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Science and EPA Decision-Making

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INTRODUCTION

Two sets of experiences have shaped my perspective on the role of science at EPA. First, I have been a practicing lawyer in the trenches, representing clients before EPA for twenty-five plus years. Second, I was a senior policymaker at EPA, serving as the Deputy Administrator, the number two official in the agency, during the Clinton Administration. In this capacity, I was at the top of the organization trying to understand how all the pieces fit together and mediating between the many constituencies who care about what EPA does.

Based on these diverse experiences, I will provide a context on EPA as an institution—how EPA was formed, how it grew, and how the political climate in which EPA operates has changed over time. Then I will focus on the many different types of decisions that EPA makes that are science-based and the factors that shape those decisions. Because those factors are complex, they are not uniform across the agency or even within specific statutes. It is very important to understand the complexity of the decision-making framework that EPA implements. Finally, I will discuss the intense debate that has occurred and is continuing about the quality and credibility of EPA science. This debate has been underway since the inception of the agency but has been particularly emotional and polarized over the last ten years.

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Mike Friedman commented that FDA has a highly professional, dedicated, and unbiased cadre of scientists and that by and large FDA's scientific decisions have a high degree of legitimacy.[1] This is not the common perception of EPA and its scientists, who are typically challenged and attacked on all sides.[2] I submit, however, that many of the criticisms of EPA science are really criticisms of the policy judgments that EPA makes, often in response to the direction it has received from Congress.

I. THE HISTORICAL CONTEXT

EPA is now thirty-three years old. President Nixon presided over the creation of the Agency in 1970.[3] Thirty-three years, of course, is a very long time in the life of an institution. Many of us forget that in 1970 there was a flush of public enthusiasm for environmental protection. Earth Day 1970 was one of the great populist events in postwar America. It brought out hundreds of thousands of people to celebrate the environment and call for its protection. It was in that heady atmosphere that EPA was born.[4] Early on EPA addressed some environmental needs that all of us would agree were obvious. For example, EPA required tail pipe emission controls on automobiles.[5] It is remarkable, but before 1970 automobile emissions were unregulated, a situation which, by today's standards, would be unthinkable. To give another example, discharges of sewage and pollutants into the nation's streams and waters by industry and municipalities were largely unregulated as well. Again, such a situation is unfathomable today because treatment of sewage and industrial wastes is viewed as the

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[1] *See* Michael A. Friedman, M.D., *What Is the Value of an FDA Approval in a Judicial Matter?*, 12 J.L. & POL'Y 559 (2004).

[2] Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals and the Like- Should Federal Agencies Use Them To Bind the Public?*, 41 DUKE L. J. 1311 (1992).

[3] Jack Lewis, *The Birth of the EPA*, EPA J. (Nov. 1985) [hereinafter *The Birth of the EPA*], *available at* http://www.epa.gov/history/topics/epa/15c.htm (last visited Mar. 11, 2004).

[4] *Id*.

[5] *Id*.

hallmark of a civilized, advanced society.

In its early days, the public benefits of EPA's actions were tangible and immediate and were widely recognized and appreciated.[6] This strong public support continued during the twenty years after EPA's creation, when the agency experienced a period of remarkable institutional growth and expanding jurisdiction driven by virtually non-stop legislative activity. During this period, Congress passed and asked EPA to implement a large array of statutes such as the Toxic Substances Control Act[7], which regulates the safety of industrial chemicals, the Superfund law or CERCLA[8], which provides for the clean-up of contaminated sites, and the Community-Right-To-Know Law or EPCRA[9], which authorizes the reporting of toxic emissions by industrial facilities and the development of a national emergency response management system.

Congress gave EPA these new mandates in reaction to perceived environmental catastrophes that were well publicized and dominated the front page news. For example, concern about PCBs, persistent, toxic, ubiquitous chemicals, almost single-handedly accounted for the enactment of the Toxic Substances Control Act.[10] DDT, made infamous by Rachel Carson in *Silent Spring*, was the major motivator of the laws that govern pesticides in this country.[11] Love Canal, near Niagara Falls, became the poster-child for contaminated industrial properties and gave birth to the Superfund statute.[12] And the catastrophic release of methyl isocyanate at the Union Carbide facility at Bhopal, India, which

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[6] *The Birth of the EPA*, *supra* note 3.

