

Asbestos

Raising the Bar in Asbestos Litigation

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Speculation v. Fact: The Dangers of the Proposed Risk Assessment on Chrysotile Asbestos

A Commentary by Dennis Paustenbach, Ph.D., C.I.H., D.A.B.T. and David Brew, Ph.D.

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In June 2020, Mark Zellmer published a “Perspectives” paper in this journal titled “Chrysotile and the EPA: Part of a Continuing Saga.”¹ In response, Blouin, Kelly, and Wetmore published a rebuttal in the August 2020 issue titled “Dangerous Denial: Illogical Defense Bar Commentary Ignores Well-Established Science that Chrysotile Asbestos Kills.”² This prompted Mark Zellmer to write another article in the October 2020 issue of this journal.³

The senior author of this piece has studied asbestos for the past 20+ years, focusing his attention on historical exposure to gaskets, brakes, and other encapsulated products. He has published nearly 30 papers on the toxicology of, and/or exposures to, these products. He is of the opinion that the August 2020 article by Blouin et al. had virtually no basis, and is among the weakest articles regarding proposed asbestos regulations or asbestos litigation, and it represented no more than a plaintiff lawyer’s “opening argument” in a toxic tort case. Unfortunately, it seems to mimic a recent trend of stating fiction as fact.

In this paper, we attempt to correct the narrative regarding the scientific underpinnings of the EPA’s 2020 *Proposed Risk Assessment for Chrysotile*.⁴ We comment on errors in the “Dangerous Denial” paper and share with readers the shortcomings in the EPA proposal. If readers want a more in-depth understanding of

issues surrounding EPA’s draft risk evaluation, they can read our comments available on the Paustenbach and Associates web site: www.paustenbachandassociates.com.

Shortcomings of the ‘Dangerous Denial’ Piece

Blouin et al. claim that Mark Zellmer’s article was “... nothing more than a blatant attempt by the well-funded asbestos defense bar to cast doubt on the inescapable conclusion that chrysotile asbestos causes cancer.”⁵ Such hand waving often works to the benefit of plaintiff lawyers in the courtroom, but has no place in scientific or legal journal dialogue.

The weight of scientific evidence of the last 20 years indicates that chrysotile can cause lung cancer in *some* people. However, it takes relatively large lifetime

doses (e.g., around 100 - 200 fiber/cc-years) to increase the risk of developing lung cancer. Basically, you need to have asbestosis-producing doses for chrysotile to cause lung cancer. The jury is still out regarding chrysotile’s ability to alone cause mesothelioma but, if it does, most scholars agree that chrysotile doses must be in the vicinity of those that cause asbestosis, and fibers likely must be much longer than 5 µm (probably closer to 25 - 40 µm) and have a 3:1 aspect ratio.⁶⁻¹² The vast majority of such exposures ended 40 or more years ago in the United States!

It was laughable when the authors threw stones at what they called the “well-funded asbestos defense bar.” We would agree that approximately 40 - 50 years ago, the plaintiff bar was often unable to gather sufficient monies to match the well-funded defense bar. However, due to the smoking settlement, 30+ years of asbestos



Brake-wear debris (left) is a different material than friable asbestos insulation (right). Jurors in asbestos trials often get the two confused.

litigation, and many major wins in pharmaceutical litigation, the most talented lawyers within the plaintiff bar are far from being paupers. The best of these lawyers are now among the wealthiest Americans outside the world of venture capitalists and tech entrepreneurs. I am hard-pressed to think of a single defense lawyer who is a near billionaire or has a private jet. Yet, as Grisham has joked for years in his various books, every aspiring plaintiff lawyer dreams about owning a \$60 million aircraft and/or a yacht.¹³

It is worth noting that Dr. Arthur Frank, an expert primarily retained to testify on behalf of plaintiffs, and an unidentified plaintiff attorney petitioned EPA Administrator Scott Pruitt on March 13, 2017, to consider asbestos as a toxic material that the EPA should ban.¹⁴ Rather than promoting a ban on asbestos imports, the claimed objective of this risk assessment, the apparent goal of the trial lawyers appears to have been to encourage the EPA to suggest that even today, gaskets, brakes, and other chrysotile exposures at very low doses pose a significant risk to human health. Beyond opining on the hazards of these products, the EPA also chose to offer views on the toxicology of pure chrysotile asbestos, and the alleged hazards of resin encapsulated chrysotile asbestos in gaskets, brakes, and packing. The only way the EPA had any authority over such products was to claim that they were still routinely sold in the United States, which is not the case. Only the chloralkali industry imports raw chrysotile asbestos, and the data indicate that exposures are well controlled.¹⁵

Not surprisingly, Blouin et al. repeat the mantra, “there is no assurance of a safe exposure for a substance with known carcinogenic properties.”¹⁶ When repeated 100 times or more, as is the case in most asbestos trials, this claim seems to resonate with jurors. Not only is this phrase taken out of context, but it is always touted as a fact in court proceedings and motions when it is clear that the state-

“The assumption of ‘no safe dose’ is just that: an assumption. It is an artifact of regulatory policy where agencies embraced a mathematical model that ‘assumes’ all doses pose a risk.

ment cannot be true. The assumption of “no safe dose” is just that: an assumption. It is an artifact of regulatory policy where agencies embraced a mathematical model that “assumes” all doses pose a risk. This topic has been examined in dozens of papers in the field of radiation biology and as stated in an article from the Health Physics Society:

“Although risks cannot be measured reliably at low dose, a risk is nevertheless assumed since the absence of evidence of risk is not evidence of absence of risk. However, the risk is theoretical, and linking negative events — exposure to low doses of carcinogens with cancer — is nearly impossible. For complex diseases like cancer, cause and effect are not always clear.”¹⁷

