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VIA OVERNIGHT DELIVERY

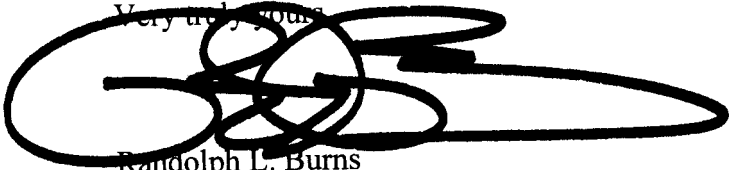
NIOSH Docket Office
Robert A. Taft Laboratories
M/S C34
4676 Columbia Parkway
Cincinnati, OH 45226

Re: NIOSH B Reader Certification Program
Looking to the Future
Public Meeting of March 4, 2004
DOCKET NO. NIOSH-015, B READER PROGRAM

Dear Madame/Sir:

Enclosed please find the Written Comments and Exhibits of Edwards & George LLP to the topics discussed at the above-referenced meeting. The written comments were forwarded by my paralegal, Daphne Taylor, via email on April 5, 2004.

Thank you for your attention to the matter.

Very truly yours,

Randolph L. Burns

RLB/dyt

Enc.

**NIOSH B Reader Certification Program:
Looking to the Future
Public Meeting of March 4, 2004
Docket Number NIOSH-015, B Reader Program**

**Written Comments of Edwards & George, LLP
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SUMMARY OF POSITION

Under the existing system, once a B Reader becomes NIOSH-certified, that person has a consequence-free environment in which to put his or her credentials to whatever use he or she deems fit—irrespective of whether the reader's activities run afoul of state or federal laws or the policies and purposes of the B Reader program. Because periodic testing is the only form of NIOSH oversight, none of these activities would ever be detected by NIOSH. Testing and qualification of B Readers, obviously, is an important critical threshold for receiving certification. However, as discussed and shown below, if more controls and oversights are not implemented, certain B Readers and litigation-driven, mass X-ray screening companies will continue to hijack the goodwill and reputation of NIOSH in a consequence-free environment—purely for their own financial gain. For these reasons, it is recommended that NIOSH develop recordkeeping requirements, a random audit system, rules governing what types of X-rays a B Reader can read, and some form of disciplinary system for punishing abuses.

INTRODUCTION

NIOSH created the B Reader program in the 1970s as a way to monitor coal miners for pneumoconiosis common to that trade.¹ Over the ensuing 30 years, for-profit litigation screening companies, law firms, and others have hijacked the good will of the B Reader program and used it to create and sustain litigation against various defendants sued in asbestos cases.² They have done so using an assembly-line approach to litigation in which B Readers are used to render an individual diagnosis—or something passed off to courts as a diagnosis—of asbestos-related pneumoconiosis in hundreds of thousands of men and women.

B Readers are not supposed to be cogs in an assembly line-like machine designed to manufacture lawsuits. The original intent of the B Reader program was not to create a group of diagnosticians, cloaked with authority from NIOSH, to go forward into communities across the country and open doors to the court system. Nor was the intent of the program to bestow NIOSH authority upon B Readers so that they could use their credentials to enrich themselves financially. Yet, for the past two decades, B Readers have borrowed the integrity and authority of NIOSH to render hundreds of thousands of individual diagnoses—and they've profited, along with many lawyers and litigation screening companies, from doing so.

The B Reader program is being widely abused. If NIOSH maintains the current certification criteria without modification, the program will continue to be abused. These facts are not in dispute, and these written comments do not attempt to

¹ See <http://www.cdc.gov/niosh/pamphlet.html>.

² These comments are limited to asbestos cases. However, based on comments made at the public meeting in March, similar problems appear to exist in cases involving silica exposure. For more information on similar practices to those discussed below being used in cases involving silica exposure, see Jonathon D. Glater, *Suits on Silica Being Compared to Asbestos Cases*, N.Y. Times, September 6, 2003, attached as Exhibit 1.

prove the existence of these abuses. Others have done so already. Rather, the purpose of these comments is to discuss in more detail than was possible during the public hearing where the abuses occur, why reforms are necessary, and to make sensible suggestions about how to fix the problem. Specifically, these comments address the following topics:

- The Historical Origins of the B Readers' Rise to Prominence in Asbestos Litigation.
- The Role of the B Reader in Today's Assembly Line-Style Asbestos Lawsuits.
- Specific Examples of Abuses on the Part of Certain B Readers.
- Sensible Suggestions for New Rules that NIOSH Could Enact to Restore the Integrity of the B Reader Program.

DISCUSSION

I. The Historical Origins of the B Readers' Rise to Prominence in Asbestos Litigation.

The B Reader program finds its genesis in the Federal Coal Mine Safety and Health Act of 1969.³ The Act required the operator of a coal mine to make available each miner to have a chest roentgenogram.⁴ The statute specified that the films were to be read and classified in a manner to be prescribed by the Secretary of Health and Human Services.⁵

Beginning in the early 1970s, NIOSH responded to Congress' mandate by creating detailed regulations that govern the voluntary and mandatory examination of coal miners.⁶ In 1974, NIOSH created the B Reader examination to ensure the quality of those who examined the films.⁷ Later, to ensure uniform standards of interpretation, NIOSH adopted the 1980 revision of the International Labor Organization Guidelines for classifying radiographs for pneumoconiosis.⁸

Importantly, the regulations require all records from the roentgenographic examinations to be on file with the Appalachian Laboratory for Occupational Safety Health ("ALOSH").⁹ Any miner who believes the interpretation for pneumoconiosis reported to him or her is in error may file a written request that his or her roentgenogram

³ See 30 U.S.C.A § 801 (West Group 1986).

⁴ See *Id.* at § 843(a).

⁵ *Id.*

⁶ See 42 C.F.R. § 37.60(a), attached as Exhibit 2.

⁷ See <http://www.cdc.gov/niosh/pamphlet.html>.

⁸ See 49 Federal Register 7562-02, attached as Exhibit 3.

⁹ See 42 C.F.R. § 37.60(a), attached as Exhibit 2.

be reevaluated.¹⁰ Furthermore, detailed specifications ensure the accuracy of the roentgenograms. All chest roentgenograms must be administered with the proper equipment in the proper format.¹¹ The regulations leave nothing to chance. Finally, ALOSH must approve roentgenographic facilities before they can test miners.¹² Each facility must prove its worth to an independent panel.¹³ In doing so, the facility must show that it can provide roentgenograms of the highest quality.¹⁴

Thus, from the 1970s through the present, NIOSH developed a system with sufficient safeguards to accomplish the purposes of Congress when it enacted the Federal Mine and Safety Health Act—namely, (1) to provide more effective means and measures for improving the working conditions and practices in the nation's coal or other mines, and (2) to prevent occupational diseases originating in such mines.¹⁵

A. Asbestos Litigation Creates a Demand For Qualified Readers of X-rays.

While NIOSH was developing the B Reader program in the 1970s, trial lawyers were beginning to bring the first product liability actions related to the hazards associated with exposure to asbestos.

1. The Advent of Mass X-ray Screenings.

At first, asbestos litigation was brought by only a small number of plaintiffs against a small number of defendants.¹⁶ Primarily, suits were brought by workers with legitimate asbestos-related injuries against the larger producers of asbestos-containing products, particularly Johns-Manville, Inc., the market leader.¹⁷ In 1982, Johns-Manville filed for bankruptcy because of the costs associated with present and future asbestos litigation.¹⁸ The federal bankruptcy laws prevent direct lawsuits against bankrupt corporations, so Johns-Manville's bankruptcy halted all present and future cases against it.¹⁹ However, as part of its reorganization plan, Johns-Manville created a personal injury trust for asbestos claimants.²⁰ Today, that trust has received record numbers of claims from people claiming non-malignant, asbestos-related injuries.²¹

¹⁰ *Id.* at §37.70.

¹¹ *Id.* at § 37.41.

¹² *Id.* at § 37.42.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ See 30 U.S.C.A. § 801 (West Group 1986).

¹⁶ For an excellent background discussion of the history of asbestos claims in American courts, see Lester Brickman, *On the Theory Class's Theories of Asbestos Litigation: The Disconnect Between Scholarship and Reality*, 31 Pepperdine Law Review 33, 54-59 (2003), attached as Exhibit 4.

¹⁷ *Id.* at 128.

¹⁸ *Id.* at 54-55.

¹⁹ See 11 U.S.C.A. §362(a)(West Group 1993).

²⁰ See Brickman, *supra* note 16, at 128-129.

²¹ *Id.* at 136.

Virtually every claimant to the Manville Trust relies upon the opinion of a B Reader to support entitlement to cash payments.²²

As the 1980s progressed, plaintiffs' lawyers pursued more creative strategies to minimize their risk and maximize the available profits from asbestos litigation. It quickly became apparent that a successful strategy was to group as many plaintiffs into one trial as possible.²³ If plaintiffs' lawyers could group together thousands of plaintiffs and extract small individual settlements—even in the most suspect non-malignant cases—then all the claims together would add up to a big payday.²⁴ Furthermore, by grouping together those who suffered from lung cancer and mesothelioma with weaker cases, the total amount at stake in each case could make the prospect of trial a bet-the-company proposition for many defendants.²⁵ Defendants would have no choice but to settle. The strategy was virtually fool-proof, as is evidenced by the graveyard of more than 60 companies bankrupted by hundreds of thousands of questionable asbestos lawsuits.²⁶ The initial problem faced by the trial lawyers was: how to sign up such a high volume of plaintiffs?