[7] 15 U.S.C. §§ 2601-92 (2000).

[8] 42 U.S.C. §§ 9601-74 (2001).

[9] 42 U.S.C. §§ 11001-50 (2000).

[10] *See* 15 U.S.C. §§ 2601-92. *See also* Pep Fuller & Thomas O. McGarity, *Beyond the Dirty Dozen: The Bush Administration's Cautious Approach to Listing new Persistent Organic Pollutants and the Future of the Stockholm Convention*, 29 WM. & MARY ENVTL. L. & POL'Y REV. 1, 2 (2003).

[11] RACHEL CARSON, SILENT SPRING (1962).

[12] J. Richard Shotts, Morrison Enterprises v. McShares, Inc.*: Innocent PRPS and Section 107 Claims in the Tenth Circuit*, 52 U. KAN. L. REV. 491, 491-92 (2004); 42 U.S.C. §§ 9601-74 (2001).

killed hundreds of people, led to the creation of a community right-to-know and emergency response system in this country.[13]

One result of the crisis mentality that defined Congress's approach to environmental issues is that there is very little consistency across statutes. Each statute is tailored to the immediate environmental problem at hand, often without any regard to how that environmental problem relates to other environmental problems and other programs that EPA implements. In contrast to the Federal Food, Drug and Cosmetic Act, which is the organic statute that guides FDA, there is no organic statute within which EPA operates.[14] Instead, EPA is subject to numerous free-standing, crisis-driven statutes passed at different times and for different reasons. These statutes are highly detailed and prescriptive. They do not give EPA much discretion to set priorities, to rank environmental problems, or to decide what is important and what is not. Congress in its wisdom has made those decisions in the statutes themselves.

II. AN AGENCY UNDER SIEGE

Since 1990, EPA's world has changed dramatically. From an agency which was on the receiving end of increased resources, new statutory mandates, and new problems to address, EPA has turned into an agency under siege. The frenetic pace of legislative activity on the environment has come virtually to a standstill. There is now polarization of opinion about environmental policy and therefore basic disagreement about EPA's mission and performance. For example, there is no consensus about whether EPA does too much or too little. One can find violently held views on both sides of that question.[15] Nor is there a consensus on

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[13] John D. Echeverria & Julie B. Kaplan, *Poisonous Procedural "Reform": In Defense of Environmental Right-To-Know*, 12 KAN. J.L. & PUB. POL'Y 579, 583 (2003); 42 U.S.C. §§ 11001-50 (2000).

[14] 12 U.S.C. §§ 301-397 (2001).

[15] Alan Charles Raul & Julie Zampa Dwyer, *"Regulatory Daubert": A Proposal To Enhance Judicial Review of Agency Science By Incorporating Daubert Principles Into Administrative Law*, 66 LAW & CONTEMP. PROBS. 7, 9-11 (2003).

whether EPA is an honest broker serving the public interest as opposed to the handmaiden of special interests. Finally, there is major debate about whether EPA's decisions are driven by science or politics.[16] Although EPA science has its defenders, there are many cynics who believe that science has very little to do with what EPA does and that politics explains most of EPA's actions.

As you might expect, one trend that has resulted from this absence of consensus is the increasing role of litigation as an environmental policy tool.[17] Very few EPA actions are not challenged in the courts. And litigation is used by everybody. It is used by environmental activists who feel EPA has dropped the ball and has not done enough to address a problem. It is used by members of industry who feel that EPA has done too much or that its regulations are excessive or unreasonable. In effect, all the constituencies who disagree about EPA's role and mission routinely bring those disagreements to the courts.

Because we are no longer addressing visible environmental problems, the public benefits derived from EPA actions are less obvious and more difficult to measure than they were in 1970. For this reason, it is easier to disagree about whether we are getting value for our money from EPA. Some people would say that environmental problems that are not obvious, like global warming, are enormously important and will affect the future of the planet. Others will argue that concerns about global warming or the impact of chemicals on children's health are based on fear-mongering or sensationalism and have no basis in fact. Because key constituencies often disagree violently about whether many environmental problems are real and should be addressed by government, numerous EPA decisions are bitterly debated.