In recent years, even the EPA recognized that estimating risks at extremely low doses is highly uncertain,¹⁸ so an entirely different method is now often used in rulemaking. It would be wise for EPA to change their outdated guidance documents to reflect this change. Over the past 15 years, there has been considerable work regarding whether the hormesis model better describes the dose-response relationship for low dose exposures than

the traditional low dose-response models (i.e., linear no-threshold and threshold models).¹⁹ A special issue of *Chemico-Biological Interactions* was dedicated to understanding the scientific basis and limitations of the linear no-threshold models in 2019.²⁰

Dr. Bruce Ames, a Berkeley scientist revered for his work on carcinogens, was known to say that if you embrace the “no-safe-dose” mantra, then you should be labeling carrots, spinach, pepper, and various forms of lettuce as a cancer hazard, and remove them from your diet because they all contain relatively large quantities of naturally occurring carcinogens.²¹ Ames, and many other respected scientists who do not testify in court, have recognized for nearly 35 years that the “no-safe-dose” concept is nonsense.^{22,23}

For the record, as occupational health professionals and toxicologists who have exhaustively studied asbestos, we support a ban, as long as certain exceptions are made for uses required for national security, critical medical applications, or if there is no other safe, reasonable substitute. Based on the EPA’s draft risk evaluation, individuals are already exposed to insignificant doses of asbestos that are well below the contemporaneous OSHA

“One major shortcoming, in our view, of the EPA meeting, was that the ‘charge questions’ which the panelists were asked to address did not focus on the most important and thorny aspects of the document. Thus, by not asking the right questions of the panelists, EPA failed to obtain the insight that the Agency deserved.”

Permissible Exposure Limit (PEL)! We agree with Zellmer that a ban on importing asbestos-containing materials (ACM) is unnecessary because, due to nearly 40 years of litigation and regulatory pressure, one is already functionally in place.

Shortcomings in the EPA’s Draft Risk Evaluation for Asbestos

We have much respect for the role the EPA serves in society. However, in the senior author’s 40+ years of reading EPA documents and serving on numerous EPA panels, he does not recall a situation where they “got it so wrong.” The assumptions surrounding the exposure scenarios, the epidemiology, and dose-response assessment, it seems, could have been taken directly from the testimony of plaintiff experts in asbestos litigation.

One of the key issues that readers deserve to be reminded of is that the EPA has no authority to regulate workplace exposures. So, for it to weigh in on the topic of “asbestos exposures to workers,” they must evaluate “future exposures” to products in commerce. Perhaps the biggest

flaw in the EPA assessment is its belief that asbestos-containing gaskets, packing, and brakes continue to be easily purchased in the United States and that thousands of people are exposed to those products. That is simply not true. The agency presented no facts or evidence that these products were commercially available other than to say that they can be found on the internet. Advertising does not equal availability, or that the products do contain asbestos. The EPA relied exclusively on a 10-year-old report by a trade association with a vested interest, which suggested that approximately 1 percent of imported brakes contained asbestos. We found no evidence supporting that claim, either 10 years ago or today. The letter feels more like an association trying to protect its members rather than the result of any investigation.

Beyond the fact that we (the authors) contend that the EPA failed to document that exposures to chrysotile asbestos in new products were still happening, we were equally surprised that the EPA could not locate a large fraction of the relevant published and unpublished liter-

ature that was relevant to their evaluation. This was despite its claim that they conducted a first-rate systematic review! For example, it is inexplicable that studies which show the lack of biologic activity of resin-soaked fibers, the conversion of chrysotile to forsterite during braking, the 16 epidemiology studies of mechanics, the four published meta-analyses of mechanics, and the studies describing the low potency of chrysotile compared to amphiboles were not mentioned in the EPA’s Draft Risk Evaluation document. How is that possible?

Our firm identified nearly 100 papers relevant to such a risk assessment that the EPA failed to consider in their Draft Risk Evaluation. It seems the EPA decided, *a priori*, that the conclusions of the risk assessment had to land in a particular spot to gather support for the asbestos ban, which has been one of EPA’s stated objectives since 1989.²⁴ It appears, as Zellmer wrote in his second article, that the EPA decided on policy first and let that policy affect or even dictate the scientific conclusions.²⁵ There are a number of scientific shortcomings apparent in the document, including evidence that the EPA seems to have decided on its conclusions before conducting the analysis where they developed a combined Inhalation Unit Risk for both lung cancer and mesothelioma. This has never been done previously in any published paper or assessment of asbestos. Given the strong possibility that pure chrysotile, at any lifetime dose (possibly, in some persons, at doses that are sufficient to cause asbestosis), may not cause mesothelioma, there is no scientific basis for attempting to derive a combined lung cancer and mesothelioma cancer potency factor. We want to believe that EPA attempted to conduct this analysis carefully and objectively, but its assessment was so riddled with flawed assumptions and a lack of awareness of the published literature that it makes one question the EPA’s scientific objectivity.

Where Are These Products Supposedly Entering The U.S.?

If the EPA attempted to quantify the number of chrysotile-containing brakes brought into this country, they would find that it is nearly impossible to purchase an asbestos-containing brake originating from Canada, India, Russia, China, or other alleged countries. Those of us who have studied this topic in depth since 2000, or earlier, have not purchased a single asbestos-containing brake or gasket after multiple attempts via the internet. We have even found that products labeled as having asbestos do, in fact, not.



Historically, asbestos disc brakes contained approximately 30 – 50 percent chrysotile asbestos, as well as glues, metal shavings, resins and binders.