Mass litigation-driven X-ray screenings quickly supplied the answer, and X-ray screening companies popped up around the country to meet the demand.²⁷ These companies often worked through unions to sponsor so-called “medical” screenings for the union members. Yet, the “medical” screenings involved nothing related to the treatment and care of the individuals being screened. Nor did the screening companies have any legitimate ties to the health-care or public-health community. For example, in a deposition recently taken, one official from a screening company testified that the screening company's sole purpose was to screen people for lawyers.²⁸ Health care was not and is not the objective. The screenings were and are designed and intended to accomplish nothing more than the “discovery” of asbestos-related conditions in large populations of industrial workers. These companies used (and still use) advertising, inside connections, and mass marketing to attract workers. They advertise the screenings directly to lawyers, through union halls, and even in the general media.

The assembly-line process by which lawsuits were and are created by these screening companies, and the lawyers that hire them, has changed little since the 1980s. Potential plaintiffs are herded into mobile X-ray trailers, lured by advertising offering potential cash payments. Several examples of these advertisements are attached as Exhibit 8. It is not as if the screening companies and their law firm sponsors try to

²² See 2002 [Manville] Trust Distribution Process, attached as Exhibit 5, at 11. The Trust now requires a reading by a certified B Reader for all living, non-malignant claimants.

²³ See Griffin B. Bell, *Asbestos Litigation and Judicial Leadership: The Courts' Duty to Help Solve the Asbestos Litigation Crisis*, National Legal Center for the Public Interest (2002), attached as Exhibit 6, at 19.

²⁴ *Id.* at 19; see also, Brickman, *supra* note 16, at 63.

²⁵ See Bell, *supra* note 23, at 11.

²⁶ *Id.* at 4.

²⁷ The support for the following paragraphs can be found in Professor Brickman's thoroughly researched article, *supra* note 16, at 62-83.

²⁸ Deposition of Jeffrey H. Bass, 5/10/2003, attached as Exhibit 7, p. 56-57.

hide what they are doing. One rather direct (and very alarming) advertisement in a New York newspaper proclaimed: "A Picture of Your Lungs Could Be Worth Million\$."²⁹

Once these new, potential litigants respond to these ads, the people are X-rayed. The films are sent to a doctor (or several doctors) for review and interpretation. If the doctors "see" interstitial scarring on the radiograph, the diagnosis of asbestosis or a condition "consistent with" asbestosis is given. At first, the screening companies did not necessarily rely upon B Readers to read the chest X-rays. But that changed as courts and bankruptcy trusts demanded that plaintiffs come forward with legitimate medical evidence of disease.

2. The Necessity of Qualified Experts.

At the time mass screenings began to occur on a widespread basis, state and federal courts began casting a more critical eye on expert testimony in the courtroom. These trends met head-on for the first time in a Kansas court in the late 1980s—with the result being a scathing judicial critique of unqualified medical experts in asbestos-disease screenings.³⁰ Raymark Industries, Inc. sued a group of lawyers and doctors over a massive class action settlement in an asbestos lawsuit. Raymark alleged that in 1986 the plaintiffs' lawyers founded an organization called the "National Tire Workers Litigation Project" ("NTWLP"), ostensibly to promote employee safety and awareness.³¹ The group funded the purchase of vans equipped with X-ray equipment, known as "examobiles."³² The NTWLP contacted union representatives in order to arrange massive employee examinations in tire manufacturing plants throughout the country.³³ It was understood that if any adverse findings were noted, the tire worker would become a client of the attorneys and would file a claim for his or her asbestos-related injuries.³⁴ This process yielded thousands of plaintiffs, with whom Raymark entered into a massive class action settlement.³⁵

According to Raymark's complaint, the doctors who reviewed the X-rays possessed, at best, the most limited of credentials.³⁶ One was not licensed in the United States. A second was a radiologist and not qualified to diagnose asbestos disease. A third had been previously sued for misrepresenting her qualifications and for submitting incompetent medical reports.³⁷

The federal court in Kansas denied the lawyers' and doctors' motion for summary judgment.³⁸ The court took particular note of the screening doctors' intent to

²⁹ See Shapiro & Shapiro Asbestos Screening Advertisement, attached as Exhibit 9.

³⁰ See *Raymark Industries, Inc. v. Stemple*, 1990 WL 72588 (D. Kan. 1990), attached as Exhibit 10.

³¹ *Id.* at *5.

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.* at *3.

³⁶ *Id.* at *5.

³⁷ *Id.*

³⁸ *Id.* at 29.

make lots of money from the venture. According to the judge, the doctors were willing to accept a very low amount for each diagnosis in exchange for the opportunity to do many diagnoses.³⁹ The three doctors received between \$225,000 and \$400,000 each for their efforts.⁴⁰ Additionally, the Court noted that NIOSH had evaluated the X-rays of 795 tire workers and had only found two that had any signs of parenchymal change and only 19 who showed pleural abnormalities.⁴¹ The Court reasoned that a jury could reasonably conclude that the doctors recklessly disregarded normal medical procedure in making their “diagnosis.”⁴²

B. B Readers Become a Fixture in Asbestos Litigation.

NIOSH B Reader certification arguably provided X-ray readers with the added qualifications necessary to pass the increased scrutiny of the courts. It was not long before both plaintiffs’ and defendants’ attorneys began to retain B Readers (almost exclusively) to provide expert opinions in thousands of asbestos cases nation-wide. Indeed, as asbestos litigation “matured,” the role of B Readers became all but institutionalized. For example, in 2002, the governing document of the Johns-Manville Trust was revised to specifically provide that all living claimants who make a claim for a nonmalignant asbestos-related disease must support their claim with an X-ray reading by a certified B Reader.⁴³ A recent legislative proposal in Texas similarly would halt litigation of all non-malignant asbestos cases unless and until the plaintiff proves respiratory impairment and supplies the opinion of a B Reader on the severity of interstitial changes.⁴⁴ An American Bar Association Commission studying asbestos litigation acknowledged that B readings are already prevalent in the litigation and that a “B Reader” requirement would help obtain uniform standards for diagnosis.⁴⁵ Effectively, B Readers have become such fixtures in asbestos litigation, despite the intent of NIOSH’s program, that they are the de facto diagnosticians for hundreds of thousands of unimpaired asbestos claimants.

Despite recent efforts to create a legislative solution to asbestos litigation, it continues virtually unabated. The United States Supreme Court has referred to asbestos litigation as an elephantine mass that requires Congressional intervention.⁴⁶ It has now been almost twenty years since the NTWLP conducted the first mass screenings of potential asbestos plaintiffs. Unfortunately, the use of mass litigation-driven screenings

³⁹ *Id.* at *14.

⁴⁰ *Id.*

⁴¹ *Id.* at *16.

⁴² *Id.* at *29.

⁴³ See 2002 [Manville] Trust Distribution Process, attached as Exhibit 5, at 11.

⁴⁴ See Senate Bill No. 8 [Draft], attached as Exhibit 11, at 4.

⁴⁵ See Recommendation of American Bar Association Commission on Asbestos Litigation, attached as Exhibit 12, at 1, 14. The Commission acknowledged that many physicians were qualified to read X-rays but chose to adopt the B Reader requirement in an attempt to create uniform standards.

⁴⁶ See *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 821 (1999).

has only increased.⁴⁷ For the reasons described above, B Readers now play an integral part in fueling the spread of asbestos litigation.

Ironically, the use of B Readers in for-profit litigation screenings parallels in many respects the surveillance of coal miners that spawned the B Reader program in the first place, with one major difference—the lack of regulatory safeguards to insure that proper medical procedure is followed. As will be shown below, litigation screening companies, law firms, and others have taken advantage of this lack of oversight to engage in shoddy medical practices (or to the extent regulations do exist, have simply ignored them). Certain B Readers, for significant financial reward, have been, at least, willfully ignorant of or, at most, active participants in these unethical and illegal practices.

II. The Elephantine Mass: Present Day Asbestos Litigation

A. Lawsuits, Assembly-Line Style.

Despite the admonitions of the judge in the tire-worker case, mass screenings have only increased in quantity—without any appreciable increase in quality.⁴⁸ Today, one cannot travel to an industrial area of the country without seeing some form of advertisement in a newspaper, on a billboard, or on television for a law firm that specializes in asbestos litigation or asbestos screening. For-profit litigation screening companies, following the model of the NTWLP, have become big business. A recent set of articles in the *Mobile Register* noted that revenues for these companies, many of which are based in Southern Alabama, easily reach into the millions of dollars a year.⁴⁹ Putting aside the self-serving statements of their founders (and their lawyer affiliates), these companies do not exist for any medical purpose. Their objective is to “find” asbestos-related diseases in as many men and women as possible and to “sell” those cases to law firms.

B. The Present Day Assembly-Line.

The fine details about how screenings are conducted can vary from company to company, and law firm to law firm. However, for virtually every screening, the basic processes involve the same assembly-line style processes, which can be summarized by three general steps.

1. Certain populations of people, usually those who live in industrialized areas, are targeted for screening through newspaper, television, direct mail, or through a union. In recent months, screening companies even have begun to target the spouses of industrial workers.⁵⁰ The

⁴⁷ See Brickman, *supra* note 16, at 135-137 (discussing the marked increase in claims in the last decade for the Manville trust).

⁴⁸ *Id.*

⁴⁹ See Eddie Curran, *Mystery Companies, Massive Payouts*, *Mobil Register*, March 28, 2004, attached as Exhibit 13.

⁵⁰ See below at Section III. F.

advertisements take many forms. Virtually, all state that certain blue-collar trades, such as pipefitters, electricians, welders, and others, may be entitled to collect cash payments if an asbestos-related disease is detected in their bodies. Some of these ads are more conspicuous about the real motives of the screening. For example, one law firm in New York used a rather tasteless ad to entice older workers to attend the screening. That ad announced: "A Picture of Your Lungs Could Be Worth Million\$."⁵¹ In many instances, the same populations are targeted over and over, year after year, sometimes by the same law firms or screening companies. In certain communities, the screening advertisements are continuous.

