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IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

Gloria Whalen, Plaintiff, v. E.I. DuPont de Nemours and Company, et al., Defendants.	C.A. No. N23C-09-059 ASB
Howard B. Altena, et al., Plaintiffs, v. E.I. DuPont de Nemours and Company, et al., Defendants.	C.A. No. N23C-09-107 ASB

PLAINTIFF'S MOTION TO EXCLUDE DEFENSE EXPERT JOHN SPENCER AND ANY TESTIMONY RELATING TO HIS OCCUPATIONAL EXPOSURE ASSESSMENT OF REMINGTON SHOTGUN SHELLS

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Plaintiffs move this Court for an order to exclude, or at least limit, the testimony of Defendant's expert Mr. John Spencer, CIH, CSP, on the grounds that (1) he is unqualified to give the opinions he espouses in these cases, (2) his methodology does not meet the standards for expert opinion testimony set forth under *Daubert* and Evid. R. 701 and 702, (3) his opinions lack foundation and are not the product of reliable scientific principles and methods, and (4) his opinions will only confuse and mislead the jury. Additionally, Plaintiffs move to exclude entirely any reference to Mr. Spencer's occupational exposure assessment of Remington shotgun shells.

Plaintiff understands it will have the opportunity to make a formal presentation on these issues at a *Daubert* hearing, which has been scheduled for November 25, 2024, and November 26, 2024.

STATEMENT OF FACTS

Shooters Exposed to Remington Shotshells Develop Mesothelioma. Before this Court are two cases of mesothelioma, each with many years of exposure to asbestos fiber from recreational use of Remington shotgun shells. The toxic health effects of asbestos exposure have been known for over one hundred years, and the unique relationship between asbestos exposure and mesothelioma since at least 1960. Mesothelioma is a rare cancer of the mesothelial cells that line the lungs and

abdomen. It is considered a signal tumor for asbestos exposure, and it is invariably fatal.

Howard Altena was born in South Dakota and raised on a 2000-acre grain and cattle farm in Doon, Iowa. He has spent his life farming. In 1963, at the age of ten, his father showed him how to hold a shotgun, and Howard has been an avid hunter and trap shooter ever since. He has used Remington shotgun shells his entire life, and did not learn they contained asbestos until after he was diagnosed with mesothelioma. Exhibit 1, Altena Complaint at page 2; Exhibit 2, Altena Affidavit.

Eugene Schoepke has a similar story. Raised on a farm in Varna, Illinois, he spent his adult life farming crops and raising livestock. He was an avid hunter and used Remington shotgun shells from the 1960's through the 1980's. Exhibit 3, Janet Schoepke Deposition[1] at 13:17-14:24 and Exhibit 4, Jeffrey Schoepke Deposition at 24:2-26, 27:17-22; 154:1-155:12. He too was diagnosed with mesothelioma. Exhibit 5, Schoepke Complaint at page 2. It is the opinion of Plaintiffs' medical causation experts Drs. Arthur Frank and David Zhang that each man's mesothelioma was caused at least in part by his exposure to asbestos from Remington shotshells. Exhibit 6, Frank Report Altena; Exhibit 7, Frank Report Schoepke; Exhibit 8, Frank Affidavit; Exhibit 9, Zhang Report Altena; Exhibit 10, Zhang Report Schoepke.

These are not the first individuals to allege exposure to asbestos from Remington shotshells caused them to develop mesothelioma. The first was

Huntington Eldridge Jr., a bank executive and a passionate outdoorsman who spent his life raising money for Ducks Unlimited, a nonprofit organization and leader in wetland and waterfowl conservation. Eldridge was diagnosed with mesothelioma at the age of 65 with no exposure to asbestos other than a lifetime of using Remington shotgun shells. He quickly succumbed to his cancer, and his estate filed suit against E. I. du Pont de Nemours (Du Pont) and Sporting Good Properties, Inc., as Successor in Interest to Remington Arms Company (Remington), alleging exposure to asbestos from Remington shotshells contributed to cause his death. Exhibit 11, Eldridge Complaint, Cir. Ct. of Cook County, Ill, County Dept. – Law Division, No. 2017 L 003421. The case was settled prior to trial.

There are now at least ten other similar cases pending in courts around the country that allege exposure to asbestos from Remington shotshells is causing mesothelioma, including a number of cases in Delaware which will be affected by this Court's rulings in *Altena* and *Schoepke*. The Delaware claimants who have offered affidavits and deposition testimony regarding their exposures to Remington shotgun shells include Dorman Laycox, Dale Zick, Darrel Buchholz, and the late James Chorey. Exhibit 12, Laycox Affidavit; Exhibit 13, Zick Affidavit; Exhibit 14, Buchholz Affidavit; Exhibit 15, Chorey Affidavit. Despite many years of using Remington shotgun shells, none had any idea that they contained asbestos.

History of Remington and Du Pont's Asbestos Shotshells. E. I. du Pont de Nemours & Company was founded in Delaware in 1802 as a manufacturer of gunpowder. Remington Arms Company, Inc. was founded in New York in 1816 as a manufacturer of firearms. In 1933, Du Pont acquired a majority interest in and assumed management responsibility for Remington. Exhibit 16, 1933 Remington Annual Report at page 10. Du Pont had already been supplying a major part of the powder used in Remington's shotgun shells for many decades, and the two companies had been working together to develop and improve their products. Exhibit 17, 1933 Du Pont Annual Report, at pages 24-25. Remington was well known at the time as a leading manufacturers of sporting arms and ammunition. Id. In the years that followed, Du Pont exercised considerable control over Remington Arms' engineering, manufacturing and marketing activities, formally acquiring Remington on February 1, 1980.

