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### Expert Analysis

## The Rise of Gatekeepers and The 'Single Fiber' Theory

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#### WHAT HAVE WE LEARNED SINCE THE 16TH CENTURY?

This commentary will look briefly at the convergence of two theories that lie at the heart of 21st-century asbestos litigation: the role of the judge as gatekeeper and the treatment of the scientific concept of dose applied to extremely low exposure levels. Our story begins with two 16th-century scholars, both unconventional, modern thinkers and ahead of their time.

The first was a Swiss physician, Paracelsus, who died in 1541 at the age of 48, after a bar fight. He was a hands-on doctor, much admired by his students. He first used the phrase: "What is it that is not poison? All things are poison and nothing is without poison. It is the dose only that makes a thing not a poison."

This principle has been widely regarded as fact in virtually all substances, but modern hysteria about pesticides, synthetic chemicals and asbestos has driven people to forget nuance when dealing with these and certain other chemicals. This prompted Alice Ottoboni, a toxicologist with the state of California, to remind us in her book, "The Dose Makes the Poison."<sup>2</sup> Attorneys give lip service to dose in discussing asbestos exposures, but pry open the door and allow that all exposures to asbestos might, or do, contribute to an existing disease.

The second thinker was Galileo, technically Galileo Galilei, an Italian scientist who dared to state in a scientific journal that the earth revolves around the sun, not the other way around. He was tried by the Roman Inquisition, found guilty of heresy and put under house arrest, where he remained for the rest of his life.

Galileo's role in this story is not about his opinion as much as about the treatment he received at the hands of the ruling tribunal of the day. Twentieth-century courts, perhaps fearing overzealous control like the inquisitors of Rome, have trod very lightly when limiting scientific evidence presented by experts. This attitude was extreme enough that in 1991, a man named Peter Huber, who had been a law clerk to Supreme Court Justice Sandra Day O'Connor, and who was then with the conservative Manhattan Institute, wrote a book titled "Galileo's Revenge:







Junk Science in the Courtroom." Its principal thesis, that courtroom judges go to extremes to allow scientific heresy to be heard by juries,<sup>3</sup> is now slowly being applied to certain asbestos cases, and judges throughout the United States are being given a broader role in controlling what experts may say to juries.

#### THE SCIENCE OF LOW DOSE

We are all intuitively aware that the ingestion or inhalation of small amounts of many substances is neutral to or even beneficial for our bodies. We know the benefits of low-dose aspirin for heart health and that taking two aspirin can cure a headache, but we also know that 100 aspirin taken at one time may kill us.

Studies have shown beneficial or neutral effects of red wine or other alcohol, but we also know the varied and sometimes fatal effects of the overuse of alcohol. All substances, even oxygen and water, can be fatal if absorbed in large enough amounts. A lesser known toxin such as the bacteria that causes botulism is used in small doses for cosmetic reasons even though it can be fatal if ingested in food.

What about asbestos? Today, the principal diseases attributable to asbestos exposure are asbestosis, lung cancer and mesothelioma. It is generally accepted that there must be at least a moderate exposure to asbestos, almost always occupational, before asbestos can be cited as a cause of either asbestosis or lung cancer.

Mesothelioma is a different story. Mesothelioma is the most feared asbestos-related malady, both by potentially exposed workers and by potentially liable companies. Far lower levels of asbestos exposure can cause mesothelioma, but at very low levels, is any exposure sufficient to cause the disease? This has been the subject of an enormous amount of both good and bad science over the past four decades.

Some 3,000 cases of mesothelioma are diagnosed in the United States each year. The disease is aggressive, and most who develop it die within 18 months. The only fully recognized cause of the disease in the United States is asbestos, though for certain forms of the disease and for certain population subgroups, between 10 percent and 50 percent of those who develop the disease might not have gotten it from exposure to asbestos.

Even this statement about percentages is subject to wide dispute, with some commentators even arguing that perhaps all the mesotheliomas in the United States have some connection to some asbestos exposure somewhere.

