THE COMPLEMENTARY ROLES OF COMMON LAW COURTS AND FEDERAL AGENCIES IN PRODUCING AND USING POLICY-RELEVANT SCIENTIFIC INFORMATION

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The regulatory agencies that administer the federal health and environmental laws rely on scientific information of varying quality and reliability from a variety of sources ranging from published scientific articles to unpublished reports from regulatees on the results of product testing to adverse effects reports indicating that particular products or activities pose unacceptable risks. Common law courts overseeing modern toxic tort and products liability lawsuits likewise rely upon a variety of sources of scientific information of equally diverse quality and reliability. Unlike the staffs of regulatory agencies, however, the attorneys for the parties in common law litigation have a strong incentive to dig deeply into the origins and bona fides of the scientific information upon which the courts rely. They have access to powerful legal tools for probing the provenance of scientific studies and for uncovering information about otherwise undisclosed studies and candid internal evaluations of the studies that are made available to regulatory agencies.

Although cooperation between regulatory agency staff and common law litigants in making scientific information available to agencies and courts would seem to be in the overall public interest, it is usually the exception, rather than the rule. Relying on a case study of the regulatory and litigation history of the ubiquitous chemical compound PFOA, this Article probes that potential and the impediments that stand in the way of its full realization, including limitations on agency authority to demand information from regulatees, trade secrecy restrictions on the release of information in agency files, Daubert*-inspired judicial barriers to the admissibility of expert testimony, and gag orders imposed by court-issued protective orders and court-approved settlement agreements. The Article concludes with suggestions for reducing or eliminating some of these impediments to cooperation.*

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I. INTRODUCTION

Beginning in the early 1970s, Congress empowered federal agencies, like the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration, and the Food and Drug Administration, to protect human health and the environment from a variety of risks posed by useful consumer products and less useful activities that result in discharges of pollutants into the nation's air and water. The agencies implement their often overwhelming responsibilities by promulgating rules governing private conduct or, in some cases, by approving products for public marketing. To assess the risks posed by such products and activities properly, these agencies rely upon scientific information from a variety of sources ranging from published scientific articles to unpublished reports from regulatees on the results of product testing to adverse effects reports indicating that particular products or activities pose unacceptable risks.[1] The agencies have

[1] *See* EPA, GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY THE ENVIRONMENTAL PROTECTION AGENCY 19 (2002) *available at* http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf [hereinafter EPA GUIDELINES].

become repositories of huge amounts of scientific information that they may use in taking regulatory action or disseminate to the public by way of warnings or cautionary statements.

Common law courts entertaining products liability and toxic tort claims rely upon the same kind of scientific information in 1) assessing whether the defendant's products are defective or its activities subject workers or neighbors to unreasonable risks and 2) determining whether the defendant's products or activities caused damage to the plaintiff. Defendants in such actions are often subject to federal regulatory requirements as well, and they can provide the courts with the same information that they supply to the agencies.[2] Private litigants can also commission their own studies and hire experts to assess and opine on the scientific literature.[3] Unlike regulatory agencies, litigants can also dig through the files of the opposing parties in an effort to uncover additional scientific information and evidence that they may or may not have shared with the appropriate regulatory agencies.[4] The situation therefore offers the potential for cooperative sharing of scientific information between regulatory agencies and common law courts.[5] Relying on a case study of the regulatory and litigation history of the ubiquitous chemical compound perfluorooctanoic acid (PFOA), this Article probes that potential and the impediments that stand in the way of its full realization.

II. SCIENTIFIC INFORMATION IN REGULATORY AGENGIES

Agencies can draw on a wide variety of sources of scientific information to use in promulgating rules and regulating products. Agency staff with expertise in the relevant scientific disciplines can comb the published literature for relevant studies. During the rulemaking process, agencies ask members of the public to provide any information they possess that might be relevant.[6] This typically yields large submissions from the regulated entities and sometimes from nongovernmental public interest groups.[7] In the context of product licensing, the primary source of agency information, however, is neither the published scientific literature nor public comments. It is the entity that is seeking the agency's approval to market the product. Submitters of health and environmental information in these contexts typically claim that the information is "trade secret" or "confidential business information" that the agency may not disclose to the public.[8] Finally, agencies can commission their own health and environmental studies.[9] Although some agencies have modest research

[2] *See* Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 700 (2007).

[3] *Id.*

[4] *Id.*

[5] *Id.* at 696.

[6] *See* EPA GUIDELINES, *supra* note 1.

[7] *See* Wagner, *When All Else Fails*, *supra* note 2, at 706.

[8] *Id.* at 699–700.

[9] *See* Wendy Wagner, *The "Bad Science" Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 LAW & CONTEMP. PROBS. 63, 98–99

budgets, very few of those very limited dollars go into health and environmental testing and analysis.[10]

A. Adverse Effects Reporting Requirements

Several health and environmental statutes require regulatees to report to the relevant regulatory agency any information they acquire indicating their products or activities may have a significant adverse effect on human health or the environment.[11] In particular, section 8(e) of the Toxic Substances Control Act (TSCA) requires any manufacturer, processor, or distributor of a chemical substance who has "information which reasonably supports the conclusion that such substance . . . presents a substantial risk or injury to health or the environment" to "immediately inform" EPA of such information, unless the agency has already been adequately informed of the information.[12] Since this very broad requirement is backed up by criminal penalties,[13] it should have a profound impact on a company. It is, however, very difficult to enforce, and what little evidence exists suggests that noncompliance rates are high. According to Professor Arnold Reitze's treatise, the adverse effects reporting requirements are at the bottom of EPA's list of regional inspections.[14]

B. TSCA Testing Rules

A few agencies have the authority to require regulatees to conduct scientific testing to evaluate the health and environmental risks posed by their products and activities. The most comprehensive of these testing authorities is section 4 of TSCA, which authorizes EPA to order manufacturers of new or existing chemical substances to test those substances.[15] If EPA can support one of several findings, it may promulgate an appropriate testing rule. First, EPA may require testing if it finds that the manufacture, distribution, or other covered uses of a chemical substance "may present an unreasonable risk of injury to health or the environment," that "there are insufficient data and experience upon which the effects" of the chemical "on health or the environment can reasonably be determined or predicted," and that "testing . . . with respect to such effects is necessary to

(2003).

10 *See* ARNOLD W. REITZE, JR., AIR POLLUTION CONTROL LAW: COMPLIANCE AND ENFORCEMENT 491 (2001).

11 *See, e.g.*, Toxic Substances Control Act, 15 U.S.C. § 2607(e) (2000). *See also* 40 C.F.R. § 158.20(b) (2005) (describing the purpose of data and information requirements for pesticide registration with EPA under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y (2000)).

12 15 U.S.C. § 2607(e) (2000).

13 *Id.* § 2615(b) (2000) (indicating violations of failing to submit reports, notices, or other information shall be subject "to a fine of not more that $25,000 for each day of violation, or to imprisonment for not more than one year, or both").

14 REITZE, *supra* note 10, at 491.

15 15 U.S.C. § 2603 (2000).

develop such data."[16] Alternatively, EPA may base a testing rule on a finding that the substance "will be produced in substantial quantities" and either "enters or may reasonably be anticipated to enter the environment in substantial quantities" or "there is or may be significant or substantial human exposure to such substance."[17] Finally, if "there are insufficient data and experience upon which the effects" of the chemical "on health or the environment can reasonably be determined or predicted," then "testing . . . with respect to such effects is necessary to develop such data."[18] The statute also creates an Interagency Testing Committee (ITC), composed of representatives of several federal agencies, to nominate for testing chemicals that meet this multi-faceted threshold test.[19] Once a chemical appears on the ITC "priority list" of fifty chemicals, EPA must in theory decide within one year whether to issue a rule ordering further testing.[20]

Surprisingly, EPA has exercised this power quite sparingly. Instead of initiating rulemaking actions, it tends to invite manufacturers to meetings with agency staff to negotiate about the nature and extent of additional testing that needs to be done.[21] These negotiations can drag on for years, and they do not always result in especially stringent testing requirements. Former Assistant Administrator Lynn Goldman admits that EPA is "quite gun shy" when it comes to regulating under TSCA, and points out that "[w]hen you don't have the ability to regulate in your armamentarium, you are in a very weak negotiating position."[22] The Government Accountability Office concluded that "EPA does not routinely assess the human health and environmental risks of existing chemicals and faces challenges in obtaining the information necessary to do so."[23] As of 1998, at least one-third of the toxic chemicals produced in the highest volumes still failed to satisfy minimal data requirements.[24]

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16 *Id.* § 2603(a)(1)(A) (2000).

17 *Id.* § 2603(a)(1)(B)(i) (2000).

18 *Id.* § 2603(a)(1)(B) (2000).

19 *Id.* § 2603(e) (2000).

20 *Id.* § 2603(e)(1)(B) (2000).

21 *See* Melissa Lee Phillips, *Obstructing Authority*, 114 ENVTL. HEALTH PERSP. A706, A708 (2006), *available at* http://www.ehponline.org/docs/2006/114-12/toc.html.

22 *Id.*

23 *Oversight on the Toxic Substances Control Act and the Chemicals Management Program at EPA*: *Hearing Before the S. Comm. on Environment and Public Works*, 109th Cong., 2d Sess. 2 (2006) (statement of John B. Stephenson, Director, Natural Resources and Environment, U.S. Government Accountability Office).

24 ENVTL. DEFENSE FUND, TOXIC IGNORANCE 15 (1997), *available at* http://www.environmentaldefense.org/pdf.cfm?ContentID=243&FileName=toxicignorance.pdf; *Testing: CMA More Optimistic Than EDF on Lack of Data for 100 Chemicals*, 230 Daily Env't Rep. (BNA) A-4, (Dec. 1, 1997); *What Do We Really Know About the Safety of High Production Volume Chemicals?*, 22 Chemical Reg. Rep.(BNA) 261 (May 1, 1998).

III. SCIENTIFIC INFORMATION IN COMMON LAW COURTS

Many kinds of products liability claims and most toxic tort claims at common law demand large amounts of scientific information. Ordinarily, plaintiffs need such information to establish a cause-effect relationship between exposure to a toxic product or discharge and actual damage to the plaintiff's health or economic well-being.[25] Common law courts do not have the power to order private entities to conduct testing. Since the burden of proof in common law cases is on the plaintiff, it behooves plaintiffs' attorneys to identify existing studies or commission new ones to be presented to the fact-finders through the testimony of qualified experts.[26] Like agency staffers, experts for plaintiffs can pour through the existing scientific literature, but they do not always have the same access to the information that companies provide to regulatory agencies for reasons that we shall probe below. Unlike agencies, plaintiffs' attorneys have a strong incentive to probe another source of information—the files of the companies (frequently the same companies that the agencies regulate) for scientific information and, importantly, for evidence that the companies knew in advance of the risks that their products and activities posed to the attorneys' clients.

In the now famous case of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[27] the Supreme Court seized an opportunity to address complaints from traditional tort defendants and their allies in the think tanks that the courts were relying too heavily on "junk science" in products liability and toxic torts cases.[28] The Court declined to employ the *Frye* "general acceptance in the scientific community" standard for admitting expert testimony and instead interpreted Rule 104(a) of the Federal Rules of Evidence to require the district judge to be a gatekeeper, determining the admissibility of "scientific, technical, or other specialized knowledge" under Rule 702.[29] The trial judge must determine whether expert testimony is relevant and reliable before allowing the jury to consider that testimony, and the trial judge is to determine the reliability of scientific proof by reference to its scientific validity when measured against the methods and procedures of science.[30] The Court's elaboration on the *Daubert* criteria in *General Electric Co. v. Joiner*[31] clarified the trial judge's role of ensuring that scientific testimony fits the judge's view of the relevant issues of the case, and had the foreseeable effect of increasing the lower courts' degree of scrutiny.[32] Furthermore, dicta in that opinion suggests that the trial court is obliged to

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[25] *E.g.*, Bonner v. ISP Techs., Inc., 259 F.3d 924, 928 (8th Cir. 2001).

