OSHA Regulation of Low-Exposure Carcinogens: A New Approach to Judicial Analysis of Scientific Evidence

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I. SCIENTIFIC UNCERTAINTY IN RISK ASSESSMENT: INTRODUCTION

Both industry and worker safety advocates often complain that our country's system of risk management for low-exposure carcinogens is not at a regulatory level sufficient to provide optimal "benefits" to society in the worker safety area. While industry may not consider regulations to be unfair on their face, as they are designed to correct for market failures

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1. This Article examines the problems of judicial reaction to scientific uncertainty in risk assessment by OSHA because the OSHA substantial evidence standard and the Benzene case's interpretation of it provide a good illustration of the basic problems in applying traditional legal concepts of proof to areas in which only probability exists. See Industrial Union Dep't, AFL-CIO V. American Petroleum Inst., 448 U.S. 607 (1980) (the Benzene case). However, these same problems crop up in other agency risk assessment contexts and in toxic tort causation as well. A judicial approach that embraces and applies the scientific concepts of uncertainty and probability may provide more satisfactory societal results in these areas as well.

2. In this Article, the term low-exposure carcinogens refers to those substances which can cause cancer over long periods of time by exposure to amounts that are at or near the detection levels of current scientific instrumentology, such as gas chromatographs for organic compounds.

3. Although the term "benefits" has been ascribed various definitions depending on the circumstances, in this Article the word "benefits" refers to any and all qualities generally recognized by society as desirable as measured by "utiles" (an arbitrary but constant unit of utility or value to society). In risk assessment terms, benefit can be the level of health improvement from exposure reduction, though this is often difficult to measure. Overall, the "optimal level of benefits" can be described as that point at which utiles are maximized in a closed system.

4. In this instance, benefit refers to the anticipated level of risk reduction. Thus, if it is hard to quantify the effects of regulation on risk reduction, it is hard to quantify the benefits of a regulation.
by internalizing certain costs such as lost productivity and medical expenses, industry often considers the regulations to be unfairly applied and overly expensive. Industry claims that these regulations impose great cost on it both directly and indirectly, while the benefits are not certain or easily quantifiable.

Many consumer and worker advocate organizations also feel that the benefits of low-exposure carcinogen regulation are not easily quantifiable. They would argue, however, that society is not at an optimal level of regulation because benefits are undervalued. Nowhere is this disagreement and uncertainty more apparent than in the case of suspected low-exposure carcinogens in the workplace. Such disagreements can be expected to increase as more and more substances are recognized as carcinogens at low-exposure levels. The decision to regulate such substances is clearly a congressional policy choice. However, the ultimate implementation of regulations depends upon our court system's analysis of agency regulation, including analysis of the scientific data or evidence which the agency relies upon in making its regulatory decisions. Congress provided the Occupational Safety and Health Administration (OSHA) with the power to assure a "safe and healthful" working environment for the nation's employees and the Secretary of Labor with the authority to promulgate occupational safety and health standards which are "reasonably necessary or appropriate" to accomplish this goal.

This Article submits that the current judicial analyses of scientific studies or data upon which OSHA relies in its regulation of low-exposure carcinogens are often uninformed and inadequate, and that these analyses may prevent OSHA from achieving the level of substance regulation mandated by Congress. This Article advocates an alternative approach to judicial review of the scientific evidence upon which OSHA relies in its regulatory duties. A uniform judicial approach toward the analysis of statistical evidence and the use of a scientific master in judicial review may approximate more closely the preferred level of regulation within the legal framework estab-

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6. See, e.g., Stern & Taylor, Is the Golden State Losing It?, FORBES, at 86 (October 29, 1990) (a recent article decrying the effect of local environmental regulation on business and industry).
8. 29 U.S.C. §§ 651(b), 652(1), 652(8), and 655(b) (1988).
lished by Congress. This Article does not criticize the statutory requirements governing OSHA's regulation of low-exposure carcinogens; rather, it criticizes the judiciary's analytical approach to the evidence upon which OSHA relies when determining appropriate regulatory levels of low-exposure carcinogens.

This Article will examine the legal framework governing OSHA risk regulation, the scientific studies and evidence that the judiciary currently accepts for challenging or supporting this regulation, and the effect of this standard of judicial acceptance on OSHA regulation. This Article will then compare the present state of judicial analysis of scientific evidence with alternative analyses in order to determine the most effective means of promoting a level of worker safety regulation that creates the greatest benefit to society within the legal framework established by Congress.

II. CURRENT JUDICIAL APPROACHES TO SCIENTIFIC EVIDENCE IN OSHA RISK ASSESSMENT CASES

A. The Statutory Framework for OSHA Regulation of Toxic Substances

The Occupational Safety and Health Act (OSH Act) of 1970\(^9\) seeks to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions."\(^{10}\) Unlike other federal environmental regulatory agencies where rulemaking procedures are governed by the notice and comment requirements of the Administrative Procedure Act,\(^{11}\) OSHA must have a hearing with cross-examination before it can promulgate rules.\(^{12}\) In order to attain the goal of safe and healthful working conditions, Congress gave the Secretary of Labor the power to promulgate occupational safety and health standards, which must be "reasonably necessary or appropriate to provide safe or healthful employment and places of employment."\(^{13}\) If the standard involves a toxic material or harmful physical agent, it is to be set at the level that "most adequately assures, to the extent feasible, on the
basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity."\textsuperscript{14} The Secretary's determinations are conclusive if "supported by substantial evidence in the record considered as a whole."\textsuperscript{15} The seminal case interpreting the OSH Act's standard for regulation of toxics is \textit{Industrial Union Department, AFL-CIO v. The American Petroleum Institute},\textsuperscript{16} which is commonly known as the \textit{Benzene} case.