An October 1951 edition of Popular Science magazine featured an article entitled "How They Make Shotgun Shells", which detailed a visit to Remington's manufacturing plant in Bridgeport, Connecticut and described the manufacturing process for the various components of a Remington shotgun shell. Exhibit 22, Kendall W. Goodwyn, *How They Make Shotgun Shells*, POPULAR SCIENCE, Oct. 1951. The shot is made in a 167-foot-tall shot tower, and is composed of 95% lead, 4% antimony and 1% arsenic. The shot is screened for roundness, sorted for size,

polished and banked. In 1951, Remington made approximately 532,000,000 shot and 1,800,000 shotshells per day. Id. at 172.

The shot is housed in the top of shell. The rest of the components, as detailed in a cross-sectional view, sit just beneath the shot. Id. at 173. Those include a charge of gun powder, a battery cup – which contains the volatile priming mixture that when struck by the anvil ignites the gun powder, and a ***base wad*** – which fills the base of the shell around the battery cup and beneath the gun powder. Id. The battery cup has been referred to in Remington patent filings as the "**boiler room**" of the shell, where the explosive gases of combustion are created, which propel the shot out of the gun at a rate of approximately 1300 feet per second. Exhibit 23, U.S. Patent No. 3,656,434 (issued Apr. 18, 1972). The purpose of the base wad, which is inserted into the head of the shell during the manufacturing process, is to help seal in the explosive gases of combustion, to keep the power behind the shot and keep it from leaking, and to help absorb the shock of the blast. Id. For decades prior to 1960, the base wad as well as the outer body (casing) of the shell was made of paper.

In 1960, Remington redesigned its shells to incorporate a casing made of Du Pont plastic. An explanation of the design and benefits of using plastic for shotshell casings is described in a patent filing dated June 21, 1960, which "relates to seamless, tubular articles which are formed of synthetic olefinic polymers and which are subjected in use to forces of great magnitude at high temperatures, which forces

tend to tear said articles apart." Exhibit 24, U.S. Patent No. 3,103,170 (issued Sep. 10, 1963). A September 1960 issue of Du Pont Magazine boasts that: "Rugged, all-weather hunters need no longer worry about shotgun shells that swell in rain, snow or sleet. Remington Arms has just announced two new premium type shells (Remington and Peters brands) made with steel heads and polyethylene bodies... [t]he weatherproof qualities of the new SP shells, which guard against dampness and humidity, also result in loads which stay factor fresh for longer periods." Exhibit 25, *Torture Tests for an All-Weather Shotgun Shell*, DU PONT MAGAZINE, Sep./Oct. 1951. A central component of the new SP shells was, as Du Pont put it, "***a new exclusive base wad***".

In 1965, Remington filed for a patent on this exclusive new base wad. Exhibit 26, U.S. Patent No. 3,270,671 (issued Sep. 6, 1966). The patent filing describes a novel wad molded from low-cost fibrous material, with a preferred embodiment containing ***40% asbestos fiber by weight***.

A video produced by Remington describes the development and manufacture of its plastic shells. Exhibit 27, Remington Arms Company, Inc., *Plastic Shells - How They Were Developed*. The video illustrates how the shotshell casings are discharged from the side of the shotgun upon firing. It demonstrates that the asbestos containing basewad, as part of the shotgun shell casing, is released not at the end of barrel but at the side of the shotgun, much closer to the hunter's breathing zone

(VIDEO at 4:50-5:25), whereas the shot is discharged out the end of the barrel (Id. at 10:05-12:55). It also shows how the shot is kept in pattern by the use of a shot wad, which, unlike the base wad, is designed to leave the barrel with the shot, before falling away. Id.

By 1966, its 150th anniversary year, and a year of record profit, Remington had discontinued paper shells and converted its entire shotshell line to plastic. Exhibit 28, 1966 Remington Annual Report, at SGPI1000139-SGPI1000141. As a result, virtually every shell manufactured by Remington contained an asbestos base wad. Exhibit 29, 1964 Product Dwg. Dry Molded Base Wads. As Remington would later report to the Environmental Protection Agency (EPA), it used approximately 500 tons of asbestos fiber per year to manufacture its shells. Exhibit 30, U.S. EPA, *Background Information on National Emission Standards for Hazardous Air Pollutants – Proposed Amendments to Standards for Asbestos and Mercury*, Oct. 1974, at page 5. Remington made the shells in different gauges and lengths and with different size shot pellets. It made them in high-brass construction for long-range hunting, and in low-brass construction for closer-range hunting. Exhibit 31, 1966 Remington Catalog, at pages 37-41. From the mid-1960's through 1980, all hunting loads with the exception of the smallest .410 bore shells contained the asbestos base wad. Remington was the only shotshell manufacturer that included asbestos in its product. Exhibit 49, *infra.*, at page 276.

Remington Shotshells Were Manufactured with Asbestos from 1960-1981. The medical consensus as of October 1964, as presented at a Conference on Biological Effects of Asbestos attended by Du Pont doctors and summarized in correspondence to Du Pont's Corporate Medical Director C.A. D'Alonzo, was that "the risk of persons not normally thought of as engaged in work with asbestos, and certainly not thought of as being in the asbestos industry, is greater than was originally thought. This fact should be borne in mind and embraces not only the person's occupation but also his hobbies." Exhibit 34, Stopps Trip Report, Nov. 2, 1964, at page 6. Despite this knowledge, and despite the ever-increasing regulatory activity and public concern regarding the hazards of asbestos, Remington continued to use hundreds of tons of asbestos every year throughout the 1960's and 1970's. Between 1960 and 1981, Remington manufactured and sold many hundreds of millions if not billions of asbestos-containing shotgun shells to consumers for recreational hunting and target shooting all over the world.

