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When 'Likely' Does Not Mean 'More Likely Than Not': The Dangers of Allowing Government Chemical Classifications and Numeric Risk Assessments at Trial

By Mark P. Fitzsimmons, Sneha Desai, and Leah M. Quadrino

When the International Agency for Research on Cancer (IARC) recently declared cell phone use to be ''possibly carcinogenic'' to humans, the news headlines were widespread, prominent, and bordered on frantic. Almost immediately some commentators tried to clarify that ''possibly carcinogenic'' was in fact a very low ranking, and did not mean that cell phone use actually *causes cancer*. But the damage was already done, and the alarm still continues.

Government and quasi-government agency chemical classifications and ''risk assessments'' can wreak similar havoc in a courtroom. Anyone familiar with the regulatory process knows that whether a given substance has been labeled ''possibly carcinogenic'' or even ''probably carcinogenic'' by an agency has little to no bearing on whether it specifically harmed a plaintiff in a particular situation, or even whether it was capable of doing so—but the agency's choice of language sure sounds like it might. Saying that a particular exposure is 1,000 times above the allowed limits, or that it causes a 0.65 in 100 increase in the risk that someone will contract cancer, will cause the same confusion and level of misplaced alarm.

Government agency chemical classifications and risk assessments are policy-oriented, protection- and prevention-based tools, designed to aid in public health-related decisions. They are not predictive, yet, they unfortunately employ terminology and a misplaced sense of precision suggestive of legal causation, such that a jury might be asked to answer the following question: Please determine whether a ''probably carcinogenic'' substance ''more likely than not'' caused harm to the plaintiff. It is easy to see how that jury might think that the question answers itself: If the substance is probably carcinogenic, then it probably caused the damage. The flaw in that assumption is rooted in a misunderstanding of how the classification or assessment was derived and why it cannot substitute as evidence in support of a plaintiff's burden of proof.

This article examines the potential for misuse of government agency chemical classifications and risk assessments in the context of toxic tort litigation. Specifically, the article discusses some of the numerous types of classifications, ratings and numeric risk assessments now employed by regulatory and quasi-governmental agencies, and how plaintiffs frequently seek to introduce them as evidence in support of elements of tort claims (in particular, general and specific causation and increased risk). It further examines how courts have treated such efforts, and concludes by asking whether the same rules should apply to defendants seeking to

Mark P. Fitzsimmons is a partner at Steptoe & Johnson LLP in Washington, D.C. He has over 30 years of experience in litigating toxic tort, product liability, and environmental cases, and can be reached at MFitzsimmons@steptoe.com.

Sneha Desai is senior counsel for litigation at BASF Corp., in Florham Park, N.J., where she manages the company's material litigation portfolio. Desai can be reached at sneha.desai@basf.com.

Leah M. Quadrino is of counsel in the Washington, D.C., office of Steptoe & Johnson. She is the chair elect of the ABA's Tort, Trial and Insurance Practice Section Committee on Excess, Surplus Lines and Reinsurance, and can be reached at lquadrino@steptoe.com.

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use agency classifications or risk assessments as a shield.

Government Agency Risk Assessments and the Default Assumptions They Employ

Numerous government and quasi-government agencies classify chemicals using qualitative terms, and also generate numeric risk assessments to identify potential safety and health risks associated with exposure to chemicals. Examples of these qualitative assessments include the following:

■ The U.S. Environmental Protection Agency has developed the Guidelines for Carcinogen Risk Assessment, which call for the use of qualitative descriptors in generating weight-of-evidence narratives for the toxicology of a given chemical. These ''descriptors'' are: ''carcinogenic to humans,'' ''likely to be carcinogenic to humans,'' ''suggestive evidence of carcinogenic potential,'' ''inadequate information to assess carcinogenic potential,'' and ''not likely to be carcinogenic to humans.'' *See generally* Risk Assessment Forum, U.S. Environmental Protection Agency, *Guidelines for Carcinogen Risk Assessment* (March 2005) at 2-49 to 2-58 (providing guidelines for weight-of-evidence narratives and descriptors).

■ Similarly, the United Nations World Health Organization's International Agency for Research on Cancer (''IARC'') has developed Monographs for chemicals, using the following descriptors: ''carcinogenic to humans,'' ''probably carcinogenic to humans,'' ''possibly carcinogenic to humans,'' ''not classifiable as to its carcinogenicity to humans,'' and ''probably not carcinogenic to humans.'' *See IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble* at 22-23. This organization has no regulatory authority, but it is widely respected and its classifications are accorded great weight by governmental agencies that do regulate.

