck Cominco Metals*, 830 F.3d 975 (9th Cir. 2016); 42 U.S.C. § 9607(a)(3).

92. *Pakootas*, 830 F.3d at 981–82.

93. *Id.* at 984 (quoting *Carson Harbor Vill. Ltd. v. Unocal Corp.*, 270 F.3d 863, 879 (9th Cir. 2001)).

94. *Id.* at 986.

95. 42 U.S.C. § 9613(g)(2)(B).

96. *Dave Drilling Envtl. Eng’g, Inc. v. Gamblin*, Case No. 14-cv-02851, 2015 WL 6123070, at \*2 (N.D. Cal. Oct. 19, 2015); *Cal. River Watch v. Fluor Corp.*, 139 F. Supp. 3d 1027 (N.D. Cal. 2015).

97. *Dave Drilling Envtl. Eng’g*, 2015 WL 6123070, at \*2.

98. *Cal. River Watch*, 139 F. Supp. 3d at 1029–30.

ical on-site construction of the remedial action can occur only after the final remedial action plan is adopted.’”<sup>99</sup>

#### VIII. CLEAN AIR ACT

##### A. *EPA Denies Petitions to Review Startup and Shutdown Issues Under Mercury Air Toxics Standards Rule and Utility New Source Performance Standards*

On August 8, 2016, the U.S. Environmental Protection Agency (EPA) denied two petitions by environmental and industry groups to reconsider startup and shutdown issues under the Mercury and Air Toxics Standards (MATS) Rule and the Utility New Source Performance Standards (NSPS).<sup>100</sup> The specific provisions under the MATS Rule and NSPS, which were finalized in February 2012, impose operational requirements to minimize emissions during periods of startup and shutdown rather than numeric limits.<sup>101</sup> In their petition for reconsideration, the environmental groups argued that numeric limits should apply during these periods and that they did not have the opportunity to adequately comment on this issue.<sup>102</sup> EPA denied the environmental groups’ petition. EPA concluded that the groups had adequate opportunity to submit comments during earlier rulemaking proceedings in 2012.<sup>103</sup>

##### B. *EPA Takes First Step to Regulate Airplane Greenhouse Gas Emissions*

On July 25, 2016, EPA finalized the first step to create domestic greenhouse gas (GHG) emissions standards for commercial airplanes when it officially issued an “endangerment finding” that elevated concentrations of GHG in the atmosphere “endanger the public health and welfare.”<sup>104</sup> Now that EPA has issued this determination, it is required to regulate these emissions under the Clean Air Act (CAA).<sup>105</sup> EPA will issue a separate notice and

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99. *Id.* at 1029 (quoting *Cal. Dep’t of Toxic Substances Control v. Neville Chem. Co.*, 358 F.3d 661, 667 (9th Cir. 2004)).

100. Reconsideration on the Mercury and Air Toxics Standards (MATS) and the Utility New Source Performance Standards Startup and Shutdown Provisions, Final Action, 81 Fed. Reg. 52346 (Aug. 8, 2016).

101. See National Emission Standards for Hazardous Air Pollutants from Coal and Oil-Fired Electric Utility Steam Generating Units and Standards of Performance for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial Institutional Steam Generating Units, 77 Fed. Reg. 9304 (Feb. 16, 2012) (to be codified at 40 C.F.R. pts. 60 and 63).

102. U.S. Env’t. Prot. Agency, Denial of Petitions for Reconsideration of Certain Startup/Shutdown Issues: MATS, Docket No. EPA-HQ-OAR-2009-0234 (July 29, 2016).

103. *Id.*

104. Finding That Greenhouse Gas Emissions from Aircraft Cause or Contribute to Air Pollution That May Reasonably Be Anticipated to Endanger Public Health and Welfare, Final Rule, 81 Fed. Reg. 54422 (Aug. 15, 2016).

105. 42 U.S.C. § 7571(a)(2)(A).