It was not until 1980, and due to increased attention from the Environmental Protection Agency (EPA) and the Consumer Product Safety Commission (CPSC), that Remington finally began to remove asbestos from its shells. But it never provided any information to the public about the asbestos in the shells, and it never issued a recall. As a result, hunters were unaware that Remington shells ever contained asbestos, and many still have them in their possession. Given the

construction of the shells and their seemingly unlimited shelf life, it can fairly be assumed that the asbestos shells are still being fired today thereby further exposing unwitting hunters and their families to toxic asbestos fibers.[1]

Asbestos Fiber Release from Remington Shotshells. During its investigation into the *Eldridge* case, Plaintiff's counsel gathered dozens of unused Remington shotshells from online re-salers, including both paper and plastic bodied shells, and sent them for testing to MVA Scientific Consultants. MVA is a licensed and accredited full-service microscopy lab that uses standard microscopy methods published by organizations such as the American Society for Testing and Materials (ASTM), the National Institute for Occupational Safety and Health (NIOSH), and the United States Environmental Protection Agency (EPA). MVA also offers courses in microscopy. Dr. Steven Compton, Ph.D, a physicist with experience in materials science, microscopy, industrial hygiene and environmental forensics, currently serves as MVA's Executive Director. Exhibit 35, Curriculum Vitae, Steven P. Compton, Ph. D.

In its initial analysis, MVA confirmed that all of the Remington plastic shells contained asbestos base wads. Exhibit 36, MVA Scientific Consultants, Examination of Remington Shotgun Shell Basewads for Asbestos, Apr. 26, 2019.

[1] The shells used in the fiber release studies discussed *infra* were all manufactured prior to 1982 and were fired without any issues.

MVA prepared a report summarizing its results that contains numerous photographs of the shell components including the unfired base wads. Id. Following confirmation that the shells contained asbestos, a study was developed to investigate whether and to what extent the shells release asbestos fiber when fired, which study took place in October 2019 and is summarized in a report dated March 2020. Exhibit 37, MVA Scientific Consultants, Investigation of Asbestos Fiber Release During Discharge of Remington Shotgun Shells, Mar. 2, 2020.

Given the study involved potential exposures to airborne asbestos, live ammunition and a firearm, MVA took measures to ensure the study was conducted in a controlled and safe manner. MVA identified a study site in a remote location and hired an abatement contractor to build an isolation chamber in which to perform the experiment. Id. at 2. MVA also engaged the services of a firearms instructor and forensic science consultant to oversee handling and firing of the shotgun, and to help ensure the safety of all involved. Id. A target of steel and ballistics rubber was custom-built to catch the shot, and a stand was built on which to mount and fire the shotgun. Id. at 3. A string was run from outside the chamber to the trigger of the shotgun to allow for remote firing, which would limit the risk associated with any potential malfunction. Id.

MVA set up air filters in multiple areas around the shotgun, including near the muzzle at the end of the gun barrel (where the shot is ejected), near the discharge

chamber (where the shells are ejected), and in the breathing zone of a hypothetical shooter. Id. at 3-4, 20. MVA conducted four tests (air sampling events) with the asbestos shotshells. Id. The first three involved the discharge of 2 shells over the course of 15 minutes, and the fourth involved the discharge of 8 shells over 16 minutes. Id. In each test, and at every location, MVA's air sampling filters captured asbestos fibers in the air. Id. at 10-11.

To fully characterize the extent and nature of the asbestos fiber release from the shotshells, MVA used a variety of methods to analyze the air filters. It used the light microscope method specified by the Occupational Safety and Health Administration (OSHA) for evaluating workplace exposures. It also used two methods specified for evaluating asbestos in ambient air, including EPA's AHERA method and ISO10312 - a method developed by the International Organization for Standardization. Both of the ambient air methods call for the use of a transmission electron microscope (TEM) given its superior ability to resolve asbestos fibers.

Limitations of OSHA's PCM Method. As explained by NIOSH, phase contrast optical microscopy (PCM) is the method specified for meeting OSHA's standard for asbestos **in the workplace**. Under the PCM method:

> Asbestos fibers are defined as those particles with a length greater than 5 μm (micrometers) and a length-to-diameter ratio of 3:1, or greater. ***This technique, by which only fibers longer than 5 μm are counted, is recognized as only an index of total fiber exposure and does not imply that shorter fibers do not pose a health hazard...***Despite its limitations, phase contrast microscopy represents the only technique

> available that can reasonably be used for routine asbestos fiber sampling and analysis. (emphasis added)

Exhibit 38, NIOSH Revised Recommended Asbestos Standard, Dec. 1976, at page 69.

After noting that "***[e]xcessive cancer risks*** have been demonstrated ***at all fiber concentrations studied to date***... and [e]valuation of all available human data provides ***no evidence for a threshold or for a 'safe' level of asbestos exposure***", NIOSH recommended that the workplace exposure standard be set at ***"the lowest level detectable*** by available analytical techniques, an approach consistent with NIOSH's most recent recommendations for other carcinogens." Id. at 92-93. NIOSH defined that lowest detectible level as 100,000 fibers >5 μm in length per cubic meter of air (0.1 fibers/cc), as measured by PCM, but cautioned that this standard was designed not to prevent but only to reduce the risk of asbestos related cancers. Id. NIOSH cautioned further that: "***This standard was not designed for the population-at-large, and any extrapolation beyond general occupational exposures is not warranted***. The standard was designed only for the processing, manufacturing, and use of asbestos and asbestos-containing products as applicable under the Occupational Safety and Health Act of 1970." Id. at 94.

In reviewing the available sampling and analysis techniques for asbestos, NIOSH discussed optical and electron microscopy and the difficulties in identifying and quantifying occupational and environmental exposures. Id. at 58. According to

NIOSH, electron microscopic techniques represent the "best available methods" for asbestos fiber analysis, but "application of these techniques to routine samples is not practical" because of high analysis costs, long analysis times, and limited equipment availability. Id. at 64.

As Dr. Richard Lemen, retired Assistant Surgeon General of the United States and retired Acting and Deputy Director of NIOSH, noted in 2004, "[t]he PCM method was chosen based on its ability to count fibers only and not on a health effect basis." Exhibit 39, Richard A. Lemen, Asbestos in Brakes - Exposure and Risk of Disease, American Journal of Industrial Medicine Vol. 45, 229-237 (2004), at 230. While PCM has been the international regulatory method for analysis, it counts only fibers greater than 5 μm in length, and it is unable to detect thin diameter fibers (<0.2 μm in diameter). Id. There is no debate that thin fibers, including those undetectable via PCM, are biologically significant. And while there is some debate over the relative potency of shorter fibers, researchers have not identified a precise fiber length that did not demonstrate biologic activity. Id.