2. Individuals that respond to the ads usually are told to report, on a specific date, to a mobile X-ray trailer that often is located in a union hall or a hotel/motel parking lot. Once they arrive, the individuals usually fill out some forms or give an interview to an employee of the screening company or law firm. The paperwork involved usually includes a retainer-type letter that authorizes a lawsuit in the event the screening is "positive." At some point, the individual undergoes a chest X-ray in the mobile unit. Sometimes, a pulmonary function test is administered. In either case, the individual administering the test rarely has any prior experience in the medical field (before going to work for the screening company).⁵² Furthermore, despite American Thoracic Society guidelines that call for a lengthy period of time for proper tests, the whole procedure can take as little as 80 seconds for an X-ray and a few minutes for a pulmonary function test.⁵³ Since litigation screening companies (and often the B Readers who review their handiwork) are paid by the reading, the overarching goal is quantity over quality. As a result, these slipshod screenings are often in violation state health and safety laws.⁵⁴
3. The collection of X-rays from the screening is then shopped to a B Reader, and often more than one, for interpretation.⁵⁵ The goal of the screening companies is clear at this point: Find a B Reader who will provide a positive diagnosis of asbestosis, or parynchemal changes or abnormalities of the lungs "consistent with asbestosis." The screeners do this in a variety of ways. For one, they shop the X-rays to a number of B Readers.⁵⁶ A recent article by an expert who testifies primarily for plaintiffs' lawyers noted that a film can be sent to as many as six B Readers.⁵⁷ Additionally, a positive diagnosis will pay more than a

⁵¹ See Shapiro & Shapiro Asbestos Screening Advertisement, attached as Exhibit 9.

⁵² See Brickman, *supra* note 16, at 67, 81-83.

⁵³ *Id.* at 90.

⁵⁴ *Id.* at 78-79.

⁵⁵ See Dr. David Egilman, *Asbestos Screenings*, 42 *American Journal of Industrial Medicine* 163 (2002), attached as Exhibit 14.

⁵⁶ *Id.*

⁵⁷ *Id.*

negative one.⁵⁸ This arrangement creates a powerful financial incentive for B Readers to “diagnose” or, more appropriately, “find” an asbestos-related condition.⁵⁹ The results of these tests are not reported to the individual or to the individual’s doctor. Rather, the B Reader sends the results to the screening company or directly to a law firm. Shortly thereafter, some form of liability claim or lawsuit is created and instituted on the individual’s behalf. Many times, these individuals have no idea that a claim or lawsuit has been filed on their behalf.

C. The Problems Created By the Assembly-Line Style Use of B Readers in Litigation is Well Documented and Really Not in Dispute.

B Readers play an essential role in this process. It should be noted, however, that only a few B Readers participate in this lawsuit factory. The American Bar Association noted that of over 500 certified B Readers, only a handful provided a significant number of the non-malignant claims submitted to the Johns-Manville trust.⁶⁰ This handful of doctors, however, actively use the benefits bestowed upon them by NIOSH through B Reader certification for personal financial gain. In doing so, these doctors have cast a blind eye to proper medicine. The following is a basic list of some of the more egregious abuses of B Readers involved in asbestos litigation:

- The unlicensed practice of medicine in states throughout the country.
- Complete disclaimer of any doctor-patient relationship with those who are screened.
- Disregard of the ILO Guidelines.
- A statistically significant overreading of films to provide more positive diagnoses.
- A failure to keep any records of the work they do for litigation screening companies or law firms.
- a failure to investigate the circumstances under which X-rays are taken, even if the process fails to comply with state law.

These questionable practices have been the subject of numerous court opinions and articles in both the legal and medical literature.

⁵⁸ See Brickman, *supra* note 16, at 93-94.

⁵⁹ *Id.*

⁶⁰ See Recommendation of the American Bar Association Commission on Asbestos Litigation, *supra* note 45, at 8.

1. The unlicensed practice of medicine in states throughout the country.

In 1989, a Washington state court rejected all opinions rendered in a group of asbestos cases by Dr. Jay Segarra, a very active litigation-B Reader who lives in Biloxi, Mississippi.⁶¹ The court did so because Dr. Segarra was violating public policy and arguably Washington state law. The court, in its order, castigated Dr. Segarra because he “participated in union screenings of certain plaintiffs, he performed examinations, rendered diagnoses, and recommended treatment without being licensed in Washington, a criminal offense.”⁶² Dr. Segarra continues to this day to review X-rays and write reports for screening companies and law firms. Now, however, he at least obtains a medical license (or a temporary one) in the state where the screening will take place before traveling to conduct asbestos screenings.

2. Failure to acknowledge a doctor-patient relationship with those who are screened.

It wasn't long before the handful of B Readers heavily involved with asbestos litigation found a solution (or thought they found a solution) to the licensing (as well as malpractice issues) raised by their work. They began to disclaim any doctor-patient relationship with those whose films they reviewed.

This washing-of-the-hands reached an absurd level in the case of *Adams v. Harron*, 1999 WL 710326 (4th Cir. 1999). In that case, Dr. Ray Harron, a NIOSH-certified B Reader, examined the X-ray of a former Armco Steel Corporation employee who attended an asbestos screening.⁶³ Dr. Harron concluded from his review of Adams' X-ray that Mr. Adams might have cancer.⁶⁴ Dr. Harron notified the law firm who hired him of the findings.⁶⁵ Dr. Harron suggested that Mr. Adams be told to see his family doctor.⁶⁶

The law firm did not inform Mr. Adams of his potential cancer.⁶⁷ His family doctor diagnosed him with cancer a year later.⁶⁸ Mr. Adams died shortly thereafter. His spouse sued Dr. Harron for malpractice. Dr. Harron based his defense on the lack of a doctor-patient relationship with Mr. Adams and WON!⁶⁹

The failure to acknowledge a doctor-patient relationship strikes at the heart of the true motives of many of these B Readers: they do not perform this work to

⁶¹ See Brickman, *supra* note 16, at 66, n. 98.

⁶² *Id.*

⁶³ See *Adams v. Harron*, 1999 WL 710326 (4th Cir. 1999), attached as Exhibit 15.

⁶⁴ *Id.* at *1.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* at *3.

practice medicine but rather do it to obtain the lucrative financial benefits that asbestos litigation can provide.

3. Disregard of the ILO Guidelines.

Many B Readers cut corners with respect to adherence to the ILO Guidelines. One doctor, as will be detailed below, even went so far as to testify under oath that part of the 1980 ILO Guidelines was wrong and that he did not follow them in his work for screening companies and law firms.⁷⁰ Another litigation-B Reader writes reports that proclaim that the features he sees on x-rays are “virtually pathognomonic of asbestosis.”⁷¹ Given that the 1980 and 2000 versions of the ILO guidelines expressly state that no features of a radiograph are pathognomonic of pneumoconiosis, these types of statement by the B Reader are irresponsible and an abuse of his certification.

4. A statistically significant overreading of films to provide more positive diagnoses.

Related to this disregard for ILO Guidelines is the well-documented statistically significant overreading of films. The great majority of diagnoses of asbestos-related conditions, or conclusions that a claimant’s film shows signs “consistent with asbestosis,” are on the low end of the ILO scale. It is widely acknowledged that inter-reader variability can be high on the lower end of the ILO scale. Nevertheless, as Professor Lester Brickman recently noted in a Pepperdine Law Review article:

In the aggregate, however, when we are dealing with tens of thousands X-ray readings, the possibility that huge and consistent discrepancies between the interpretations of neutral X-ray readers not concerned about a future flow of revenue and X-ray readers who read thousands and tens of thousands of X-rays and who realize tens and millions of dollars in repeat business from finding evidence of asbestosis and pleural plaques, can be explained as mere “inter-reader variability” recedes to near zero.⁷²

Three studies confirm Professor Brickman’s conclusion.

First, in numerous cases in Cincinnati between 1987 and 1990, the judge hired independent experts to review all reports, X-rays, and other pertinent material about claimants who alleged an asbestos-related condition.⁷³ None of these plaintiffs would have filed a lawsuit had they not been “diagnosed” with an asbestos-related condition through a screening. The independent experts, however, found that almost two-thirds of

⁷⁰ See Dr. Levine’s testimony below, at Section III. E.

⁷¹ See Report of Dr. Brent Mainwaring, attached as Exhibit 16.

⁷² See Brickman, *supra* note 16, at 42.

⁷³ See Judge Carl B. Rubin and Laura Ringenbach, *The Use of Court Experts in Asbestos Litigation*, 137 F.R.D. 35 (1991), attached as Exhibit 17.

all the plaintiffs did not have an asbestos-related condition.⁷⁴ Of the 65 plaintiffs, 42 (64.42%) were found to be free of any condition giving rise to a cause of action.⁷⁵ Over 80% of the time, the expert found no evidence of asbestosis.⁷⁶ Most of the cases settled out of court.

In the 1990s, the increased number of claims brought about by mass screenings placed the Johns-Manville Trust under severe financial strain, to the point to that it had to cease operations. To keep its head above water, in 1995 the Trust took the unprecedented step of instituting a limited medical audit program in which neutral B Readers analyzed and evaluated 5% of the claims submitted by each law firm during each payment cycle.⁷⁷ The review process was intentionally designed in favor of confirming the disease documented by the claimant and to give the benefit of any doubt to the claimant.⁷⁸ The 1996 submissions revealed that approximately 41% of the claimants had either no disease at all, or had a less severe condition than alleged in the submission, and that the ten physicians used most frequently by plaintiffs' law firms had an average failure rate of 63%.⁷⁹

A more recent study occurred of a West Virginia case that combined thousands of non-malignant plaintiffs. The study reviewed 558 chest X-rays, which were provided by a plaintiffs' law firm and initially screened by B Readers chosen by that firm.⁸⁰ The plaintiffs' B Readers graded 91.7% of the films as 1/0 or higher, but a panel of six independent B Readers graded only 4.5% of the films as 1/0 or higher.⁸¹ The researchers noted that no X-ray studies on the entire planet reflected the 91.7% positivity rate of the plaintiffs' B Readers.⁸² The study concluded that the variation found between the initial B Readers and the neutral B Readers was statistically significant and beyond reasonable inter-reader variability.⁸³

These studies are only the tip of the iceberg. Individual examples of overreading abound. In one particularly egregious example, Dr. Gregory A. Nayden reviewed over 14,000 films sent by a litigation screening and determined that over 14,000 of them had asbestosis.⁸⁴ Based upon Dr. Nayden's deposition testimony, the Claims Resolution Management Corporation, which processes asbestos claims for the Johns-Manville Trust, suspended acceptance of any claims which relied on medical records prepared by Dr. Nayden.