\textbf{B. The Benzene Case}

In the \textit{Benzene} case, the Supreme Court held that OSHA's regulation lowering the exposure levels for airborne benzene from a previously allowed exposure level of 10 ppm (parts per million) to a proposed level of 1 ppm was an invalid exercise of administrative discretion under the OSH Act. A four judge plurality made up of Justices Stevens, Stewart, Burger, and Powell held that the OSH Act required the Secretary of Labor to make specific determinations and presumably held that OSHA's evidence did not show a significant risk at a level to be regulated. In other words, in order to regulate a toxic material or harmful agent, the Secretary must determine that a significant risk exists at the present exposure level and that this risk can be alleviated by the proposed change in the exposure level.\textsuperscript{17} Justice Rehnquist, concurring in the result and thereby completing the majority needed to overturn OSHA's action, found that the OSH Act was invalid as an impermissible delegation of legislative power to the Secretary of Labor. In Justice Rehnquist's interpretation, the OSH Act provided the Secretary with no guidance on where to set a regulatory standard.\textsuperscript{18} In a spirited dissent, Justices Marshall, Brennan, White, and Blackmun attacked the plurality opinion's interpretation of what constitutes substantial evidence for purposes of regulation.\textsuperscript{19}

The \textit{Benzene} case and the later \textit{Cotton Dust} case\textsuperscript{20} dictate a two pronged approach to health regulations promulgated

\begin{itemize}
\item 14. 29 U.S.C. § 655(b)(5).
\item 15. 29 U.S.C. § 655(f).
\item 16. 448 U.S. 607 (1980).
\item 17. \textit{Id}. at 642-46; see 29 U.S.C. §§ 652(a) and 655(b).
\item 18. \textit{Industrial Union Dep't}, 448 U.S. at 685 (Rehnquist, J., concurring).
\item 19. \textit{Id}. at 688, 706 (Marshall, J., dissenting).
\end{itemize}
under the OSH Act. First, OSHA must show that the proposed standard will cause a reduction of a "significant risk" specifically at the level being regulated. Second, the agency must show that the proposed standard is feasible from an economic and technical point of view. What the Benzene Court was less clear about, and what this Article examines, is the proper judicial analysis of scientific evidence upon which OSHA may rely in meeting the first prong of this test. In other words, the Benzene Court did not make clear the kinds of studies that will constitute "substantial evidence" to establish that there will be a reduction of a significant health risk. OSHA's findings are conclusive only if "supported by substantial evidence in the record considered as a whole." However, in judicial analysis of OSHA regulation of low-exposure carcinogens, it is difficult to determine what constitutes "substantial evidence."

The Benzene Court did not define "substantial evidence" directly. However, the Benzene case must be regarded as the critical case in determining what constitutes "substantial evidence" for low-exposure carcinogen regulation. Benzene is the only case in which the Supreme Court has examined evidence relied upon by OSHA in the regulation of low-exposure carcinogens. Moreover, when interpreting "substantial evidence" in low-exposure carcinogen cases, other federal courts have relied on the Benzene Court's standard. The Benzene Court never specifically defined "substantial evidence." However, examination of the studies offered by OSHA in that case as evidence of the need for exposure reduction and the Benzene Court's general approach and rejection of these studies provide a useful picture of the Court's conception of "substantial evidence."

The Benzene Court's analysis included an evaluation of the studies relied on by OSHA in formulating its benzene standard. OSHA considered both the nonmalignant and malignant (carcinogenic) effects of benzene in establishing its standard.

23. Id. at 639-40; American Textile Mfgs. Inst., 452 U.S. at 506-08.
24. Industrial Union Dep't, 448 U.S. at 653; see 29 U.S.C. § 655(f).
26. See, e.g., ASARCO, Inc. v. OSHA, 746 F.2d 483 (9th Cir. 1984).
for occupational exposure to airborne benzene.\textsuperscript{27} In determining benzene's malignant effects, OSHA relied primarily upon studies of epidemiologic data. However, the Court found these studies flawed in two respects. First, some studies measured the impacts of benzene at a level higher than the level regulated. Second, the other studies demonstrated effects from exposure within the regulated range but in the presence of other possible carcinogens.\textsuperscript{28} The agency did not construct a dose response curve in which estimates of risks at lower exposures are derived from higher exposure levels, because it claimed that it was impossible to do so without more certain data.\textsuperscript{29} Instead, the agency relied on scientific opinions indicating that in several of the utilized studies, the risk of leukemia from benzene was actually much higher than the studies had indicated.\textsuperscript{30}

In its analysis of the evidence presented by OSHA, the Court was somewhat fractured. The three judge panel, consisting of Justices Stevens, Stewart and Burger, held that "the burden was on the agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material health impairment."\textsuperscript{31} Without examining the agency evidence in detail, this panel found that OSHA did not meet its burden of providing substantial evidence to support its regulation. OSHA had erred by relying on a "cancer policy" which stated that carcinogens had to be regulated at the lowest possible level of risk.\textsuperscript{32} The panel thus rejected the notion that any abstract scientific theory regarding carcinogenesis provides substantial evidence upon which OSHA could rely in lowering the exposure level of a proven carcinogen.

This three-judge panel also criticized OSHA for failing to supply a dose response curve which would have related the evidence of higher exposure effects to lower exposure.\textsuperscript{33} OSHA did offer studies which showed a non-mathematical effect between the two levels of benzene exposure. The Court appa-

\textsuperscript{27} Industrial Union Dep't, 448 U.S. at 697 (Marshall, J., dissenting).
\textsuperscript{28} Id. at 633.
\textsuperscript{29} Id. at 702-03 (Marshall, J., dissenting).
\textsuperscript{30} Id. at 707 (Marshall, J., dissenting) (the dissent contains a thorough discussion of all the evidence upon which the Secretary relied).
\textsuperscript{31} Id. at 653.
\textsuperscript{32} Id.
\textsuperscript{33} Id. at 653-54.
ently rejected these studies because the industry challenger suggested that a dose response curve could be feasibly constructed.34

In his separate, concurring opinion, Justice Powell found that studies showing an increase in cancer with benzene exposure of over 10 ppm and another study showing the relationship between cancer and benzene below 10 ppm did not provide substantial evidence supporting a reduction in the regulatory level.35 In making this determination, Justice Powell noted that OSHA's evidence not only failed to provide precise numerical estimates of risks but also was not the "best available evidence."36 In the absence of showing exact numerical risk, "best available evidence" can constitute substantial evidence.37

Even Justice Rehnquist, who concurred in the result but voted to overturn the regulation based on the doctrine of impermissible delegation of power, seemed to base his conclusion on the question of scientific certainty in providing substantial evidence. Justice Rehnquist would have invalidated that part of the OSH Act that empowered the Secretary to promulgate standards for toxic materials or harmful physical agents.38 Justice Rehnquist found this delegation of authority inappropriate because the Secretary had stated that a safe level of exposure was either unknown or not determinable from the available scientific studies.39 It follows that Justice Rehnquist viewed the evidence proffered by the Secretary as so inconclusive that the risk of exposure was unknown. Therefore, Justice Rehnquist's opinion indicates that risk assessment

34. Id. at 654.
35. Id. at 667 (Powell, J., concurring in part and concurring in the judgment).
36. Id.
37. Id.; see 29 U.S.C. 655(b)(5).
38. See Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 687-88 (1980) (Rehnquist, J., concurring in the judgment). J. Rehnquist would have invalidated as an impermissible delegation of power the first sentence of § 6(b)(5) of the OSH Act of 1970. 29 U.S.C. 655(b)(5). The first sentence § 6(b)(5) provides that "[t]he Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set a standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." 29 U.S.C. § 655(b)(5).
39. Industrial Union Dep't, 448 U.S. at 687-88 (Rehnquist, J., concurring in the judgment).
evidence that cannot provide an exact determination of a safe level of exposure can not constitute substantial evidence.