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comment rulemaking in the coming months to promulgate GHG emission standards for the aircraft subject to its endangerment finding.<sup>106</sup>

### C. *Diligent Prosecution No Basis for Subject Matter Jurisdiction Dismissal*

On January 6, 2016, the Third Circuit held that the CAA's diligent prosecution bar is not a proper basis for dismissal of a citizen suit for lack of subject matter jurisdiction.<sup>107</sup> Certain federal environmental laws, such as the CAA, contain provisions that bar citizen suit actions when regulators are "diligently prosecuting" an action against an alleged violator.<sup>108</sup> The basis for dismissal in accordance with this bar is unclear.<sup>109</sup> In *Group Against Smog & Pollution, Inc. v. Shenango, Inc.*, the court "look[ed] to the condition's text, context, and relevant historical treatment to determine whether the condition [was] jurisdictional" in nature.<sup>110</sup> The court first looked at the plain language of the CAA, which "does not reference the court's jurisdiction in any way, nor is it phrased in a way that clearly suggests it is a jurisdictional requirement."<sup>111</sup> Looking at the bar's context, the court noted that the Supreme Court had held other similar threshold requirements to be non-jurisdictional.<sup>112</sup> Finally, the court looked to legislative history but found no support for a finding that the diligent prosecution bar was jurisdictional.<sup>113</sup> Therefore, the Third Circuit held that the bar is the proper basis for dismissal for failure to state a claim, joining the Third and Fifth Circuits, which had ruled similarly.<sup>114</sup>

### D. *EPA Updates Cross-State Air Pollution Rule*

In September 2016, EPA finalized an update to the Cross-State Air Pollution Rule (CSAPR) for the 2008 Ozone National Ambient Air Quality Standards.<sup>115</sup> Under the CSAPR update, EPA issued Federal Implementation Plans (FIPs) for twenty-two states. These FIPs will update NO<sub>x</sub> emission budgets for these states, requiring the reduction of NO<sub>x</sub> emissions at electric generating units that contribute significantly to down-

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106. See 81 Fed. Reg. at 54423.

107. Grp. Against Smog & Pollution, Inc. v. Shenango, Inc., 810 F.3d 116 (3d Cir. 2016).

108. *Id.* at 128.

109. *Id.* at 123–24.

110. *Id.* at 122.

111. *Id.* at 124.

112. *Id.* at 125 (citations omitted).

113. *Id.* at 126.

114. *Id.* at 122; *Adkins v. Vim Recycling, Inc.*, 644 F.3d 483, 492 (7th Cir. 2011) (holding that the diligent prosecution bar is not jurisdictional in a Resource Conservation and Recovery Act action); *La. Env'tl. Action Network v. Baton Rouge*, 677 F.3d 737, 749 (5th Cir. 2012) (holding that the diligent prosecution bar is not jurisdictional in a Clean Water Act action).

115. Cross-State Air Pollution Rule Update for 2008 Ozone NAAQS, 81 Fed. Reg. 74504 (Oct. 26, 2016) (to be codified at 40 C.F.R. pts. 52, 78, and 97).

wind ozone pollution in other states. EPA's FIPs require states to comply with the budgets for the 2017 ozone season, i.e., May–September 2017.<sup>116</sup>

## IX. CLEAN WATER ACT

### A. *Supreme Court Allows Court Review of U.S. Army Corps of Engineers-Approved Jurisdictional Determinations*

The Supreme Court held that an approved jurisdictional determination (JD) made by the U.S. Army Corps of Engineers as to whether property contains “waters of the United States” constitutes a final agency action that is reviewable under the Administrative Procedure Act<sup>117</sup> (APA).<sup>118</sup> *U.S. Army Corps of Engineers v. Hawkes Co.* was brought by three peat mining companies seeking to challenge the Corps' approved JD that their properties included wetlands that qualified as “waters of the United States” and that discharge onto those properties required a permit under Section 404 of the CWA.<sup>119</sup>

