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THE ALI & MEDICAL MONITORING: RISKS FOR RESTATEMENTS' EMBRACE OF A NOVEL TORT

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INTRODUCTION

In 2004 the American Law Institute (ALI) approved the start of work on a third edition of a restatement of the law concerning economic torts. The project is designed to focus on torts that involve economic loss, or pecuniary harm generally not resulting from physical harm to a person or property. The undertaking was designed to update coverage of economic torts in the Restatement (Second) of Torts and address some topics not covered in prior Restatements. One of those new topics is medical monitoring. This tort involves claims by persons allegedly exposed because of a defendant's wrongful conduct to a proven toxic substance, and who are thus at substantially increased risk of a latent disease for which periodic medical monitoring exists that will early detect the disease if it manifests itself and will lead to better treatment or an increased chance of a cure. While the project is likely to last several years before completion, it has reached a stage in which the ALI has released a "Council Draft" for comments.[1]

Section 21 of that draft concerning medical monitoring raises several issues worthy of discussion, and indeed, ought to be carefully reconsidered by the Reporters in the next iteration. First, it seems somewhat premature for the Restatement to attempt to state a general rule permitting recovery of medical

[1] *See* Council Draft 1, RESTATEMENT (THIRD) TORTS: ECONOMIC TORTS AND RELATED WRONGS.

monitoring expenses when there is no clear trend towards adoption of this tort, and those jurisdictions that have adopted it vary significantly in their formulation and application of the claim. Moreover, while the current draft purports to recognize medical monitoring claims under only "limited circumstances," those circumstances are not nearly limited enough. Finally, its attempt to limit the claim probably will not work as envisioned by the drafters.

I. AN OVERVIEW OF §21 OF THE COUNCIL DRAFT

The Council Draft at §21 would recognize an action to recover a monitoring expense to prevent or mitigate a risk of serious bodily harm when: a) the defendant would be liable to the plaintiff for the bodily harm under general principles of negligence, strict liability or products liability law if the bodily harm became manifest; b) the expense is required by a risk of bodily harm created by the defendant and the expense provides no other material benefit to the plaintiff; c) the plaintiff has incurred or will incur the expense; and, d) the liability is not indeterminate.

Commentary to the section clarifies that the risk of bodily harm created by the defendant "must require the preventive expense." Also, in the case of medical monitoring, a defendant is liable for the expense only when its conduct places the plaintiff in a position where monitoring is medically warranted by the prospect that an early diagnosis of a latent condition will improve the chance of beneficial medical intervention. A defendant is not liable for monitoring that would have been warranted in any event. Nor is a defendant liable for monitoring of "speculative medical value."[2]

[2] *See* Council Draft 1, RESTATEMENT (THIRD) TORTS: ECONOMIC TORTS AND RELATED WRONGS §21, comment c.

II. IS IT PREMATURE FOR THE RESTATEMENT TO STATE A GENERAL RULE PERMITTING RECOVERY OF MEDICAL MONITORING EXPENSES?

As mentioned in the Reporter's Note to the draft of §21, courts are split on the availability of an action for medical monitoring expenses, and commentators sharply disagree on the desirability of allowing a tort action for medical monitoring expenses. Beyond that fundamental disagreement, there are two additional observations to be made. First, the trend for several years has been *against* the recognition of medical monitoring claims. The most recent case cited by the Reporter's Note in support of medical monitoring is seven years-old. The Supreme Court's decision in *Metro-North*[3] rejecting such a claim stands as an inexact but unmistakable turning point away from this type of claim. *Hinton, Wood, Henry*, and *Badillo*[4] are among the cases which have rejected medical monitoring since the last state recognized such a claim.[5] Recently, several federal courts have weighed in, adding to the opposition toward medical monitoring as a cause of action for currently uninjured plaintiffs.[6] Last year, the Western District of Texas predicted that the Texas Supreme Court would not recognize a cause of action for medical monitoring.[7]

Since the Council Draft was circulated for comment, the Mississippi court has answered the medical monitoring issue certified to it in *Paz v. Brush*

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[3]*Metro-North Commuter Railroad Co. v. Buckley*, 521 U.S. 424 (1997) (rejecting claim for lump sum award of future medical monitoring expense under Federal Employers' Liability Act).

