Ethics and *Daubert*: The Scylla and Charybdis of Medical Monitoring

NATHAN A. SCHACHTMAN
MCCARTER & ENGLISH, PHILADELPHIA, PA*

Build a courtroom and they will come. The floodgates argument, all too quickly rejected by the judiciary, has now proved all too true in West Virginia. West Virginia built a courtroom that would entertain multiple claims from virtually every West Virginian. This jurisprudential hospitality offers medical monitoring that requires no predicate present injury. *Bower v. Westinghouse Electric Corp.*, 522 S.E.2d 424 (W.Va. 1999). Everyone is exposed to hazardous substances and to medications with potential side effects. In West Virginia, almost everyone is a potential plaintiff in a medical monitoring case. Universal health care may be attainable, after all, funded by the manufacturers of predominately beneficial products. Almost heaven, indeed.

Type 2 diabetes mellitus, or adult-onset diabetes, is a devastating disease that results from uncontrolled blood sugars. The medical complications of diabetes are extensive and well known: blindness, gangrene, kidney failure, heart attack, stroke, liver disease, and others. The costs of this medical care are staggering, and diabetics are among the neediest patients in our health care system. Imagine if the "compensation goals" of the tort system could be subverted to provide medical monitoring to diabetic patients. If possible anywhere, it would seem West Virginia would be the most likely candidate.

Between March 1997 and March 2000, many Type 2 diabetics achieved control of their blood sugars with the help of a new oral medication, Troglitazone (Rezulin®). Troglitazone modifies the Type 2 diabetic patient's resistance to insulin. The drug effectively reduces blood sugar, and it avoids the need for exogenous insulin. Most drugs have side effects, and Troglitazone is no exception. Physicians, knowledgeable about Troglitazone's efficacy and its potential for rare, idiosyncratic liver toxicity, prescribed the drug to help their patients gain control over their blood sugar levels and to avoid the serious complications of diabetes. In March 2000, the manufacturer of Troglitazone voluntarily withdrew the drug from the market. Adverse publicity over liver toxicity and the availability of two other more recent glitazones, which initially had the appearance of a safer adverse event profile, had shifted the risk-benefit balance against Troglitazone.

No one can be surprised that Rezulin plaintiffs sought class certification in West Virginia state court; nor can anyone, in view of *Bower*, be surprised that asymptomatic plaintiffs sought medical monitoring as a remedy, within the context of the class action. Observers unfamiliar with the weakness of the Rezulin plaintiffs' scientific proofs might, however, be surprised at the plaintiffs' failure to win class certification in West Virginia, for a medical monitoring class. *In re West Virginia Rezulin Litigation*, Civil Action No. 00-C-1180H, Amended Order Denying Class Certification (Dec. 12, 2001) (Hutchison, J.), Mealey's Class Action Lit. Reports, Vol. 1, No. 20, at C-1 (Dec. 20, 2001).

The West Virginia trial court's rejection of the proposed Rezulin medical monitoring class is remarkable for many reasons. Some commentators regard West Virginia law as the outer limits of medical monitoring jurisprudence. In the Rezulin case, however, Judge John Hutchison delivered a thorough, analytical opinion, which demonstrated that the liberal West Virginia criteria for a medical monitoring remedy cannot be satisfied as easily as once thought. Among the notable holdings were the trial court's insistence that:

(1) the monitoring proponents adduce epidemiologic evidence that the exposure at issue can actually cause the latent injury for which monitoring is sought;
(2) the proponents of monitoring identify highly sensitive tests, which when deployed on the exposed population that has a relatively high prevalence of the latent injury, will have a high predictive value; and
(3) the proposed monitoring will allow for early preventive care.

In determining whether the class plaintiffs had met the criteria for medical monitoring, Judge Hutchison did not face any significant evidentiary gatekeeping responsibility. The trial court did not have to ponder the contours of any reliable epidemiologic studies. The court found no epidemiologic studies to show that Rezulin can cause latent injury months or years after the drug is discontinued.

Similarly, the court did not have to delve into any evidentiary thicket of contradictory scientific proof to determine whether the proposed medical monitoring program was based upon reliable scientific and medical methods. The court found that most of the proposed

* The views expressed here are Mr. Schachtman's personal opinions; they are not the position of any client. Nathan is a partner in the Philadelphia office of McCarter & English. His practice focuses on defense of product liability and toxic exposure cases and class actions.

tests had low sensitivity, and that there were no diagnostic tests that can determine whether any liver injury was caused by Rezulin. Given the many other causes of liver diseases among the plaintiff class members, there was no evidence of any prevalence of latent injury from Rezulin. Without an assessment of prevalence of latent injury, any proposed test would have no predictive value. The proposed program failed for lack of substantial evidentiary support.