The EPA's suggestion, then, that nearly one million people in the coming years might be exposed to asbestos due to products entering commerce is a complete folly. The EPA SAB members who evaluated this matter in June did not have sufficient experience to know that it is virtually impossible to find new gaskets, packing, or brakes that contain chrysotile asbestos being sold today in the United States! Before spending millions on this regulatory initiative, it would have been prudent for the EPA to have purchased 20 - 30 sets of brakes from these websites and assay them to

confirm that, indeed, their underlying assumptions about exposure were valid. Then, a careful study of the number of potentially exposed persons should have been conducted.

Another shortcoming in the EPA's analysis, even if chrysotile-containing brakes could be obtained, is the lack of significant inhalation exposure associated with changing brakes. The preponderance of data cited in the assessment shows that the airborne concentrations to which persons were exposed 40+ years ago, when brakes contained 40 - 80 percent chrysotile, was very low, at approximately 0.04 f/cc (as an eight-hour time-weighted average [TWA]),²⁶ a value that appears in the senior author's 2004 paper on this topic and one that EPA validated independently. When one considers conversion to forsterite during braking, the lack of biologic potency of resin-soaked fibers, and the minimal number of persons who are plausibly exposed to gaskets, packing, or brake dust in the coming years, it is difficult to see why conducting a chrysotile risk assessment should be a priority for the EPA. Again, this raises questions about the plaintiff bar's role in encouraging this assessment because, functionally, they are the only ones to benefit from the EPA's proposed conclusions.

We saw at least fifteen significant shortcomings in the EPA assessment, which are presented in more detail in our official 139 pages of comments submitted to the EPA:

1. It is nearly impossible to find an imported asbestos product in the United States, despite the few products advertised on the internet. In our experience, the asbestos products on the internet are either no longer available when you attempt to order them, or do not contain asbestos despite being labeled as such.

2. Claims that over one million Americans annually, in the upcoming years, might be exposed to new chrysotile containing products lack factual foundation.

3. Starting 50 years ago, when OSHA promulgated its earliest asbestos regulations, exposures in the workplace began dropping dramatically. Today, virtually no one is exposed to asbestos in new products. This is noted in the EPA's Draft Risk Evaluation for Asbestos, where identified exposures were generally far below the current OSHA PEL of 0.1 fibers/cc except for a couple of "one-off" situations.

4. About 40 years ago, most firms told their purchasing departments not to purchase asbestos-containing products, including gaskets, packing, and brakes. This remains a fact, and it makes sense considering the massive liabilities associated with asbestos litigation.²⁷

5. For decades, the airborne concentrations of chrysotile have been very low, and we now know that the fibers likely lacked significant biologic activity since they were either degraded during use or were soaked in phenolic resin (which appears to eliminate the toxicity).^{28,29}

6. The EPA based their cancer potency factor for chrysotile on the erroneous assumption that a textile mill in the 1950s - 1970s³⁰⁻³² could be a surrogate for describing the potency of fibers from gaskets and brakes. For the past 20 years, research has told us that chrysotile fibers need to be closer to 15 to 40 μ m in length to pose a significant hazard.³³⁻³⁴ Nearly 30 years ago, such lengths were generally found only in textile mills, and they are virtually absent from brake dust or any dust associated with brake or gasket manipulation today.

7. The EPA assumed in their risk assessment that textile workers in four mills in North Carolina and the GARCO mill in South Carolina were exposed only to chrysotile, which is untrue. It has been known for many years that amphiboles were used in the GARCO textile mill and the UNARCO textile mill in North Carolina (this was mentioned in the original published papers).^{35,36} This was confirmed by researchers who assayed at least one worker's lungs, showing that amphiboles were present.^{37,38}

8. The EPA failed to recognize or consider 16 epidemiology studies³⁹⁻⁵⁴ and three meta-analyses⁵⁵⁻⁵⁷ of auto mechanics. Such workers happen to be an ideal cohort for evaluating the risks of exposure to brake dust and gaskets. If the EPA had considered the studies, it would have found, based on a weight of the evidence approach, that no increased risk of mesothelioma has been found in these workers.

9. If there is no increased risk of mesothelioma, there is no increased risk of lung cancer or asbestosis associated with exposure to brake dust or cutting/removing gaskets.⁵⁸

10. It seemed unnecessary and inappropriate for the EPA to conduct this risk assessment since it has commissioned two evaluations previously, and there have been no less than a dozen published papers that support the conclusions of those panels. The EPA, like the trial lawyers, should not use the word asbestos as if it were a family of similar fibers, as they are not remotely similar in potency.⁵⁹⁻⁶⁵ Chrysotile, amosite, crocidolite, tremolite, and anthophyllite all have different chemical structures, all have different iron content, and all have different solubilities in lung tissue fluids.⁶⁶

11. The serpentine fibers have a biologic half-life in the lung that is dramatically shorter than the amphibole fibers.⁶⁷ Amphibole fibers, depending on length, can have a half-life in the lung as long as one decade.⁶⁸ Many believe that this is yet another explanation for the negligible potency of chrysotile in both animals and humans.

12. The EPA proposed a combined Inhalation Unit Risk for lung cancer and mesothelioma for chrysotile that

13. When identifying the appropriate data regarding the number of individuals that may be at increased risk of asbestos exposure in the coming years, our estimate of those who might interact with a new asbestos-containing product is between 0 and 100 persons! If put under a microscope, it seems highly unlikely that the Office of Management and Budget (OMB) would have approved of EPA spending tax dollars on this exercise if the number of possible workers is anywhere close to our estimate (which likely cost millions to pay contractors and staff for more than 2.5 years, as well as the effort to convene the SAB panel, and staff time to deal with the mountain of comments, etc.).