⁷⁴ *Id.* at 39.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ See Brickman, *supra* note 16, at 130.

⁷⁸ *Id.* at 131.

⁷⁹ *Id.* at 132.

⁸⁰ *Id.* at 105-106, n. 228.

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.* at 93, n. 178.

5. Failure to keep any records of the work they do for litigation screening companies or law firms.

One difficulty with conducting studies to uncover any problems with overreading is the failure of B Readers who work for screening companies and law firms to keep records. B Readers will almost universally testify that they do not keep records of the people (since they are not "patients") whose films they review.⁸⁵ No repository like ALOSH exists in asbestos litigation to allow for the independent review of the work of B Readers. As a result, to the extent wrongdoing exists, the evidence quickly disappears.

6. Failure to investigate the circumstances under which X-rays are taken, even if the process fails to comply with state law.

Any B Reader will (or should) acknowledge that the proper administration of an X-ray is fundamental to a proper reading of an X-ray. One need look no further than the detailed regulations governing roentgenograms for coal miners to understand the importance of proper technique. The chest roentgenogram specifications detail the size of the projection, temperature of the room, the type of X-ray machine, the type of generator, the maximum exposure time, the distance of the miner from the machine, and the recommended use of intensifying screens.⁸⁶ All qualified facilities must have a quality assurance program in place. To qualify as a facility, the facility must verify to ALOSH that it is capable of producing high quality chest roentgenograms.⁸⁷

Such safeguards are completely lacking in the world of asbestos screening companies. It is well documented that unqualified personnel administer tests as quickly as possible without regard to proper procedure.⁸⁸ This slipshod quality has been the subject of litigation and numerous complaints by state enforcement agencies.

The B Readers who work for these screening companies and law firms disavow any participation in the administration of these X-rays, other than to mark the quality of the film on the standard B Reader form.⁸⁹ They simply assume that if they receive the X-ray, it was administered properly (notwithstanding the well-known questionable practices of the industry that administers the X-rays).⁹⁰ If the goal of these asbestos screenings was to help monitor industrial workers, such as the coal miners whose welfare served as the inspiration for the B Reader program, then these B Readers should take at least a passing interest in the qualities of the X-rays. Instead, they do nothing.

⁸⁵ See below at Section III. D.

⁸⁶ See 42 C.F.R. § 37.41, attached as Exhibit 2.

⁸⁷ *Id.* at § 37.42.

⁸⁸ See generally, Brickman, *supra note 16*, at 111-128.

⁸⁹ See below at Section III. B.

⁹⁰ *Id.*

III. A Closer Look At What B Readers Are Doing And Saying After They Pass the Exam.

The actions and words of many of these litigation B Readers make the case for reform. Most of them use their NIOSH credentials to bolster their opinions, while at the same time, taking positions that are inconsistent with NIOSH goals and that are likely unacceptable to their peers, NIOSH, and the ILO. While the sources cited above provide compelling evidence, NIOSH need not look any further than the sworn testimony of some of the most prolific litigation B Readers to see the abuses being wrought by these individuals.

Towards that end, these comments include the sworn testimony of several active, or formerly active, B Readers. For each, the entire deposition is included as an exhibit.⁹¹ The excerpted testimony is used to highlight both areas of abuse (no recordkeeping, X-ray only diagnoses) and provide support for suggested changes (audit procedures, record keeping, suspension of qualifications) which could prevent future abuse.

The current system of a four-year-recertification period for B Readers may ensure B Readers are qualified to read and classify chest films. However, the current system does nothing to ensure that B Readers (1) use their skills to further and promote the purposes and intent of the B Reader program, (2) interpret films in an objective manner, and (3) use their qualifications and skills for the public and not for individual financial gain.

State and federal governments issue licenses, permits, and qualifications for dozens of privileges. But even the most basic of these government-granted privileges—obtaining a driver's license, for example,—has more oversight and consequences attached to abuses of the privilege than the current B Reader program. No one would argue that a driver that is qualified, and indeed does, repeatedly pass a driver's license exam should not be permitted to keep driving if the person regularly violates the law. That, arguably, is why licenses are subject to suspension when violations are detected.

As a matter of public policy, some of the same principles should apply to B Readers. The government dispenses the privilege of being NIOSH-certified to qualified applicants, but then effectively has no way to determine whether the B Readers (1) follow NIOSH or ILO guidelines, or (2) otherwise act in a manner contrary to the public interest.

⁹¹ The deposition of Dr. Richard Levine, M.D., 4/21/2003, is attached as Exhibit 18. The deposition of Dr. Ray A. Harron, M.D., 3/3/1999, is attached as Exhibit 19. The deposition of Dr. Jay Segarra, M.D., 6/18/2003, is attached as Exhibit 20. The deposition of Dr. Mark Klepper, M.D., 6/20/2000, is attached as Exhibit 21.

As shown in this section by several examples, B Readers who currently involve themselves in asbestos litigation, openly and without hesitation, testify about activities that clearly run afoul of ILO guidelines and even the law!

By way of preview, the testimony of the B Readers included in these comments shows some troubling facts. Litigation-B Readers completely disclaim a doctor-patient relationship and want none of the responsibility ordinarily attached with interpreting chest films in a clinical practice. Most of the time, the B Reader has no involvement in the actual X-ray procedure and disclaims all knowledge about anything, other than the quality of the actual film. While these litigation-B Readers “diagnose” an astounding number of people with asbestos-related disease each year, none keep any records—no records on positivity rates, populations examined, etc. Effectively, there is no way to objectively test whether the litigation-B Reader is overreading for financial gain or “calling it like they see it” as many will claim in deposition.

Without some change in certification procedure, the profiteering and financial enrichment of lawyers and for-profit litigation screening companies, largely because of the credibility a NIOSH-certified B Reader brings to the process, will continue. B Readers should be accountable to the certifying agency for what they say and do after being certified. For any given B Reader, NIOSH should have the ability to determine how many positive and how many negative X-rays the B Reader sees—if for no other reason than to determine if the Centers for Disease Control needs to investigate a public health issue. Such a requirement creates both an audit/accountability system and allows NIOSH to use the B Reader’s results to monitor populations being examined by the B Reader. As shown by these examples, if the most rudimentary recordkeeping requirements, auditing, and regulations are put in place, many of the current abuses can be detected and likely prevented.

A. Background on the B Readers Whose Testimony Appears in These Comments.

Dr. Richard Levine: Dr. Levine is a very active litigation B Reader. He lives in a suburb of Philadelphia and runs the radiology department at a small community hospital. Dr. Levine has read hundreds of thousands of X-rays throughout his career and has received films from at least 40 different states for his review. Dr. Levine is also one of the experts most retained by plaintiffs for claims submitted to the Manville Trust. Dr. Levine has read films for some of the most notorious litigation screening companies active in asbestos litigation. One screening company, in its promotional materials to lawyers, identified Dr. Levine as its radiologist. “Our radiologist, Richard Levine, M.D., is a NIOSH “B” reader”⁹² Dr. Levine keeps no records of his readings, openly criticizes the ILO guidelines, and professes to diagnose asbestosis from only a chest X-ray.

Dr. Ray Harron: Dr. Harron lives in a small town in West Virginia. He likely used to be the most active B Reader in the asbestos litigation. At some point in the

⁹² Most Health Services Marketing Letter to Lawyers (1996), attached as Exhibit 22.

late 1990s, Dr. Harron stopped practicing medicine and began a 100% X-ray-only B Reader practice.⁹³ Currently, he is either retired or reading a very limited number of films. Dr. Harron, when he was active, claims to have had no other interests other than film reading. He read films in his office, in his house, in motel rooms, and in his recreational vehicle while his wife visited relatives. Like Dr. Levine, Dr. Harron claims to have read hundreds of thousands of films. He also has kept no records of just about anything. Dr. Harron, while changing positions repeatedly, has testified under oath that he too can diagnose asbestosis from only a chest X-ray.

Dr. Jay Segarra: Dr. Segarra lives in Biloxi, Mississippi. Dr. Segarra currently is a very active B Reader in asbestos litigation. He has rendered opinions in thousands of asbestos cases in Texas alone. He also has traveled all over the country with screening companies to X-ray and “examine” potential litigants for lawyers. Dr. Segarra has the distinction of being accused by a Washington state court of practicing medicine without a license during his litigation-screening activities in that state.⁹⁴ He recently obtained a license to practice medicine in Texas for the purpose of traveling there to lawfully examine potential litigants.

Dr. Mark Klepper: Dr. Klepper practices pulmonary medicine in Austin, Texas. Several years ago, Dr. Klepper and his partners became involved in asbestos litigation and began conducting screenings. Unlike some of the other B Readers, Dr. Klepper’s group actually was involved in organizing screenings. Dr. Klepper, like the others, keeps no records. Nor does he pay attention to whether health and safety regulations are followed when potential litigants are herded through mobile X-ray equipment. Dr. Klepper also has an astoundingly high 50% positive rate for the films he read for the presence of asbestosis. His rate has been as high as 90%. The high positivity rate does not concern Dr. Klepper, and he has never reported any of the results to the CDC or anyone else. Dr. Klepper and his partners recently started another business under the acronym CPOM, which is the business arm of Dr. Klepper’s group that now conducts the litigation screenings.