[26] *See* Erica Beecher-Monas, *A Ray of Light for Judges Blinded by Science: Triers of Science and Intellectual Due Process*, 33 GA. L. REV. 1047 (1999).

[27] 509 U.S. 579 (1993).

[28] *Quayle's Crusade*, 24 NAT'L J. 344, 344 (1992); Owen Ullmann, *President Quayle?*, WASHINGTONIAN, Sept. 1992, at 68, 71, 152.

[29] *Daubert*, 509 U.S. at 588–89 (referring to Frye v. United States, 298 F. 1013 (1923)).

[30] *Id.* at 590 & n.9.

[31] 522 U.S. 136 (1997).

[32] *See id.*

evaluate the scientific validity of an expert's conclusions as well.[33] The data and methodology that the *Joiner* expert employed also accelerated an existing trend in the lower courts toward aggressive judicial scrutiny of plaintiffs' expert testimony.[34] Soon thereafter, Rule 702 was amended to incorporate the *Daubert/Joiner* tests.[35]

IV. A CASE STUDY IN COOPERATION

In October 2000, Joe Kiger of Lubeck, West Virginia, was surprised when a letter he received from his utility company contained not the usual bill, but a notification that the water that he and 8000 of his neighbors had been consuming for the last several years contained a contaminant with the not especially informative name "C-8."[36] Kiger was not reassured by the letter's statement that the water was safe to drink. Determined to "find out what this was all about," the former labor union official called the county health department, the state Department of Environmental Protection (DEP), and the federal EPA.[37] All of them told him that little was known about the chemical except that it was a "perfluorinated" organic compound with a technical name of perfluorooctanoic acid, or PFOA, and that it was completely "unregulated."[38] After additional inquiries, EPA's regional office sent him some information on the chemical and suggested he hire a lawyer. After reading the information, Kiger immediately took that advice.[39]

It turned out a Cincinnati trial lawyer named Rob Bilott knew quite a bit about the chemical Kiger had been drinking.[40] Bilott had already been hired to represent Wilbur and Sandra Tennant in a recently settled case against E. I. DuPont de Nemours & Co. in which the Tennants alleged that releases of PFOA from DuPont's Dry Run Landfill and other nearby DuPont facilities into groundwater and streams in the vicinity of their farm killed almost 300 head of their cattle and caused them numerous health problems.[41]

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[33] *Id.* at 146.

[34] *Id.*; *see also* D. Alan Rudlin, *The Judge as Gatekeeper: What Hath* Daubert-Joiner-Kumho *Wrought?*, 29 Prod. Safety & Liab. Rep. (BNA) (Jan. 1, 2001) (arguing that as a result of *Daubert*, *Joiner*, and *Kumho* federal trial judges now "play an active role in deciding what expert testimony goes to the jury"). Professor Finley reads *Joiner* to express "a normative judgment that judges are to be trusted more than juries (and sometimes more than scientists) in areas where law intersects with science." Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 345 (1999).

[35] FED. R. EVID. 702 advisory committee's note (stating 702 was amended "in response to" *Daubert* and "to the many cases applying *Daubert*").

[36] Ken Ward, Jr., *Both Sides Hope for Answers on C8*, CHARLESTON GAZETTE, Mar. 6, 2005, at B1.

[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] *Id.*

[41] Amy Cortese, *DuPont's Teflon Dilemma: How Chad Holliday, the Champion of Sustainability, is Managing an Environmental Challenge*, CHIEF EXECUTIVE, Nov. 1, 2003, at 22; Letter from Robert A. Bilott, Taft, Stettinius & Hollister LLP, to Christine T. Whitman et. al.

The materials Kiger received from EPA contained a letter from Bilott to EPA putting the agency on notice of information that he had uncovered during discovery in the Tennant's case against DuPont. It was information that DuPont so badly wanted to keep out of the hands of EPA and people like Rob Kiger that it sought a "gag" order from the judge hearing the case that would hold Bilott in contempt of court if he revealed what he had learned to EPA.[42] DuPont's lawyers argued that if EPA got the information, it "could easily reach the mass media."[43] Fortunately, the judge refused to issue the order, and Bilott sent a letter to EPA on March 6, 2001 demanding that the federal government take action to prevent further releases and to force DuPont to clean up existing contamination.[44]

In addition, Billot asked EPA to use its power under the Toxic Substances Control Act to order DuPont to cease all production activities related to C-8 at its Parkersburg, West Virginia plant until it had conducted scientific studies demonstrating that C-8 and related compounds did not present an "unreasonable risk of injury to health or the environment."[45] The DuPont lawyer's concern that the information would wind up on the front page of a local newspaper was, however, unwarranted. The letter rested undisturbed in EPA's files until Kiger and many of his neighbors filed a new lawsuit on behalf of the townspeople who had been drinking the contaminated water.[46]

A. Teflon, C-8, and other Perfluorinated Compounds

The compound C-8 is one of a chemical family of "perfluorinated" organic compounds and is a man-made chemical that does not naturally occur in the environment.[47] A scientist working for the 3M Corporation discovered an astonishingly useful property of these compounds when he spilled an experimental chemical on a lab assistant's tennis shoe and could not wash it out, even with soap and water.[48] Further research culminated in the isolation and production of a compound called perfluorooctanyl sulfonate (PFOS) that became the critical ingredient in 3M's highly successful water repellant Scotchgard®.[49] For many years, PFOS was manufactured at 3M's plant in Decatur, Alabama.[50]

(Mar. 6, 2001) (regarding request for Immediate Governmental Action/Regulation Relating to DuPont's C-8 Releases in Wood County, West Virginia and Notice of Intent to Sue Under the Federal Clean Water Act, Toxic Substances Control Act, and Resources Conservation and Recovery Act) [hereinafter letter from Robert A. Bilott].

42 Ward, *Both Sides Hope for Answers on C8*, *supra* note 36.

43 *Id.*

44 *Id.*; Letter from Robert A. Bilott, *supra* note 41, at 3.

45 Letter from Robert A. Bilott, *supra* note 41, at 3.

46 Ward, *Both Sides Hope for Answers on C8*, *supra* note 36.

47 David Shaffer, *Former 3M Chemical is Widespread*, STAR TRIB., Aug. 15, 2004, at A1.

48 *Id.*

49 *Id.*

50 *Id.*

DuPont used a related compound perfluorooctanoic acid (PFOA or C-8) at the Parkersburg, West Virginia plant to make its highly successful product Teflon® and related products.[51] Until 2000, DuPont purchased C-8 from 3M's Cottage Grove, Minnesota plant.[52] Teflon and related compounds are widely used throughout the world as coatings for products including cooking utensils, glasses lenses, and even medical devices that need to be waterproof.[53] Since PFOA is not a naturally occurring chemical, all PFOA found in the environment is the result of human activity.[54]

During the 1970s and 1980s, both 3M and DuPont conducted numerous tests related to the toxicity and persistence of perfluorinated compounds, and they shared the results of such tests with each other.[55] By 1978, 3M studies had demonstrated that the compounds were "completely resistant to biodegradation."[56] A great deal of testing has reinforced EPA's more recent conclusion that PFOA is "persistent in the environment."[57] Like their cousins, the chlorinated hydrocarbon pesticides, perfluorinated compounds also bioaccumulate and bioconcentrate in the environment.[58] The compounds are very poorly metabolized by human beings.[59] When human beings consume these compounds, they remain in the bloodstream, circulating through their bodies over and over again.[60] According to 3M medical director Larry Zobel, the perfluorinated compounds are "very unlike other materials that get in the body and stay a long time, which might go to fat or to bone," because they are "actively moving around the body."[61] He also noted that they remain in the body for three to five years after they enter it.[62]

This might not be a problem, except for the fact that the perfluorinated compounds may also be toxic to humans. Because they have never been regulated by any governmental entity in the United States, relatively little data on toxicity in human beings is available. EPA has, however, concluded

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51 *Id.*

52 *Id.*

53 Perfluorooctanoic Acid (PFOA), Fluorinated Telomers; Request for Comment, Solicitation of Interested Parties for Enforceable Consent Agreement Development, and Notice of Public Meeting 68 Fed. Reg. 18,628 (Apr. 16, 2003) [hereinafter, PFOA Request for Comment].

54 *Id.*

55 Letter from Robert A. Bilott, *supra* note 41, at 5.

56 ENVTL. WORKING GROUP, PFCS: GLOBAL CONTAMINANTS: PFCS LAST FOREVER (2003), *available at* http://www.ewg.org/node/21716 (citing a 1978 study done by 3M Corporation that confirmed PFOA was "completely resistant to biodegradation"); 3M CORP., TECHNICAL REPORT SUMMARY, BIODEGRADATION STUDIES OF FLUOROCARBONS—III, at 2 (July 19, 1978).

57 *See generally* PFOA Request for Comment, *supra* note 53, at 18,628–29.

58 ENVTL. WORKING GROUP, PFCS LAST FOREVER, *supra* note 56.

59 ENVTL. WORKING GROUP, PFCS: GLOBAL CONTAMINANTS: DUPONT'S SPIN ABOUT PFOA (2003), *available at* http://www.ewg.org/node/21776.

60 ENVTL. WORKING GROUP, PFCS: GLOBAL CONTAMINANTS: PFOA IS A PERVASIVE POLLUTANT IN HUMAN BLOOD, AS ARE OTHER PFCS (2003), *available at* http://www.ewg.org/node/21715.

61 Mike Edgerly & Sasha Aslanian, *Toxic Traces: Part 1: The Science* (Minnesota Public Radio Broadcast Feb. 22, 2005), *available at* http://news.minnesota.publicradio.org/projects/2005/02/toxictraces/.

62 *Id.*; *see also* Perfluorooctyl Sulfonates; Proposed Significant New Use Rule, 65 Fed. Reg. 62,319, 62,326 (proposed Oct. 18, 2000) (to be codified at 40 C.F.R. pt. 721).

that PFOA is carcinogenic in laboratory animals at high dose levels.[63] Although this conclusion has not been validated by human epidemiological studies, EPA has traditionally taken the "conservative" view that animal carcinogens pose a carcinogenic risk to human beings absent strong evidence to the contrary.[64] The perfluorinated compounds may also cause hypothyroidism.[65]

Perhaps the most significant end point identified in the animal studies, however, is the perfluorinated compounds' reproductive toxicity. It causes birth defects in laboratory animals at dose levels not much higher than some human exposures.[66] In a preliminary "rangefinder" screening study conducted by 3M in 1981, rats exposed to a perfluorinated compound at high doses during pregnancy suffered from eye defects.[67] The company reported these results to EPA on March 23, 1981.[68] In a 1982 study conducted at 3M's expense, the incidence of skeletal abnormalities (a telltale sign of chemically induced birth defects) in rabbit fetuses was significantly higher in exposed animals than in control animals.[69] As we shall see, DuPont later became aware of other information indicating that PFOA caused birth defects in humans.[70]

B. 3M Gets Out of the Business

During the late 1990s, 3M received scientific studies indicating that perfluorinated compounds were more ubiquitous in the environment and more toxic than scientists had previously supposed.[71] Armed with newly developed analytical tools capable of detecting PFOS in the parts per trillion range, the company decided to compare PFOS levels in the blood of 3M workers with the levels of the same compound in randomly selected blood samples from Red Cross blood banks around the country.[72] To the surprise of everyone, the Red Cross samples were not "clean," but in fact contained PFOS at levels lower than the workers, but still significantly higher than expected.[73]

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63 PFOA Request for Comment, *supra* note 53, at 18,629 (referencing results of animal toxicity studies conducted with salts derived from PFOA).

64 EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT A-3 (2005), *available at* www.epa.gov/IRIS/cancer032505.pdf.

65 ENVTL. WORKING GROUP, PFCS: GLOBAL CONTAMINANTS: PFC HEALTH CONCERNS (2003), *available at* http://www.ewg.org/node/21726.