■ In a congressionally mandated *Report on Carcinogens*, the U.S. Department of Health and Human Services' National Toxicology Program (NTP) utilizes two qualitative descriptors: ''known to be a human carcinogen'' and ''reasonably anticipated to be a human carcinogen.'' *See Since You Asked—12th Report on Carcinogens*, available at http://www.niehs.nih.gov/news/sya/sya-roc/ (last visited Jan. 23, 2012).

Numeric ''risk assessments'' generated by agencies such as the U.S. EPA are often employed to serve the same public health-oriented purpose as the qualitative classifications identified above, but instead express ''risk'' by identifying a theoretical mathematical probability that cancer or non-cancer effects will occur as a result of exposure. To determine a cancer risk assessment in the context of developing a specific regulation, for example, agencies will multiply a hypothetical lifetime average daily dose of a chemical by its ''cancer slope factor,'' which is a numeric expression of how carcinogenic a particular chemical is to laboratory animals in experiments. The numeric risk estimate will typically be expressed as how many people per million will develop cancer based on a lifetime of exposure. *See, e.g.*, Phillip L. Williams, et al., eds., *Principles of Toxicology* (2d ed. 2002) at 459, for a good layman's description of how the process works. Other examples of numeric risk assessments include the development of an Acceptable Daily Intake (ADI), or a safe level, of a particular chemical in drinking water or food.

In generating both qualitative and numeric risk assessments, government agencies employ certain default assumptions, consistent with their purpose of protecting public health. As explained by the EPA, the ''[u]se of health protective risk assessment procedures as described in these cancer guidelines means that estimates, while uncertain, are more likely to overstate than understate hazard and/or risk.'' *See* Risk Assessment Forum, U.S. Environmental Protection Agency, *Guidelines for Carcinogen Risk Assessment* (March 2005) at 1-7.

One such assumption—which could have real significance in the litigation context—is that the results of animal testing may be transferred directly to humans. The EPA, IARC and NTP all generate qualitative classifications of chemicals that can be based solely on the results of animal studies. For example, the EPA's designation, ''likely to be carcinogenic in humans,'' IARC's designation, ''probably carcinogenic in humans,'' and NTP's designation, ''reasonably anticipated to be carcinogenic in humans,'' each require no actual results from human data at all. Similarly, numeric risk assessments are infused with the same assumption: The cancer slope factor from which the mathematical probability of risk to humans is derived is usually based solely on the results of animal studies.

Additionally, when agencies model data to determine quantitative or qualitative risk assessments, they also assume that the results caused by exposure to a high dose of a particular chemical will similarly occur by exposure to a low dose of that chemical, albeit at a lesser frequency. *See, e.g.*, John B. Sullivan & Gary R. Krieger, eds., *Clinical Environmental Health and Toxic Exposures* (2d ed. 2001) at 87 (explaining that the EPA's ''linear multistage model assumes that all carcinogens act by genotoxicity and that if any dose of a toxic substance can cause cancer, then every dose can cause cancer in equal proportion.'').

''Safety factors'' are also frequently imbedded within numeric assessments regarding safe levels of a particular chemical in drinking water or food. For example, the World Health Organization (''WHO'') has explained that ''[t]he message communicated with an ADI is that there is no significant risk if the chemical is ingested at or below the ADI.'' *See* Report of the Joint FAO/WHO Expert Consultation, *Application of Risk Analysis to Food Standards Issues* (1995) at 5.3.4. Because of that intended message, certain precautionary steps are taken when generating these Acceptable Daily Intakes to ensure the assessment of risk is conservative:

> A safe level or Acceptable Daily Intake (ADI) is derived from an experimental NOEL [no observed effect level] or NOAEL [no observed adverse effect level] by applying appropriate safety factors. The conceptual basis for their use is that thresholds will exist at reasonably comparable doses in both humans and experimental animals. For humans, however, sensitivity may be greater, genetic outbreeding may be larger and dietary habits may be more variable. As a consequence, a safety factor is applied . . . to take into account these uncertainties. . . . Other health agencies adjust the ADI for the severity or irreversibility of the effect. *Id.*

As a result, a numeric ADI may be lower than that which the underlying data would justify, because of an attempt to account for the uncertainties in human re-

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sponses, as well as the seriousness of the potential health effect (as opposed to its actual likelihood or predicted frequency). In simpler terms, the worst is always assumed, whether there is a good basis for it or not.

