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Dear Panel Members:

RE: Updated Comments by Paustenbach on EPA Draft Risk Evaluation for Asbestos of March 30, 2020

Thank you for the opportunity to respond to the document entitled "Draft Risk Evaluation for Asbestos" that was released for comment around March 30, 2020. It represents an enormous effort on the part of the Agency, and it is among the most detailed and transparent EPA analyses that I have read. Alas, there are many portions of the document where I believe the Agency will need to make significant changes for it to be considered scientifically rigorous. It is also possible that the Agency will conclude that the document need not be revised, and will not issue a next version, since it does not materially identify a hazard that requires regulatory intervention.

I am submitting these comments about two weeks before the deadline, so the panelists have time to evaluate them carefully.

## Background

I am a toxicologist certified by two different boards and a certified industrial hygienist. I have been an adjunct professor at five universities over the years while also actively serving in a professional role in the environmental and occupational health sciences for 45 years. I have written nearly 300 peer-reviewed papers, 55 book chapters, and three books on topics relevant to the work of this committee. I have also edited, perhaps, the most popular text on health risk assessment, which has been used for 30 years by many universities.

I considered it crucial that I submit comments since I have likely studied and conducted more original research in the areas covered in this EPA draft document (e.g., gaskets, packing, and brakes) than most persons in the field. In total, I have published 30 peer-reviewed articles addressing asbestos, of which, the Agency cited eight in its draft document to evaluate asbestos exposures under several scenarios.

My CV is posted on our website.

## Relationship to EPA

I have often given lectures in which I note that the contributions of the environmental movement (very much led by the U.S. EPA) brought about a revolutionary improvement in the quality of life for hundreds of millions of Americans. Its influence on global attitudes has been profoundly positive. It was my good fortune to have served as a member of the EPA Board of Scientific Counselors (BOSC) Executive Committee for six years (2008-2014). I had previously served on several Ad Hoc Science Advisory Boards

(SABs) addressing specific chemicals. Today, I am a member of the EPA Science Advisory Board Chemical Assessment Advisory Board (2019 - 2022).

To varying degrees, I have submitted documents to EPA and interacted with the Agency on many levels for nearly 40 years.

### Disclosure

This SAB, the Ad-hoc advisory panel, and the EPA ethics lawyers should be aware that I have conducted a considerable amount of research on the topics addressed in this document. I have also consulted with companies who used to have chrysotile asbestos in their brakes and in their gaskets, and those that used asbestos to manufacture other encapsulated products. Generally, I was paid for those efforts. I have also testified in perhaps 400 depositions and 20-30 courtrooms over the years on the hazards of chrysotile in brakes, gaskets, packing, Bakelite, roofing materials, and other encapsulated products.

These organizations, where I served as an expert in these matters, have financially supported some of my published work. Additionally, my previous firm, ChemRisk, performed several million dollars of work in this area without any outside support. The financial ties to any law firm or industry who supported our research or papers have been disclosed in our manuscripts for almost 20 years (unless, for some reason, the editor or publisher did not feel it was appropriate; which rarely was the case).

My colleagues at Paustenbach and Associates and I have invested approximately 200 hours in preparing these comments. We have not received compensation from anyone for this effort, which would typically be billed in the vicinity of approximately \$70,000. The opinions expressed within these comments are our own. No lawyers or other experts have seen or commented on this submission.

### Executive Summary of My Concerns

Asbestos has been one of the most studied chemicals within all of toxicology, epidemiology, industrial hygiene (exposure science), and occupational medicine. One can spend 30-50 years studying this topic and still not master all issues that relate to its potential to affect human health. There are about 300 papers related to the matters addressed in this *Draft Risk Evaluation for Asbestos* (March 24, 2020), which deserve to be understood by the panel to do a proper peer review.

### *Note Regarding This SAB Panel*

The matters addressed in the 500+ pages of documents associated with this initiative are complicated and controversial. I feel that it was a bit unwise for the Agency to take on this task without considerable input along the way by the most knowledgeable scientists in the field. Perhaps that occurred, but that is not clear to me.

