

## MISCHARACTERIZING UNCERTAINTY IN ENVIRONMENTAL-HEALTH SCIENCES

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**Abstract.** Researchers doing welfare-related science frequently mischaracterize either situations of decision-theoretic mathematical/scientific *uncertainty* (defined in terms of purely-subjective probabilities) as situations of *risk* (defined in terms of reliable, often frequency-based, probabilities), or situations of *risk* as those of *uncertainty*. The paper (1) outlines this epistemic/ethical problem; (2) surveys its often-deadly, welfare-related consequences in environmental-health sciences; and (3) uses recent research on diesel particulate matter to reveal 7 specific methodological ways that scientists may mischaracterize lethal *risks* instead as situations of *uncertainty*, mainly by using methods and assumptions with false-negative biases. The article (4) closes by outlining two normative strategies for curbing misrepresentations of risk and uncertainty, especially in welfare-affecting science.

**Keywords:** carcinogen, default rule, diesel exhaust, diesel particulate matter, false negative, Inter-agency Review Group on Cancer (IARC), particulate matter, pollution, special interests, risk, uncertainty.

### Introduction: Epistemic and Ethical Problems with Risk and Uncertainty

Today nearly 70 percent of the global population uses cellphones,<sup>1</sup> but scientists disagree about whether they are harmful. The World Health Organization and International Agency for Research on Cancer say cellphones are likely carcinogenic to humans,<sup>2</sup> and many neuro-oncologists have confirmed a linear relationship between cell-phone usage and brain-tumor incidence.<sup>3</sup> However, some epidemiologists – mainly those paid by the mobile-phone industry – say that, despite insufficient data, their test results do not show excess brain tumors from using cellphones.<sup>4</sup> The mobile-phone debate is a typical example of scientific/mathematical disagreement about *risk* (defined in terms of reliable, often fre-

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<sup>1</sup> CISCO (2016).

<sup>2</sup> IARC (2011).

<sup>3</sup> E.g., Carlberg, Hardell (2017).

<sup>4</sup> E.g., Alexiou, Sioka (2015).

quency-based, probabilities), given that these researchers have access to frequency-based data on cellphone safety.

However, because there are neither reliable deterministic nor probabilistic/statistical explanations for some phenomena, they represent situations of decision-theoretic scientific/mathematical *uncertainty* (defined in terms of merely subjective probabilities). One example of such uncertainty is thousand-year predictions of future terrorist attacks at dangerous chemical or radiological sites.<sup>5</sup>

As the cellphone case illustrates, appropriate behavior in scientific/mathematical situations of decision-theoretic *risk* is mostly a matter of making correct epistemic and methodological judgments (mainly by using reliable data, techniques, models, and assumptions to understand the situation). Because correct epistemic and methodological judgments make the relevant risk clear, they usually provide a sufficient basis for protecting human welfare. For instance, when people are playing games of chance with fair dice, theoretically they know how to protect their financial welfare, because the risks are clear and uncontroversial.

As the future-terrorist-attacks case illustrates, however, appropriate decisions in scientific/mathematical situations of decision-theoretic *uncertainty* are much more controversial, precisely because they involve making not only reliable epistemic/methodological judgments, but also correct ethics/policy/welfare judgments in situations where there is little reliable mathematics and science on which to depend. That is, appropriate behavior under such uncertainty requires successfully addressing not only scientific, mathematical, epistemic, and methodological issues, but also many controversial questions of ethics, policy, and human welfare.<sup>6</sup>

These latter questions include how safe is safe enough? How safe is informed and consensual enough? How safe is just and fair enough? One of the most central of these ethics/policy/welfare questions is whether, in situations characterized by probabilistic/statistical uncertainty, researchers should minimize false positives (false assertions of some harmful effect) or false negatives (false denials of some harmful effect), when both cannot be minimized. To date, the answer to this last question appears to depend largely on whether the relevant science/mathematics is welfare-affecting, versus pure. That is, in situations of uncertainty in pure science, minimizing false positives appears more appropriate, both because it provides greater protection from epistemic error, and because protect-

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<sup>5</sup> US-NRC (1995).

<sup>6</sup> E.g., Harsanyi (1975); Rawls (1971).

ing human welfare (by definition) is not needed in situations of pure science. However, in situations of uncertainty in welfare-affecting science, minimizing false negatives typically is more appropriate, both because it gives people greater protection from potentially serious harm, and because when both cannot be achieved, protecting people from serious harm is more important than protecting from purely epistemic error.<sup>7</sup>

## 2. Overview: Misrepresenting Risk and Uncertainty

Two key ways that researchers, doing welfare-affecting science, can go wrong in their analyses of uncertainty and thus cause harm are by either characterizing reliably quantified, serious decision-theoretic *risks* instead as phenomena exhibiting decision-theoretic *uncertainty*, or characterizing severe threats, about which there is inherent *uncertainty*, instead as confirmed, well-understood *risks* that are minor or manageable. For instance, when some researchers deny reliable evidence for severe risk from anthropogenic climate change and instead claim it is uncertain, they do the former.<sup>8</sup> Subsequent sections of this paper analyze how some researchers misrepresent severe risk from diesel exhaust/diesel particulate matter as uncertain.

A prominent example – of how researchers can misrepresent scientific evidence of *uncertainty* about a potential catastrophe instead as evidence of a quantified, well-understood *risk* that is minor or manageable – comes from the US National Academy of Sciences investigation of the proposed Yucca Mountain nuclear-waste repository. Despite inherent, million-year *uncertainty* about this grave threat, these academy scientists claimed it is possible to do a reliable “performance assessment” to ensure the million-year safety and low *risk* of underground repositories for high-level-radioactive waste and spent-nuclear fuel.<sup>9</sup>

To begin the analysis of mischaracterizations of risk and uncertainty, this article surveys the often-deadly, welfare-related consequences of such mischaracterizations in environmental-health sciences. Next it uses recent research on diesel particulate matter to reveal 7 specific methodological ways that scientists can mischaracterize lethal *risks* instead as situations of *uncertainty*, mainly by using false-negative biases. Finally it outlines two possible normative strategies for curbing such misrepresentations.

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<sup>7</sup> Shrader-Frechette (2014): 196-205, (1993). See previous note.

<sup>8</sup> Conway, Oreskes (2010); Shrader-Frechette (2014); Michaels (2008); McGarity, Wagner (2012).

<sup>9</sup> US-NRC (1995); Shrader-Frechette (1996).

### 3. Harm from Mischaracterizing Scientific Risk and Uncertainty

What can happen as a result of mischaracterizing decision-theoretic risk and uncertainty? Especially in areas of environmental-health science, such as pollutant-or-product safety, such mischaracterizations can stop, or at least delay, regulations that could help protect people from threats to life.