Because precise measurement is impossible, there are no epidemiologic studies demonstrating that a very low dose of asbestos was the definitive cause of a person's mesothelioma. Rather, measurements have been taken and studies conducted of people with moderate to heavy exposure.

Plaintiff attorneys and experts describe the exposure/disease pattern as a linear projection down to zero, claiming that extremely low asbestos doses do not cause many diseases, but do cause some disease, no matter how low the exposure. They point to government regulations that state that there is no known safe exposure to asbestos.

Defense attorneys and experts describe the exposure/disease pattern as an S curve, where at very low doses there is no disease, but at some level of exposure disease

begins. They point to government regulations as simply prophylactic protection without real scientific backup. They point to the lack of epidemiologic data to show low exposure as a cause, and to the body's numerous defense mechanisms to protect itself against low doses of asbestos, just as those defense mechanisms protect the body against insults from thousands of other foreign bodies — from bacteria to arsenic to silica to the effects of the sun. What should an expert be allowed to say in court about exceptionally low asbestos exposure and disease?

#### GATEKEEPER LAW: DAUBERT AND FRYE

It might be useful to describe traditional differences in courts' attitude toward scientific evidence between *Daubert* states and *Frye* states. Since the early part of the 20th century, courts have limited judicial interference with scientific testimony. *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), involved the admissibility of polygraph tests and emphasized the experimental nature of the test at that time.

Since then, through most of 20th-century jurisprudence, courts have been reluctant to follow the broad inquisitorial power of the Roman judges during Galileo's time, and have bent over backwards to keep from interfering in scientific testimony. With few exceptions, courts have tended to limit scientific testimony *only* when it was derived from a novel scientific test or novel scientific theory, but have allowed it without much interference when based on more accepted tests or literature.<sup>4</sup>

The U.S. Supreme Court, in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), took a different approach. This was a toxic-exposure lawsuit involving the ingestion of pharmaceuticals. The court in *Daubert* looked not only at the scientific literature in the field, but also at the methods used by expert witnesses to interpret that literature; the high court determined that to be admissible, expert testimony must be both relevant and reliable.<sup>5</sup>

This turned out to be a broad expansion of the traditional 20th-century reluctance of courts to challenge expert analysis. *Daubert*, however, involved at its core an interpretation of the Federal Rules of Evidence, and so was limited to federal courts and then to the courts of those states (typically smaller states with a less robust individual history) that adopted federal evidence rules as part of their jurisprudence.

So-called *Frye* states continued to follow the more limited gatekeeper role as it applied to scientific testimony. Such states, including Pennsylvania, New York, Illinois and California, have traditionally had heavy asbestos dockets, and their courts have traditionally been influential in neighboring states.

#### 2011: GATEKEEPERS MEET THE LOW-DOSE PROPOSITION

In the 1980s, with most asbestos cases arising in shipyards, doses varied, but for the most part were significant. In the past 20 years, however, typical doses for which defendants might be held liable have continued to drop, to the point where some companies are defending against doses admittedly equal to or less than the dose the average citizen would receive from the atmosphere. Recently, courts have had to weigh in on experts' opinions about those doses.

Two courts decided similar issues during the summer of 2011. The first, *Butler v. Union Carbide Corp.*, 712 S.E.2d 537 (Ga. Ct. App. June 15, 2011), came from the Georgia Court of Appeals. In that case, Laura Butler sued for the death of her husband,

"What is it that is not poison? All things are poison and nothing is without poison. It is the dose only that makes a thing not a poison."

— 16th-century Swiss physician Paracelsus Walter, from mesothelioma. The allegation was that Walter developed the disease from his exposure to Union Carbide asbestos fiber, among other causes.

Butler hired pathologist John C. Maddox to testify about causation.<sup>6</sup> Maddox stated that each exposure to asbestos above background levels (levels present in the ambient air) contributed to causing the disease. He also said, "To the extent that the patient was exposed to any of these products, they contributed in a cumulative fashion to his total asbestos dose, which is what caused his mesothelioma."<sup>7</sup> The court struck that testimony, and the Court of Appeals affirmed.