“As it is currently written, [the risk assessment] certainly is in no shape to be used to support a ban on those few products that are allegedly still entering the marketplace.”

was very close to that of amphiboles. This is despite the fact that every scientific panel convened to address this matter over the past 25 years concluded chrysotile was at least 100 fold less potent than amosite and may not have any potency to cause mesothelioma.⁶⁹⁻⁷² The cancer potency factor (CPF) they identified doesn't make sense when comparing their estimate to that identified by others since it approaches the CPF for some amphiboles.⁷³

Where Do Things Stand Now?

There was a virtual public meeting held on June 8 - 11, 2020, of the EPA Science Advisory Board (SAB) panel, which reviewed the *Draft Risk Evaluation for Asbestos* (released in March 2020). Out of the approximately 100 written comments that were submitted, it appears that only about 20 ended up being received by the panel participants before the meeting due to inadequate staffing at the EPA to process and distribute them. This put the SAB panel members in a difficult position because most of them were unfamiliar with the vast amount of literature on the mechanism of action, epidemiology, exposure data, and product use data surrounding chrysotile asbestos and encapsulated products prior to joining the panel. Why the EPA was in a rush is open to conjecture, but many believe it was an attempt to get it through the Agency before the end of the year.

The SAB review process, which is normally a good one, did not work for this document. Due to the “rush” to process this EPA proposal, the SAB panelists had to assume that the document assembled

by the Agency was thorough and accurate, regardless of whether it actually was. The new conflict of interest rules embraced by the EPA prevented virtually all of the most knowledgeable experts in the field from serving on the panel because of involvement in litigation. However, three panel members who have testified for years as experts for plaintiffs were on the panel. None of the highly published experts who have typically served for the defense were included on the panel.

When tackling such a complex topic, it seems to us the EPA needs to reflect on whether it is time to re-evaluate if a “perceived” conflict of interest is enough to keep the most knowledgeable scientists from serving on these panels. For decades, the EPA SAB panelists were asked to disclose real conflicts and identify perceived conflicts before serving. The ethics lawyers at the EPA then evaluated their disclosures before panelists could serve. Back then, perceived conflicts would not eliminate someone from serving on the panel. Beginning about 15 years ago, if members of the public (often trial lawyers) complained about an expert being biased, the Agency began preventing them from serving without any discussion with that expert. Why were procedures different for selecting members of this panel?

The SAB Report

The Meeting Minutes and Final Report for the TSCA SAB were released on August 27, 2020. The panelists’ views differed significantly on nearly every topic, which is not surprising. One major shortcoming, in our view, of the EPA meeting, was that the “charge questions” which the panelists were asked to address did not focus on the most important and thorny aspects of the document. Thus, by not asking the right questions of the panelists, the EPA failed to obtain the insight that the Agency deserved.

Consistent with what one would expect when the panel was asked to focus on many of the wrong topics, the SAB report is a mishmash of views and opinions which contained a number of factual errors. In our view, the EPA allowed the committee to “go off on a tangent” on far too many occasions, making the report hopelessly unfocused. For exam-

ple, some of the members thought the scope was too narrow, and they wanted it to address legacy issues, which are traditionally outside the purview of EPA, but rather are addressed by OSHA. Others wanted the risk assessment to address the amphiboles. Some wanted one single cancer potency factor for all forms of asbestos, even considering the nearly uni-



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He is a recognized expert in industrial hygiene, occupational disease, toxicology, environmental pollution, several aspects of chemical engineering and health risk assessment. Over the past 35 years, he has published nearly 300 peer-reviewed papers in scientific journals, about 50 book chapters, and has authored nearly 500 papers which have been presented at various scientific conferences. Dr. Paustenbach has served as an expert witness in more than 500 depositions and has testified in court approximately 35 times. He has been accepted as an expert to give testimony in numerous cases involving dioxins, asbestos, benzene, chromium, lead, beryllium, cobalt, chlorinated solvents, and other chemicals. He has served as an adjunct professor at five different universities and has served on science advisory boards over the years for NIOSH, EPA, OSHA, CDC and ATSDR.



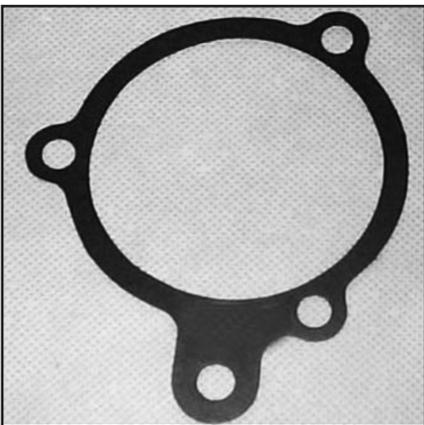
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PERSPECTIVES

versal acceptance that the relative potency for mesothelioma differs across various fiber types. Some wanted the analysis to evaluate more than just brakes, the chlorine industry, and gaskets.

The EPA report on the SAB deliberations, sent to the Director of the Office of Pollution, Prevention, and Toxics, was 91 pages in length (112 pages with references) and contained 103 suggestions for improvement. Had the members had a chance to read the more than 100 written comments, they surely would have had more than 200 suggestions for improvement. Although it was obvious the EPA prepared this report in nearly record time, and that the EPA SAB panel was convened in a hurried manner, it is unclear what the EPA can do with the SAB report. If the Agency has to respond to the more than 100 written letters (containing several hundred suggestions) submitted by non-panel members to the EPA and the 103 comments of the panel members, it could take years to generate a new version of this risk assessment. As it is currently written, it certainly is in no shape to be used to support a ban on those few products allegedly still entering the marketplace.

One might ask, “what is the harm in banning asbestos-containing products?” The answer is nothing. The problem with using a faulty risk assessment that concluded that working with brakes and gaskets “posed an



Unlike the loose fibers found in asbestos insulation, asbestos fibers in gaskets are “locked in” with various binders.