The court was further impressed by the riskiness of the proposed monitoring program. The proposed tests, lacking sensitivity and specificity, were likely to result in "false positives," which in turn would lead to liver biopsies. Such biopsies, however, are painful, invasive, and carry a risk of death. Furthermore, the court found that the proposed tests would not facilitate medical interventions that could prevent or resolve the detected problem.

This failure to obtain class certification for medical monitoring is noteworthy for more than the case holdings. There is intriguing *obiter dictum*. The court noted that one of the plaintiffs' expert witnesses admitted that the proposed monitoring program was an "experiment." The court found this admission directly relevant to the plaintiffs' failure to produce epidemiologic evidence that the substance at issue could actually cause latent injury. Apparently, the plaintiffs' witness was advocating implementation of the monitoring program so it might yield the evidence that the class must proffer before it could obtain the monitoring remedy. The court readily dismissed this *Alice in Wonderland* insistence upon "[s]entence first—verdict afterwards." The court showed little patience for the "stuff and nonsense" of trying to satisfy the criterion of epidemiologic evidence with the anticipated results that would come from the proposed monitoring program itself.

Implicit in the court's rejection of evidentiary bootstrapping is a larger, ethical concern. There is something unsettling about a court-ordered medical monitoring program that is an "experiment." Class certification decisions are complicated enough without having to endorse experimentation on human beings. Perhaps the suggestion of human experimentation chilled any residual enthusiasm for the notion that medical monitoring might otherwise be a suitable judicial remedy for achieving corrective justice in a mass tort case.

And yet there is an "experimental" aspect to many, if not most, proposed monitoring programs. Little or no clinical experience is available to support the claimed benefits of many proposed large, lifelong monitoring regimes. Indeed, such programs are not wholly benign. The potential harms of monitoring, some of which were acknowledged in Judge Hutchison's opinion, are significant. The imposition of potentially harmful monitoring should, indeed, trouble our courts and cause their reticence in embracing monitoring as a remedy. Courts need to confront the ethical implications that flow from the experimental nature of many medical monitoring proposals.

Proposals for monitoring differ from expert witness opinion that is typically offered in personal injury cases involving present injuries. Physician witnesses, at the request of the parties, usually examine claimants, evaluate and diagnose their conditions, and opine about prognosis and etiology. Although such witnesses use their medical experience, training, and knowledge, they generally are not acting within the context of a patient-physician relationship. *Adams v. Harron*, 191 F.3d 447, 1999 WL 710326 (4th Cir. 1999). In the usual personal injury case, physician witnesses are not advocating medical interventions; at most, they are endorsing or criticizing the reasonable medical necessity of medical plans of treating physicians.

In medical monitoring class actions, physician expert witnesses advocate medical interventions for people they have often never met and have never evaluated. Recommendations for preventive health measures carry risks of harm, and these risks must provoke ethical scrutiny of the proposed monitoring. The offering of an opinion that a plaintiff, or a class of plaintiffs, should receive medical monitoring is the practice of medicine. As medical practice, the presentation of such opinions is subject to ethical constraints, which courts should observe and foster.

Medico-legal opinions that recommend preventive interventions represent a significant involvement in the claimant's actual medical care. Screening or monitoring recommendations must acknowledge and avoid the highly individualized risks of harm and the essential need for informed consent to protect individual autonomy. Physicians who prepare medical monitoring litigation plans cannot absolve themselves of ethical and professional responsibility by disclaiming the existence of physician-patient relationships. Such physicians are not practicing mere courthouse medicine; they are engaged in medical practice, both under AMA policy, AMA Policy H-265.993, and in the sense that they are seeking to control future medical interventions for the class members.