As Dr. Lemen said again in 2011 in his chapter on Epidemiology of Asbestos-Related Diseases and the Knowledge That Led to What Is Known Today, "[t]he data to date strengthen the role of short fibers in the etiology of asbestos related diseases." Exhibit 40, Lemen, Richard A., *Epidemiology of Asbestos-Related Diseases and the Knowledge that Led to What Is Known Today*, Asbestos Risk Assessment,

Epidemiology, and Health Effects (2nd Edition), 2011, at page 167. Studies have repeatedly shown that the "overwhelming majority" of asbestos fibers found in the lungs of asbestos exposed individuals are less than 5 μm in length. Exhibit 39 at 231. In other words, the PCM method underestimates exposures and health risks. Id. at 230. The hazard of thin fibers is well-established, and any assumption that short fibers less than 5 μm are not hazardous cannot be justified by the science.

Du Pont has been aware of the limitations of PCM for the quantification and qualification of asbestos fibers since at least 1979. Exhibit 41, Hemingway, R.E., *Asbestos Fibers – Quantification and Qualification*, Apr. 24, 1979. Du Pont's in-house Haskell Laboratory for Toxicology and Industrial Medicine prepared a memo on the subject, describing as two "serious problems" the fact that: "(1) only fibers greater than 5 μm are counted, thus the count is considered only an index of total fiber exposure and (2) asbestos fibers cannot generally be discriminated from other fiber types present in the industrial environment." Id. By contrast, "TEM allows better resolution of smaller fibers to get a more complete size distribution and count and the electron diffraction patterns aid in the identification of asbestos." Id. The author notes that "[w]ithin Du Pont, there are electron microscopes which are capable of this type of work." Id.

A study prepared for Du Pont to evaluate the effectiveness of Du Pont's Tyvek material as a barrier to asbestos fibers found that optical light microscopy is an

especially poor method for airborne concentrations of short fiber asbestos of the type used in Remington shotshells, and that electron microscopy is superior. Exhibit 42, Arthur D. Little, Inc., *The Effectiveness of Tyvek 1422A as a Barrier to Asbestos Fibers*, DUP 1140144-1140157. The study measured the penetration of Quebec Grade 7R chrysotile asbestos when passed through samples of Tyvek. Id. at 1140144. Grade 7R was chosen "because it contains the shortest fiber lengths and provides a significant percentage of fibers within the respirable size range", thus representing a "worst case condition." Id. at 1140147. The study report indicates "there is general agreement that the NIOSH method for determining the concentration of asbestos in occupational settings is inadequate for detecting a large fraction of the fibers in the size range that is most respirable" (Id. at 1140146), and that was borne out by the results:

> From the TEM results, it is concluded that Tyvek 1422A provides an effective barrier to chrysotile asbestos fibers of all lengths and diameters present in a sample of Quebec Grade 7R...Less than 1.2 percent of these fibers were sufficiently large to be detected by the NIOSH optical microscopy method.

Id. at 1140149. Grade 7 asbestos fibers were marketed as "asbestos shorts." Beginning in 1961, Remington used exclusively Grade 7T asbestos fiber, which is even finer than Grade 7R, acquiring its product from Canadian chrysotile mines operated by Johns-Manville and Carey Canadian.

EPA Emission Standards on Limitations of PCM and Significance of Short Fibers. On April 6, 1973, acting under authority authorized by the Clean Air Act, the EPA promulgated the Asbestos National Emission Standards for Hazardous Air Pollutants (NESHAPs) to protect the public from exposure to asbestos. Exhibit 43, U.S. EPA, *National Emission Standards for Hazardous Air Pollutants,* 38 Fed. Reg. 8820 (Apr. 6, 1973). To help protect against the human health effects of asbestos exposure, EPA set a "no visible emissions" standard for asbestos. Id. at 8829. In support of the regulation, EPA explained that asbestos is a hazardous air pollutant, and that many persons exposed to asbestos dust have developed lung disease, including asbestosis, a progressive and potentially fatal scarring of the lungs caused by chronic exposure to high levels of asbestos dust. Id. at 8820. Furthermore, asbestos has been identified as a causal factor for lung cancer and mesothelioma, and there have been reports of mesotheliomas associated with non-occupational exposures to asbestos. Id. Evidence indicated that mesotheliomas occur after much less exposure to asbestos dust than the exposure associated with asbestosis. Id. EPA also noted "that the effects of asbestos inhalation are cumulative; that is, low-level and/or intermittent exposure to asbestos over a long time may be equally as important in the etiology of asbestotic disease as high level and/or continuous exposure over a shorter period." Id.

A report on the development of the Asbestos NESHAP discussed existing air sampling methods, noting that it had been only recently that methods for determining concentration for industrial hygiene purposes had been standardized, specifically a method using phase contrast microscopy (PCM). Exhibit 44, U.S. EPA, *Background Information on Development of NESHAPs: Asbestos, Beryllium, and Mercury* (Mar. 1973), at page 23. However, as EPA notes, the PCM method "accounts for less than 5% of the total number of fibers present in a sample", and there is no evidence that only those fibers visible under the PCM method (5 μm and longer) are significant in the production of adverse health effects in humans. Id. at 24. Electron microscopic methods "give a much more complete indication of the total fiber content of the air." Id. at 23.

