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The Sword or the Shield: Use of Governmental Regulations, Exposure Standards and Toxicological Data in Toxic Tort Litigation

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The Sword Or The Shield: Use Of Governmental Regulations, Exposure Standards And Toxicological Data In Toxic Tort Litigation

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I. Introduction

Plaintiffs and defendants in toxic tort actions are regularly confronted with the issues of admissibility and utility of governmental regulatory standards, governmental assessments of the toxicity of particular chemicals, and the variety of federal and state statutes and regulations governing industries' conduct in the environmental, occupational, and consumer contexts. There are no absolute rules governing the admissibility and utility of scientific data or its regulatory framework in the courtroom.[1] Issues of negligence per se, private causes of actions, implied causes of action, judicial notice, public records, "administrative collateral estoppel," and the distinct but related issue of federal preemption often arise in toxic tort actions.

This note will first explore how litigants and the courts have addressed exposure levels in a variety of toxic tort actions, the data available in toxic tort actions and the importance of understanding the bases and nuances of the toxicity data, including the impact of risk assessment methodology in formulation of regulatory levels, prior to applying it in litigation. Evidentiary issues pertaining to this data, including judicial notice and public records, will then be addressed. The doctrine of negligence per se will be analyzed, followed by what defendants frequently assert as a logical corollary, federal preemption. Lastly, the concept of administrative collateral estoppel will be discussed.

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[1] Issues regarding admissibility and utility of governmental standards, regulations, and findings, which often arise in cases involving scientific evidence, were not addressed in the recent REFERENCE MANUAL ON SCIENTIFIC EVIDENCE. FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (1994). These issues have not been systematically studied.

II. Exposure Levels

The Federal government regulates the environment through the Environmental Protection Agency (EPA) and the many statutes governing conduct pertaining to air and water pollution, waste disposal, and hazardous and toxic substances.[2] State agencies, and in some circumstances local governmental agencies, also are charged with regulating pollution. Local regulation may occur independently or in conjunction with federal laws. Furthermore, hazardous and toxic substances also are regulated in the occupational context by the Department of Labor's Occupational Safety and Health Administration (OSHA) and its many sister state agencies. Thus, the same chemical can have different exposure levels in the environmental and occupational contexts. For example, the EPA may allow a certain amount of a chemical to be discharged into the ambient air, while the OSHA may permit a different amount of the same chemical to be emitted in the workplace, which is often an interior setting such as a factory or laboratory. The agencies allow different amounts to be emitted because the health effects resulting from exposure differ depending on the locus of exposure.

In toxic tort actions disputes naturally arise as to the import of the varied agency-set levels, particularly when the exposure of a plaintiff is different from the exposure intended for regulation by either the EPA or OSHA. For example, a homeowner may be breathing a certain chemical twenty-four hours a day and also may have been exposed to the same chemical from years of gardening in contaminated soil and then consuming the produce grown in the tainted soil. Levels of exposure for those endpoints, however, are generally not specifically measured, studied, or regulated. Thus, toxic tort cases typically involve extrapolations by toxicologists, occupational and environmental physicians, epidemiologists, and industrial hygienists, who relate the various governmentally-established levels to the exposure of the particular plaintiff.[3]

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[2] Such statutes include the following: Clean Air Act, 42 U.S.C. §§ 7401-7671q (1994); Clean Water Act, 33 U.S.C. §§ 1251-1376 (1994); Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), 42 U.S.C. §§ 9601-9675 (1994); Toxic Substances Control Act, 15 U.S.C. §§ 2601-2629 (1994); Resource Conservation and Recovery Act (RCRA), 42 U.S.C. §§ 6901-6992k (1994).

[3] *See* Ellen Relkin, *Some Implications of* Daubert *and Its Potential for Misuse: Misapplication to Environmental Tort Cases and Abuse of Rule 706(a) Court-Appointed Experts,* 15 CARDOZO L. REV. 2255, 2260-2262 (1994) [hereinafter "*Implications of Daubert*"].

In a toxic tort suit each party's position with respect to governmental data is fact-sensitive and will depend upon the chemical and exposure levels at issue in each case. In various circumstances both plaintiffs' and defendants' lawyers have relied on governmental data as an important tool in constructing their arguments.[4] If the pollutant at issue in a particular case is detected at a level below a governmental standard, the defendant will assert the government's standard, claiming that the exposure was *de minimis* and innocuous because the pollutant did not exceed the government exposure level. However, if the pollutant exceeded the pertinent standard, the plaintiff will offer that fact as evidence of wrongdoing, and the defendant will predictably argue that the governmental standard is irrelevant and inadmissible.

A few cases have been published concerning the issue of governmental assessments of the carcinogenicity of particular chemicals, but their results have been inconsistent. One court excluded a plaintiff's claims when the exposure was below governmental levels;[5] another court disregarded the fact that the exposure exceeded the governmental levels;[6] and yet a third court allowed a case to proceed with levels below governmental standards.[7] Thus, the actual impact of governmental assessments may vary from case to case.

Standards set by regulatory agencies, however, have been used effectively by defendants in toxic tort actions. In *Johnston v. United States*[8] the federal district court paid great deference to the standards developed by government scientists:

> [T]he most knowledgeable and eminent [governmentally appointed] scientists have spent many hours studying scientific papers that in turn reflect many hours of scientific work in order to determine what levels or amounts of radiation should be considered safe enough to use as safety standards. This Court is certainly ill-equipped to second guess those scientists by setting different standards of safety in these tort suits.[9]

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[4] *See* Michel F. Baumeister & Ellen Relkin, *Why Toxic Waste Reporting Can be a Mixed Bag for Plaintiffs*, THE PRACTICAL LITIGATOR, July 1990, at 87; John Endicott, *Using Government Health Assessment Documents In Defending Toxic Tort Litigation*, 9 TOXICS L. REP. (BNA) 198 (1994).

[5] Gideon v. Johns-Manville Sales Corp., 761 F.2d 1129 (5th Cir. 1985).

[6] Quinn v. Amphenol Corp., No. 94-1631, 1995 U.S. App. LEXIS 30788 (4th Cir. Oct. 26, 1995).

[7] German v. Federal Home Loan Mortg. Corp., 885 F. Supp. 537, 559 (S.D.N.Y. 1995).

[8] 597 F. Supp. 374 (D. Kan. 1984).

[9] *Id.* at 391.

In *Gideon v. Johns-Manville Sales Corp.*[10] the Fifth Circuit used an OSHA standard for permissible airborne asbestos exposure as a basis for reversing a judgment against a defendant whose products were alleged to have emitted less than the OSHA emergency standard.[11] The *Gideon* court also found that since the acceptable levels in the mid-1960s were higher than the plaintiff's alleged exposure, "[c]ompliance with such government safety standards constitutes strong and substantial evidence that a product is not defective."[12]

In a different twist, the Fourth Circuit recently affirmed the dismissal of plaintiffs' claims arising from exposure to trichloroethylene (TCE) from drinking water on their property. Even though TCE levels allegedly were *above* the EPA and the Department of Health and Environmental Control (DHEC) drinking-water-contamination levels, the appellate court affirmed the dismissal because, in part, "there was no evidence that the level of TCE on the Quinns' property was of toxicological concern or that anyone used any of the waters at issue in this litigation for drinking."[13]

However, in *German v. Federal Home Loan Mortg. Corp.*,[14] a recent class action lawsuit for children exposed to lead paint in their apartment homes, the court denied the defendants' motion for summary judgment. Defendants moved for summary judgment on the ground that the exposure to lead was below the Center for Disease Control defined danger blood level of 10 ug/dL. The plaintiffs, however, presented an expert affidavit that "blood lead levels even well below 10 ug/dL . . . are directly related to cognitive and neurobehaviorial deficits."[15] In denying the defendants' motion, the court held that there were "[q]uestions regarding the risk of harm . . . [that] cannot be decided on the motions for summary judgment before this court."[16]

As the above examples demonstrate, government levels are somewhat instructive, but courts do not mechanistically assume that exposure below set levels is trivial or that exposure above set levels is alone proof of injury. Accordingly, parties in toxic tort litigation must have a complete understanding of all the data potentially relevant to their cases in order to

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[10] *Gideon*, 761 F.2d 1129.
[11] *Id.* at 1144.
[12] *Id. See infra* Part III discussing issue of judicial notice of governmental standards.
[13] *Quinn*, 1995 U.S. App. LEXIS 30788, at *3n.1.
[14] *German*, 885 F. Supp. 537.
[15] *Id.* at 559.
[16] *Id.*

persuade the court that the scientific data is admissible and useful in resolving the underlying issues of liability in the case.