When read together the studies relied upon by OSHA in setting its standard and the separate plurality opinions and concurrences of the Benzene Court begin to define the confines of the "substantial evidence" requirement. These studies and opinions make clear that substantial evidence does not include studies which do not show a reduction in risk at the level under consideration (either through direct studies or by use of a dose response curve), studies which do not eliminate synergistic effects, and studies which do not indicate some definite safe exposure level.

The Benzene case also indicated that the Supreme Court had difficulties with basic scientific concepts when analyzing OSHA's proffered studies. For instance, the reasoning of the 3-judge plurality in the Benzene case demonstrates a misunderstanding of the mathematics underlying the risk assessment studies. The plurality makes the common mistake of comparing apples with oranges when analyzing statistical information. First, the Court states that it is unreasonable for OSHA to regulate a chemical if studies indicate that only two lives will be spared per 30,000 persons every six years.\(^\text{40}\) The Court later states that one life endangered per 1,000 (presumably over the course of a lifetime, which could conservatively be estimated at 48 years) could reasonably be considered a significant risk.\(^\text{41}\)

In the first instance, the Court is discussing excess deaths in six years, whereas in the other it is presumably discussing excess deaths in one lifetime. It is obvious that the number of excess deaths due to cancer will increase between six years and a lifetime. A comparison of the figures, by expressing the six-year statistics in terms of one lifetime, demonstrates the Court's confusion. Assuming a linear relationship between years and excess deaths, the six-year figure can be expressed as 16 deaths per 30,000 workers \( (2 \times \frac{48}{6}) \). Therefore, the Court has concluded without explanation that 16 deaths occurring per 30,000 workers is not substantial evidence of a serious risk, while 30 deaths occurring per 30,000 workers \( (1 \times 30) \) is significant. These numbers differ by less than one order of magnitude.

Other federal courts have attempted to apply the Benzene

\(^{40}\) Id. at 654.

\(^{41}\) Id. at 655.
standard in the face of conflicting scientific evidence for low-exposure carcinogens. The Benzene Court’s confusing interpretation of substantial evidence review has provided these courts with little guidance. For example, in ASARCO, Inc. v. OSHA\textsuperscript{42} the Ninth Circuit attempted to establish a more logical reading of the substantial evidence standard in relation to low-exposure carcinogens. However, a close reading of this case indicates that it is not consistent with Benzene. In ASARCO, the Ninth Circuit utilized the definition in the Cotton Dust case and defined substantial evidence as “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.”\textsuperscript{43} The ASARCO court claimed that the Benzene case supported its use of this definition. Specifically, the court referred to language in the Benzene case authorizing OSHA to use conservative assumptions in interpreting data and to regulate as long as its findings are supported by body of reputable scientific thought.\textsuperscript{44} This is not the most logical interpretation of what constitutes “substantial evidence” in the context of low-exposure carcinogens. First, the definition used in the Cotton Dust case is a general interpretation under the OSH Act and does not specifically address the kind of scientific evidence necessary to meet the substantial evidence test for a low-exposure carcinogen. Cotton dust does not meet the definition of a low-exposure carcinogen.\textsuperscript{45} Therefore, the Cotton Dust case does not explore the requirement of scientific studies that provide substantial evidence at the point where exact predictions become difficult. Furthermore, the Cotton Dust case does not focus on the requirement that OSHA must show a significant health risk. Rather, the Cotton Dust Court explores the second prong of OSHA health regulation analysis, the requirement that the regulation be feasible.\textsuperscript{46} The only Supreme Court guidance for the interpretation of substantial evidence in the low-exposure carcinogen context is found in the Benzene case, and ASARCO seems to misapply this standard. The passage quoted from Benzene in ASARCO

\begin{itemize}
\item[42.] 746 F.2d 483 (9th Cir. 1984).
\item[43.] Id. at 490 (citing American Textile Mfrs. Inst., v. Donovan, 452 U.S. 490, 522 (1981)).
\item[44.] Id. at 490 (citing Industrial Union Dept’ \textsuperscript{4}v. American Petroleum Inst., 448 U.S. 607, 656 (1980)).
\item[45.] See supra note 2.
\item[46.] See supra note 23 and accompanying text.
\end{itemize}
reflects the views of the three judge panel only. Specifically, Justice Powell did not concur in the section of the panel's opinion which discussed the substantial evidence standard. Furthermore, although the three judge panel did note that OSHA did not have to support its finding with scientific certainty, the same three judge panel stated that OSHA regulations must be supported by evidence that shows that an exposure "more likely than not" poses a serious health risk.\textsuperscript{47} This indicates that the evidence must show some certainty and that an agency's evidence must be stronger than that of the challenger.

Thus, the \textit{Benzene} Court's real view of what constitutes "substantial evidence" seems stricter than that applied by the \textit{ASARCO} court. As Justice Marshall noted in the dissent in \textit{Benzene}, the "existing evidence may frequently be inadequate to enable the Secretary to make the threshold finding of 'significance' that the Court requires today."\textsuperscript{48} Although the \textit{ASARCO} case may not accurately reflect the \textit{Benzene} Court's view of substantial evidence, it does demonstrate the confusion which characterizes judicial analysis of substantial evidence in OSHA risk assessment cases.