In 1974, the EPA proposed amendments to the Asbestos NESHAP that extended the "no emissions" standard to the manufacture of shotgun shells, which the EPA had recently determined to be a "major source" of asbestos emissions. Exhibit 45, U.S. EPA, *National Emission Standards for Hazardous Air Pollutants*, 40 Fed. Reg 48291 (Oct. 14, 1975); Exhibit 30 at pages 5-6. A report of background information on the amendment explains the approach to the emissions standards as, first, identifying ambient concentrations of the regulated pollutants which were judged to provide an ample margin of safety to protect the public health. Exhibit 30 at page 2. In the case of asbestos, however, "it is impossible to prescribe and enforce

allowable numerical concentrations or mass emission limitations known to provide an ample margin of safety to protect public health, since ***no safe level has been identified***." Id. Accordingly, the standard for asbestos was set at no visible emissions.

In proposing that the manufacture of shotgun shells be covered by the Asbestos NESHAP, the EPA conducted an investigation which "included a visit to the only shotgun shell manufacturing plant in the United States that is known to use commercial asbestos." Id. at 4.[2] Discussions with the plant operator revealed that the plant was using approximately 500 tons of asbestos annually, which was larger than many of the plants already covered by the asbestos standard. Id. at 5.

Although the EPA was initially focused on limiting emissions during manufacturing processes, as the 1970's wore on it became increasingly concerned about exposures to consumers during asbestos product use, and it found a like-minded regulatory partner in the newfound U.S. Consumer Product Safety Commission (CPSC).

CPSC Actions on Asbestos-Containing Consumer Products. The CPSC was established in 1973 by the Consumer Product Safety Act. The CPSC's primary purpose "is to protect the public from unreasonable risks of injury from consumer

[2] The subject plant was Remington's Bridgeport Works. Id. at p 18. See also, Exhibit 48 at p. 249.

products – which are generally defined as any article for sale to a consumer for use in or around a household, a school, in recreation, or otherwise." Exhibit 46, Report by the Comptroller General of the United States, *The CPSC Should Act More Promptly to Protect the Public from Hazardous Products* (Jun. 1, 1978), at page 1). The CPSC first became aware of asbestos hazards shortly after it began operations in May 1973, but "it did not deal with asbestos at that time because its policy was to emphasize immediate or short-term hazards rather than chronic or long-term hazards such as those associated with asbestos." Id. at 24.

In March 1976, in response to growing public interest into the hazards associated with the use of asbestos in consumer products, the CPSC's Deputy Executive Director directed the Bureau of Biomedical Sciences to Review the background information on asbestos. Id. at 27. In April 1976, the Bureau recommended that the CPSC ban the use of all free-form asbestos in consumer products. Id. Over the next year, the CPSC received petitions seeking specific bans on asbestos containing drywall compounds and artificial fireplace ash. Id. at 28. The petitions were reviewed by various CPSC divisions and bureaus, including the Office of the Medical Director, which stated:

> It is necessary to point out that because of the wide range of individual susceptibility to carcinogenic substances the 'threshold' or 'no effect' level may not be applicable…To the best of our knowledge, **a *'no effect' level has not been demonstrated for asbestos***. (emphasis added)

Id. at 29-30.

In December 1977, the CPSC published regulations banning asbestos in patching compounds and artificial ashes. Exhibit 47, CPSC, *Consumer Patching Compounds and Artificial Emberizing Materials*, 42 Fed Reg 63354 (Dec. 15, 1977). In deciding to approve the bans, the CPSC found that ***OSHA regulations only apply to workplaces and not to places where consumers would use the products themselves, and therefore that any OSHA regulation could not "reduce or eliminate to a sufficient extent the unreasonable risk of injury to consumers."*** Id. at 63356.

In April of 1978, shortly after the ban on patching compounds went into effect, the CPSC published a comprehensive review of asbestos use in consumer products with the intent of identifying asbestos products, determining the amount of asbestos in them, and assessing "if and how asbestos might be released" during normal consumer use. Exhibit 48, CPSC, *Review of Asbestos Use in Consumer Products* (Apr. 1978). The Introduction to the review addresses the health risks of asbestos exposure:

> Recent research indicates that ***much lower levels of exposure over shorter periods of time increase the probability of cancer***. The most interesting type of cancer, from a medical standpoint, is mesothelioma, which spreads rapidly through the pleural or peritoneal cavity. It is interesting because ***the only identified cause of this disease is asbestos***. (emphasis added)

Id. at I.

Appendix A consists of "CPSC Asbestos Product Fact Sheets" for a variety of products, including Ammunition Shell Wadding. The Fact Sheet for Ammunition Shell Wadding, citing information provided by Remington and two competitors, describes the product as:

> A compressed plug of asbestos and cellulose is interference press fitted into the base of shot shells... ***Only one manufacturer reports the present use of asbestos***. (emphasis added)

Id. at page 32. The Fact Sheet indicates the wadding contained 1 to 5% asbestos, is designed for consumer use, and could release asbestos fibers upon discharge. Id.

Concern over the release of asbestos fibers from Remington shotshells arose again a few months later, when the EPA's Office of Toxic Substances issued an analysis to assess sources of environmental contamination, including asbestos. Exhibit 49, U.S. EPA, *Chemical Market Analysis* (Aug. 1978). As stated by the EPA, "***the only shotgun shell manufacturing plant known to use asbestos is operated by Remington Arms Company.***" Id. at 276. Although "the exact need for asbestos in some base wads is not clear", manufacturing emissions are assumed to be very small. Id. at 277-278. However, as regards use emissions, the EPA notes: "When a shot gun shell is fired from a gun, the base wad is normally expelled from the cartridge and is commonly fragmented into many separate pieces. Monitoring data for asbestos fiber release is not available; however, it may be possible that free fibers

are released when a shotgun is discharged with an asbestos-containing base wad." Id. at 278.