Having served on several EPA SAB panels and having addressed similar panels over the years, I am sympathetic to the challenge by those who have not been immersed in the relevant asbestos literature for one or two decades or more. With the fairly recent restrictions regarding "conflict of interest" (real or perceived), it is almost impossible to convene a panel of experts who know the topics at a depth

necessary to adequately address the more complicated questions posed by the Agency in this document. I would encourage the Agency to consider returning to the prior policy where it asked prospective EPA candidates to disclose their perceived conflicts and then allow the ethics lawyers at EPA decide if those present a problem.

This would allow professionals who are highly accomplished and true experts to be part of future panels. I am not suggesting that the current SAB for this document is inadequate, but I do believe that the Agency would benefit from the wisdom of professionals who serve as experts in litigation or are consulting experts to the private sector.

While developing these comments, I frequently referred to the 200 or more published papers that are relevant to the topics in this document. I hardly think that it is fair for volunteers who are not “deep” into the study of asbestos to expect them to master these topics in a relatively short period of time. But, for many SAB panels, this is precisely what is expected of them.

I applaud this SAB panel as it attempts to master the relevant literature and deal with the many comments which you will undoubtedly receive. I must note, however, that I was disappointed that EPA released this document on March 22 (during the peak of the COVID-19 crisis) and then requested an April 22 submission of comments (still during the crisis). Like 300,000,000 other Americans, all of us have been cloistered. Thus, I was pleased that the Agency extended the deadline and the date of the SAB meeting.

I believe the SAB panels should be aware that, although I am not a lawyer, I am not convinced that the EPA is required to address this topic to fulfill its responsibilities under the Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act. While not mentioned in the document, it could have a dramatic impact on current and future toxic tort litigation. It may not be a concern of the Agency, but I think it is nevertheless important to recognize.

Overall, I am surprised that in light of the many competing priorities facing EPA, this topic, which may affect 10 - 100 or fewer persons annually in the coming years rather than the 1.5 million persons the Agency identified as at risk, deserved this level of effort. I address these and other matters, as summarized here, and discussed in detail in the comments below.

- 1) The foundation of this document is that Americans today, and in the future, are going to be exposed to raw or encapsulated asbestos. This document estimates that it could be as high as nearly 1,500,000 persons per year. In my experience, and based on my knowledge of the topic, that is not even remotely close to being accurate.**
- 2) Based on my studies, the number of persons potentially exposed in the coming years is minimal. Indeed, I estimate that perhaps no more than 100 persons in the United States may work with raw or encapsulated asbestos where there could be measurable or significant exposure. In chlor-alkali facilities, many workers are allegedly exposed (according to this document), but the exposures are *de minimus* compared to the OSHA PEL based on the data presented.**
- 3) The data presented for the one or two facilities that occasionally punch out “asbestos-containing gaskets” indicate that the exposures of those 2-3 workers, who might work the**

press occasionally, are well controlled. The information presented by the Agency about the number of persons who “might” work with asbestos-containing gaskets in the coming years is not accurate.