A. Available Data

The federal government produces a wealth of data that, depending on the circumstances, may be useful to either side in toxic tort litigation. Examples of relevant information include: Agency for Toxic Substances and Disease Registry (ATSDR) "Health Assessments" performed specific to Superfund sites; ATSDR "Toxicological Profiles" on the most common hazardous substances found at Superfund sites; Environmental Protection Agency (EPA) "Health Assessment Documents;" the National Institute for Occupational Safety and Health (NIOSH) Criteria Documents for Industrial Chemicals; the World Health Organization's monographs called "Environmental Health Criteria" on major industrial chemicals; and the International Agency for Research on Cancer's (IARC) publications on known or suspected carcinogens. The above documents set forth consensus and published data about the substances at issue. Also available are the Occupational Safety and Health Administration's (OSHA) standards for permissible occupational exposures to air contaminants for hundreds of chemicals published in the Federal Register,[17] Safe Drinking Water standards, and a myriad of other pertinent regulatory standards promulgated by federal and state governing bodies.[18] The industry sponsored American Conference of Governmental and Industrial Hygienists (ACGIH) in Cincinnati, Ohio also has numerous publications including its annual list of "Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents and Biological Exposure Indices."[19] While ACGIH

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[17] Air Contaminants, 58 Fed. Reg. 35,338 (1993) (to be codified at 29 C.F.R. § 1910).

[18] Litigants should carefully review the fine points of these promulgations. For example, OSHA states the following under the "Other Issues" section of the Air Contaminants Levels provision:

> OSHA continues to believe that many of the old limits which it will now be enforcing are out of date (they predate 1968) and not sufficiently protective of employee health based on current scientific information and expert recommendations. In addition, many of the substances for which OSHA has no PELS [(Permissible Exposure Limits)] present serious health hazards to employees.

58 Fed. Reg. 35,340 (1993). Further, OSHA explains that the levels were being revised pursuant to an Eleventh Circuit Court of Appeals decision vacating revised air contaminants standards which had impermissibly lowered Permissible Exposure Limits, (PELS). *Id. See* AFL-CIO v.OSHA, 965 F.2d 962 (11th Cir. 1992).

[19] The ACGIH defines "Threshold Limit Values" (TLVs) as "airborne concentrations of substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects." AMERICAN CONFERENCE OF

is not a governmental agency, its TLVs are used and adopted by some governmental entities and are considered industry standards. Parties should be cognizant of the inherent biases in these industrial-based standards.[20]

Litigants must also be well versed in the nuances of the particular standards at issue. For example, a defendant may argue that the plaintiff was not exposed to dangerous levels of a chemical because the air levels of a chemical in the plaintiff's home were below an OSHA PEL or a NIOSH TLV. This argument, however, can be refuted because PELs are based upon occupational exposure derived from an eight-hour work day, while children or the elderly reside in a home twenty-four hours a day; therefore, the occupationally derived PELs and TLVs are inapposite.

There has been recent controversy on the issue of the admissibility of expert testimony in a toxic tort case premised upon a methodology utilized by the Environmental Protection Agency (EPA) to classify a chemical as a carcinogen. The EPA's "weight of the evidence" analysis was used to classify the chemical ethylene oxide as a carcinogen. In *Allen v. Pennsylvania Engineering Corp.*,[21] the Fifth Circuit held that while regulatory agencies use the method to assess the carcinogenicity of substances, the threshold of proof is lower in the regulatory setting because the agencies are charged with protecting public health, while the tort system imposes a higher burden on the plaintiff to prove it is more likely than not that the chemical caused the particular injury. The court rejected the weight of the evidence methodology, leading one commentator to call

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GOVERNMENTAL INDUSTRIAL HYGIENISTS, 1993-1994 THRESHOLD LIMIT VALUES FOR CHEMICAL SUBSTANCES AND PHYSICAL AGENTS AND BIOLOGICAL EXPOSURE INDICIES 2 (1993).

The ACGIH statement acknowledges that "[b]ecause of wide variation in individual susceptibility, however, a small percentage of workers may experience discomfort from some substances at concentrations at or below the threshold limit . . . ." *Id.* ACGIH specifies that "[t]hese limits are intended for use in the practice of industrial hygiene as guidelines or recommendations in the control of potential health hazards and for no other use, e.g., in the evaluation or control of air pollution nuisances; in estimating the toxic potential of continuous, uninterrupted exposures . . . ." *Id.*

ACGIH defines "Biological Exposure Indices" (BEIs) as "reference values intended as guidelines for the evaluation of potential health hazards in the practice of industrial hygiene. BEIs represent the levels of determinants which are most likely to be observed in the specimens collected from a healthy worker who has been exposed to the same extent as a worker with inhalation exposure to the TLV." *Id.* at 50.

[20] *See* Barry I. Castleman & Grace E. Ziem, *Corporate Influence on Threshold Limit Values*, 13 AM. J. INDUS. MED. 531 (1988). *See also* David E. Lilienfeld, *The Silence: The Asbestos Industry and Early Occupational Cancer Research - A Case Study*, 81 AM. J. PUB. HEALTH 791 (1991) (discussing the concealment of data by the asbestos indurstry).

[21] *Allen*, 102 F.3d 1994 (5th Cir. 1996).

the methodology an "ouija board technique not grounded in scientific principles but driven by a pre-conceived, result oriented belief system."[22] This holding conflicts with the analysis of the Third Circuit in *In re Paoli Railroad PCB Litigation*[23] which accepted expert causation opinions that were based upon the weight-of-the-evidence methodology utilized by the EPA in assessing the carcinogenicity of polychlorinated biphenyls (PCBs). This recent split between the circuits on this issue may result in a certiori petition to the U.S. Supreme Court.[24]

B. Risk Assessment

It is important to distinguish between setting the appropriate levels for exposure to a particular chemical in the regulatory framework and evaluating the ability of a chemical exposure to cause an injury under the tort system. Regulators often set standards of permissible exposure levels based on the methodology of Quantitative Risk Assessment (QRA). Risk assessment has been defined by the recent Federal Judicial Center's REFERENCE MANUAL ON SCIENTIFIC EVIDENCE as "[t]he use of scientific evidence to estimate the likelihood of adverse effects on the health of individuals or populations from exposure to hazardous materials and conditions."[25] The use of risk assessment began in response to public concerns about cancer caused by pollution.[26] The first federal agency to develop a risk assessment methodology was the Food and Drug Administration, followed by the Environmental Protection Agency.[27] They were later joined by the Occupational Safety and Health Administration after the Supreme Court's decision in *Industrial Union Department, AFL-CIO v. American Petroleum Institute.*[28]

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[22] 11 Toxics L. Rep. (BNA) 866 (Jan. 15, 1997).

[23] 35 F.3d 717, 741-71.

[24] 11 Toxics L. Rep. (BNA) 865-66 (Jan. 15, 1997).

[25] FEDERAL JUDICIAL CENTER, *supra* note 1, at 216 (defining "risk assessment" but not discussing the basis of risk assessment and its limitations).

[26] Paul A. Locke, *Reorienting Risk Assessment*, Environmental Law Institute Research Brief No. 4, Sept. 1994, at 5-6.

[27] *Id.*

[28] 448 U.S. 607 (1980). *See* Locke, *supra* note 22 at 5-6. The fact that OSHA findings of fact were required to be made by the Supreme Court in *Industrial Union Dep't v. American Petroleum Inst.* was significant in a trial court's holding that those findings of fact should be admissible as trustworthy under Federal Rule of Evidence 803(8)(c). *See infra* Part III discussion the admissibility of governmental findings. *See also* Coates v. AC and S., Inc., 844 F. Supp. 1126, 1133 (E.D. La. 1994).

QRA guidelines were later standardized by the National Research Council (NRC) for use in assessing the risks from exposure to chemicals.[29] The NRC guidelines were recently explained in a law journal article that contrasted tort law with regulatory law:

> The NRC articulated a distinction between risk assessment and risk management and then identified four separate steps or phases in risk assessment. These are hazard identification, the identification of a causal link between exposure to a particular chemical and a particular health effect; dose-response assessment, the determination of a relation between the magnitude of exposure and the probability of occurrence of the health effect; exposure assessment, an estimate of the extent of human exposure to the chemical; and risk characterization, a description of the nature and magnitude of the risk arrived at through these first three steps. The level of uncertainty about the risk characterization is part of the final risk number.[30]

The guideline factors for risk assessment differ to some extent from methodologies used by physicians in diagnosing a patient's condition. While helpful in analyzing the toxic effects of a substance, the factors are not dispositive. Nor were the factors intended to be dispositive in medical causation determinations on an individual basis.[31] Instead, the guideline factors comprise a risk calculation for policy formulation. The calculation is based in large part on economic constraints — defining what is the "acceptable" number of chemically induced cancers arising from exposure to a certain chemical at a particular level.

One fundamental problem with most risk assessment models is that "most QRA's focus on cancer effects, but this is a narrow indicator which is inexact as a measure of broad effects."[32] Chemicals can cause many harms in addition to cancer, yet carcinogenicity is often the only effect or "endpoint" analyzed in risk assessments. Clearly, a risk assessment predicated on carcinogenicity is of little or no value when a toxic tort case

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[29] NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983). This is commonly referred to as "the Redbook."

[30] Mary L. Lyndon, *Tort Law and Technology*, 12 YALE J. ON REG. 137, 160 (1995).

[31] *See* Relkin, *supra* note 3, at 2258. *See also* George W. Conk, *Against The Odds: Proving Causation of Disease with Epidemiological Evidence*, 3 SHEPHARDS EXPERT AND SCIENTIFIC EVIDENCE Q. 103 (1995)(critiques over-reliance on epidemiological evidence in proving medical causation).