B. Litigation-B Readers Have No Knowledge (And Sometimes Profess Not to Care) About the Circumstances Under Which the X-rays are Taken, Even if The Process Fails to Comply With State Law.

Almost every state has some regulation about the use of X-ray equipment. Some common regulations include the necessity of a doctor’s order before an individual can undergo an X-ray examination. Others include certification of X-ray equipment. Even the federal regulations for the monitoring of coal miners include fairly stringent requirements.

Even though litigation-B Readers are licensed physicians, some of whom maintain clinical practices, licensure in several states, and are aware of these requirements, when it comes to litigation-screenings, compliance with these regulations is

⁹³ Deposition of Ray A. Harron, M.D., 3/3/1999, p. 61.

⁹⁴ See Brickman, *supra* note 16, at 66, n. 98.

usually of no concern to them. The only concern of theirs appears to be film quality. Query whether they can be assured of even that if the X-ray equipment is not operated properly, maintained properly, etc. Nevertheless, this deliberate indifference to quasi-illegal use of X-ray equipment in tens or even hundreds of thousands of instances essentially undermines the policies and protections the regulations are designed to effect. Two simple solutions to the complicity of these B Readers in violation of state or federal regulations are (1) prohibit them from reading X-rays when the proponent of the films cannot prove the films were taken in compliance with applicable law and (2) prohibit B Readers from reviewing films from states in which the reader is not licensed to practice medicine.⁹⁵ Both of these solutions are simple, protect the public, and cause no harm or burden to the B Readers.

- **Dr. Richard B. Levine**

Dr. Levine has testified that he has received chest X-rays for his review from 40 states in the United States, even though he is licensed to practice medicine in only three of them.⁹⁶ When asked about a state in which he is not licensed, like Texas, Dr. Levine disclaims all prior knowledge of the X-ray process and states his only concern is for film quality. In essence, if the litigation-screening company is not following state health regulations on the issues of prescriptions for X-rays or otherwise, they can be assured that Dr. Levine will ask no questions and provide the services requested.

Q: Do you know if the State of Texas requires somebody to have a prescription before they get a chest X-ray?

A: I'm involved in the process way after X-rays are taken. I'm not involved in the organization of taking the X-ray, the taking of the X-ray. I am involved as a consultant in the interpretation of the X-rays after the fact.

Q: So what that sounds like to me is whatever happens up until the time you receive the film in terms of how the X-ray is produced, where it's taken, under what circumstances, et cetera, there's nothing you can offer the jury about that process?

⁹⁵ As a practical matter, the B Reader, if unlicensed in a state, should be unable to practice medicine there whether for clinical or litigation purposes. However, as shown by Dr. Segarra's conduct in Washington and the lawsuit for malpractice against Dr. Harron, not all B Readers follow these rules. To prevent these abuses, NIOSH simply could insist that B Readers read films only from states in which they are licensed, and therefore familiar with laws governing X-ray equipment and the like. Note also that the Texas legislative proposal cited earlier provides that a physician who is licensed in Texas must provide the medical testing and physical examination to support a claim. See Senate Bill No. 8 [Draft], attached as Exhibit 11, at 4.

⁹⁶ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 39 ("I mean, over the years I've probably received them from 40 states.").

A: No, other than if the film is inadequate⁹⁷

- **Dr. Mark Klepper**

Dr. Klepper also shows a remarkable lack of concern over how the X-rays are generated and whether the process complies with applicable law and regulations—even though he knows full well what regulations apply in Texas. Dr. Klepper and some of his partners and associates also organize screenings, which makes his deliberate indifference inexcusable.

Q: Who sends you the X-rays?

A: In my office. There are a variety of firms that—I don't know the term for it, but get patients from Tyler Pipe.

Q: So the law firm sends you these X-rays, correct?

A: Correct.

Q: And do you know anything about the conditions under which those X-rays were taken?

A: Yes.

Q: Okay. What do you know?

A: Well, what I know is what the X-ray looks like, the quality and the technique. . . .

Q: Other than what you see in the physical X-ray, what I'm trying to get at, has anybody told you anything about how the X-rays were taken?

A: No.⁹⁸

Q: Now, what, if anything, do you know about the screening program [that generated the plaintiffs in this case]? Do you know who was responsible for it?

A: No, ma'am.

⁹⁷ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 113.

⁹⁸ Deposition of Mark Klepper, M.D., 6/20/2000, p. 56-57.

Q: Now, do you know if there was any doctor or physician who had ordered the X-rays on the individuals that you had reviewed?

A: By law there has to be a physician's order, and I don't know whose order that was. Occasionally, I will be asked to sign a document so a group of people can X-rayed.

Q: But you didn't do that up – for the ones [in this case]?

A: I don't recall honestly. I could have. I don't think I did.⁹⁹

Q: Going back to the [industrial facility at issue], you personally don't know who the physician was that ordered the X-rays or if, in fact, there was a physician for that matter?

A: I don't know if there was a physician, and I don't know who it was if there was.

Q: And you don't know who the technician was?

A: There could have been multiple technicians and multiple X-ray screened groups and in fact, probably were because there were so many workers.

Q: And you don't know what type of X-ray equipment was used, fair?

A: Correct.

Q: And there are certain standards that would govern the testing and maintenance of X-ray equipment, correct?

A: Yes.

Q: You don't know if those were followed in this case, fair?

A: That would be a fair statement.¹⁰⁰

- **Dr. Ray Harron**

Q: How did you come to be marked for identification in this case?

A: I have no idea. People send me X-rays from all over the country to read. Read lots of 'em from your place out there at Seattle.

⁹⁹ Deposition of Mark Klepper, M.D., 6/20/2000, p. 57.

¹⁰⁰ Deposition of Mark Klepper, M.D., 6/20/2000, p. 59.

Bremerton Navy yards out there send me films. Films are sent to me. How they get there, I don't know. I just read them and send them back.¹⁰¹

The profound lack of concern for the circumstances by which the X-rays are taken is troubling. Given that many of these screening companies are not owned or operated by physicians, operate with little to no regulatory oversight, and perform X-rays on thousands of people per year, it seems appropriate that a physician charged with the care of individuals should not be complicit in violation of the law. Simply (1) requiring a B Reader to be licensed in the state from which the films originate and (2) requiring proof of compliance with state regulations regarding X-rays would all but eliminate the unregulated and perhaps dangerous X-rays of thousands of Americans. These are the most basic requirements these physicians are required to follow in their own clinical practices when ordering X-rays. Why shouldn't the same requirements apply when they are asked to read thousands of litigation-driven X-rays?

C. Litigation-B Readers Admit That They Have No Doctor-patient Relationship, Are Not Involved in the Person's Care or Treatment, and Their Services in Litigation are Requested by Law Firms and Screening Companies, Not Health-care Professionals.

Virtually every B Reader involved in litigation has no role in the care or treatment of the person whose X-ray is being read. Indeed, in the screening context, the B Reader's opinion is sent to the screening company or the law firm paying the screening company. In fact, Dr. Harron was sued for malpractice because he reported the presence of a potential lung cancer to the law firm paying him and not to the individual whose film he was reading.¹⁰² Litigation-B Readers, while purporting to diagnose individuals with disease, the effect of which is to open doors to the court house, also readily admit they have no doctor-patient relationship with the individual whose films they are reading. While some of them purport to read X-rays for screening companies that they say conduct true health-related screenings, in virtually every instance, the screenings are litigation driven.

There is nothing wrong or improper about a B Reader, without a doctor-patient relationship, objectively reading X-rays on a population level for research or other related purposes. No one is suggesting that the epidemiological review of chest X-rays is improper or should be regulated. However, these litigation B Readers are not engaged in a study or a population survey. They are involved in rendering a diagnosis or an opinion about the condition of an individual's lungs for the express purpose of opening the door to the court house. B Readers were not intended to be diagnosticians. If they are rendering a diagnosis, however, there is something wrong with a B Reader washing his or her hands of all the consequences attendant to doing so in a clinical setting.

• **Dr. Richard Levine**

¹⁰¹ Deposition of Ray A. Harron, M.D., 3/3/1999, p. 11-12.

¹⁰² See *Adams v. Harron*, 1999 WL 710326 (4th Cir. 1999), attached as Exhibit 15.

Dr. Levine testifies that the cases he receives come from “reputable” health screening companies, companies that do “real” medical screenings.

Q: Are you familiar with the company called Health Screen [that screened this particular individual]?

A: I’ve never met them. But they are a very capable, good imaging company that sends work to me.¹⁰³

Health Screen is not an imaging company; it is a litigation screening company—only, as illustrated in the testimony of a Health Screen official.

Q: Healthscreen doesn’t do any work except for lawyers? In other words, it doesn’t do any type of work except testing for lawyers.

A: To the best of my knowledge.¹⁰⁴

Dr. Levine also appears to be “mistaken” about the real business of another “imaging” company that has sent him work.

Q: Do you know whether or not Most [Health Services] is in the business of screening for litigation purposes people for pneumoconiosis?

A: The vast majority of what they do is industrial work, not for litigation. They go and they offer occupation services to industries all across the country.¹⁰⁵

That is not quite how Most Health Services characterizes itself in marketing materials:

Our organization provides comprehensive on-site testing. We have tested over 175,000 union members for asbestos related diseases. All medical testing is performed by certified medical staff on forty-five (45) foot trailers¹⁰⁶

The letter then lists 15 law firms as references. Most is also the screening company that tells these law firms about its radiologist: “Our radiologist, Richard Levine, M.D. is a NIOSH “B” reader”¹⁰⁷ Most Health Services is no longer in business.

¹⁰³ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 126.

¹⁰⁴ Deposition of Jeffrey H. Bass, M.D., 5/10/2003, attached as Exhibit 7, p. 56.

