

Hearing on “Mismanaging Chemical Risks: EPA’s Failure to Protect Workers”

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Environment and Climate Change Subcommittee***

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Chairman Tonko, Ranking Member Shimkus, and Members of the Subcommittee—thank you for the opportunity to testify on this important topic.

I am one of the few individuals in the 49 years since OSHA and EPA were created who was fortunate enough both to have directed the rulemaking operations of one of the agencies (OSHA) and to have served as a Regional Administrator in charge of all enforcement, partnership, and outreach operations in one of the ten regions of the U.S. (also at OSHA). As Director of Health Standards at OSHA for five years in the 1990s, I helped promulgate five of the eight chemical exposure regulations OSHA has issued over its past 27 years, including our 1997 rule on methylene chloride (MC). I have served on the EPA Science Advisory Board, its Board of Scientific Counselors, and was a member of both of the two committees that the National Academy of Sciences has convened (in 1994 and in 2009) to review EPA’s progress in using sound methods of quantitative risk assessment to help it regulate and communicate with the public. Before joining the faculty at Michigan, I taught cost-benefit analysis, decision theory, and regulatory law and policy at Princeton, Rutgers, and the University of Pennsylvania.

I am a strong supporter of quantitative risk assessment and cost-benefit analysis, having helped pioneer some of the methods now in common use at EPA and elsewhere to estimate risk from carcinogens and non-carcinogens, quantify uncertainty in health risk

¹ For identification only: the views I am expressing here are my own and not necessarily those of the University of Michigan School of Public Health.

and regulatory cost, and assess the impact of regulation on jobs, longevity, quality of life, and public perceptions. Recently, I helped lead a multi-year project at the Univ. of Pennsylvania exploring how by “listening, learning, and leading,” regulatory agencies around the world could succeed or fail at being a “best in class” agency (Coglianese 2016).

I will discuss EPA’s recent actions and inactions, and its science and pseudo-science, by trying to answer the following four questions: (1) Why *should* EPA protect workers from chemicals?; (2) How and why did Congress give EPA statutory authority to help protect workers?; (3) How is EPA failing to help workers? and (4) How is EPA also failing to help all citizens, regardless of age, race, or income, who are also exposed to toxic substances?

My central message is that I know how much time and effort so many Members, staff, and stakeholders put into revising TSCA over decades, culminating in the Lautenberg Act. Every paragraph in that law was carefully crafted to balance competing interests (not necessarily the way I think they should have been balanced, but that’s why you are here for years and I’m here for a few hours). The law requires EPA to provide protections to workers, and requires it to use all reasonably available information and the best available science to do so. EPA’s actions and inactions over the past two years with regard to TSCA are an affront to the legislative process. I think many of its current actions will eventually be overturned as contrary to the plain meaning of the law, arbitrary and capricious under the APA, and unscientific, and that some of its unjustified and impermissible delays will result in court-ordered deadlines—but these remedies will take time during which workers and non-workers will suffer needlessly. *In the hope of righting a ship that has veered far off course, Congress needs to give EPA clear direction to follow the law it enacted, and to oversee the Agency’s corrective actions.*

1. *Why should EPA protect workers?*

It is not well-understood that occupational exposures to toxic chemicals remain a huge public health problem, and *by far* the major harmful impact of these substances that

EPA has been studying and controlling since 1970. All of the independent biostatistical studies of the problem agree that roughly 50,000 U.S. workers each year die prematurely (primarily from cancer, lung diseases, and cardiovascular disease) from toxic exposures on the job (Leigh 2011, Steenland et al. 2003, Leigh et al. 2004). If we chose to list these deaths in their own category where they belong, occupational disease would be the 9th leading cause of death in the U.S., just below influenza/pneumonia and just above kidney disease and suicide. We have deindustrialized the nation to some extent in the past decades, but (see below) while exposures to asbestos, benzene, and other substances have declined, the overall problem is not decreasing significantly, as other exposures stay high and new substances replace older ones, sometimes with equal or greater toxicity.

In various federal environmental statutes (SDWA, FQPA, CAA Amendments, etc.), Congress has instructed EPA to reduce grave risks to a level of one chance in one million where possible. OSHA, however, has always chosen to interpret the 1980 Supreme Court decision in the *Benzene* case to require it only to reduce worker risks to below one chance per *thousand*.² Based on this difference, one might think that, concentrations of toxic substances in workplaces would generally be about 1000 times higher ($1,000,000 \div 1000$) than we are exposed to in our communities. But the reality is far worse: I've looked at many chemicals, comparing the roughly 3 million air samples OSHA has taken against EPA's measured and modeled concentrations in communities, and found that occupational levels are ten thousand, often *one million times higher* than in the ambient environment (Finkel and Ryan, 2007). There is a reasonable belief that because workers are compensated and (ought to be!) informed about their risks before bearing them, they can face more risk than the general population—but a million times more? *To fulfill EPA's primary mission—protecting human health—the Agency has always sought to prioritize larger problems over smaller ones.*