[32] Lyndon, *supra* note 26, at 162.

alleges nervous system poisoning, or some other adverse health consequence. While noncarcinogen risk assessments are conducted to some extent, cancer risk assessment "drives most of the regulatory decision making and dominates risk assessment practice" of the EPA.[33]

Furthermore, while regulators in establishing policy may have found a statistical risk of one in a million cancers to be acceptable and, as a result, may have formulated an air or water pollution standard for a particular pollutant at a level where it is expected to cause cancer in only one in a million persons, polluters should not be exonerated when the unfortunate millionth person contracts the chemical induced leukemia. Likewise, when more than the predicted number of people succumb to the disease, and it becomes apparent that the risk assessment calculations (which are inherently predictions) were wrong, the polluter should not be shielded from liability. Accordingly, exposure levels predicated on risk assessments are subject to criticism. Therefore, polluters should use caution when asserting the statistical risk to discount medical causation proof in the toxic tort setting.[34]

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[33] Locke, *supra* note 22, at 8. As stated by the Director of the Environmental Law Institute's Center for Public Health and Law:

> The EPA's Noncancer Risk Assessment methodology has changed little since the 1960's, except for a few technical alterations and attention to health effects other than cancer has remained flat. Even the way that these health effects are catalogued together is telling. Diverse acute and chronic endpoints such as impaired lung function, reproductive effects, developmental abnormalities, and immune reactions are lumped together under the noncancer rubric. Dramatically different and vitally important health effects have been tossed into this catchall category. As a result, both science and policy are shortchanged.
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> Consider, for example, the categories of adverse reproductive and developmental effects, neurotoxic effects, and immune system disruption, all of which fall under the broad umbrella of noncancer health outcomes. . . . Approximately 250,000 babies are born with birth defects in the United States each year. Environmental factors, including exposure to chemicals, are identified as a cause with relative certainty in 2 to 3 percent of these cases. In more than 60 percent of cases the cause is unknown, but the environment could potentially play a role . . . .
>
> Neurotoxic compounds pose substantial threats to human health and well being. Like reproductive and developmental toxicants, insufficient data exists to paint a comprehensive picture of neurotoxic risks. FEWER THAN 10 PERCENT OF THE 70,000 CHEMICALS USED IN COMMERCE HAVE BEEN TESTED FOR NERVOUS SYSTEM EFFECTS.

Id. at 9-10 (emphasis added).

[34] *Compare Coates*, 844 F. Supp. at 1132-33 (trial court noted that OSHA and EPA position papers concerning the health effects of asbestos exposure went through "a plethora of epidemiologic studies and risk assessment data" before admitting those papers as government records).

III. Judicial Notice & Public Records

One trial technique for presenting regulatory levels of exposure or related issues, such as the inclusion by the EPA of a chemical on its formulated list of known human carcinogens, is to use the device of judicial notice. Federal Rule of Evidence 201 provides, "[A] judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned."[35]

This technique has been successfully employed in a number of federal court cases. In *Gideon v. Johns-Manville*[36] the Fifth Circuit took judicial notice of OSHA promulgated standards pertaining to the permissible level of asbestos fibers per cubic centimeters.[37] In *Pantry, Inc. v. Stop-N-Go Foods, Inc.*,[38] the court took judicial notice "of the fact that benzene is a known human carcinogen" based upon "data and conclusion relied upon by the United States Environmental Agency and published in an official government publication . . . that benzene is a known carcinogen beyond reasonable dispute."[39] Finally, in *United States v. Rainbow Family*,[40] the court took judicial notice that certain portions of an Army field manual established suitable standards for sanitary measures.[41]

An additional vehicle for presenting findings of the EPA, OSHA, NIOSH, or other agencies pertaining to a particular toxin, or of an agency's investigation of a particular factory or dumpsite is the "Public Records and Reports" hearsay exception, which enables the admission of:

> Records, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth (A) the activities of the

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[35] FED. R. EVID. 201(b).

[36] *Gideon*, 761 F.2d at 1129.

[37] *Id.* at 1144.

[38] 777 F. Supp. 713 (S.D. Ind. 1991).

[39] *Id.* at 733. The court in *Pantry, Inc.* conducted a detailed analysis of the pertinent standards. The court recognized that there is a distinction between Recommended Maximum Contaminant Levels (RMCL), promulgated pursuant to the Safe Drinking Water Act, 42 U.S.C. §§ 300f to 300j-26 (1994), 40 C.F.R. § 141.50 (1996) and the groundwater standards. The courts, however, acknowledged that placement by EPA of benzene in a certain category (Category I) reflects the conclusion that it is a known human carcinogen "in any concentration." *Pantry, Inc.*, 777 F. Supp. at 733. The court, therefore, extrapolated the standard in a logical manner. *Id.*

[40] 695 F. Supp. 314 (E.D. Tex. 1988).

[41] *Id.* at 330 n.5.

> office or agency, or (B) matters observed pursuant to duty imposed by law as to which matters there was a duty to report. . . or (C). . . factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness.[42]

This Rule allows the use of public records without the proofs required to admit ordinary business records. These records may be admitted without the testimony of a foundation witness, and they may be admitted even though they do not satisfy the requirements of being made in the regular course of business near the time of the event the record refers to. Further, to proffer a public report, one generally does not have the burden of proving trustworthiness because "[m]ost government sponsored investigations employ well-accepted methodological means of gathering and analyzing data."[43] Governmental reports have been admitted under Federal Rule of Evidence 803(8) by a variety of federal courts. In *Ellis v. International Playtex, Inc.*[44] the court admitted a Center for Disease Control (CDC) report about toxic shock syndrome, despite objections that the report was based on data compiled from case reports by doctors who had no absolute duty to report accurately to the CDC and that the reports were not verified by the agency.[45] It is anticipated that this issue will arise in the ubiquitous breast implant litigation in light of a recent report issued by the Food and Drug Administration.[46] In another case, *United States v. Northernaire Plating Co.*,[47] pursuant to Federal Rule of Evidence 803(8), a federal trial court admitted reports of the EPA and the Michigan Department of Natural Resource (MDNR), finding that the reports "clearly fall within the purview" of the rule and that the opponent failed to meet its burden of showing the untrustworthiness of the reports.[48]

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[42] FED. R. EVID. 803(8).

[43] Ellis v. International Playtex Inc., 745 F.2d 292, 301 (4th Cir. 1984).

[44] *See id.*

[45] *Id.* at 301. *See also* Kehm v. Proctor & Gamble Mfg. Co., 724 F.2d 613 (8th Cir. 1983) (another toxic shock syndrome case admitting the CDC report).

[46] This FDA report was recently published in the ANNALS OF INTERNAL MEDICINE. Barbara G. Silverman et al., *Reported Complications of Silicone Gel Breast Implants: An Epidemiologic Review*, 124 ANNALS INTERNAL MED. 744 (1996). The FDA report reviewed the range of local and systemic complaints attributed to silicone breast implants and evaluated the epidemiologic literature on these complications. The report concluded that "[n]o epidemiologic study has indicated that the rate of well-defined connective tissue disease or breast cancer has greatly increased in women with silicone breast implants, but no studies have ruled out a moderately increased risk for these diseases." *Id.* at 744.

[47] 670 F. Supp. 742 (W.D. Mich. 1987).

[48] *Id.* at 743-44.

A variety of governmental reports were addressed in the context of Federal Rule of Evidence 803(8) in *O'Dell v. Hercules, Inc.*[49] In that case the Eighth Circuit had to decide whether the trial court had properly admitted a report of the Arkansas Department of Pollution Control and Ecology (ADPCE) that found it a likelihood that chemicals were entering a creek from the defendant's plant site where thousand of drums of chemical waste had been buried and stored.[50] The court ultimately found the report trustworthy and, therefore, admissible at the discretion of the trial court.[51] The *O'Dell* court also decided to uphold the admission of a Center for Disease Control Report "predicting the possible health risks from exposure to soil containing the levels of dioxin found at the plant and in the landfills."[52] The court found that the report did not exhibit any indicia of untrustworthiness.[53]

The Eighth Circuit, however, upheld the exclusion of EPA reports that listed the site on the National Priority List of Superfund.[54] These reports were excluded because the listing was found to "serve primarily informational purposes. . . [and] does not in itself reflect a judgment of the activities of its owner or operator."[55] The Eighth Circuit concluded that the report was irrelevant and to admit it would be unfairly prejudicial.[56] The Eighth Circuit also upheld the trial court's exclusion of ATSDR health assessments. The Eight Circuit found that the trial court did not abuse its discretion in excluding the ATSDR health assessments. The reports exhibited an indicia of untrustworthiness because certain data were missing and because there were problems with the methodology.[57]

In a different toxic tort context involving a case that arose from the use of smokeless tobacco,[58] the Tenth Circuit held inadmissible a report by the International Agency for Research on Cancer and a report from the Consensus Development Conference of the National Institute of Health.

