IN THE COURT OF APPEALS OF MARYLAND

No. 97, September Term, 2012

JOSEPHINE CHESSON, et al.,

Petitioner,

v.

MONTGOMERY MUTUAL INSURANCE CO.,

Respondent.

On Appeal from the Court of Special Appeals of Maryland
No. 2454, September Term, 2009

AMICI CURIAE BRIEF OF COALITION FOR LITIGATION JUSTICE, INC., CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AMERICAN INSURANCE ASSOCIATION, AMERICAN CHEMISTRY COUNCIL, AMERICAN COATINGS ASSOCIATION, AND NFIB SMALL BUSINESS LEGAL CENTER IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Did the Court of Special Appeals err in holding that the standard for the admissibility of scientific expert opinion in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1023), as adopted by this Court in *Reed v. State*, 283 Md. 374, 391 A.2d 364 (1978), requires a consensus in the relevant scientific community supporting that opinion?

INTEREST OF *AMICI CURIAE*

Amici[1] are organizations whose members are named as defendants in toxic tort cases and their insurers. *Amici* encourage courts to take seriously their proper role as gatekeepers under *Frye-Reed* to exclude expert testimony that is unreliable and lacking a basis in science. Consequently, *amici* have a significant interest in the issues before this Court.

STATEMENT OF THE CASE

Amici adopt Respondent's Statement of the Case.

STATEMENT OF FACTS

Amici adopt Respondent's Statement of Facts as relevant to *amici*'s argument here.

SUMMARY OF THE ARGUMENT

This appeal is the third in a series of matters this Court has taken for review that deal with the intersection of science and law in the courtroom. In *Dixon v. Ford Motor Co.*, No. 82, Sept. Term, 2012, a group of *amici* similar to this one discussed the inappropriate use of the *any exposure* theory in asbestos litigation. In *Georgia-Pacific, LLC v. Farrar,* No. 102, Sept. Term, 2012, another similar *amici* group urged the Court to adopt causation and expert standards more in line with modern toxicology than that provided by the "frequency, proximity and regularity" standard in *Lohrmann v.*

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[1] None of the parties or their counsel, or anyone other than the *amici*, their members, or their counsel, authored this brief in whole or in part or made a monetary contribution intended to fund the brief's preparation or submission.

Pittsburgh Corning Corp., 782 F.2d 1156 (4th Cir. 1986), in the context of *any exposure* testimony in low dose asbestos cases.

This third appeal raises a related but different spectrum of issues – the nature of *Frye-Reed* review of an expert whose entire methodology is outside the scope of science. *Amici* urge the Court not only to affirm the Court of Special Appeals' opinion rejecting Dr. Shoemaker's testimony, but to do so in a much more vigorous manner. This Court should articulate clearly the manner in which *Frye-Reed* should be applied to prevent unreliable expert testimony in Maryland courts.

The Court of Special Appeals, even though it ultimately rejected Dr. Shoemaker's testimony, was in many ways too generous to Dr. Shoemaker. This expert has invented a mold disease methodology and used it to market a bizarre approach to medical causation and build a practice almost exclusively around that approach. The Maryland State Board of Physicians in February reprimanded Dr. Shoemaker for numerous practices in his "mold" clinic that failed to meet the required standard of care.[2] Dr. Shoemaker "retired" from his mold disease practice shortly before the Board issued its reprimand ruling, thus apparently preventing a more severe sanction. If Dr. Shoemaker tries to return to practice, he will be on supervised probation for two years to prevent him from repeating these practices, several of which relate to his methodology here.

In addition to Dr. Shoemaker's problems with the Maryland State Board of Physicians, multiple courts have rejected Dr. Shoemaker's self-invented mold-disease diagnosis and testimony for a host of reasons – only one of which was Dr. Shoemaker's inappropriate use of the discredited *any exposure* theory to find causation with no dose assessment whatsoever. As a District of Columbia federal court stated:

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[2] *See* Consent Order, *In the Matter of Ritchie C. Shoemaker, M.D.*, Nos. 20010-0765 & 2010-0912 (Md. State Bd. of Physicians Feb. 11, 2013), at http://www.owndoc.com/pdf/RitchieShoemakerReprimanded.pdf. The trial court and Court of Special Appeals did not have this ruling because it post-dates their decisions. Dr. Shoemaker is no longer practicing his version of mold diagnosis and treatment; if he attempted to do so he could be subject to further sanctions including loss of his license.

> Without [information on the levels of exposure at issue], Dr. Shoemaker's testimony about the health effects of any such "exposure" cannot possible be anything other than conjecture. Even if such knowledge existed, Dr. Shoemaker would be unable to offer any concrete evidence as to what substances existed at what levels. Thus, there is no basis up[on which to conclude that plaintiffs' exposures were sufficient to account for the variety of symptoms they have experienced.