In the later case of \textit{Public Citizen Health Research Group v. Tyson},\textsuperscript{49} the D.C. Circuit recognized the distinction between the general interpretation of "substantial evidence" recognized by the courts and the additional requirements for "substantial evidence" set out by the \textit{Benzene} Court.\textsuperscript{50} In its eagerness to provide a logical way of accommodating scientific uncertainty, however, the D.C. Circuit did not follow the most logical interpretation of substantial evidence from \textit{Benzene}.

In \textit{Public Citizen}, the D.C. Circuit upheld an OSHA regulation based upon types of scientific studies that were implicitly rejected by the \textit{Benzene} Court.\textsuperscript{51} The \textit{Public Citizen} court

\textsuperscript{47} \textit{Industrial Union Dep't}, 448 U.S. at 653.
\textsuperscript{48} \textit{Id.} at 690 (Marshall, J., dissenting).
\textsuperscript{49} 796 F.2d 1479 (D.C. Cir. 1986).
\textsuperscript{50} \textit{Id.} at 1485-86.
\textsuperscript{51} In the \textit{Benzene} case, the "Dow" study showing a relationship between benzene and leukemia below 10 ppm was rejected because of the presence of other chemical risk factors. The "Dow" study was part of OSHA's evidence supporting regulation, and as discussed, the three judge panel explicitly rejected OSHA's preferred reasons for regulation, Justice Powell rejected the preferred evidence, and Justice Rehnquist overturned the regulations because of uncertainty of the offered evidence. \textit{Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.}, 448 U.S. 607, 633 (1980). The three judge plurality explicitly required a relationship between harmful effects and the regulated exposure level. \textit{Id.} at 654.
held that the studies relied upon by OSHA showed a causal link between ethylene oxide and cancer, even though no quantifiable causal link was shown in one of the studies and there were problems with synergistic reactions in another.\textsuperscript{52}

In summary, if an OSHA regulation of low-exposure carcinogens is challenged, OSHA may face judicial substantive evidence review under the \textit{Benzene} test which requires studies of exposure either at the level regulated or related to the regulated level by a direct mathematical formula. Furthermore, the studies must not have possible questionable features such as synergistic effects, must utilize risk reduction terms understandable by the court, and must be definite enough to show that the regulation will "more likely than not" reduce the significant risk. The actual requirement for OSHA, however, may be uncertain and will depend upon the particular reviewing court's interpretation of the requirements of the \textit{Benzene} case.

III. \textbf{EFFECT OF COURT ANALYSIS OF SCIENTIFIC STUDIES OF LOW-EXPOSURE CARCINOGENS ON OSHA RISK REGULATION}

Several commentators have claimed that the \textit{Benzene} Court's analysis of the substantial evidence standard of review has put an impossible burden on OSHA because the kind of proof required to meet this legal standard for regulating low-exposure carcinogens may not be seen for many decades.\textsuperscript{53} Specifically, these commentators claim that science cannot meet the \textit{Benzene} Court's requirement of direct evidence of causation at particular levels. Science offers competing hypotheses, but the \textit{Benzene} Court seems to require one definitive answer. An examination of the scientific methods utilized by OSHA in light of the legal standard lends support to this criticism.

This criticism does not question the issue of whether OSHA should be required to show that a new standard is reasonably necessary and appropriate to remedy a significant risk of health impairment.\textsuperscript{54} Rather, it addresses the weaknesses in the \textit{Benzene} Court's opinion regarding the type of statistics or

\textsuperscript{52.} Public Citizen Health Research Group, 796 F.2d at 1487-88.

\textsuperscript{53.} See, e.g., Cranor, \textit{Epidemiology and Procedural Protection for Workplace Health in the Aftermath of the Benzene Case}, 5 INDUS. REL. L. J. 372, 379.

\textsuperscript{54.} See 29 U.S.C. §§ 652(8) and 655(b)(5); Industrial Union Dep't, 448 U.S. at 642.
studies necessary to show a relationship between cancer and certain exposure levels.

Historically, carcinogenicity has been particularly difficult to test because of the low levels of a carcinogen that may cause cancer. Because of the difficulty in testing at such low-exposure levels, carcinogenicity has typically been tested through animal studies using a much higher dosage of the regulated substance than that found in the environment or the workplace. Epidemiologic studies comparing exposure data and disease incidence have become increasingly important in testing carcinogenicity. As detection instruments have become more sophisticated, regulatory agencies have been able to relate lower dosages of substance exposure to increased cancer rates in humans. Animal studies and epidemiologic studies remain the primary scientific methods of measuring health risk from suspected carcinogens. However, neither standard animal test studies nor epidemiologic studies, the best types of evidence available regarding cancer risks, can automatically pass muster under the substantial evidence standard of review announced in the Benzene case.

Agencies still use animal studies to test carcinogenicity because of the ability to rigorously control the testing environment. This type of study has wide acceptance in the scientific and regulatory communities. However, animal studies of low-exposure carcinogens give rise to legal challenges because their relevance to human beings at low-exposure levels depends upon the construction of large dose response curves. The Benzene Court did not explicitly accept this methodology; moreover, because doses are not given at the “regulated” levels, animal studies may well not pass muster under the Benzene standard. Even though the three judge panel in Benzene criticized OSHA for not producing a dose response curve, this was in relation to human epidemiologic studies. The comparison

55. See Cranor, supra note 53, at 379.
56. Id. at 381.
58. Cranor, supra note 53, at 379.
59. A dose response curve attempts to extrapolate the effect of lower doses of a suspected carcinogen to health risks by observing the relationship between higher doses of a carcinogen and health impairments and then constructing a curve which expresses the relationship mathematically.
of human to animal reactions is different and much more problematic. Substances that affect certain animals, even those animals closely related to humans, may easily be challenged because it is hard to prove that they affect humans in the same manner.

Epidemiology’s usefulness in proving relationships between risk and exposure levels to low-exposure carcinogens is also problematic under the Benzene standard. Epidemiologists study population groups to find statistical differences between groups exposed to different environmental pollutants or statistical associations between a single group and an environmental pollutant. This study is commonly retrospective. First, medical records and past exposure histories of two or more groups are selected in an effort to isolate possible exposure to the suspected carcinogen. Then, these records are statistically correlated with any differences in health problems between the two groups. Several well-known statistical tests may be used to analyze these possible correlations.