¹⁰⁵ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 129.

¹⁰⁶ Most Health Services Letter to Lawyers (1996), attached as Exhibit 22.

¹⁰⁷ *Id.*

- **Dr. Mark Klepper**

Q: When you say patients, do you consider these people that you're examining on behalf of Baron & Budd to be your patients?

A: I don't consider them my patients, but as a physician, there's just something that doesn't sound right about calling someone a client, so I don't know what else to call them.

Q: All right. They're not a patient, and you don't like the word client?

A: Well, they're a patient, but there is not a doctor-patient relationship because they are sent to see me by someone else.¹⁰⁸

- **Dr. Ray Harron**

Q: In terms of your role, do you consider yourself to have a doctor/patient relationship with the people whose X-rays you reviewed that are sent to you?

A: Absolutely not. I'm being an expert witness in litigation—potential litigation or claim for benefit.

Q: So from your perspective, your review purely for litigation purposes, not for treatment and care?

A: Not for treatment and care. . . .

Q: It's your understanding that you're reviewing so that the lawyers can pursue some kind of claim in connection with it?

A: Yes, sir.¹⁰⁹

It is no wonder that Dr. Harron so vehemently disclaims a doctor-patient relationship. He was sued over one of his "screening" reads and was forced to litigate the case all the way to a federal court of appeals.¹¹⁰

- **Dr. Jay Segarra**

¹⁰⁸ Deposition of Mark Klepper, M.D., 6/20/2000, p. 44-45.

¹⁰⁹ Deposition of Ray A. Harron, M.D., 3/3/1999, p. 14-15.

¹¹⁰ See *Adams v. Harron*, 1999 WL 710326 (4th Cir. 1999), attached as Exhibit 15.

Q: You've indicated that these individuals that you see here are -- you don't consider them to be patients in the traditional sense; is that correct?

A: Yes, that's true. I consider there to be a limited doctor-patient relationship based on flow of information at the time that I see them and identification of life threatening conditions that might come to light during the course of the examination. But they are not longitudinal patients, and they're patients that I consult on, on a one-time basis.¹¹¹

As these examples illustrate, these particular litigation B Readers appear to have no concern about the source of their "patients" and, despite rendering a diagnosis, want to disclaim the responsibility that comes with doing so. They want to "act" like disconnected observers but have the effect of being a diagnosing physician. NIOSH never intended B Readers to be engaging in these activities or putting themselves in the bizarre position of a non-doctor-patient doctor.

D. Litigation-B Readers Do Not Keep Records—Of Anything.

Litigation-B Readers do not keep records. Often they cannot tell you who sent them X-rays, when the X-rays were sent, how many X-rays were sent, how many reads they have conducted, how much money they received for reading, or anything else related to the quantity or details of their activities. They do not keep records of discrete populations of workers whose films they have studied. They do not keep track of how many positive X-rays versus negative X-rays they read. In fact, some B Readers scoff at the suggestion that it might be useful to compare their individual positivity rates with that of a background population. Knowing that the B Reader program was designed to monitor workers, not diagnose individuals, the negative comments of these B Readers on the issues of recordkeeping or reporting of results is stunning.

- **Dr. Richard B. Levine:**

Q: How did you receive the X-rays [in this particular case]?

A: I have no record. I have no file on them. So they must have been sent to me, but I don't know who sent them because I don't have a file on any of them¹¹²

Q: Any idea how many B reads you've done this year?

A: No. Definitely as a function of tort reform, it's dramatically decreased by a significant percentage. It's a small fraction of what it has been because of what's going on all around the country?¹¹³

¹¹¹ Deposition of Jay Segarra, M.D. 6/18/2003, p. 13.

¹¹² Deposition of Richard B. Levine, M.D., 4/21/2003, p. 19.

- Q: Any idea how many you've done this month?
- A: You know, like today, for example, I had 16 from one group and 6 from another. But I don't know. Tomorrow I could get 100 . . .¹¹⁴
- Q: What's been your most active year doing reads?
- A: I couldn't tell you. I just don't keep records like that . . .¹¹⁵
- Q: Do you have files that have the names and who these people are that you receive from imaging services that conduct these?
- A: I don't keep any of that. It all gets returned back. As I say, I don't keep any sort of filing system. . . .¹¹⁶
- Q: What do you do with the negative reads?
- A: Exact same thing I do with the positive reads. They are interpreted and sent back to the referral source.¹¹⁷
- Q: What was your annual income last year?
- A: God, I have no idea. I have no idea.
- Q: Did you file an extension on your tax return or just not pay attention to it when you filed in on April 15th [6 days before the deposition]
- A: No. But I file so many different taxes because of the state. But I have no idea.
- Q: Ballpark?
- A: I'm not sure that it's any of your business, but I have no idea.
- Q: You don't have a ballpark figure?
- A: I don't want to be inaccurate because there's really—gross? Collections? My expenses to run the corporation? Just from

¹¹³ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 36.

¹¹⁴ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 36.

¹¹⁵ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 37.

¹¹⁶ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 52-53.

¹¹⁷ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 67.

malpractice for the group and everybody? I wouldn't even want to venture a guess.

Q: Do you think it is more or less that half a million dollars?

A: I have no idea. I wouldn't even want to venture a guess.

Q: And so if I was to ask you questions about what percentage of your annual income you attribute to medical legal film reading, would you be able to answer that question?

A: That's been asked and answered. I have no idea. I just don't keep those types of records.¹¹⁸

Q: My question, though, was do you ever keep statistics of your B readings to determine that X percentage of the fire workers, for examples, or the firefighters, for example, had positive radiographic findings?

A: No.¹¹⁹

Q: What would you say is the total number of individual X-rays that you've read as a NIOSH B Reader?

A: Probably over the last close to 20 years, here at the hospital? Could be in the hundreds of thousands¹²⁰

• **Dr. Mark Klepper**

Q: Well, I'm asking you, can you tell me in a given year approximately if it's [his positive read for lung disease] more to the 50 or more to the 90 percent?

A: It's more to the 50, and I quite honestly don't keep track because I try to stay honest, and I try to read the X-ray blindly, if you will, so I don't keep track of my positivity rate.¹²¹

Q: All right. Well, now, I'm not asking you about a positivity rate. I'm asking about absolute numbers. Do you know how the number of positive findings you were making compares to the number of reported cases of pneumoconiosis kept by any governmental agency?

¹¹⁸ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 149-50.

¹¹⁹ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 169.

¹²⁰ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 170.

¹²¹ Deposition of Mark Klepper, M.D., 6/20/2000, p. 50-51.

A: I don't know.¹²²

Not only does Dr. Klepper not keep records that would be useful for monitoring populations, but he also considers any investigation into whether his findings are disproportionate to background to be a valueless endeavor.

Q: Do you think it would be worthwhile for you to investigate to determine if the absolute number of positive findings which you yourself are making is disproportionate to those found by any governmental agency?¹²³

A: I don't see the value in that.

Dr. Klepper, despite being a B Reader, has no intention, unless specifically asked, to report his results.

Q: Well, I guess I'm wondering if perhaps it might be—if a government agency might want to know about the incidence of pneumoconiosis that you yourself are finding?

A: Well, I suppose if they requested that information, I would be happy to provide it.

Q: But otherwise, you don't plan to contact any government agency?

A: No, ma'am.¹²⁴

- **Dr. Ray Harron**

Dr. Harron claims to have read hundreds of thousands of X-rays over his career, yet, he keeps no records—records that would allow an objective body to assess the quality of his readings.

Q: Doctor, do you have an estimate, any kind of estimates to how many cases you have reviewed X-ray in the asbestos litigation?

A: No.

Q: Can you give me an idea of whether it's dozens or hundreds or thousands or something?

¹²² Deposition of Mark Klepper, M.D., 6/20/2000, p. 53.

¹²³ Deposition of Mark Klepper, M.D., 6/20/2000, p. 53.

¹²⁴ Deposition of Mark Klepper, M.D., 6/20/2000, p. 54.

A: Hundreds of thousands probably. You mean classified under this ILO system?

Q: Yes.

A: Oh, I probably classified over the years somewhere between six and seven hundred thousand cases. . . .

Q: Doctor, can you give me your best estimate as to what percentage or how many of these six hundred to seven hundred thousand B-reading examinations that you have done were associated with work for plaintiff lawyers pursuing some claims or civil litigation?

A: No, I can't. Sorry.¹²⁵

Q: Doctor, do you have an estimate as to how much income you have derived over the years in connection with doing B-readings or expert consultations in the asbestos litigation?

A: No, sir.¹²⁶

Q: What records if any have you maintained regarding the work you've done in connection with litigation and doing B Reader examinations and providing expert consultation?

A: I personally have not maintained any.¹²⁷

Putting aside the striking uniformity in the answers given by three different litigation B Readers to virtually the same questions, many of the abuses of the B Reader program would disappear if some simple recordkeeping was required. If B Readers were required to (1) keep track of how many films they read, (2) the results of the reading (even just positive/negative), and (3) the source of the film, objective audits could readily be conducted. Indeed, many of these problems could be solved if B Readers completed the ILO forms in duplicate and kept one.

E. Even Though the ILO Guidelines Say Otherwise, Litigation B Readers Claim to Diagnose an Asbestos-Related Disease or a Condition "Consistent With" an Asbestos-Related Disease Only From an X-ray.

The 1980 and 2000 versions of the ILO guidelines clearly say that chest radiographs are not pathognomonic of pneumoconiosis.¹²⁸ Indeed, the 2000 version

¹²⁵ Deposition of Ray A. Harron, M.D., 3/3/1999, p. 42,44.

¹²⁶ Deposition of Ray A. Harron, M.D., 3/3/1999, p. 46.