Mischaracterizing serious, confirmed *risks* instead as a situations of *uncertainty* often occurs when polluter-paid scientists wish to dismiss well-known, pollution-caused risks (like anthropogenic climate change) as phenomena whose causes are inherently uncertain.<sup>10</sup> Yet the consensus of leading medical scientists is that pollution annually causes roughly 8.4 million premature, preventable, global deaths, 5.5 million of them, through air pollution. Preventable pollution thus annually kills far more people than malnutrition, obesity, alcohol-and-drug abuse, and unsafe sex. It is at least the fourth-leading cause of death, not far behind high blood pressure, the greatest global health threat.<sup>11</sup>

### 4. Welfare Harm from Characterizing Diesel-Exhaust Risks as *Uncertain*

Consider how the US Environmental Protection Agency (US-EPA) characterizes confirmed, quantifiable, severe diesel-vehicle-exhaust *risks* as *uncertain*, thus contributes to inadequate regulation and completely preventable, diesel-induced, lung-cancer deaths. Consider also how the International Agency for Research on Cancer (IARC), part of the World Health Organization (WHO), and virtually all other medical-scientific groups avoid this mischaracterization, thus contribute to stricter diesel regulations and saving thousands of people/year from avoidable death from diesel exhaust.

For many decades, lung cancer has been the most common cancer in the world. Virtually all medical/health experts, including IARC-WHO, say that lung cancer prematurely and avoidably kills 170,000 people/year in the US and 1,600,000 people/year globally. These international experts agree that scores of independent, replicated, animal, human, experimental, and observational studies show that roughly 6 percent of all lung-cancer deaths are caused by diesel-engine exhaust, almost all by diesel particulate matter (DPM), by far the deadliest component of diesel exhaust. Scientists often measure DPM threats as a surrogate for diesel-exhaust threats. If diesel exhaust/DPM were adequately regulated, up to 96,000 global deaths/year and 10,200 US deaths/year could be saved. The international medical-scientific consensus is that regulations that mandate DPM filters,

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<sup>10</sup> McGarity, Wagner (2012); Michaels (2008).

<sup>11</sup> Cohen et al. (2017).

ultra-low-sulfur diesel fuel, and old-diesel-engine retrofitting could stop most of these premature, preventable deaths.<sup>12</sup>

Why don't all governments require DPM filters and other safeguards for all diesel vehicles? Part of the reason appears to be that some scientists reject international medical-scientific consensus about diesel *risk* and instead say that it is merely an *uncertain* threat.

#### 4.1. Welfare Benefits from Characterizing Serious Diesel Risks as Risks

The recent history of scientific analyses of diesel exhaust begins with a classic 1989 IARC-WHO study of diesel-exhaust carcinogenicity. For the study, about 30 IARC/WHO scientific experts, drawn from different nations, carefully examined roughly the 500 major animal-experimental and human-epidemiological scientific studies done 1921–1989 on diesel exhaust and cancer. As a result, the 1989 IARC-WHO study concluded that “Diesel engine exhaust is probably carcinogenic to humans.” IARC made this determination because although there were scores of compelling, well-controlled animal experiments confirming diesel-exhaust carcinogenicity, there were only a handful of human-epidemiological studies having reliable, measured, diesel-exhaust doses. Instead most human-epidemiological experimenters merely recorded years of workplace exposure to diesel exhaust and consistently found that the higher the years of diesel exposure, the greater the numbers of lung-cancer.<sup>13</sup> Consequently, IARC-WHO voted to wait for the completion of the large (tens of thousands of subjects), dose-quantified, US National Institutes of Health (NIH) study of underground workers exposed to diesel-exhaust equipment, before it made its assessment of whether diesel exhaust was a *known*, rather than merely a *probable* human carcinogen.<sup>14</sup>

Immediately after IARC-WHO publicized its 1989 conclusion, the state of California began its own diesel studies – and with good reason. California has the sixth-largest economy in the world, after the US, China, Japan, Germany, and the UK,<sup>15</sup> and the largest population of any US state. California also has some of the dirtiest air in the US, mostly from diesel exhaust, and thus strong incentives to protect its citizens. Post-1989 diesel assessments by the California Environmental Protection Agency (CAL-EPA) included hundreds of animal studies and more than 30 human-epidemiological studies, many done during the 1990s among workers exposed to diesel exhaust/DPM; they tied diesel-exhaust exposure to in-

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<sup>12</sup> IARC (2017); Vermeulen et al. (2014).

<sup>13</sup> E.g., US-NIOSH (1988); Garshick et al. (1988).

<sup>14</sup> IARC-WHO (1989): 153

<sup>15</sup> Reuters (2016).

creased-lung-cancer risk.<sup>16</sup> (Given its population and pollution problems, California has long applied “emissions standards which are more ambitious than federal [US] standards.” The US government also allows other US states to adopt the more-stringent California standards, which 15 states already have done. California’s diesel-emission standards are not only stricter than US standards, but both California and the US have “tighter [diesel-emission] standards and [a] more advanced stage of implementation” than the EU.)<sup>17</sup>

In 1992, the US National Cancer Institute (NCI) and National Institute for Occupational Safety and Health (NIOSH) set out to obtain more robust human-epidemiological data on diesel-exhaust/DPM risk. That year they began jointly administering the \$12 million Diesel Exhaust in Miners Study (DEMS). This retrospective cohort-mortality and nested-case-control study of 12,315 workers showed a clear association between increasing diesel-exhaust exposure (from mining equipment) and increasing lung cancer.<sup>18</sup>

In 1993 California required cleaner-burning-diesel fuel – partly because of CAL-EPA’s scientific assessments, occupational studies, and the 1988 US NIOSH assessment of recent diesel-exhaust studies. NIOSH warned that workplace-diesel exposure is tied to lung cancer, that recent animal studies “confirm an association between the induction of cancer and exposure to whole diesel exhaust. The lung is the primary site identified with carcinogenic or tumorigenic responses following inhalation exposures.” NIOSH also said human-epidemiological data “suggests an association between occupational exposure to diesel-engine emissions and lung cancer,” especially because of “the consistency of these [animal]-toxicologic and [human]-epidemiologic findings.”<sup>19</sup>

In 1998 CAL-EPA, relying on NIOSH, other US-government, and its own studies, identified DPM, the deadliest part of diesel exhaust, as a toxic air contaminant because of its potential to cause cancer in humans.<sup>20</sup> In the same year, 1998, an IARC Advisory Group recommended “that diesel engine exhaust be treated as a high priority for re-evaluation.”<sup>21</sup>

By 1999, both American Public Health Association (APHA) and the Cambridge, Massachusetts scientists from the Health Effects Institute (HEI) had inde-

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<sup>16</sup> E.g, Steenland et al. (1992).