These (and other, similarly conservative) default assumptions, guided as they are by public policies supporting health protection and disease prevention, may well be prudent and appropriate in the regulatory context in which they were developed and are used. But assuming something is the case without proof necessarily must limit the application of chemical classifications or numeric risk assessments in other contexts, particularly litigation. Indeed, the agencies who promulgate these standards universally caution against extrapolating any quantitative value from a qualitative classification. For example, the EPA has explained that ''[a]lthough the term 'likely' can have a probabilistic connotation in ***other*** contexts, its use as a weight of evidence descriptor ***does not*** correspond to a quantifiable probability of whether the chemical is carcinogenic.'' *See* Risk Assessment Forum, U.S. Environmental Protection Agency, *Guidelines for Carcinogen Risk Assessment* (March 2005) at 2-53 (emphasis added). As such, the EPA has expressly explained that these values should not be used to establish causation:

> In general IRIS values cannot be validly used to accurately predict the incidence of human disease or the type of effects that chemical exposures have on humans. This is due to the numerous uncertainties involved in risk assessment, including those associated with extrapolations from animal data to humans and from high experimental doses to lower environmental exposures. The organs affected and the type of adverse effect resulting from chemical exposure may differ between study animals and humans. In addition, many factors besides exposure to a chemical influence the occurrence and extent of human disease.

See U.S. Environmental Protection Agency, ''IRIS Limitations,'' available at http://www.epa.gov/iris/limits.htm (last updated July 26, 2011). Thus, the descriptor, ''likely carcinogenic'' does not in fact mean that a chemical ''more likely than not'' causes cancer. And it is that distinction that increasingly has given rise to confusion in the context of toxic tort litigation.

Implications of Plaintiffs' Use of Agency Risk Assessments at Trial

Despite their irrelevance to questions of causation, plaintiffs frequently attempt to shortcut their burden of proof and enlist the apparently neutral and persuasive authority of the government by introducing evidence at trial of agency chemical classifications or numeric risk assessments. The proposed use of such evidence most often arises in the context of causation and increased risk.

In a typical toxic tort lawsuit, plaintiffs must prove both general and specific causation—i.e., generally that a chemical can cause the type of harm that is alleged to have occurred, and specifically that the chemical did in fact cause the alleged harm to the particular plaintiff. General causation is effectively a prerequisite to specific causation, because if the chemical cannot cause the particular alleged harm, then it cannot have done so to the specific plaintiff. Where a government agency has determined that a particular chemical agent is ''possibly carcinogenic'' or ''probably carcinogenic,'' it is a short leap for a plaintiff to allege that his burden of proving ''general causation'' has already been met. To wit: If something is ''possibly'' or ''probably'' carcinogenic, does it not have the potential to cause the alleged harm?

The same problems arise in the context of demonstrating increased risk, either as its own tort or as an element of a medical monitoring claim. Evidence of risk assessments or agency classifications may appear to present an easy way to demonstrate an increased risk of harm due to exposure to a chemical agent. For example, where a risk assessment indicates that a safe exposure level should be less than a specific ADI, and a plaintiff demonstrates that his exposure has exceeded that level, has he met the burden of proof required to show an increased risk? Or where the mathematical probability of contracting cancer due to exposure to a certain chemical is at an apparently high or significant level, has the plaintiff demonstrated an increased risk above background levels sufficient to sustain his burden of proof? The answer to these questions is key to understanding the dangers in using these government ratings or risk assessments as substitutes for establishing the elements of a tort claim.

Importantly, preventing the admission of government agency classifications or risk assessments (or use of the risk assessment procedure) at trial does not necessarily mean excluding evidence of the underlying studies on which those assessments have been based. Rather, the potential for lack of relevance or undue prejudice is particularly tied to the classification or rating itself (because of its potential to be misleading and confusing when taken out of its prevention-oriented context) as opposed to the underlying data. As a result, a defendant seeking to exclude risk assessments at trial need only seek a fairly narrow remedy that would leave plaintiffs free to make use of the underlying studies or data on which the assessments were based.

As discussed below, strong arguments support the exclusion of agency classifications and risk assessments at trial on both relevance and prejudice grounds.