Young v. Burton, 567 F. Supp. 2d 121, 133 (D.D.C. 2008), *aff'd*, 354 Fed. Appx. 432 (D.C. Cir. 2009).[3]

Amici urge the Court to use the opportunity of this appeal to strengthen the rejection of Dr. Shoemaker and redirect Maryland trial courts and the Court of Special Appeals to apply *Frye* vigorously to opinions and experts such as Dr. Shoemaker. Considering the nature of Dr. Shoemaker's flawed approach and its repeated criticism by other courts, it is surprising that the trial court allowed him to testify. Although the Court of Special Appeals narrowly rejected Dr. Shoemaker's testimony, the court predicted that his opinion would potentially survive under a *Daubert* review where factors other than general acceptance come into play. (It would not, and has not in other courts applying *Daubert; see, e.g., Young*, 567 F. Supp. 2d at 131). Dr. Shoemaker's testimony is not, and should never have been, a close call.

A narrow application of *Frye*, applied to such a broadly unreliable and eccentric approach to medicine, will leave Maryland courts open to a wide array of bad science. *Amici* thus request that the Court affirm the Court of Special Appeals in rejecting

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[3] Other opinions excluding Dr. Shoemaker include *Herzner v. Fischer Attached Homes, Ltd.*, 2008 WL 2004473 (Ohio Ct. App. May 12, 2008), *appeal refused*, 894 N.E.2d 334 (Ohio 2008); *Jones v. Noah's Preferred Prop.*, 2010 WL 5834265 (Md. Cir. Ct. Frederick County July 7, 2010); *Norlander v. Ku*, 2009 WL 7450521 (Md. Cir. Ct. Montgomery County Apr. 22, 2009); *Wright v. Fort Lincoln Realty Co.*, No. 03-CA-4555 (D.C. Super. Ct. Oct. 15, 2007); *Racic v. Chana, LLC*, No. 06-7172-B (D.C. Super. Ct. Dec. 12, 2008); *Curry v. Persica Design & Constr., Inc.*, No. 03-CA-0586 (Fla. Cir. Ct. Leon County Apr. 30, 2004); *Kim Stewart Ford v. Summit Realty Group Inc.*, No. LR2009-1 (Va. Cir. Ct. City of Richmond Mar. 24, 2006) (oral order); *Folmar Kenner, LLC v. Capaci*, No. CV-2004-2311 (Ala. Cir. Ct. Sept. 8, 2006) (oral order).

Dr. Shoemaker's testimony under *Frye*, but at the same time clarify that Dr. Shoemaker's approach is in no way acceptable in the courts of Maryland. Vigorous *Frye* review does not keep valid claims out of court – it merely prevents experts such as Dr. Shoemaker from distorting and using the court system to advance an agenda well outside the science mainstream.

ARGUMENT

The speculative nature of Dr. Shoemaker's approach does not leave much doubt that his testimony should not have been admitted. *See Jones v. Noah's Preferred Prop.*, 2010 WL 5834265 (Md. Cir. Ct. Frederick County July 7, 2010) ("One need not proceed past the first tier to observe just how speculative and inconsistent the case definition protocol pioneered by Dr. Shoemaker...is."). The Court of Special Appeals erred in not rejecting this flawed testimony more forcefully by applying the rules of science across the board to Dr. Shoemaker's approach.

I. COURTS MUST ACT AS GATEKEEPERS TO PROTECT THE LITIGATION PROCESS FROM DISINGENUOUS TESTIMONY AND UNTESTED THEORIES

The United States Supreme Court in the *Daubert* trilogy of cases recognized the necessity of judges performing a "gatekeeping" task to prevent unproved or unreliable science from entering the courtroom. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *General Electric Co. v. Joiner*, 522 U.S. 136 (1997); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). This Court has determined likewise under Maryland's *Frye* standard. *See Blackwell v. Wyeth, Inc.*, 408 Md. 575, 971 A.2d 235 (2009). The principle hurdles expert testimony must clear include, first and foremost that *the testimony must originate from a reliable methodology.* Under Maryland Rule 5-702 and *Frye-Reed*, expert opinion is not admissible unless it is premised on sufficient facts and is the result of reliable methodology. *See id.* at 581-90. Sufficient facts are those that "permit reasonably accurate conclusions as distinguished from mere conjecture of guess." *State Health Dep't v. Walker*, 238 Md. 512, 520, 209 A.2d 555, 559-60 (1965).

More importantly for this case, reliable methodology requires that a conclusion flow from its premises. *See Blackwell*, 408 Md. at 605-06.

Second, *the testimony must have undergone true review and assessment by the scientific community.* The *Daubert* court recognized this and included "peer review" among its criteria for expert testimony admissibility. *Frye* relies even more heavily on this criteria, because testimony under *Frye* cannot be admitted unless the proposition and methodology have already been generally accepted in the scientific community.