<sup>17</sup> EP (2016): 9, 14, 15, 19, 31.

<sup>18</sup> Silverman et al. (2012); Attfield et al. (2012); see Furlow (2012).

<sup>19</sup> US-NIOSH (1988).

<sup>20</sup> CARB (1998); CARB (2016a).

<sup>21</sup> IARC-WHO (2012): 34.

pendently, quantitatively confirmed the diesel-exhaust/DPM and human-lung-cancer association. Again they confirmed the *consistency* of this cancer risk across both human-epidemiological and animal studies.<sup>22</sup>

In 2001, as a result of repeated, consistent, confirmation of the diesel-exhaust-lung-cancer association in both animals and humans,<sup>23</sup> CAL-EPA required cleaner diesel engines in the state. In 2003, it also issued stronger requirements for cleaner diesel fuel.<sup>24</sup>

Yet in 2008 CAL-EPA calculated that its diesel standards still were not strict enough. On the basis of even more scientific evidence,<sup>25</sup> it concluded that mobile-pollution sources like vehicles continued to caused 90 percent of California's total-air-pollutant-cancer risk, but vehicle DPM alone caused 70 percent of these cancers. Of 188 government-monitored air toxics such as lead, benzene, mercury, and DPM, CAL-EPA said DPM alone causes 7 times more cancer than all the other 187 air toxics combined.<sup>26</sup> CAL-EPA warned in 2008 that roughly 20,280 then-current California residents would die prematurely from lifetime DPM exposure and that such deaths would continue unless the state put better regulations in place.<sup>27</sup>

In 2008, as California discovered increased evidence of DPM harm, it required additional diesel regulations. Beginning in 2012, it required DPM filters on all, and retrofitting all pre-2010, heavy-duty-diesel trucks/buses that operate in California.<sup>28</sup>

California's extensive analysis of diesel risk and its resulting, strictest-in-the-world diesel regulations seem to have worked. CAL-EPA reported that during 1990-2012, California's DPM concentrations declined 68 percent, California's DPM-caused cancers declined by nearly 76 percent, nearly 100,000 California residents thus were saved from premature death, yet California's population increased 31 percent, diesel vehicle-miles-traveled increased 81 percent, and California's gross-state product increased 74 percent.<sup>29</sup>

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<sup>22</sup> Lipsett, Campleman (1999); HEI (1999).

<sup>23</sup> E.g. Silverman (1998); Bhatia et al. (1998); Crump (2001).

<sup>24</sup> CARB (2016b).

<sup>25</sup> E.g., Garshick et al. (2004, 2008); Laden et al. (2006); Hoffmann, Jöckel (2006).

<sup>26</sup> CATF (2005a, 2005b); CAL-EPA (2008); SCAQMD (2008); See US-EPA (2014b).

<sup>27</sup> SCAQMD (2005); SCAQMD (2008); CARB (2016a, 2016b).

<sup>28</sup> CAL-EPA (2011).

<sup>29</sup> Propper et al. (2015).

Finally, in 2012, IARC-WHO (and virtually all medical-scientific associations who had not done so earlier) essentially confirmed what California-government scientists concluded earlier. IARC-WHO confirmed that the diesel-exhaust threat is *not uncertain* but instead poses a well-confirmed, quantifiable, severe *risk* as a “known human carcinogen.” IARC-WHO called for stricter diesel regulations.<sup>30</sup> Unfortunately, however, these 2012 IARC-WHO conclusions should have been published in 1995. Their publications were delayed solely because of diesel-industry legal actions against journals and scientists who were slated to publish the US NIH-NIOSH findings that confirmed diesel/DPM was a “known human carcinogen.”<sup>31</sup> In 2012, when they were finally published, the EU immediately enacted regulations requiring DPM filters, cleaner diesel fuel/engines, and retrofitting older diesel vehicles, similar to what the state of California began doing years earlier.

#### 4.2. Welfare Harm from Characterizing Diesel Risks as Uncertain

Despite the IARC-WHO, APHA, HEI, US NIOSH, and other confirmations of diesel-caused human cancers, the US Environmental Protection Agency (US-EPA) – that sets US diesel regulations – continues to deny (as of 2017) that diesel exhaust/DPM is a “known human carcinogen” *risk* that requires stricter regulations. Instead it says this carcinogenicity is *uncertain*. US-EPA claims hundreds of controlled-human-epidemiological and animal-experimental studies are too uncertain to develop a DPM quantitative unit risk estimate (URE), without which US-EPA says it cannot provide a precise, quantitative, human-cancer risk.<sup>32</sup>

Because US-EPA scientists have not defined diesel exhaust/DPM as a “known human carcinogen,” US-EPA has not designated diesel exhaust/DPM as a “hazardous air pollutants” As a result, diesel pollution does not face greater regulation under the 1990 US Clean Air Act (CAA) Amendments.<sup>33</sup>

This lack of CAA regulation is one reason that in the US, only 2007-and-later, heavy-duty-diesel vehicles must have DPM filters. Unlike the EU and the state of California, the US requires no engine-retrofit for 80 percent of the 15 million heavy-duty-diesel-transport trucks responsible for the majority of diesel pollution. These vehicles have lives of one million miles/30–40 years. Thus weak US (not California) diesel regulations mean that the 11 million oldest/dirtiest/long-

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<sup>30</sup> IARC (2012). See Neumeyer-Gromen et al. (2009) and Olsson et al. (2011).

<sup>31</sup> Furlow (2012).

<sup>32</sup> US-EPA (2014a). CATF (2005a, 2005b).

<sup>33</sup> CFR (2012). US-EPA (2014c).



-distance-heavy-duty-diesel trucks remain largely unregulated. They will continue to release hundreds of tons of DPM/day, for at least another 30–40 years.<sup>34</sup>

The health consequences of US failure to name diesel exhaust/DPM a “known human carcinogen” are massive. By using diesel DPM filters and retrofits, as mandated by California and by the EU, the US could avoid 90 percent of DPM from traditional diesel exhaust. That is why the US Clean Air Task Force estimates that if the US immediately implemented diesel retrofitting and filters, it would save nearly 4000 US lives/year.<sup>35</sup>

## 5. An Objection

Preceding sections of this paper have summarized the health benefits from naming diesel exhaust/DPM a “known human carcinogen” *risk*, reducing its exposure, and thus following international medical-scientific consensus that the human threats from diesel are not *uncertain*. However, one might object that whether diesel-exhaust/DPM-caused lung cancer is a confirmed risk, or uncertain, is part of what is at issue in the diesel debate. Consequently, objectors might say that the preceding *quantitative discussions of diesel harm* beg the question that diesel pollution actually is a risk to humans.