Most importantly, EPA should begin its risk assessment and management in the workplace, because the risks themselves begin there. *The reason* that those of us who don't

² This is (unfortunately) so even though the Supreme Court merely said that OSHA should stop reducing toxic-substance concentrations when it reached risk levels of somewhere *between* 1/1000 and one in one *billion*. See *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980).

work for half our waking hours still face chronic-disease risks from the air we breathe is largely because these exposures emanate from workplaces. Just like it is cheaper to put salt on a frozen sidewalk than to put a plate into a broken leg, *the most efficient way to reduce concentrations in the general environment is to reduce them where they are highest, so they don't diffuse as much into the air that non-workers breathe all day and that workers breathe when they come home at night.* In many cases, businesses will find it less expensive and illogical to control workplace and environmental exposures *simultaneously using integrated controls* than to install controls that only deal with one half of the problem or the other, and then have to retrofit later. Worst of all, there is growing evidence (Piltingsrud et al. 2003; OSHA/NIOSH/EPA 1999) that in some cases, pollution control devices required by EPA reduce emissions to the general environment *by increasing them inside the plant/factory.*

For all these reasons, EPA's Air Office and Chemicals Office should regard workers exposed to chemicals as their *primary* constituency; EPA does not ignore water pollution because Congress also created the Fish and Wildlife Service, and it shouldn't ignore workers just because we also have an OSHA.

2. *Why was EPA given statutory authority to protect workers?*

Of course, TSCA is not the first or only statute that has given EPA authority to protect workers, either on its own or in conjunction with OSHA (notably, FIFRA and pesticide applicators; CAAA and the Risk Management Plans). But with regard to TSCA, I've been dismayed to see industry groups, notably the Halogenated Solvents Industry Alliance (HSIA, 2016) and the American Chemistry Council (ACC, 2017), advancing the factually-incorrect claim that EPA *must* coordinate with OSHA before doing anything that might reduce worker risks, and making the misleading claim that TSCA is only supposed to be used to protect workers when OSHA has declined to regulate.

The legal errors in these misstatements are easy to correct. TSCA §9a, 15 USC 2608(a), has been unambiguous since TSCA's first enactment in 1976: once the EPA Administrator determines that a chemical poses an unreasonable risk, AND "determines, **in**

[her] discretion,” that the risk might be reduced by OSHA or another agency “to a sufficient extent,” she needs to check in with that agency to seek their input before regulating and to give that agency a chance to take the lead (emphasis added). HSIA miquotes §9a to “require[] unreasonable risks to be addressed under statutory authority other than TSCA wherever possible.” That statement has been *untrue* for the past 43 years, and the 2016 amendments strengthened EPA’s hand further by requiring it to act even when the risk affects only a “potentially exposed or susceptible subpopulation,” which of course now includes workers explicitly.³

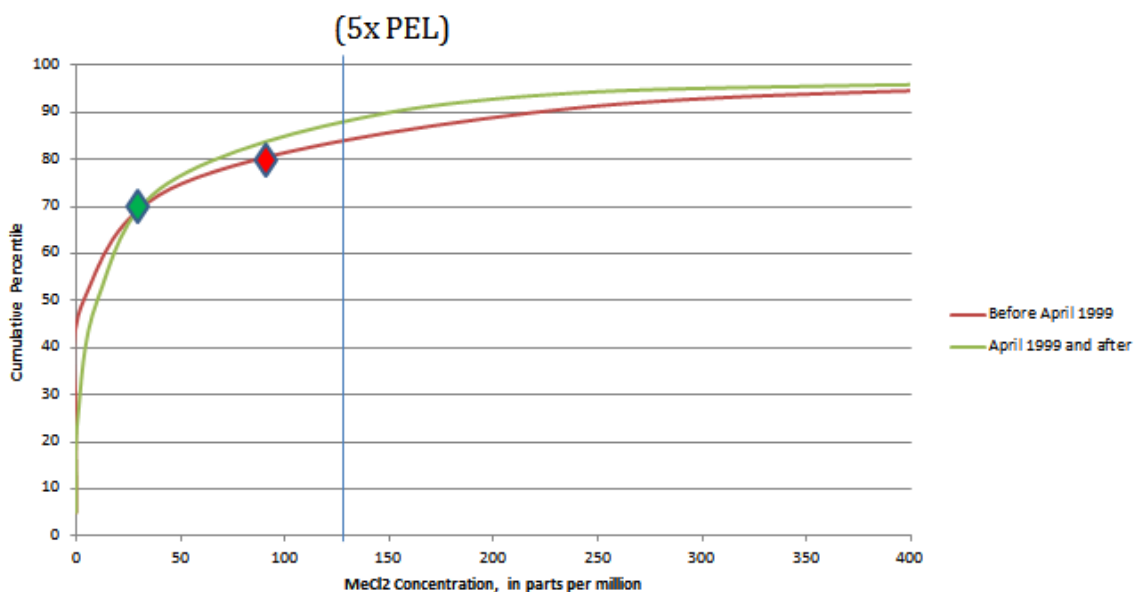
Why did Congress instruct EPA to consult with OSHA, but at its discretion? *The answer is that for most or all of the chemical risks EPA finds are unreasonably high to workers, OSHA’s accurate answer to the question “can you do more?” would be “no,”* and so asking the question will complicate and delay a simple question of whether unreasonable risks will indeed be reduced. I have very high regard for the dedication and accomplishments of my former colleagues and staff at OSHA, but for many reasons, OSHA is simply overmatched and unable to reduce unreasonable risks. Among other things:

- OSHA cannot (by law or appropriations riders) provide any protection to public-sector workers, independent contractors, do-it-yourselfers, employees at small farms, or bystanders whose only exposures occur because in proximity to hazardous work;
- OSHA’s budget is about 1/20th the size of EPA’s across-the-board, but is particularly thinly-funded in rulemaking. In 49 years, OSHA has only set comprehensive standards for 19 chemical substances, as compared (for example) to over 1000 such standards by the German equivalent of OSHA.
- As I mentioned before, OSHA *stops* regulating at a risk level far above where EPA would normally *start* reducing risk. The OSHA “1 case of grave disease in 1000” goal is the highest risk level at which any public health agency anywhere in the world, to my knowledge, would contemplate declaring “mission accomplished.”
- Congress and the Supreme Court also circumscribed OSHA’s ability to regulate, in two important ways: (1) it must demonstrate “significant risk,” which gives it a higher

³ ACC notes that §9(d) of TSCA requires EPA to coordinate with other agencies so as to “impose the least burdens of duplicative requirements.” There is, *of course*, no “duplication” if OSHA at one time allows employers to use a chemical so long as they control it to a certain concentration, and if EPA then later imposes a ban on such use.

burden of proof than EPA's when human epidemiologic data on effects is still being assembled; and (2) it must show "economic feasibility," which severely limits OSHA's ability to require engineering controls that reasonable employers haven't *already* installed and found effective. EPA, by contrast, can consider the benefits of banning a substance, or one or more of its uses, without regard to these constraints.

- OSHA simply has never given a proportionate amount of its own attention to worker health, as opposed to worker safety. Although OSHA claims that about 20-25% of its inspections are undertaken to look for health hazards, I've analyzed the data and found the true percentage is closer to 2-3%⁴. This helps explain why, unfortunately, even in the 19 cases where OSHA has set a modern exposure limit, *workplace exposures remain significantly above even the relatively lax limits OSHA has set*. We will be talking a good deal about methylene chloride (MC) today, a probable human carcinogen and known cause of acute cardiovascular death. I led the development of that standard, which was promulgated in 1997 and took full effect in 1999. Even at the time of promulgation, OSHA admitted that it was impermissibly weak by law, because we knew the risk at the new Permissible Exposure Limit (PEL) of 25 ppm was too high but we had failed to analyze the economic feasibility of a 10 ppm level (at which the risk would have been just at the magic 1/1000 cutoff). *But employers have widely failed to comply even with that weak exposure limit*.



⁴ The discrepancy is easily explained: OSHA codes any inspection that one of its inspectors with an industrial hygiene (IH) personnel classification does as a "health inspection," but the IHs at OSHA are increasingly being called upon to perform safety inspections at fixed establishments and construction sites.