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[49] 904 F.2d 1194 (8th Cir. 1990).
[50] *Id.* at 1204 n.23.
[51] *Id.* at 1204-05.
[52] *Id.* at 1205.
[53] *Id.*
[54] *O'Dell*, 904 F.2d at 1205.
[55] *Id.* at 1206.
[56] *Id.*
[57] *Id.* at 1206-07. *See also* United States v. Summit Equip. & Supplies, Inc., 805 F. Supp. 1422 (N.D. Ohio 1992) (holding that an on-site coordinator's affidavit and reports on which it was based were admissible in a CERCLA action under the hearsay exception for records of regularly conducted activity to prove the existence of a release or threatened release of hazardous substances; the report was also admissible under the public records exception as it set forth factual findings resulting from an authorized investigation).
[58] Marsee v. United States Tobacco Co., 866 F.2d 319 (10th Cir. 1989).

These reports, which concluded that smokeless tobacco caused mouth cancers, were not admitted under Federal Rule of Evidence 803(8) because they did not reflect the findings of a governmental agency "authorized by law to report on the adverse health effects of smokeless tobacco." The agencies that produced these reports are not "public agencies" within the meaning of Rule 803(8).[59]

In another case, however, Fifth Circuit held that "the duty to prepare the report can be delegated, under government regulations, to an independent agency or to a foreign government without the report losing its character when submitted through the appropriate United States agency, as a report of a department or agency of the United States."[60]

Government reports can serve as a form of expert testimony. In *Beech Aircraft Corp. v. Rainey,*[61] the Supreme Court held that statements in the form of opinions or conclusions are not necessarily excluded from the scope of Federal Rule of Evidence 803(8)(C). They will be admissible as long as they are "based on factual investigation and satisf[y] the Rule's trustworthiness requirement."[62] Thus, through the admission of government reports, parties can proffer what is essentially the equivalent of expert opinion with the imprimatur of the federal or state government.[63] Although all of the usual expert rules apply to opinions set forth in public reports, these reports can be advantageous because they are presumed trustworthy. Therefore, the burden is on the opponent to show that the report fails to meet standards for expert testimony.[64]

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[59] *Id.* at 324-25.

[60] *See* United States v. Central Gulf Lines, Inc., 974 F.2d 621, 627 (5th Cir. 1992) (citing United States v. Lykes Bros. S.S. Co., 432 F.2d 1076, 1079 (5th Cir. 1970)).

[61] 488 U.S. 153 (1988).

[62] *Id.* at 170.

[63] Because of the often technical nature of the government reports at issue, this commentator expects there to be, if they are not happening already, *Daubert* hearings over questions of admissibility. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993) (prompting *Daubert* hearings in federal cases to determine the admissibility of scientific expert testimony, thereby making federal judges "gatekeepers" on the issue of admissibility of scientific evidence).

For an analysis of the admissibility of governmental reports, see Daniel J. Capra, *The Use of Public Records in Civil Cases*, N.Y. L. J., Jan. 12, 1996, at 3.

[64] *See* Jenkins v. Whittaker Corp., 785 F.2d 720, 726-27 (9th Cir. 1986)(an investigative report was excluded because the government investigator was found to be unqualified to reach the conclusions contained in his report). *But see* Clark v. Clabaugh, 20 F.3d 1290, 1295 (3d Cir. 1994) (rejecting the opponent's position that Rule 803(8) requires that the investigator and author of the government report must be qualified as an expert before the report becomes admissible). In *Clark,* a Pennsylvania Police Report was admitted in a civil rights action because it was presumed trustworthy and the opponents failed to demonstrate its untrustworthiness; therefore, the court admitted the report, including its opinions, conclusions, and recommendations. *Id.* at

While governmental reports containing expert opinion based in part on hearsay are admissible,[65] governmental reports that are in draft or preliminary form are generally not admissible because they do not contain factual findings made at the conclusion of an investigation.[66] Admitting testimony of an expert in a product liability action premised on the absence of a governmental investigation of a safety hazard as a basis to infer that the product was safe has been deemed reversible error.[67]

IV. Negligence Per Se

Courts addressing negligence per se in the toxic tort context have arrived at varied results. The mixed results appear to flow from the confusion arising over the applicability of the doctrine itself. According to the doctrine of negligence per se, applicable statutes constitute the governing standard of care, and violation of those statutes is negligence as

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1294-95.

[65] Moss v. Ole South Real Estate, Inc., 933 F.2d 1300, 1310 (5th Cir. 1991) (based on the rationale that experts may rely on hearsay).

[66] *See, e.g.*, Toole v. McClintock, 999 F.2d 1430 (11th Cir. 1993). The Eleventh Circuit reversed a compensatory and punitive damages jury verdict for the plaintiffs in a breast implant action on the basis that it was evidentiary error for the district court to admit into evidence a proposed rule about implants prepared by the FDA. The document contained the agency's proposal to require pre-market approval for silicone-gel filled breast prostheses and stated the agency's "proposed findings" on risks posed by the devices. The court held:

> [t]he FDA report is not the kind of trustworthy report described in Rule 803. By its own terms, the FDA report contained only 'proposed' findings. The report invited public comment and forecasted the issuance of a 'final' document after more study. Rule 803 makes no exception for tentative or interim reports subject to revision and review.

Id. at 1434-35.

The court also noted that after the trial the FDA issued its final rule requiring premarket approval of breast implants and that "the differences between the final rule report and the proposed rule report points out the tentative nature of the earlier report." *Id.* at 1435 n.11. The final report stated that 29 of the references cited in the proposed rule report were "miscited" and that the report reached "substantially more equivocal" conclusions about some of the health risks of the implants. *Id.* at 1435 n.11.

The finality requirement is not, however, absolute. In a pesticide exposure case a draft report of the EPA was admitted as a public record. The proponents of the 1987 Technical Support Document (TSD), prepared by the EPA pertaining to the risks of the pesticides chlordane and heptachlor, submitted an affidavit from the Senior Science Advisor and Chief Toxicologist of the EPA which stated that the TSD represents the Agency's "final conclusions" and is "marked 'draft' not because the conclusions are tentative but because Velsicol agreed to take the product off the market." Conde v. Velsicol Chemical Corp., 804 F. Supp. 972, 994 (S.D. Ohio 1992). In light of that affidavit and the presumption of admissibility set forth in The Advisory Committee Notes to Rule 803, the Court concluded that the TSD was admissible under Rule 803(8)(C). *Id.*

[67] *See* Adelman v. Lupo, 677 A.2d 230 (N.J. Super. Ct. App. Div. 1996).

a matter of law.[68] In a recent analysis of Restatement (Second) section 286, this concept was explained: Negligence as a matter of law exists when:

> (1) an applicable statute prescribes certain actions or defines a standard of conduct, either explicitly or implicitly;
> (2) the plaintiff is in the class of persons sought to be protected by the statute;
> (3) the plaintiff's alleged harm or injury is generally of the type the legislature sought to prevent by enactment of the statute; and
> (4) the defendant violated the statute (an issue for the jury).[69]

Parties addressing claims under the doctrine of negligence per se must distinguish between the different purposes for which the doctrine is to be applied. This need to distinguish arises from the simple fact that violation of a statute is generally not, by itself, a sufficient basis for liability nor is compliance with a statute a sufficient basis for exoneration of liability.[70] Therefore, in using a particular statute or regulation as a basis for asserting a claim, it must be ascertained whether the statute is being used as proof that the defendant has breached a pre-existing duty, or whether the statute is being used to establish that the defendant owed a duty in the first place. If there is no duty owed by the defendant to the plaintiff independent of the statute, or created explicitly in the statute by providing a private right of action, then the court would need to imply a cause of action from the statute in order to find negligence per se.[71] However, courts are generally reluctant to imply causes of actions. The cases that follow should be instructive on the distinction, and the consequences that flow therefrom.

In *Myers v. United States,* plaintiffs were the survivors of miners killed in an explosion who brought an action against inspectors from the Mine Safety and Health Administration (MSHA) under the Federal Tort Claims Act (FTCA). Plaintiffs sought to invoke the doctrine of negligence per se as a source of liability, arguing that violation of MSHA regulations constituted negligence per se and, therefore, provided the state-law basis for liability under the FTCA. In explaining that the doctrine of negligence per se is never, by itself, a basis for liability, the court said:

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[68] RESTATEMENT (SECOND) OF TORTS § 286 (1977).

[69] Schwartzman, Inc. v. Atchison, Topeka & Santa Fe Ry. Co., 857 F. Supp. 838, 847 (D. N.M. 1994).

[70] Myers v. United States, 17 F.3d 890, 899 (6th Cir. 1994).

[71] *Id.* at 901.

> The doctrine of negligence per se was created, not as a means of deciding when a duty of care arises, but rather as a means of defining the particular standard of conduct such a duty requires. Restatement (Second) of Torts Sections 285-288(1965) (hereinafter "Restatement"). Thus, a plaintiff, whether under state law or the FTCA, must first establish the existence of a relationship giving rise to a duty before attempting to rely on the doctrine of negligence per se to establish the standard of conduct required.[72]

The "subtle but crucial distinction between a duty and a standard of care" requires a plaintiff to establish an underlying duty before relying upon the doctrine of negligence per se.[73] The *Myers* court found that while the relationship between miners and mine owners might be sufficient to create a duty of care under common law such that violation of MSHA could support a presumption of negligence as against the owners, no such relationship existed between the miners and the government inspectors, who were the defendants. Thus, absent the duty under either federal or state law, plaintiffs' claim that liability existed under the doctrine of negligence per se was dismissed.[74]

Apparently, in an attempt to provide an alternative basis for its decision, the *Myers* court went on to analyze the MSHA violations as negligence per se under the four Restatement section 286 factors. The court found that the MSHA violations raised by the plaintiffs were "concerned solely with the manner in which compliance with safety regulations [was] monitored rather than the regulations that actually [imposed] the safety standards."[75] The court concluded that the regulations were not intended to protect plaintiffs from the specific harm they suffered and, therefore, that the regulations could not constitute a statutory

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[72] *Id.* at 899.