However, epidemiologic studies often have complicating factors such as exposures to other suspected carcinogens. These synergistic effects render the epidemiologic evidence less clear. For instance, the Benzene Court rejected evidence offered by OSHA because of possible synergistic effects of other substances. This demand for epidemiologic studies without synergistic effects can result in a legal straightjacket, because observational epidemiologic studies which separate synergistic effects of all other exposures are rare. For example, the Dow study upon which OSHA relied in promulgating its benzene regulation included exposure to other chemicals. However, OSHA used other studies to indicate that the Dow study was valid. Statistical studies that seek to screen out synergistic effects are at present time routinely accepted in the scientific community as valid.

In addition to problems separating synergistic effects, statistical epidemiologic studies may not produce a level of signifi-

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61. See Black & Lilienfeld, supra note 57, at 761; Cranor, supra note 53, at 385-93.
62. See Black & Lilienfeld, supra note 57, at 761; Cranor, supra note 53, at 385-93.
63. The common tests are all algebraic equivalents of a form of normal curve used to approximate the binomial distribution.
64. Industrial Union Dep't, 448 U.S. at 633-34.
65. Cranor, supra note 53, at 384.
66. Industrial Union Dep't, 448 U.S. at 699 (Marshall, J., dissenting).
67. Black & Lilienfeld, supra note 57, at 757.
cance high enough to be considered legally adequate. Therefore, these studies may not meet the exacting evidentiary standards of the Benzene case, which seems to require a direct correlation of exposure to disease incidence. For instance, in Asbestos Information Ass’n/North America v. OSHA, the Fifth Circuit purportedly relied upon the substantial evidence standard of review established in the Benzene case in rejecting epidemiologic evidence relied upon by OSHA. Although the Asbestos Information court was only concerned with an emergency temporary standard, the court’s application of the substantial evidence standard from Benzene revealed the limitation of requiring such a strict standard of proof of epidemiologic studies of low-exposure carcinogens. The studies relied on by OSHA examined lifetime exposures, but the temporary standards would only be in effect for six months. The court held, therefore, that the studies did not provide evidence over the term of the exposure. Unfortunately, epidemiologic studies can rarely be analyzed over such a short time period.

Thus, OSHA’s primary tools for studying and regulating the risk of exposure to carcinogens—animal studies and epidemiology—may not be very useful in meeting the Benzene Court’s substantial evidence requirement in relation to OSHA regulation of low-exposure carcinogens.

OSHA’s attempt to promulgate new regulations governing benzene is a good example of its dilemma in trying to meet the Benzene Court’s standard. Relying on new mathematical analyses of prior studies, and using new studies as well, OSHA repromulgated the benzene standards that the Supreme Court struck down in the Benzene case as being unsupported by “substantial evidence.” OSHA had seven years to prepare its new regulations between the Supreme Court’s rejection of its former benzene standard and the time of its new promulgation of benzene standards. When repromulgating these regulations, OSHA was very careful to address specific questions raised by the Court about its method of determining risks. However, the agency still has not produced a standard that can unequivocally meet the Benzene Court’s evidentiary requirements.

68. 727 F.2d 415 (5th Cir. 1984).
69. See id.
70. Id. at 425-26.
71. See id.
For example, when promulgating the new benzene regulations in 1987, OSHA claimed that it was very careful to lower the allowed exposure standard only to levels where some statistical evidence showed a direct correlation between the lower exposure level and a change in the risk of carcinogenesis. However, OSHA may not be able to prove to a court's satisfaction that the scientific evidence relied upon substantially supported its new conclusions because a court could rely on an alternative mathematical interpretation of this data presented by a challenger to the regulation.

In attempting to prove the necessity for a lower exposure level for benzene in its new regulations, OSHA focused on epidemiologic studies in the range to be regulated (less than 10 ppm/TWA exposure to approximately 5 ppm). It also cited several major epidemiologic studies that evaluated benzene's relation to leukemia at exposures of between 10 ppm and 1 ppm. It then reported a statistical analysis of these sets of epidemiologic data even though some of the data did not show correlations at the lowered exposure levels. OSHA concluded that a reduction of the exposure standard would result in a reduction in excess deaths of over 85 persons per 1,000.

The American Petroleum Institute has already paved the way for a possible legal challenge regarding these statistics by conducting a different statistical analysis of the same data. Interpreting the same data used by OSHA, the API concluded that there might be only eight excess deaths or lower per 1,000 persons at a 10 ppm exposure level. These statistical analyses may not be equally justified. However, a scientifically uninformed court could well conclude that OSHA had failed to prove the necessary relationship between risk and exposure level. When faced with such opposing studies or opposing

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73. See 52 Fed. Reg. 34,461-63.
74. 52 Fed. Reg. 34,462. The studies used were the Ott 1978 study, the Bond 1986 study, and the Rinsky study estimate. These studies were converted to risk assessments in the Environmental Protection Agency-Carcinogen Assessment Group (EPA-CAG) estimate, the White risk assessment, and the Crump & Allen risk assessment. Id.
75. See 52 Fed. Reg. at 34,462-63. The Crump and Allen statistical analysis used the weighted cumulative dose and relative risk models.
76. 52 Fed. Reg. at 34,510. This represented an estimated 90 percent reduction in excess deaths.
77. This statistical test correlates the effect of one variable on another. The API analyzed the Rinsky study using a conditional logistic regression analysis.
78. 52 Fed. Reg. at 34,462-63. The API also based its analysis on the Rinsky study.
interpretations, a court may be reluctant to find that OSHA's regulation satisfies the substantial evidence requirement of Benzene. OSHA's evidence may not be sufficient to prove its conclusions on a "more likely than not" basis because of apparent statistical "trickery."

As this example shows, it is difficult for OSHA to produce scientific studies that unequivocally meet the legal standard established for proving a reduction in risk because of OSHA's inability to definitely quantify that risk by the elimination of all other statistical interpretation alternatives. The question then becomes whether a court's review of OSHA's proferred scientific evidence under the Benzene Court's substantial evidence test would approximate the preferred level of regulation given the congressionally dictated standard of risk assessment.80

IV. THE OPTIMAL JUDICIAL ANALYSIS OF SCIENTIFIC STUDIES IN OSHA RISK ASSESSMENT

Assuming that our society values efficiency and desires to weigh change and regulation from a cost benefit standpoint,81 then we prefer a system of regulation that is more beneficial to society as a whole than its alternatives. Therefore, the present analysis of scientific evidence is preferred if benefits are maximized by the Benzene's Court's substantial evidence analysis. Otherwise, some change in the substantial evidence analysis is necessary to reach optimal results.