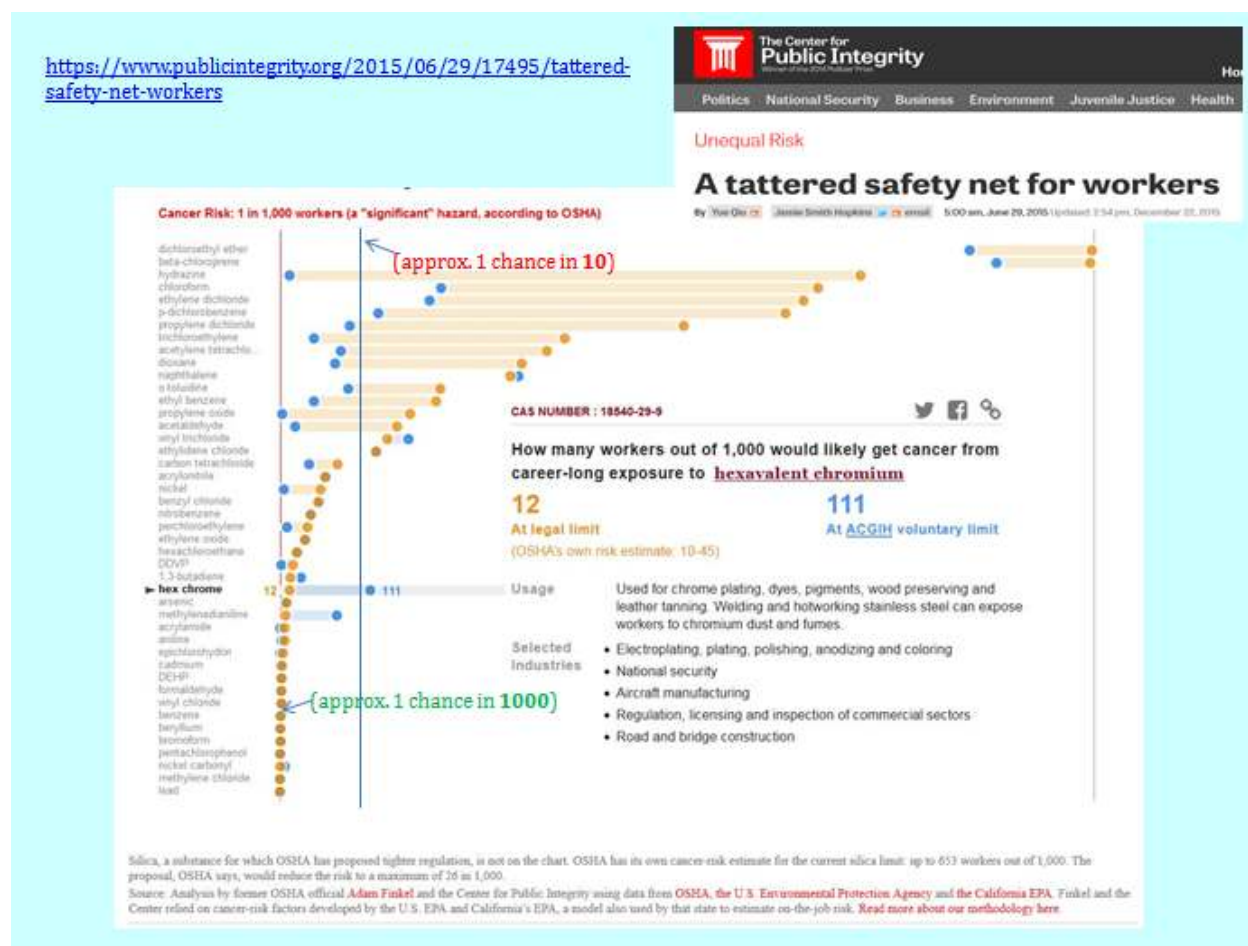
I've analyzed the more than 12,400 air samples of MC that OSHA has taken during all of its inspections between 1984 and 2018. The chart above (cumulative distribution of all samples, in ascending order of concentration, for the pre- and post-rule time periods) shows that the average MC level found in U.S. workplaces for the 15 years before the new standard was about 85 ppm (see the red diamond)—but in the 19 years since the standard took full effect, exposures have only gone down to an average of 69 ppm (green diamond), nearly three times higher than the legal limit. *Both before and after the standard, the same proportion (66 percent) of samples exceeded the PEL, and still about 12% of all samples are above five times the PEL.* These disheartening data, which are similar for other substances OSHA has regulated, show that EPA is simply wrong to assume, as it has in the MC and 1-bromopropane problem formulation documents, that current worker risks are at all constrained by what OSHA has made legally permissible.

I emphasize that I've looked at the establishment names for all 12,400 samples, and although as expected there are many small businesses among them, OSHA also found violations of its 25 ppm PEL at many multi-billion-dollar corporations, including some of the nation's largest automobile, furniture, mattress, aircraft, photographic film, athletic shoe, chemical, paint, and piano manufacturers.

And as unreasonable as *these* worker risks are (3.6 cancers per thousand workers, *even if* employers complied with the MC standard, plus several acute fatalities each year among workers and more among independent contractors), methylene chloride is a *regulated* chemical, and OSHA has regulated only a vanishingly small fraction of all the chemicals workers are exposed to. The chart below, which I helped the Center for Public Integrity create several years ago (Hopkins 2015), emphasizes the excess cancer risk levels for several dozen chemicals where OSHA can only enforce grandfathered standards it inherited in 1970. The yellow circles show the risk levels would often exceed *one chance in ten* if employers allowed levels this high⁵; this is why former OSHA Assistant Secretary

⁵ In a separate analysis (Finkel 2013), I looked at the roughly 500 OSHA PELs that were set (almost all of them in 1970 based on prior consensus standards) to consider *non*-carcinogenic health effects. I compared them with the EPA Reference Concentrations (RfCs) for each substance; the RfC is supposed to be a concentration