- 4) Concerning brakes, it is unlikely that there are many persons purchasing or installing brakes with asbestos. Even if one is able to do so, they will almost always be disc brake pads rather than drum brake linings. The Agency’s estimate that as many as 750,000 mechanics in the U.S. might be expected to work with such brakes in the coming years is off target. At best, 20-100 “shade tree mechanics” may find drum brakes containing asbestos in the United States and install them, but that is unlikely since drum brakes are only needed for a select few antique cars. Shade-tree mechanics typically work outdoors, so those exposures would be *de minimus* (if they occur at all).
- 5) No dealership or brake shop would knowingly install an imported brake if it contained asbestos. The liability is too significant. As noted, only a handful of car owners may replace their brakes at home, but generally speaking, drum brakes have not been used in cars in the United States for almost 40 years. Furthermore, it is exceedingly rare to find persons in the modern era who would attempt to replace drum brakes themselves. It is a relatively complex process that is best done with equipment typically not found in a non-mechanic’s home garage.
- 6) In the document, the Agency claims that it is only concerned with brake changes going forward. As such, the Agency assumes that modern era control technologies for brake changes will be implemented by those in the general public and DIY mechanics. However, all the calculations in the document are based on studies involving techniques used from approximately 1940 to 1980.
- 7) The Agency would be familiar with the exposures in the modern era if it referred to the five or six papers written by NIOSH in the late 1970s and early 1980s. NIOSH specifically measured the exposures associated with using modern techniques. None of those papers were cited in this document.
- 8) Some of the assumptions about exposure frequency for those working with gaskets and brakes are not reasonable based on the existing scientific literature.
- 9) According to the document, only a limited number of asbestos-containing sheet gaskets rolls are imported each year for one specific use in one industry. That is why they can be produced by one firm on a handful of days per year (involving just two employees). In my view, this is not worthy of attention compared to the vast responsibilities of EPA, given that the exposures are insignificant.
- 10) I find it troubling that the Agency has concluded that exposures in certain occupations, which have been known for decades not to pose a significant hazard to workers, have been categorized as presenting an “unreasonable risk to the health of workers.” The only way that the Agency could have reached such a conclusion is by changing the cancer potency factor (CPF) for asbestos and, in particular, for chrysotile. The scientific basis for

this change is flawed and casts serious doubt on the validity of the conclusions of the document.

- 11) The Agency appears to have been convinced that it is possible to identify a CPF for chrysotile alone, even though, after nearly 70 years of study, no other body in the world has ever claimed that such a CPF could be offered. The Agency relies on the North and South Carolina textile cohorts for deriving its CPF, which is inappropriate for several reasons. First, some members of this cohort have been known to have been exposed to amphiboles. This was noted in the original manuscripts by Dement et al. (2009), Loomis et al. (2009), and in depositions of Dr. Dement. Beyond that, Roggli et al. (1998) studied the lungs of at least one of these workers and found amphiboles (Roggli et al., 1998; Pavlisko et al., 2020). The amphiboles are at least 100-fold more potent for causing mesothelioma than chrysotile. Thus, the Carolina cohorts are not “chrysotile only” and should not be used to derive a chrysotile CPF. Consultants to EPA (Berman and Crump, 2003), I believe, reached this decision almost 20 years ago when EPA funded their work.
- 12) It is well known in the asbestos literature that if chrysotile could produce mesothelioma (which remains in dispute), it may do so only at doses that are in the vicinity that cause asbestosis (50-400 f/cc-year) (Churg, 1988; Churg et al., 1993; Pierce et al., 2016). Additionally, the fibers are likely to be exceedingly long (like those only found in textile mills) and, therefore, vastly different in length and aspect ratio from the short asbestos fibers that were used as filler in brakes and gaskets.
- 13) In my view, the Agency missed essential epidemiology studies conducted in vehicle mechanics exposed to encapsulated asbestos. At least 15 studies have evaluated these cohorts for the periods when asbestos could have been in brakes in the United States. These are addressed, quantitatively and critically, in several peer-reviewed meta-analyses of lung cancer and/or mesothelioma, which are the most relevant studies for understanding possible cancer risks of chrysotile in brakes and can be extrapolated to gaskets and packing. I would refer the SAB to the comments submitted by Moolgavkar et al., dated May 18, 2020, and by Dr. Garabrant, dated May 20, 2020, for an in-depth discussion of these studies.
- 14) Several papers have addressed the biologic activity or potency of fibers that have been either heated or simply filled with phenolic resins, such as brakes, Bakelite, and gaskets. Bernstein et al. (Bernstein et al., 2003; Bernstein and Hoskins, 2006; Bernstein et al., 2013, 2018, 2020a, 2020b) have found that that asbestos loses its toxicological potency when filled with resins or when the fibers are converted to forsterite. These papers were not mentioned in the EPA document.
- 15) The Agency discusses the possibility that fibers will drift from a point source and possibly cause a serious potential hazard to nearby workers or that they provide an almost infinite source of fibers for resuspension. This is generally not the case, especially for the fibers which have a length of 5-40  $\mu\text{m}$ . Fibers of this length tend to agglomerate, fall due to gravitational forces, or are attracted to one another due to van der Waals forces. The half-life for these so-called OSHA fibers (e.g., longer than 5  $\mu\text{m}$  with an aspect ratio of 3 or