CPSC/NIOSH Test Hair Dryers for Asbestos Fiber Release. In March 1979, newspapers all over the country reported on a private study of new and used hair dryers that found approximately one in five models contained asbestos. Exhibit 50, *Asbestos-Lined Hair Dryers Raise Fears of Cancer Risk*, The Morning News (Wilmington, DE), Mar. 30, 1979. In response, the CPSC promptly issued a Special Order compelling the hair dryer manufacturers to provide information on their products including any testing conducted to determine whether respirable asbestos is emitted into the air during use. Exhibit 51, CPSC Special Order, Portable Hand-Held Electric Hair Dryers, Mar. 29, 1979. The CPSC sent telegrams to the top executives calling for them to come to Washington for a meeting with the CPSC early the next week. See Exhibit 50. Additionally, the CPSC ordered studies "to determine the nature of the fibers that are released and the degree of hazard to consumers in foreseeable use of the product." It ordered the studies be done with electron microscopic methods, as opposed to the optical light method used by OSHA for assessing workplace exposures. Id.

CPSC engaged NIOSH to perform the fiber release testing on the hair dryers, and the testing methodology specified by NIOSH is described in a report published under an Interagency Agreement between NIOSH and the CPSC. Exhibit 52,

Charles L. Geraci, Jr., Ph.D., Testing of Hair Dryers for Asbestos Emissions, Sept. 1979. NIOSH tested 30 hair dryers for the release of asbestos fibers into the effluent air to evaluate potential consumer exposure. Id. As described in the report, they determined that "the identification and quantitation of fibers emitted by the dryers having lengths and diameters of as little as 1 micrometer or less would be necessary", which would require analysis by a transmission electron microscope. Id. at 1. A system to determine asbestos emissions from hair dryers was fabricated and validated by NIOSH. Id. at 2. The study was conducted in a small "test chamber" adapted for the tests and measured airborne asbestos concentrations during operation of the dryers that ranged from 0 to 0.11 asbestos structures/cc. Id. at 11. The results and publicity resulting therefrom prompted a recall of the asbestos containing hair dryers from all major manufacturers.

CPSC and EPA Target Asbestos-Containing Consumer Products. In October 1979, shortly after the hair dryer recall, the EPA and CPSC issued a joint statement detailing a coordination of regulatory activities, as well as two Advance Notices of Proposed Rulemaking (ANPR) regarding asbestos. Exhibit 54, CPSC and EPA, *Commercial and Industrial Use of Asbestos Fiber and Consumer Products Containing Asbestos*, 44 Fed. Reg. 60056, Oct. 17, 1979. Despite prior regulatory actions taken by each to control human exposures to asbestos, "both continue to be

concerned that human exposure to asbestos from many sources may present an unreasonable health risk." Id. at 60056.

Regarding the health risks related to asbestos exposure, the CPSC described "increasing evidence" since the early 1960's including epidemiologic studies showing an increased incidence mesothelioma among non-occupationally exposed populations, including individuals with only brief or intermittent exposures. Id. at 60057. Regarding its regulatory policy approach, the CPSC concluded that:

> ...exposure to any respirable asbestos fibers from consumer products presents a health risk because ***there has not been demonstrated to be a threshold or no-effect level below which exposure to asbestos fibers would be considered safe***. (Id. at 60058). (emphasis added)

Id. at 60058. Consequently, the CPSC proposed to "seek the elimination of all non-essential uses of asbestos in consumer products from which asbestos fibers are released during reasonably foreseeable conditions of use, including misuse." Id. at 60060.

The EPA ANPR, for its part, outlined a broad effort "to systematically gather information on asbestos exposure sources and evaluate health risk based on the 'life cycle' concept", which EPA defined as "the cumulative risk from exposure to asbestos as examined from primary processing through end use and disposal." Id. at 60056. The EPA explained that "[c]ertain exposures to asbestos are controlled under various Federal and State authorities, but due to limited mandates (i.e. focused on specific populations or exposure sources), technical difficulties (e.g. available

fiber measurement techniques), and other analytical constraints, these authorities are not able to deal with the total asbestos problem." Id. at 60061. EPA expressed its intent to gather exposure information and economic information to assess the risk. Id. at 60062. As support for that action, EPA cited as evidence the fact that "[s]tudies of exposed populations have shown that asbestosis, a progressive deterioration of lung function, and various types of cancer are associated with asbestos exposure, even at low concentrations or after short exposure periods." Id.

Attached as an Appendix to the EPA ANPR was a list of various asbestos containing products, including several of "particular concern" that may release asbestos fibers during normal use, and about which EPA intended to gather additional information. Id. at 60067. The EPA was interested in determining the necessity of using asbestos in those products and gathering information regarding what exposures are associated with each use, including rate of fiber release, frequency, duration, population exposed, and conditions of use. Id. Amongst those products identified was Remington's ammunition shell wadding. Id. at 60068.

The EPA would not publish its "Life Cycle" Report until 1982, but the information gathering process began soon after issuance of the ANPR in 1979. Exhibit 55, U.S. EPA, Life Cycle of Asbestos Report, Feb. 1982. As evidenced in Remington's Corporate Minutes, EPA approached Remington in early 1980:

> The Chairman said that our Public Relations people have been called by the EPA, inquiring about exposure of both factory employees and shooters."

Exhibit 56, Remington Corporate Minutes, Feb. 26, 1980.

According to EPA's Life Cycle Report, the investigation into shotgun shell base wads included a telephone conference with Ted McCawley of Remington Arms. Exhibit 55, at pages 249, 256. Remington reported that it was phasing out asbestos and replacing it with a non-asbestos shell which was both more stable and less costly. Id. at 249. Although manufacturing emissions were judged to be minor, it was reported that "***fiber emissions probably occur when the shotgun shell is fired from a gun*** but there is presently no means of determining the amount of fibers that become airborne as opposed to those that remain encased in the wad mixture." Id.

In May 1980, a few months after the interview with Ted McCawley, an inspector with the Air Compliance Section of Connecticut's Department of Environmental Protection visited Remington's Bridgeport plant to perform a premise evaluation of environmental emissions control equipment, as required under state law. Exhibit 57, Department of Environmental Protection, Air Compliance Section, Premises Evaluation Report (Jun. 30, 1980). In his report, the inspector noted that: "Asbestos for shell wadding is carefully controlled during mnf – seems irrelevant since it is later fired into the air." Id.