David Michaels said last year (Michaels 2018) that “no major company follows the OSHA PELs, and they’d be crazy to do so.” *THIS is why Congress increased EPA’s authority to protect workers when it amended TSCA just a couple of years ago: because if we seek to take the most meaningful steps towards eliminating unreasonable risks our society has allowed from chemical exposures, all roads lead to the workplace.*



And yet, I have rarely seen a more brazen, more inaccurate, and more offensive statement in my 35 years in and around government as this one from ACC’s March 2017 comments to EPA on the first ten TSCA chemicals: “given that OSHA protocols are designed to regulate risk to worker populations, *it should be the unusual case where an unreasonable risk may present to a worker population under conditions of use*” (emphasis added). I am

that provides substantial protection against the health effect, but is not without some risk. In the vast majority of the cases, the OSHA PEL was between *500 and 10,000 times higher than the RfC*.

here to emphasize that **in every single case** where OSHA has regulated and in every single case where OSHA has not regulated, **unreasonable risks to workers do remain**. Fifty thousand annual premature deaths, and workplace concentrations tens of thousands of times higher than EPA limits, attest to the willful blindness of ACC's statement and to the need for Congress to make good on its legislative amendments.

3. *How is EPA failing to protect workers?*

EPA's current indifference to the "most unreasonable" risks in its purview (the workplace) manifests in various different ways. I see at EPA a general pattern rather clumsily designed to make worker risks "go away" without doing anything helpful. These occur both in specific TSCA evaluations of high-volume chemicals and in the dozens of §5(a)(3) determinations EPA is making on premanufacture notifications (PMNs).

Among the most troubling general tendencies of the recent EPA documents on chemicals with worker exposures are:

- Excluding many "legacy uses" of substances. This is inappropriate and arbitrary, since in some cases (e.g., asbestos products previously used in manufacturing and construction) it is precisely the remediation, maintenance, and disposal tasks where workers are exposed to the highest concentrations.
- Violating one of the most fundamental principles of industrial hygiene by estimating worker exposures based on the assumed concentrations inside of properly-functioning and properly-fitting respirators (and the risks of dermal exposure assuming properly-functioning gloves). OSHA and the IH field in general rely on the "hierarchy of controls," which puts engineering controls (and substitution of less hazardous substances) above personal protective equipment (PPE) in terms of desirability and often regulatory requirements (in many OSHA standards, employers cannot achieve the PEL by using respirators until they have exhausted feasible substitutions and engineering controls). This principle exists because respirators are hard to fit properly, prone to leakage both through the filter media and at the seal with the wearer's face, and can place a physiologic and a safety burden on the user.

- Inappropriately imagining OSHA authority that doesn't exist. For example, in the recent draft risk evaluation for Pigment Violet 29, EPA stated that "oral and inhalation exposures for downstream processors and users are possible; however, occupational exposures from these downstream users are likely to be limited due to the expected use of PPE (per Safety Data Sheet for C.I. Pigment Violet 29)." This statement is doubly inaccurate. First, PPE does not reliably "limit" exposures, as discussed above. More importantly, though, EPA is assuming that *recommendations* by the manufacturer of a toxic chemical, present on the Safety Data Sheet, create any obligation on the part of the employer. This is the most fundamental misreading possible of the entire OSHA Hazard Communication Standard (HCS), which creates obligations for manufacturers to create and disseminate accurate information, and for employers to make the Data Sheets available to workers, but as the standard clearly says, "while the ... HCS requires the provision of information on recommended control measures, including respiratory protection, personal protective equipment, and engineering controls, *there is no requirement for employers to implement the recommended controls*. An employer should use all available information when designing an appropriate protective program, but a recommendation on a Safety Data Sheet by itself would not trigger the need to implement new controls." (77 *Federal Register* No. 58, March 26, 2012, p. 17693).

Specific Case Examples:

Methylene Chloride:

If, as expected, EPA publishes a rule this week or next that abandons the proposed rule's steps towards protecting workers from MC exposure, there is no scientific or legal doubt that it would be failing to follow Congressional intent: the unreasonable risks that OSHA was unable to control will remain. Apparently, EPA will soon move forward with a truncated final rule to "protect" only consumers, but (see below) it is not clear whether its chosen means of consumer protection make any sense now that the January 2017 proposed rule will be split in two. EPA will apparently turn back the clock on worker protection by several years or more and begin from scratch with a pre-rule announcement leading to a "training, certification, and limited access program" for workers exposed to MC. Besides abdicating its responsibility, there are two giant problems with this approach. First, in most cases the only respirators that provide any protection against MC (supplied-air respirators) require more expensive retrofits of the workplace than the engineering

