

**SILICA LITIGATION:
SCREENING, SCHEMING & SUING**

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INTRODUCTION

In June 2005, a federal district court, charged with responsibility for the multidistrict litigation (MDL) of silica cases, found that the plaintiffs' lawyers, the plaintiffs' diagnosing physicians, and various screening companies were all willing participants in a "scheme" to manufacture silicosis diagnoses for profit. *In re Silica Products Liab. Lit.*, 2005 WL 1593936, 150 (S.D. Tex. June 30, 2005) ("*In re Silica*"). At the heart of the scheme, physicians employed "shockingly relaxed standards of diagnoses" to provide plaintiffs' counsel with the expert reports required by the federal courts' Orders. *Id.* at 59. These physicians' "diagnoses were driven neither by health nor justice;" they were cynical and sometimes fraudulent attempts to maintain, and to prevail in, lawsuits. *Id.* at 60. The effects of the scheme were the consumption of limited court resources, the delay of meritorious cases, the waste of defendants' assets, and the deprivation of plaintiffs' access to full, accurate information about their own health.

The “scheme” — the assembly-line production of dubious or fraudulent diagnoses — has become an important business model for many plaintiffs’ lawyers in the field of mass torts. Previously, litigation suggested fraud in the submission of claims in asbestos bankruptcy proceedings. *See, e.g., Raymark Industries, Inc. v. Stemple*, 1990 WL 72588 (D. Kan. May 30, 1990). The opinion of Judge Janis Graham Jack, however, by applying a careful *Daubert* analysis to the diagnosis-manufacturing process, exposed the inner workings of the mass screeners and their unreliable diagnoses. Judge Jack’s opinion changes how we look at mass torts, as perhaps author Upton Sinclair, a century ago, changed the way the world looked at the sausage. Unlike Sinclair, however, Judge Jack needed no literary license to evoke shock, dismay, and disgust.

I. DAUBERT REQUIRES RELIABLE DIAGNOSES

The clinical criteria for diagnosing silicosis are straightforward and generally accepted in the medical profession. A reliable clinical diagnosis requires:

- Adequate exposure to crystalline silica, with adequate passage of time (latency) since first exposure;
- Radiographic evidence; and
- The absence of any other cause of the radiographic changes.

In re Silica at 48.

Judge Jack found convincing indicia of pervasively unreliable evidence for all three criteria in the thousands of cases before her in the MDL.

A. Unreliable Exposure Histories

The occupational exposure histories, in the great majority of the silica MDL cases, were taken by people with no medical training, and with a significant financial bias to report a history of sufficient exposure. *Id.* In some cases, the “history” was nothing more than a statement from a clerk or paralegal that a claimant had “an occupational history consistent with silicosis.” *Id.* at 36. Judge Jack found the exposure histories “devoid of meaningful details,” such as duration, intensity, and latency of exposure, or whether the claimants used respirators or other personal protection equipment. *Id.* at 48.

Some of the more colorful examples of bogus occupational histories were developed through the testimony of plaintiffs’ diagnosing physician, Dr. Barry S. Levy, who devoted less than four minutes to each of his 1,389 diagnostic evaluations. *Id.* at 38. For example, Dr. Levy opined that one claimant had sufficient silica exposure working “near sandblasting” while employed as an elementary school teacher. *Id.* at 38-39. When pressed for specifics about how an elementary school teacher worked near sandblasting for 27 years, Dr. Levy simply retreated and withdrew his diagnosis. *Id.* at

40. Although Dr. Levy provided a “protocol” for taking occupational histories, he did not take them himself and he did not know whether others followed his directions. *Id.* at 37. Dr. Levy did not review claimants’ medical charts or speak with their treating physicians or employers. *Id.* Judge Jack found in the thousands of silica cases before her, “diagnosed” by Dr. Levy and by others, that the exposure histories were not reliably established by expert witness testimony. The reliability requirements of Federal Rule of Evidence 702 implicitly requires that occupational histories be “physician guided,” and of the same thoroughness as when taken from clinic patients. *Id.* at 50.