Yet as already explained, even US-EPA, denying that diesel exhaust/DPM is a “known human carcinogen” risk, says it can provide upper-bound “estimates” of lives saved by reducing diesel pollution.<sup>36</sup> In other words, despite US-EPA “estimates” of diesel-pollution lives saved, US-EPA considers those estimates neither reliable nor able to avoid basic uncertainty about the diesel-lung-cancer association. Instead, as US-EPA says, its diesel-harm estimates merely provide “a sense of the possible significance of the lung-cancer hazard from environmental-[diesel] exposure,” yet give neither “a definitive quantitative characterization of cancer risk” nor a quantitative “estimation of exposure-specific population risks.... The development of risk estimates does not constitute endorsement of their... suitability for estimating numbers of cancer cases.”<sup>37</sup> Thus this article’s analysis does not beg the diesel risk-versus-uncertainty question but simply repeats US-EPA estimates to show that “the stakes are high” in this diesel-risk-versus-uncertainty debate.

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<sup>34</sup> CFR (2012). US-EPA (2014c).

<sup>35</sup> CATF (2005b); see US-EPA (2014b).

<sup>36</sup> US-EPA (2016b).

<sup>37</sup> US-EPA (2002): 8–16.

How should one determine who is right in the diesel risk-versus-uncertainty debate? One first step is considering potential methodological problems with US-EPA scientists' claiming that diesel human-carcinogenicity is uncertain.

## 6. US-EPA's Three Reasons for Claiming *Uncertainty* about DPM Risk

Often when researchers mischaracterize situations of serious, well-confirmed mathematical/scientific *risk* as situations of *uncertainty*, they use scientific methods that produce false-negative accounts of that risk. Consequently, they claim that because their methods showed no *risk* of harm, therefore the situation is one of *uncertainty*. Some of the most common false-negative biases are to use studies with low power, small-sample sizes, or short duration, all of which usually make tests too insensitive to detect some harmful risk.<sup>38</sup>

Besides using insensitive tests for risk, other false-negative biases arise when scientists use methods/assumptions that set too high a standard for confirming some risk. For instance, as the following DPM-cancer analysis reveals, scientists may have a false-negative bias if they require an environmental-health-risk probability

- to be known with *near-infallible certainty*, something that never obtains outside of a closed system of logic that is inapplicable to empirical science;
- to be explained by a specific *causal mechanism*, something that is not necessary for affirming probabilistic risk; or
- to meet the same standards of methodological precision as those for *pure science*.

Consider whether the US-EPA, in rejecting international scientific consensus by characterizing DPM risk instead as a situation of uncertainty, shows any false-negative methodological biases.

In its latest (2015) assessment of the 187 air-toxics, of which DPM is one, US-EPA stated: "Note that in this assessment, the potential carcinogenic risk from diesel PM is not addressed because there currently is no unit risk estimate available." Immediately after this single sentence, the US-EPA document offers only one tab to click, "Learn more about the EPA's qualitative assessment of diesel PM."<sup>39</sup> When one clicks this tab, one finds only the decades-old, 2002 US-EPA, diesel-

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<sup>38</sup> Shrader-Frechette (2014): 196–205.

<sup>39</sup> US-EPA (2015).

exhaust, health assessment.<sup>40</sup> This 2002 document provides only three reasons that US-EPA scientists (unlike most other international experts) say the DPM-human-cancer *risk* is *uncertain*. These three uncertainties focus, respectively, on the lack of historical-DPM-exposure data, on ignorance about DPM-human-cancer mechanisms, and on the absence of a quantitative URE and PM/DPM cancer hazard.

The first US-EPA reason for the absence of a quantitative DPM-human-cancer *risk* (the lack of historical-DPM-exposure data),<sup>41</sup> is questionable because the latest studies cited by US-EPA's 2002 diesel assessment are from 2001. These studies are outdated by decades and predate the best, classic 2012 IARC-WHO and US NIH/NIOSH studies that used "historical measurements" of diesel "exposure data" for tens of thousands of US miners exposed to diesel- polluting underground equipment.<sup>42</sup> Because US-EPA did not update its decades-old analysis and because it ignored the best studies, all of which developed a quantitative DPM-human-cancer *risk*, US-EPA begs the question and assumes there is no quantitative-DPM-human-cancer risk. Thus the first of three US-EPA arguments fails, on grounds of logic.

The second US-EPA reason for the absence of a quantitative DPM-human-cancer *risk* (ignorance about DPM-human-lung-cancer mechanisms) also errs, and on both logical and conceptual grounds. The main logical problem with US-EPA's second argument is that it again begs the question (this time, about the absence of a DPM-human-lung-cancer mechanism) because it fails to address any DPM studies since 2001. Yet many scientists claim to have confirmed the existence of such mechanisms.<sup>43</sup> For instance, the classic 2012 IARC-WHO studies, confirming the quantitative risk of DPM as a "known human carcinogen" explicitly included not only animal experiments that showed "strong mechanistic evidence" for DPM carcinogenicity, but also human-epidemiological evidence that DPM can induce human-lung cancer through genotoxic mechanisms.<sup>44</sup> IARC confirms that DPM induces "DNA damage (e.g., oxidative lesions and bulky adducts), gene mutations, DNA-strand breaks, chromosomal alterations (e.g., chromosome breaks, sister-chromatid exchange, and aneuploidy) and morphological-cell transformation in vivo and in vitro" in mice, rats, rodent primary cells, rodent-, and human-cell

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<sup>40</sup> US-EPA (2002): 8-16.

<sup>41</sup> US-EPA (2015).

<sup>42</sup> US-EPA (2002): 8-16.

<sup>43</sup> E.g., Steiner et al. (2016).

<sup>44</sup> IARC (2012): 461.

lines, and gene mutations in bacteria.<sup>45</sup> Yet the outdated US-EPA second argument examines none of these data.

Moreover, US-EPA may be misleading in claiming that mechanisms of DPM-induced-human-lung cancer are unknown. Researchers have long known that all cancer occurs in part as a result of chronic inflammation, and that PM causes inflammation wherever it settles in the body.<sup>46</sup> Even US-EPA itself admitted, more than a decade ago, that possible DPM-cancer mechanisms included chronic inflammation and producing reactive-oxygen species, both long-established cancer mechanisms.<sup>47</sup>

The main conceptual problem with US-EPA's second DPM argument (that there is no mechanism associated with the DPM-lung-cancer risk) is that one can know *that* something is a carcinogen – without knowing the precise mechanism by which it causes harm, *how* it causes harm. Indeed, the history of science/medicine has many examples *showing that* scientists typically confirm harm from something before *showing how* some mechanism caused this harm. A decade before the germ theory of disease, physician John Snow *knew that* cholera in London spread through contaminated water. Hence he convinced officials to remove the handle from a London water pump, so that more people would not die. Yet Snow did not *know how* some mechanism caused the contaminated-water deaths. Had Snow waited for knowledge of this *how*, before warning *that* contaminated water spread disease, thousands more Londoners would have died of cholera. The same is true for potential DPM-related deaths.