[4]*Hinton ex rel. Hinton v. Monsanto Co.*, 813 So.2d 827 (Ala. 2001); *Wood v. Wyeth-Ayerst Laboratories, Div. of Am. Home Products*, 82 S.W.3d 849 (Ky. 2002); *Henry v. Dow Chemical Co.*, 473 Mich. 63, 701 N.W.2d 684 (Mich. 2005); *Badillo v. Am. Brands, Inc.*, 117 Nev. 34, 16 P.3d 435 (Nev. 2001).

[5]*See also* La. Acts, No. 989, §2 (eliminating medical monitoring by statute after the courts had adopted it); *Lowe v. Philip Morris USA, Inc.*, 207 Or.App. 532, 142 P.3d 1079 (2006).

[6]*Trimble v. ASARCO, Inc.*, 232 F.3d 946, 962-63 (8th Cir. 2000) (Nebraska law); *Duncan v. Northwest Airlines, Inc.*, 203 F.R.D. 601, 605-06 (W.D. Wash. 2001) (Washington law); *Jones v. Brush Wellman, Inc.*, 2000 WL 33727733 (N.D. Ohio 2000) (Ohio law); *Thompson v. American Tob.* Co., 189 F.R.D. 544, 552 (D. Minn. 1999) (Minnesota law); *but see Allgood v. General Motors Corp.*, 2005 WL 2218371 (S.D. Ind. 2005)(denying motion to dismiss under Indiana law).

[7]*Norwood v. Raytheon Co.,* 414 F. Supp. 2d 659, 667 (W.D. Tex. 2006) ("the Texas Supreme Court would *follow the recent trend* rejecting medical monitoring") (emphasis added).

Engineered Materials, Inc., 445 F.3d 809 (5th Cir. 2006). The state Supreme Court held that in there is no cause of action under Mississippi law for a medical monitoring cause in the absence of a showing of current physical injury.[8]

Second, among "the jurisdictions generally permitting recovery of medical monitoring in the absence of physical injury, there is little unanimity in terms of explanations for departing from the traditional physical injury rule."[9] Beyond divergent policy rationales, those few states that do recognize medical monitoring do not agree on significant aspects of the doctrine. For example, courts have articulated different standards on the level of exposure necessary to trigger a claim, and the resultant degree of risk of future disease needed to support the claim. The states that have recognized the claim differ in whether medical monitoring ought to be a cause of action or a new remedy under existing torts. The courts vary in their analysis of the conduct element of the claim. They also diverge on the medical benefit that the requested medical monitoring must or should provide.[10]

Because the doctrine is so new in most jurisdictions, there have been insufficient opportunities for appellate courts to resolve such debates and evolve workable elements based on practical experience drawn from real-world fact patterns. The Council Draft attempts to resolve some of these material disagreements without the benefit of such experience, including whether medical monitoring is a cause of action or remedy. In the Comments and/or notes, it suggests possible resolution of other medical monitoring debates. For example, Comment c requires that the monitoring should improve the chance of beneficial medical intervention, although some medical monitoring jurisdictions do not require a clinical benefit. Whatever the appropriate resolution of these debates,

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[8] *Paz v. Brush Engineered Materials*, 2007 WL 14891 6 (Miss. Jan. 4, 2007).

[9] *Lowe*, 207 Or.App. at 539, 142 P.3d at 1083.

[10] Compare *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993), with *Redland Soccer Club, Inc. v. Dept. of Army*, 548 Pa. 178, 196 n.8, 696 A.2d 137, 146 n.8 (1997).

should medical monitoring be recognized by the Restatement, the fact remains that the Restatement would be adopting a doctrine that is both in growing disfavor *and* is in flux in the minority of states that employ it. A prudent course, therefore, might be to postpone consideration of medical monitoring claims until the states can provide a fuller living experiment to be drawn upon.

III. ARE THE "LIMITED CIRCUMSTANCES" IN §21 LIMITED ENOUGH?

Comment a to §21 states that medical monitoring would be available only "in what remain very limited circumstances." While, as discussed below, the comments do seek to contain somewhat the potentially broad reach of this novel claim, the section does not adequately recognize the potentially broad and arguably inappropriate reach of medical monitoring as formulated.

