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Commentary

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Background on the Draft Risk Evaluation

On March 30, 2020, the Environmental Protection Agency released its Draft Risk Evaluation for Asbestos, which examines cancer risks associated with current uses of asbestos in the United States.¹ The Draft Risk Evaluation is the EPA's first evaluation of asbestos in decades and its findings will have broad implications for industry and consumers. Since asbestos usage is extremely limited, it is almost certain that the EPA's final risk evaluation for asbestos will be used more in asbestos litigation than by the government, private industry, or the general public.

This risk evaluation was performed in accordance with the Frank R. Lautenberg Chemical Safety for the 21st Century Act which passed in 2016 and amended the Toxic Substances Control Act (TSCA).² Prior to this amendment, the EPA did a similar risk evaluation of asbestos under TSCA in the 1980s that resulted in a 1989 ban of many asbestos-containing products. That ban was largely overturned in the courts, and since the overturning of the 1989 ban, the EPA has not succeeded in regulating any existing chemicals using TSCA. When the Lautenberg Chemical Safety Act was signed into law, President Barack Obama remarked the legislation was necessary, saying, "The [old] system was so complex, it was so burdensome that our country hasn't even been able to uphold a ban on asbestos."³

The Lautenberg Chemical Safety Act requires the EPA to conduct risk evaluations not only of asbestos, but of

numerous other substances “to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors.”⁴ Notably, this requirement is contrary to TSCA’s express legislative intent that the EPA “shall consider the environmental, economic, and social impact of any action [it] takes or proposes” under TSCA.⁵

Asbestos is presently subject to extensive Federal and state regulations and reporting requirements. The Federal Occupational Safety and Health Administration (OSHA) oversees working conditions for U.S. workers by implementing and managing occupational safety and health standards, including regulations that pertain to handling asbestos in the workplace. In the consumer setting, the Consumer Product Safety Commission (CPSC) protects consumers and families from consumer products that pose hazards. The CPSC has instituted bans and restrictions on asbestos-containing patching compounds, garments, and fireplace materials. The EPA has successfully banned new uses of asbestos in products such as asbestos-containing insulation and fireproofing materials.

The EPA has also addressed all asbestos-products not currently in use in the U.S., sometimes described as “legacy uses.” In April 2019, the EPA finalized an Asbestos Significant New Use Rule (SNUR) under TSCA. The Asbestos SNUR prohibits the future manufacture (including import) or processing of discontinued uses of asbestos before the EPA has the opportunity to evaluate each intended use for risks to health and the environment and to take any necessary regulatory action, which may include a prohibition.

Findings

The Draft Risk Evaluation purports to analyze current asbestos uses and evaluate risk with each such use.⁶ The EPA notes that while asbestos is no longer mined or processed, ongoing uses include diaphragms in the chlor-alkali industry, sheet gaskets in chemical production facilities, oilfield brake blocks, aftermarket automotive brakes/linings, other vehicle friction products, and other gaskets.⁷ Consumption of asbestos in the United States has decreased from a record high of 803,000 tons in 1973 to an estimated 100 tons in 2019.⁸ The chlor-alkali industry accounted for 100% of the nation’s asbestos mineral consumption in 2019.⁹

Specifically, asbestos diaphragms are used in 11 chlor-alkali plants in the United States which account for about one-third of domestic chlorine production.¹⁰ Additionally, in 2019, only “a small, but unknown, quantity of asbestos was imported within manufactured products, including brake blocks for use in the oil industry, rubber sheets for gaskets used to create a chemical containment seal in the production of titanium dioxide, certain other types of preformed gaskets, and some vehicle friction products.”¹¹ The EPA also noted that chrysotile is the only type of asbestos being used today, and they will review legacy asbestos uses and other fiber types in a future evaluation.¹²

After identifying uses, the EPA reviewed monitoring data and published literature to evaluate the risk to human health.¹³ The EPA then calculated risk for lung cancer and mesothelioma from the uses by using a standard of 1 death per 10,000 for occupational workers and 1 death per 1,000,000 for consumers and bystanders.¹⁴ The EPA reported risk in excess of its benchmark for occupational usage of sheet gaskets in chemical industry, UTV gasket replacement, and high-end exposures for the chlor-alkali industry, sheet gasket stamping, and friction replacement.¹⁵ For consumers, the EPA found risk in excess for brake and gasket work.¹⁶ The findings are based on several assumptions and uncertainties, namely that asbestos is still used in friction products and the fiber release levels.¹⁷