“The problem with using a faulty risk assessment that concluded that working with brakes and gaskets ‘posed an unreasonable risk to the health of workers’ to support a ban is that it is scientifically incorrect. Perhaps more importantly ... it opens the doors for billions (if not tens of billions) of dollars of scientifically unwarranted litigation in the coming years....”

unreasonable risk to the health of workers” to support a ban is that it is scientifically incorrect. Perhaps more importantly, on a practical level, it opens the doors for billions (if not tens of billions) of dollars of scientifically unwarranted litigation in the coming years because, even though substantial exposures generally ended about 35 years ago, there are at least 300 - 1,000 spontaneous mesotheliomas every year in the United States.⁷⁴ These have nothing to do with exposure to asbestos. This is a transparent attempt to construct a regulatory foundation, almost completely without any scientific evidence, that can extend asbestos litigation for decades even though exposures to asbestos from encapsulated products are de minimus. This ultimately serves to enrich the Plaintiff bar rather than protect the public health and brings about an inappropriate redistribution of wealth during a time when such monies could improve the welfare of millions of Americans.

Our Recommendations for Bringing Science Back to The Process

Our team has spent more than 250 hours studying the original EPA Draft Risk Evaluation for Asbestos, writing comments, listening to the public meeting, and reading the August 27, 2020, SAB report. To us, if

just seven actions were taken, the EPA would be equipped with the information that they need to conduct a risk assessment on chrysotile asbestos properly. These recommendations also capture requests that some panelists made to the Agency, which they believed were missing from the EPA’s proposed assessment. The same criticisms are found in the 100 letters from the public.

1. The regulated community should order the brakes that allegedly contain asbestos, which are supposedly manufactured in China, Russia, and Canada. The brakes should then be assayed to see if they contain chrysotile. Results should be published in a peer-reviewed journal.
2. If any of these products can be obtained, then a serious effort should be made to determine how many might be entering the country and the number of potentially exposed persons. This is important information to the Office of Management and Budget (OMB), who is normally tasked to decide if the monies spent on this effort by EPA make economic sense.
3. Assemble all the relevant toxicology studies on chrysotile, including those which evaluated the toxicity of fibers soaked in resins. These studies need to

be incorporated into the next draft of the risk assessment.

4. Assemble all the relevant epidemiology studies and build a chart that identifies all of the strengths and weaknesses of these studies. There are at least 20 of them even though the EPA relied on two (that were not applicable).

5. Assemble all of the various science panel views and published papers of the past 30-40 years that are relevant to understanding the cancer potency of chrysotile and the various low dose extrapolation models.

6. Critically evaluate the above topics and then, using the current EPA cancer guidelines, decide if the benchmark dose approach is more appropriate than the linearized multistage model for chrysotile (then conduct the appropriate analysis) for identifying a virtually safe dose or reference concentration (RFC).

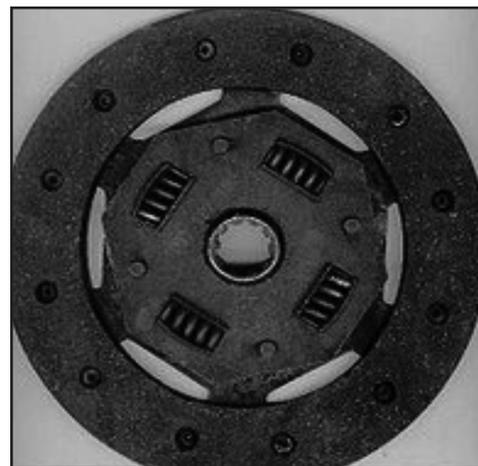
7. Collect additional data, if necessary, to be certain that an adequate industrial hygiene database is available for understanding the exposure to asbestos associated with changing brakes and interacting with gaskets in the 1950s - 1980s time frame. Although the SAB panel seemed to believe the data on that time period is inadequate, there are hundreds of samples that have been collected, and most appear in published, peer-reviewed papers. Given the time constraints on the panel, it is not surprising that this data set was not fully understood by SAB members.

Closing

If the EPA concludes that they want to consider the 500 + pages of comments from nearly 100 divergent camps and write a better risk assessment, the challenge is substantial. There is no hope of satisfying all those who submitted comments or those who served on the SAB panel. This is because each party wanted this assessment to do “what they wanted it to do.” Those in a position of leadership within the EPA and OMB need to define objectives and disregard comments that are not pertinent, or this document will never be completed. If EPA decides to move forward with this initiative, a new SAB panel should be convened, and scientists who have decades of experience, from both sides of the aisle, should be called upon and presented with a truly comprehensive basket of information.

However, we argue that it does not need to be completed because, going forward, with the exception of chrysotile use in the chlorine industry, there will be virtually no possible exposure to workers from imported asbestos-containing products. As pointed out by the EPA, the exposures reported by the firms involved in the chlorine industry are far below the OSHA PEL. If there is a genuine concern about workplace exposure to chrysotile, that matter should come before the appropriate agency (OSHA).

Like most health professionals, we have never opposed a ban on asbestos. However, one



Historically, asbestos-containing automotive clutches contained between 30 – 60 percent chrysotile asbestos that were encapsulated in phenolic resins or other bonding agents.

does wonder why the EPA chose the same studies used by the plaintiff bar in litigation without taking into account the overwhelming science that told an entirely different story than the one they put forward in its published document.

If EPA chooses to move forward, hopefully, they will address the comments of the more than 100 professionals who submitted letters, along with the SAB's 103 recommendations. At the very least, EPA should, in our view, for now, say it was premature in concluding that exposure to asbestos-containing gaskets and brakes, today, poses “an unreasonable risk to public health.”