controls that would reduce concentrations below the OSHA PEL. So, training workers in this setting is not likely to reduce exposure and risk unless EPA requires actual controls instead of placing the onus on the worker. Secondly, in the proposed MC rule itself, EPA already considered and rejected that very option: “EPA viewed the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products as a significant limitation for this approach” (82 *Federal Register* No. 12, 1/19/17, p. 7474). Finally, whereas a use ban on MC for paint and coating removal, as proposed (with the proposed exemption for military needs), would not (see footnote 3 above) have run afoul of the TSCA §9(d) requirement to avoid duplication with OSHA, a training program *does* duplicate various provisions of our 1997 MC rule, and would therefore seem less compliant with TSCA than what EPA proposed in 2017.

1-Bromopropane:

1-bromopropane (1-BP) is a potent multi-site animal carcinogen and a known cause of human neurological damage (NIOSH 2016; Urbina 2013). In 2011 a state environmental agency and an industry group (competitors of the 1-BP manufacturers) petitioned EPA to add 1-BP to the list of 188 Hazardous Air Pollutants in the Clean Air Act Amendments. By law, EPA had 18 months to rule on this petition. As an expert in hazard classification and risk assessment, I can assure you that this decision was literally a no-brainer: the legal criteria for addition require the Administrator merely to judge whether an air pollutant is “known or reasonably may be anticipated to cause adverse effects to human health.” No estimation of the probability or severity of such effects is relevant, and science has known about 1-BP’s unequivocal neurotoxicity since around 2004 (when many human case reports and controlled epidemiologic studies were available), and known it to be a carcinogen since roughly 2006.⁶

⁶ Indeed, several major manufacturers in the U.S. and Europe ceased all production of 1-BP circa 1999-2001, when earlier reports and data were already indicative of extreme toxicity.

But it took EPA until 2015 to propose adding 1-BP to the HAPs, and until January 2017 to announce that it was prepared to add it based on the comments received. Inexplicably, the EPA later in 2017 repeated a call for more comments, and has taken no steps to finalize that listing since. In my October 2017 comments to that docket, I urged EPA to require OCSPP Deputy Assistant Administrator Nancy Beck to play no part in this listing decision, because when she was an ACC staff member she testified before an EPA committee in 2015 and offered many flatly erroneous comments trying to exculpate 1-BP as an animal carcinogen.

The disdain for workers during this EPA proceeding has been extreme. The two most relevant facts here are: (1) 1-BP has caused neurological damage in workers exposed to roughly 7 ppm, and in the animal cancer bioassay, mice exposed to 62.5 ppm developed lung tumors at 8 times the rate of control animals; and (2) to put these levels in perspective, I've analyzed the roughly 250 samples OSHA has taken for 1-BP between 1998 and 2015, and found the *average* workplace exposure of roughly 30 ppm, with nearly 15 percent of all samples exceeding 62.5 ppm. In 35 years of doing risk assessments based on animal data, I have never seen a case where so many worker exposures exceed the doses found to be highly carcinogenic in the laboratory—the animal exposures are designed to be high enough to show enormously high rates of cancer, which we hope never to see in humans. And yet, EPA appears to take seriously comments prepared for industry by Gradient Corp., stating that “the exposure concentrations used by the National Toxicology Program (62.5 - 500 ppm) are several orders of magnitude greater than those modeled for ambient air ... [and therefore] may be qualitative with regard to potential carcinogenic effects, but not reliable for quantitative extrapolation from animals to humans.”

Let's parse that sentence more clearly: with no evidence to support this claim, Gradient says that we may not be able to reliably *extrapolate* risks from higher doses to lower ones, but fails to mention that human *workers* are at this moment breathing *more* 1-BP than the animals who got cancer did. It's not uncommon for the chemical industry and some academic scientists to “manufacture doubt” and say without foundation that “because the animals were exposed to more than humans would be, we can't be 100% sure of the

human risk,” but cavalier in the extreme to say so when the animals were exposed to *less* than the humans are! Yet again, workers don’t count: but TSCA says EPA must count them.

I am concerned that although EPA’s May 2018 TSCA “problem formulation” document on 1-BP promises to conduct risk assessments for the major occupational uses, it will underestimate occupational exposures (I have a more complete database, received under a successful FOIA lawsuit in 2007, than OSHA has made available to the public, and have sent all the 1-BP (and the MC) samples to EPA), will repeat the unfounded claims about uncertainty in cancer dose-response, and will fail to conclude that *by definition*, the neurotoxicity risk is unreasonable at or above a few ppm, given the human case reports and epidemiologic studies, and that therefore an acceptable level of human exposure to 1-BP should be in the part per billion range.

Trichloroethylene:

EPA has moved proposed rules to ban the use of TCE in vapor degreasing and spot cleaning from “active” status on its Regulatory Agenda to a “long-term action.” From my years at OSHA, I know that “long-term action” is often a euphemism for “never.”