B. Unreliable Radiologic Opinions

The second diagnostic criterion for silicosis is the radiographic demonstration of changes consistent with silicosis. The disease silicosis is actually several different clinical entities, each with a different radiographic picture. Acute silicosis, which has a rapid onset and clinical course, looks very different on a chest X-ray from chronic simple silicosis, which manifests after a long latency, presents usually without symptoms, and progresses slowly or not at all. Chronic simple silicosis presents with small rounded opacities in the upper zones of both lungs. Chronic silicosis may become “complicated” when, after many years, small silicotic nodules coalesce into nodules greater than one centimeter across. These large,

conglomerate nodules are seen as “large opacities” on a chest X-ray, and they carry very different implications, in terms of impairment, disability, and progression, from simple silicosis. There is also an accelerated silicosis, which has features of both acute and chronic silicosis. Acute and accelerated silicosis cases have become vanishingly rare in the United States.

Because of idiosyncratic medical terminology used in describing chest X-ray changes in the various dust diseases of the lungs, the International Labour Office (ILO) developed a classification system for harmonizing the radiographic descriptions used by radiologists and pulmonary physicians. In the United States, the ILO classification system was incorporated into a program of coal worker surveillance to help standardize interpretations and reduce some of the variability in film readings between readers. This program eventually became known as the “B-reader” system, which included a proficiency examination that tested readers’ ability to interpret films accurately and consistently. *Id.* at 51-52.

The ILO system was never intended to be used in the legal system, and indeed the ILO guidelines have always stated that the ILO was not to be used for designating disease or determining compensation in legal proceedings. The National Institute on Occupational Safety and Health (NIOSH) ultimately came to provide courses in the ILO system and to administer the B-reader examination and to certify physicians as “B-

readers.” Litigants, both plaintiff and defendant, eager to present well-qualified physicians in dust-disease litigation sought out physicians with this credential. The examination is known to be difficult, and the failure rate is substantial.

Many of the plaintiffs’ expert witnesses, challenged under *Daubert*, were NIOSH-certified B-readers. The clear implication from Judge Jack’s opinion, however, is that the plaintiffs’ expert witnesses were able to pass the difficult B-reader examination by consistently and accurately interpreting chest films in the ILO system, but when these witnesses applied this classification system in litigation contexts, they deliberately misread the films to advance the litigation interests of their “clients.”

Judge Jack found several lines of evidence of unreliability in the reading of chest films. First, over 50% of the 9,000 claimants had previous or concurrent asbestosis claims. In the current parlance of silica litigation, these cases are known as “double dippers” or “retreads.” The court observed that it was more likely for a golfer to hit a hole-in-one than for an occupational physician to find a single case of combined radiographic asbestosis and silicosis. *Id.* at 31. To add to their credibility problems, some of the plaintiffs’ expert witnesses rendered two separate reports based upon the same film. In one report, they reported silicosis; in the other, they reported asbestosis. The ILO and B-reader systems require physicians to

report *all* their findings from a single X-ray, on a single form.

Many of the films were “reversals;” the claimant had been diagnosed previously with asbestosis, but now he was being diagnosed with only silicosis. The ILO system requires reporting all findings, regardless whether they are the subject of a pending lawsuit. Asbestosis is a permanent, progressive condition that would not disappear. Judge Jack found that these “opportunistic transformations” raised serious concerns about an unacceptably high error rate in the radiographic interpretations. *Id.* at 54.

The anecdotal testimony from the plaintiffs’ B-readers themselves helped ensure the finding of unreliability. One diagnosing physician described his involvement as “easy money” for “easy work,” although he had never before diagnosed anyone with silicosis. *Id.* at 17. Most of the plaintiffs’ witnesses used word-processed language, such that the same diction errors appeared identically in every report from one witness. *Id.* at 18. Many of the witnesses did not write, read, or sign their reports. For some witnesses, their reports included diagnostic language with which they disagreed, but when the screening company insisted, they “capitulated.” *Id.* at 32. Some of the witnesses were biased by their compensation, which was greater for finding silicosis than for not finding it. *Id.* at 53.

Judge Jack’s finding that the radiographic interpretations were unreliable was based also upon statistical analyses. The ILO system

describes findings of dust diseases of the lungs in terms of the profusion of opacities. The system codes the size, shape, and profusion of the opacities. For simple silicosis, the opacities would be small and rounded, and their profusion would be assessed on a scale of 0 (normal), 1 (mild), 2 (moderate), or 3 (severe). Judge Jack found that the plaintiffs' film readers called virtually all the films category 1, although it was quite improbable that all of the screened cases, if truly silicosis, would be limited to category 1. What the plaintiffs' B-readers were doing was positioning themselves to avoid criticism by being able, in any single case, to claim that their reading was within their profession's tolerated inter-reader variability of one ILO category in the event highly credible reader read the same film as category zero.