It is unclear what if any testing Remington conducted to assess the hazard associated with use of the asbestos shotshells. It is also unclear whether Remington ever released any information to the media or the public, although McCawley indicates the company's intent to keep it confidential, writing: "Obviously, we do not intend to make any general release of this, but rather only to use it to answer questions." Exhibit 58, E.S. McCawley, Jr., Asbestos basewads, Nov. 7, 1980.

MVA 's Fiber Release Study Found Predominantly Short and Thin Asbestos Fibers. As indicated above, the majority of the asbestos fibers MVA measured during its fiber release experiment were short and thin fibers not visible under OSHA's light microscope. The concentration of fibers measured by MVA in the breathing zone of a shooter ranged from 0.04 to 0.08 fibers/cc using OSHA's method, and from 1.0 to 1.9 structures/cc using EPA's method. To provide a comparison between these levels and those present in "clean", "background" air, MVA took background samples prior to testing which measured no asbestos structures at a level of detection of 0.006 s/cc. In other words, the use of Remington shotgun shells caused the shooter to experience asbestos exposures ***more than 100 times above background***, and more than 10 times that found in NIOSH and CPSC's study of fiber release from asbestos containing hair dryers.

As is customary, MVA retained the air filters from its experiment should Defendants desire to validate MVA's fiber counts. Instead, Defendants decided to

conduct an entirely different experiment of their own, and they hired John Spencer to help them do that.

John Spencer's "Occupational Exposure Assessment" Involving Remington Shotgun Shells. John W. Spencer, CIH, CSP is an industrial hygienist who has consulted for defendants in asbestos litigation for over 25 years. He founded Environmental Profiles, Inc. (EPI) in 1992 and served as its President until it was acquired by JS Held in 2021. With EPI, he was routinely retained as a consulting expert by defendants in asbestos litigation to conduct work practice studies and then to testify about those studies at deposition and trial. Invariably, Mr. Spencer's studies were designed to find that the potential "worst case exposure" from any and all of his client's products was below current and historical occupational exposure limits.

Mr. Spencer started doing litigation consulting work for Crowell & Moring LLP 20 years ago. The Crowell firm serves as national counsel for several national asbestos defendants, including Du Pont and Caterpillar. In 2003, Crowell hired Mr. Spencer to conduct a study "to determine the concentration of fibers in the air during maintenance and repair activities involving friction products (brake band linings, brake disc linings, brake shoe linings, and clutch linings), and gaskets (engine head, exhaust and intake manifolds, etc.) from heavy equipment manufactured by Caterpillar, Inc." Exhibit 59, Spencer, Boelter, Caterpillar Equipment Study (Oct. 9,

2003), at page 1. Mr. Spencer's firm carried out the study with that of another industrial hygienist named Fred Boelter, who also routinely testifies in asbestos litigation. The product of the study is a report, now commonly cited by litigation experts hired by Caterpillar and other manufacturers of heavy equipment in defense of asbestos related product liability suits. Ultimately, Spenter concluded that "[t]he airborne asbestos fiber concentration of a person performing these tasks would be significantly less than the current OSHA 8-hour Time Weighted Average (TWA) Permissible Exposure Limit (PEL) of 0.1 f/cc." Id. at page 38. Mr. Spencer's Caterpillar study was submitted for publication and rejected. As it turned out, many of the air samples were overloaded and unreadable. More concerning is the fact that only 22 of the 62 gaskets that were analyzed for fiber release actually contained asbestos, which fact was not clearly disclosed in the report, and about which many defense experts now citing to his study are wholly unaware. It was casually revealed at a presentation given at an industrial hygiene conference two years later. Exhibit 60, AIH Conference Presentation (May 2005), at page 16.

By the time Mr. Spencer was hired to do the Caterpillar study, he had already conducted several other exposure assessments for asbestos defendants, including for gasket manufacturers Durabla, Garlock and AW Chesterton. He has also done studies for manufacturers of asbestos floor tiles, asbestos lab equipment, and even asbestos containing toaster ovens. In each of these studies, he has conducted air

sampling in what he has described as an "isolation chamber", purposely designed to eliminate any ventilation and air circulation to create a static environment in which to accurately measure the asbestos fiber release from the product being tested. In 2020, after receiving the results of MVA's fiber release experiment, the Crowell firm asked Mr. Spencer to conduct a study on Remington shotgun shells. But unlike MVA, he used a method specifically designed for assessing occupational exposure, and he did it outside in a completely uncontrolled environment.

Spencer's Study was Engineered to Find No Asbestos. Spencer conducted his study outdoors. On September 15, 2020, he and his colleagues fired 16 asbestos shotshells into the air outside Flintstone, Maryland. Exhibit 61, EPI, Exposure Assessment – Evaluation of Airborne Fiber Concentrations during the Discharge of Vintage Asbestos-containing Remington Shotgun Shells (Oct. 22, 2020). Like MVA, they set up air filters around the shotgun to measure for fiber release. After testing, they sent the samples to a third party for analysis, but they requested that the samples be analyzed only via PCM, and not via electron microscopic methods. According to the microscopy lab that did the fiber counting, they did not see any OSHA fibers longer than 5 μm in length. Mr. Spencer concluded that "[t]he results of this evaluation demonstrated that shooting shotshells with asbestos-containing base wads did not produce any measurable concentrations of airborne asbestos fibers." Id. at page 17.

Mr. Spencer intends to rely on his study to testify in these cases that Remington shotshells are incapable of releasing asbestos fiber, and that there is no potential for exposure when shooting them outdoors. He also intends to present a "dose reconstruction" of both Mr. Altena and Mr. Schoepke's exposures based on measurements of OSHA fibers to suggest that any potential exposure was below OSHA Permissible Exposure Limits (PEL), consistent with ambient air, and below a level which would have increased their risk of mesothelioma. See Exhibit 62, Spencer Report Altena; and Exhibit 63, Spencer Report Schoepke.