Pigment Violet 29:

EPA’s draft risk assessment for PV29 turns the scientific rules for weight of evidence on their head, inappropriately concluding that PV29 is “unlikely to be a carcinogen” based on two ostensibly “negative” studies of an endpoint (genotoxicity) that has only a limited value in predicting carcinogenicity, and on a vague “consideration of the structural activity of the compound.” I’ve analyzed one prominent case (NTP, 2013) to show how pronouncements about structure-activity relationships can be completely wrong: the peer-reviewed article by Rozman and Doull (2002) claiming that 1-BP would be found non-carcinogenic in a bioassay ongoing at that time. Soon thereafter, it was found to be a more potent animal carcinogen than the “analogous” chemical Rozman and Doull were using to make their structural claim. It is also troubling that EPA bases all its worker (and general-

population) exposure estimates for PV 29 on a single “personal communication,” whose content is not revealed to the public, from a manufacturer of the substance.

Various PMNs:

I’ve looked at a small but representative sample of recent EPA Determinations for Premanufacture Notice, and all of them seem to rely on the “voodoo industrial hygiene” concept that “workers will use appropriate PPE, consistent with the Safety Data Sheet prepared by the PMN submitter, in a manner adequate to protect them.” This cavalier statement fails to consider, of course, whether the PPE will in fact result in acceptably low risks if it is used as recommended, or whether the employers who use the manufacturer’s product will follow the SDS in the absence of legal requirements for them to do so.

A General Observation:

I have interacted with EPA officials for three decades, and I’ve not seen before the kind of public statements from political appointees that signal such disdain for occupational health and such incomprehension of basic environmental/occupational health science. Here are two examples:

- Weeks before his confirmation hearing, during oral argument seeking (unsuccessfully) to overturn over OSHA’s new silica standard in front of DC Circuit, Bill Wehrum told the Court that “people are in dusty environments all the time, and it doesn’t kill them.” This displays a shocking misunderstanding of how scientific evidence works (risk *means* that not everyone will die when exposed), of how many workers *do* die “all the time” in dusty environments, and how fractured silica particles are “not just dust.” Hippocrates and Pliny the Elder wrote about silicosis 2000 years ago, but the head of EPA’s Office of Air and Radiation apparently didn’t get that memo.
- In 2017, the former acting head of OCSPP reportedly was concerned (Lipton, 2017) that her deputy (Nancy Beck) regarded failure to follow warning labels for MC as the cause of acute worker fatalities. Beck apparently offered that “only a small number,”

either around 1 percent or less than that proportion, had been harmed by the solvent. To give Beck the most benefit of the doubt about her statement, she was suggesting that a risk of 1 in 10 would *not* be acceptable, but that risks below that would be—this from an Agency instructed by Congress for decades to regard risks below 1 in 1 million (5 orders of magnitude lower than 1 in 10) as acceptable.

4. *How is EPA failing everyone else under TSCA?*

Some of the flaws in recent TSCA actions—and inactions—do not only imperil workers, but will leave the *other* 150 million Americans without needed protections. Again, reducing worker exposures is often the most efficient way to reduce general-population exposures. But it must also be said that even workplace toxicants not “emitted” into the general environment can harm non-workers: (1) science is increasingly finding (Julvez and Grandjean 2009; Anderson 2005) that children born to workers – both women and men—who are exposed to chemicals on the job are at increased risk of a variety of health problems, including cancer, neuro-developmental disorders, and reproductive problems; and (2) families of workers can be exposed to unreasonable risks from the smaller quantities workers bring home on their clothes, hair, and skin (Knishkowsky and Baker 1986; NIOSH 1995).

In addition to giving a few specific examples of how recent TSCA actions leave behind unreasonable risk across-the-board, I want to then step back, having advised EPA on risk assessment methodology since the 1980s, and offer some cautionary observations about unscientific and illogical steps EPA is taking more generally.

- The MC rule that is at OIRA as of this writing may harm consumers as well as workers. EPA has also delayed any action on n-methyl-pyrrolidone (NMP), which consumers can purchase in a variety of paint-stripping formulations, even though there are safer and equally (or more) effective substitutes for MC (Morose et al. 2017). It is also not clear if and how consumers will be protected if workers have continued access to small cans of MC. The means of protecting consumers in the

2017 rule was simply to ban the sale of MC in drums of less than 55 gallons; now, this safeguard may no longer be applicable since unaffected “commercial uses” presumably include the needs of independent contractors.

- In its 1-BP problem formulation document, EPA says that “consumers will avoid 1-BP for engine degreasing because it is expensive.” That is an interesting bit of behavioral-economics speculation, but EPA is not allowed by TSCA to avoid analyzing an exposure pathway because it asserts that consumers will not avail themselves of an unregulated and permissible use for a product.