### 7. US-EPA's Third Reason for Claiming DPM-Human-Cancer Uncertainty

What about US-EPA's third reason for claiming the DPM-lung-cancer hazard is *uncertain*, namely, its denying a quantitative DPM unit-risk estimate (URE)?<sup>48</sup>

Subsequent sections of this article investigate 7 methodological and epistemic reasons that US-EPA likely errs in claiming that hundreds of controlled-human-epidemiological and animal-experimental studies are too uncertain to develop a DPM URE and lung-cancer-risk estimate.<sup>49</sup> Namely, US-EPA:

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<sup>45</sup> Ibidem: 461.

<sup>46</sup> E.g., Coussens, Werb (2002).

<sup>47</sup> Cogliano (2002): 17.

<sup>48</sup> US-EPA (2002): 7-145; US-EPA (2015).

<sup>49</sup> US-EPA (2014a); CATF (2005b).

1. *Begs the question* whether most other distinguished scientists erred in developing a URE.
2. *Is internally inconsistent* with US-EPA's own words because US-EPA says that it cannot develop a DPM numeric estimate of cancer risk/URE because existing data are uncertain; yet US-EPA says that the URE range is between 1 in 1,000 and 1 in 100,000 – and that diesel exhaust is a likely human carcinogen that ranks among those posing the “greatest relative risk.” How can US-EPA claim to know relative *risk* and yet claim something is *uncertain* and not a quantified risk?
3. *Is internally inconsistent* in requiring certainty about a point-estimate URE, because this requirement contradicts US-EPA's own “weight of evidence” and “coherence” approach to cancer-risk assessment.
4. *Is conceptually incoherent* because uncertainty about the precise *measurement* of some causal relationship is not the same thing as uncertainty about the *fact* of that relationship.
5. *Ignores the different requirements of pure and welfare science*, partly because it contradicts US-EPA's own warning not to emphasize the precise certainty of cancer harm with the serious consequences of that harm.
6. *Is externally inconsistent with good science*, as it presupposes a Cartesian account of certainty as near-infallibility rather than an empirical-science account of certainty “beyond a reasonable doubt.”
7. *Seems practically irrelevant* because scientists agree that DPM has no safe dose, and that both ends of US-EPA's “URE range” put DPM well inside the level of extremely dangerous hazards that must be regulated as much as possible.

Consider, in order, each of the preceding apparent flaws in the No-DPM-URE claim by US-EPA.

### 7.1. Question-Begging in the No-URE Argument

When US-EPA scientists say that uncertainty in the hundreds of diesel studies do not allow them to develop either URE or DPM-cancer-risk figures, they beg the question about whether most other distinguished scientists erred in developing a URE. They beg this question in providing no analysis whatsoever of *why* the URE of IARC-WHO, CAL-EPA (used by other states like New Jersey, New York, and Washington), the HEI, the US-NIOSH,<sup>50</sup> and so on, are wrong.

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<sup>50</sup> E.g., NJDEP 2016. As US-EPA (2016a) notes: “In 2012, [US-]EPA requested that the Health Effects Institute (HEI) evaluate the suitability of the new epidemiology studies for developing a cancer potency [URE]. In November 2015, HEI published its *report* on these new studies, and concluded

Yet as early as 1998, the Scientific Review Panel for the California Air Resources Board estimated the URE for DPM as 3 cancers per 10,000 persons per  $\mu\text{g}$  DPM.<sup>51</sup> This URE is 2 orders of magnitude higher than that required to trigger federal regulations, and other scientists have confirmed that the URE for DPM is at least this high.<sup>52</sup> Yet, US-EPA has neither named DPM a human carcinogen, nor explained what is allegedly wrong with this URE, nor argued precisely why “the available data are not sufficient to develop a confident [URE] estimate.”<sup>53</sup> US-EPA question-begging in the DPM case is especially worrisome because the stakes are so high in this debate. CAL-EPA scientists say that roughly 84 percent of south-coast-California-air-pollution risk is from diesel exhaust. Many people might die if US-EPA is wrong here.<sup>54</sup>

In rejecting these other UREs without arguing what is wrong with them, US-EPA also fails to follow standard US-EPA guidelines for situations of uncertainty. These guidelines recommend expert elicitation in cases of uncertainty,<sup>55</sup> like the URE for DPM. Yet, if one uses expert elicitation in the DPM case, it seems reasonable to rely on the unanimous and apparent consensus-judgment of IARC-IARC, CAL-EPA, HEI, US NIOSH, and so on, that DPM presents “a known human carcinogen” risk.

## **7.2. Internal Inconsistency in the Third or No-URE Argument**

US-EPA scientists also seem internally inconsistent with their other US-EPA statements when they claim that DPM uncertainty does not allow them to develop a DPM-URE/cancer risk, and thus name DPM a “known human carcinogen.” Yet these US-EPA scientists say the DPM-URE range is between 1 in 1,000 and 1 in 100,000; that DPM/diesel exhaust is a likely human carcinogen; and that it ranks among the deadliest pollutants, like dioxins, that pose the “greatest relative risk.”<sup>56</sup> US-EPA scientists seem unable consistently to claim both that uncertainty prevents developing a quantitative-DPM-URE/cancer risk – yet to claim specific quantitative risk ranges and relative risk for DPM.

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that they are sufficiently robust to estimate quantitative cancer risks.” US-EPA thus did not follow the advice of its own consultants.

<sup>51</sup> CAL-EPA (2008). CATF (2005b).

<sup>52</sup> Rosenbaum et al. (2011).

<sup>53</sup> US-EPA (2010).

<sup>54</sup> SCAQMD (2008).

<sup>55</sup> US-EPA (2005): 3–32.

<sup>56</sup> US-TTN (2016).

### 7.3. Weight-of-Evidence Inconsistency in the Third Argument

Because US-EPA DPM assessors apparently ignore DPM-cancer “weight-of-evidence” (WOE) considerations, their results appear contrary to assessment methods mandated by the US-EPA, IARC-WHO, and most medical-scientific assessors.<sup>57</sup> WOE requires “a collective evaluation of all pertinent information”; because of WOE, US-EPA warns that no single “assessment factor” like point-estimate UREs, are necessary for WOE.<sup>58</sup> Yet US-EPA scientists who assess DPM claim its threat is uncertain mainly because they have no quantitative DPM URE/cancer-risk figures.

Moreover, other federal agencies also warn against the US-EPA-DPM demand for point-estimate UREs. The US Occupational Safety and Health Administration (OSHA) issues this warning against URE demands when it explains the carcinogenicity of wood dust.