A. Present Law

As discussed above, the Benzene substantial evidence standard appears to require statistical analyses or studies with a very high statistical confidence level. Such studies may be impossible to produce or their authority may be uncertain because of the possibility of opposing statistical interpretations which a court could choose to accept. Additionally, animal


80. As stated above, this Article does not examine the wisdom or validity of the Benzene Court's interpretation of the standard governing an agency's assessment of risk as established by Congress. This Article simply examines the Court's analysis of what constitutes substantial evidence when OSHA proposes to regulate low-exposure carcinogens.

81. This assumption may not be entirely correct if our society values a certain distribution of wealth rather than total wealth maximization.
studies that are generally acceptable to the scientific community may be rejected. Furthermore, the indirect manner with which the Benzene Court addressed the substantial evidence standard and the resultant analyses in other cases leaves OSHA and those who may challenge an OSHA regulation uncertain as to whether a scientific study supported by statistical evidence can meet the Benzene test even if the regulation might be otherwise scientifically justifiable. Thus, the present substantial evidence standard is uncertain at best. Some regulations may be upheld and others overturned depending upon a federal court's understanding of the Benzene substantial evidence standard and of the statistical interpretations relied upon by OSHA in its regulatory decision.

This system can be justified from a cost-benefit standpoint only in those cases where any federal court could determine that OSHA's supporting studies and statistical interpretation were scientifically more accurate than any other interpretation. It is unlikely, however, that such a situation ever occurs. As we have seen, the benzene standards published in 1987, which do show some correlation with risk reduction, could easily be challenged using the very same studies which supported them. Furthermore, the federal courts of appeals cases applying the Benzene standard to OSHA regulation of low-exposure carcinogens seem not to be in exact conformance with the Benzene standard. This leaves a system where regulations may be accepted or rejected haphazardly. Such a system will probably not maximize social benefits.

This is particularly true since the benefits of low-exposure carcinogen regulation are usually undercounted or overcounted because of the likelihood that most regulated substances have similar carcinogenic properties. Much of the uncertainty in scientific studies analyzing the effects of low-exposure carcinogens comes from the lack of information on the causal pathways of cancer. Whatever the ultimate answers are regarding cancer causation (e.g., can one carcinogenic molecule cause cancer), the causal pathways for many low-exposure carcinogens are likely to be similar. Therefore, neither a system in which studies and statistical analyses are rejected as insub-

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82. See supra notes 42-52 and accompanying text.
substantial without certain standards or guidelines nor a system which produces uncertain outcomes with little basis in scientific realities, as the present system does, is likely to be cost effective.

There is an additional cost that flows from the present system—litigation costs. In the area of low-exposure carcinogen regulation, the Benzene decision has led to much disagreement and uncertainty regarding the statistical analysis of significant risks. In addition, the financial stakes for regulated industries are very high. An affected industry could reasonably challenge almost any OSHA standard regarding a low-exposure carcinogen. Even if an industry has reason to believe that its challenge would ultimately fail, if the standard could be suspended for the course of the litigation without worry of penalties for a frivolous claim, compliance costs could be saved or delayed long enough to cover the cost of the legal challenge. To society this tactic may represent a costly delay of needed regulations. A stay of the standard pending judicial review is within the discretion of the court, and a court is very likely to issue such a stay under the present system. A challenger can usually show likelihood of success on the merits because of the uncertainty of scientific evidence and the difficulty of satisfying substantial evidence review. A challenger can usually show likelihood of irreparable harm because of large initial compliance costs. For example, in the Benzene case, the Fifth Circuit issued a temporary stay for affected businesses for approximately one month and another stay until the disposition of the case. Thus, the cost of the present system is high. The question then becomes whether alternative ways of determining whether scientific studies constitute substantial evidence are possible or preferable.

B. Alternative Analysis

As an alternative to the present system, a reinterpretation of the Benzene substantial evidence standard would ensure that all future courts analyze scientific studies consistently and in a manner that provides the highest level of societal benefit

85. See Taylor Diving & Salvage v. United States Dep't of Labor, 537 F.2d 819 (1976).
within the established OSHA regulatory standards. Two obvious alternatives to a change in court analysis of "substantial evidence" would be to strengthen the presumption of validity of OSHA's scientific data or strengthen the presumption of validity of a challenger's scientific data. The Benzene Court's requirement that evidence must demonstrate a proposition on a "more likely than not" basis could be interpreted so that "definitive" studies, actual "proof" instead of statistical likelihood, are required for substantial evidence. The analysis of OSHA's new benzene standards demonstrates that this is a very difficult burden to bear. Both OSHA and the challenger to the agency regulation typically rely on the same data. However, each side interprets that data differently, using differing statistical analyses. Both analyses may be mathematically valid but may have different levels of support in the scientific community. Therefore, to force one side or the other to present evidence which proves rather than supports the correctness of its position would mean that almost all regulation of low-exposure carcinogens would either pass or fail automatically. Even if low-exposure carcinogens exhibit many of the same causation properties, neither of these alternatives are likely to be cost efficient.

1. Forcing OSHA to Provide Proof Rather Than Statistical Likelihood

An interpretation of the Benzene Court's requirement for substantial evidence requiring the agency to produce definitive or essentially unchallengeable evidence of risk would have the practical result of decreasing the regulation of low-exposure carcinogens. Under such an interpretation, a court would reject all scientific studies proffered by OSHA not unequivocally showing an increase in cancer deaths at specific exposure levels. Forcing OSHA to provide such proof of a needed regulation rather than a statistical probability of need would, because of the difficulty of meeting such a level of proof, likely reduce the amount of regulation of low-exposure carcinogens. At the same time, this method of analysis would not appear to increase benefits. Although litigation costs might decrease, it seems unlikely that all of the risk assessment regulations at the low-exposure levels are truly superfluous.\textsuperscript{87} Even assuming that many of these suspected carcinogens "stand or fall

\textsuperscript{87} Cranor, \textit{supra} note 53, at 379.
together" (i.e., they have the same type of causal pathways), there are certain levels where known fatal effects occur and grayer areas that are difficult to pin down uniformly for all carcinogens. Thus, requiring OSHA to provide strict "proof", rather than a statistical likelihood, seems inefficient.