Exclusion on Relevance Grounds

The default assumptions that form the basis for government agency risk assessments intentionally swing the results toward a conservative, health protective outcome. As noted earlier, both qualitative classifications of chemicals and numeric risk assessments are routinely based solely on animal studies. That means there has been no proof of any kind that the chemical has the actual ability to cause harm in humans. Similarly, embedded within numeric risk assessments are certain safety factors designed to ensure a conservative estimate of risk, taking into account that human genetics or pre-existing medical conditions could cause one person to react differently than another. And there is a further default assumption that where a high dose of a chemical has been shown to cause harm, a very low dose will, as well. From a precautionary, public welfare standpoint, the agency assessments may be justified, as their purpose is to prevent harm before it happens. From a litigation standpoint, however, they do not aid in the proof of the general causation requirement nor in the increased risk element in a toxic tort suit, and should not be permitted to serve as a substitute for concrete evidence supporting the plaintiff's burden.

Indeed, the distinction between regulatory classifications of chemicals and the burden of proof required in

court has been widely recognized. *See, e.g., Gates v. Rohm & Haas Co.*, No. 10-2108, 2011 U.S. App. LEXIS 17756, * 33 (3d Cir. Aug. 25, 2011) (holding that ''plaintiffs could not carry their burden of proof for a class of specific persons simply by citing regulatory standards for the population as a whole''); *Wright v. Willamette Industries Inc.*, 91 F.3d 1105, 1107 (8th Cir. 1996) (''Whatever may be the considerations that ought to guide a legislature in its determination of what the general good requires, courts and juries, in deciding cases, traditionally make more particularized inquiries into matters of cause and effect. . . . It is therefore not enough for a plaintiff to show that a certain chemical agent sometimes causes the kind of harm that he or she is complaining of.''); *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 198 (5th Cir. 1996) (''The agencies' threshold of proof is reasonably lower than that appropriate in tort law, which 'traditionally make[s] more particularized inquiries into cause and effect' and requires a plaintiff to prove 'that it is more likely than not that another individual has caused him or her harm.' ''); *Meade v. Parsley*, No. 2:09-cv-00388, 2010 U.S. Dist. LEXIS 125217, * 25 (S.D.W. Va. Nov. 24, 2010) (''Inasmuch as the cost-benefit balancing employed by the FDA differs from the threshold standard for establishing causation in tort actions, this court likewise concludes that the FDA-mandated [black box] warnings cannot establish general causation in this case.''); *Stites v. Sundstrand Heat Transfer Inc.*, 660 F. Supp. 1516, 1525 (W.D. Mich. 1987) (critiquing expert testimony for its reliance on regulatory standards and noting that the court was ''not concerned with regulatory standards in this case . . . but rather must base its decision on the Michigan legal standard''); *see also* Federal Judicial Center, *Reference Manual on Scientific Evidence* 413 (2d ed. 2000) (''While risk assessment information about a chemical can be somewhat useful in a toxic tort case, at least in terms of setting reasonable boundaries as to the likelihood of causation, the impetus for the development of risk assessment has been the regulatory process, which has different goals. Because of their use of appropriately prudent assumptions in the areas of uncertainty and their use of default assumptions when there are limited data, risk assessments intentionally encompass the upper range of possible risks.'').

For this reason, many courts have excluded expert testimony for its reliance on regulatory ratings or standards. *See, e.g., Baker v. Chevron USA Inc.*, 680 F. Supp. 2d 865, 880 (S.D. Ohio 2010) (excluding expert testimony in part upon finding that expert's reliance on plaintiff's exposure to benzene above regulatory limits was ''insufficient to establish causation'' because ''regulatory agencies are charged with protecting public health and thus reasonably employ a lower threshold of proof in promulgating their regulations''); *Glastetter v. Novartis Pharmaceuticals Corp.*, 107 F. Supp. 2d 1015, 1036 (E.D. Mo. 2000) (excluding expert testimony in part upon finding that the FDA statement alone did not support the experts' causation theory because government agencies' methodology is prevention-based and employs a lower threshold of proof than tort law); *but see Hirsch v. CSX Transportation Inc.*, No. 09-4548, 2011 U.S. App. LEXIS 18613 (6th Cir. Sept. 8, 2011) (affirming summary judgment against plaintiffs but implicitly recognizing validity of using government agency numeric risk assessments as benchmarks for determining increased risk).