Georgia is a *Daubert* state. The appeals court went carefully through the *Daubert* criteria for admissibility of an expert opinion and concluded that Maddox's testimony did not meet any of the four criteria.<sup>8</sup> It stated that under *Daubert*, trial courts are imbued with "substantial discretion in deciding how to test an expert's reliability."<sup>9</sup>

The court noted that Maddox' specific causation opinion was not the product of reliable principles and methods. Georgia, using rules derived from the Federal Rules of Evidence, places the burden of establishing the reliability of the expert's opinion on the proponent, here, the plaintiff. Laura Butler argued that Maddox relied upon generally accepted and reliable methodology and based his opinion on reliable scientific literature. But the court found that "[t]he literature, however, does not support his specific causation opinion based on the evidence shown in this case."<sup>10</sup> It stated in essence that Maddox's "no threshold" theory was scientifically unreliable.

The second decision, *Moeller v. Garlock Sealing Technologies*, 660 F.3d 950 (6th Cir. Sept. 28, 2011), similarly rejected low-dose testimony, but without directly performing the gatekeeper role. The 6th U.S. Circuit Court of Appeals, applying Kentucky law, reversed a jury verdict for the plaintiff, finding that the evidence was not sufficient to support the verdict.

Olwen Moeller sued for the death of Robert Moeller from mesothelioma, and Garlock was sued for exposing Robert to its gaskets.<sup>11</sup> Garlock did not deny that asbestos caused Robert's mesothelioma, but argued that its gaskets were not a substantial factor, particularly in light of Robert's extensive exposure to asbestos-containing insulation.<sup>12</sup>

The plaintiff produced. Arthur Frank, a medical doctor and professor at Drexel University, who has studied occupational exposure to asbestos for some 40 years.<sup>13</sup> Frank testified that all types of asbestos can cause mesothelioma and that any asbestos exposure counts as a "contributing factor."<sup>14</sup>

No expert actually testified that exposure to Garlock's gaskets was a substantial factor, but the plaintiff argued that one could so infer from the evidence. The appellate court disagreed. Though not directly addressing the validity of Frank's low-dose testimony, the court ruled that such testimony alone was not sufficient to support the verdict.<sup>15</sup> The court thus effectively rejected that "any exposure" could constitute a substantial factor.

#### 2012: THE GATEKEEPER ROLE IS RECOGNIZED

The *Butler* and *Moeller* cases were a prelude to a significant decision by the Pennsylvania Supreme Court in *Betz v. Pneumo-Abex LLC*, 44 A.3d 27 (Pa. May 23, 2012). The *Betz* court followed the Georgia appeals court and the 6th Circuit into the

Twentieth-century courts, perhaps fearing overzealous control like the inquisitors of Rome, have trod very lightly when limiting scientific evidence presented by experts. twin concepts of low asbestos dose and the gatekeeping function of trial judges, but there were two significant differences.

First, Pennsylvania is a large state with a long history of asbestos litigation, somewhat ingrained into the fabric of its jurisprudence. Second, and just as important, Pennsylvania is a *Frye* state.

The *Betz* decision changed that landscape. The facts of the case are not very different from those in *Butler* and *Moeller*. Indeed, though such trials can have a very high reward for plaintiffs and very high exposure for defendants, they are relatively common.

Charles Simikian died from mesothelioma and the executor of his estate, Diana Betz, sued, claiming that his disease was caused by past exposure to asbestos from his work as an automotive mechanic.<sup>16</sup> Again, as in *Butler*, John Maddox was prepared to testify for the plaintiff. Here, he was subjected to a *Frye* hearing, to determine whether his opinion was generally accepted in the relevant scientific community.<sup>17</sup>

#### His opinion stated the following:

Asbestos-related mesothelioma ... is a dose response disease: each inhalation of asbestos-containing dust from the use of products has been shown to contribute to cause asbestos-related diseases, including mesothelioma. Each of the exposures to asbestos contributes to the total dose that causes mesothelioma. ... [E]ach exposure to asbestos is therefore a substantial contributing factor in the development of the disease that actually occurs, when it occurs.<sup>18</sup>

Two experts testified on behalf of the defense. Maddox was not allowed to testify.<sup>19</sup> The intermediate appeals court reversed the trial court's decision, but the Pennsylvania Supreme Court upheld the trial court's ruling and excluded Maddox's testimony.