In response to those commenters who argued that none of the studies...presented sufficient dose-response data...for establishing a [precise URE] limit, the Agency emphasizes that it is not relying on any single study to determine...risk of material health impairment. Instead, OSHA is making this determination [of known human-cancer harm] on the basis of the findings in...dozens of studies... The Agency finds...these studies biologically plausible and their findings reproducible and consistent... Some of these studies, like all human studies, have limitations of sample size, involve confounding exposures, have exposure-measurement problems, and often do not produce the kind of dose-response data that can be obtained when experimental animals are subjected to controlled laboratory conditions. What the large group of [human-epidemiological] studies being relied upon by OSHA...do show is that the overall weight of evidence that such exposures are harmful and cause loss of functional capacity and material impairment of health is convincing beyond a reasonable doubt.<sup>59</sup>

Contrary to US-EPA claims of “uncertainty” because of its having no point-estimate URE, OSHA does not claim “uncertainty” in such cases. Instead OSHA says WOE provides certainty “beyond a reasonable doubt” because human-epidemiological and animal-experimental studies are “biologically plausible... reproducible, and consistent,” despite the fact that human-epidemiological situations “often do not produce the kind of dose-response data that can be obtained

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<sup>57</sup> IARC (2012).

<sup>58</sup> US-EPA (2011): 6, 3–33, 230.

<sup>59</sup> CFR (1989).

when experimental animals are subjected to controlled laboratory conditions.”<sup>60</sup> This OSHA warning seems to undercut US-EPA claims of DPM-human-cancer uncertainty.

The US-EPA cancer guidelines and US OSHA-wood-dust conclusions also are consistent with good scientific methodology because they do not ignore the role of consistency and coherence in science and do not focus on a single point-estimate URE, as US-EPA does in the DPM case. Especially in areas of science that deal with very small or very distant phenomena, such as high-energy physics and radio-astronomy, scientists rely heavily on consistency, coherence, and WOE. And especially in areas of science that are extremely complex/inaccessible/not manipulable, but mainly model-able, such as climate science, geology, hydrology, ecology, and parts of medical/public-health sciences, researchers must rely heavily on consistency, coherence, and WOE.

If US-EPA had relied on consistency, coherence, and WOE, instead of demanding a point-estimate URE, it might have developed a DPM URE, just as CAL-EPA, IARC-WHO, US NIOSH, and other scientists did. After all, CAL-EPA researchers focused on consistency/coherence when they noted their URE “was derived from two separate approaches which yield similar results.”<sup>61</sup> Similarly, the US NIH relied heavily on consistency, coherence, and WOE when it concluded that DPM caused human cancer:

Other comparisons showed similar levels of agreement... Method evaluations indicated that the final estimates were consistent with those from alternative-time-trend models and demonstrated moderate to high agreement with external data.<sup>62</sup>

In short, US OSHA, NIH, NIOSH, IARC-WHO did not demand the impossible, as US-EPA appears to do. Instead, they relied on consistency, coherence, and WOE.

#### **7.4. Conceptual Incoherence in the Third or No-URE Argument**

Another flaw in the US-EPA-DPM analysis is its apparent conceptual incoherence. It seems incoherent for US-EPA to claim that the absence of a DPM point-estimate URE/cancer probability dictates the absence of a known human-causal relationship for DPM-induced cancer. Uncertainty about a point-estimate measurement of some cause need not entail uncertainty that it is a cause. Besides, US-EPA itself says that in seeking air-pollution:

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<sup>60</sup> Ibidem.

<sup>61</sup> CAL-EPA (2008).

<sup>62</sup> Stewart et al. (2010).



[...] standards that provide an adequate margin of safety, the [US-EPA] administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful, but also to prevent lower pollutant level that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.<sup>63</sup>

Thus, US-EPA itself says that knowing the precise URE/cancer risk is not necessary for identifying a known human risk, any more than knowing the tempo and mode of anthropogenic climate change is necessary for confirming anthropogenic climate change itself.<sup>64</sup>

If not, then US-EPA DPM analyses appear conceptually incoherent in confusing the fact of DPM-cancer risk with its *precise measurement*. Indeed, US-EPA warns in its cancer-assessment guidelines, that “the data that support cancer assessments generally are not suitable for numerical calculations of the probability that an agent is a carcinogen.”<sup>65</sup> Again, US-EPA DOM-cancer assessment appears inconsistent with US-EPA cancer-assessment guidelines.

### 7.5. Ignoring Differences in Science in the Third Argument

Because US-EPA DPM assessment appears to overemphasize URE *probability* point-estimates and underestimate practical welfare *consequences* of not confirming DPM-human carcinogenicity, it also confuses differences between pure and welfare-related sciences. US-EPA’s DPM assessment seems more appropriate for pure sciences, where the highest epistemic standards dominate because, by definition, there are no relevant welfare-related threats in pure science. Yet in welfare-related sciences – like those concerned with DPM harm – potentially dire consequences, such as many human deaths, might trump the importance of knowing point-estimate-cancer probabilities before confirming a human-cancer risk.

Besides, US-EPA cancer-assessment guidelines specifically warn that “weighing of the evidence includes addressing not only the *likelihood* of human-carcinogenic effects...but also the conditions under which such *effects* [consequences] may be expressed.”<sup>66</sup> In other words, because it is critical to avoid grave consequences (like many DPM or climate-change deaths), scientists arguably should tolerate less quantitative precision in welfare-related scientific decisions about probabilities.

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<sup>63</sup> US-EPA (2013): 3090.

<sup>64</sup> Oreskes (2007, 2004).

<sup>65</sup> US-EPA (2005): 2–53.

<sup>66</sup> Ibidem: 1–12.

### **7.6. Requiring an Empirically Unrealistic Certainty in the Third Argument**

Another flaw in the US-EPA analysis – that claims “uncertainty” about whether DPM is a “known human carcinogen” – is that US-EPA seems to build its case on an empirically unrealistic, Cartesian account of certainty, rather than on the standard-scientific account of certainty as “beyond a reasonable doubt.” Cartesian certainty typically requires something close to infallibility, something that transcends the logical possibility of error; yet empirical science never claims such transcendence,<sup>67</sup> including in demands for point-estimate UREs.

Moreover, there are few good practical reason for US-EPA to demand a point-estimate-DPM URE, or else claim uncertainty about DPM human carcinogenicity. The current DPM URE, used by IARC, CAL-EPA, and so on, spans a range of 100, two orders of magnitude.<sup>68</sup> Yet this is still a relatively narrow range, given that risk assessors accept standard-interspecies (from animals to humans) variation/uncertainty that spans one order of magnitude, and intraspecies (within-humans) variation/uncertainty that spans another order of magnitude.<sup>69</sup> Besides, as earlier section 7.2 showed both ends of the DPM-URE range present extraordinarily high risks, on the order of dioxin, and both ends are well within the range of US-EPA high-risk threats that require federal regulation. Given all these factors, there are no clear grounds for EPA’s assuming that it needs a DPM-URE/cancer range less than two orders of magnitude, in order to deny DPM-human-cancer uncertainty.