A. Needed Limits: Involuntary, Environmental Exposure Toxic Torts

Recent case law has rejected medical monitoring, even in states that recognize the doctrine, in contexts that are removed from the narrow policy origins of the notion – that is, involuntary, environmental exposures of confined populations to proven toxic substances. Several of the earliest, foundational cases cited in the Reporter's Note make clear that the remedy was designed to deal with such environmental exposures. *Friends For All Children*,[11] described in Illustration 3 of draft §21, involved plane crash survivors seeking monitoring for involuntary effects of sudden de-pressurization of the aircraft cabin. *Paoli Railroad Yard*[12] revolved around alleged PCB exposure to plaintiffs who were neighbors of the environmentally contaminated rail yard. *Ayers*[13] resulted from

[11] *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816 (D.C. Cir. 1984).
[12] *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990).
[13] *Ayers v. Township of Jackson*, 106 N.J. 557, 525 A.2d 287 (1987).

chemical contamination of plaintiffs' water supply, and held that medical monitoring is not a separate cause of action but, rather, a special tort remedy – a type of compensable damage available only if liability is established. Entitlement to the remedy is not automatic; rather, it is a special remedy that is not easily invoked.[14]

That medical monitoring ought to be limited to the involuntary, environmental toxic exposure context has been explored recently by a series of cases in New Jersey, one of the first jurisdictions to recognize a form of medical monitoring. In *Sinclair v. Merck & Co.*, 2005 WL 1278364 (N.J. Super. 2005), the trial court dismissed the medical monitoring claim against a prescription drug manufacturer on the grounds that the claim was appropriate only for the environmental toxic tort situation. The policy concerns regarding the latency periods, the lack of alternative remedies, the need to deter environmental polluters, and the absence of alternative remedies for the victims of a toxic tort, were not implicated in the context of the voluntary consumers of a prescription drug regulated by the FDA and prescribed by a learned intermediary charged by law to weigh the risks and benefits of the product. Similarly, in *Vitanza v. Wyeth*, 2006 WL 462470 (N.J. Super. 2006), the court dismissed the medical monitoring claims of plaintiffs who were consumers of hormone replacement therapy drugs. Although plaintiffs sought to distinguish *Sinclair* by alleging long latency periods, and relying in part on the state Consumer Fraud Act, the court observed that the "test was derived specifically for environmental tort actions" and that "medical monitoring is to be applied sparingly." The *Ayers* court had recognized medical monitoring in New Jersey in part because the nature of environmental tort actions made proving and establishing causation extremely difficult. This will not be the case in the context of drugs approved by the FDA, extensively clinically tested, and

[14] *Id.* at 606, 525 A.2d at 312 (stating "the cost of medical surveillance is a compensable item of damages"); *see also Theer v. Philip Carey Co.*, 133 N.J. 610, 627, 628 A.2d 724, 733 (1993)..

prescribed by physicians who know the plaintiffs' medical history and condition before and after taking the drug. Plaintiffs who voluntarily purchase and use a product know and can prove when and where they did so, and the dosage they were exposed to, through pharmacy records. "Medical monitoring was designed to fill a gap which doesn't exist here."[15]

More recently, the New Jersey appellate court vacated what it termed as the "carefully reasoned" trial court decision in *Sinclair*.[16] In doing so, the appeals court expressed no opinion as to the ultimate viability of plaintiffs' medical monitoring action. But the court found the dismissal to have prematurely terminated plaintiffs' opportunity to try to establish the existence of a legally cognizable claim. The matter was remanded for discovery and a hearing on the availability of compensation for medical monitoring in the drug context, in light of the significance and extent of plaintiffs' exposure to the alleged toxin, the drug's toxicity, the seriousness of the diseases for which the exposed plaintiffs were at risk, the level of increased risk presented, the value of early diagnosis, and "in light of relevant facts, science and policy."[17] The court admitted it lacked a factual foundation for making a determination as to "what, if any, relief is reasonable and necessary in the circumstances, bearing in mind that the remedy sought by plaintiffs cannot be easily invoked."[18] Clearly, the debate continues about the limited circumstances under which medical monitoring might be available, and the Restatement should not in any way act to truncate this debate.