Third, *the testimony must not result from significant "analytical gaps" in the expert's reasoning from the underlying studies and data.* Specifically, a generally accepted methodology must be coupled with a generally accepted analysis in order to avoid an "analytical gap" that would defeat the expert's opinions. *Id.* at 608. In discussing the concept of an "analytical gap," this Court in *Blackwell* paid close attention to the United States Supreme Court's decision in *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997):

> [Joiner] claims that because the District Court's disagreement was with the conclusion that the experts drew from the studies, the District Court committed legal error and was properly reversed by the Court of Appeals. But conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. **But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert.** A court may conclude that there is simply too great an **analytical gap** between the data and the opinion proffered.

Id. at 146. (emphasis added). The *Joiner* Court excluded an expert who, like Dr. Shoemaker, was relying on a self-supported methodology derived from his own re-interpretation of articles that did not support his conclusions – thus the data gap criticized by the *Joiner* court. Dr. Shoemaker has similar issues here.

Fourth, *the court must not let experts testify based on their own say-so, or* ipse-dixit *self-supporting opinions.* Judges can detect much of the error in courtroom

testimony through one of the above techniques. The challenge, however, often lies in the details. Most experts are adept at citing and quoting from material they claim supports their positions. The sometimes-daunting task facing courts is to delve into this material and understand exactly what proposition the expert is attempting to draw from the studies and whether they in fact support the proposition. Only under such an exacting review do the analytical gaps, erroneous logic, and lack of scientific support come to light. Federal courts are required to perform this sort of review under the *Daubert* standard. *See, e.g., Bland v. Verizon Wireless, LLC*, 538 F.3d 893, 898 (8th Cir. 2008), *Ruggerio v. Warner-Lambert Co.*, 424 F.3d 249 (2d Cir. 2005). Maryland courts likewise must engage in a serious gate-keeping function through this state's exacting *Frye* review as set forth in the *Blackwell* opinion. 408 Md. at 591.

These requirements go well beyond the limited holding of the Court of Special Appeals, that Dr. Shoemaker narrowly failed *Frye* only because the literature did not uniformly accept his asserted link between mold disease and neurological conditions. As discussed next, there were numerous other flaws in Dr. Shoemaker's testimony that merited excluding him from the case.

II. DR. SHOEMAKER'S APPROACH AND OPINIONS ARE NOT SOUND AND DO NOT SATISFY THE *FRYE-REED* STANDARD

The tests and court inquiries for expert testimony are designed to detect scientists who are attempting to present biased evidence based on conjecture and poor reasoning. Novel causation theories such as Dr. Shoemaker's are one of the most fruitful grounds for this sort of evidence. Courts routinely reject efforts to evade the gatekeeping bar in *Daubert* and *Frye*. Dr. Shoemaker uses many of these previously rejected techniques; his opinions, like others of this nature, are unscientific and should not be admitted.

A. Dr. Shoemaker's Methodology and Opinions Do Not Conform to the Scientific Method or *Daubert/Frye* Principles

As confirmed by other courts that have rejected his testimony, Dr. Shoemaker's approach to mold disease does not pass the basic tests of the scientific method and legally admissible evidence.

1. Dr. Shoemaker Has Not Approached His Theories from the Neutral, Evidence-Based Process Required by the Scientific Method

On even a cursory review of Dr. Shoemaker's approach, it is apparent that he has not conformed to a neutral scientific approach or a method that merits admission of his testimony. Instead, he has latched onto a causation theory (his unique mold disease and diagnosis approach) and performed his tests to prove that he is right.

At bottom, Dr. Shoemaker has created an island all to himself. He has adapted tests and techniques (e.g., the misuse of the eye screening test to detect mold disease; the misuse of Cholestyramine to diagnose mold disease as well as treat it) to his purpose that have never before or since been used in that way by anyone else. *Jones*, *supra*, at 33. He created a symptomology-based diagnostic tool that allows him to find a "pattern" where none exists, because he merely selects from among a wide array of self-reported and subclinical findings. He performed no inspections of the premises and did not test for particular mold exposures or levels in the air (presumably for fear he would find nothing, given that the mold was located only behind a wall and was not even visible until the wall was removed). Dr. Shoemaker has no evidence the plaintiffs were ever exposed to measurable levels of toxic mold. He published a few articles on his approach and a book called *Mold Warriors,* none of which have found acceptance or favor in the broader and independent scientific community.[4] He converted his practice from the family physician work he once did to a business devoted largely, if not entirely, to diagnosing "mold

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[4] Even Dr. Shoemaker recognizes that his theories "are the subject of intense controversy." *See* Ritchie C. Shoemaker et al., *Sick Building Syndrome in Water-Damaged Buildings: Generalization of the Chronic Biotoxin-Associated Illness Paradigm to Indoor Toxigenic Fungi*, Health Effects II – Toxicology and Neurological Effects, at 52-63 (2006).

disease" in individuals and supporting disability, workers compensation, and litigation claims.