This paper was to be submitted to HarrisMartin on December 29, 2020, but, due to inclement weather, it was held until December 30, 2020. That morning, the EPA released its final version of the Chrysotile Risk Assessment, which reached essentially the same conclusions as was published in the March 2020 draft.⁷⁵ There was always speculation that the EPA would issue this document before a change in the administration occurred in 2021, and they did.

On Jan. 29, 2021, HarrisMartin published an article noting that several groups have asked the 9th Circuit to review the EPA risk assessment on chrysotile because they didn't believe it was sufficiently broad or sufficiently strict. The petition was filed by the Asbestos Awareness Disease Awareness Organization and five other organizations. A number of experts joined in the petition, as well, including Barry Castleman, Raja Flores, Arthur Frank, Philip Landrigan, Richard Lemen, and Celeste Monforton. An assessment conference has been scheduled for March 9. For more on the petition, see the related article in this issue.



Endnotes

- ¹ Zellmer, M. G. Chrysotile and the EPA: Part of a Continuing Saga. *HarrisMartin COLUMNS - Asbestos* vol. 20 (2020).
- ² Blouin, D. P., Kelly, O. P. & Wetmore, J. B. Dangerous Denial: Illogical Defense Bar Commentary Ignores Well-Established Science that Chrysotile Asbestos Kill. *HarrisMartin COLUMNS - Asbestos* vol. 20 (2020).
- ³ Zellmer, M. G. Strange Bedfellows: DACA, Asbestos, the EPA, and a Reply to 'Dangerous Denial'. *HarrisMartin COLUMNS - Asbestos* vol. 20 (2020).
- ⁴ U.S. Environmental Protection Agency. *Draft Risk Evaluation for Asbestos*. 310 (2020).
- ⁵ Blouin. Dangerous Denial. *HarrisMartin COLUMNS - Asbestos* vol. 20. 2020.
- ⁶ Pierce, J. S., Ruestow, P. S. & Finley, B. L. An updated evaluation of reported no-observed adverse effect levels for chrysotile asbestos for lung cancer and mesothelioma. *Crit. Rev. Toxicol.* **46**, 561–586 (2016).
- ⁷ Berman, D. W. & Crump, K. S. A Meta-Analysis of Asbestos-Related Cancer Risk That Addresses Fiber Size and Mineral Type. *Crit. Rev. Toxicol.* **38**, 49–73 (2008).
- ⁸ Berman, D. W. & Crump, K. S. Update of Potency Factors for Asbestos-Related Lung Cancer and Mesothelioma. *Crit. Rev. Toxicol.* **38**, 1–47 (2008).
- ⁹ Berman, D. W. & Crump, K. S. *Technical Support Document For A Protocol to Assess Asbestos-Related Risk*. 474 (2003).
- ¹⁰ Garabrant, D. H. *et al.* Mesothelioma among Motor Vehicle Mechanics: An Updated Review and Meta-analysis. *Ann. Occup. Hyg.* **60**, 8–26 (2016).
- ¹¹ Garabrant, D. H. & Pastula, S. T. A comparison of asbestos fiber potency and elongate mineral particle (EMP) potency for mesothelioma in humans. *Toxicol. Appl. Pharmacol.* **361**, 127–136 (2018).
- ¹² Hodgson, J. T. & Darnton, A. The Quantitative Risks of Mesothelioma and Lung Cancer in Relation to Asbestos Exposure. *Ann. Occup. Hyg.* **44**, 565–601 (2000).
- ¹³ Grisham, J. *The King of Torts*. (Dell Publishing Company, 2003).
- ¹⁴ Frank, A. L. Re: Consideration of Asbestos as a Toxic Material. (2017).
- ¹⁵ Giannasi, F. Ban on Asbestos Diaphragms in the Chlorine-related Chemical Industry and Efforts toward a Worldwide Ban. *INT J OCCUP Env. Health* **13**, 5 (2007).
- ¹⁶ Blouin. Dangerous Denial. 2020.
- ¹⁷ Mossman, K. L. Cancer Complexity and Radiation Protection: *Health Phys.* **107**, 73–79 (2014).
- ¹⁸ U.S. Environmental Protection Agency. *Guidelines for Carcinogen Risk Assessment*. 166 (2005).
- ¹⁹ Calabrese, E. J. Hormesis: a revolution in toxicology, risk assessment and medicine: Re-framing the dose–response relationship. *EMBO Rep.* **5**, (2004).
- ²⁰ Calabrese, E. & Golden, R. Special Issue: Assessing the Scientific Basis of the Linear No Threshold (LNT) Model with Threshold Models for Cancer Risk Assessment of Radiation and Chemicals. *Chem. Biol. Interact.* **301**, 1–146 (2019).
- ²¹ Ames, B. N. & Gold, L. S. Environmental Pollution, Pesticides, and the Prevention of Cancer: Misconceptions. *FASEB J.* **11**, 1041–1052 (1997).
- ²² Calabrese. Hormesis. *EMBO* (2004).
- ²³ Calabrese. The linear No-Threshold (LNT) *Chem. Biol. Interact.* (2019).
- ²⁴ U.S. Environmental Protection Agency. *Asbestos Ban and Phase-Out Federal Register Notices*. (2018).
- ²⁵ Zellmer, M. G. Strange Bedfellows. *HarrisMartin COLUMNS - Asbestos* vol. 20 (2020).
- ²⁶ Paustenbach, D. J., Finley, B. L., Lu, E. T., Brorby, G. P. & Sheehan, P. J. Environmental And Occupational Health Hazards Associated With The Presence Of Asbestos In Brake Linings and Pads (1900 To Present): A “State-of-the-Art” Review. *J. Toxicol. Environ. Health Part B* **7**, 25–80 (2004).
- ²⁷ Paustenbach, D. J. Environmental And Occupational Health Hazards. *J. Toxicol. Environ. Health Part B* **7**, 25–80 (2004).
- ²⁸ Bernstein, D. M. *et al.* Evaluation of the dose-response and fate in the lung and pleura of chrysotile-containing brake dust compared to chrysotile or crocidolite asbestos in a 28-day quantitative inhalation toxicology study. *Toxicol. Appl. Pharmacol.* **351**, 74–92 (2018).
- ²⁹ Bernstein, D. M., Rogers, R. & Smith, P. The Biopersistence of Canadian Chrysotile Asbestos Following Inhalation. *Inhal. Toxicol.* **15**, 1247–1274 (2003).
- ³⁰ Dement, J. M., Loomis, D., Richardson, D., Wolf, S. H. & Kuempel, E. D. Estimates of historical exposures by phase contrast and transmission electron microscopy for pooled exposure-response analyses of North Carolina and South Carolina, USA asbestos textile cohorts.