If the Restatement is going to recognize a medical monitoring claim at this time, it should be limited to involuntary, environmental toxic torts. Voluntary use of medical or consumer products do not fit the policy rationale for the adoption of medical monitoring, and confound any finding that the risk of bodily harm was

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[15] 2006 WL 462470 at 9.
[16] *Sinclair v. Merck & Co., Inc.*, 389 N.J. Super. 493, 496, 913 A.2d 832, 834 (N.J. Super.A.D. 2007).
[17] *Id.* at 508, 913 A2d at 841.
[18] *Id.* at 509, 913 A.2d at 842, quoting *Thee*r, 133 N.J. at 627, 628 A.2d at 724.

created by the defendant. In the pharmaceutical context, all drugs are risky, at some dose, to some people. The FDA weighs the safety and efficacy of the drug in general, and the prescribing physician weighs the risks and benefits to the individual patient. Very often, had the physician not prescribed the product at issue, the doctor would have prescribed a competitive drug in the same class, carrying similar risks. Unless it is clear that the future bodily harm will come to all who use the drug (*i.e.,* that it is so risky that no reasonable doctor would ever prescribe it), the benefits of the product outweigh the risks to some patients, and the risk of future bodily harm should not be actionable in this non-injury context.

B. Needed Limits: Tortious Conduct

The immaturity of medical monitoring as a distinct theory is also exemplified by the confusion over the wrongful conduct element of the claim. In some jurisdictions, the plaintiff's exposure must be caused by a defendant's negligence; in others, undefined "tortuous conduct" by the defendant is required. In most, it is unclear what underlying torts, including strict liability and consumer fraud act claims, will serve as the predicate for a monitoring claim. If the Restatement is to endorse medical monitoring, it ought to make clear not only that wrongful conduct by the defendant is required, and that mere exposure to an allegedly harmful product sold or used by the defendant is not enough. It should also clarify what type of wrongful conduct will support the claim, and that the wrongful conduct must have a sufficient causal nexus to the plaintiff's need for medical monitoring. The need for clarity is underlined by the fact that each underlying tort may carry with it different affirmative defenses.

The Council Draft begins with the observation that a claim could exist "under general principles of negligence, strict liability, or products liability law," which is not further defined. That the action is available only when the actor would be liable to the claimant if actual bodily harm had occurred suggests that all

the elements of some certain type of underlying tort must be established. It would also apparently exclude consumer fraud and unfair and deceptive trade act claims, which are currently in vogue as a basis for medical monitoring claims because there is no liability for bodily harm under such acts. Yet, the Reporter's Note, at Section c, refers to "wrongful exposure" without elaboration, and Illustration 3 refers to the defendant being liable for a manifest injury again under undefined "principles of negligence or products liability law."

If the Restatement is to recognize medical monitoring, it should be on the basis of negligent conduct only. While strict liability may have its place in the governance of certain product safety issues, fault should be the basis of any claim that is an exception to the general rule that denies recovery for preventive expenses and that permits plaintiff to sue for the mere risk of injury and again when the injury manifests itself.

C. Needed Limits: Causation

Related to this is the confusion, even in the courts that recognize medical monitoring, over the meaning of the causation element of the claim. Does the defendant's conduct need to cause the exposure to the hazardous product, or the increased risk, or both? Must the defendant's conduct have caused the "need" for medical monitoring? When the claim requires proof of an underlying tort, must the plaintiff also show causation in some traditional sense akin to the showing required by the underlying tort?

Plaintiffs in actual medical monitoring cases have argued that any "negligent" conduct regarding the product containing the toxic agent is sufficient. Thus, the alleged causal chain runs: 1.) defendant commits some unreasonable act regarding a product; 2.) plaintiff uses the product; and 3.) use of the product entails a risk of future harm. In actual medical monitoring battles, plaintiffs have thus relied on negligence "in the air" – conduct that is related to the product but

not necessarily related to the plaintiffs' use of the product nor their alleged need for medical monitoring. It is enough, they assert, that use of the product caused their risk.