66 *See* PFOA Request for Comment, *supra* note 53, at 18,629.

67 *See* Memorandum from Bruce W. Karrh, M.D., to C. De Martino (Mar. 25, 1981) (summarizing the results of a study that found a fluorinated surfactant C-8 compound to cause scarring on the fetuses of rats).

68 *Id.*

69 ENVTL. WORKING GROUP, PFCS LAST FOREVER, *supra* note 56, at 7.

70 EPA, Perfluorooctyl Sulfonates; Proposed Significant New Use Rule, 65 Fed. Reg. 62,319, 62,326 (proposed Oct. 18, 2000) (to be codified at 40 C.F.R. pt. 721).

71 David Barboza, *3M Says it Will Stop Making Scotchgard*, N.Y. TIMES, May 17, 2000, at A19.

72 Terry Fiedler, *3M to Drop Scotchgard Lines*, MINNEAPOLIS STAR-TRIB., May 17, 2000, at A1; Edgerly & Aslanian, *supra* note 61.

73 Edgerly & Aslanian, *supra* note 61.

At roughly the same time, a rat reproduction study commissioned by 3M indicated that PFOS caused postnatal deaths and other adverse developmental effects in offspring.[74] At the higher doses all of the first generation offspring died and at the lowest dose many of the progeny in the second generation died.[75] A preliminary review by EPA toxicologists indicated that this was "of significant concern," and a preliminary risk assessment "indicated potentially unacceptable margins of exposure (MOEs) for workers and possibly the general population"[76] (the "margin of exposure" is the ratio between the lowest dose at which a substance causes or is predicted to cause a toxic effect in human beings and the level or predicted level of human exposure to the substance in the real world).[77]

On May 16, 2000, 3M announced it would be "phasing out of the perfluorooctanyl chemistry used to produce" most Scotchgard® products.[78] The company would immediately cease production of certain carpet and upholstery sprays, and it would stop selling all other Scotchgard® products containing PFOS by the end of the year.[79] The action attracted kudos from EPA and a major environmental group.[80] The press release announcing this decision, however, referred exclusively to PFOS's ubiquity and persistence in the environment, and a company spokesperson emphasized that "this chemistry has been used for more than 40 years and our products are safe."[81] The company made no mention of the rat reproduction study that worried EPA scientists.[82] EPA followed the 3M announcement with a regulatory action under section 5 of the Toxic Substances Control Act to "limit any future manufacture or importation of PFOS" until EPA had an opportunity to review its health and environmental risks.[83]

Perhaps because its action simultaneously co-opted any governmental action and projected the image of a responsible corporation, 3M did not suffer huge economic consequences at the time. Both the price of its stock and the sales of Scotchgard® products actually went up immediately following the announcement.[84] In the long term, the announcement "had

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74 David Brown & Caroline E. Mayer, *3M to Pare Scotchgard Products*, WASH. POST, May 17, 2000, at A1.

75 Perfluorooctyl Sulfonates, 65 Fed. Reg. at 62,326.

76 E-mail from Charles Auer to numerous recipients (May 16, 2000, 11:11 AM) (on file with author).

77 EPA, *supra* note 64, at 5-5.

78 Press Release, 3M, 3M Phasing Out Some of its Specialty Materials (May 16, 2000), *available at* http://www.secinfo.com/d215r.58.d.htm.

79 Barboza, *supra* note 71.

80 Fiedler, *3M to Drop Scotchgard Lines*, *supra* note 72, at A1 (quoting EPA Administrator Carol Browner); Brown & Mayer, *supra* note 74, at A1 (quoting Gina Solomon of the Natural Resources Defense Council); Barboza, *supra* note 71, at A19 (quoting Linda Greer, Natural Resources Defense Council).

81 Press Release, 3M, *supra* note 78.

82 *Id.*

83 PFOA Request for Comment, *supra* note 53, at 18,628; Perfluorooctyl Sulfonates, *supra* not 62, at 62,319.

84 Terry Fiedler, *3M Plans Revival of Dropped Products Scotchgard Brand Being Reformulated*, MINNEAPOLIS STAR-TRIB., Sept. 22, 2000, at D1.

virtually no effect on consumer attitudes" toward the trade name Scotchgard®, which continued to be used on products that were not removed from the market.[85] By the end of the year, several of the previously withdrawn products were back on the market with formulations that did not contain PFOS.[86]

C. DuPont Expands Its Business

Fully aware of the fact that the chemical it was using to make Teflon® was almost identical to the chemical that 3M decided to phase out if its Scotchgard® products, DuPont quietly continued to purchase PFOA from 3M and initiated construction of its own PFOA manufacturing facility in Fayetteville, North Carolina.[87] DuPont had received the scientific information that 3M had collected on PFOA through the years, and it had generated some studies of its own. During the 1990s, DuPont established a voluntary "community exposure standard" for PFOA exposure in and near its facilities of 3 micrograms per cubic meter (µg/m3) for ambient air and 1 part per billion (ppb) for drinking water.[88]

Both companies had taken action in 1981 to limit exposure of their female workers to perfluorinated compounds because of the information they received concerning the possibility that the compounds had caused birth defects in the offspring of at least two workers.[89] DuPont had been engaged in a screening program to determine the levels of PFOA in the blood of female workers since 1978 when 3M had detected PFOS in the blood of its workers.[90] After finding PFOA in umbilical cord blood from one baby and in the blood of another baby born to female workers at its Parkersburg, West Virginia plant, it discovered that one out of seven monitored offspring was born with a severe nostril and eye defect and another was born with an unconfirmed eye and tear duct defect.[91] DuPont did not inform EPA of this discovery. In a proposed "follow-up" communication to its female employees, the company confirmed that children of "two women who worked in this area before or during pregnancy" "reportedly had defects detected at birth," and it suggested that exposure to PFOA during pregnancy was "a matter of sufficient concern that, as a precaution, a female who has

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85 *Id.*

86 *Company News*; *Minnesota Mining Bringing Scotchgard back to Market*, N. Y. TIMES, Sept. 23, 2000, at C3.

87 Michael Hawthorne, *Internal Warnings*, COLUMBUS DISPATCH, Feb. 16, 2003, at A1.

88 *Id.*; Letter from Robert A. Bilott, *supra* note 41.

89 Memorandum from R.J. Burger to Supervision through Division Superintendents on C-8 Compounds (Mar. 31, 1981) (on file with author); *see also* Jim Morris, *Did 3M and DuPont Ignore evidence of Health Risks?*, MOTHER JONES, Sept./Oct. 2001, at 17.

90 Burger, *supra* note 89.

91 Draft DuPont Document on C-8 Blood Sampling Results (undated, ca: Aug., 1981) (unpublished manuscript, on file with author); *see also* ENVTL. WORKING GROUP, PFOA IS A PERVASIVE POLLUTANT IN HUMAN BLOOD, AS ARE OTHER PFCS, *supra* note 60.

an organic fluorine blood level above background level should consult with her personal physician prior to contemplating pregnancy."[92]

Although the communication did not concede that PFOA was in fact responsible for the eye defects in the children of exposed workers, the finding was of sufficient concern that DuPont's Medical Office urged the company to undertake an epidemiological study of the offspring of pregnant workers at the plant.[93] After a meeting between the Medical Division and the Products Production Division on July 22, 1981, however, the company decided to put the epidemiological study "'on hold' until further notice."[94] The study was never undertaken.[95]

The company eventually reversed its protective policies upon completing four full-scale animal teratology studies in laboratory animals indicating that the compounds did not pose reproductive risks at the levels of exposure typically encountered in the workplace.[96] A DuPont internal "communication" to workers at the plant noted that the results of "[e]xtensive animal studies" initiated after the rangefinder test had "concluded that the alterations observed in the preliminary study were not caused by exposure to C-8 as originally suspected, but instead were caused by 3M's technique of preparing the fetal eye tissue for microscopic examination."[97] The company therefore concluded that "female employees of childbearing capability no longer need to be excluded from areas where there is potential for exposure to C-8."[98]

After a 1993 study conducted by the University of Minnesota found an association between PFOA exposure and prostate cancer in human beings, 3M and DuPont initiated a series of toxicity studies on laboratory monkeys.[99] In November 1998 one of the monkeys at the high 30 mg/kg dose level was suffering adverse health effects, and by February 1999 it was clear that one of the monkeys receiving the low dose of 3 mg/kg had suffered severe adverse health effects and had to be sacrificed.[100] All of the monkeys in the

92 Wash. Works, Proposed Communication to Females Who Had Worked in Fluoropolymers Area, Attachment A (Apr. 9, 1981) (on file with author).

93 Memorandum from Bruce W. Karrh to Carl DeMartino on Epidemiology Study—C-8 (FC-143) (Apr. 2, 1981).

94 DuPont Document, regarding Project Control No. 57 (summarizing Primary Objectives, Study Design, and Status of Project); *see* Letter from Kenneth A. Cook to Richard H. Hefner on DuPont's Failure to Submit Key Health Studies Under the Requirements of TSCA 8(e), 15 U.S.C. § 2607(e) (Aug. 15, 2003), *available at* http://www.ewg.org/node/21308.

95 Ken Ward, Jr., *DuPont Proposed, Dropped '81 Study of C8, Birth Defects*, CHARLESTON SUNDAY GAZETTE-MAIL, July 10, 2005, at 1A, *available at* http://library.cnpapers.com/cgi-bin/texis/search?uquery="dupont+proposed+dropped" (follow "DUPONT PROPOSED, DROPPED '81 STUDY OF C8, BIRTH DEFECTS" hyperlink; then login or sign up to news library service).

96 Letter from Andrea V. Malinowski, DuPont Corporate Counsel, to Richard H. Hefter (June 20, 2003), *available at* http://www.ewg.org/node/pdf/DuPont_2003_EPA_response.pdf.

97 Memorandum from DuPont to Employees (Mar. 1, 1982) (advising employees with C-8 exposure to resume blood donations if desired).

98 *Id.*

99 Letter from Robert A. Bilott, *supra* note 41, at 5.

100 *Id.*

test group suffered adverse liver effects.[101] EPA did not learn of these results until November 1999, when 3M reported them to EPA.[102] Soon thereafter, EPA initiated the discussions that lead to 3M's May 2000 decision to phase out production of PFOS.[103]

The discovery of PFOA in the blood of its workers also inspired DuPont in 1984 to test the groundwater in surrounding communities. DuPont soon discovered PFOA in an adjacent drinking water well used to supply the small town of Lubeck, West Virginia.[104] Instead of addressing the problem directly by cleaning up the unlined anaerobic digestion ponds at its facility, DuPont simply purchased the public well property, and the wells were moved two miles down gradient.[105] DuPont also quietly began testing the drinking water supplies throughout the area. Surprisingly, it found traces of PFOA in tap water in Little Hocking, Ohio, a town located immediately across the Ohio River from the DuPont plant.[106] DuPont made no effort to communicate this fact to government officials, and Little Hocking citizens continued to drink the potentially contaminated water until January 2002, when city officials petitioned the West Virginia Department of Environmental Protection to test its water for PFOA.[107] Those tests, which were performed by DuPont contractors, revealed PFOA at levels of up to 2 ppb (twice DuPont's own "community exposure guideline" of 1 ppb) in the wells of the Little Hocking Water Association.[108]

At a May 22, 1984 meeting on PFOA held at DuPont's headquarters in Wilmington, Delaware, a consensus was reached "based on all the information available from within the company and from 3M" that PFOA did "not pose a health hazard at low level chronic exposure."[109] Still, the group agreed that the issue was not what the company currently knew about the toxicity of PFOA, but rather "corporate image" and "the incremental liability from this point on if we do nothing."[110] Noting that the company had already detected PFOA in drinking water in Lubeck, West Virginia and Little Hocking, Ohio, the group predicted that the company's legal and medical departments would "most likely take a position of total elimination" of PFOA production and the group responsible for the product would "take a position that the [business] cannot afford it."[111] The author of the memo predicted that the company would ultimately decide to "eliminate all C-8 emissions at

101 *Id.*

102 *Id.* at 6.