Occup. Environ. Med. **68**, 593–598 (2011).

³¹ Elliott, L. *et al.* Lung cancer mortality in North Carolina and South Carolina chrysotile asbestos textile workers. *Occup. Environ. Med.* **69**, 385–390 (2012).

³² Loomis, D., Dement, J. M., Wolf, S. H. & Richardson, D. B. Lung cancer mortality and fibre exposures among North Carolina asbestos textile workers. *Occup. Environ. Med.* **66**, 535–542 (2009).

³³ Berman, D. W. & Crump, K. S. A Meta-Analysis of Asbestos-Related Cancer Risk. *Crit. Rev. Toxicol.* **38**, 49–73 (2008).

³⁴ Berman, D. W. & Crump, K. S. *Technical Support Document For A Protocol to Assess Asbestos-Related Risk.* 474 (2003).

³⁵ Elliott, L. *et al.* Lung cancer mortality. *Occup. Environ. Med.* **69**, 385–390 (2012).

³⁶ Dement, J. M., Harris, R. L., Symons, M. J. & Shy, C. M. Exposures and mortality among chrysotile asbestos workers. Part I: Exposure estimates. *Am. J. Ind. Med.* **4**, 399–419 (1983).

³⁷ Pavlisko, E. N., Liu, B., Green, C., Sporn, T. & Roggli, V. L. Malignant Diffuse Mesothelioma in Women: A Study of 354 Cases. *Am. J. Surg. Pathol.* **44**, 293–304 (2020).

³⁸ Roggli, V., Oury, T. & Moffatt, E. Malignant Mesothelioma in Women. in *Anatomic Pathology* vol. 2 147–163 (ASCP Press, 1997).

³⁹ McDonald, A. D. & McDonald, C. Malignant Mesothelioma in North America. *Cancer* **46**, 1650–1656 (1980).

“As was pointed out by the EPA, the exposures reported by the firms involved in the chlorine industry are far below the OSHA PEL. If there is a genuine concern about workplace exposure to chrysotile, that matter should come before the appropriate agency (OSHA).”

⁴⁰ Teta, M. J. *et al.* Mesothelioma in Connecticut, 1955 - 1977. *J. Occup. Med.* **25**, 8 (1983).

⁴¹ Teschke, K. *et al.* Mesothelioma Surveillance to Locate Sources of Exposure to Asbestos. *Can. J. Public Health.* **88**, 163–168 (1997).

⁴² Hessel, P. A., Teta, M. J., Goodman, M. & Lau, E. Mesothelioma Among Brake Mechanics: An Expanded Analysis of a Case-Control Study. *Risk Anal.* **24**, 547–552 (2004).

⁴³ Rake, C. *et al.* Occupational, Domestic and Environmental Mesothelioma Risks in the British Population: A Case-Control Study. *Br. J. Cancer* **100**, 1175–1183 (2009).

⁴⁴ Agudo, A. *et al.* Occupation and Risk of Malignant Pleural Mesothelioma: A Case-Control Study in Spain. *Am. J. Ind. Med.* **37**, 159–168 (2000).

⁴⁵ Hansen, J. & Meersohn, A. Kræftsygelighed (1970-97) blandt danske lønmodtagere fordelt på Arbejdstilsynets 49 branchegrupper. 123 (2003).

⁴⁶ Aguilar-Madrid, G. *et al.* Case-control study of pleural mesothelioma in workers with social security in Mexico. *Am. J. Ind. Med.* **53**, 241–251 (2010).

⁴⁷ Merlo, D. F. *et al.* A historical mortality study among bus drivers and bus maintenance workers exposed to urban air pollutants in the city of Genoa, Italy. *Occup. Environ. Med.* **67**, 611–619 (2010).

⁴⁸ Rolland, P. *et al.* Occupations and industries in France at high risk for pleural mesothelioma: A population-based case-control study (1998-2002). *Am. J. Ind. Med.* **53**, 1207–1219 (2010).

⁴⁹ Woitowitz, H.-J. Mesothelioma Among Car Mechanics. *Ann. Occup. Hyg.* **38**, 635–638 (1994).

⁵⁰ McElvenny, D. M., Darnton, A. J., Price, M. J. & Hodgson, J. T. Mesothelioma mortality in Great Britain from 1968 to 2001. *Occup. Med.* **55**, 79–87 (2005).

⁵¹ Milham, S. *Washington State occupational mortality database, 1950 - 2010.* (2011).

⁵² NIOSH. *Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research.* (2011).

⁵³ Health & Safety Executive. *Mesothelioma Occupation Statistics: Male and Female Deaths Aged 16 - 74 in Great Britain.* 54 (2013).