The plaintiff's attorneys presented the traditional argument in *Frye* states, that Maddox's methodology in forming his "any exposure" opinion was in no way novel, but rather rested within the scientific mainstream.<sup>20</sup>

The Pennsylvania Supreme Court went through an exhaustive analysis of the opinions of various courts and made this statement: "[C]ourts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery. ... A manifestation of this trend is that challenges generally are vetted through the *Frye* litmus, which winnows the field of the attacks by application of the threshold requirement of novelty."<sup>21</sup>

However, the court also recognized the influence wielded by experts, finding that "it would be naïve, in this regard, to assume that the possibility for distortion is limited to the very newest realms of science."<sup>22</sup> The court explained:

[W]e conclude that a *Frye* hearing is warranted when a trial judge has articulable grounds to believe that an expert witness has not applied accepted scientific methodology in a conventional fashion in reaching his or

Far lower levels of asbestos exposure can cause mesothelioma, but at very low levels, is any exposure sufficient to cause the disease? her conclusions. We believe a narrower approach would unduly constrain trial courts in the appropriate exercise of their discretion in determining the admissibility of evidence.<sup>23</sup>

The court finally agreed with the defendant-appellants that even when an expert is not relying upon novel science, the expert's extrapolation from that science is relevant to the scientific acceptance of his methodology.<sup>24</sup>

#### GATEKEEPING GOES WEST

Other recent case law has supported a strong gatekeeper approach in this context. In *Barabin v. AstenJohnson Inc.*, 700 F.3d 428 (9th Cir. Nov. 12, 2012), the 9th Circuit upheld the gatekeeper role on this subject.

In *Smith v. Ford Motor Co.* the U.S. District Court for the District of Utah upheld the gatekeeper role. This case was interesting to defense lawyers because it focused on a particular statement by plaintiff's expert Samuel Hammar: that Ronnie Smith's mesothelioma "was caused by his total and cumulative exposure to asbestos, *with all* exposures and all products playing a contributing role."<sup>25</sup> The court said "[t]his asks too much from too little evidence as far as the law is concerned."<sup>26</sup>

#### California

Traveling west, this discussion should logically end with California. Ironically, California was the venue of the *Daubert* case before it was removed to federal court. The state has firmly been a *Frye* state for decades and remained a *Frye* state past *Daubert*, generally limiting gatekeeping to novel scientific processes.<sup>27</sup>

But in *Sargon Enterprises v. University of Southern California*, 288 P.3d 1237 (Cal. Nov. 26, 2012), the California Supreme Court weighed in heavily to provide a broader and more robust gatekeeper role for trial judges.

This was not an asbestos case. The plaintiff's expert at issue was an economist theorizing about future profits at a dental implant company. The trial court excluded the expert's opinion regarding lost profits as speculative, and the plaintiff appealed.

At the beginning of the discussion, the court proclaimed that expert testimony must not be speculative and that "[u]nder California law, trial courts have a substantial 'gatekeeping' responsibility."<sup>28</sup> Rather than follow old *Frye* customs, the court interpreted California's Evidence Code as it applies to experts. Section 801 follows the typical *Frye* criteria and requires that the testimony be "of a type that reasonably may be relied upon by an expert in forming an opinion upon the subject."