103 *Id.*

104 *Id.* at 7.

105 *Id.*

106 Envtl. Working Group, *DuPont Hid Teflon Pollution for Decades*, http://www.ewg.org/node/8735 (last visited Nov. 18, 2007).

107 *Id.*

108 Hawthorne, *Internal Warnings, supra* note 87.

109 Memorandum from J.A. Schmid to T.M. Kemp & T.L. Schrenk 11 (May 23, 1984), *available at* http://www.ewg.org/files/dupont_elim_PFOA_1984.pdf (summarizing the May 22, 1984 meeting about company policy toward C-8).

110 *Id.*

111 *Id.* at 12.

our manufacturing sites in a way yet to be developed which does not economically penalize the [business], and addresses the C-8 emission[s] and exposures of our dispersion customers."[112]

That prediction proved overly optimistic. Instead of informing the citizens of the neighboring communities that their water was tainted and taking immediate action to reduce emissions of PFOA, the company elected to adopt a business-as-usual approach. Sporadic testing of the drinking water in nearby communities continued to detect PFOA.[113] The affected communities and EPA did not, however, learn of these tests until 2002, after the information came out as the result of a lawsuit.[114]

In the midst of its discussions with 3M, EPA in April 2000 requested all of the information that DuPont had in its files that might be relevant to assessing the toxicity of PFOA.[115] In September 2002, EPA initiated a "priority review" of PFOA in light of data that it had received on developmental toxicity, carcinogenicity, and blood monitoring in response to its request for information.[116] EPA risk assessors also continued to be puzzled by the frequency with which PFOA was detected in human blood samples.[117] DuPont scientists briefed EPA risk assessors in November 2002 on what they had learned about possible exposure routes, and the briefing materials were placed in EPA's public file for PFOA.[118] They were soon removed, however, after company officials complained they might contain confidential business information.[119]

By the end of March 2003, EPA scientists had concluded that PFOA was ubiquitous in the environment and that human exposure levels approached levels at which PFOA caused birth defects in laboratory animals.[120] Therefore, like PFOS, the "margin of exposure" was unacceptably small.[121] The agency recognized, however, that "there remain[ed] considerable uncertainty regarding potential risks," and DuPont took the position that there was "no evidence or data that demonstrates [PFOA] causes adverse health effects."[122] For a time it appeared that EPA might take action under

112 *Id.*

113 Memorandum from Terry Vandell to Walt Stewart (Sept. 19, 1991) (regarding meeting minutes of the on-site Washington Works meeting on September 4, 1991, on the proposed C-8 Sampling Program); Memorandum from Anthony J. Playtis to Roger J. Zipfel (Jan. 30, 1989) (regarding test results of C-8 in drinking water).

114 Envtl. Working Group, *DuPont Hid Teflon Pollution for Decades*, *supra* note 106.

115 Letter from Robert A. Bilott, *supra* note 41, at 6.

116 PFOA Request for Comment, *supra* note 53, at 18,628 (regarding PFOAs and Fluorinated Telomers).

117 Michael Hawthorne, *DuPont Chemical Showing up in Blood of Children, Adults*, COLUMBUS DISPATCH, Apr. 5, 2003, at A1, *available at* http://www.dispatch.com/live/contentbe/dispatch/news/special/c8/1725075.html.

118 *Id.*

119 *Id.*

120 *EPA Weighs Rare TSCA Regulation for Widely Used Industrial Chemical*, INSIDE EPA WKLY. REP., Mar. 28, 2003, at 1, 10.

121 *Id.*; *see* PFOA Request for Comment, *supra* note 53.

122 Ken Ward, Jr., *DuPont's C8 Risks Above Acceptable Limits, Feds Find*, CHARLESTON GAZETTE, Mar. 28, 2003, at D3.

TSCA, as it did with PFOS, to ban or limit production of PFOA pending the development of additional toxicity and exposure data, but Assistant Administrator Steve Johnson put DuPont officials' minds at ease when he told them on a conference call that EPA would not be assigning a high priority to PFOA.[123] Instead, the agency would entertain "letters of intent" from companies to conduct further research.[124] According to Johnson, "[w]e need to get the science sorted out first" and "then undertake regulatory action if necessary."[125]

On April 11, 2003, the Environmental Working Group (EWG) wrote to EPA Administrator Christine Todd Whitman to inform her of evidence that the group had obtained from attorneys engaged in litigation with DuPont, indicating DuPont had failed to report information it collected in 1981 on the presence of PFOA in umbilical cord and baby blood and birth defects in two babies born to mothers who worked in the DuPont plant.[126] This omission was especially egregious, in EWG's view, because DuPont scientists made a site visit to the 3M laboratories in March 1981 and confirmed the validity of 3M's conclusion that PFOA caused "scarring of the eyes" in the offspring of exposed female rats.[127] Although the 3M study was immediately reported to EPA and received coverage in *The New York Times* and *The Wall Street Journal*,[128] DuPont's subsequent study of PFOA's effects on the offspring of its female workers was not reported to EPA and received no press coverage at the time.[129]

EWG further alleged that DuPont had failed to report to EPA the drinking water monitoring studies that it had undertaken between March and June of 1984 in which it found PFOA at levels ranging from 0.6 to 0.8 ppb in the Little Hocking, Ohio tap water.[130] At the time, DuPont was aware of the two-year cancer study, completed in 1983, in which PFOA caused abnormalities in rats at all dose levels, leaving the scientists unable to establish a "no observable effect level" for that chemical.[131] EWG noted that at the time it would have been difficult for DuPont to argue that the PFOA did not pose a "substantial risk" to the townspeople who were drinking the

123 *EPA Suspends Plan for Expedited Regulation of Controversial Chemical*, INSIDE EPA WKLY. REP., Apr. 11, 2003, at 5.

124 *Id.*

125 Michael Hawthorne, *Environmental Safety; DuPont Chemical Under Scrutiny*, COLUMBUS DISPATCH, Apr. 15, 2003, at A1.

126 Letter from Kenneth A. Cook, President Environmental Working Group, to Christine Todd Whitman, EPA Administrator (Apr. 11, 2003), *available at* http://www.ewg.org/node/21317.

127 Memorandum from J.W. Raines to R.L. Richards (Apr. 1, 1981), *available at* http://www.ewg.org/files/April1_memo_3Mvisit_attE.pdf; Memorandum from Dr. Bruce Karrh, *supra* note 67.

128 *DuPont Reassigns 50 Women Workers in Chemical Case*, WALL ST. J., Apr. 8, 1981 at 40; *50 Women Workers Shifted by DuPont to Avoid Peril*, N.Y. TIMES, Apr. 8, 1981.

129 Letter from Kenneth A. Cook, President, Environmental Working Group, to Richard H. Hefner, Chief, High Production Volume Chemical Branch (Aug. 15, 2003), *available at* http://www.ewg.org/node/21308.

130 *Id.*

131 *Id.*

water.[132] The EWG maintained that DuPont's failure to report all of this information within the required sixty-day reporting period violated the TSCA's requirement that companies inform EPA of all information that "reasonably supports the conclusion that" a chemical substance "presents a substantial risk of injury to health."[133]

To counter the EWG's increasingly persuasive calls for action, an industry-friendly think tank called the Center for Regulatory Effectiveness (CRE) weighed in on DuPont's behalf. After a West Virginia Circuit court ordered the company to test residents living adjacent to the manufacturing plant for PFOA in their blood (an order that an appellate court later reversed), CRE warned that any procedures used for such testing would have to be consistent with the Data Quality Act.[134] That federal statute consisted of an obscure one-paragraph rider inserted into the FY 2000 Appropriations Bill at the behest of CRE's director Jim Tozzi.[135] Since the statute was limited to information disseminated by federal agencies and not data collected by the private sector, CRE's position was patently untenable as a legal matter. However, the Washington D.C. think tank's interest in the West Virginia dispute doubtless sent a thinly veiled threat to EPA that any TSCA testing requirements imposed over industry objections at the end of the ongoing negotiations would be vigorously challenged.

On June 20, 2003, DuPont filed a formal response to the EWG charges in which DuPont explained that it had not reported the two possible birth defects in 1981 because they did not meet the "reportability" requirements of TSCA.[136] In particular, DuPont argued that the hastily prepared assessment of birth defects in pregnant workers could not "reasonably support" the conclusion that PFOA presented a substantial risk to health.[137] The company argued that even if PFOA was in the blood of the pregnant workers and their offspring, the "presence of a substance alone does not support the conclusion that the substance caused or likely caused an adverse human health effect."[138] Although the company was not at liberty to share "confidential employee medical records" with EPA, it felt at liberty to disclose at least the fact that the eye defect reported in 1981 "did not involve lens damage, which is the only type of teratogenic effect ever even

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132 *Id.*

133 15 U.S.C. § 2607(e) (2000).

134 *Industry Seeks to Limit Impact of State Court's Biomonitoring Order*, INSIDE EPA WKLY. REP., May 30, 2003, at 5; Treasury and General Government Appropriation Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515 app. C (also known as the Data Quality Act or Information Quality Act).

135 A. Baba, D.M. Cook, T.O. McGarity & L.A. Bero, *Legislating "Sound Science": The Role of the Tobacco Industry*, 95 AM. J. PUB. HEALTH S20–27 (2005); Sidney A. Shapiro, *The Information Quality Act and Environmental Protection: The Perils of Reform by Appropriations Rider*, 28 WM. & MARY ENVTL. L. & POL'Y REV. 339, 339 (2004).

136 Letter from Andrea V. Malinowski, *supra* note 96.

137 *Id.* at 3.

138 *Id.* at 4.

suggested . . . to have been caused by pre-natal exposure to PFOA."[139] The company's response, however, did not reveal the basis for this conclusion.

DuPont took the position that the information concerning the presence of PFOA in the drinking water in nearby communities was likewise not reportable because there was "no evidence that the presence of those ppb levels of PFOA in drinking water, or any levels subsequently found in drinking water in that area, presents any risk of injury, let alone a substantial risk, which would be necessary to trigger reporting obligations."[140] Thus, DuPont took the position that it is perfectly legal for a company knowingly to pollute the drinking water of neighboring communities with an animal carcinogen so long as the company concludes that the levels of contamination present an acceptable risk to the people drinking the polluted water.

D. EPA Acts

On July 8, 2004, EPA surprised many observers when it responded to the EWG petition by filing a complaint against DuPont alleging that it had violated section 8(e) of TSCA by failing to report to EPA its May 1981 discovery that PFOA crossed the placenta in humans and by failing to report to EPA the results of the testing that it performed on drinking water in nearby towns during the 1980s and early 1990s.[141] EPA also claimed that DuPont had violated its hazardous waste disposal permit by failing to submit the same information.[142] The head of EPA's Office of Enforcement told the press that the complaint was "intended to send a message to DuPont and everyone else that this type of information must be provided" to EPA.[143] Although the maximum fine for the violations under the statue would exceed $300 million, EPA did not indicate how large a fine it would seek from the company for the longstanding violations.[144] The EPA action apparently inspired the Justice Department to launch a criminal investigation into DuPont's TSCA violations. In May 2005, a District of Columbia grand jury issued a subpoena to DuPont for relevant documents.[145]

In responding to press inquiries, DuPont repeated its position that the company did not "reliably ascribe harm to human health and the environment" from the information on transplacental transfer of PFOA and on the presence of PFOA in local drinking water, and therefore concluded

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139 *Id.* at 4–5.

140 *Id.* at 6.

141 Complaint and Notice of Opportunity for Hearing at 9–10, 12, 19–20, *In re* E.I. duPont de Nemours & Co., Nos. TSCA-HQ-2004-0016, RCRA-HQ-2004-0016 (July 8, 2004), *available at* http://www.epa.gov/compliance/resources/complaints/civil/mm/dupont-pfoa-complaint.pdf.