On this island, Dr. Shoemaker apparently believed he had immunized himself from scientific examination and criticism and could pursue his highly unusual mold practice without interference. He failed. Not only have multiple courts rejected his approach and testimony, but now even his mold-disease practice has ended via the threat of a major sanction from the Maryland State Board of Physicians. Due to highly irregular conduct, the Board reprimanded Dr. Shoemaker and placed him under severe restrictions should he re-engage his practice. Some of those same practices taint his testimony here.[5] The "pilings" of his theory have not only not been driven to ground, they have been uprooted by courts and the Maryland Board of Physicians. Dr. Shoemaker's testimony must be excluded.

2. Dr. Shoemaker's Approach Fails the "Test and Retest" Step of the Scientific Method

Dr. Shoemaker's theories have not been sufficiently tested by others in the scientific community to consider them any more than hypotheses. What is particularly missing is confirmatory testing of virtually all of his highly novel techniques for identifying mold disease. His use of biomarkers to detect mold disease should be readily testable by epidemiology and similar studies, but no such study exists. *See Young*, 567 F. Supp. 2d at 136. His use of VCS technology – intended for Air Force eye-testing and glaucoma diagnostic purposes – as a method of detecting mold disease is also readily testable, but once again Dr. Shoemaker has no independent or replicated testing showing that his novel (and somewhat bizarre) application of this tool can indeed indentify persons with mold disease. *See id.* Dr. Shoemaker's identification of a distinctive group

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[5] The Maryland State Board of Physicians peer review panel found that Dr. Shoemaker had used potentially toxic drugs for inappropriate purposes, had ordered numerous lab tests with no clinical signs of the purpose for which they were being ordered, and had failed to document his treatment rationale for starting medications. *See* Consent Order, *supra*, at 4-5.

of symptoms for diagnosis of a mold-related illness is testable, yet he cannot point to any testing or publications within the scientific community that confirms this technique. *See id.* at 133. Indeed, other courts of this state have looked at these tests and found that "it is clear at this time that Dr. Shoemaker's theories are simply unproven hypotheses and cannot be accepted as reliable []." *Norlander v. Ku*, 2009 WL 7450521 (Md. Cir. Ct. Montgomery County Apr. 22, 2009).

3. Dr. Shoemaker's Methods Have Not Been the Subject of True Peer Review and Acceptance in the General Scientific Community

Dr. Shoemaker's approach has not been adopted by any major medical body or made part of any medically-recognized diagnostic procedure for mold disease other than in his own clinic. He has published only a few articles, enough perhaps to put the hypothesis in writing, but we are aware of no record evidence that he has actively sought a thorough vetting, review, and approval by the scientists who work in this field. In particular, Dr. Shoemaker's views that mold exposures cause a whole range of neurological and other conditions outside the realm of respiratory conditions is not an accepted theory. This error formed the sole basis of the Court of Special Appeals exclusion, and that ruling was correct, as far as it went.

4. Dr. Shoemaker's Method is Unreliable and is Full of Analytical Gaps

Dr. Shoemaker fails the most critical tests under *Frye* and *Daubert* – his methodology is not reliable and is built on large gaps in reasoning and evidence. This is the essence of the finding of numerous other courts. For example, without proof of documented exposure, there is no way to causally relate disease and causation. *See Jones, supra*, at 31. Dr. Shoemaker does not plug this analytical gap with any scientific literature that established a dose of exposure to a particular mold and the symptom that is exhibited by one of his patients. Additionally, Dr. Shoemaker does not rule out other potential causes for symptoms and abnormal biomarkers. This means that one cannot be

certain that the mold exposure caused the claimed illness, and is a large analytical gap that has not been plugged. *See id.*

5. Dr. Shoemaker's Opinion Is Based on Classic *Ipse Dixit* Testimony

Dr. Shoemaker believes that after diagnosing a plaintiff with a mold illness, he has established causation through the highly unusual approach to mold disease he has developed. He asserts this his model is established in several published studies – and then cites to *his own articles. See* Ritchie C. Shoemaker et al., *Sick Building Syndrome in Water-Damaged Buildings: Generalization of the Chronic Biotoxin-Associated Illness Paradigm to Indoor Toxigenic Fungi*, Health Effects II – Toxicology and Neurological Effects (2006). This is precisely the form of *ipse-dixit* testimony that the United States Supreme Court cautioned courts to be wary of in *Joiner*. An expert cannot skirt around the requirements of presenting general causation evidence in the form of scientific evidence merely because the expert self-proclaims the evidence to be true. *See, e.g., Lofgren v. Motorola, Inc.*, 1998 WL 299925, *11 (Ariz. Super. Ct. June 1, 1998) ("[When] a scientist claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist, the [] court should be wary that the method has not been faithfully applied.").

These failings of Dr. Shoemaker illustrate just how far short of the *Frye-Reed* principles his testimony falls. Every one of these failings supplied ample basis for the trial court and Court of Special Appeals to exclude Dr. Shoemaker's testimony.