The Court held that the approved JD satisfied both conditions required for agency action to be “final” and reviewable under the APA: the JD marked the “consummation of the agency's decision-making process” and was a decision “from which legal consequences will flow.”<sup>120</sup> The Corps argued that the approved JDs were not reviewable because there were adequate alternatives to APA review in court. Specifically, the mining companies could either operate without a permit and challenge the Corps' jurisdictional determination as part of EPA enforcement proceedings or complete the permit application process and seek judicial review after that.<sup>121</sup> The Court held that “neither alternative is adequate,” particularly given the risk of “serious criminal and civil penalties” presented by an enforcement action.<sup>122</sup>

### B. *Sixth Circuit Stays Clean Water Rule and Holds That It Is Subject to Direct Circuit Court Review*

The U.S. Army Corps of Engineers and EPA promulgated the Clean Water Rule<sup>123</sup> in June 2015 for the purpose of clarifying the CWA's jurisdiction.<sup>124</sup> The new rule defines “waters of the United States” as in-

116. *Id.* at 74506.

117. 5 U.S.C. § 701.

118. *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1812–13 (2016).

119. *Id.*; see also 33 U.S.C. § 1344(a).

120. *Hawkes*, 136 S. Ct. at 1813 (citing *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)).

121. *Id.*

122. *Id.* at 1815 (citation omitted).

123. Clean Water Rule: Definition of “Waters of the United States,” 80 Fed. Reg. 37054 (June 29, 2015).

124. *Id.* at 37057.

cluding “[a]ll waters which are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce” and “all waters determined to have a significant nexus to a water” that otherwise qualifies as a “water of the United States.”<sup>125</sup>

Shortly after the Rule was finalized, eighteen states (petitioners) filed lawsuits challenging the rule in various federal circuit courts.<sup>126</sup> Those actions were consolidated in the Sixth Circuit.<sup>127</sup> The petitioners moved to stay the rule pending judicial review.<sup>128</sup> Some petitioners also moved to dismiss the Sixth Circuit action, arguing that the rule was not subject to direct circuit court review under the CWA and that their challenges should be heard by a district court.<sup>129</sup>

The Sixth Circuit granted the petitioners’ motion to stay the rule on October 9, 2015.<sup>130</sup> The court found that the petitioners demonstrated a substantial chance of success on the merits of their claims that the rule contravenes the Supreme Court’s 2006 ruling in *Rapanos v. United States*<sup>131</sup> and that the agencies did not comply with APA notice-and-comment requirements.<sup>132</sup> The court also stated that “the sheer breadth of the ripple effects caused by the Rule’s definitional changes counsels strongly in favor of maintaining the status quo for the time being.”<sup>133</sup>

On February 22, 2016, a fractured court denied the pending motions to dismiss, with one judge concurring in the lead opinion and one judge dissenting.<sup>134</sup> The lead opinion held that the rule constitutes an “effluent limitation or other limitation” and an agency action “issuing or denying a permit,” both of which are directly reviewable by circuit courts under the CWA.<sup>135</sup> On September 2, 2016, certain petitioners filed a writ of certiorari to the U.S. Supreme Court seeking review of the Sixth Circuit’s direct review decision.<sup>136</sup>

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125. 33 C.F.R. § 328.3(a)(1), (a)(7).

126. *Ohio v. U.S. Army Corps of Eng’rs (In re Env’t. Prot. Agency & Dep’t of Def. Final Clean Water Rule)*, 803 F.3d 804 (6th Cir. 2015). Various challenges were likewise filed at the district court level. *See, e.g., N. Dakota v. U.S. Env’t. Prot. Agency*, 127 F. Supp. 3d 1047, 1052 (D.N.D. 2015).

127. *In re Env’t. Prot. Agency*, 803 F.3d at 805.

128. *Id.* at 806.

129. *Id.*; *see also Murray Energy Corp. v. U.S. Dep’t of Def. (In re U.S. Dep’t of Def. Clean Water Rule)*, 817 F.3d 261, 270 (6th Cir. 2016).