His dose reconstruction opinions rely upon the application of an 8-hour Time Weighted Average (TWA) workday – derived from OSHA PEL's, which methodology is inapplicable here, where the Plaintiffs were exposed non-occupationally through recreational use of a product manufactured and sold for consumer use. His dose reconstruction opinions are inadmissible as (1) they are not based on matters reasonably relied upon; (2) the methodology he uses is not accepted in the scientific community; (3) the data he used to calculate dose is speculative and completely unrelated to the facts of these cases; and (4) any speculative result of this unreliable methodology is irrelevant to Defendants' liability for Plaintiffs' injuries. They are also, along with his exposure assessment, scientifically dishonest and dangerous.

ARGUMENT

Spencer's Methodology and Opinions as to Plaintiffs' Exposures to Asbestos from Remington Shotgun Shells are Not Generally Accepted as Reliable in the Scientific Community and Are Not Based on Matters Reasonably Relied Upon. In 1999, the Delaware Supreme Court adopted the *Daubert* test. M.G. Bancorporation v. Le Beau, 737 A.2d 513, 522 (Del. 1999). It has continued to be used ever since.

Du Pont's "Exposure Assessment" is Irrelevant, Unreliable, and Scientifically Dishonest. John Spencer is an industrial hygienist and a career expert for defendants in asbestos litigation. He is not a medical doctor, not a toxicologist, not an epidemiologist, and not a microscopist. As discussed above, John Spencer regularly concludes that no asbestos product manufactured by any defendant who has ever retained him increases a plaintiff's risk of developing mesothelioma. His opinion regarding increased risk is based on his "hypothetical" dose reconstruction, which in this case is based on a study specifically designed to underestimate the exposure. His reconstruction is further based on a TWA, which is derived from the OSHA PELs – exposure limits specific for occupational settings. These OSHA PELs and TWAs have no application to the subject cases. Outside of workplace regulations, there is no scientific justification for diluting a task-based asbestos exposure by dividing it over several hours to create a false "average" exposure.

Defendants hired John Spencer to conduct what he repeatedly characterized at his deposition as an occupational exposure assessment. Exhibit 64, Spencer

Deposition Eldridge (2021), at pages 47:22-48:8, 62:12-19, 64:5-16, 72:3-14, 111:1-112:3. Mr. Spencer has been conducting such occupational exposure assessments for defendants in asbestos litigation since the late 1990's and explains his role in these cases as "the industrial hygienist that applies the occupational health standards and the basis for those occupational health standards." Exhibit 65, Spencer Deposition Altena and Schoepke (2024), at page 178:14-24.

As here, his testimony is rooted in studies he has done to evaluate asbestos fiber release, which studies he has often done indoors. At deposition, he agreed, as is self-evident, that indoor studies are more readily reproducible than outdoor studies, given the variability in an outdoor environment. Id. at 157:7-21. Here, however, he chose to conduct the study outdoors, firing sixteen asbestos shotgun shells into the open air. At the time he developed the protocol for his study, he had the benefit of MVA's results. He was aware that MVA had found numerous short and thin fibers that are undetectable via PCM, but he did not set out to challenge or invalidate the MVA results. Instead, he set out to cast a recreational exposure to an asbestos containing consumer product as something other – as an occupational exposure, so that he might then put such exposure in the context of occupational exposure limits, which have no relevance here. As discussed above, NIOSH, the scientific arm of OSHA, has explicitly cautioned against applying occupational air

sampling methods and occupational exposure limits outside of the occupational context. Exhibit 38 at page 94, *supra*.

Mr. Spencer's study sheds no light on the actual fiber release from Remington shotshells. Had he been concerned with measuring actual fiber release, he would have analyzed the air samples using electron microscopy, which he chose not to do. He would have also conducted the study indoors, in a controlled environment. Instead, what Mr. Spencer sought to do was to conduct a study designed to measure no release, and then to suggest that any recreational shooter would have no exposure whatsoever. His study does not say that, so he should not be permitted to.

Even Du Pont's state of the art witness, John Henshaw, himself an industrial hygienist, testified that environmental conditions need to be taken into account when determining to what extent somebody could be potentially exposed to asbestos fiber, including wind conditions, humidity, temperature, conditions that vary from location to location and from day to day. Exhibit 66, Henshaw Deposition Altena and Schoepke (2024), at pages 47:13-49:24. All of these confounding variables introduce an unacceptable level of uncertainty into the results of the experiment conducted by Mr. Spencer, which is by definition incapable of being reproduced.

As indicated in his report, Mr. Spencer retained AMA Analytical Services to count the fibers measured during his outdoor experiment. Exhibit 60 at page 8, *supra*. Spencer asked that the air samples be analyzed using only OSHA's method.

In other words, he specified that fibers less than 5 μm in length and less than 0.25 μm in width would not be counted, even if the microscopist by chance happened to see them under the light microscope. Spencer did not request any photomicrographs be taken, so there is no evidence of what the microscopist saw or didn't see.

It is not by accident that Defendants have not disclosed any microscopist to testify on its behalf in these cases. AMA, which has also done contract microscopy work for the EPA, describes on its website the various methods available for the analysis of asbestos air samples, including those requiring an electron microscope. AMA indicates that: "The Transmission Electron Microscope is one of the most powerful tools that we have available for asbestos analysis. TEM analysis can be conducted on a variety of matrices and is often times the most definitive and legally defensible technology available." As regards Phase Contrast Microscopy (PCM), AMA writes: "PCM analysis is typically used to determine exposure during work practices." Exhibit 67, Ex. 5 to Spencer Dep., Eldridge.

In conclusion, the methodology underlying John Spencer's exposure assessment and dose reconstructions is deeply flawed and unreliable. His opinions regarding occupational exposures are irrelevant and confusing in a case involving a non-occupational exposures to an asbestos containing consumer product. His exposure assessment study, and any testimony relying thereon, should not be permitted by this Court.