This improbable clustering of the film interpretations around category 1 would likely escape attention in a single-plaintiff case, but Judge Jack enjoyed a wider perspective, which allowed her to discern the scheme. In addition, many of plaintiffs' B-readers were the subject of a published study that demonstrated that their ILO reads *in asbestos litigation* were highly discordant with the interpretations of the same films by leading radiologists and pulmonary physicians responsible for the teaching and testing of the B-read system. See Gitlin, et al., "Comparison of 'B' Readers' Interpretations of Chest Radiographs for Asbestos-Related Changes," 11 ACADEMIC

RADIOLOGY 843 (2004).

C. Unreliable Differential Diagnoses

The third criterion of diagnosis requires a differential diagnosis. This criterion requires the physician to eliminate other diagnoses that might give rise to the radiographic abnormalities found in the patient. Because other diseases, conditions, infections, and drugs can cause radiographic opacities similar to silicosis, the diagnosing physician must reliably assess patients to rule out these other causes before ruling in silicosis.

Judge Jack found that the plaintiffs' expert witnesses failed to perform the differential diagnoses reliably. Some of the witnesses never even intended to diagnose silicosis, but acquiesced in lawyers' or screening companies' demands for "magic language" of diagnosis. One such witness acknowledged that his diagnoses were not "real" diagnoses such that he would prescribe medicine, surgery, or a follow up as a result. *Id.* at 31. Even when the witnesses clearly intended to render diagnoses, the Court found that the medical histories, physical examinations, and other tests were "nonexistent or cursory." *Id.* at 56.

In the publications of plaintiffs' witness Dr. Barry Levy, the proper diagnosis of silicosis is described as depending "critically on a comprehensive and appropriate patient history that adequately explores the relation of the disease to the occupation." *Id.* at 39, 49. In the litigation

work of Dr. Levy, however, he did not take occupational, medical, or social histories that would allow him to rule out other causes for radiographic changes. *Id.* at 40. The court found that “Dr. Levy had an agenda: diagnose silicosis and nothing else.” *Id.* at 40-41.

In summary, the court concluded that expert witnesses must employ the same “intellectual rigor” used in their respective fields when they hold forth in a courtroom. *Id.* at 46-47, 64 (citing and quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Physicians cannot abandon the methodology they use in the clinic when they step into a courtroom. *Id.* at 63. The deviations from the obvious standard of care were too much for the court to abide. The assembly-line diagnoses were defective through and through; the “phantom epidemic” was clearly the result of misdiagnoses. *Id.* at 6, 60-61.

II. IMPLICATIONS OF UNRELIABLE SCREENING DIAGNOSES

The legal, medical, and social implications of *In re Silica* are profound and wide-ranging. The court’s careful exposition uncovers a cynical disregard for the ethical practice of medicine. Physicians referred to plaintiffs as their “clients,” not patients. *Id.* at 59. One plaintiff-side witness explained that an opinion to a “reasonable degree of medical certainty” was “not a real diagnosis.” *Id.* at 31, 59. When pressed to explain how he could

complete each diagnostic evaluation in under an average of four minutes, plaintiffs' witness Dr. Levy stated "I was not practicing medicine." *Id.* at 37n. 85. These witnesses failed not only to meet *Kumho Tire's* standard of appropriate "intellectual rigor;" these physicians failed, by their own admissions, to satisfy the ethical requirements of the practice of medicine. The American Medical Association, for example, has held that serving as an expert witness *is* the practice of medicine. AMA policy states that "[t]he giving of medico-legal testimony by a physician expert witness [is] considered the practice of medicine." AMA policy H-265.993, Peer Review of Medical Expert Witness Testimony, <http://www.ama-assn.org>, last visited September 7, 2005.