### **7.7. Requiring Impractical Knowledge of Cancer Potency in the Third Argument**

Particulate matter (PM) itself presents another, related problem with the US-EPA claim that diesel “data are not sufficient to develop a quantitative estimate of carcinogenic potency” for DPM and therefore not sufficient to name DPM a “known human carcinogen.”<sup>70</sup> This problem is that, for more than a decade, scientists have universally agreed with the classic US NIH statistically-robust, long-term, 600,000-member-air-pollution studies that show no safe dose of PM<sub>2.5</sub>.<sup>71</sup> This is fine-particulate pollution (PM<sub>2.5</sub>), each particle of which is two and one half microns or less in width.

The absence of a safe dose of PM<sub>2.5</sub> arises from its small size and therefore very large surface area, ability to penetrate bodily barriers including the blood-

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<sup>67</sup> Scriven (1974): 229–230.

<sup>68</sup> US-EPA (2010).

<sup>69</sup> E.g., US-EPA (2014d).

<sup>70</sup> US-TTN (2016).

<sup>71</sup> Pope, Dockery (2006); Pope et al. (2009).

brain barrier, and its extraordinarily high inflammatory properties. Each PM<sub>2.5</sub> particle thus can move directly and immediately into the brain and lungs, then to the blood and all organs, where it can cause inflammation, oxidative stress, blockage, diseases like cancer, or death.<sup>72</sup> Because virtually all DPM is PM<sub>2.5</sub>, because DPM is responsible for nearly all diesel-exhaust risk, and because diesel exhaust is a major source of PM<sub>2.5</sub>, the preceding air-pollution findings mean that DPM has no safe dose. Thus, US-EPA claims that diesel “data are not sufficient to develop a quantitative estimate of [URE and] carcinogenic potency,” and therefore not sufficient to name DPM a “known human carcinogen,”<sup>73</sup> seem beside the point, almost practically irrelevant. Why?

If all PM<sub>2.5</sub> is a known-human carcinogen with no safe dose, and if both ends of the US-EPA DPM-URE range fall within the range of the deadliest chemicals that government says must be regulated, then US-EPA should attempt as soon as possible to reduce DPM as much as possible. Admittedly the regulatory urgency might be less for a pollutant that had a safe dose. But a DPM-URE seems less relevant for a known carcinogen that has no safe dose. US-EPA could lower DPM risks by a factor of 10, yet still be within the range in which US regulation was required. That is, US-EPA could be reasonably confident that it was not overregulating in naming DPM a known human carcinogen.

## **8. One Solution: Enforcing Methodological Norms for Regulatory Science**

How might other scientists avoid some of the same mistakes about uncertainty that US-EPA researchers appear to make? One way might be for professional scientific associations to mandate norms for welfare-related science used for regulatory purposes. Such norms are especially needed because welfare-related scientists often face pressures from regulated industries. Roughly 50 percent of all environmental-health scientists report being harassed by industry groups because of their pollution findings.<sup>74</sup> As already noted, for at least 17 years, the diesel industry successfully blocked US NIH-NIOSH DPM studies that showed increased cancers among miners from underground-diesel-equipment emissions. Both problems might be reduced if the methodological norms used in welfare-related and regulatory science were both clear and clearly enforced.

One suggestion for such methodological norms comes from prominent medical and environmental scientists, responding to a recent US-EPA pesticide

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<sup>72</sup> IARC (2012).

<sup>73</sup> US-TTN (2016).

<sup>74</sup> McGarity, Wagner (2008).

case that has been dominated by chemical-industry litigation. The case began in 1993 when a committee of the US National Academy of Sciences warned that existing US-pesticide regulations did not adequately protect US children from pesticide-induced neurological and developmental effects.<sup>75</sup> As a result of this warning, the US Congress passed the Food Quality Protection Act (FQPA) of 1996 that mandated an increased, 10-fold, “safety factor” for allowable pesticide residues – unless by 2006 new pesticide studies could show that this 10-fold safety factor was not needed to protect children. (This factor is in addition to the two existing, 10-fold, safety factors, respectively, for interspecies and intraspecies variation/uncertainty.)

In response to the 1996 law, the chemical industry began conducting 22 different pesticide experiments on children, seeking to avoid the additional 10-fold safety factor mandated by FQPA.<sup>76</sup> When Congressional investigators examined these 22 human-pesticide experiments that industry submitted for regulatory rule-making, they found not only that the experiments harmed children and failed to obtain parental informed consent, but also that they dismissed adverse outcomes and lacked scientific validity. The lack of scientific validity arose from all the studies’ being designed to produce false-negative results about pesticide harm and not even measuring possible neurological or developmental harm. All of the pesticide-industry studies were of short duration (hours or days with a few several months long), too short a time to detect neurodevelopmental harm in infants, and all had low power and small sample sizes.<sup>77</sup> By using the wrong tests, endpoints, study-duration, sample sizes, and assumptions, none of the chemical-industry studies found any neurodevelopmental harm from known-neurotoxic pesticides. As a result, in 2006 the US Bush administration weakened pesticide protections for US children, precisely because it relied on these unpublished, scientifically flawed, chemical-industry studies.<sup>78</sup>

The US government used unpublished, flawed, chemical-industry studies (that defined severe, quantifiable, pesticide *risk* as *uncertain*) and therefore failed to protect US children in precisely the way that the US National Academy of Sciences and the US Congress said children should be protected. Top scientists warned that although government has ethics requirements for its studies, “the US-EPA has no formal, detailed...requirements at the present time” for any scientific research

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<sup>75</sup> Shrader-Frechette (2007).

<sup>76</sup> Ibidem.

<sup>77</sup> Ibidem.

<sup>78</sup> Ibidem.

“submitted by private corporations for use in making regulatory decisions.” Thus US-EPA (and likely many other government agencies throughout the world) need both *methodological* requirements for its own welfare-related science and *methodological and ethical requirements* for research provided by special interests for use in setting policies/regulations.<sup>79</sup>

To remedy the preceding scientific and ethical deficiencies exhibited with the pesticide studies, the Center for Children’s Health and the Environment of New York’s Mount Sinai School of Medicine convened an expert workshop for leading ethicists, physicians, scientists, and policy analysts. During a peer-consensus process, they developed 12 unanimous recommendations for doing welfare-related science in a regulatory context.<sup>80</sup>

Interestingly, in the DPM case, US-EPA appears not have followed at least 4 of these 12 Mt. Sinai recommendations, namely, those dealing with using biased research, enforcing research guidelines, ensuring scientific validity, and taking account of possible environmental-justice consequences. Below are the four recommendations.