130. *In re Env’t. Prot. Agency*, 803 F.3d at 808–09.

131. 547 U.S. 715 (2006).

132. *In re Env’t. Prot. Agency*, 803 F.3d at 807–08.

133. *Id.* at 808.

134. *In Re U.S. Dep’t of Def. Clean Water Rule*, 817 F.3d at 274.

135. *Id.* at 266–74. The concurring judge issued a separate opinion, stating that he joined in the result only because he was bound by Sixth Circuit precedent regarding the interpretation of actions “issuing or denying a permit.” *Id.* at 282 (Griffin, J. concurring).

136. *Petition for Certiorari, Nat’s Ass’n of Mfrs. v. Murray Energy Corp.* (No. 16-299). The petition for certiorari remains pending. In addition, a group of thirty states has filed a

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*C. District Court Limits Reach of Diligent Prosecution Bar*

On October 20, 2015, the U.S. District Court for the Middle District of North Carolina held that a state enforcement action did not bar a CWA citizen suit.<sup>137</sup> The case involves allegations about the Duke Energy Carolinas LLC Buck Steam Station. In August 2013, the North Carolina Department of Environment and Natural Resources (DENR) initiated an enforcement action alleging that Duke Energy violated state regulations.<sup>138</sup> More than a year later, in September 2014, citizen groups Waterkeeper Alliance and Yadkin Riverkeeper brought a CWA citizen suit alleging Duke Energy violated similar federal regulations, namely its water discharge permits.<sup>139</sup> In denying Duke Energy's motion to dismiss under the diligent prosecution bar, the court held that DENR had failed the "diligence" portion of diligent prosecution. Although DENR had filed suit well over a year before the citizen groups, the Department failed to take a single deposition, file a single motion, or even seek a case management order.<sup>140</sup> Indeed, after the citizen groups had filed suit, DENR moved to stay its own prosecution.<sup>141</sup> Given the lack of progress—and DENR's stated willingness to stay prosecution—the court held that diligent prosecution did not bar the citizen suit.

#### X. RESOURCE CONSERVATION AND RECOVERY ACT

In May 2016, various environmental groups brought a citizen suit against EPA in the U.S. District Court for the District of Columbia.<sup>142</sup> This pending suit seeks to compel EPA to revise Subtitle D regulations and guidelines for the disposal, storage, handling, and transport of oil and gas wastes.<sup>143</sup> The environmental groups argue these revisions are needed in light of rapidly increasing oil and gas development, particularly fracking, which has generated large quantities of liquid and solid wastes.<sup>144</sup>

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petition with the Tenth Circuit requesting that it revive their district court-level challenges to the Clean Water Rule, notwithstanding the Sixth Circuit's jurisdictional ruling. *See* Chamber of Commerce v. U.S. Env't. Prot. Agency, No. 16-5038 (10th Cir.). The Tenth Circuit has not yet ruled in that action.

137. *Yadkin Riverkeeper, Inc. v. Duke Energy Carolinas, LLC*, 141 F. Supp. 3d 428, 454 (M.D.N.C. 2015).

138. *Id.* at 435.

139. *Id.* at 436–37.

140. *Id.* at 442.

141. *Id.* at 443.

142. The following environmental groups filed this lawsuit: Environmental Integrity Project; Natural Resources Defense Council; Earthworks; Center for Health, Environment & Justice; West Virginia Citizen Action Group; Responsible Drilling Alliance; and San Juan Citizens Alliance. Complaint, *Env'tl. Integrity Project v. McCarthy*, No. 1:16-cv-00842-JBD (D.D.C. May 5, 2016), ECF No. 1.

143. *Id.* ¶¶ 1, 7.

144. *Id.* ¶ 2.