Even those who challenge regulation of carcinogens generally recognize that doses of carcinogens lower than the regulated level may also cause cancer, thus leaving only the rate of occurrence in the question. Also, in almost all examples of risk assessment, whether it be low-exposure carcinogens or automobile safety restraints, the risk of future death and the health benefits of regulation may be significantly undervalued due to the lack of immediate experimental proof. This does not imply that any kind of regulation would be cost beneficial, only that the summary denial of recognition of benefits of some type of regulation because of a strict "proof" requirement may be socially inefficient. Indeed, the major cost benefit criticism of most environmental and worker safety regulation is based upon the implementation of the regulation, not the methodology determining the risks involved. From a cost benefit standpoint, requiring proof of a definitive risk reduction for a new regulation would complicate an agency's implementation regulations.

2. Evidentiary Presumption In Favor of Agency

An interpretation of the Benzene substantial evidence standard similar to the standard the court articulated in the ASARCO case would permit the use of almost any study as proof of a causal link between cancer and risk reduction. Under this interpretation, a court could decide that a connection of any sort constituted substantial evidence. Such an easy requirement for "substantial evidence," however, is probably not preferred from a cost benefit standpoint. If some burden of proof is not required of agency regulation, the agency will

88. Id.
92. See ASARCO, Inc. v. OSHA, 746 F.2d 483 (9th Cir. 1984).
likely not engage in a careful, systematic review of the scientific evidence that is available. With such meager scientific analysis, it would be pure luck if the proposed regulation by a regulatory agency bore a reasonable relationship to the true benefit of regulation at that level. This would lead to the aggrandizement of the regulating agency, or of the few who do benefit by the regulation, and to a probable loss in total societal welfare. One much-criticized example of this approach is California’s “Proposition 65,” which puts the burden on a regulated party to determine the appropriate level of carcinogen regulation.

Thus, the two most obvious solutions—requiring a showing of definitive scientific evidence by either the regulatory agency or its challenger—seem to offer no promise of the optimal level of benefit to society.

3. Other Alternatives

Enabling the courts to determine whether OSHA has successfully proffered substantial evidence by increasing the court’s understanding of the scientific, statistical, and mathematical nature of risk assessment and regulation will lead to a more satisfactory solution. Thus, this Article proposes that a total increase in benefits could be obtained within the legal framework of Benzene if our courts could determine the substantiality of offered evidence by reviewing the statistics and scientific viewpoint underlying OSHA regulation and regulatory challenges in a systematic fashion.

93. See Lave, Methods of Risk Assessment, in Quantitative Risk Assessment in Regulation 23-54 (L. Lave ed. 1982).
96. As yet another alternative, many regulators and scientists have proposed a sort of “seat of your pants” analysis of regulation which allows the agency to be somewhat intuitive or “generally right” about a regulation if it has met a minimum scientific burden and acted according to accepted scientific principles. See Crandall & Lave, Introduction and Summary, in The Scientific Basis of Health and Safety Regulation 4-5 (R. Crandall & L. Lave eds. 1981). Though the language may sound different, this alternative basically puts regulators and those that may challenge regulation in the same position in which they are today—being subject to the whims of the judiciary in determining what is current scientific knowledge or what is scientifically reasonable. As noted earlier, the inability of the judiciary to analyze the relative merits of these scientific studies is one of the major causes of the risk assessment difficulty that results in a lower net benefit to society.
To accomplish these benefits, the courts should increase their scientific expertise through the use of a special scientific master in the areas of current scientific theories of carcinogenesis, health risk, and mathematical theories of statistical analysis. Adoption of this proposal would eliminate some of the uncertainty surrounding the regulatory process because all parties would speak the same language of acceptable scientific theory. This would also discourage or eliminate those regulations or challenges to regulations that are based only on pseudo-scientific statistical analysis. In addition, the courts would have the tools for discerning the relevance of different statistical analyses. The courts could then better recognize true risks and, thus, the necessity of regulation.

C. Proposed Change in Court Analysis

When approaching a question of a risk assessment under the Benzene standard, a specific and uniform analysis of studies upon which OSHA relies in regulating low-exposure carcinogens would result in an increase in overall benefits. This analysis should include a uniform review of any epidemiologic surveys or animal studies, with assistance of special masters to determine (1) whether the results are based on well founded correlations (i.e., the relationship between two sets of data is interpreted correctly), and (2) whether the correlation is in the range of statistical relevance accepted by the scientific community. Such an approach has already been proposed when a court must examine statistical evidence in general.

When asked to review evidence purportedly relating groups of people by health effects or toxic substance exposure, courts should first subject this data to a statistical analysis. It is often easy to be mistaken about whether a statistical relationship is significant when acting upon intuition alone (or even when acting upon the belief of some experts). Because scientifically trained personnel are able to conduct valid statistical relationship tests with reasonable ease, courts should be

97. Of course, persons who engage in scientific endeavors disagree over specific scientific analyses. However, certain parts of scientific analysis, such as methods of proof and study, are commonly accepted.


99. Intuition is recognized as one of the major problems of risk recognition from a Congressional level down to the parlor game level. See P.G. MOORE, THE BUSINESS OF RISK at 49-62 (1983) for a thorough discussion of intuition and risk problems.
particularly careful to require them.\textsuperscript{100} These tests may disclose whether a perceived relationship or disparity is truly significant, obviating the need for total reliance on expert opinion in the area. Requiring appropriate statistical analyses would increase overall benefits by forcing OSHA to eliminate regulation when no acceptable scientific or statistical study can support its conclusion.

If OSHA or a party challenging a regulation offers statistical analyses as evidence, the court should analyze potential problem areas with these tests and their underlying data to assure that commonly accepted scientific principles underlying statistical analyses have been followed. One basic problem often occurring with any statistical analysis is the formulation of correct assumptions. Whether the groups were drawn to create a true control group and whether the group represented is really isolable for only one particular environmental exposure must always be closely considered when evaluating epidemiologic surveys. In other words, group comparisons should inquire into whether the only difference between the groups is the exposure to one relevant chemical or whether other existing factors account for statistical deviations. This issue arose in the Benzene case when the Court dismissed a study undertaken by Dow Chemicals because OSHA had allegedly not considered the effects of other chemicals.\textsuperscript{101}

As in the Benzene case, other exposure factors may be involved but such factors may be irrelevant if accepted scientific principles indicate that they probably would not act synergistically. A scientific master versed in current theories could seek to determine substance interaction and could provide some guidance to a court in determining the relevance of other substance exposures to the proffered statistical analysis. A court in reviewing the adequacy of such statistical epidemiologic studies, as did the Supreme Court in Benzene, must have the tools at its disposal to analyze the relative strengths of studies.