Other ethical provisions of the AMA Code of Medical Ethics are implicated in the conduct of the silica mass screenings. In some or all of the screening, these physicians likely violated the requirement that physicians not be subjected to interference in the practice of medicine and that they eschew contingency fees. AMA Codes E-8.05, E-6.01. These screening physicians also likely breached the requirement to keep appropriate records, AMA Code E-7.05, as well as the requirements of remaining objective, disclosing conflicts of interest, and informing and counseling patients about their medical findings. AMA Code E-10.03, E-8.03, E-8.054.

The legal and ethical lapses documented by Judge Jack are

noteworthy for many reasons. The lapses were not committed solely by courtroom hacks. Dr. Levy, for instance, is a past president of the American Public Health Association. The documented lapses reveal a cynical belief that “anything goes” in mass tort litigation, and there are no consequences for abandoning professional and moral standards of honesty and intellectual rigor. Occupational medical journals regularly publish editorials and articles criticizing and deriding scientific positions taken by corporations, especially tobacco companies. To date, there has been an astounding silence from the occupational physician community in response to the revelations about Dr. Levy and his ilk in the silica litigation.

Perhaps predictably, the plaintiffs’ lawyers involved in this fiasco have defended these practices by attacking the defendants and their lawyers. When the first plaintiff witness gave unfavorable deposition testimony, plaintiffs’ counsel accused defendants of exerting undue influence to “flip” the witness. Now that all the witnesses have described the “scheme,” the plaintiffs’ counsel have shifted their attack to claim that defendants have covered up an epidemic of silicosis. What is not predictable or excusable is that plaintiffs’ counsel would be party to a scheme to manufacture misdiagnoses of silicosis, or that an expert witness such as Dr. Barry Levy, a former epidemiologist at CDC, would “diagnose” 1,389 cases, but never lift up the telephone to alert CDC about the “epidemic.” *Id.* at 59.

Although Judge Jack exposed shameful abuses in the conduct of medico-legal screenings, it is important to realize that the whole concept of attorney-sponsored radiographic mass screenings is flawed. The flaw becomes obvious only when considering the large numbers of claimants who are recruited for mass screenings. The clinical criteria for silicosis are reasonably, but not perfectly, accurate when applied by physicians of good will. Accuracy of diagnostic criteria is usually measured in terms of their “sensitivity,” and “specificity.” Sensitive criteria tend to pick up every real case in the population screened, and specific criteria tend not to pick up anything but real cases.

High sensitivity thus translates into a low rate of “false negatives,” and high specificity translates into a low rate of “false positives.” For clinical criteria such as those for silicosis, 90% sensitivity and 95% specificity would generally be regarded as highly accurate criteria. When these accurate criteria, however, are applied to a large screened population of people, recruited by lawyers, the accurate criteria will yield many false-positive cases. To illustrate, suppose a screening company screened a population of 10,000 people, among whom there were 500 true silicosis cases. The 90% sensitive criteria applied in the screening would find 450 of the 500 true silicosis cases. The 95% specific criteria would result in 475 false positive cases of silicosis, more than the number of true positives found.

In actual clinical practice, the potential for false-positive diagnoses is real and substantial. In a study by leading radiologists at the University of Pennsylvania, investigators found that 15% of a hospital-based population had rounded or irregular opacities, although the patients had no known occupational exposures. Epstein, et al., “Application of ILO Classification to a Population without Industrial Exposure: Findings to Be Differentiated from Pneumoconiosis,” 142 AM. J. ROENTGENOLOGY 53 (1984). Clearly chest films and the ILO system, even in the hands of scientific investigators, lack the specificity needed to avoid significant numbers of false-positive cases. Studies such as this one illustrate how the ILO system, in the hands of physicians of ill will, has the potential for the creation of phantom epidemics.

Imperfectly accurate criteria can undermine the correctness of a clinical diagnosis rendered by a treating physician of a particular patient, but the usual circumstances of the physician-patient relationship make misdiagnoses less likely. Patients usually seek out medical evaluations when they experience disturbing or disabling symptomatic conditions. Their physicians take the diagnostic process seriously and care about the patients in ways beyond the ability or imagination of the physicians described in *In re Silica*. Mistakes may be inevitable, but the diagnostic process in the hands of most treating physicians has indicia of trustworthiness not present

in mass screenings, using the same set of diagnostic criteria.