[73] Johnson v. Sawyer, 4 F.3d 369, 376 (5th Cir. 1993).

[74] *Myers*, 17 F.3d at 899 (citing *Johnson*, 4 F.3d at 376 (mere violation of federal statute by government employee does not give rise to FTCA suit on negligence per se grounds)). *See also* Kane v. J.R. Simplot Co., 60 F.3d 688, 695 (10th Cir. 1995) (finding violation of OSHA regulations was not negligence per se when the defendant owner of a building did not owe a duty under the OSHA regulations to the painting sub-contractor because the defendant had insufficient control of the work performed under the subcontract); Art Metal-U.S.A., Inc. v. United States, 753 F.2d 1151, 1159 n.15 (D.C. Cir. 1985) (characterizing plaintiffs' attempt to invoke doctrine of negligence per se without establishing an underlying state-law duty as a "mistake" and a "flawed analysis").

[75] *Myers*, 17 F.3d at 901.

standard of conduct.[76] The *Myers* court noted, however, that had these specific MSHA regulations concerned safety, detailing "the standard of conduct owed by mine owners to miners and by miners to each other," violation would be conclusively presumed to be negligence.

In contrast to *Myers*, the defendant's motion to dismiss a negligence per se claim was denied in the groundwater pollution case of *Evco Associates, Inc. v. C.J. Saporito Plating Co.*[77] The defendant relied upon an earlier Illinois case, *Davis v. Marathon Oil Co.*, which held that a violation of a statute does not constitute negligence per se because "the evidence of negligence may be rebutted by proof that the party acted reasonably under the circumstances, despite the violation."[78] The federal district court rejected defendant's claim that *Davis* stands for the proposition that while violation of a statute designed to protect human life or property is prima facie evidence of negligence, it does not constitute negligence per se. Rather, the court construed *Davis* as holding that "another analysis must be engaged before a statutory violation will be deemed negligence per se,"[79] but a violation of a statute may constitute negligence per se.

In *Pratico v. Portland Terminal Co.*,[80] the First Circuit considered whether the Federal Employers' Liability Act (FELA)[81] incorporated the doctrine of negligence per se and, if it did, whether the doctrine could be applied to an OSHA violation. The court noted:

> Before a violation of an OSHA regulation can be considered negligence per se, there must be an independent cause of action established by either state or federal law which establishes the right of an employee to be free from negligence, the duty of the employer to take reasonable precautions, and the liability of the employer for injuries caused by the failure to take reasonable precautions.[82]

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[76] *Id.* at 900, (citing Teal v. E.I. DuPont de Nemours & Co., 728 F.2d 799 (6th Cir. 1984) (employer's breach of OSHA regulations was negligence per se under Tennessee law)). *See also* Ellis v. Chase Communications, Inc., 63 F.3d 473, 477-78 (6th Cir. 1995)(clarifying *Teal*).

[77] No. 93 C 2038, 1993 U.S. Dist. LEXIS 12423 (N.D. Ill. 1993).

[78] Davis v. Marathon Oil Co., 356 N.E.2d 93 (Ill. 1976).

[79] *Evco*, 1993 U.S. Dist. LEXIS 12423, at *10.

[80] 783 F.2d 255 (1st Cir. 1985).

[81] 45 U.S.C. §§ 51-60 (1994).

[82] *Pratico*, 783 F.2d at 265.

After reviewing the history of FELA the court found that the Act was basically predicated upon negligence and that it specifically created a federal cause of action for injured employees such as the plaintiff. The court then found that § 653(b)(4) of the Occupational Health and Safety Act (OSHA), which provides that OSHA may not be used to affect employer liability, did not prevent the plaintiff from borrowing the relevant OSHA regulations to act as "guides for the determination of standards of care."[83] Plaintiff's claim for negligence per se was, thus, allowed to proceed.

Several other cases appear to provide hope for bringing viable negligence per se claims based upon violations of statutes or regulations. In *Kleen Laundry & Dry Cleaning Services, Inc. v. Total Waste Management, Inc.*,[84] the court cites two opinions wherein the courts held that violations of the standard of conduct of the New Hampshire version of CERCLA[85] could support a negligence per se theory.[86] In *United States ex rel. Dep't of Fish and Game v. Montrose*,[87] the defendants were allowed to proceed with a counterclaim for indemnity of their CERCLA liability pursuant to a California statutory negligence per se provision. Finally, in *Stanton by Brooks v. Astra Pharmaceutical Products*,[88] the court found that because section 130.35 of Title 21 of the Code of Federal Regulations was promulgated in accordance with the Food and Drug Act to protect individuals from precisely the type of harm that occurred — an adverse reaction to Xylocaine — the plaintiff had a viable claim for negligence per se under Pennsylvania law.[89] These cases notwithstanding, negligence per

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[83] *Id.* (quoting Nat'l Marine Serv., Inc. v. Gulf Oil Co., 433 F. Supp. 913, 919 (E.D. La. 1977)). In finding that section 653(b)(4) created no obstacle to plaintiff's negligence per se based on OSHA, the court relied upon the following line of cases out of the 5th Circuit: Dixon v. International Harvester Co., 754 F.2d 573, 581 (5th Cir. 1985); Rabon v. Automatic Fasteners, Inc., 672 F.2d 1231, 1238 (5th Cir. 1982); Melerine v. Avondale Shipyards, Inc., 659 F.2d 706, 709 (5th Cir. 1981). *But see* Ries v. Nat'l R.R. Passenger Corp., 960 F.2d 1156, 1162-63 (3d Cir. 1992)(stating that such use of OSHA does affect employer's statutory duty in contravention of Congressional intent).

[84] Kleen Laundry & Dry Cleaning Serv., Inc. v. Total Waste Management, Inc., No.CIV.91-493-JD, 1994 WL 287747 (D. N.H. 1994) [hereinafter "*Kleen Laundry*"].

[85] N.H. REV. STAT. ANN. § 146-A: 1 to 146-A:17 (1995).

[86] *Kleen Laundry*, 1994 WL 287747, at *3 (citing Mesiti v. Microdot, Inc., 739 F. Supp. 57, 63, 66 (D. N.H. 1990); Johnson v. Mobile Oil Corp., No. 92-151-JD, slip op. at 4-5 (D. N.H. Apr. 22, 1994)).

[87] 788 F. Supp. 1485 (C.D. Cal. 1992).

[88] 718 F.2d 553 (3d Cir. 1983).

[89] *Id.* at 563-64. For a series of older state and federal cases on point, *see* Joseph A. Darrell, Esq., *Standards, Rules, and Toxic Tort Litigation*, *in* TOXIC TORTS: LITIGATION OF HAZARDOUS SUBSTANCE CASES 212-26 (G.Z. Nothstein, Esq., 1984).

se claims that rely upon statutes and regulations to create both the relevant duty as well as the standard to be followed in observance of that duty are not likely to succeed. The courts have been almost uniform in holding that where the plaintiff proposes the statute for both purposes, in order to recover damages, the plaintiff must demonstrate that the underlying statute is capable of supporting a private right of action for damages.

In *Rodriguez v. American Cyanamid Co.*,[90] for instance, the owners of a mobile home polluted by a "bug bomb" brought action against the distributor and manufacturer of the insecticide. The plaintiffs asserted that defendants were negligent per se for their violation of § 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[91] The court first found that the duty prong of Restatement section 286 had not been satisfied because plaintiffs apparently were not members of the class intended to be protected by § 6(a)(2) reporting requirements.[92] In deciding whether to recognize the negligence per se claim despite this failure, the court observed:

> Courts considering whether to recognize negligence per se based on violations of broad environmental and public health statutes and regulations such as FIFRA have approached this issue by determining whether, in enacting the statute, the legislature intended to create a private right of action.[93]

The *Rodriguez* court held that the appropriate test for making this determination was set out by the Supreme Court in *Cort v. Ash*.[94] The test espoused in *Cort* is as follows:

> (1) is the plaintiff a member of the class for whose special benefit the statute was enacted; (2) is there any indication of legislative intent to create such a remedy or to deny one; (3) is it consistent with the underlying purposes of the legislative scheme to imply such a remedy; (4) is the cause of action one not traditionally relegated to state law in an area basically the concern of the state,

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[90] 858 F. Supp. 127 (D. Ariz. 1994).

[91] *Id.* at 129.

[92] *Id.*

[93] *Id.* (citing Lutz v. Chromatex, Inc., 718 F.Supp. 413, 428 (M.D. Pa. 1989)). *See also Schwartzman*, 857 F. Supp. 838.

[94] 422 U.S. 66 (1975).