Under this proposed new approach, an agency could not simply isolate any group in order to create an incidence rate,

\textsuperscript{100} See Lave, \textit{Introduction} in \textit{Quantitative Risk Assessment in Regulation} 15-17 (L. Lave ed. 1982) (The discussion of EPA regulation of photochemical oxidants in this article is another extreme example of judicial avoidance to submit data to statistical analysis).

but neither could a challenger successfully attack a regulation based on the fact that other scientifically insignificant factors were present. This new approach would increase benefits by eliminating “false” incidents and considering true statistical connections.

For instance, the Benzene plurality and dissenting opinions clearly disagreed on the acceptability of the Dow study. However, the plurality offered no reason for rejecting the study other than that other chemicals might be involved. It did not make a detailed examination of the agency’s reasons for using the study. Without such an examination, the Court may have incorrectly discounted the validity of the Dow study in formulating OSHA’s conclusions.

A second basic question to be asked with any statistical test is what level of significance is acceptable. Certainly, in a carcinogenic risk assessment, a court would consider significant a 99 percent chance that a correlation exists between cancer incidence in a group and the level of chemicals in the workplace air. However, it is unclear whether a court would consider a figure of 80 percent or 60 percent significant. In many parts of the scientific community, the probability that a study indicates a false negative is set at the 95 percent level to indicate “significance,” which is considered the “null hypothesis.” However, this is simply a convention and may not always be appropriate in a court’s analysis of risk assessment cases or other scientific analyses where exposure levels are particularly low.

A court should note that it is not only the reliability of the scientific data but also the size of the groups under consideration which determines significance. Thus, even though a correlation may be suggested by other studies, in certain cases an affected group might be very small, making it impossible to show a 95 percent statistical significance. Therefore, a challenger to such a statistical analysis could claim with mathematical certainty that the results are not “significant.” However, such small exposure groups, which may be common with low-exposure carcinogens, deserve closer analysis or a lower acceptable level of significance. A scientific master could look at data in relation to the particular statistical analyses employed and their relation to other studies or factors and

102. See id. at 633 and 707 (Marshall, J., dissenting).
103. Cranor, supra note 53, at 385.
advise a judge in the areas in which he or she may need explication.  

For instance, in *Asbestos Information Ass'n/North America v. OSHA* the Fifth Circuit rejected a proposed temporary standard for airborne asbestos fibers in holding that studies supporting the standard were not definite or certain as to the number of lives saved. In that case, OSHA was unable to statistically demonstrate the exact number of lives that would be saved over a period of six months, although there was clear statistical evidence that exposure to asbestos over the long term was a significant health risk. This does not mean that the ultimate conclusion of the Fifth Circuit in the *Asbestos Information* case was incorrect, only that the court may have dismissed risks for lack of statistical correlations without examining other proof which may have confirmed those risks.

A scientific master would also provide a general increase in scientific knowledge to the court which would be beneficial for overall analysis of test data. For instance, the use of animal tests to measure risk of exposure is becoming increasingly controversial because of possible deaths due to the effects of toxicity. A scientific master versed in the complex nature of specie differences, size, and metabolism could provide an informed opinion in this very volatile area. In addition, statistical theory may indicate that opposing statistical analyses are both relevant. A scientific master can explain the differences in the analyses and the importance of the information to the court in a neutral manner. This will allow the court to make a better and more informed decision.

The use of a scientific master in judicial review of agency evidence could be quickly and easily implemented. The Federal Rules of Civil Procedure already allow for the appointment of a special master on a case-by-case basis in exceptional circumstances. Special masters are routinely used in environmental contaminant cases because of the threat to public health and the complexity or difficulty of the scientific issues

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104. For an excellent and thorough discussion of the relationship between sample size and statistical significance, see Cranor, *supra* note 53, at 386-89.

105. Asbestos Information Ass'n/North America v. OSHA, 727 F.2d 415, 425 (5th Cir. 1984)).


107. FED. R. CIV. P. 53.
involved. Therefore, the adoption of special mastery would require no legal changes and would depend only upon acceptance by the judges themselves.

Special masters can monitor the implementation of feasible statistical tests, help the court interpret the meaning of competing statistical analyses, and provide general scientific information to the court. As previously noted, such expertise would have been helpful in the Benzene case and in later cases. Providing the courts with such expertise will probably lead to a more consistent and preferred level of regulation. Although the use of special masters would add to the cost of litigation, this cost would probably be offset by the time saved by the court personnel, who would have to spend far less time becoming scientifically knowledgeable in order to begin a case. In addition, costs would be saved by providing for a regulation which is more predictable and consistent with the law.

V. CONCLUSION

There are no simple, easy methods for ensuring that benefits outweigh costs in the regulation of low-exposure carcinogens. The scientific uncertainty of epidemiologic data and animal studies used to assess risks makes this impossible at the present time. This does not mean that regulation is unnecessary, only that the absolute optimal level of regulation is difficult to determine because the scientific studies upon which OSHA relies are not certain. As a society, it is important to find the method that most consistently approaches the optimal level of regulation—the amount of regulation where society’s total benefits are maximized.

The method used by the Supreme Court to analyze whether evidence is substantial in OSHA regulation of suspected low-exposure carcinogens does not attain optimal regulation and a net benefit to society. Likewise, an interpretation of the substantial evidence standard requiring OSHA or the industry challenging the regulation to provide “proof” of effects instead of statistical likelihood would not seem to reach the optimal amount and type of regulation.

Optimal regulation can be more closely approximated by standardizing an approach in the federal courts to substantial evidence review of OSHA regulation. This approach should
take a close look at the scientific evidence and the mathematical formulas used to reduce such evidence to a risk assessment. In addition, a scientist’s critical eye should be added to examine the underlying presumptions relied on in risk assessments. By using this approach, our courts could eliminate the most egregious examples of superfluous regulation or regulatory challenge, thus making regulation itself more certain. This system would also bring the court into line with the most correct scientific assumptions in the risk assessment area and allow quick changes to accompany advances in scientific certainty when they occur. This type of analysis is a possible way to maximize societal benefits in the regulation of low-exposure carcinogens.