The Restatement Draft states that the medical monitoring must be required by a risk of harm created by the defendant. *See* §21(b); Comment a. At Comment c, the Draft notes that the defendant's conduct must place "the claimant in a position where monitoring is medically warranted." It should clarify that causation in the medical monitoring context involves two aspects. The creation of the risk of harm – if that is the language employed to carry the first aspect of the causation load – must be akin to causation in a traditional negligence context. The mere sale of a risky product is not the "creation of risk." Sale of a product as to which plaintiff can criticize some aspect of defendant's design, manufacture, or marketing, is not creation of the risk. Creation of the risk occurs when defendant's wrongful conduct creates the risk that plaintiff needs to be monitored for, both by creating (or negligently permitting) the hazard of the product and causing plaintiff to be exposed to the risk improperly. For example, when a drug company makes a medicine that has real and definite hazards (potential side effects) which it could theoretically be monitored for, it has not created the "risk" for purposes of this tort when the FDA has approved the drug for sale despite those risks. Also, if there is wrongful conduct with regard to the product, such as a misrepresentation as to its efficacy, but the plaintiff (or prescribing physician) did not rely on that representation and voluntarily encounters the risk, there is no causal link: the conduct may have created a risk in the abstract but did not create any risk to *this plaintiff*. It ought to be clear that this is not "creation of the risk." Secondly, the particular expense being sued for must be required by the risk, that is, damages causation.

Anything short of this view of causation would arguably violate the tenet that the defendant must have been liable to the claimant for the bodily harm had it

actually occurred – in which context it must be shown that the defendant is legally responsible for the defect in the product, that the product is capable of causing the harm alleged, that the defect caused the specific injury plaintiff suffered from, that plaintiff did not assume the risk, and that the damages flowed directly from the injury caused. Medical monitoring, which replaces the traditional injury element of a tort with a mere increased risk analysis, should not provide a lesser standard of causation.

D. Needed Limits: Risk of Future Bodily Harm

The Council Draft recognizes an action for monitoring expenses to prevent or mitigate a "risk of serious bodily harm." If the Restatement recognizes medical monitoring, it should clarify this "risk" element. Most jurisdictions do not, as echoed by the Draft in Comment b, require that the risk rise to such a level as to be certain, or even probable, absent intervention. The Draft, though, seemingly allows any level of risk to justify an award of medical monitoring. Even those jurisdictions that do recognize medical monitoring, and do not require that the future harm be certain, typically require more than a mere "risk" of future injury. Instead there must be a significant risk, a measurably increased risk, a medically significant risk, or the like. It is crucial for the section to not permit de minimis, insignificant, or essentially background level risks to support the cause of action.[19]

Secondly, it should be clarified that the risk that must be shown – whatever levels may attach to it – is the risk to an individual plaintiff created by the harmful exposure above and beyond the background level of risk for that outcome in a relevant population *and* above and beyond that created by other risk factors attendant to that particular plaintiff. To some degree this notion of "over and

[19] *See O'Neal v. Department of the Army*, 852 F. Supp. 327, 336 (M.D. Pa. 1994); *see Allgood v. General Motors Corp.*, 2006 WL 2669337 at 27 (S.D. Ind. 2006) ("abnormal" exposure is necessary to show "significant" exposure, beyond that normal for daily life, demonstrating that plaintiffs' need for monitoring exceeds that of the rest of the population).

above" may be indirectly reflected in the requirement in the Council Draft at §21(b) that the monitoring provide no other material benefit to the plaintiff. But it is more than that. Plaintiffs typically will allege that the monitoring regime must only be different from testing that would be given to the population at large, and that the risk to be shown is merely that, in general, use of a product may increase the risk in some of the people using the product. However, properly viewed, plaintiffs must do more than establish merely that a product generally causes an increased risk in some people who use it. Rather, plaintiffs should have to prove that the product sufficiently increased the risk of future disease in each particular plaintiff seeking medical monitoring. This is a crucial distinction, requiring more than a general, quasi-epidemiological, population-based analysis, entailing instead a plaintiff-particular showing akin to specific causation in the traditional tort context.[20]

E. Needed Limits: Expense is Required by the Risk

The language in §21(b) that the "expense is required by a risk of bodily harm," is perhaps the only language in the Draft that could possibly carry out three distinct and important functions. Further thought is warranted on the part of the Reporters as to whether this language is most suitable to carry all three, and if so, how to clarify this fact. First, as part of a proper causation element, as noted above, the defendant's negligent conduct must necessitate the medical monitoring. It is necessary but not sufficient that the defendant's conduct created the risk and caused plaintiff to suffer the risk. The risk of bodily harm created by the defendant must require the particular preventive expense being demanded. As alluded to in Comment b, the conduct must place the claimant in a position where monitoring is medically warranted. The monitoring proposed must be necessitated by the risk created by the defendant.

[20] *In re Prempro Products Liability Litigation*, 230 F.R.D. 555, 570 (E.D. Ark. 2005).