> so that it would be inappropriate to infer cause of action based solely on state law.[95]

After reciting this four-part test, the *Rodriguez* court made two important observations. First, it noted that when considering whether to imply a private right of action for damages under environmental and public health legislation, courts tend to focus on the first and second elements of the *Cort* test.[96] Second, the court noted that other courts also tend to find that when statutes are enacted with the broad purpose of protecting the public, the requisite legislative intent is usually considered lacking with regard to a private right of action for damages.[97] The court then reviewed several Ninth Circuit decisions that held that FIFRA did not provide a private right of action, and subsequently held the same in this case.[98]

The court also reviewed the district court's decision in *Welch v. Schneider Nat'l Bulk Carriers*, which construes § 1263(a) of the Federal Hazardous Substances Labeling Act and a companion state statute dealing with the labeling of hazardous substances.[99] In *Welch* the court rejected the negligence per se claim of the plaintiff, a professional sewer cleaner, for his chemically-induced injuries.[100] The court found that the statutes were intended to require adequate warnings for household substances and not for compounds involved in municipal and industrial use. Therefore,

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[95] *Rodriguez*, 858 F. Supp. at 129-30, (citing *Cort*, 422 U.S. at 78).

[96] *Id.* at 130 (citing Gammill v. United States, 727 F.2d 950 (10th Cir. 1984) and Welch v. Schneider Nat'l Bulk Carriers, 676 F. Supp. 571 (D. N.J. 1987)).

[97] *Rodriguez*, 858 F. Supp. at 130.

[98] *Id.* at 130-31, (citing Fiedler v. Clark, 714 F.2d 77 (9th Cir. 1983); Almond Hill Sch. v. United States Dep't of Agric., 768 F.2d 1030 (9th Cir. 1985); *In re* Agent Orange Product Liab. Litig., 635 F.2d 987 (2d Cir. 1980)). *See also* Miller v. E.I. DuPont de Nemours and Co., 811 F. Supp. 1286 (E.D. Tenn. 1992). For other cases using a similar analysis to explicitly hold that certain environmental and public health statutes and regulations do not create a private right of action *see, e.g.*, Satterfield v. J.M. Huber Corp., 888 F. Supp. 1567, 1571 (N.D. Ga. 1995) (federal and Georgia Clean Air Acts do not provide for an action for private recovery); 325-343 E. 56th St. Corp. v. Mobile Oil Corp., 906 F. Supp. 669, 688 (D.D.C. 1995) (Resource Conservation and Recovery Act (40 C.F.R. 280) and the District of Columbia Underground Storage Tank Act (D.C. UST)); Fallowfield Development Corp. v. Strunk, Nos.Civ.A.89-8644, 90-4431, 1991 WL 17793 (E.D. Pa. 1991) (Pennsylvania's Hazardous Sites Cleanup Act and Solid Waste Disposal Act); *Schwartzman*, 857 F. Supp. 838 (New Mexico Hazardous Waste Act and Water Quality Act); *German*, 885 F. Supp. at 566 (dismissing negligence per se claim based upon violation of New York City Administrative Codes regarding lead paint because the regulations were not intended to support an implied claim).

[99] 676 F. Supp. 571 (D. N.J. 1987).

[100] *Id.*

the court held that the plaintiff could not recover because he was not in the class protected by the statute.

It is important to note that bringing a tort claim under a theory of negligence per se will not enable one to avoid the issue of proximate cause. Simply stated, even if negligence is charged in violation of a statute constituting negligence per se, liability does not attach without a causal connection between the negligence and the injury.[101]

Plaintiffs should also be aware that citing a violation of federal statutes as a negligence per se claim may invite unwanted removals by defendants seeking to take the action out of state court. While the cases seem to hold that such removals are inappropriate when premised solely on negligence per se claims alleging violations of a federal statute in which the plaintiff could not recover damages under the statute, much time will be lost in moving for a remand.[102]

Defendants need to be aware of how the forum in which they are construes § 1446(b) of Title 28 of the United States Code with regard to when the 30-day removal period begins to run once a plaintiff seeks leave to amend the complaint by adding a negligence per se claim alleging federal statutory violations. Under the minority view, which purports to apply the clear language of the statute, the 30-day removal period commences when the defendants first receive the motion to amend stating a theory based on federal law.[103] The majority, on the other hand, holds that the 30-day removal period begins to run only after the motion to amend has been granted and the amended complaint has been served.[104] Defendants should be aware of the forum's view to avoid inadvertently waiving the right to remove.

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[101] *See, e.g.*, Steagall v. Dot Mfg. Corp., 446 S.W.2d 515, 518 (Tenn. 1969) (construing Tennessee law and the Federal Hazardous Substances Labeling Act). *See also* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 36, at 220 (5th ed. 1984).

[102] *See,e.g*, Mulcahey v. Columbia Organic Chems. Co., Inc., 29 F.3d 148, 152 (4th Cir. 1994) (holding that since the negligence per se claims under federal environmental statutes are only one of plaintiffs' numerous theories of recovery, the federal issue raised is not substantial). *Accord* Polcha v. AT & T Nassau Metals Corp., 837 F. Supp. 94 (M.D. Pa 1993).

[103] *See, e.g.*, Webster v. Sunnyside Corp., 836 F. Supp. 629, 630 (S.D. Iowa 1993); Harriman v. Liberian Maritime Corp., 204 F. Supp. 205, 206-07 (D. Mass. 1962).

[104] *See, e.g.*, Graphic Scanning Corp. v. Yampol, 677 F. Supp. 256, 258-59 (D. Del. 1988) (grounds for removal must first be "clearly established"); Schoonover v. West Am. Ins. Co., 665 F. Supp. 511, 514 (S.D. Miss. 1987) (an unrecorded proceeding cannot start the running of the time for removal); Lesher v. Andreozzi, 647 F. Supp. 920, 922 (M.D. Pa. 1986) (a formal order of dismissal is not a prerequisite to removal); Miller v. Stauffer Chem. Co., 527 F. Supp. 775, 777 (D. Kan. 1981) (date of service of amended pleading should control).

V. Preemption

The doctrine of federal preemption, stating that federal law displaces state law,[105] is related to the issues involving government standards and negligence per se. "Tort reformers," particularly the chemical, tobacco, manufacturing, and insurance industries, have used this doctrine as a successful means of utilizing governmental regulations as a shield to avoid tort liability.[106] In the past few years, some courts have held that language in certain federal statutes, which prevents states from imposing "requirements" different from those contained in the federal statute, prevents the imposition of state common law tort liability since the state requirement differs from the requirement under the federal statute.[107] Common law remedies have been weakened, and in some cases removed, for classes of victims of products such as pesticides, hazardous chemicals, and medical devices.[108] Further, until the United States Supreme Court's recent pronouncement in *Medtronic, Inc. v. Lohr*,[109] it had appeared that many individuals injured by medical devices such as heart valves, which have potentially lethal ramifications if the devices fail, had lost the right to sue in common law tort. In addition to limiting victims' rights, preemption diminishes the deterrent effect of tort liability in the manufacture and sale of products.[110]

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[105] For a detailed analysis of federal preemption, see Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895 (1994); Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 S.C. L. REV. 187 (1993); Beverly L. Jacklin, Annotation, *Federal Pre-emption of State Common-Law Products Liability Claims Pertaining to Drugs, Medical Devices and Other Health-Related Items*, 98 A.L.R. FED. 124 (1996).

[106] *See* Jane Fritsch, *Sometimes Lobbyists Strive to Keep Public in the Dark*, N.Y. TIMES ABSTRACTS, Mar. 19, 1996, at A1, A20, *available in* 1996 WL 7497128. For a scholarly analysis of the "tort reform," "junk science" crusade, see Kenneth J. Chesebro, *Galileo's Retort: Peter Huber's Junk Scholarship*, 42 AM. U. L. REV. 1637 (1993). *See also* George W. Conk, *Legend vs. Pragmatism*, 2 B.U. J. SCI. & TECH. L. 9 (1996).

[107] *See* Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 906-25 (1996).

[108] *Id.* at 926-28.

[109] 116 S. Ct. 2240 (1996).

[110] One scholar has noted:

> When courts rush to find preemption they also ignore fundamental deterrence dynamics, including the place of compensation in the overall legal scheme. Deterrence and compensation are often treated as separable for analytic purposes, but this does not mean that they can easily be separated in practice. In the tort scheme, compensation acts as the fine or tax that enforces the deterrence signal. Compensation attempts to reflect actual social costs, and thus is a basic part of the market's legal infrastructure. Regulation is not designed to provide or account for compensation; usually regulators

The doctrine of federal preemption emerges from the Supremacy Clause of the United States Constitution which states that the laws of the United States shall be the "supreme Law of the Land."[111] The respect for federalism and the desire to avoid "unintended encroachment on the authority of the States"[112] have caused courts in the past to be extremely reluctant to find that federal law preempts state law, unless it is "the clear and manifest purpose of Congress." [113]

In the case of *Silkwood v. Kerr-McGee Corporation*,[114] a nascent discussion of the concept of compliance with governmental standards as a defense evolved into a full-blown preemption analysis by the time the case was heard on appeal to the United States Supreme Court. The defendant argued that compliance with governmental regulations at a plutonium facility was "conclusive evidence of non-negligent conduct."[115] The trial court rejected that argument holding:

> Had this Court instructed the jury that substantial compliance with governmental regulations would bar an award of actual damages in the area of nuclear power, the Court would have paved a new road

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> intend neither to account for it nor to prevent it. If identifying an appropriate cost-benefit allocation were the only legal function with respect to technologies, then we could invoke preemption and dismiss tort claims with apologies to the plaintiffs, the unfortunates who bear the harms imposed by an otherwise acceptable risk-benefit allocation. But if compensation is a part of the deterrence function, then we cannot preempt tort claims without replacing that enforcement mechanism. In this light, tort plaintiffs are proxies for all members of society.