Some plaintiffs' counsel attempt to defend mass screenings on eleemosynary grounds. These counsel claim that they are providing healthcare benefits free of charge. These claims are false. Being misdiagnosed and becoming a participant in a scheme are hardly benefits. Most screenings require participants to give a power of attorney to the sponsoring law firm, along with a 40% contingency fee. These screenings are anything but "free."

In her opinion, Judge Jack addressed the harm that may be caused by unreliable screening diagnoses. As for the "clients" who, in fact, have no disease she wrote:

In the case of the Plaintiffs who are healthy, at least some of them can be expected to have taken their diagnoses seriously. They can be expected to have reported the diagnoses when applying for health insurance and life insurance – potentially resulting in higher premiums or even the denial of coverage altogether. They can be expected to report the diagnoses to their employers and to the Social Security Administration. And they can be expected to report the diagnoses of this incurable disease to their families and friends.

Id. at 60.

The "clients" who actually do have abnormal X-ray readings are left no better off. Judge Jack noted:

Then there is the toll taken on the misdiagnosed Plaintiffs. If these Plaintiffs truly have abnormal x-rays, then the radiographic findings may be caused by a number of

conditions other than silicosis. And when the diagnosing doctors fail to exclude these other conditions, it leaves the Plaintiffs at risk of having treatable conditions go undiagnosed and untreated.

Id.

Still, some plaintiffs' counsel will insist that the offered chest X-rays have the ability to detect lung cancers early and lead to early treatment and cure. This attempted justification of their entrepreneurial business model fails on several levels. First, the carcinogenicity of silica remains controversial. In a 1985 Surgeon General's Report, CDC reported that the available evidence did not establish a causal relationship between silica and lung cancer. U.S. Dep't of Health & Human Services, Public Health Service, *The Health Consequences of Smoking: Cancer and Chronic Lung Disease in the Workplace* 348 (Washington, D.C. 1985). Most textbooks and reviews in the early 1990s rejected the claim that silica causes lung cancer. In 1997, a working group of the International Agency for Research (IARC) on Cancer voted to re-classify crystalline silica, in some occupational exposure circumstances, as a known carcinogen. Although the IARC vote was divided and close, the decision triggered many domestic regulatory reclassifications. Nevertheless, the scientific community has remained sharply divided, especially given that several large studies, published after the 1997 IARC decision, found no association between silica exposure or silicosis and lung cancer.

Second, even for people known to be at increased risk of lung cancer, periodic surveillance by chest X-ray is not medically indicated. The United States government has acknowledged that the current data simply do not justify routine screening for lung cancer. Humphrey, et al., "Lung Cancer Screening with Sputum Cytologic Exam, Chest Radiography, and Computed Tomography: An Update for the U.S. Preventive Services Task Force," 140 ANN. INTERNAL MED. 740 (2004). In the context of asbestos exposure, which in some circumstances is known to cause lung cancer, the American Thoracic Society (ATS) has recommended against annual or periodic radiographic surveillance for lung cancer. ATS, "Diagnosis and Initial Management of Nonmalignant Diseases Related to Asbestos," 170 Am. J. RESPIR. CRIT. CARE MED. 691, 711 (2004).

CONCLUSION

The pretense of beneficence in providing mass screenings is paper thin. The legality of many attorney-sponsored mass screenings is even thinner. Chest X-rays require a physician's prescription or order, by law. In the absence of physicians' orders, some states allow "healing-arts screenings" that have been properly registered and authorized by the appropriate state agency. The state agencies typically regulate every aspect of radiographic screening, including such details as the selection, calibration, and operation of the X-ray equipment. Other "details" include

requiring a physician, licensed within the state, to be present on site during the screenings. Several of the screening companies involved in the scheme uncovered by Judge Jack, as well as others, have failed to comply with the legal requirements for conducting mass X-ray screenings. Whether courts dismiss, on public policy grounds, cases brought on the basis of unlawful, unauthorized chest X-rays remains to be seen. The attorneys who sponsor these mass screenings bear a heavy burden to explain these regulatory violations.

Some will find curious irony in the discovery that the plaintiffs' bar, which has touted itself as a safety brake on the free market, has revealed itself as ruthlessly driven by the profit motive, flouting professional ethics and the law. The high volume, assembly-line business model inherent in mass screenings is an unacceptable departure from the standard of care for lawyers and physicians, alike. The time has come to outlaw this business model.