142 *Id.* at 24.

143 Juliet Eilperin, *EPA to Fine DuPont for Silence on Teflon Chemical*, WASH. POST, July 9, 2004, at A3.

144 Marla Cone, *EPA Says DuPont Withheld Chemical's Danger*, L.A. TIMES, July 9, 2004, at A12.

145 *Perfluorooctanoic Acid Materials Subpoenaed By Federal Grand Jury in D.C., DuPont Says*, 33 Prod. Safety & Liab. Rep. (BNA) 555 (May 30, 2005).

that "it would not be reportable."[146] A DuPont spokesperson explained that EPA should have known that chemicals like PFOA "are expected to pass through the placenta."[147] In its formal response to EPA's complaint, DuPont argued that "[t]he small amounts of PFOA" that it "discovered in a blood sample and in drinking water did not suggest that there was any risk to human health, let alone the sort of 'substantial risk' that is necessary to trigger reporting requirements."[148]

E. DuPont's Litigation Woes

In early September 2004, DuPont announced that it had agreed to pay up to $340 million to settle a class action lawsuit brought on behalf of the citizens of Parkersburg, West Virginia and Marietta, Ohio.[149] Under the settlement, DuPont agreed to pay $50 million to the 60,000 or so members of the class, $22.6 million to the lawyers for their fees and expenses, $20 million to fund local health projects, $10 million to build new water treatment facilities, and $5 million for a two-year health study conducted by independent scientists from the London School of Hygiene, the University of North Carolina School of Public Health, and Emory University.[150] Finally, if the study demonstrated that PFOA was harming the health of the residents, DuPont agreed to pay up to $235 million for continuing doctor visits to monitor their health.[151] A judge approved the settlement on February 28, 2005.[152]

In providing for a two-year health study by independent scientists, the agreement ensured that a great deal of new scientific information on the health risks posed by PFOA would become available to regulatory agencies and the public. One of the plaintiffs' attorneys hoped that the study would "provide a real scientific answer to the question . . . based on real facts and real data."[153] While this may have been an overly optimistic assessment of the capabilities of a single scientific study, the agreement provides a good example of the capacity of common law to generate fresh scientific research.

Although not thrilled with the prospect of receiving only $800 apiece on average for the risk that DuPont had imposed upon them without their knowledge or consent, some of the citizens of the affected communities had

146 Eilperin, *EPA to Fine DuPont for Silence on Teflon Chemical*, *supra* note 143, at A3.

147 Juliet Eilperin, *DuPont Defends its Reporting on Teflon Ingredient*, WASH. POST, Aug.13, 2004, at A3.

148 Answer and Request for Hearing at 1, *In re* E.I. duPont de Nemours & Co., Nos. TSCA-HQ-2004-0016, RCRA-HQ-2004-0016 (Aug. 11, 2004), *available at* http://www2.dupont.com/PFOA/en_US/pdf/answer_and_request_for_hearing.pdf.

149 Mike Lafferty, *DuPont Settles Lawsuit*, COLUMBUS DISPATCH, Sept. 10, 2004, at A1.

150 *Id.*; Ward, *Both Sides Hope for Answers on C8*, *supra* note 36, at B1.

151 Mike Lafferty, *Few in Village Seem Angry About Proposal in DuPont Suit*, COLUMBUS DISPATCH, Sept. 11, 2004, at B1.

152 Ward, *Both Sides Hope for Answers on C8*, *supra* note 36.

153 Bebe Raupe, *Court Approves Class Action Settlement with Possible $340 Million DuPont Payout*, [36 Current Reports] Env't Rep. (BNA) 424 (Mar. 4, 2005).

the satisfaction of knowing that DuPont was at least to some extent being held accountable for its reprehensible behavior.[154] They could also take some comfort in knowing that the matter would receive further study from independent scientists and that additional medical surveillance would be forthcoming if adverse health effects were attributed to human exposure to PFOA. Finally, the settlement left open the possibility of individual suits for compensation for those who did in fact suffer adverse effects from PFOA exposure, and DuPont would be precluded from arguing that PFOA did not cause any disease that the independent investigators determined had been caused by that exposure.[155] Little Hocking resident Ed Beikirch said that the extra money would "help with my model-airplane building," but he noted philosophically that if the lawsuit had not been pressed by attorneys willing to take the risk of losing all of their expenses, "who knows how long it would have taken DuPont to do anything."[156]

DuPont's troubles did not end with the settlement of the class action lawsuit. Along with several other companies, it still faced the possibility of litigation from consumers who had been exposed to PFOA when using other telomers that DuPont marketed for use in grease- and stain-resistant coatings for clothing, carpets, and commercial items like restaurant take-out boxes.[157] Telomers break down into PFOA and related compounds.[158] With respect to this latter possibility, industry spokespersons are surprisingly cavalier. The president of the Society of the Plastics Industry observed that "[i]t's not as if we've got people dropping in the streets out there,"[159] implying that it would take something that dramatic to inspire the industry to take action to limit human exposure to PFOA and related compounds. In July 2005, DuPont was named as a defendant in a $5 billion class action lawsuit alleging that it had engaged in deceptive trade practices and failed to warn consumers of the risks of outgassing from Teflon®-coated products.[160]

F. The Scene Shifts Back to EPA

DuPont also continued to contest EPA's very serious allegations that it had failed to report "substantial risk" information under TSCA. Matters got worse for the company on that front in November 2004 when EWG petitioned EPA to take additional action under TSCA to punish DuPont for failing to report the results of a July 29, 2004 study in which "DuPont learned of high levels of the Teflon chemical PFOA in serum from 12 people living"

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154 Lafferty, *Few in Village Seem Angry About Proposal in DuPont Suit*, *supra* note 151.

155 *See* Ken Ward, Jr., *DuPont Agrees to Pay $107 Million*, CHARLESTON GAZETTE, Sept. 10, 2004, at A1; Ward, *Both Sides Hope for Answers on C8*, *supra* note 36.

156 Lafferty, *DuPont Settles Lawsuit*, *supra* note 149.

157 *See* Tom Avril, *Chemical in Teflon, other goods is turning up in disturbing places*, SEATTLE TIMES, Oct. 1, 2004, at A3.

158 *Id.*

159 *Id.*

160 Dean Scott, *$5 Billion Lawsuit Filed Against DuPont; Teflon's Effect on Consumer Health Targeted*, 36 Env't Rep. (BNA) 1529 (July 22, 2005).

near the West Virginia plant.[161] According to EWG, DuPont received a report in July that levels of PFOA in nearby residents who had consumed contaminated tap water were up to twelve times higher than in the general population.[162] Fully one-quarter of the residents tested had levels higher than had ever been measured in the U.S. general population.[163] Although DuPont was required by TSCA to report these results to EPA by August 14, 2004, EPA did not learn of the study until Robert Bilott, the lawyer for the plaintiffs in the subsequently settled class action lawsuit, revealed the results to EPA on September 15, 2004.[164] DuPont officials once again took the position that the results were not reported because "they did not represent a health threat."[165]

EPA quickly responded to the EWG petition with another administrative action alleging that DuPont had violated the TSCA reporting requirement by failing to report the community serum sampling results.[166] EPA noted that the human sampling tests were the first such results that it had seen "concerning individuals exposed in a community setting."[167] In the agency's view the information "reasonably supports the conclusion that PFOA presents a substantial risk of injury to human health."[168] Although EPA's complaint noted that DuPont was potentially liable for civil penalties of $32,000 per day per violation, it again refused to specify an exact dollar amount that it would seek in the administrative proceeding.[169] DuPont once again took the position that the information was not "reportable" because the high blood levels that the tests revealed were below typical occupational exposure levels "where we have not observed any adverse health effects resulting from exposure to PFOA."[170]

In December 2005, DuPont and EPA settled the entire administrative action with an agreement in which DuPont did not admit guilt but did agree to pay $16.5 million in total penalties for its violations.[171] The penalty dwarfed all previous penalties that EPA had imposed under TSCA.[172]

In the meantime, DuPont continued to manufacture PFOA at its new Fayetteville, North Carolina facility, which became the exclusive United States supplier of PFOA.[173] On January 12, 2005, the company reported the

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161 Letter from Kenneth A. Cook, President, Environmental Working Group to Michael Leavitt Administrator, U.S. EPA 2 (Nov. 17, 2004), *available at* http://www.ewg.org/node/8738.

162 *Id.*

163 *Id.*

164 *Id.*

165 Juliet Eilperin, *DuPont Faces New Complaint*, WASH. POST, Nov. 18, 2004, at A15.

166 Complaint and Notice of Opportunity for Hearing, *In re* E.I. duPont de Nemours & Co., No. TSCA-HQ-2005-5001 (Dec. 6, 2004).

167 *Id.* at 9.

168 *Id.* at 7–8.

169 *Id.* at 9.

170 Jeff Montgomery, *EPA Challenges DuPont on C-8 Levels in W. Va.*, NEWS J., Dec. 7, 2004, at B1, *available at* http://nl.newsbank.com/ (must purchase article after searching in archives).

171 Juliet Eilperin, *DuPont, EPA Settle Chemical Complaint*, WASH. POST, Dec. 15, 2005, at D3.

172 Pat Phibbs, *DuPont to Pay $16.5 Million to Settle Alleged Violations of EPA Reporting Rules*, 3 Env't Rep. (BNA) No. 36, at 2581 (Dec. 16, 2005).

173 Avril, *supra* note 157, at A3.

results of a study of 1025 workers in its West Virginia plant, some of whom had levels of up to 1000 ppb of PFOA in their blood.[174] The study concluded that while PFOA produced no major observable adverse health effects, it did find higher levels of cholesterol in the blood of workers who have the highest levels of PFOA in their blood.[175] On March 15, 2005, DuPont announced that it would reduce by ninety percent the amount of PFOA in the liquid version of Teflon®, the only version that still contained the chemical.[176] DuPont maintained that this measure was taken purely "because of the perception," and not the reality of health risk, that this reduction would predictably reduce human exposure to PFOA.[177]

EPA likewise continued to address PFOA's health risks by preparing a risk assessment and asking its Science Advisory Board (SAB) to evaluate its scientific underpinnings.[178] The draft risk assessment described the scientific information available on cancer, reproductive, and developmental effects of PFOA on human health, but it noted that in virtually every instance, the effects of PFOA had not been adequately studied.[179] This pessimistic conclusion was not surprising, given DuPont's reluctance to enter into an enforceable testing agreement with EPA. The draft did not draw any specific conclusions with regard to the risks that PFOA posed to human beings.[180] The agency wanted to withhold judgment until after a panel of its SAB had reviewed and critiqued its scientific reasoning.[181]

While the SAB panel was still deliberating, an industry funded group called the American Council on Science and Health (ACSH) empanelled its own group of scientists to examine the information. That entity rushed out a booklet and accompanying press release, based upon a position paper that was "peer reviewed" by scientists likewise chosen by ACSH, entitled *Teflon and Human Health: Do the Charges Stick?*[182] Not surprisingly, given its origin, the panel reported that PFOA posed "no likely risk" to humans in the "trace amounts" found in human blood.[183] The ACSH medical director noted in a press release that the ACSH panel's report "shows that scientific evidence does not indicate any reason for us to fear PFOA at current levels."[184]

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174 Spencer Hunt, *DuPont Study Finds No Link Between C8, Health Problems*, COLUMBUS DISPATCH, Jan. 12, 2005, at B8.

175 *Id.*

176 Mike Lafferty, *DuPont to Trim C8 in Teflon*, COLUMBUS DISPATCH, Mar. 17, 2005; Ken Ward, Jr., *DuPont Agrees to Reduce C8 Emissions*, CHARLESTON GAZETTE, Mar. 16, 2005, at C2.