B. Dr. Shoemaker Is Relying on a Number of Fallacious Techniques to Avoid Detection of His Unreliable and Unscientific Opinions

In addition to failing the tests of good science and Maryland *Frye* analysis, Dr. Shoemaker's approach bears the hallmarks of other "novel-theory" experts who seek admission of testimony in court through approaches that can only be described as biased and disingenuous. Dr. Shoemaker, like others before him, presents at best an unscientific and unproven hypothesis, but he wishes to make it appear to be much more than that. His effort should be rejected.

1. Dr. Shoemaker is Using the *Differential Diagnosis* Methodology as a Shield to Hide His Illogical and Unscientific Reasoning

Dr. Shoemaker is hiding behind an accepted medical technique known as *differential diagnosis* to disguise the lack of scientific integrity in his methodology. In the twenty years since *Daubert* was issued, experts who claim novel causation theories have learned that they must appear to conform to the standards of reliability courts now apply to testimony.

In this case, Dr. Shoemaker erroneously relies on a standard mantra to avoid rejection – the use of *differential diagnosis*. A "differential diagnosis" is a recognized tool of a treating physician, but it is not an excuse for an improper opinion. Differential diagnosis is the broad label attached to the process of weeding out possible causes and arriving at a conclusion as to the likely cause. A physician will first "rule[s] in all scientifically plausible causes of the plaintiff's injury. The physician then 'rules out' the least plausible causes of injury until the most likely cause remains." *Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1209 (10th Cir.), *cert. denied*, 537 U.S. 1088 (2002). Then, the remaining cause is the expert's conclusion. *See id.*

A differential diagnosis, however, can be abused, and the conclusion can be erroneous if a physician does not adhere to the proper scientific principles. As the Sixth Circuit has explained when addressing the reliability of a differential diagnosis:

> Calling something a 'differential diagnosis' . . . does not by itself answer the reliability question but prompts three more: (1) Did the expert make an accurate diagnosis of the nature of the disease? (2) Did the expert reliably rule in the possible causes of it? (3) Did the expert reliably rule out the rejected causes? If the court answers 'no' to any of these questions, the court must exclude the ultimate conclusion reached.

Pluck v. BP Oil Pipeline Co., 640 F.3d 671, 678 (6th Cir. 2011) (citing *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010), *cert. denied*, 131 S. Ct. 2454 (2011)).

To that end, the real test for a legitimate differential diagnosis is the way in which the physician ascribes causation to certain factors and eliminates others. A trial court would never wave through the gate an expert who testifies (as people in the Victorian era

believed) that "bad air" causes diseases like cholera, simply because he or she claims to have performed a differential diagnosis to that effect. Indeed, many courts across the country have rejected the improper use of differential diagnosis.[6]

Dr. Shoemaker masks three fundamental errors behind his twisted version of *"differential diagnosis."* First, he has improperly ruled in mold exposure as a potential cause of the many neurological and other conditions he attributes to those exposures. *Chesson*, 51 A.3d at 25. This is a classic error. Experts who use differential diagnosis in this fashion often merely assume the conditions are the result of the disease and then move to causation, without properly satisfying the first step. As the Court of Special Appeals correctly noted, the current literature simply does not support Dr. Shoemaker's wide array of mold-induced symptoms. *See id.* at 41.

Second, Dr. Shoemaker has not even confirmed *any* exposure to the correct types of mold. He simply assumes that such exposures occurred based on a finding that mold was in the building, and without differentiating among the toxicity patterns of numerous molds that might have been present. Without taking these additional steps, Dr. Shoemaker has no way to causally relate disease to the substance. *See Young*, 567 F. Supp. 2d 121. ("[A] person cannot be made ill by mold toxins to which she has not been exposed."). Thus, not only did Dr. Shoemaker fail to select literature-documented endpoints of mold exposure, he also never demonstrated these plaintiffs had sufficient exposure to the correct types of mold to cause any harm (e.g., respiratory) at all. *See Chesson*, 51 A.3d at 28.

Third, Dr. Shoemaker has made no effort to rule out the many other causes of the varied neurological symptoms he identifies. There are a multitude of diseases and

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[6] *See e.g., Huerta v. Bioscrip Pharm. Servs., Inc.*, 429 Fed. Appx. 768, 773-776 (10th Cir. 2011) (finding that physicians use of a differential diagnosis when ascribing harm to a pharmaceutical product was too weak to support causation); *Tamraz*, 620 F.3d at 675-767 (excluding expert because there is "too great an analytical gap between the data and the opinion proffered"); *Goeb v. Tharaldson*, 615 N.W.2d 800 (Minn. 2000) (Differential diagnosis was undercut by "too great a leap to get from 'mere exposure' to a toxic substance to conclusions about appellants' illnesses").

ailments that can cause the symptoms like fatigue, memory loss, and shortness of breath complained of by the claimants, including a number of endocrine disorders, depression, substance abuse, sleep apnea, and even a common cold. *See* Inst. of Med., *Damp Indoor Spaces and Health*, at 245 (2004). Dr. Shoemaker fails to account for these logical alternatives, or provide any general causation evidence connecting mold to these symptoms.