¹²⁷ Deposition of Ray A. Harron, M.D., 3/3/1999, p. 49.

emphasizes this fact by disassociating B reads with entitlement to compensation schemes.¹²⁹ For a B Reader to testify that he or she can diagnose asbestosis only from an X-ray appears to be the height of abuse of his or her position as a NIOSH-certified B Reader. Yet, some B Readers do so with impunity.

- **Dr. Richard B. Levine**

Dr. Levine intones the NIOSH standards when answering questions about his ability to diagnose asbestosis from an X-ray, which is, of course, completely inconsistent with the prefatory remarks in the 1980 and 2000 versions of the ILO guidelines.

Q: And when you're reading these X-rays, you're not giving a diagnosis, are you?

A: I give a diagnosis when I read the films, sure.

Q: You give a diagnosis just from the X-ray?

A: Of course. . . .

Q: Based on the X-ray alone?

A: That's what radiologists do. . . . When I take the NIOSH exam, they don't give me histories. They don't give me latency periods. They don't give me the patient's occupational background. They don't tell me the ambient saturation with respect to asbestos or silica. . . .

Q: Well, from that alone you can't establish that the lung changes are due to dust disease and not something else.

A: Yes I can. . . .¹³⁰

Q: Doctor, in this particular case, Mr. Doelitsch, you diagnosed him based upon your NIOSH report with asbestosis, correct?

A: True.¹³¹

¹²⁸ See 2000 Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, at 2.

¹²⁹ *Id.* at 1.

¹³⁰ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 54-56.

¹³¹ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 96.

Q: And in addition to not knowing anything about [Mr. Doelitsch's] work or medical history, you don't know a lick about his exposure to asbestos or under what conditions he would have been exposed?

A: True.¹³²

Q: In your mind any time you, Dr. Levine checks, SS and the mid and lower lung zones and a 1/0, that would be asbestosis and nothing else, correct?

A: True. If I thought it was something else, I would indicate it under other comments¹³³

When asked later about the statement in the ILO Guidelines that chest X-rays are not in-and-of-themselves diagnostic of a pneumoconiosis, Dr. Levine responds by bashing the guidelines and making false statements about the 2000 revisions, calling the particular section of the guidelines the "Achilles heel of the document."

Q: NIOSH establishes that scheme by promulgating a set of guidelines that you use to interpret chest films in addition to a set of standard chest films that you use to compare X-rays, right?

A: Absolutely, right.¹³⁴

Q: I take it given how you've, it appears to me, taken pride at how well you do on these exams—follow the guidelines that the ILO promulgates fairly strictly?

A: I believe so.¹³⁵

Q: I've got copy of the 1980 guidelines here under a section called general instruction for the use of classification, the first sentence says there are no features to be seen in a chest radiograph which are pathognomonic of dust exposure. And what I want to know is what does pathognomonic mean?

A: Equivalent to would be to me a pretty good correlate. Pathognomonic being equivalent.

Q: And as I understand that sentence, it is saying that whatever you see on a chest X-ray is not pathognomonic, diagnostic of, or equivalent with, as you just said, dust exposure?

¹³² Deposition of Richard B. Levine, M.D., 4/21/2003, p. 124.

¹³³ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 103-04.

¹³⁴ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 115.

¹³⁵ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 115.

A: That's not true. I know it's in there but it's not true, because Because the very fact that that was written in 1980 is also the Achilles heel of the document, because even the document—that's why the standards are being changed. And there are new standards that are coming out. . . .¹³⁶

Q: There's another statement in the ILO guidelines I want to ask you about. It appears on Page 20 under the larger section called using the classification in the subsection that's called number of readers. And it says it is strongly recommended—this is the second sentence and I'm going to read the whole thing—it is strongly recommended that at least two and preferably three independent reading are made for each radiograph. And as it explains earlier, it's because of intra-reader variability. Do you have anybody else read Mr. Doelitsch's chest X-ray as recommended by the ILO guidelines.

A: As a practical matter, it's not done by anybody.

Q: Irrespective of whether it's a practical matter --

A: Not irrespective. As a practical matter it's not done by anybody. And not done by me.¹³⁷

- **Dr. Ray Harron**

Dr. Harron testifies that, from an X-ray, he can render an opinion that the X-ray is "consistent with" some asbestos-related disease.

Q: Would you agree with me that you cannot diagnose asbestosis on the strength of an X-ray alone?

A: No. I don't think that I'd agree with that. I think that if you have calcified pleural plaques and irregular opacities, then you can diagnose it.¹³⁸

Q: You write one, "consistent with asbestosis," and on your B Reader form, down under 4C, "other comments," you checked the box that's marked "consistent with asbestosis."

A: Yes, sir.¹³⁹

¹³⁶ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 115-17.

¹³⁷ Deposition of Richard B. Levine, M.D., 4/21/2003, p. 120.

¹³⁸ Deposition of Ray A. Harron, M.D., 3/4/1996, p. 78.

¹³⁹ Deposition of Ray A. Harron, M.D., 3/3/1999, p. 26.

To make interpretation of his findings easier for lawyers, Dr. Harron modified the ILO form to include information on asbestos-related disease. Of particular note, he made this modification only for lawyers.

Q: Now, the three boxes on your B Reader report that say “no asbestosis, consistent with asbestosis, consistent with asbestos-related disease” – those three boxes are not normally part of the ILO B Reader form; is that correct?

A: In 4C, you can write anything you want to write in there –

Q: Understood.

A: -- anything you feel – okay. And this is a form that we use when we’re doing work with lawyers’ – lawyers’ offices as a rule. It may slip out into government agencies or into other places too, but usually we use this with the lawyers, because generally nonlegal persons are reviewing these. . . . So this is something that we added at the request of some attorneys, to help their office personnel.¹⁴⁰

Dr. Harron clearly is a willing participant—and takes steps to make the process easier and smoother for the lawyers—to make it easier for the lawyers.

F. Tying It All Together—A Current Example of Abuse At Work.

Milam County, Texas is a small county in the central part of the state. There is a large aluminum smelting facility in that county, but otherwise, the county is rural and agricultural. One law firm in the county seat with a population of no more than 5,000 currently represents more than 100 spouses of the aluminum plant workers. These elderly women, surprisingly, all have been diagnosed with asbestosis. This is certainly an epidemiological phenomenon if the diagnoses are accurate.

Not surprisingly, these ladies were all diagnosed through a litigation screening. The screening company advertised in the local newspapers and suggested screenings for the spouses of the aluminum workers. These ladies’ only alleged exposure is from washing their husband’s clothing. By their own admission, none of these women have respiratory impairment (they may be sick but their maladies have nothing to do with pneumoconiosis). Some of these women—literally—have no idea how they became asbestos plaintiffs. Their testimony on the issues is eerily similar. Each of them responded to a newspaper ad, targeted directly to them, that offered “health” screenings for the spouses of these workers. Each of the ladies went to the X-ray truck. At some point, they were sent a letter telling them their X-ray was positive and to see another pulmonary doctor.

¹⁴⁰ Deposition of Ray A. Harron, M.D., 3/3/1999, p. 32-33.

Ms. Ruby Seidel is a typical example.¹⁴¹

On the issue of how she was “diagnosed” with asbestosis:

Q. If Dr. Gaffney [plaintiff’s family doctor] had never told you that you had any problems related to asbestos, how was it that you got or decided to come and talk to these lawyers? I don’t want to know what you told them, but how did you personally make the decision to come here and talk to them?

A. Well, I took X-rays when they had X-rays going on here.

Q. Okay. Back up for a minute. Who had X-rays?

A. Well, they had X-rays for us to take -- well, I don’t know who it was at those X-ray places and they were taking X-rays. It was in the paper, and we came up here to have it done.

Q. Okay. So you saw an ad in the newspaper?

A. Yeah, to take X-rays. Yeah, for X-rays.

Q. And where did it tell you to go to get the X-rays?

A. Well, they had them here in Rockdale.

Q. At a medical clinic?

A. No. It was a mobile --

Q. A trailer?

A. Yes.

Q. Have you ever gone to a trailer to seek medical attention before?

A. No.

Q. Do you know if there was a doctor present in the trailer?

A. No, I didn’t know.

Q. Did anybody in the trailer give you a diagnosis –

¹⁴¹ See Deposition of Ruby Seidel, 2/2/2004, attached as Exhibit 23.

A. No.

Q. -- or talk to you about your condition at all?

A. No.

Q. Did they give you the X-rays when you left the trailer?

A. No.

Q. Do you know where the X-rays went after you got them taken?

A. No, I didn't.

Q. Do you know how many people were at the trailer that day getting X-rays?

A. There was a lot of people there. I don't know.¹⁴²

On the issue of how she came to be sitting in a deposition:

Q. All right. Do you know why all of us are sitting here in this room asking you questions today?

A. Well, I don't know, not for sure. Can you tell me?

Q. Has somebody told you that you have a disease related to asbestos exposure?

A. Well, no.¹⁴³

Q. Do you know how you came to be sitting here today with all of us nice folks here asking you questions?

A. Well, what do you mean by that?

Q. Well, let me start that over. You just told me -- let me make sure I understand you right -- no one has ever told you that you have a disease related to asbestos; right?

A. Only what I got from the doctor at one time, you know, from Waco. That's the one that I got there.

Q. Do you have a doctor in Waco?

¹⁴² Deposition of Ruby Seidel, 2/2/2004, p. 21-23.

¹⁴³ Deposition of Ruby Seidel, 2/2/2004, p. 13.

- A. Well, we just went for a checkup there.
- Q. Who is that doctor?
- A. Richey,¹⁴⁴ I think.
- Q. Okay. Is that a man or a woman?
- A. It's a man.
- Q. Have you ever seen Dr. Richey before that?
- A. No.
- Q. How did you find out about Dr. Richey?
- A. Well, they just sent us there.
- Q. Who is "they"?
- A. Well, they sent me a letter to go up to Waco to get a check up.
- Q. Okay. Well, what I'm trying to figure out is the "they" you're referring to.
- A. Pardon?
- Q. Who is the "they" you're referring to?
- A. Oh, from here, the lawyer.
- Q. The lawyer sent you a letter to tell you to go to Dr. Richey; is that correct?
- A. Well, that's what we all did.
- Q. All right. And you didn't go see Dr. Richey because you were feeling sick; right?
- A. No.
- Q. And Dr. Richey is not your regular doctor; right?
- A. No.