177 Ward, Jr. *DuPont Agrees to Reduce C8 Emissions*, *supra* note 176.

178 OFFICE OF POLLUTION PREVENTION AND TOXICS, EPA, DRAFT RISK ASSESSMENT OF THE POTENTIAL HUMAN HEALTH EFFECTS ASSOCIATED WITH EXPOSURE TO PERFLUOROOCTANOIC ACID AND ITS SALTS 3 (2005).

179 *Id.* at 3.

180 *Id.*

181 Juliet Eilperin, *Teflon Chemical's Potential Risk Cited*, WASH. POST, Jan. 13, 2005, at A4.

182 *Teflon-Production Chemical Does Not Pose Health Risk to General Population, Science Panel Finds*, MEDICAL NEWS TODAY, Mar. 19, 2005, *available at* http://www.medicalnewstoday.com/articles/21512.php.

183 *Id.*

184 *Id.*

In June 2005, the SAB panel posted a draft report on EPA's website in which it concluded that PFOA was a "likely carcinogen."[185] The full SAB issued a final report reaching the same conclusion in February 2006.[186] Seeing the writing on the wall, DuPont and seven other companies announced in January 2006 their entry into a voluntary agreement with the EPA.[187] Under the agreement, they would reduce environmental releases of PFOA by 95 percent by 2010 and virtually eliminate them by 2015.[188] It remains to be seen whether the companies will reach their voluntary goals.

V. THE ADVANTAGES OF COOPERATION

As discussed above, federal agencies can obtain scientific information from many different sources, including literature searches, public comments, submissions by applicants for product approvals, adverse effects reporting, and negotiated or (rarely) mandatory testing requirements promulgated under TSCA. Agency staff have expertise in reviewing and analyzing the various sources of information and using the information to reach alternative decisions about whether to allow potentially dangerous products on the market or to intervene proactively to reduce risks posed by particular products or activities.[189] For particularly difficult issues, agencies can call on august bodies like the National Research Council of the National Academy of Sciences to assemble a panel of experts to provide input into scientific questions that arise during the decision-making process.[190] In theory, all of this very valuable information could be made available to litigants in common law cases. In fact, much of it is available from agency websites and via requests under the Freedom of Information Act.[191] Agencies do not, however, go out of their way to be helpful to common law litigants. Most agencies, for example, severely restrict the extent to which their employees are available to testify in common law courts, and they vigorously resist subpoenas for the deposition testimony of their officials.[192]

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185 EPA, SCIENCE ADVISORY BOARD DRAFT REPORT DATED 6/27/2005 TO ASSIST MEETING DELIBERATIONS 2, *available at* www.epa.gov/sab/pdf/rev_draft_pfoa_ex_sum-report_w-intro_062705.pdf; *see also* Juliet Eilperin, *Compound in Teflon A "Likely Carcinogen,"* WASH. POST, June 29, 2005, at A4.

186 Dee DePass, *Panel Links 3M Chemical to Cancer*, MINNEAPOLIS STAR-TRIB., Feb. 16, 2006, at D1.

187 Juliet Eilperin, *Harmful Teflon Chemical To Be Eliminated by 2015*, WASH. POST, Jan. 26, 2006, at A1.

188 *Id.*

189 *See* Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2150–51 (2000) (unsophisticated jurors); W. Kip Viscusi, Steven R. Rowland, Howard L. Dorfman & Charles J. Walsh, *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1438–46 (1994).

190 *See* Steven P. Croley & William F. Funk, *The Federal Advisory Committee Act and Good Government*, 14 YALE J. ON REG. 451, 454, 457 (1997).

191 Freedom of Information Act, 28 C.F.R. § 16 (2006).

192 *See, e.g.*, 40 C.F.R. §§ 2.402–2.405 (strict restrictions on EPA employees' testimony and depositions).

The common law courts have formalized the role that administrative regulations can play in negligence and product liability actions. In a negligence action, the plaintiff has the burden of pleading and proving that the defendant's conduct did not come up to that of a reasonable person in the circumstances.[193] In most states, however, the plaintiff may gain a procedural advantage by showing that the defendant violated a federal regulation intended to protect a class of people that includes that plaintiff, from the type of harm that the plaintiff suffered. Such a showing will ordinarily be sufficient to establish negligence unless the defendant can demonstrate that the violation was excused.[194] The defendant may likewise introduce evidence that her conduct complied with a federal regulation as evidence that her conduct was reasonable, but compliance does not give rise to any presumption of non-negligence.[195] The common law courts assume that federal regulations establish minimum standards that companies are free to exceed when necessary to avoid damage to others.[196]

In a products liability action under the original Restatement (Second) approach, the plaintiff had the burden of demonstrating that the product that injured him was in "a defective condition unreasonably dangerous to the user or consumer."[197] Under the more recent Restatement (Third) of Products Liability approach, which has not been universally accepted by the courts, the focus is on whether the product causing injury was "defective." A "defect" is defined to include 1) a "manufacturing defect" that occurs when the product "departs from its intended design," 2) a design defect that results "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe," or 3) a warning defect that occurs "because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings . . . and the omission of the instructions or warnings renders the product not reasonably safe."[198] The Third Restatement directly addresses the issue of compliance with regulatory standards, stating that "noncompliance with an applicable . . . safety [standard] renders the product defective with respect to the risks sought to be reduced by the statute or regulation . . . ."[199] By contrast, compliance "is properly considered in determining whether the product is defective . . . but such compliance does not preclude as a matter of law a finding of product defect."[200]

While regulatory agencies can provide common law courts with both a standard to apply and such scientific information as is available under the

193 RESTATEMENT (SECOND) OF TORTS § 283 (1965).

194 *Id.* §§ 286, 288A, 288B; DAN B. DOBBS, THE LAW OF TORTS 311–28 (2000).

195 RESTATEMENT, *supra* note 193, § 288C.

196 DAVID G. OWEN, PRODUCTS LIABILITY LAW 93 (2005); Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2051 (2000).

197 RESTATEMENT, *supra* note 193, § 402A.

198 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 1, 2 (1998).

199 *Id.* § 4(A).

200 *Id.* § 4(B).

Freedom of Information Act, common law litigants can return the favor by providing regulatory agencies with information produced as a result of or in response to litigation. Parties to litigation often commission literature reviews and even original scientific research that might be of use to busy regulatory agency scientists. Although infrequent, settlement agreements like the PFOA class action settlement with DuPont occasionally require the defendant to undertake original research under the supervision of independent scientists that can be invaluable to regulatory agencies like the EPA.

Far more frequently, common law litigants can contribute to agencies information gleaned from company files, such as the PFOA studies that provided the basis for the EPA's TSCA enforcement action against DuPont. Agencies typically assume that the information they receive from regulated entities is free from bias and manipulation, and thus rarely probe into agency files or require employees of regulatees to testify under oath regarding the bona fides of the information supplied. Indeed, most agencies lack the necessary subpoena power to access such information and testimony. Common law discovery frequently reveals evidence of studies regulatees did not bother to provide to the relevant agency, manipulated scientific information, and even fraud on the public and the agencies interested in dealing with consumer fraud and agency manipulation.

Documents produced in common law litigation over Eli Lilly's blockbuster schizophrenia drug Zyprexa, for example, showed that the company for more than a decade downplayed two serious side effects (rapid weight gain and diabetes) in its promotional materials and presentations to doctors.[201] Other documents indicated that Eli Lilly had circulated one set of data from a clinical trial internally, but another set of data, much more favorable to Zyprexa, to doctors.[202] It was unclear from the documents whether Lilly initially shared the internal data with the FDA.[203] Although the company was prepared to share the clinical studies, adverse event reports, and literature reviews demonstrating the dramatic weight gain to doctors if asked for them, Eli Lilly instructed its sales representatives not to "introduce the issue."[204] Worse, the documents indicated that the company promoted the drug, which accounted for over four billion dollars in sales and represented thirty percent of Eli Lilly's overall revenues, for unapproved uses such as dementia in the elderly, which, if true, was a clear violation of federal law.[205] The agency was, of course, entirely unaware of this information. The company settled the resulting civil litigation, which was

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201 Alex Berenson, *Eli Lilly Said to Play Down Risk of Top Pill*, N.Y. TIMES, Dec. 17, 2006, at A1.

202 Alex Berenson, *Disparity Emerges in Lilly Data on Schizophrenia Drug*, N.Y. TIMES, Dec. 21, 2006, at C1.

203 *Id.*

204 Berenson, *Eli Lilly Said to Play Down Risk of Top Pill*, *supra* note 201.

205 Alex Berenson, *Drug Files Show Maker Promoted Unapproved Use*, N.Y. TIMES, Dec. 18, 2006, at A1; Alex Berenson, *Blockbuster Drugs Are So Last Century*, N.Y. TIMES, July 3, 2005, at C1.

brought by about 28,500 patients who alleged that the drug had caused diabetes and other health problems, for approximately $1.25 billion.[206]

In cautioning against allowing a "regulatory compliance" defense to common law tort litigation, Professor Robert Rabin has argued that insofar as lawsuits "provide the educational function of revealing massive cover-ups of health information by industries like asbestos or occasional efforts to conceal risk information from regulatory agencies," then it is undeniably the case that tort law is serving "a positive function of some consequence." [207] Common law litigants will perform this "positive function," however, only to the extent that they are willing and able to make information that is produced in private litigation available to regulatory agencies and the public. The next section of this Article probes some of the impediments that might discourage litigants from performing this positive role.

VI. IMPEDIMENTS TO COOPERATION

While cooperation between regulatory agencies and common law litigants in making scientific information available to agencies and courts would seem to be in the overall public interest, it is usually the exception rather than the rule. This is not altogether surprising, given the serious impediments that stand in the way of either side's ability to share information with the other. This section will examine a few of the more serious impediments.

A. Agency Impediments

EPA was very slow to implement its power under section 4 of TSCA to require manufacturers of chemicals to conduct toxicity testing. In 1981, after the court ordered EPA to initiate rulemaking proceedings requiring the testing of priority chemicals, EPA began to issue a few testing rules.[208] Even though these rules had no immediate regulatory consequences, many of them were challenged. EPA then entered into a period of litigation that fleshed out the showings that the agency had to make to justify testing requirements. In *Chemical Manufacturers Association v. EPA*,[209] the D.C. Circuit reviewed an EPA testing rule for 2-ethylhexanoic acid (EHA), a chemical used as a chemical intermediate in the production of metal soaps, peroxy esters, and other products used in industrial settings.[210] The agency

206 Alex Berenson, *Lilly Settles with 18,000 Over Zyprexa*, N.Y. TIMES, Jan. 5, 2007, at A1.

207 Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2069 (1999–2000); *see also* TIMOTHY D. LYTTON ET AL., SUING THE GUN INDUSTRY: A BATTLE AT THE CROSSROADS OF GUN CONTROL AND MASS TORTS 1, 30 (2005); Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 613 (2005); Carl T. Bogus, *War on the Common Law: The Struggle at the Center of Products Liability*, 60 MO. L. REV. 1, 85 (1995).

208 Natural Res. Def. Council, Inc. v. Costle, 11 Envtl. L. Rep. (Envtl. Law Inst.) 20,202 (S.D.N.Y. Jan. 9, 1981).

209 859 F.2d 977 (D.C. Cir. 1988).