III. KEY EPA DECISIONS BASED ON SCIENCE

This section provides concrete examples of the science-based public health decisions that EPA makes. This list will illustrate that EPA has enormous influence on many different sectors of our

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[16] *Id.*

[17] Anthony, *supra* note 2.

society, including industries, state and local governments, and individual citizens. EPA sets allowable ambient levels for our major air pollutants, which include ozone and particulate matter.[19] It regulates the releases of toxic chemicals from industrial facilities of all types, sets emission standards for cars and trucks, determines permissible levels of contaminants in drinking water, and sets health-based cleanup standards for contaminated sites.[20] EPA implements a regulatory regime that determines what active ingredients can be used in pesticides, how those pesticides can be applied, and what sort of labeling those pesticides need to have.[21] EPA reviews all new chemicals before they are introduced into commerce. And finally, EPA sets safe exposure levels for widely known and distributed environmental toxins like lead, asbestos, and radon in homes and schools.[22]

Even though all of these decisions are focused on public health and have a scientific component, the factors that govern them can vary dramatically. The statutes assign different weights to a number of key decision criteria. Cost is a good example. Is cost important in setting environmental standards, or is it immaterial? Another example is the significance of the risk. Is the risk remote or widespread or severe? Are these relevant or immaterial factors? Yet another example is scientific uncertainty. What if we have imperfect information about the chemicals and activities we are regulating? Do we err on the side of caution and impose restrictions in the face of uncertainty or do we wait for better scientific information? What about cost/benefit tradeoffs? How important is it that a hazardous industrial chemical plays a critical role in producing socially useful products? Should the chemical's utility be weighed against its risks or is that immaterial? And finally, what weight do we assign to the cost and availability of cleanup technology? Is that a factor that should determine the

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[19] *See* Clean Air Act, 42 U.S.C. §§ 7401-50 (1970).

[20] S*ee The Birth of the EPA*, *supra* note 3.

[21] *See* Envtl. Prot. Agency, Pesticides: Regulating Pesticides, EPA Website, *available at* http://www.epa.gov/pesticidies/regulating/laws.htm#fifra (last visited Mar. 11, 2004).

[22] *See* Toxic Substances Control Act, 15 U.S.C. §§ 2601-92 (2000).

levels of protection that EPA mandates, or should EPA set stringent standards that are technology-forcing and push industry to develop new pollution control techniques?

IV. MAJOR REGULATORY PARADIGMS

Looking across the major EPA statutes, there are four types of regulatory paradigms, each of which requires EPA to look at different decisional factors when using science to protect public health.

One is what I would call the *zero risk* paradigm, under which EPA seeks to provide assurance that there is no level of risk to which the population is exposed. This is the paradigm that is used to set ambient air quality standards under the Clean Air Act.[23] The statute directs that EPA must protect public health with an ample margin of safety, and that means that the Agency must provide absolute protection and even account for possible unknown or uncertain risks.[24]

On the other hand, some statutes allow EPA to set standards that eliminate significant risks but accept insignificant risks. For example, at contaminated sites we do not try to get all of the contaminants out of the ground water or the soil. Instead, we try to reduce the presence of those contaminants to some public health level which we deem insignificant and permit some residual level of risk.

The third paradigm is cost/benefit analysis. Here, EPA looks at the risks, determining how large and severe they are and what level of certainty surrounds the science, and then examines the economic and social impacts of addressing the risks. This is the paradigm that EPA uses for industrial chemicals and pesticides. Interestingly, it bears some resemblance to the approach FDA applies to pharmaceuticals and medical devices.

The final paradigm involves risk only to a very limited extent and instead allows technological achievability and cost to drive limits on exposure and release. This is the approach EPA follows

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[23] 42 U.S.C. §§ 7401-50 (2001).

[24] *Id.*

for industrial emissions of toxins, which have to be controlled using maximum available control technology. EPA uses the same approach to control new air pollution sources and regulate discharges of toxic pollutants into waters and streams.