greater) or equivalent particles to settle out is on the order of approximately 5 minutes, not the hours or days as this document suggests.

- 16) The myth that the particles remain in air for days or are easily resuspended, with the potential to cause inhalation exposure for weeks after they are generated lacks scientific merit. The only studies supporting this view contain no quantitative discussion of the air concentrations of OSHA fibers over time (e.g., no settling rates with half-life by fiber size). Rather, quantitative historical reports show that the fibers that remain suspended are generally too small to be of biological importance, i.e., much less than 5  $\mu\text{m}$ . The tendency of these fibers to be resuspended is also quite low as they stick fairly tightly to flat surfaces. The data from the work at the World Trade Center make this abundantly clear (see the report by the oversight panel on exposure in which I participated).
- 17) One cannot rule out that, given the information provided in this document, some brakes purchased online by an individual may contain asbestos. However, as noted by the Motor & Equipment Manufacturers Association (MEMA), these purchases comprised less than one percent of the brakes sold in the United States in 2013, which is likely an overestimate, given that the letter was published over six years ago and that MEMA would like to see these purchases banned. Nonetheless, even if MEMA's estimate are accurate, one must be aware that the brakes sold online are almost certainly disc brakes. Installing or removing a new disc brake should not pose any exposure to the worker. Therefore, even if <1% of the disc brakes are in the marketplace, they are irrelevant from an exposure or health risk standpoint.
- 18) When deriving the cancer potency factor (CPF) for chrysotile, EPA adds both lung cancer epidemiological data to the mesothelioma epidemiological data, which is scientifically inappropriate on several levels. First, during the lung cancer epidemiology for the era in question (the 1940s – 2000s), a substantial portion of the male worker population smoked for short or long periods of time. Studies show that persons frequently do not recall accurately if they smoked for only a few years or find it socially unacceptable to admit to any smoking history. This compromises nearly all studies when attributing lung cancer to an inhaled carcinogen. Without a comprehensive smoking history for each person or a comprehensive knowledge of the exposure to various forms of asbestos (and other airborne carcinogens), these studies cannot be used to identify a "chrysotile only" potency factor for lung cancer. The potency of cigarettes overwhelms the cancer potency of chrysotile. In 1955, Doll did his best to address the potency of asbestos alone but knew that smoking was a confounder that is difficult to control (Doll, 1955).
- 19) Regarding chrysotile only CPF, lung cancer and mesothelioma are generally believed to act through entirely different mechanisms of action. To combine them into one CPF is highly questionable and contrary to the current EPA Cancer Guidelines. Long fiber chrysotile, if these can cause mesothelioma, probably do so via clogging the stoma and subsequent chronic inflammation (Lynn, 1983; Englert et al., 2014). Chrysotile probably increases the lung cancer risk primarily in persons who smoked for some period of time – chrysotile fibers absorb the many carcinogens present in cigarette smoke. Roggli et al and others

have addressed these issues over the years (Englert et al., 2014). On top of these factors, the Agency has identified the incorrect cohorts for calculating its CPF.