210 *Id.*

found that existing data and experience were not a sufficient basis upon which to predict EHA's health effects and that the additional testing it proposed would yield the necessary data.[211] The agency further found that, even though EHA was not distributed in commerce, it might present an "unreasonable risk of injury" to the health of workers who could become exposed to the chemical.[212] EHA and chemicals with a similar chemical structure caused liver damage and adverse reproductive and developmental effects in laboratory animals, and structurally similar chemicals were also oncogenic in laboratory animals.[213] In upholding the testing rule, the court found that EPA may issue such a rule "when there is a more-than-theoretical basis for suspecting that some amount of exposure takes place and that the substance is sufficiently toxic at that level of exposure to present an 'unreasonable risk of injury to health.'"[214]

In a very similar case decided the same year, the Third Circuit upheld an EPA testing rule for fluoroalkene monomers, noting that "[a]lthough mere scientific curiosity does not form an adequate basis for a rule," as the seriousness of risk becomes known and the extent of exposure increases, the need for testing fades into the necessity for regulatory safeguards.[215] Consequently the job of the reviewing court is "to see if the Administrator produced substantial evidence to demonstrate not fact, but doubt and uncertainty."[216]

Two years later, however, the Fifth Circuit, in *Chemical Manufacturers Association v. EPA*,[217] served notice on the agency that its testing rules would not be so favorably treated in all of the courts of appeals. Following the recommendation of the Interagency Testing Committee, EPA issued a testing rule for cumene, a ubiquitous chemical in a petrochemical complex, based on its finding that it was produced in substantial quantities, workers were regularly exposed to it, and more than three million pounds were released into the environment every year through uncontrolled "fugitive" emissions.[218] In a lengthy opinion that probed the support for EPA's conclusion in exquisite detail, the court concluded that the rule had to be remanded because the agency had failed to provide an adequate administrative definition or criteria for the statutory term "substantial."[219] The court recognized that "substantial" was "an inherently imprecise word,"

211 *Id.* at 981.

212 *Id.*

213 *Id.* at 996.

214 *Id.* at 984. *See also* Ausimont U.S.A., Inc. v. EPA, 838 F.2d 93, 96 (3d Cir. 1988) (explaining how the "unreasonable risk of injury" need not be scientifically proven). *Cf.* Chem. Manufacturers Ass'n v. EPA, 899 F.2d 344, 360 (5th Cir. 1990) (remanding testing rule for cumene to EPA for further elaboration on whether "substantial quantities" of cumene were likely to enter the environment).

215 *Ausimont U.S.A., Inc.*, 838 F.2d at 96.

216 *Id.*

217 899 F.2d 344.

218 *Id.* at 348.

219 *Id.* at 360.

but the agency was obliged to articulate a definition or set of criteria sufficient to limit its discretion and to inform reviewing courts.[220]

Perhaps out of an understandable reluctance to litigate every testing rule in the Fifth Circuit, where the companies subject to such rules would predictably bring such challenges, EPA has in the last two decades been very reluctant to promulgate full-fledged testing rules, preferring instead to negotiate with manufacturers over the nature and extent of the additional testing that will satisfy EPA's statutory obligations.[221] This approach, however, has also proved highly unsatisfactory. A good example of the difficulties that EPA faces in negotiating testing agreements is provided by the lengthy negotiations that the agency and the petroleum industry engaged in over a testing rule for the fuel additive methyl tertiary-butyl ether (MTBE), which later became a notorious groundwater pollutant when it proved especially adept at escaping from underground storage tanks at filling stations.[222] When Arco Chemical Company (Arco) first began producing MTBE in 1979, very little was known about its chronic toxicity.[223] Five months after EPA granted a waiver for MTBE to be used as a major fuel additive, representatives from Exxon, Texaco, Phillips, and Arco began informal negotiations with EPA over whether additional toxicological testing of MTBE would be required.[224]

By the time the Interagency Testing Committee (ITC) took up MTBE in 1985,[225] it was already in wide use as a substitute for tetraethyl lead, which EPA was phasing out because of its adverse health effects and deleterious impact on catalytic converters.[226] The petroleum industry was by now aware of the fact that MTBE "was beginning to contaminate groundwater in many states as a result of leaking [underground storage tanks]" and it was becoming clear that MTBE "migrated faster in groundwater than other gasoline constituents."[227] The Toxicology Committee of the industry trade association, the American Petroleum Institute, approved several inhalation toxicology tests on MTBE in 1980 as Phase I of a larger project, but it rejected suggestions that it be tested in drinking water.[228] When the inhalation studies showed that MTBE was relatively benign, the committee decided to forego Phase II of the project in the hope that its voluntary "efforts would 'preclude . . . an unnecessary test rule by EPA under TSCA.'"[229]

220 *Id.* at 359.

221 *See* Kurt A. Strasser, *Cleaner Technology, Pollution Prevention and Environmental Regulation*, 9 FORDHAM ENVTL. L. REV. 1, 37 (1997).

222 Thomas O. McGarity, *MTBE: A Precautionary Tale*, 28 HARV. ENVTL. L. REV. 281, 281, 287, 297–301 (2004).

223 *Id.* at 297.

224 *Id.*

225 *See id.* at 297–98 (discussing the authority of the EPA to compel chemical manufacturers to conduct "specific health and environmental toxicity testing" under the Toxic Substance Control Act and the corresponding creation of the ITC to nominate chemicals for such testing).

226 *Id.* at 294.

227 *Id.* at 298.

228 *Id.*

229 *Id.* at 299 (quoting American Petroleum Institute, Post Completion Critique 4 (Aug. 12, 1984)) (on file with the Harvard Environmental Law Review).

On October 31, 1986, the ITC recommended that MTBE be tested for chronic inhalation toxicity, but did not even mention MTBE-contaminated groundwater.[230] Arco responded that chronic inhalation testing was "not necessary," because "worst case" exposures to MTBE from gasoline vapors were "well below the 'no observable adverse effect level' even when very conservative safety factors are applied."[231] This was, of course, unresponsive to the concern that MTBE might present nonthreshold risks like mutagenicity or carcinogenicity.[232] Arco did not mention the possibility that chronic exposure might occur via ingestion of contaminated groundwater.

On December 17, 1986, EPA invited the companies to a "public focus meeting" to discuss a possible consent order for performing additional testing on MTBE.[233] At the meeting, EPA's project manager noted that "an additional concern" identified by EPA's Test Rules Development Branch was "contamination of ground water supplies by MTBE."[234] The companies, however, belittled these concerns, arguing that the agency should have "very little cause for concern of health hazards with MTBE."[235] A year later, EPA published notice of a Consent Order to which EPA and five major oil companies agreed to conduct several mutagenicity tests, several pharmacokinetics tests to determine oral, dermal, and inhalation routes of exposure, three neurotoxicity tests, an inhalation oncogenicity test in two species and an inhalation two-generation reproduction and fertility effects study.[236] The agreement contained very little testing on the toxicity of MTBE in drinking water.[237]

Even when an agency does obtain scientific information from private companies, there may be impediments to making that information available to common law litigants. As a starting point, the Freedom of Information Act requires agencies to release all governmental information except that which may fall into nine categorical exceptions.[238] The relevant exemption for our purposes is "exemption four," which exempts "trade secrets and commercial or financial information obtained from a person and privileged or confidential."[239] The Trade Secrets Act establishes criminal penalties for the disclosure of "proprietary information" unless such disclosure has been "authorized by law."[240] Congress has specifically resolved the "trade secrets" problem in the Toxic Substances Control Act, which specifically exempts "health and safety" studies from the protections otherwise afforded to

230 McGarity, *supra* note 222, at 300; Nineteenth Report of the Interagency Testing Committee to the Administrator; Receipt and Request for Comments Regarding Priority List of Chemicals, 51 Fed. Reg. 41,417, 41,418 (Nov. 14, 1986).

231 McGarity, *supra* note 222, at 300.

232 *Id.*

233 *Id.*

234 *Id.* at 301.

235 *Id.*

236 *Id.*

237 *Id.*

238 5 U.S.C. §§ 552(b)–(c) (2000).

239 *Id.* § 552(b)(4) (2000).

240 18 U.S.C. § 1905 (Supp. IV 2004).

proprietary information.[241] "This type of provision falls squarely within the "except as otherwise provided by law" proviso of the Trade Secrets Act."[242] TSCA defines a 'health and safety study' as any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture."[243] This definition is clearly broad enough to encompass results of any product testing that involves laboratory animals or human subjects, as well as epidemiological studies. The question whether background data, notably chemical identities, proportions, or manufacturing processes should be included is a more difficult question.[244]

The fact that health and safety studies should be available to the public does not, of course, mean that they are in fact available. Rather than posting health and safety information on its website for the public to see, EPA effectively presumes that all of the information submitted under TSCA is trade secret and demands that anyone interested in seeing such information make a special request for it.[245] EPA's responses to such requests are never accomplished within the ten days specified in FOIA because the agency first notifies the company that submitted the information and gives it an opportunity to object.[246] The companies often do object, and the burden then shifts to the person requesting the data to demonstrate that it does in fact come within the health and safety testing data exception.[247] This is, of course, a difficult showing to make when the requestor has no idea what the documents that it is addressing contain. Requestors that prevail at this stage often receive severely redacted documents that are difficult to read and interpret.

B. Common Law Impediments

The extent to which information from common law litigation is available to regulatory agencies is limited by similar constraints. Initially, the information that common law litigants produce or dig out of company files will not be available to anyone if the courts refuse to admit the testimony of the experts who present that information in the judicial forum. It has now become quite apparent that the lower courts have applied the *Daubert* test for the admissibility of expert testimony quite vigorously to exclude expert

241 15 U.S.C. § 2613(b) (2000).

242 Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 875 (1980) (discussing the argument against disclosure).

243 15 U.S.C. § 2602(6) (2000).

244 *See* McGarity & Shapiro, *supra* note 242, at 848–56.

245 *Id.* at 879.

246 Christopher J. Lewis, *When is a Trade Secret Not So Secret? The Deficiencies of 40 C.F.R. Part 2, Subpart B*, 30 ENVTL. L. 143, 158 (2000).

247 *See id.* at 162.

testimony.[248] Most courts have adopted an approach I have referred to as a "corpuscular" approach to determining the admissibility of expert testimony in toxic tort cases.[249] Under this approach, the party offering scientific expert testimony must establish the relevance and reliability under the *Daubert/Joiner* criteria of each individual study upon which the expert relies as well as the relevance and reliability of the expert's overall conclusions.[250] If the plaintiff fails to establish the scientific reliability of a sufficient number of the individual studies, the trial judge will exclude the expert's testimony.[251] This approach invites defendants to focus upon flaws in the corpuscles of data underlying the testimony rather than upon the scientific reliability of the expert's overall conclusions.[252]

The corpuscular approach effectively prevents experts in toxic torts cases from applying the cumulative weight-of-the-evidence approach that regulatory agencies universally employ in assessing the risks toxic substances pose to human beings. The weight-of-the-evidence approach focuses upon the totality of the scientific information and asks in a holistic way whether a cause/effect conclusion appears warranted.[253] Given the inevitability of flaws in individual studies and the fact that some of the studies were not undertaken with the litigative or regulatory process in mind, this necessarily involves the exercise of scientific judgment grounded in scientific expertise, and regulatory agencies are supposed to be repositories of scientific expertise. The corpuscular approach to judicial review focuses upon the inevitable flaws in individual studies and asks whether a sufficient number of relevant studies with sufficiently few flaws remain to support a conclusion that is itself relevant and reliable.[254] Under the corpuscular approach, a study is either valid or invalid, and it is either relevant or irrelevant to the scientific issue the agency must resolve.[255] Both determinations are made by judges who generally lack any scientific expertise.[256]

To the extent that courts applying the corpuscular approach exclude expert testimony, the scientific information underlying those studies is either unavailable to regulatory agencies or is cast in such deep suspicion that it may be of little use to the agencies, which must support their regulatory determinations with a record that must itself pass judicial

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248 Janet Raloff, *Benched Science*, 168 SCI. NEWS 232, 232–34 (2005) (reporting the view of Lloyd Dixon of the RAND Institute for Civil Justice that the impact of *Daubert* and its progeny has been profound); Jeffry D. Cutler, *Implications of Strict Scrutiny of Scientific Evidence: Does* Daubert *Deal a Death Blow to Toxic Tort Plaintiffs?*, 10 J. ENVTL. L. & LITIG. 189, 214 (1995); Finley, *supra* note 34, at 341–42. *See also* Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 391 (1992).

249 Thomas O. McGarity, *On the Prospect of "Daubertizing" Judicial Review of Risk Assessment*, 66 LAW & CONTEMP. PROBS. (SPECIAL ISSUE) 155, 172 (2003).