Lyndon, *supra* note 26, at 172.

Critics of tort law espouse the notion that tort liability is unnecessary and counterproductive when an administrative agency has performed a cost-benefit assessment of a regulated product or technology, claiming that these specialized agencies are better equipped than a judge and jury to assess the safety of a technology. *See, e.g.*, Susan Rose-Ackerman, *Tort Law in the Regulatory State*, in TORT LAW AND THE PUBLIC INTEREST 80 (Peter Schuck ed., 1991). It is the fiction that administrative agencies ensure product safety that is used as a justification for preemption. For a comprehensive analysis, see Lyndon, *supra* note 26. Professor Lyndon analyzes the marked limitations of regulatory agencies in assuring safety of technologies. *Id.*

A recent commentator, critical of broad preemption, has advocated that courts reconsider the possibility of finding implied private rights of action in statutes with preemption provisions, or, in the alternative, apply *Cipollone* as a federal common law rule accepting the government standards defense rather than as a true preemption defense. Lars Noah, *supra* note 103, at 906, 976-77.

[111] U.S. CONST. art. VI.

[112] CSX Transp. v. Easterwood, 507 U.S. 658, 664 (1993).

[113] Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

[114] 485 F. Supp. 566 (W.D. Okla. 1979), *rev'd on other grounds*, 667 F.2d 908 (10th Cir. 1981), *rev'd*, 464 U.S. 238 (1984), 769 F.2d 1451 (10th Cir. 1980), *cert. denied* 476 U.S. 1104 (1986).

[115] *Id.* at 577.

> in jurisprudence that heretofore has not existed in any other comparable area of the law. Liability for operators and manufacturers of aircraft represents a situation analogous to that in the instant case. The federal government has occupied the field of regulating aircraft, and no aircraft may fly in this country without a federal certification of its airworthiness. . . . It is commonly the rule in the field of aviation law that a defendant's complete compliance with governmental safety regulations is only some evidence of the defendant's exercise of reasonable care, but is not conclusive. Evidence of compliance is therefore admissible for consideration by the jury, but it does not bind the jury to find that a defendant's conduct was reasonable under the circumstances.[116]

On appeal, a split panel of the Court of Appeals adopted a broad preemption analysis with regard to the punitive damages award, holding that "any state action that competes substantially with the [Atomic Energy Commission (Nuclear Regulatory Commission)] in its regulation of radiation hazards associated with plants handling nuclear material" was not permissible.[117] Thus, the circuit court overruled the punitive damages verdict on a preemption basis.

The Supreme Court, however, overruled the Tenth Circuit's holding, finding the award of punitive damages was not preempted by federal law.[118] The Court relied in part on a legislative history analysis, concluding that Congress did not intend to provide tort remedies by the states for those suffering nuclear related injuries.[119] Since there was no evidence of legislative intent to preempt state remedies, the Court held, "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."[120]

A more recent Supreme Court decision, however, has resulted in a proliferation of federal preemption litigation. In *Cipollone v. Liggett Group, Inc.*,[121] the Court held that although certain state law damage claims were not preempted, tort claims related to the failure to warn were expressly preempted by the warning labels required on cigarette packages

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[116] *Id.* at 577-78 (citations omitted).
[117] *Silkwood*, 667 F.2d at 923.
[118] *Silkwood*, 464 U.S. at 248-58.
[119] *Id.* at 251.
[120] *Id.* (citing Constr. Workers v. Laburnum Corp., 347 U.S. 656, 663-64 (1954)).
[121] 505 U.S. 504 (1992).

pursuant to the Public Health Cigarette Smoking Act of 1969. [122] Prior to *Cipollone* the majority of courts held that compliance with a federal safety statute or regulation constituted some evidence of due care, but was not conclusive.[123] The pre-*Cipollone* cases often stated that compliance was admissible evidence that shifted the burden to the plaintiff to prove that the reliance upon the standard was not due care under the circumstances, but it was generally regarded as a minimum standard of care. Despite compliance, the defendant could still be liable for failure to take further precautions. [124]

The Supreme Court's holding of partial express preemption in *Cipollone* prompted a surge of preemption defense motions, particularly in the medical device contexts due to a strained interpretation of ambiguous language in the 1976 Medical Device Amendments (MDA) to the Federal Food, Drug and Cosmetic Act.[125] Until the *Medtronic* decision, many defendants prevailed in claiming that, as a result of regulations embodied in the MDA,[126] medical device manufacturers are immune from tort liability for certain categories of medical devices.[127]

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[122] *Id.* at 525-27. The language interpreted by the court to preempt the failure to warn claims is as follows: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." 15 U.S.C. § 1334(b) (1994).

[123] *See* NORTHSTEIN, *supra* note 85, at 223. *See also* Adler & Mann, *supra* note 101, at 904; LaGorga v. Kroger Co., 275 F. Supp. 373, 378 (W.D. Pa. 1967), *aff'd*, 407 F.2d 671 (3d Cir. 1969); Burch v. Amsterdam Corp., 366 A.2d 1079, 1085-86 (D.C. Cir. 1976).

[124] NORTHSTEIN, *supra* note 85, at 223. *See also* Clarence Morris, *The Role of Administrative Safety Measures in Negligence Actions*, 28 TEX. L. REV. 143, 159-60 (1949).

[125] Federal Food, Drug and Cosmetic Act, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C.).

[126] The controversial language with alleged preemptive effect that does not mention tort law provides:

> (a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (1994).

[127] The MDA categorizes devices in three groups based upon available information, their capacity to cause potential injury and the controls available to provide safety, effectiveness and their medical utility. 21 U.S.C. § 360c(a)(1) (1994). Class I devices posing little or no health threat are subject to only general controls. 21 U.S.C. § 360c(a)(1)(A). Class II devices, posing a slightly greater health risk, require postmarket surveillance, patient registries and performance standards in certain circumstances. 21 U.S.C. § 360c(a)(1)(B). Class III medical devices present a serious risk of injury and are therefore required to go through a "thorough" premarket

The classifications of medical devices are based upon the review required by the FDA to be performed prior to a device receiving pre-market approval (PMA) by the FDA. The classification was a factor in the preemption analysis performed by courts prior to the *Medtronic* decision. Classes I through III were subject to varying levels of scrutiny by the FDA, and some courts were finding that Class III devices, subject to the most thorough regulatory review, were subject to sufficiently specific federal regulations to warrant preemption. Other courts found the less rigorous Class II review also warranted preemption. Additionally, there were two exceptions to the MDA which permitted a device to be exempted from PMA approval — if the device was on the market prior to the 1976 effective date of the MDA, or, if the device was "substantially equivalent" (known as 510K) devices to pre-MDA devices. Prior to June 1996, all but one federal appellate court found that the MDA preempted certain common law actions.[128] The Ninth Circuit found that the MDA did not preempt any state common law causes of actions.[129]

In the medical device context, this trend has concluded as a result of the United States Supreme Court's decision in *Medtronic*. The Court held that the MDA does not bar state tort claims against the manufacturer of a cardiac pacemaker because the labelling, manufacturing and other requirements imposed by the Food and Drug Administration (FDA) were not sufficiently rigorous or specific to the particular device to warrant federal preemption. The pacemaker was a 510(k) device that gained FDA approval through the "substantial equivalence" route. The Court was unanimous in holding that design-defect claims concerning 510(k) devices are not preempted. However, the decision by Justice Stevens was the opinion of the Court only as to certain parts (I, II, III, V and VII). Three other Justices joined the complete opinion, while Justice Breyer concurred in the judgment in full and joined in Parts I, II, III, V and VII. The other four Justices concurred and dissented in part in an opinion by Justice O'Connor. Justice Stevens believed that there should be no preemption

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approval before being allowed on the market. 21 U.S.C. § 360c(a)(1)(C). The majority of preemption cases have pertained to Class III devices, although some courts had begun to expand the analysis to Class II devices.

[128] Michael v. Shiley, Inc., 46 F.3d 1316, 1323 (3d Cir. 1995); Martello v. Ciba Vision Corp., 42 F.3d 1167, 1168 (8th Cir. 1994); Nat'l Bank of Commerce of El Dorado v. Kimberly-Clark Corp., 38 F.3d 988, 990-91 (8th Cir. 1994); Gile v. Optical Radiation Corp., 22 F.3d 540, 542-43 (3d Cir. 1994); Duncan v. Iolab Corp., 12 F.3d 194, 195 (11th Cir. 1994); Stamps v. Collagen Corp., 984 F.2d 1416, 1420-21 (5th Cir. 1993); Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 49-50 (D. Mass. 1994); Slater v. Optical Radiation Corp., 756 F. Supp. 370, 373 (N.D. Ill. 1991); Covey v. Surgidev Corp., 815 F. Supp. 1089, 1094-95 (M.D. Pa. 1992).