- 20) When coupled with the fact that chrysotile is almost certainly a threshold carcinogen, i.e., it acts through two different mechanisms to cause lung cancer and mesothelioma (if it can do so at any reasonable dose), and because it does not appear to cause either disease until asbestosis-producing lifetime doses are reached (probably only with very long fibers), it seems scientifically unfounded to try to derive a single CPF for chrysotile for both diseases. If it were scientifically valid, it would have been done long ago.
- 21) I would direct you to significant EPA contracts and peer review panels, which were oddly not cited in the Agency's document, where it was concluded that chrysotile may not have potency for mesothelioma or lung cancer (at least not until very high cumulative doses and/or long fibers are involved). Be reminded that Dr. Agnes Kane convened an EPA SAB to address this issue and, while the committee failed to reach agreement on a number of topics, it did conclude that the potency of different fiber types should be accounted for in regulatory decision making.
- 22) For its calculation of the CPF, I also believe that the Agency incorrectly assumed that there is no background rate of pleural or peritoneal mesothelioma in persons not exposed to asbestos. There are numerous papers demonstrating that mesothelioma occurs in persons never exposed to asbestos levels above background. The two papers that have recently questioned this view are not convincing especially when compared to the arguments presented by Price and Ware, or Moolgavkar et al., 2009 (and others). This topic deserves significant attention from both SAB panels.
- 23) A considerable number of toxicologists and epidemiologists believe that soon after about 2025 or 2030, a vast majority of mesotheliomas seen in the population were spontaneous in origin. I recognize that the opposing school of thought is that the latency for causing mesothelioma is longer than what we believed in the past. Some have postulated that the latency maybe 30-35 years or even as high as 45 years. I believe it is highly unlikely that the latency is longer than 40 years, except for perhaps radiation, but that has also been questioned in recent years. Without a lung biopsy, spontaneous mesotheliomas are indistinguishable from mesotheliomas due to asbestos exposure. Given the few workers with appreciable exposure after about 1975-1980, it is much more likely that any mesotheliomas after 40 years of the date of last exposure are spontaneous instead of the suggestion that the latency continues to get longer than once thought.
- 24) It has been evident to most scientists who have studied pleural mesothelioma that its incidence rate increases with age (even in unexposed cohorts), just like every other cancer. The trends are obvious. Critics have claimed that "they were probably exposed to asbestos at some point," but that is usually purely speculation and, for chrysotile, almost no one will claim that asbestos-related disease occurs without very significant exposure of which the person would be aware. This is entirely different than exposures to the amphiboles which can go unrecognized by persons who have been exposed over the years.

- 25) There are not many known causes of mesothelioma but it is well known that the pleural mesothelioma rate is higher in those who have had chest radiation treatments for cancer at mid-life during the 1950-1970/1980s (and who were never exposed to asbestos). Additionally, you often see peritoneal mesothelioma in persons in their 30 - 50s when their exposure history indicates that they were always office workers (not to mention that the latency would not be consistent with the disease if it was solely due to asbestos exposure). Mesothelioma clearly occurs without exposure to asbestos in probably 20 – 25% of cases, if not more. As the typical American enjoys greater longevity, we see an increased incidence of mesothelioma, that is independent of asbestos exposure.
- 26) As mentioned, it is clear from the data in the EPA's document, that few, if any, persons in the United States should ever again be exposed to chrysotile above trivial concentrations. Lifetime doses will almost certainly be 100 to 1,000-fold less than those that should cause an asbestos-related disease. I doubt that as many as 100 persons in the U.S. annually could have measurable exposure to asbestos today from brakes, gaskets, and packing (for various reasons). As mentioned, the available data presented by the Agency does not seem to identify any cohorts which might be routinely exposed above about 1/10 to 1/2 the current OSHA PEL for asbestos (and the number of plausible workers is very low).
- 27) In reviewing this document, one cannot help but think that the EPA is using this analysis as a backdoor method for supporting a ban on asbestos. Personally, I have no problem with a ban as long as critical uses of military or research significance are protected; however, given the flaws in this document, it would appear that a different approach to supporting such a ban is needed.
- 28) It also seems plausible that the EPA is using this document to cajole OSHA into revising its PELs for asbestos. Again, I would support OSHA revisiting its PELs and establishing new and separate PELs for chrysotile, amosite, crocidolite, and tremolite. This is long overdue. However, as noted above, this document is not sufficiently robust on a scientific basis for assisting OSHA in revising the PELs for the various forms of asbestos.
- 29) If there are a handful of applications in essential industries that require the importation of a limited number of asbestos-containing gaskets or packing to produce militarily or economically crucial goods, the Agency could ban the importation of asbestos, except for these special applications. It is not necessary for the Agency to overlook logic, decades of research, scientific literature, and overestimate the size of the plausibly exposed population to discuss exposure scenarios that do not exist (at least not for the almost 1.5 million workers that EPA says could be over-exposed in the coming years).
- 30) This document suggests that hundreds of thousands of persons each year in the future may be exposed to dangerous levels of asbestos. The Agency provides no scientifically credible basis for this claim. In fact, such exposures do not currently exist or are insignificant, i.e., they do not pose a hazard to the handful of potentially exposed workers. Those persons in chlor-alkali facilities, gasket stamping, and those replacing brakes on