¹⁴⁴ Dr. Richey is employed by Dr. Klepper's CPOM screening company.

Q. And you don't have any appointments to see Dr. Richey?

A. No.

Q. And Dr. Richey didn't give you any prescriptions or prescribe you any course of treatment?

A. No.

Q. And have you told Dr. Gaffney [family doctor] about what Dr. Richey told you?

A. Not yet, I haven't, no [2 years after the screening].

On the issue of whether she was sick or impaired:

Q. You're not claiming any lost wages because of any disease that's associated with asbestos, are you?

A. No.

Q. And you're not claiming any mental anguish because of some disease related to asbestos, are you?

A. No.

Q. And you're not claiming any out of pocket health care medical expenses because of some disease associated with asbestos, are you?

A. No.

Q. And you're not claiming that your relationship with your husband has been affected in any way by some disease allegedly associated with asbestos, are you?

A. No.¹⁴⁵

If it is not obvious, this process, besides the initial direct marketing, was begun when a B Reader examined the X-rays and informed the law firm the films were "positive." After learning this information from the B Reader—Dr. Levine in these cases—they sent the ladies to a pulmonary doctor for pulmonary function tests, etc.

¹⁴⁵ Deposition of Ruby Seidel, 2/2/2004, p. 17-18.

As is equally obvious from Ms. Seidel's testimony, she isn't sick and doesn't have breathing problems. Indeed, her pulmonary function tests were normal. Without Dr. Levine's B read, Ms. Seidel, even after visiting the pulmonary doctor, could not be diagnosed with an asbestos-related disease.

Truly, if these ladies had asbestosis, public health authorities should be concerned. While Dr. Levine has not been deposed in these ladies' cases yet, based on his recordkeeping, or lack thereof, there will be no way to determine how many ladies' X-rays he viewed, how many were positive, etc. This is a particularly important example of why recordkeeping is necessary—to determine if there really is a heretofore never seen cluster of asbestosis in wives of aluminum workers.

These ladies are not sick and should not be entering the tort system as plaintiffs. Without the screening company borrowing the credibility of NIOSH and without Dr. Levine abusing his qualifications for his own financial gain, her case wouldn't be in the tort system, or any other claimant-type system.

IV. NIOSH Needs a Check-and-Balance System to Prevent Abuse and Misuse of the B Reader Program.

The testimony of the individuals referenced in these comments illustrates the extent to which litigation-screening companies, law firms and the B Readers they employ hijack the integrity of NIOSH for their own financial gain. Litigation screeners knowingly use assembly-line style techniques to manufacture asbestos cases for the lawyers to whom they market their services. Litigation-B Readers, while occasionally trying to act like uninvolved or detached parts of the process, really are complicit in the system, or at a minimum, deliberately indifferent to what is happening. In either situation, the integrity of NIOSH is being used for improper purposes. Most, if not all, of these abuses could be eliminated or significantly curtailed with a few fairly simple solutions.

The premise behind each of these solutions is that the current system of re-certifying B Readers every four years does not prevent the B Reader (or others) from abusing the system. Thus, making the exam more difficult or administering it more often probably will not solve many of the existing problems.

Four straightforward solutions are proposed.

1. **Recordkeeping.** Currently, B Readers operate in a consequence-free environment when it comes to reading ten or hundreds of thousands of X-rays for litigation screeners. By not keeping any records, it becomes virtually impossible for anyone, including NIOSH, to determine if B Readers are overreading, under-reading, disregarding NIOSH or ILO Guidelines or regulations, etc. The mirror-image testimony on the utter absence of records by the

litigation B Readers raises some suspicion that the B Readers do not keep records for a reason.

One way to prevent or significantly deter overreading or similar abuses is to require recordkeeping. The requirement could be as simple as requiring the B Readers to fill out the ILO forms in carbon-copy duplicate. With a carbon-copy, NIOSH, hospital systems, litigation trusts, or anyone else that is interested would have an effective way to determine how many films a particular B Reader has read as “positive” or “negative.” With this ability, virtually anyone with some training could determine if a particular B Reader was over- or underreading or if some public health problem potentially exists.

A recordkeeping requirement puts no additional strains on NIOSH, as it would be the B Reader’s responsibility to maintain the records. It should be no argument from the individual B Readers that such a requirement is burdensome. If a B Reader is willing to and does read thousands of films from around the country each year—making thousands of dollars in the process—that reader should be required to undertake the burden necessary to ensure that he or she is acting responsibly. Virtually all of these doctors keep records in their clinical practices. Again, any complaints about recordkeeping, given that the burdens usually would be self-created, should fall on deaf ears.

The recordkeeping requirement could be much broader, depending on NIOSH’s willingness or ability to implement more stringent recordkeeping. For example, NIOSH could require B Readers, consistent with HIPPA guidelines, to include race, sex, occupation, and other vital information on the ILO forms. This information could allow for epidemiological studies of several different cohorts of workers or their spouses. NIOSH also could require the B Readers to send duplicates of their reads to a repository or require B Readers to maintain computerized records through a database administrated by NIOSH.

The possibilities are numerous, but at a minimum, requiring the readers to keep duplicate copies hardly seems to be a burden in light of the current abuses that are difficult to document because of the utter absence of records.

Recordkeeping, in the absence of fraud by an individual B Reader, would act as both a deterrent and a check-and-balance on the B Reader’s performance. Knowing that he or she is keeping records of every read for NIOSH’s or someone else’s inspection should

deter the reader from activities like “diagnosing” asbestosis from an X-ray or reading dozens of elderly women’s X-rays as positive for pneumoconiosis when it is clear they have no asbestos-related diseases or problems. Recordkeeping would serve these functions for one important reason: the potential for a NIOSH or peer-review audit.

2. **Discipline:** Presently, if a B Reader is abusing the program and his or her credentials, there is no consequence. Recall Dr. Harron’s law suit. The civil court system provided no discipline or check on his activities. He was sued for malpractice because he saw evidence of a lung cancer on an individual’s X-ray and reported it to the law firm and not the individual. Dr. Harron won because he disclaimed, and the court found, that no doctor-patient relationship existed. If NIOSH does not implement some oversight procedure with consequences attached for proven abuses, B Readers will continue to operate in a consequence-free environment—and will do so at the expense of NIOSH’s credibility.

NIOSH, therefore, should implement some form of consequence or discipline for a proven abuse. The consequence could take many forms, but the most simple one is to suspend the B Reader’s credentials or prohibit the B Reader from being re-certified (sitting for the exam) for some period of time. Without the NIOSH credentials, screening companies and lawyers would shy away from, if not completely avoid, retaining the individual for fear that he or she will not pass muster with the courts as an expert.

In spite of the purposes and policies behind the B Reader program, if an individual reader is willing to read and diagnose or quasi-diagnose tens or hundreds of thousands of potential litigants with asbestosis, that B Reader should have no reservation about defending his or her opinions to NIOSH or his or her peers. In the clinical setting, the physician likely would be forced to do the same thing in front of a peer-review group if his or her practices were questioned.

3. **An Audit Program:** This suggestion goes hand-in-hand with the recordkeeping and discipline. NIOSH should randomly (or if requested) evaluate a B Reader’s performance in addition to testing their ability to pass an exam. Like a driver’s license situation, NIOSH should have no interest in certifying B Readers who will go forth into the public and ignore or violate the law.

In its simplest form, the audit program could be no more than a review of the duplicate ILO forms to determine how many "positive" versus "negative" reads the B Reader has performed. Higher than average positives could trigger further reviews. In a more advanced form, the audit program could involve the re-review of films by other NIOSH-selected B Readers.

In the absence of intentional deception or fraud, the record review probably would be sufficient to deter and detect abuses. However, a film re-review in conjunction with a record review would not only detect abuses but also could detect any malevolence that might be occurring.

4. **Source of X-rays:** Due to the rampant violations by litigation-screening companies of state regulations regarding a doctor's order for X-rays, registering of equipment, etc., B Readers should not be permitted to read films that were taken in violation of public policy. Allowing them to do so, as was shown in the examples, acts as a catalyst for screening companies to circumvent the law. Nor should a NIOSH-certified B Reader be permitted to read X-rays, when acting in this quasi-diagnostic role, from states in which the reader is not licensed.

NIOSH should consider regulations that force B Readers, when using their NIOSH-given credentials from engaging in readings that encourage, or turn a blind eye to, violations of rules intended to protect the public health. In their clinical practices, even radiologists, cannot practice medicine in jurisdictions in which they are not licensed. It should be no different in their "other" activities. If B Readers choose to be involved in litigation screening, they at least should be restricted to reading films originating from those states in which they are licensed to practice medicine. In addition, NIOSH also should consider restricting B Readers from performing readings on films for which the B Reader has no proof were taken in compliance with state law. Both of these complementary requirements impose no more burden on the B Reader than the states in which they are licensed impose on their clinical practices every day.

All of these suggestions are simple, common sense rules or regulations that will in large measure prevent some of the abuses of the B Reader program. Out of all the certified B Readers in the program, only a small percentage likely engage in these abuses. While NIOSH should not necessarily be transformed into a policing agency, NIOSH should impose some internal controls on what B Readers are doing with their credentials, and thus, how they use the credibility of NIOSH in their activities.

Otherwise, litigation screening companies and ambitious B Readers will continue to borrow the credibility of NIOSH and enrich themselves financially.

We hope these comments provide useful, practical solutions to some of the serious problems that now plague the B Reader program.