Dr. Shoemaker has *not*, in fact, performed anything close to a proper differential diagnosis. He cannot claim to have conformed to an accepted methodology when in fact he has met none of the criteria of that methodology and has instead abused it.

2. Dr. Shoemaker is Misusing Standard Tools of the Medical Profession for Illegitimate Purposes or Conclusions

Despite Dr. Shoemaker's claim that he is using accepted "tools" of science, he is in reality misusing accepted tools for unacceptable purposes, like using a barometer that measures atmospheric pressure to instead tell the jury what the temperature was. Methodologies such as the "differential diagnosis" employed by Dr. Shoemaker require close examination to ensure that a scientific tool or mode of analysis has been properly applied.

Dr. Shoemaker falls into the trap of misapplication of standard medical tools repeatedly. None of the tools used as part of Dr. Shoemaker's approach are generally accepted for the purpose for which Dr. Shoemaker employs them. His use of the drug Cholestyramine illustrates the problem. Cholestryamine has a legitimate purpose – to reduce the amount of cholesterol and fatty substances in the blood stream.[7] Dr. Shoemaker, however, prescribes this drug for something wholly different, relief from mold-induced conditions. More telling, he then uses the drug as a means of diagnosing the very condition he is supposedly treating. This circular methodology is not logical, is fraught with potential error, and may well put his patients in danger. *See* Consent Order, *supra*, at 4. There is no body of literature among the relevant scientific community that

[7] *See* Nat'l Inst. of Health, *Cholestyramine Resin*, at http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682672.html.

suggests Cholestyramine can be used for treating a mold-related illness, much less for the purpose of diagnosing it. *See Jones*, *supra*, at 31-32.

Another clear example is Dr. Shoemaker's use of a "repetitive exposure protocol" which also has no basis in acceptable science. Dr. Shoemaker removes his patients from what he believes is a dangerous environment, asks them to self-report any improvement in their condition, and then *sends them back into what he believes is a dangerous environment* in order to confirm that they indeed get sick again. His approach relies heavily on the subjective reports of biased subjects (his patients, who believe they have mold disease per Dr. Shoemaker's advice); he has no control group to compare against his subject group; and this practice has not been replicated or used by other practitioners other than those certified by Dr. Shoemaker. *See* Clifford S. Mitchell et al., *Current State of Science: Health Effects and Indoor Environmental Quality*, 115 Envtl. Health Persps. 961 (2007) (discussing Dr. Shoemaker's efforts and concluding there is a "lack of consensus regarding the systemic effects of mold.").

Another obvious example, already discussed above, is the VCS eye test, which Dr. Shoemaker takes completely outside the realm of its intended purpose. The test is supposed to be used to determine a patient's ability to distinguish between finer and finer increments of light versus dark. It has applications for detecting eye diseases such as glaucoma. No recognized scientist or scientific literature other than that written by Dr. Shoemaker himself has suggested that VCS deficits relate to mold exposure. This tool may work well in assisting the Air Force in selecting pilots, or in detecting glaucoma, but it has no verified basis as a tool for diagnosing mold disease.

Finally, Dr. Shoemaker's use of an array of biomarkers (only some of which need be present) is also a misuse of a standard tool. Biomarkers are ways of detecting common molecular or cellular changes in the body. A great deal is currently unknown about these biomarkers, and their import is often minimal or at best uncertain – they are *not* in and of themselves evidence of disease or impairment. *See Young*, 567 F. Supp. 2d. at 136. Dr. Shoemaker looks for the presence of three of the following six biomarkers to confirm his diagnosis of a mold-related illness: deficits in visual contrast sensitivity

(VCS); presence of susceptible HLA/DR genotypes, as analyzed by PCR; elevated levels of matric metalloproteinase-9 ("MMP-9"), dysregulation of ACTH/cortisol; dysregulation of ADH/osmolality; and reduced levels of melanocyte stimulating hormone ("MSH").[8] *See Chesson*, 51 A.3d at 25-26. Dr. Shoemaker himself has invented this approach. These biomarkers have never been confirmed as associated with mold disease, much less as a valid way of diagnosing mold disease. His misuse of these tools is not generally accepted, clinically-validated, or logically related to the alleged causal factors he claims between plaintiffs' alleged exposure to mold and their claimed injuries.

If the test has not been validated by the scientific community for the purpose it is being used, it cannot be considered reliable. Dr. Shoemaker is operating outside the realm of accepted science in using these tools in the manner he has employed them.