V. THE QUALITY AND CREDIBILITY OF EPA SCIENCE

A. Safeguards to protect the Quality of EPA Scientific Analysis

In examining the credibility of EPA science, one must understand the safeguards that EPA uses to police the quality of its science. Many people do not realize that these safeguards are there, or they do not believe that they work very well. But they are in fact part of a well-established framework for applying science in the EPA decision-making process.

First, EPA follows the principle that risk assessment and risk management are separate activities that should be conducted by separate parts of the agency and insulated from each other. The concept here is that the experts should interpret the science in a policy vacuum, and then the science should be handed over to the policy makers who decide what the law requires and balance scientific and other factors to arrive at the best decision. EPA is structured to maintain this wall between risk assessment and risk management. Whether that wall really exists in practice is open to debate and discussion, but the wall is there.

Second, EPA has developed detailed risk assessment guidelines, which address major health and environmental end-points. These guidelines, which undergo a rigorous public comment process, are agency-wide and are intended to assure scientific consistency and transparency across the agency and to reflect the consensus of the scientific community on the key issues of methodology and interpretation that EPA scientists grapple with.

Third, there is an extensive peer review program within EPA. This program does not apply to all regulations issued by EPA and the level of peer review varies from one agency action to another,

but the scientific basis for most major decisions is scrutinized closely, often by EPA's Science Advisory Board, which is comprised of independent scientists from outside the agency chosen for their expertise and their scientific accomplishments.

Finally, safeguards against arbitrary or biased science reside in the administrative process for major EPA decisions and, ultimately, in the judiciary. Rulemaking at EPA, and at other agencies like FDA, is a large undertaking. The players in the rulemaking process are very sophisticated. A considerable body of scientific information and analysis is submitted by commenters. As a result, the scientific differences are framed starkly for EPA decision-makers and a full record is created during the administrative process which crystallizes the areas of scientific dispute. Judicial review is not only very common for most decisions that EPA makes, but over the years it has become more probing. This is not to say that courts do not defer to the agency. They do. Nor is it to say that courts do not recognize that they should not substitute their judgment and expertise for EPA's. They do. But, having said that, the judges, particularly in the D.C. Circuit, apply a very high level of scrutiny to EPA actions.[25] They comb through the record diligently and look for scientific judgments which ignore the evidence or seem arbitrary. And if they find these errors, they do not hesitate to strike down EPA action.

EPA wins some of the major cases it defends, but it loses a fair number as well. To point to a big win for EPA, the new air quality standards for particulate matter and ozone were ultimately upheld in two separate decisions by the D.C. Circuit after being reviewed by the U.S. Supreme Court.[26] When the dust settled, an issue that had been battled in Congress, before the agency, and within the scientific community for years was put to rest. The Bush Administration is now embracing the new standards and focusing

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[25] *See, e.g.*, Chem. Mfrs. Assoc. v. Envtl. Prot. Agency, 28 F.3d 1259, (D.C. Cir. 1994); Sierra Club v. Envtl. Prot. Agency, 167 F.3d 658, (D.C. Cir. 1999).

[26] Am. Trucking Ass'n v. Browner, 530 U.S. 1201 (2000); *Bush Administration Revisiting its Easing of Clean-Air Rules*, THE SEATTLE TIMES, July 26, 2003, at A6.

on how to implement them. But there are also many cases where the courts have not hesitated to hold EPA accountable when it has overreached on the science. A good example is the decision of the Fifth Circuit that vacated an EPA rule that would have banned the manufacture and use of asbestos in this country.[27] In that case, the Fifth Circuit concluded that EPA had not met the statutory requirements and that the science was not sufficient to demonstrate that asbestos was unreasonably dangerous in all applications.[28] As a result, that rule, which was many years in the making, was voided.[29]

B. The Debate about EPA Science

And yet, with safeguards within EPA to assure the credibility of the scientific process and with the further safeguards of notice-and-comment rulemaking and judicial review, EPA science is still under attack from all sides. Here are a few quotes from people who have railed against the quality of EPA scientific decisions: Linda Greer of the NRDC stated "EPA mismanages the scientific function to the point that it can no longer be relied upon to be either objective or fair."[30] Rep. Vern Ehlers (R-Mich) stated "Members of Congress and the judiciary do not have confidence that the agency uses science appropriately in its decisions."[32] In addition, the Expert Panel on Role of Science at EPA remarked, "EPA science is of uneven quality, and the agency's policies and regulations are frequently perceived as lacking a sound scientific

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[27] Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir.1991) (finding that Canadian workers, affected by the loss of sales due to the EPA's ban on asbestos, pursuant to the Toxic Substances Control Act, did not have standing to challenge the action because of the Act's "national emphasis").