The most far-reaching erosion of protections to consumers and residents, however, may well come from ways in which EPA, led to some extent in this by OCSPP, is either continuing to underestimate risk (particularly cancer risk) to every citizen, or actively seeking to underestimate risk more severely than ever before. I am well aware that the “conventional wisdom” asserts that cancer risk assessment methods are “conservative” (and that regulatory economics tends to underestimate regulatory cost), but in both cases, theory and evidence has shown the exact opposite—widespread underestimation of risk and overestimation of cost (for review articles summarizing both sub-literatures, see Finkel 2003 and Finkel 2014a).

EPA continues to ignore the consensus recommendations of the two National Academy of Sciences committees convened to review its risk assessment methods (NRC 1994; NRC 2009) that it must stop treating every human being as identically susceptible to the effects of any given carcinogen. EPA has always added a ten-fold safety factor to its *non*-carcinogen safety assessments, meant to account for the person-to-person variability in sensitivity, but has never done so for cancer; NRC 2009 recommended that EPA use a factor of 25 so that cancer risk assessments that otherwise might be reasonably accurate for the typical human would also provide adequate protection for 95 percent of the human population (Finkel 2014b explains further how EPA’s failure to do so also results in underestimation of the total benefits of its carcinogen-protection rules).

EPA also continues to deflect the call from the NAS committee and many other experts that it finally begin to estimate *risk* for all non-carcinogenic health effects, rather than simply assert that a given concentration (e.g., the Reference Concentration) is “likely to be without appreciable risk.” The scientific techniques to estimate the probability of harm at any exposure to a non-carcinogen have been refined for more than 20 years, but EPA remains committed to the “safety factor approach.” This approach makes benefits assessments almost impossible (as this offers no opportunity to estimate the reduced number of cases of disease associated with any policy), but causes a special problem with respect to TSCA: the law calls for decisions to be based on eliminating “unreasonable risk,” but EPA has not yet defined that term, and it *cannot* define the term for non-carcinogens when its assessments do not seek to estimate risk at all!

EPA has also embraced a goal in its risk assessment practice of “reducing reliance on default assumptions” (such as, for example, the evidence-based assumption that when large fractions of laboratory animals exposed to a substance develop malignant tumors, this finding is, *rebuttably*, worrisome for humans). I hope the Committee will take an interest in the wisdom of this far-reaching and fundamental change in how EPA assesses, and hence manages, risks of all kinds. Today is not that day, but suffice it to say that from the point of view of public-health decisionmaking, there are two disparate ways to evaluate mixed and uncertain evidence. One way, which if nothing else is very time-consuming, seeks to aggregate, “weigh,” and synthesize *all* the evidence about a hazard or risk, treating every assessment as separate from every other and not terminating the assessment until the most accurate answer possible is attained. EPA and the other agencies *used to*, however, have an explicit goal of evaluating evidence with an eye towards precaution, treating “negative” findings with some skepticism unless they were powerful and compelling rather than weak and preliminary. The point of this orientation was two-fold: (1) to reflect the reality that errors of underestimating risk or “missing” a true relationship are more costly to society than errors of overestimating risk or incorrectly assuming an association; and (2) to make it possible for assessments to be completed in years rather than decades (GAO, 2019).

I and others have long argued that EPA should seek to “reduce reliance on *incorrect* default assumptions,” not to throw our reliable and evidence-based models because it feels it must start from scratch in every assessment so as to be more than fair to those who doubt the face-value evidence of toxicology, epidemiology, and human case reports. The TSCA evaluations *cannot* protect human health as Congress intended if “systematic review” becomes paralysis.

5. *Conclusions:*

I hope Congress will use the means at its disposal—up to and including report language or appropriations riders—to spur EPA to:

- Promulgate use restrictions for MC, TCE, and NMP as originally proposed and commented upon;
- Conduct thorough risk assessments for worker risks, ones that do not make unwarranted assumptions about employer compliance with hard-to-enforce rules or unenforceable guidelines, or exclude categories of worker exposure arbitrarily; and
- Align its risk assessment methods to the central goal of the TSCA law: to eliminate so far as practicable *unreasonable* risks to consumers, residents, and workers, taking into account both the interindividual variability among human exposures *and* our susceptibilities.

In summary, I am proud of what my former agency has managed to accomplish given all the constraints on it, but there is no shame in OSHA admitting that workers need EPA too. Even if EPA changes course and begins to follow the TSCA law properly, and issues some needed controls on MC, 1-BP, and other high-risk chemicals, this alone will not solve the worker disease problem in the US—but to paraphrase a great speech, “all this will not be finished with the first 10 chemicals, or perhaps even in our lifetimes, but let us begin.”

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