The complaint alleges that EPA violated its duties under RCRA.<sup>145</sup> Subtitle D of RCRA addresses non-hazardous wastes<sup>146</sup> and makes state and local governments primarily responsible for regulating and implementing non-hazardous waste management, while EPA publishes standards and guidelines and approves state waste plans.<sup>147</sup> EPA must review and revise, as necessary, Subtitle D regulations and state plan guidelines at least every three years.<sup>148</sup>

As of September 8, 2016, North Dakota and three oil and gas industry associations have moved to intervene in the case.<sup>149</sup> According to one oil and gas industry group representative, the relief sought by the environmental groups exceeds the bounds of EPA's authority and the proper venue for the dispute is Congress, not the courts.<sup>150</sup> The plaintiffs opposed the motions to intervene, arguing that neither prospective plaintiff had a legally protected interest that would be impaired by the litigation or standing to intervene.<sup>151</sup> The motions are pending.

#### XI. TOXIC SUBSTANCES CONTROL ACT AMENDMENT

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act.<sup>152</sup> The Act amends the Toxic Substances Control Act of 1976 (TSCA) for the first time in forty years. The Act brings significant changes to the way EPA regulates the introduction of new and existing chemicals in commerce. EPA has already begun implementing the Act. It has made several determinations on whether new chemicals will present unreasonable risks in the marketplace and has begun developing rules to establish key procedures under the Act.<sup>153</sup>

The Act changes the way EPA regulates existing chemicals in the marketplace. Currently, more than 83,000 chemicals are in commerce. The original TSCA did not require EPA to affirmatively assess the safety of existing chemicals in commerce. Now, the Act requires EPA to evaluate

145. *Id.* ¶¶ 4–5.

146. 42 U.S.C. § 6941.

147. 42 U.S.C. §§ 6941–6943, 6947.

148. 42 U.S.C. §§ 6912(b), 6942(b).

149. State and Industry Motions to Intervene, No. 1:16-cv-00842-JBD (D.D.C.), ECF Nos. 11–2, 14 & 20.

150. Keith Goldberg, *Enviros Can't Force Drilling Waste Regs Update, Court Told*, LAW360 (Aug. 4, 2016, 5:45 P.M.).

151. Defendant EPA's Combined Memorandum of P & A in Opposition to the State and Industry Motions to Intervene at 7–28, No. 1:16-cv-00842-JBD (D.D.C.), ECF No. 25.

152. Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. 114–182, 130 Stat. 448 (2016).

153. For an up-to-date list of EPA actions taken pursuant to the Act, see <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

existing chemicals as follows: (1) prioritize chemicals for assessment;<sup>154</sup> (2) evaluate chemicals using a risk-based safety standard to determine whether the chemicals pose potential risks of injury to health or the environment;<sup>155</sup> and (3) manage any unreasonable risks that it finds by taking certain actions, such as restricting the amount of a chemical that can enter the marketplace.<sup>156</sup>

The Act also changes how EPA will regulate the introduction of new chemicals. The original TSCA allowed new chemicals to enter the stream of commerce if EPA did not act within a certain period of time.<sup>157</sup> Now, however, the Act requires EPA to make an affirmative finding that a new chemical is safe before the agency allows those chemicals to enter the marketplace.<sup>158</sup> EPA must review the information that a company submits as part of its pre-manufacture notice,<sup>159</sup> and the agency can manage any of the concerns it identifies by banning, limiting, or ordering additional testing for a chemical.<sup>160</sup>

Further, the Act amends the laws on preemption, protection of confidential business information (CBI), and the export and disposal of mercury.<sup>161</sup>

1. *Preemption.* Federal law will preempt state laws if EPA subsequently finds through a risk evaluation that a chemical is safe or unsafe and acts to manage a chemical's risks.<sup>162</sup>
2. *CBI.* Companies now must submit a detailed statement and certification supporting the need, if any, to keep information provided to EPA confidential upfront.<sup>163</sup> In most cases,<sup>164</sup> information will remain confidential for ten years and requests for confidentiality can be renewed.<sup>165</sup>

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154. See 15 U.S.C. § 2605(b)(1) (2016).

155. 15 U.S.C. § 2605(b)(4)(A) ("The Administrator shall conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors. . . .").