Second, for the expense to be "required" by the risk, there must be a scientific and medical underpinning to the monitoring regime requested. States that recognize the claim now typically require that the monitoring be reasonably medically necessary. Such an element goes beyond the issue of monitoring that is of only speculative medical value mentioned in Comment c to the section. That may cover the situation where plaintiffs are unable to show sufficiently certain proof of a clear value to the proposed testing. Public health experts, however, also routinely weigh the necessity, risks, and benefits of medical monitoring programs. Critical factors include whether monitoring can detect – reliably, accurately, and consistently – the disease earlier than it would otherwise be detected; whether early detection can improve mortality, as opposed to other less precise measures of outcome; whether available diagnostic testing itself has risks – either because it is invasive or because it has a high rate of "false positive" results that might lead to invasive follow-up testing; and economic costs.[21] Medical monitoring ought not be considered "required" if it does not meet this kind of criteria.

Medical monitoring proposals created for litigation may be touted as "required" by plaintiffs' experts, while containing testing not prescribed routinely by physicians in actual practice, and/or studied and rejected by the public health community. Indeed, plaintiffs' litigation-driven medical monitoring programs are frequently created by testifying experts who are not qualified to balance the risks of the monitoring versus the risk of the disease.[22] The danger here is creation of a cause of action for the prevention and treatment of disease through early detection that is at odds with the medical community's view on prevention. The Restatement should not risk recognizing a cause of action under which juries may routinely find "required" medical testing that is not routinely prescribed – and may be expressly rejected – by the medical standard of care.

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[21] *See* U.S. Preventive Services Task Force, Guide to Clinical Preventive Services (2006).

[22] *E.g., Allgood v. General Motors Corp.*, 2006 WL 2669337, at 30 (S.D. Ind. 2006) (summary judgment granted after rejection of expert opinions of plaintiffs' toxicologist and environmental health

Third, the language carries the notion of a relationship of cost to benefits of the medical monitoring program. The Draft appears to adopt a sliding scale where the probability of harm is balanced against the expense: a low level of risk may warrant medical monitoring when the probability is nevertheless sufficient to warrant the expense. Presumably, a low level of risk will justify only a low cost program. Such a notion is potentially inconsistent with the requirement that expense is required by the risk to the extent that even miniscule risks can justify modest programs. In a practical sense, such a balancing test is impossible for a jury to apply, at least without substantially more guidance. Should there be an economic, "Posner-esque" balancing of the lives that might be saved by the monitoring and the economic harm thereby avoided versus the cost of the monitoring program? Such a balancing of risk/probability of harm and the demanded expense may be unavailing in the courtroom, where plaintiffs will argue that any program is worth the cost – which wealthy defendants or their insurers will pay – if it may possibly save just one life. And defendants would be forced by this notion into the impractical and unenviable position of asserting that the economic costs of a program outweigh the remote chances that lives will be saved.

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expert; "no licensed medical doctor had reviewed the specific medical monitoring program").

IV. ARE THE COUNCIL DRAFT'S ATTEMPTS TO LIMIT THE ACTION LIKELY TO WORK, AS PRESENTLY FORMULATED?

A. Actual Use of the Remedy Provided

The Draft notes that the claimant must have incurred the expense or be certain to incur the expense. As a practical matter, plaintiffs in medical monitoring cases rarely have incurred any monitoring expenses (as distinguished, for example, from an asbestos abatement context for property damage). Thus, the analysis of this issue turns on the certainty of future expenses. Comment d to §21 suggests that a court should require the damages be used to procure insurance coverage for future medical monitoring or to be placed in a fund to cover those expenses as incurred. Insurance – the premium presumably calculated to reflect the chances plaintiffs will never even get the testing – would seem an improvement over the current windfall possibilities of lump sum damages. There may be some empirical issues regarding the actual availability of such insurance, which the courts have not yet explored.