In stark contrast to the purposes for which the EPA was created, the EPA’s 2020 Draft Risk Evaluation of Asbestos does not evaluate hazards or exposures to the general population. General population exposures to chrysotile asbestos may occur from industrial or commercial uses, industrial releases to air, water, or land, and other conditions of use. However, the EPA acknowledges in the risk assessment that those types of exposures are already covered by environmental statutes administered by the EPA.¹⁸ While the EPA reports that hundreds of thousands of people are potentially exposed to asbestos, in reality, this risk evaluation may only affect 10 to 100 or fewer persons annually in the coming years.¹⁹ Conducting an evaluation for such a small population is surprising, because the EPA recently declined to conduct a risk evaluation for perchlorate since the population of 620,000 people was too small to present a “meaningful opportunity for health risk reduction.”²⁰

The Toxic Substances Control Act requires the EPA use the best available science in the review.²¹ To identify the relevant studies, the EPA conducted a review of peer reviewed studies to identify studies relevant to the analysis.²² The EPA subsequently identified thousands of articles, but ultimately concluded that only a few dozen were relevant to its evaluation.²³

Public Comments Identify Numerous Issues with the Draft

After releasing the Draft Risk Evaluation, the EPA provided time through June 2, 2020, for public comment on the findings. The EPA ultimately received 78 comments from trade groups, pathologists, pulmonologists, law firms, and other interested parties.²⁴ Several of the comments posted were submitted before June 2, but they did not post until after the close of the comment period. A number of national experts and scientists submitted comments, including Charlie Blake, John Spencer, and Drs. Christy Barlow, Kim Anderson, Michele Carbone, Bruce Case, Suresh Moolgavkar, Fiona Mowat, Allan Feingold, David Garabrant, Bryan Hardin, Art Langer, Brooke Mossman, Victor Roggli, Thomas Sporn, Dennis Paustenbach, Bertram Price, Coreen Robbins, Jennifer Sahmel, Jennifer Pierce, and Brent Finley.²⁵ These experts noted numerous issues with the Draft Risk Evaluation, including the exclusion of friction epidemiological literature from the analysis, omission of background cases of mesothelioma, questions about ongoing usage, and sampling data problems.²⁶ Drs. Garabrant and Roggli noted that while the Draft Risk Evaluation identified studies from North Carolina and South Carolina textile mills as chrysotile-only studies, a significant amount of amphibole asbestos was used in the facilities.²⁷

As pointed out by Dennis Paustenbach in his official comments on the draft, “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 Permissible Exposure Limit for asbestos (and the number of plausible workers is low).”²⁸ Moreover, “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).”²⁹ Nevertheless, the EPA concluded in the risk evaluation that the processing and use of these products presents an

unreasonable risk, regardless of the nature, duration, or frequency of the exposure.³⁰

Comments were also submitted by noted plaintiff experts Drs. Steven Compton, Richard Lemen, Jacqueline Moline, John Dement, Arthur Frank, and Christine Oliver. Their comments sought an expansion of the Draft Risk Evaluation to include an evaluation of legacy asbestos uses, amphiboles, and asbestos contamination in products like talcum powder.³¹ Drs. Frank and Moline also requested that the EPA address other cancers and non-malignant disease.³²

Trade groups, such as the U.S. Chamber, American Petroleum Institute, The Chlorine Institute, Iron Mining Association, Vinyl Institute, and the Asbestos Disease Awareness Organization also submitted comments.³³ The U.S. Chamber objected to the EPA’s decision “to include a number of highly compensated experts for plaintiffs in asbestos personal injury cases but to exclude any testifying experts with the differing opinions from both the SACC and Ad Hoc Peer Reviewers.”³⁴ The comment also noted that inclusion of the experts – Drs. Steven Markowitz, Marty Kanarek, and Henry Anderson – runs against the EPA’s commitment to “avoid the ‘appearance of loss of impartiality, lack of independence’ when selecting ad hoc panelists.”³⁵ The U.S. Chamber Institute for Legal Reform, American Property Casualty Insurance Association, American Tort Reform Association, Aerospace Industries Association, Coalition for Litigation Justice, International Association for Defense Counsel, National Federation of Independent Business Small Business Legal Center, Product Liability Advisory Council, Inc., and Washington Legal Foundation joined the U.S. Chamber’s letter.³⁶