156. 15 U.S.C. § 2605(a) (listing risk management actions).

157. See 15 U.S.C. § 2605 (2012).

158. 15 U.S.C. § 2604(a) (2016).

159. See 15 U.S.C. § 2604(b).

160. See 15 U.S.C. § 2604(f).

161. For a comprehensive overview of the Act's reforms, see Jane E. Montgomery, Patrick F. Veasy & Amy Antonioli, *Toxic Substances Control Act Revised for the 21st Century*, SCHIFF HARDIN ENERGY & ENVTL. L. ADVISER (June 29, 2016), <http://www.energyenvironmentallawadviser.com/2016/06/toxic-substances-control-act-revised-for-the-21st-century/>.

162. See generally 15 U.S.C. § 2617 (preemption).

163. See generally 15 U.S.C. § 2613 (confidential information).

164. See 15 U.S.C. § 2613(e)(1)(A).

165. See 15 U.S.C. § 2613(e)(1)(B).

3. *Mercury*. The Act bans the export of elemental mercury and certain mercury compounds, effective January 1, 2020.<sup>166</sup> Among other new requirements, it also directs EPA to publish an initial inventory of mercury supply, use, and trade in the United States by April 1, 2017.<sup>167</sup>

EPA has been busy at work implementing the Act.<sup>168</sup> The agency has already identified and published a list of mercury compounds that are banned from export.<sup>169</sup> Also, the agency has completed risk determinations for several new chemicals. Moreover, EPA has started to develop rules to govern its prioritization and risk evaluation process.

## XII. *ELY V. CABOT OIL & GAS: SUITS REMAIN A THREAT TO FRACKING INDUSTRY*

When the oil and gas technology known as “fracking” first began proliferating, many legal experts predicted a wave of lawsuits alleging water pollution. These lawsuits have largely failed to materialize and causation has proven challenging for plaintiffs, but one case decided this year demonstrates that water pollution claims remain a legitimate threat for the industry.

On March 10, 2016, the jury in *Ely v. Cabot Oil & Gas* returned a \$4.24 million verdict for the plaintiffs.<sup>170</sup> In 2009, forty-four landowners sued the company, alleging that Cabot’s operations in the town of Dimock, Pennsylvania, had polluted drinking water supplies with methane.<sup>171</sup> Cabot reached settlements with the vast majority of these plaintiffs; by the time the case went to trial, only two plaintiffs remained.

Cabot also limited the number of claims it faced through successful pretrial motions. The plaintiffs’ original claims included personal injury, medical monitoring, property damage, breach of contract, fraud, violations of state hazardous waste law, negligence, and negligence per se.<sup>172</sup> The company won summary judgment on many of these claims because

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166. 15 U.S.C. § 2611(c)(7).

167. 15 U.S.C. § 2607(b)(10)(B).

168. See U.S. Envtl. Prot. Agency, *Frank R. Lautenberg Chemical Safety for the 21st Century Act: First Year Implementation Plan*, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-2> (last updated June 29, 2016) (EPA’s first-year implementation plan for the Act).

169. See Notice, Mercury Compounds; Prohibition of Export, 81 Fed. Reg. 58926 (Aug. 26, 2016), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0411-0001>.

170. Verdict Returned, *Ely v. Cabot Oil & Gas Co.*, No. 09-cv-2284 (M.D. Pa. Mar. 10, 2016).

171. Complaint, *Fiorentino v. Cabot Oil & Gas Co.*, No. 09-cv-2284, 2009 WL 4623704 (M.D. Pa. Nov. 19, 2009).

172. Amended Complaint, *Fiorentino*, No. 09-cv-2284 (M.D. Pa. May 17, 2010).

the plaintiffs provided insufficient evidence.<sup>173</sup> Other claims were dismissed as a matter of law.<sup>174</sup> Only two causes of action were considered during the trial—private nuisance and negligence.<sup>175</sup>

Cabot's success continued in the weeks before trial. The company successfully moved to exclude 150 of the plaintiffs' 174 exhibits.<sup>176</sup> The court also severely limited the testimony of one of the plaintiffs' experts.<sup>177</sup>

Despite Cabot's success in limiting the number of plaintiffs, claims, and the available evidence, an eight-person jury voted unanimously to award \$4.24 million to the plaintiffs—\$2.75 million to the owners of the property on which the fracked well was located and \$1.49 million to a neighbor.