250 *Id.*

251 *Id.*

252 *Id.*

253 *Id.* at 175.

254 *Id.*

255 *Id.*

256 *Id.*

scrutiny.[257] To the extent that the prospect of corpuscular review of expert testimony dissuades plaintiffs' attorneys from bringing cases to begin with, the result will be that the common law will provide even less information to regulatory agencies.

C. Protective Orders and Sealed Settlements

The most serious impediment to sharing documents produced in common law litigation between regulatory agencies and entities attempting to persuade them to take regulatory action is the fact that most litigation documents are at least initially provided to plaintiffs' attorneys pursuant to judicially enforceable protective orders, most of which are in fact negotiated by attorneys for the plaintiffs and defendants. The orders invariably prevent the parties receiving documents denoted "confidential" from sharing them with anyone other than experts and other parties to the litigation.[258] Thus, for example, when the families of two victims of an accident caused by allegedly defective tires petitioned the court to disclose "confidential" documents indicating that the company knew that it had an "ongoing safety issue" with the tires, the company quickly negotiated a settlement containing a nondisclosure agreement.[259] A public interest group that had intervened in support of the original petition to release the documents was rebuffed by the district court and appealed to the New Jersey Supreme Court, which held that "unfiled documents in discovery are not subject to public access."[260]

Some key documents will become public when they are introduced as evidence in open court, but this only happens when the parties are unable to settle the litigation, and the prospect of publicizing "smoking gun" documents can be a powerful inducement to defendants to come to the settlement table. During settlement negotiations, defendants invariably insist on the return or destruction of damning documents as a condition to settlement, and it is a rare plaintiff who is willing to leave money on the table just to see the truth come out publicly. Consequently, the vast majority of cases end with a settlement agreement containing nondisclosure clauses preventing parties and their experts from sharing any documents with anyone.[261]

The primary purpose of such protective orders is to facilitate discovery by taking away the added incentive that the possibility of publication would provide to defendants to resist discovery in the first place.[262] This, of course,

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257 RICHARD J. PIERCE, JR., 2 ADMINISTRATIVE LAW TREATISE 770 (4th ed. 2002).

258 *See* Richard L. Marcus, *Myth and Reality in Protective Order Litigation*, 69 CORNELL L. REV. 1, 11 (1983).

259 *See* Andrew D. Goldstein, *Sealing and Revealing: Rethinking the Rules Governing Public Access to Information Generated Through Litigation*, 81 CHI.-KENT L. REV. 375, 375–76 (2006).

260 Frankl v. Goodyear Tire & Rubber Co., 853 A.2d 880, 886 (N.J. 2004).

261 Laurie Kratky Doré, *Public Courts Versus Private Justice: It's Time to Let Some Sun Shine In on Alternative Dispute Resolution*, 81 CHI.-KENT L. REV. 463, 493–94 (2006); Goldstein, *supra* note 259, at 378.

262 Nancy S. Marder, *Introduction to Secrecy in Litigation*, 81 CHI.-KENT L. REV. 305, 313 (2006).

saves the parties and the courts the considerable administrative expense of fighting and resolving disputes over whether potentially "smoking gun" documents must be produced.[263] The parties are much more willing to part with revealing documents when they receive some assurance that they will not show up in the next morning's *New York Times*. Protective orders also protect the legitimate privacy interests of litigants and non-litigants as well as proprietary information that might give a litigant's competitors an undue advantage in the marketplace.[264] At the same time, unwarranted secrecy "contributes to the impotency of government regulators."[265]

The threat that protective orders pose to the ability of common law litigants to share information with regulatory agencies is suggested by the fate of the previously discussed documents on Zyprexa. Within two days after the *The New York Times* ran the first of its series of stories on the drug, a federal district court in New York ordered the attorney who had shared the documents with the reporter to return them all to the court.[266] The court later found that the attorney had obtained the documents by issuing a subpoena to a doctor who was a consulting expert for the attorneys in the class action.[267] The doctor notified Eli Lilly of the request pursuant to the protective order, but he complied with the subpoena before Eli Lilly took action to quash it.[268] The court concluded that the doctor and lawyer had conspired with the reporter to circumvent the protective order, and expressed his extreme displeasure at the "unprincipled revelation" of the documents, which "compromises the ability of litigants to speak and reveal information candidly to each other."[269] Although the judge did not require the reporter to return the documents, he referred to the reporter's behavior as "reprehensible."[270] By this time many of the documents were available at various internet sites, and it was impossible to "unring the bell."[271] Based on the newspaper stories, several state attorneys general launched civil investigations into Eli Lilly's alleged marketing of Zyprexa for unapproved uses.[272]

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263 Goldstein, *supra* note 259, at 388–89, 406.

264 *Id.* at 378; Richard L. Marcus, *A Modest Proposal: Recognizing (At Last) that the Federal Rules Do Not Declare that Discovery is Presumptively Public*, 81 CHI.-KENT L. REV. 331, 339–41 (2006).

265 Goldstein, *supra* note 259, at 404.

266 Julie Creswell, *Court Orders Lawyer to Return Documents About an Eli Lilly Drug*, N.Y. TIMES, Dec. 20, 2006, at C14.

267 *Id.*

268 Patricia Hurtado, *Eli Lilly Regains Leaked Papers*, WASH. POST, Feb. 14, 2007, at D2.

269 *Id.*

270 *Id.*

271 Tom Zeller, Jr., *Documents Borne by Winds of Free Speech*, N.Y. TIMES, Jan. 15, 2007, at C3.

272 *See* Alex Berenson, *States Study Marketing of Lilly Pill*, N.Y. TIMES, Jan. 20, 2007, at C1.

VII. TOWARD GREATER COOPERATION IN THE FUTURE

Although the serious impediments to cooperation discussed above do not prevent all cooperation, a few modest reforms could bring about more cooperation and, consequently, better informed decisions by both agencies and the courts. Three modest reforms are discussed below.

A. Ease the Burden on EPA Test Rules

So long as the Fifth Circuit precedent in *Chemical Manufacturers Association v. EPA*[273] remains good law, EPA will continue to be reluctant to issue testing rules and will continue its often-fruitless efforts to persuade companies to engage in voluntary testing.[274] As we saw in the case of the MTBE testing rule,[275] even when the agency does get around to approving a voluntary testing agreement, it does not necessarily require the kind of testing that is necessary to evaluate the actual health or environmental risks posed by the chemical at issue.[276] This may be attributable to the fact that the public does not have a seat at the negotiating table. Public comment is ordinarily elicited on proposed agreements at the end of the negotiations, but by then the likelihood that the agency will change the requirements is quite slim. Congress could enhance EPA's ability to generate much-needed information on the health and environmental effects of ubiquitous chemicals by amending section 4 of TSCA to make it easier for the agency to justify testing rules and to ensure that the public has a greater role to play in negotiating testing agreements by requiring public notice and meetings in which such rules are to be discussed. Senator Frank Lautenberg introduced a bill during the 109th Congress that would do exactly that, but it went nowhere in the hostile environment of a Republican-controlled Congress.[277]

B. Easier Access to Agency Information through FOIA or Posting on the Internet

In theory, health and safety testing data submitted to EPA under TSCA should be available for the asking through the simple expedient of a Freedom of Information Act request. We have seen that theory and practice diverge considerably in the real world because of the agency's great fear of inadvertently releasing confidential business information in violation of federal criminal laws.[278] One way to avoid this clear violation of the spirit of the TSCA exception for health and safety testing data would be for EPA to follow FDA's recent example of posting the results of clinical trials,

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273 899 F.2d 344, 355 (5th Cir. 1990).

274 *See* McGarity, *supra* note 222, at 338–39.

275 *Id.* at 339.

276 *Id.*

277 Amy Cortese, *Will Environmental Fear Stick to DuPont's Teflon*, N.Y. TIMES, July 24, 2005, at C4.

278 McGarity & Shapiro, *supra* note 242, at 838–39.

including data tables and underlying documentation, on the internet for anyone to see.[279] In the case of FDA, this came about through voluntary agreements on the part of most major drug companies in the wake of the Vioxx scandal.[280] Absent a similar scandal with respect to an environmental contaminant, EPA will probably not be able to extract a similar agreement from chemical manufacturers. Given its existing authority to release such information, however, it could come up with a procedure under which all health and safety studies and adverse effect reports would be automatically posted after allowing the company an opportunity to specify particular words or phrases for redaction. Because this solution would no doubt yield many overly aggressive demands for redaction, it may be necessary for Congress to enter the picture with an amendment to TSCA that explicitly provides for such a procedure and provides penalties for unsupported redactions.

C. Change the Rules of Practice to Allow Parties to Provide Information to Agencies

The common law courts could go a long way toward enhancing cooperation by adopting a balancing approach in determining whether to allow documents subject to protective orders to be shared with federal agencies and the public.[281] This would undoubtedly require more work on the part of district judges who would be obliged to hold hearings on disclosure requests and might have to deal with more frequent objections to producing the documents at the outset of the discovery process. But it would also make potentially life-saving information available to the federal agencies that play a critical protective role in our society. The Texas Supreme Court has articulated specific standards to guide trial court discretion in deciding whether to seal documents produced in litigation.[282] The party seeking to seal the documents must file a public motion with the court along with a public notice to alert the press and anyone else who might care to intervene to argue against sealing the documents.[283] The Florida Legislature enacted a statute providing that "no court shall enter an order or judgment" that has the effect of concealing a "public hazard."[284] A federal district court in South Carolina in 2002 promulgated a local rule discouraging secret settlements and limiting other aspects of judicially

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279 *See generally* Jennifer L. Gold & David M. Studdert, *Clinical Trial Registries: A Reform That is Past Due*, 33 J.L. MED. & ETHICS 811 (2005).

280 *Id.*

281 Goldstein, *supra* note 259, at 383–84.

282 *See* General Tire, Inc. v. Kepple, 970 S.W. 2d 520, 524–25 (Tex. 1998).

283 TEX. R. CT. 76a (West 2007); TEX. GOV'T CODE ANN. § 22.010 (Vernon 2004). *See also* Goldstein, *supra* note 259, at 422–23 (arguing that the Texas Supreme Court has interpreted the rule narrowly to limit outsider access to unproduced documents, thereby allowing the parties an opportunity to "contract around" the rule at the outset of litigation).

284 FLA. STAT. ANN. § 69.081(3) (West 2004).

sanctioned confidentiality agreements.[285] Other courts should follow these salutary examples.

At the very least, Congress should intervene to allow parties to state common law litigation to share information with appropriate federal regulatory agencies. Congress has on at least one occasion done exactly that. Reacting to the public outrage over internal documents showing that Bridgestone/Firestone knew that its tires were routinely failing on Ford Explorer sport utility vehicles, which became public only after a Texas district court agreed to grant an exception to a protective order, Congress enacted the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act of 2000.[286] One section of that statute requires manufacturers of automobiles and tires to notify the National Highway Traffic Safety Administration of repeated common law claims brought against their products, but it also prevents the agency from sharing any information stamped confidential with the public unless it becomes part of a formal public action.

VIII. CONCLUSION

Regulatory agencies and common law courts can play a complementary role in protecting the public from unnecessary health and environmental risks posed by modern industrial products and activities. Both institutions should be providing incentives to the companies that engage in those activities to take reasonable steps to protect human health and the environment. Beyond that, they can provide each other with information relevant to the risks of the products and activities that are subject to both legal regimes. Sometimes they engage in admirable efforts at cooperation; most of the time they do not. Both institutions should devote more effort to the relationship, which will always be of an arms-length nature. Failing that, Congress should encourage greater cooperation through modest amendments to the relevant regulatory statutes.

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[285] Howard M. Erichson, *Court-Ordered Confidentiality in Discovery*, 81 CHI.-KENT L. REV. 357, 358 (2006).

[286] Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act, Pub. L. No. 106-414, 114 Stat. 1800 (2000).