antique cars, based on the data presented in this document, and in my own professional experiences, are not currently over-exposed. You have to discard the OSHA PEL, generate inaccurate exposure scenarios and derive a “new” cancer potency factor for chrysotile alone to conclude that occupational conditions for the six categories of workers evaluated by the Agency (see page 26 of 310) are at “an unreasonable risk to health.”

- 31) To the best of my knowledge, in the 50-year history of the EPA and OSHA, neither agency has put forth any regulatory document focused on any hazard for which even using CPFs derived from a linearized multistage model (LMS) leads to a prediction of zero incremental cancer cases for any of the exposed cohorts (Travis and Hattermer-Frey, 1988; Dudley, 2015). Indeed, it would appear that even if one assumes that 1,000 – 10,000 persons were to be exposed to chrysotile in these applications for the next 40 years, there would not be even a single incremental case of cancer in the exposed population. Based on my review of dozens of regulations, no agency in the federal government has ever been concerned about such trivial risks.
- 32) Thus, I am more than a bit surprised that the alleged hazards described in this document would warrant 310 pages of examination. I was even more surprised that EPA concluded that many exposures in the United States today “present an unreasonable risk to health” (page 26, ln. 1106), even though the worker exposures discussed in this document were usually far below the OSHA PEL.
- 33) The litigation which could be generated by this document could involve claims of billions of dollars related to personal injury associated with alleged asbestos exposures of mechanics, pipefitters, millwrights, oil rig workers, and others who worked between 1945-1985. If EPA wants to encourage future, possibly unnecessary or unwarranted litigation, I can think of no better way to do that than issue this document as currently written.

I hope that the Agency gives some consideration to my and others’ comments before moving forward with finalizing this document. In my view, the analysis is not consistent with the high standards of many EPA initiatives. To believe in the conclusions, one must accept too many unfounded assumptions.

As noted previously, to those of us who have studied this issue, it looks very much like the Agency is trying to use this document to support a ban on the import of asbestos. I would welcome such a ban, but functionally, it is probably not necessary. The litigation environment has prevented firms from using asbestos for nearly 40 years. If the Agency wishes to provide support for such a ban to Congress, there are surely other approaches rather than assemble a cascade of assumptions that lead one to a conclusion that, on the face of it, is not supportable.

The other possible reason for producing this document, I am guessing, is to encourage OSHA to review its PELs for asbestos. That is, reduce them because some consider them to be too high. Or, EPA is encouraging OSHA set separate PELs for each fiber type. Both initiatives would be worthwhile but using this document, which contains many shortcomings, is not the appropriate way to make this happen.

In my comments, I recognize that I frequently repeat the same criticisms for different statements within this document. I did this, page by page, because, in my experience, the comments are often “separated” among various groups in the EPA who assembled the document. When that happens, some members of

those teams do not receive the entire set of comments, but instead, only those that supposedly relate to their contribution. Thus, I chose the “comment by comment” approach.