PERSPECTIVES

- ⁵⁴ Roelofs, C. R., Kernan, G. J., Davis, L. K., Clapp, R. W. & Hunt, P. R. Mesothelioma and employment in Massachusetts: Analysis of cancer registry data 1988–2003: Mesothelioma in Massachusetts 1988–2003. *Am. J. Ind. Med.* **56**, 985–992 (2013).
- ⁵⁵ Garabrant, D. H. *et al.* Mesothelioma among Motor Vehicle Mechanics. *Ann. Occup. Hyg.* **60**, 8–26 (2016).
- ⁵⁶ Wong, O. Malignant Mesothelioma and Asbestos Exposure among Auto Mechanics: Appraisal of Scientific Evidence. *Regul. Toxicol. Pharmacol.* **34**, 170–177 (2001).
- ⁵⁷ Goodman, M. *et al.* Mesothelioma and Lung Cancer Among Motor Vehicle Mechanics: a Meta-analysis. *Ann. Occup. Hyg.* **48**, 309–326 (2004).
- ⁵⁸ Pierce, J. S. An updated evaluation. *Crit. Rev. Toxicol.* **46**, 561–586 (2016).
- ⁵⁹ Berman, D. W. & Crump, K. S. *Technical Support Document For A Protocol to Assess Asbestos-Related Risk.* 474 (2003).
- ⁶⁰ Langer, A. M. Reduction of the Biological Potential of Chrysotile Asbestos Arising from Conditions of Service on Brake Pads. *Regul. Toxicol. Pharmacol.* **38**, 71–77 (2003).
- ⁶¹ Korchevskiy, A., Rasmuson, J. O. & Rasmuson, E. J. Empirical model of mesothelioma potency factors for different mineral fibers based on their chemical composition and dimensionality. *Inhal. Toxicol.* **31**, 180–191 (2019).
- ⁶² Boyles, M. S. P., Poland, C. A., Raftis, J. & Duffin, R. Assessment of the physico-chemical properties of chrysotile-containing brake debris pertaining to toxicity. *Inhal. Toxicol.* **31**, 325–342 (2019).
- ⁶³ Poland, C. A. & Duffin, R. The toxicology of chrysotile-containing brake debris: implications for mesothelioma. *Crit. Rev. Toxicol.* **49**, 11–35 (2019).
- ⁶⁴ Bernstein, D. M. *et al.* Evaluation of the dose-response and fate in the lung and pleura of chrysotile-containing brake dust compared to TiO₂, chrysotile, crocidolite or amosite asbestos in a 90-day quantitative inhalation toxicology study – Interim results Part 2: Histopathological examination, Confocal microscopy and collagen quantification of the lung and pleural cavity. *Toxicol. Appl. Pharmacol.* **387**, 114847 (2020).
- ⁶⁵ Bernstein, D. M. *et al.* Evaluation of the exposure, dose-response and fate in the lung and pleura of chrysotile-containing brake dust compared to TiO₂, chrysotile, crocidolite or amosite asbestos in a 90-day quantitative inhalation toxicology study – Interim results Part 1: Experimental design, aerosol exposure, lung burdens and BAL. *Toxicol. Appl. Pharmacol.* **387**, 114856 (2020).
- ⁶⁶ Korchevskiy, A., Rasmuson, J. O. & Rasmuson, E. J. Empirical model of mesothelioma potency factors for different mineral fibers based on their chemical composition and dimensionality. *Inhal. Toxicol.* **31**, 180–191 (2019).
- ⁶⁷ Bernstein, D. M., Rogers, R. & Smith, P. The Biopersistence of Canadian Chrysotile Asbestos Following Inhalation: Final Results Through 1 Year After Cessation of Exposure. *Inhal. Toxicol.* **17**, 1–14 (2005).
- ⁶⁸ Bernstein, D. M. *et al.* Quantification of the pathological response and fate in the lung and pleura of chrysotile in combination with fine particles compared to amosite-asbestos following short-term inhalation exposure. *Inhal. Toxicol.* **23**, 372–391 (2011).
- ⁶⁹ Eastern Research Group, Inc. *Report on the Expert Panel on Health Effects of Asbestos and Synthetic Vitreous Fibers: The Influence of Fiber Length.* 229 (2003).
- ⁷⁰ Eastern Research Group, Inc. *Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk.* (2003).
- ⁷¹ Eastern Research Group, Inc. *Appendix B: Consultant’s premeeting comments. In Report on the expert panel on health effects of asbestos and synthetic vitreous fibers: The influence of fiber length.* (2003).
- ⁷² Hodgson, J. T., McElvenny, D. M., Darnton, A. J., Price, M. J. & Peto, J. The expected burden of mesothelioma mortality in Great Britain from 2002 to 2050. *Br. J. Cancer* **92**, 587–593 (2005).
- ⁷³ Garabrant, D. H. A comparison of asbestos fiber potency. *Toxicol. Appl. Pharmacol.* **361**, 127–136 (2018).
- ⁷⁴ Moore, A. J., Parker, R. J. & Wiggins, J. Malignant mesothelioma. *Orphanet J. Rare Dis.* **3**, 34 (2008).
- ⁷⁵ U.S. Environmental Protection Agency. *Risk Evaluation for Asbestos. Part 1: Chrysotile Asbestos.* 352 (2020).

Disclosure: The authors work within Paustenbach and Associates which is a consulting firm with headquarters in Jackson Hole. The firm specializes in conducting risk assessments of occupational and environmental hazards, as well as contaminated foods, sediments, ambient air and consumer products. Paustenbach and colleagues have published more than 30 peer reviewed papers on asbestos over the past 20 years. As noted in the biography, Dr. Paustenbach has served as an expert witness for defendants and has testified in over 400 depositions, as well as more than 30 trials involving the alleged health hazards of brakes, gaskets, phenolic molding compound, mastics and other materials having encapsulated gaskets. This paper received no funding from any entity and its development was not requested by any lawyer. No lawyer had input into the text which was entirely written by Drs. Paustenbach and Brew.