The court went further, however, and provided a detailed interpretation of California Evidence Code Section 802, which states that "[t]he court ... may require that a witness before testifying in the form of an opinion be first examined concerning the matter upon which his opinion is based." The court explained that "[t]he *reasons* for the experts' opinions are part of the matter on which they are based just as is the *type* of matter. ... Evidence Code Section 802 governs judicial review of the *reasons* for the opinion."<sup>29</sup>

Finally, the California Supreme Court held as follows:

Thus, under Evidence Code Sections 801 ... and 802, the trial court acts as a gatekeeper to exclude expert opinion testimony that is (1) based on matter of a type on which an expert may not reasonably rely, (2) based on reasons unsupported by the material on which the expert relies, or (3) speculative.<sup>30</sup>

The court does give some ground to Galileo and cautions about care in excluding expert testimony, but the decision provides a solid base for defense counsel to challenge asbestos causation opinions in the future.

We end with a quote from "Galileo's Revenge": "If it is wrong to condemn the visionary whose science conflicts with established religion, it is also wrong to worship the crank whose superstition conflicts with established science."<sup>30</sup>

#### NOTES

- <sup>1</sup> M. ALICE OTTOBONI, THE DOSE MAKES THE POISON 31 (1991).
- <sup>2</sup> See generally id.
- <sup>3</sup> See generally Peter W. Huber, Galileo's Revenge: JUNK Science in the Courtroom (1991).
- <sup>4</sup> The *Frye* test is widely referred to as the "general acceptance" test as it allows expert testimony based on general acceptance in the relevant field of the underlying reasoning. *See, e.g., id.* at 14-16; *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 585 (1993).
- <sup>5</sup> Daubert, 509 U.S. at 589.
- <sup>6</sup> Butler v. Union Carbide Corp., 712 S.E.2d 537, 538 (Ga. Ct. App. 2011).
- <sup>7</sup> Id. at 539.
- <sup>8</sup> Id. at 540 (listing "the four noninclusive Daubert factors used in determining reliability: (1) whether the theory or technique can be tested; (2) whether it has been subjected to peer review; (3) whether the technique has a high known or potential rate of error; and (4) whether the theory has attained general acceptance within the scientific community") (citations omitted). See also Daubert, 509 U.S. at 593-94.
- <sup>9</sup> Butler, 712 S.E.2d at 541 (internal quotations and citation omitted).
- <sup>10</sup> Id. at 542. Maddox claimed that minimal doses of chrysotile asbestos caused Walter Butler's mesothelioma, but the literature on which he claimed to rely to form this opinion did not address chrysotile exposures. Id.
- <sup>11</sup> Moeller v. Garlock Sealing Techs., 660 F.3d 950, 952 (6th Cir. 2011).
- <sup>12</sup> *Id.* at 953
- <sup>13</sup> *Id.* at 952.
- <sup>14</sup> *Id.* at 954.
- <sup>15</sup> *Id*. at 955.
- <sup>16</sup> Betz v. Pneumo-Abex LLC, 44 A.3d 27, 30 (2012). Pneumo-Abex was named as a defendant for claimed exposures to its brake linings and related products.
- <sup>17</sup> Id.
- <sup>18</sup> *Id.* at 31 (quoting affidavit of John C. Maddox).
- <sup>19</sup> *Id.* at 31-32.
- <sup>20</sup> *Id*. at 32.
- <sup>21</sup> *Id*. at 52-53.
- <sup>22</sup> *Id.* at 53.
- <sup>23</sup> Id. (citation omitted).
- <sup>24</sup> *Id*. at 58.
- <sup>25</sup> Smith v. Ford Motor Co. et al., No. 2:08-cv-630, slip op. at 5, 2013 WL 214378 (D. Utah Jan. 18, 2013).
- <sup>26</sup> Id.

- <sup>27</sup> See, for instance, People v. Kelly, 549 P.2d 1240 (Cal. 1976).
- <sup>28</sup> Sargon Enters. v. Univ. of S. Cal., 288 P.3d 1237, 1250 (Cal. 2012).
- <sup>29</sup> *Id.* at 1251.

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- <sup>30</sup> *Id.* at 1252.
- <sup>31</sup> Huber, *supra* note 3, at 5.



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