Although courts have suggested (without mandating) the fund concept, *e.g.*, *Bower*,[23] plaintiffs typically seek traditional money damages with no restriction on how the funds are to be used. Indeed, the fund concept – designed to preclude windfall recoveries when plaintiffs do not actually incur testing costs – may raise as many questions as it answers. In contrast to claims involving present physical injury, which make it possible for courts to exercise a reasonable amount of control over the award of even future damages, medical monitoring involves plaintiffs who are not yet sick, may never get sick, may get sick from other causes, and/or may never undergo all or some of the testing awarded. At the least, the analysis of future medical monitoring costs will require an assessment of how long the

[23] *Bower v. Westinghouse Electric Corp.*, 522 S.E.2d 424 (W. Va. 1999).

individuals will live and will require monitoring, and possibly whether other cheaper, better, or more expensive procedures will become available. These uncertainties are compounded because there usually is no reliable data on the level of actual absent plaintiff interest in undergoing monitoring in the class action setting.

Given the ever-changing state of medical technology and science, the proper amount of future medical monitoring damages is often a matter of speculation. One of the reasons medical monitoring torts do not work is that the state of the medical art changes constantly. If the court is adjudicating a claim of plaintiffs who will not require the diagnostic testing to start for some years, or will require ongoing testing decades into the future, it will be impossible to assess with any confidence or reasonable certainty the screening procedures that will be available at the time plaintiffs will actually require them, let alone their cost. Think for example, of how CT scans and MRI's have replaced x-rays in some uses. Even when the "same" test is at issue, testing may become less invasive and more painless; the rates of false positives or negatives may be altered through technology as well.

Use of a fund may ensure that damages are paid only for examinations actually administered, but raises the prospect of huge rebates to defendant for unused funding. Otherwise, what happens when plaintiffs don't actually take the tests? A "pay as you go" option may make some sense, so that juries are not asked to speculate on top of speculation regarding future test costs and the number of participants. At bottom, the inherently speculative damages associated with medical monitoring, at least in a class context, argues against the Restatement draft rule.

B. Beneficial Intervention

The Draft's commentary that the monitoring must provide for a beneficial intervention is certainly a positive step away from, for example, the unsupported psychological musings of the *Bower*[24] court regarding the psychic "benefit" of testing that has no medical benefit. However, the section should be strengthened and clarified to meet the stated goal. Presently, the "prospect" that early diagnosis of a latent condition will improve the "chance" of beneficial medical intervention is insufficiently certain, resting on double possibilities: testing might provide early detection, and such detection might lead to beneficial medical intervention. While several courts require simply that testing may lead to early detection, it is crucial that early detection provide a reasonably clear medical benefit, not the mere theoretical chance.

Indeed, medical monitoring should be tied to a showing of medical benefit as required by the public health community. Typically, this would be an improvement in mortality, the gold standard used by the public health community when it judges screening. Plaintiffs should not be permitted to prevail when they show monitoring "extends lives," when all that has really happened is that the disease was detected earlier and thus the patient seemingly lives longer *post-detection*, but doesn't actually live any longer. Moreover, the medical benefit of the testing should not be assessed on the battle of hired "monitoring" experts alone, but on whether plaintiff has shown that the relevant medical standard of care would call for the specific testing program.

C. Indeterminate Liability

In one of its arguably most important, yet vague, aspects, §21(d) of the Council Draft requires that medical monitoring not be available when liability

[24] *Bower v. Westinghouse Electric Corp.*, 522 S.E.2d 424 (W. Va. 1999).

would be "indeterminate." Liability is indeterminate, according to the draft, when a potential liability is so uncertain in time, class, or amount that an actor cannot fairly or practically be expected to account for the potential liability in determining the conduct giving rise to the potential liability. It is observed that this is particularly true when the defendant's conduct exposes a large number of people to a risk of serious illness and the monitoring to detect the illness in an early stage might be medically desirable in any event. Comment e suggests a number of other ways in which liability may be deemed indeterminate: when it is uncertain whether the exposure necessitates the expense; or whether the expense provides some other benefit and the affected plaintiff can fairly be expected to bear the expense; or when liability might exceed the defendant's ability to pay damages and so reduce recovery of those actually harmed. Finally, the comment closes with the admonition that liability not be imposed when the liability would be unlimited and unpredictable.