Physicians who propose monitoring or screening for claimants operate under the ethical constraints of avoiding harm, providing benefits, and respecting individual patient autonomy. The medical community recognizes that good intentions notwithstanding, monitoring can be harmful. "[P]reventive therapies can give rise to anticipatory anxiety, side effects, the stress of false-positive results and an unhealthy preoccupation with disease." Huston, *The Perils of Prevention*, 154 Canadian Med. Ass'n J. 1463 (1996). Other potential adverse effects of monitoring include deriving false assurances of health and being labeled as "sick." Marshall, *Prevention. How Much Harm? How Much Benefit? 3. Physical, Psychological and Social Harm*, 155 Canadian Med. Ass'n J. 169 (1996). Furthermore, some screening programs will detect true-positive results with little or no clinical significance. Some nodules detected in cancer screening, for instance, will be benign. Other nodules may be extremely indo-

lent malignancies, which would never become aggressive, metastatic growths. Indeed, such masses, picked up in screening, might regress before they would have been otherwise detectable. Screening programs must come to grips with the vagaries of the diseases and conditions that are the subject of the monitoring. The potential for harm, from monitoring, may be increased by the litigation setting, in which people are encouraged to become invested in illness seeking behaviors.

Given the potential for harm, physician witnesses who advocate monitoring face ethical and evidentiary burdens to establish the efficacy and benefit of the planned screening. At a minimum, class members will have to give informed consent. The process of obtaining consent must accommodate the intensely personal and individualized judgments about the risks of monitoring. Well-established criteria for evaluating public health interventions are available and employed by such agencies and groups as the United States Preventive Task Force, the Canadian Task Force on the Periodic Health Examination, the Cochrane Collaboration, and others. The existence of generally accepted evaluative criteria has obvious implications for determining the admissibility of monitoring proposals under either *Daubert* or *Frye* standards. Expert witnesses, in this ethically sensitive area, must be held to the same intellectual rigor that would be employed to evaluate monitoring or screening programs in the field of public health. Pitfalls, fallacies, and methodological error are abundant in the field of preventive medicine. Marshall, *Prevention. How Much Harm? How Much Benefit? 2. Ten Potential Pitfalls in Determining the Clinical Significance of Benefits*, 154 Canadian Med. Ass'n J. 1837 (1996). Even well-intentioned advice, such as counseling routine mammography in women, has been the subject of heated controversy and intense methodological debate. Ernster, *Mammograms and Personal Choice*, The New York Times (Feb. 14, 2002), at http://www.nytimes.com/2002/02/14/opinion/14erns.html.

Courts must acknowledge that if a proposed preventive program does not satisfy generally accepted criteria for medical interventions and does not have proven benefits that clearly outweigh the potential harms, medical monitoring becomes a court-sanctioned human experiment. The guiding principles and corollaries for human experimental research can be found in several sources, including The Nuremberg Code, *Permissible Medical Experiments*, at http://www.uab.edu/ethicscenter/NurembergCode.html; The World Medical Association's Declaration of Helsinki, World Medical Association, *Declaration of Helsinki's Ethical Principles for Medical Research Involving Human Subjects*, 284 J.A.M.A. 3043 (Dec. 20, 2000), as restated on several occasions; regulations of the Food and Drug Administration, Protection of Human Subjects, 21 C.F.R. §50.25; and the Department of Health and Human Services, 45 C.F.R. §46. Informed consent is the absolute requirement for any human medical experimentation. Regulations and guidelines of various federal and state agencies and medical organizations, however, place further limitations on the course of permissible experimental design. The Declaration of Helsinki, for instance, requires that the research design be clearly set out in an experimental protocol, which has been approved by an independent ethical review committee. The proposed medical research "must conform to generally scientific principles, [and] be based on a thorough knowledge of the scientific literature…' Declaration of Helsinki, ¶11 (2000). *Permissible Medical Experiments*, *supra*. *Daubert* and *Frye* thus become ethical imperatives, as well as legal requirements, before any serious consideration can be given to a medical monitoring program.

In all likelihood, no court will want to serve as an Institutional Review Board, and to sit in judgment of an experimental protocol. The realization that the proposed remedy is itself an experiment should suffice to quash any advocacy for the result. Indeed, an awareness of the ethical problems entailed by poorly supported medical monitoring programs must guide and propel courts to be vigilant in their gatekeeping responsibilities. Much of the earlier case law on monitoring developed before the principles and implications of *Daubert* could be realized in monitoring cases, and these older judgments may have to be questioned in the light of these ethical and evidentiary concerns.

Judge Hutchison's decision to deny certification for a Rezulin medical monitoring class obviated consideration of the ethical and evidentiary problems posed by monitoring remedies. The clear absence of proof to support the remedy for the Rezulin plaintiffs avoided debate over how to protect the informed consent process when the personal perception of the risks of monitoring will be perceived differently by each class member. In future class certification battles, these issues may help guide courts to withhold monitoring remedies. ❖