Drs. Markowitz and Anderson – two of the experts noted in the U.S. Chamber’s letter - also have documented ties to the Asbestos Disease Awareness Organization (ADAO), a lobbying group that advocates for the “need for a global asbestos ban.”³⁷ The Alan Reinstein Ban Asbestos Now Act of 2019 (ARBAN) is named after the late husband of Linda Reinstein, ADAO’s President and CEO.³⁸ Most of the sponsors of ADAO’s annual conferences are law firms that specialize in the representation of plaintiffs in personal injury asbestos litigation. On May 28, 2020, the ADAO filed its official comments with the EPA in response to the 2020 Draft Risk Evaluation on Asbestos.³⁹ The ADAO’s

comments are in line with its strong advocacy towards a comprehensive ban on asbestos.⁴⁰

Experts who make significant amounts of money testifying on behalf of plaintiffs in asbestos litigation at the request of a handful of national law firms have been involved in this evaluation process since at least 2017. In March 2017, for the purpose of the EPA's evaluation of asbestos, Dr. Arthur Frank sent the EPA a 216-page document that he admittedly put together with the assistance of a plaintiff attorney with whom he works with in asbestos litigation matters.⁴¹ He regularly issues this same document as his report in asbestos litigation. In another instance, Dr. Frank along with Barry Castleman and others met with one of the EPA deputy administrators in Washington, D.C., to ensure that asbestos was selected for this type of evaluation and to make sure the EPA had a "proper understanding" of the risks of asbestos.⁴²

The Peer Review Hearing Reviews and Identifies Additional Questions

The EPA conducted a peer review meeting on the Draft Risk Evaluation from June 8-11, 2020. The hearing was initially scheduled for April 27-30, 2020, but the EPA postponed the meeting based on COVID-19 issues and conflicts.⁴³ Diana Wong, Louis Scarano, the SACC committee, the ad hoc peer review committee, and others from the EPA participated in the hearing. The EPA also hired Drs. Leslie Elliott, Dana Loomis, and Leslie Stayner as epidemiological consultants for the draft, and they also attended the hearing. The hearing began with time for public oral comments with everyone receiving five minutes to present. Public commenters included Linda Reinstein, Dr. David Garabrant, Dr. Christine Oliver, Dr. Dennis Paustentbach, Dr. Arthur Frank, Steve Risotto of the American Chemistry Council, Dr. Victor Roggli, attorney Robert Sussman, Dr. Suresh Moolgavkar, Dr. Jacqueline Moline, Dr. Gabor Mezei, Dr. Barry Castleman, Dr. Steven Compton, and Dr. Richard Lemen.⁴⁴ The EPA then reviewed each section of the Draft Risk Evaluation and provided time for comment from the SACC and ad hoc peer review committee.

The American Chemistry Council's written and oral comments indicated that the EPA received duplicate data in its analysis.⁴⁵ The duplicate data affected the EPA's statistical analysis and removing the data "results

in about 60 percent of the full-shift samples being below the limit of detection."⁴⁶ The EPA is now removing the duplicate data and revising the risk evaluation, which will affect the final risk determinations.⁴⁷

At the close of the peer review meeting, the EPA noted that it is seeking to finalize the risk evaluation in the next 60 days. If an unreasonable risk is found with any of the chrysotile uses, the EPA will then enter the rule-making phase, which could last over one year.

Conclusion

The Draft Risk Evaluation represents a significant amount of work and expense despite the limited and controlled ongoing asbestos uses. As this stage draws to a conclusion, the interested parties will likely continue historical precedent of bringing the findings to court. In fact, the Ninth Circuit already ruled in November 2019 that the EPA violated TSCA by excluding legacy uses of chemicals, like asbestos, from consideration in its current round of TSCA risk evaluations.⁴⁸ This ruling, lays the foundation for future litigation in the decades to come.

Endnotes

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25. *Id.*
26. Suresh Moolgavkar, Comments to the United States Env'tl. Prot. Agency Regarding March 2020 Draft Risk Evaluation for Asbestos 2, 19-20 (May 21, 2020), available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0103>.
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29. *Id.* at 5.
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