Medical monitoring, by its nature and in practice, virtually always risks indeterminate liability. The Reporter's Note observes that in the few cases in which medical monitoring has been recovered, it has generally been by a very limited group of claimants. As a practical matter, the claim does not exist outside the class action context; very few individual medical monitoring claims have ever been brought or litigated. In the medical monitoring class context, liability virtually always is unlimited and unpredictable. Until the final stage of the litigation, class size is merely estimated for the limited purpose of assessing numerosity. Actual interest of absent class members in participating in the testing – which may itself be invasive and risky – is assumed without empirical basis. And the future-oriented nature of the relief begs several questions. What is the effect of a change in medical technology? If testing is approved by the jury as having met the appropriate standard, but is later shown not to improve health (as occurred with chest x-rays seeking to detect lung cancers), how is the monitoring halted? If

medicine evolves a new test that appears to work better, can plaintiffs sue again? Can a court somehow modify an existing award of medical monitoring and order defendant to pay more for tests that were not the subject of the trial? What showing would plaintiffs need to make to get new testing? If existing programs – designed to last for decades, given the latency periods of many diseases – are not modifiable to reflect changing state of the art, what good are they from a public health and tort policy perspective?

In addition to the testing side, other state of the art issues showing the indeterminate nature of medical monitoring generally are associated with the risk side. Unless medical monitoring is confined to situations in which claimants were exposed to a product proven hazardous at the time of sale, the tort creates the possibility that a product is reasonably safe when designed, manufactured and sold, but triggers massive liability when a risk is first recognized years later. In the drug context, pharmaceutical makers always face potential liability that is uncertain in time, class, and amount, such that they cannot fairly or practically be expected to account for the potential liability in determining the conduct giving rise to the potential liability, because their products are reviewed and approved by the FDA as safe and effective. The agency approves the warning and risk information of the label before sale, and the usage of the product is determined, in the first instance, by a learned intermediary who knows the product user. Such manufacturers cannot anticipate the scope of potential medical monitoring liability created by risks identified in post-marketing surveillance.

D. Statute of Limitation

Yet another difficulty with medical monitoring is the confusion that arises concerning the ripeness, staleness, and trigger of the statute of limitation regarding such a claim. In the traditional physical injury context, application of such principles is relatively straightforward. The clock typically starts ticking

either on the date the injury occurred, or at the time the plaintiff should have discovered the injury. Possibilities in the medical monitoring context include when the exposure reaches a significant level; when the plaintiff should have known of the harmful exposure; when the risk is discovered; when risk necessitates monitoring; when a reasonable physician would prescribe the monitoring regime; when the plaintiff actually undergoes monitoring; and others.[25]

Under the Draft, all such possibilities would seem available, as the defendant must be in the position of being liable if the bodily harm had occurred. If the statute of limitation has expired, arguably the actor would not be liable. But the language of the section adds other possibilities, including when the expense is first "required" by the risk, when the claimant has incurred or it first becomes certain the claimant will incur the expense, and even when the liability first becomes determinate. The absence of a clear trigger underscores the amorphous nature of the medical monitoring claim, and calls into question the recognition of the cause of action at all.

Moreover, the changing state of the art on medical science and technology impacts the claim in numerous ways, in addition to those mentioned above. Clearly a defendant should not have indefinite liability; yet, plaintiffs may argue that their medical monitoring claims are constantly timely as each perceived advance in medical technology can be argued to finally create medical monitoring that successfully detects the latent disease early and thus is "required." Each new

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[25]*State of West Virginia ex rel. Chemtall Inc. v. Madden*, 216 W.Va. 443, 607 S.E.2d 772 (2004) (medical monitoring cause of action accrues when plaintiff knows, or should know, that he or she has a significantly increased risk of contracting a particular disease due to significant exposure to a proven hazardous substance *and* the identity of the party that caused plaintiff's exposure to the hazardous substance); *with Redland Soccer Club, Inc. v. Dept. of Army*, 548 Pa. 178, 696 A.2d 137 (1997) (medical monitoring claim accrues when the plaintiff suffers a significantly increased risk of contracting a serious latent disease); *and Hoyte v. Stauffer Chemical Co.*, 2002 WL 31892830 (Fla.Cir.Ct. 2002) (limitations period for medical monitoring claim begins running when plaintiff knew or should have known that he had been exposed to chemicals and suspected that he could suffer disease as a result of that exposure).

study concerning the efficacy of early detection can be argued to finally make ripe the argument that monitoring will provide for beneficial intervention.

CONCLUSION

The Restatement should not at this time recognize a cause of action for medical monitoring. If it does so, it should be substantially revised to outline the limited circumstances under which it would be available, to clarify the necessary elements of the claim (including substantial exposure, significant risk, and causation), and to reflect the important role of a proper individual medical assessment of the monitoring regime.

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