[28] *Id*.

[29] *Id*.

[30] Linda Greer & Rena Steinzor, *"Bad Science*", THE ENVTL. FORUM, Vol. 19, No. 1 at 28 (Jan./Feb. 2002).

[32] Representative Vernon Ehlers, "*A Bill to Improve Science at EPA*", THE ENVTL. FORUM, Vol. 19, No. 1 (Jan./Feb. 2002).

foundation."[33]

What is interesting about these quotes is the diverse sources they come from. Linda Greer is a senior scientist at the Natural Resources Defense Council, which is one of the leading environmental groups in this country and certainly an advocate of aggressive environmental regulation. Yet her view of EPA science is quite scornful. Vern Ehlers, a Republican member of Congress from Michigan, is fairly conservative, although not a rabid right-winger. His perspective is that Congress and the judiciary have lost confidence in the integrity of the agency's scientific decisions. Then in 1992, EPA itself convened a panel of esteemed scientists from outside the agency to evaluate its scientific capabilities. The verdict rendered by this group was likewise a negative one. In addition, it is easy to find statements by industry groups which are every bit as strident and critical of EPA science as these quotes here.[34]

The bottom line is that nobody likes EPA science. Congress does not like it, the scientific community does not like it, the environmental groups do not like it, and industry certainly does not like it.

What is fueling this deep mistrust of EPA science? One possible explanation is that there is a growing belief in our society—including by policy advocates of all persuasions—that regulatory science and, importantly, the scientists who participate in making it are not searchers for objective truth, but are carrying water for the people who pay the bills. This cynical perspective is often applied not only to EPA scientists but to industry scientists and even to scientists at academic institutions. It leads to a high degree of suspicion of the objectivity of any scientific judgment that EPA reaches, even where the underlying basis is clearly spelled out in the record and subject to external peer review.

Another reason for the lack of confidence in EPA science is that its decisions are rarely black and white. EPA rarely has complete information. Instead, the research and studies it uses for

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[33] U.S. ENVTL. PROT. AGENCY, SAFEGUARDING THE FUTURE: CREDIBLE SCIENCE, CREDIBLE DECISIONS, THE REPORT OF THE EXPERT PANEL ON THE ROLE OF SCIENCE AT EPA TO ADMINISTRATOR WILLIAM REILLY (March 1992).

[34] Raul & Dwyer, *supra* note 15, at 10 (NRC criticism of the EPA).

decision-making often have significant gaps. In contrast to FDA, EPA generally lacks the ability to prescribe the type of data that it wants the industry to develop to support a decision. For a new pharmaceutical, FDA always has the option of saying, "the data you have given me is not sufficient, it does not answer all the questions, go back to the drawing board and do more research." But EPA generally does not control the direction and the timing of the research that is done on environmental problems. This research is performed by government laboratories, academia, or industry for reasons largely unrelated to EPA's needs. EPA is then forced to take the data set as it finds it. The result is that EPA is constantly wrestling with uncertainty in the science and deciding how to accommodate it.

Although some might disagree, I would submit that the role of uncertainty in decision-making is not a scientific issue. It is a policy issue. How one feels about uncertainty really depends on how one views the role of precaution in protecting public health and whether one believes that regulators should err on the conservative side when they have insufficient information or should instead wait for conclusive proof before taking action. Groups in our society have very different views on this fundamental question.

C. Policy Choices in the Risk Assessment Process

Because there is uncertainty in the science, EPA has to make many choices in the risk assessment process. These are only in part scientific choices. Instead, they are largely policy judgments. The following are examples of these policy judgments.