*Ely* adds to a growing body of law applying state evidentiary presumptions for water pollution to private tort actions. Pennsylvania is one of a number of states that has codified a presumption that a well operator is responsible for any water pollution that occurs within a specified distance of a fracked well.<sup>178</sup> Over Cabot's objections, the court in *Ely* held that this presumption is available to private litigants in tort cases.<sup>179</sup> The court noted that Pennsylvania state courts have not addressed the question, but the U.S. District Court for the Middle District of Pennsylvania had ruled that the presumption applied in two prior cases. Similar statutory presumptions exist in a number of states, including Illinois, Maryland, and West Virginia.<sup>180</sup>

### XIII. FIFRA MINIMUM RISK PESTICIDE PRODUCT REGULATIONS ADD CLARITY ON LABELING REQUIREMENTS

On December 28, 2015, the EPA published a final rule revising minimum risk pesticide product regulations promulgated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).<sup>181</sup> The new regulations

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173. Report and Recommendation of Magistrate, *Ely v. Cabot Oil & Gas Co.*, No. 3:09-cv-2284 (M.D. Pa. Mar. 28, 2014).

174. *See, e.g.*, *Ely v. Cabot Oil & Gas Co.*, 38 F. Supp. 3d 518 (M.D. Pa. 2014) (granting summary judgment for the defendant on the strict liability claims after holding that fracking is not an abnormally dangerous activity).

175. Plaintiff's Amended Pretrial Memorandum at 32, *Ely*, No. 3:09-cv-02284 (M.D. Pa. Feb. 1, 2016).

176. Memorandum of Magistrate, *Ely*, No. 3:09-cv-02284, 2016 WL 590370 (M.D. Pa. Feb. 12, 2016).

177. Memorandum of Magistrate, *Ely*, No. 3:09-cv-02284, 2016 WL 4169220 (M.D. Pa. Feb. 17, 2016).

178. 58 PA. CONS. STAT. §§ 3218(c)-(d) (2012).

179. *Ely v. Cabot Oil & Gas Co.*, No. 3:09-cv-02284, 2016 WL 454817 (M.D. Pa. Feb. 5, 2016).

180. 225 ILL. COMP. STAT. 732/1-85 (2013); MD. CODE ANN. §§ 14-110.1(b)-(d), (j)-(k) (2012); W. VA. CODE § 22-6A-18(b)-(d) (2011).

181. Pesticides; Revisions to Minimum Risk Exemption, 80 Fed. Reg. 80653 (Dec. 28, 2015).

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more clearly describe the active and inert ingredients that are allowed in minimum risk pesticide products by codifying the inert ingredients list, and by adding specific chemical identifiers, where available, for all eligible active and inert ingredients.<sup>182</sup> The goal of the revisions is to make it easier for manufacturers and others to understand what substances are permitted in minimum risk pesticide products.<sup>183</sup> The new regulations also update labeling requirements for minimum risk pesticide products.<sup>184</sup> The products must list ingredients on the label using the “designated label display name” (i.e., the name listed for the ingredient under Tables 1 or 2 of 40 C.F.R. § 152.25(f)) and provide the product producer’s contact information on the product label.<sup>185</sup> While the final rule became effective February 26, 2016, manufacturers have until February 26, 2019, to comply with the new labeling requirements.<sup>186</sup>

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182. *Id.* at 80654; 40 C.F.R. § 152.25(f) (2016).

183. 80 Fed. Reg. at 80654.

184. *Id.*; 40 C.F.R. § 152.25(f) (2016).

185. 80 Fed. Reg. at 80654.

186. *Id.* at 80653.