Where an agency classification or risk assessment is irrelevant to general causation, it is even less relevant to the particularized inquiry of specific causation. *See, e.g., Sutera v. The Perrier Group of America Inc.*, 986 F. Supp. 655, 664 (D. Mass. 1997) (finding that a regulatory standard, such as the EPA's permissible level of benzene in drinking water, is not a ''measure of causation,'' but rather a ''public-health exposure level that an agency determines pursuant to statutory standards set by Congress''). As noted by the Fifth Circuit in *Allen*, ''the fact that [the chemical at issue] EtO has been classified as a carcinogen by agencies responsible for public health regulations is not probative of the question whether Allen's brain cancer was caused by EtO exposure.'' *Id.* at 196. The Court also reiterated its belief in '' 'the very limited usefulness of animal studies when confronted with questions of toxicity.' '' *Id.* (citations omitted).

Similarly, the U.S. District Court for the Southern District of West Virginia applied West Virginia law and found that ''[r]isk assessments have largely been developed for regulatory purposes and thus serve a protection function in providing a level below which there is no appreciable risk to the general population. They do not provide information about actual risk or causation.'' *Rhodes v. E.I. du Pont de Nemours and Co.*, 253 F.R.D. 365, 377 (S.D.W. Va. 2008). After noting that risk assessments '' 'intentionally encompass the upper range of possible risks,' '' the court specifically held that ''[m]edical monitoring, as a common law tort, requires more certainty than that provided by an estimate of the 'upper range of possible risks.' '' *Id.* (citations omitted). Applying West Virginia law, the court then denied a motion for class certification in part due to plaintiffs' expert's misplaced reliance on a risk assessment report as evidence of putative class members' individual injuries. The court explained:

> Accordingly, a risk assessment *cannot* provide the requisite reasonable certainty required to show a medical monitoring injury. Because a risk assessment overstates the risk to a population to achieve its protective and generalized goals, it is impossible to conclude with reasonable certainty that any one person exposed to a substance above the criterion established by the risk assessment has suffered a significantly increased risk.

Id. at 378 (emphasis added); *see also Abarca v. Franklin County Water District*, No. 1:07-CV-0388, 2011 U.S. Dist. LEXIS 1603, *97-104 (E.D. Cal. Jan. 5, 2011) (following *Rhodes* and finding that a risk assessment prepared for a government body for the purpose of health protection did not establish proof of general exposure and granting partial summary judgment on that ground). Thus, while numeric risk assessments are ''quantitative'' in nature, they are based on the same default assumptions that undercut any reliance on them for a quantitative purpose.

Exclusion on Prejudice Grounds

Another reason to exclude agency classifications and risk assessments is the very real danger of unfair prejudice at trial. Because the classifications use terminology that is highly similar to causation terminology and/or connotes a sense of scientific precision that is not present, there is a substantial danger that use of these classifications could confuse and mislead a jury. This genuine risk of confusion is made worse by the seem-

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ingly neutral and authoritative source of the ratings—the government.

An initial source of confusion relates to the burden of proof standard applied commonly in civil litigation: preponderance of the evidence. The standard is frequently described to juries as ''more likely than not'' or ''more probable than not.'' In a toxic tort setting, a plaintiff will therefore be asked to prove that exposure to a particular chemical ''more likely than not'' caused his alleged injury. From a juror's perspective, the introduction of evidence that a chemical is ''likely'' or ''probably'' a carcinogen will understandably seem to mirror the burden of proof a plaintiff must meet. And yet, as discussed above, the very agencies who developed these chemical classifications have explained that they lack any quantitative value whatsoever, such that ''probably'' *does not mean* ''more probable than not'' in this context. Indeed, the agencies who develop these classifications uniformly acknowledge the inappropriateness of applying them to a causation analysis. Juror confusion of this kind would very arguably lead to unfair prejudice against defendants. *See, e.g, Byrne v. Liquid Asphalt Systems Inc.*, 238 F. Supp. 2d 491, 492 (E.D.N.Y. 2002) (excluding evidence of OSHA standards where they did not apply to the defendant manufacturers and where the court found that ''allowing such evidence to be introduced would likely confuse or mislead the jury'').