3. Dr. Shoemaker Ignores Established Epidemiology in Favor of Much Weaker Evidence

Dr. Shoemaker attempts to support his novel and unproven opinions through misuse of the literature, much like the situation in *Daubert*, where plaintiffs' experts "reanalyzed" a series of epidemiology studies, none of which found any link between birth defects and the morning-sickness drug at issue, to find proof of their novel causation theories. Similar misuse of PCB studies later led to the Supreme Court's "analytical gap" holding in *Joiner*.

This type of error can prove challenging for judges – it requires them to read the studies and try to understand what the experts are doing with them. "Although making determination of reliability may present a court with the difficult task of ruling on matters that are outside of its field of expertise, this is less objectionable than dumping a barrage of scientific evidence on a jury, who would likely be less equipped than the judge to make reliability and relevance determinations." *Rider v. Sandoz Pharm. Corp.*, 295 F.3d

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[8] Dr. Shoemaker claims that abnormal HLA/DR genotypes, elevated levels of MMP-9, and MSH are symptoms of a biomarkers of a mold-related disease. These abnormalities may be caused by a number of other factors, including age, diabetes, or thyroid conditions.

1194, 1197 (11th Cir.) (internal quotation marks omitted), *reh'g denied*, 48 Fed. Appx. 330 (11th Cir. 2002). Thoughtful opinions frequently dissect the leading studies, one after the other, with a view toward whether the expert is fairly relying on them. Less thoughtful opinions simply repeat what the expert claims the study says, with no analysis as to whether the expert is correct or is simply misusing the study.

Controlled epidemiological studies are generally considered the "gold standard" for human causation. *See Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, 311 (5th Cir.) ("Undoubtedly, the most useful and conclusive type of evidence in a case such as this is epidemiological studies."), *modified by* 844 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990). Epidemiology is the only basis for addressing what actually happens in a human exposure situation involving potentially toxic exposures and latent disease, because medical ethics prevent the intentional dosing of humans with such substances, and animal studies cannot easily be extrapolated to determine what happens in human organs. Many courts have emphasized the importance of epidemiology.[9]

As to this case, Dr. Shoemaker's theory is that mold exposure at all levels can cause "sick building syndrome," which carries with it a number of mostly subjective physical ailments including fatigue, memory loss, joint pain, muscle aches, confusion,

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[9] *See Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996) ("[T]he most useful and conclusive type of evidence in a case such as this [ethylene oxide toxic tort claim] is epidemiological studies."); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1412-13 (D. Or. 1996) ("[T]he existence or nonexistence of relevant epidemiology can be a significant factor in proving general causation in toxic tort cases."); *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1025-26 (S.D. Ohio 1992) ("Epidemiologic studies are the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or a disease."), *aff'd*, 24 F.3d 809 (6th Cir. 1994); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 884-85 (10th Cir. 2005 ("We agree with the district court that epidemiology is the best evidence of general causation in a toxic tort case."); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998) ("The most important evidence relied upon by scientists to determine whether an agent (such as breast implants) cause [sic] disease is controlled epidemiologic studies."); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999) ("[I]n the face of controlled, population-based epidemiological studies which find otherwise, these case studies [of alleged breast implant injury] pale in comparison.").

weakness, depression, or disorientation. In support of this theory, Dr. Shoemaker presents no epidemiological evidence that links mold exposure with these symptoms. Rather, Dr. Shoemaker cites two studies that purport to find a link between a damp and moldy home and depression and other cognitive defects. The first article, Edmond D. Shenassa et al., *Dampness and Mold in the Home and Depression: An Examination of Mold–Related Illness and Perceived Control of One's Home as Possible Depression Pathways,97* Am. J. of Pub. Health 1893 (2007), concludes that damp or moldy houses are linked to a moderately elevated risk of depression. The article moves on to suggest that the link was merely an association, and had not been proved to be causal. If the trial court had paid close attention to this conclusion, the court would have immediately realized that it does not support Dr. Shoemaker's hypothesis, and is thus unreliable.

The second article, Luke Curtis et al., *Adverse Health effects of Indoor [Molds],* 23 J. Aust. Coll. Nutr. & Envtl. Med. 3 (2004), purports to find that exposure to mold can cause a variety of ailments. This study is essentially a "meta-analysis" in which otherwise insignificant or inconsistent findings have been pooled to generate a single finding. While meta-analyses can provide useful information if conducted pursuant to proper scientific methodology, they have frequently reported causal relationships that do not survive scientific scrutiny.[10] Particularly questionable are meta-analyses that claim to find a causative link when the underlying studies did not find evidence of such a link. Exposure to certain types of mold at the appropriate dose may cause *respiratory* issues, as documented in numerous studies. No such studies support the very different claim of Dr. Shoemaker that mold exposure causes a wide array of very common and subjective neurological symptoms. The second article relied on by Dr. Shoemaker states only that there may be an association between certain mold exposures and neurological impairment, but the article stops short of declaring causation and instead requests

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[10] *See generally* Douglas L. Weed, *Interpreting Epidemiological Evidence: How Meta-Analysis and Causal Inference Methods are Related*, 29 Int'l. J. Epidemiology 387 (2000); Samuel Shapiro, *Is Meta-Analysis a Valid Approach to the Evaluation of Small Effects in Observational Studies?*, 50 J. Clin. Epidemiology 223 (1997).

additional studies to determine causative effect. Once again, the trial court should have examined this study and realized that it does support Dr. Shoemaker's claims.