[129] Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995).

of medical device tort claims, but the dissenters stated that federal law does preempt many medical device tort claims on the grounds that the term "requirement" in § 360k(a) of the MDA preempts any state common law claim if it imposes any requirement which is different from or in addition to any requirement applicable under the statute and its regulations. Justice Breyer, as the swing vote, wrote that some claims involving certain devices remain preempted. Therefore, preemption still will be raised in a variety of medical device claim situations including those where the devices were subject to full pre-market approval, labelling requirements, and in cases where devices were marketed through an investigational, device exemption.

Since *Medtronic*, several courts have rejected preemption arguments in other medical device contexts.[130] Certainly, the Court's analysis in *Medtronic* will be raised in other preemption cases and the outcome will be dependent largely upon the similarity of the MDA and the other statutory language being construed.

Preemption has also been successfully argued by pesticide manufacturers in toxic tort cases. Courts frequently have held that claims for failure of manufacturers to warn of the dangers of pesticides are preempted by EPA mandated warnings pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),[131] which provides that "[a] State shall not impose or continue in effect any requirement for labelling or packaging in addition to or different from those required under this subchapter."[132]

Subsequent to *Cipollone*, defendants litigating product liability actions involving products regulated by the Federal Hazardous Substances Act (FHSA)[133] have also argued that the regulatory scheme embodied in the

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[130] Connelly v. Iolab Corp., 927 S.W.2d 848 (1996) (reversing a decision granting summary judgment and holding that claims against the manufacturer for negligence, strict liability failure to warn and failure to obtain informed consent and fraud were preempted by the MDA); Kernats v. Smith Indus. Med. Sys., Inc., 669 N.E.2d 1300 (1996) (reversing a preemption decision that dismissed claims against the manufacturer of chorionic villus catheters, devices used early in pregnancy for insertion into the cervix of pregnant women for prenatal diagnosis); Walker v. Johnson & Johnson Vision Prod., Inc., 552 N.W.2d 679 (1996) (reversing a summary judgment decision dismissing a case against the contact lens manufacturer holding that Congress did not intend to preempt plaintiff's claims of negligent design and manufacture, negligent failure to warn, and breach of implied warranty).

[131] 7 U.S.C. §§ 136-136y (1994).

[132] 7 U.S.C. § 13v(b) (Supp. V 1993). Quite a few courts have interpreted the *Cipollone* construction of the cigarette labelling requirement to provide that the pesticide labelling requirements must likewise preempt liability claims based upon failure to warn for pesticide injuries. *See* MacDonald v. Monsanto Co., 27 F.3d 1021 (5th Cir. 1994); King v. E.I. DuPont de Nemours & Co., 996 F.2d 1346 (1st Cir. 1993); Pappas v. Upjohn Co., 985 F.2d 516 (11th Cir. 1993).

[133] 15 U.S.C. § 1261 (1994).

FHSA preempts common law suits. Prior to *Cipollone*, one court held that compliance with FHSA served as a rebuttable presumption that the product was not defective,[134] but such a presumption is distinct from actual preemption. Since *Cipollone*, preemption has been found in some cases.[135] There is one line of preemption cases, interpreting a provision of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly referred to as Superfund.[136] The provision expressly preempts state statute of limitations for claims for damage caused by hazardous waste. The limitations period begins to run no earlier than the date on which the plaintiff should have discovered the injury and its cause, which is a standard more liberal than many states' statute of limitations.[137] Although this argument has not been as successful as the preemption defenses raised in the MDA and FIFRA contexts, it is an issue of which future litigants should be aware.

VI. Administrative Estoppel

Plaintiffs may use the doctrine of administrative estoppel in bringing toxic tort claims. The traditional collateral estoppel doctrine provides that when an issue of ultimate fact has been determined by a valid judgment, that issue cannot be relitigated between the same parties in future litigation. The concept of "administrative estoppel" or "regulatory estoppel" is based on the idea that a party should be estopped from denying something in a tort case which it previously admitted in an administrative proceeding. For example, if a company previously conceded in an enforcement action brought by a state agency that it was responsible for disposal of a chemical at a particular site and signed a consent order to remediate the problem, the same company should not be able to deny

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[134] Hickman v. Thomas C. Thompson Co., 664 F. Supp. 1531, 1535 (D. Colo. 1986). *But see* Lee v. Boyle-Midway Household Prod., Inc., 792 F. Supp. 1001, 1008 (W.D. Pa. 1992), a pre-*Cipollone* case holding that FHSA impliedly preempts certain common law tort claims.

[135] Moss v. Parks Corp., 985 F.2d 736, 741 (4th Cir. 1993) (paint thinner); Lee v. Boyle-Midway Household Prod., Inc., 792 F. Supp. 1001, 1007-09 (W.D. Pa. 1992) (dry cleaner); State *ex rel.* Jones Chem., Inc. v. Seier, 871 S.W.2d 611 (Mo. Ct. App. 1994) (hydrochloric acid).

[136] 42 U.S.C. § 9658(a)(1) provides that "[i]n the case of any action brought under State law for personal injury or property damages, which are caused or contributed to by exposure to any hazardous substance, or pollutant or contaminant, released into the environment from a facility, if the applicable limitations period for such action (as specified in the State statute of limitations or under common law) provides a commencement date which is earlier than the federally required commencement date in lieu of the date specified in such state statute." 42 U.S.C. § 9658(a)(1).

[137] Kowalski v. Goodyear Tire and Rubber Co., 841 F. Supp. 104 (W.D. N.Y. 1994); Angeles Chemical Co. v. Spencer & Jones, 51 Cal. Rptr. 2d 594 (Cal. Ct. App. 1996).

responsibility for the waste in a subsequent tort action. Administrative estoppel disallows plaintiffs from denying what they had previously admitted.

However, in the typical consent decree scenario "admissions" are made with all sorts of qualifications and "non-admissions," which preclude use of the consent decree in a subsequent litigation. Therefore, the issue of administrative estoppel rarely arises. However, where a defendant neglects to take these precautions, the question of whether the prior admission should be admissible in a subsequent tort suit arises. Another question involves a situation where a defendant does not enter into a consent order, but instead litigates responsibility in the administrative arena and is found responsible. There is even more support to use administrative estoppel, but even here there are potentially persuasive arguments on each side of the issue.

Questions of administrative estoppel have been litigated primarily in the area of insurance coverage. The law that does exist on the issue has ironically been made by toxic tort defendants seeking to prevent their insurers from denying pollution coverage. In the process of seeking approval for language regarding pollution coverage in particular policies, insurance carriers represented to State Commissioners of Insurance that the policy language was intended to have a less onerous impact on policy holders.[138]

Claimants are attempting to use these representations to prevent carriers from denying coverage. In cases where the pollution language of a policy could conceivably lead to the denial of coverage, claimants have argued that the insurers are estopped from denying pollution coverage on the basis of representations made to state insurance regulatory boards in setting rates and policy language. In one notable case, the Georgia district court held that contemporaneous representations of insurance industry intent in adopting "sudden and accidental pollution exclusion" language was consistent with the intent of the insurers to exclude only intentional polluters.[139]

The Delaware Supreme Court recently remanded a pollution insurance coverage case to the trial court due to arguments of regulatory estoppel. The court was reviewing interpretations of the pollution exclusion clauses in various umbrella and excess policies that had been issued to E.I. du Pont de Nemours & Co. At the trial level DuPont's arguments that the

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[138] Claussen v. Aetna Cas. & Sur. Co., 676 F. Supp. 1571, 1583 (S.D. Ga. 1987). *See also* Morton Int'l v. General Accident Ins. Co. of Am., 629 A.2d 831 (N.J. 1993).

[139] *Claussen*, 676 F. Supp. at 1571.

insurers should be estopped from arguing that "sudden" means "abrupt" based upon representations made by the insurance industry to state regulators were not found persuasive. The court instead was persuaded by an *amicus curiae* brief in support of the policyholders filed by the State of Delaware; therefore, the court remanded the case so the court might consider "regulatory estoppel," in light of the position taken by the State of Delaware.[140] Since then the trial court further explored the regulatory estoppel issue, but ultimately found an insufficient factual basis for regulatory estoppel.

In light of this recent ruling, one may see regulatory estoppel applied in contexts beyond insurance coverage disputes.

VII. Conclusion

Government regulations and findings can have a major impact on toxic tort litigation. However, these regulations are not always determinative. Litigants should understand the context in which the various standards and reports were formulated and any particular constraints that may apply to them. Once the regulations and findings are properly understood, they can be effectively utilized or opposed depending on the particular factual and legal circumstances at hand. The function of administrative agencies is distinct from the function of tort liability. This distinction must be recognized to prevent the misuse of governmental regulations as standard proof of safety and to prevent preemption of common law liability.

[140] E.I. du Pont de Nemours & Co. v. Allstate Ins. Co., 10 MEALEY'S LITIG. REP. C-1 (Del. Sept. 5, 1996).