In contrast to pharmaceuticals, where we rely on clinical trials to make judgments about safety, we do not have extensive human epidemiological data on the effects of the chemicals in our society. Therefore, many of the safety decisions we make on chemicals are based on animal studies and the extrapolation of the results of these studies to humans, who are different organisms from rats and mice. Moreover, the animal studies used to assess chemicals can have conflicting results so it is necessary to decide which study to rely on and which study is of lesser weight in the risk assessment

process. In determining the implications of animal data for humans, relative levels of exposure often raise important issues. Animal studies are typically conducted at very high doses with the intent of producing an adverse effect that is observable and measurable, but people are often exposed to doses that are many orders of magnitude lower. Do we assume that the same effects occur in humans at low levels of exposure that are observed in animals at high doses or, instead, do we assume that there are threshold doses below which chemicals will not produce any harm?

If we do conclude that there is some likelihood of adverse effects in humans, how do we determine whether the level of risk is significant or insignificant? This is a particularly important issue for chemicals that are suspected of being carcinogenic. For these chemicals, the common technique of regulators, not only at EPA but at FDA, is to express the probability of a carcinogenic event in statistical terms. In other words, is the risk of cancer 1 in 10,000, 1 in 100,000, 1 in 1 million, or 1 in 10 million? At what point do you decide that the level of risk is too small to warrant action? Does it depend on whether people are exposed to the risk voluntarily or involuntarily? Does it depend, for example, on the size of the exposed population? Is it important that, for a certain chemical, only 1,000 people are exposed in the workplace, whereas the entire U.S. population may be exposed to other chemicals as a result of the widespread use of consumer products? And finally, do you consider the level of confidence that the chemical is a carcinogen to begin with? If the strength of the evidence is weak, does that mean that the Agency will tolerate a level of statistical risk which it would not tolerate where the evidence is strong?

A related issue that EPA grapples with is whether to apply safety factors to account for uncertainty in the risk assessment process. Because it does not know, for example, whether animal data is relevant to humans and to what extent, and what the variability of response is within the human population, should the Agency add safety factors to its calculation of acceptable levels of exposure to account for the uncertainty? And what should those safety factors be? For example, there are some chemicals for which EPA applies a safety factor of 10,000, which is huge. That means

that the safe level is many orders of magnitude below the level at which a chemical has exhibited adverse effects. The safe level is set at such a low level because we are uncertain about the chemical's properties and we want to be conservative and protective.

These examples are important because they illustrate the point that policy choices are a major component of risk assessment, and when people are debating the quality of EPA science, they are really debating the policy choices EPA makes in interpreting scientific data, not what the science itself is saying, which in many cases may be uncontroversial.

VI. EPA SCIENCE IN THE COURTROOM

The following are a few tips on what judges should look for when an EPA science decision comes before them in the courtroom. First, make sure you understand the factors that Congress directed EPA to apply in making the decision. That means going back to the statutory underpinnings of the decision to understand what type of judgment Congress was interested in and what factors Congress said were important. Second, you should differentiate clearly between science and policy judgments and make sure you understand what portions of an EPA decision are science-based in the narrow sense, and what portions are based on policy considerations. Third, you should recognize the role of uncertainty in the decision that EPA has made and try to understand the assumptions that EPA has made to deal with that uncertainty. Fourth, make sure you understand the level of public comment and peer review that has been applied during the EPA decision-making process. There is a very big difference between an EPA standard which has undergone full and careful review by the agency's Science Advisory Board and an EPA standard which has not undergone any external review at all. And the final point, which is obvious but always worth repeating, is that the safe levels that EPA sets are designed for overall protection of the population, not to prevent harm in any individual case. Thus, the mere fact that an EPA standard has been violated does not establish causation in

a case where a product, emission, or waste is the alleged cause of injury. Violation of a standard may mean that there is an increased risk of injury, but that increased risk may or may not be relevant to an individual plaintiff compared to many other factors that could be at play. Thus, the significance of an EPA standard is a case-specific decision; the EPA science can inform that decision, but it is not going to eliminate the need for the court or jury to exercise judgment under the facts of each case.