Recommendation 1: Government should develop research guidelines for all research that a government regulator “conducts, sponsors, or accepts,” in order to prevent conflicts of interest, false-negative bias, inadequate peer review, and so on.

Recommendation 4: “Oversight and enforcement mechanisms must be developed and implemented” by government agencies “to ensure compliance” with guidelines.

Recommendation 8: “Any study that is not scientifically valid—for example, does not include a sufficient number of subjects to provide statistically valid answers to the questions under investigation—must not be considered in [regulatory] standard setting.”

Recommendation 11: “Human biomonitoring must be conducted” for every pollutant “currently in use or present in the environment and that poses human exposure risks. Special consideration must be paid to the body burdens... in children.”<sup>81</sup>

US-EPA’s own Scientific Advisory Board also emphasized preceding recommendations 8 and 11. It warned that “Bad science is always unethical; research protocols that are fundamentally flawed, such as those with sample sizes inade-

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<sup>79</sup> Oleskey et al. (2004): 917-918.

<sup>80</sup> Ibidem.

<sup>81</sup> Ibidem.

quate to support reasonable inferences about the matter in questions, are unjustifiable.” It also dictated that

[...] any policy adopted by the [US-EPA] Agency must reflect a special concern for the interests of vulnerable populations, such as fetuses, children, adolescents, pregnant women, the elders, and those with fragile health due to compromised respiratory function or other reasons.<sup>82</sup>

If US-EPA’s DPM assessments begin to follow the preceding recommendations, especially 4, 8, and 11, at least three benefits might occur. (1) US-EPA would seem more likely to take account of DPM’s special neurodevelopmental and environmental-justice risks to children.<sup>83</sup> (2) It also might avoid unreliable, 2002 science about DPM and instead use the latest science. Finally, (3) US-EPA might ensure compliance with its own cancer-assessment guidelines, and thus to avoid both overemphasizing URE point-estimate *probabilities* and underestimating the potentially harmful *consequences* of not naming/regulating DPM as a human carcinogen.

### 9. Another Uncertainty Solution: Recognizing Special Interests Scientific Bias

Of course, US-EPA may not have named DPM a “known human carcinogen” because it feared repetition of the 17-year regulatory delay caused by the court challenges of the diesel industry. Industry might again use the same costly, delaying, tactics that it used to avoid diesel regulations of mining. After all, the powerful trucking and diesel industries repeatedly have used the courts to try to block clean-air and DPM standards. They have long lobbied and presented “research” against naming DPM a “known human carcinogen.” Both industries also have tried to block diesel and DPM studies – fearing what researchers would discover – and yet argued, at the same time, that such studies were needed prior to any additional DPM regulation.<sup>84</sup>

“From the early days,” says a prominent science-journal editor, DPM studies have “been subject to a series of legal actions [including lawsuits] initiated by industry bodies concerned about...[regulatory] implications, which has delayed the publication of these [DPM] papers.”<sup>85</sup> Indeed, industry-caused publication delays have been especially obvious in the classic studies of how DPM harms under-

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<sup>82</sup> US-EPA-SAB (2000).

<sup>83</sup> E.g. Calderón-Garcidueñas et al. (2014).

<sup>84</sup> Monforton (2006).

<sup>85</sup> Ogden (2010): 727.

ground miners using diesel-powered equipment.<sup>86</sup> A coalition of diesel-industry interests led a successful, 17-year battle to stop release of the classic US NIH studies showing sharp lung-cancer increases in tens of thousands of miners exposed to emissions of underground-diesel equipment. Those classic studies were only published in 2012,<sup>87</sup> 20 years after they began, and 15 years after their long-term follow-up concluded.

NIH DPM-lung-cancer-study publication delays occurred because the diesel industry in 1992 used its congressional representatives and the courts to try to keep the DPM studies from being done. When that eventually failed, the industry argued (in response to proposed new DPM regulations) that adequate scientific studies (the very ones that the industry tried to block) had not yet been completed. In 1999, the diesel industry used the courts to begin blocking release of study results by suing and demanding that industry be allowed to review all scientific data prior to publication. In 2001, when the US Department of Labor issued new DPM regulations, the industry successfully blocked them. Again in 2005 the diesel industry again used the courts and industry-friendly Congresspeople to delay the 2005 DPM regulations until 2011. Meanwhile, the industry succeeded in delaying the publication of the NIH's classic DPM-miners' study until 2012.<sup>88</sup>

To simply view US-EPA methodological problems with "uncertainty" about DPM-human carcinogenicity as another scientific problem – and to ignore the financial/regulatory/political biases in the DPM battle – is to misunderstand how/why discussions of scientific uncertainty often take place amid conflict of interest. This means that resolving many contemporary debates over scientific uncertainty demands more than merely scientific understanding. It also demands taking account of external factors that bias the scientific process. Of course, reasonable people have disagreements over the conduct of research, and obviously no scientific findings should be assessed as unbiased or biased, simply on the basis of who or which scientists developed them. However, regardless of who is right in the DPM case, there is no justification for trying either to stop a legitimate study or to prevent its release, especially a study that has massive human-health consequences, that has undergone legitimate peer review and evaluation of its protocols, and that has been accepted for scientific publication.

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<sup>86</sup> Monforton (2006).

<sup>87</sup> Silverman et al. (2012); Attfield et al. (2012).

<sup>88</sup> Ibidem.

## 10. Conclusion

The preceding accounts – of methodological flaws in US-EPA treatment of uncertainty about DPM risks and of how biased science and special interests may encourage mischaracterization of grave pollution risks as *uncertain* – are important in part because they show that epistemology and philosophy of science should not be divorced from real-world ethics and concerns about the common good. These practical problems also are unlikely to go away, the way theoretical resolution makes pure-science problems go away. Instead practical uncertainty problems in applied and welfare-related science are likely to be ongoing because so much science is tied to profits and markets. That is one reason, even now, that the trucking and diesel industries have multiple lawsuits to stop pollution regulations, including a lawsuit alleging that the state of California has no legal right to try to protect its people from DPM pollution.<sup>89</sup>

Resolving such lawsuits – and the costs they impose on public health and public monies – would be easier if scientists, ethicists, and philosophers of science were more aware, both of the way that science often is done in the real world, and of the way that special interests can dominate both scientific and health-related decisions. With such awareness, scholars might better understand and help remedy the problems that “real world science” encounters. Without such efforts, “uncertainty” and inadequate regulation may continue to plague welfare-affecting and regulatory science.

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<sup>89</sup> Lobet (2017).



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