This unfair prejudice is compounded by the inherent persuasiveness of a government-backed determination that a chemical is possibly harmful. The imprimatur of the government—a perceived neutral and authoritative third party—can be a powerful element at trial. In a trial setting, where jurors are tasked with making numerous credibility determinations, there will be an understandable trust associated with any evidence that purports to come from a ''neutral'' and ''authoritative'' source, like a government agency analyzing chemicals with an aim toward protecting the public's health. Where the jury already feels conflicted over which side to believe—a chemical manufacturer or its alleged victims—the introduction of evidence not generated by either side but rather a neutral and knowledgeable arbiter may be a welcome relief. Add to that the notion that the government has generated these risk assessments or chemical classifications with the public's welfare in mind. The potential weight the jury might grant such evidence cannot be underscored enough.

Numerous courts have excluded government agency reports where their probative value is substantially outweighed by the risk of unfair prejudice due to the inordinate weight jurors are likely to grant them. *See, e.g., Fowler v. Firestone Tire & Rubber Co.*, 92 F.R.D. 1, 2 (N.D. Miss. 1980) (granting defendant's motion *in limine* to exclude two government reports in part upon finding that ''because this documentary evidence is in the form of reports promulgated by agencies of the United States government, its apparent 'official' nature is likely to cause a jury to give the evidence inordinate weight and for this reason, any probative value the evidence might have would be far outweighed by the danger of unfair prejudice, confusion of the issues or misleading the jury.''); *Stevenson v. Felco Industries Inc.*, 216 P.3d 763, 771 (Mont. 2009) (finding that the admission of a government report was not harmless error because of the highly prejudicial nature of a government report due to its official nature and its attendant '' 'badge of trustworthiness,' '' causing a jury to give it undue weight). The same reasoning would also support excluding agency risk assessments at trial.

There is also an appearance of precision in government risk assessments and chemical classifications that further increases the persuasiveness of the evidence and correspondingly the risk that they will be weighted inappropriately by the jury. There is something innately comforting in a specific numeric assessment—a decimal point level of precision—that implies a greater authority than deserved once default assumptions and safety factors are taken into account. Where the purpose of the risk assessment or agency classification is to prevent harm from occurring, there is probably nothing wrong with drawing conclusions that err on the side of caution and that impute a risk of harm *just in case* there really is one. But translating that assessment into a legal framework, where default assumptions of harm have no place in satisfying a burden of proof, is highly problematic.

Agency Risk Assessments as a Shield?

In light of everything stated above, it may now seem like the height of hypocrisy to suggest that defendants should be permitted to make use of government agency chemical classifications and numeric risk assessments at trial while plaintiffs should be prohibited from doing so. In fact, however, a defendant's proposed use of such ratings and assessments at trial would serve a wholly different function and purpose than a plaintiff's proposed use, and thus not be subject to the same relevance and prejudice arguments outlined above.

A defendant in a toxic tort suit typically needs to show that the plaintiff cannot meet his burden of proof at trial—for example, an inability to show general causation or increased risk due to exposure to the defendant's chemical. Where a government agency or process has analyzed the impact of exposure to a particular chemical with every presumption made in favor of there being a problem, but found it to be benign, is such evidence probative and relevant as to whether a plaintiff can demonstrate general causation? Similarly, where the plaintiff is unable to show exposure to a chemical above the threshold amount established as an ADI, does such evidence strongly suggest the lack of an increased risk?

A good argument can be made that what is good for the goose is not good for the gander here. Protective but not affirmative use of the agency processes should be permissible because the default assumptions embedded within those processes err on the side of caution. Effectively, they work to stack the deck against the defendant. Where a defendant can prove that the plaintiff has not even been exposed to the baseline minimum amount, above which there may only be the *potential* for harm, and below which the government has deemed to be safe—the defendant has proven that it can prevail even when all presumptions are stacked against it. It would be advisable for a defendant embarking on building such a case, however, to carefully consider a court's tolerance in allowing the one without the other—however legitimate the bases may be—as well as the potential strength of a risk assessment the plaintiff may develop.

Conclusion

Government and quasi-government agencies have a number of programs that classify chemicals as to their potential effects. These classifications may be legitimate exercises of public health, policy-oriented regulation. But they have no place in support of a plaintiff's case-in-chief. They have no place because they are based on standards and rules of decision that vary significantly from prevailing burdens of proof; they are thus not legally relevant, and they further pose a significant risk of confusion and prejudice. Because these classifications are so inherently conservative, however, an argument might be made that they are appropriate for defendants to use as a shield, even if not by plaintiffs as a sword. Nevertheless, defense counsel should proceed very carefully if seeking to use these classifications in their case, lest a court decide plaintiffs should be afforded the same opportunity.

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