In contrast to Dr. Shoemaker's opinion, there are multiple studies analyzing the hypothesized association of mold and neurological injury and concluded that there is no relation between the two (or at most that more research is required). *See* Inst. of Med., *supra*, at 252. Other reviews of this area of science have discussed the state of scientific knowledge as to the nature of fungal related disease and concluded, "Current scientific evidence does not support the proposition that human health has been adversely affected by inhaled mycotoxins in the home, school, or office environment." Am. College of Occupational & Envtl. Med., Evidence-Based Statement, *Adverse Human Health Effects Associated with Molds in the Indoor Environment*, 45 J. of Occupational & Envtl. Med. 470 (2003).

Amici request that this Court make it clear that Maryland trial courts must pay close attention to the conclusions made by the studies proffered by a testifying expert. If the conclusions do not match what the expert is saying, the court may find that the expert is using an unreliable methodology and exclude the expert. The error here is twofold, both (1) in over-interpreting and cherry-picking among the available studies, and (2) in refusing to acknowledge the superiority of epidemiology over biomarker, "repeated exposure protocol," and other novel and inferior tests that Dr. Shoemaker relies on.[11] When an expert cites to animal studies, cellular studies, subclinical findings, trace evidence in blood, case reports, and the like – all while ignoring a large body of contrary epidemiology – alarm bells should go off. Dr. Shoemaker does exactly that here, and this should have been a focus of the trial court and Court of Special Appeals analysis and findings.

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[11] When a causation expert relies on epidemiological studies to support his opinions, a trial court must analyze those studies in such a way that determines whether they provide a proper foundation for the expert's testimony under the scientific method. The finding in an epidemiological study of an association between a substance and an injury is not equivalent to causation. *See* Michael D. Green, *Reference Guide on Epidemiology*, Reference Manual on Scientific Evidence 336 (2d ed. 2000).

4. Dr. Shoemaker Relies on the "Any Exposure Theory" and Circular Reasoning to Avoid the Required Assessment of Dose and Exposure

Amici have already addressed this flaw at length in the *Dixon* and *Farrar* briefs and will not repeat those discussions here. In low or non-existence exposure cases, experts frequently abjure any attempt to determine the actual exposure or dose to avoid having to admit how low or non-existent the exposure really was. The asbestos litigation use of the theory is the most prominent but hardly the only such usage. Dr. Shoemaker has applied his version of the 'any exposure theory' in this case. His theory disregards fundamental scientific principles and cannot be deemed acceptable expert testimony.

In this case, Dr. Shoemaker failed to perform a proper risk assessment of the plaintiff's work environment which includes a reasonable quantification of the dose of exposure to molds, and a fair comparison of that dose to the scientific literature that recognizes a particular result at those levels. Dr. Shoemaker is relying purely on a finding of Aspergillus and Stachybotrys within the walls of the facility by the building's maintenance crew. *See Chesson*, 51 A.3d at 20. Dr. Shoemaker has not performed any of his own assessment into the presence and type of mold present in the facility, nor has he analyzed the potential pathways of exposure to identify whether or not these claimants were in fact exposed to the mold. He has no evidence of actual exposure, other than his circular reasoning that since the plaintiffs exhibit symptoms consistent with Dr. Shoemaker's methodology, they must have been exposed. This also is not science.

CONCLUSION

Courts in Maryland must be more forceful than either the trial court or the Court of Special Appeals were with Dr. Shoemaker to keep biased and speculative testimony out of the courtroom. Maryland's *Frye* standard should be applied vigorously. *Amici* urge this Court to perform a thorough and proper analysis of Dr. Shoemaker's body of work and follow the lead of other courts that have criticized and excluded his testimony.

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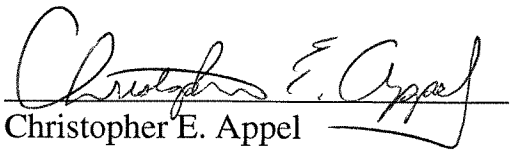
Dated: May 9, 2013

STATEMENT OF RULE 8-504 COMPLIANCE

Pursuant to Rule 8-504(a)(8), I certify that the foregoing brief is in Times New Roman font with a 13-point typeface.



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CERTIFICATE OF SERVICE

I certify that two copies of the foregoing were sent by first class U.S. mail, postage prepaid, on May 9, 2013, to the following:

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