

## Principles of the Law of Aggregate Litigation

### **PROPOSED AMENDMENT TO §2.04**

This amendment deletes current Illustrations 2-9 (from page 116, line 16 through page 120, line 9 of the Proposed Final Draft), and both rearranges and reduces the number of medical monitoring-related illustrations in §2.04. The amendment makes likewise changes the corresponding Reporters' Notes (from page 122, line 19 through page 124, line 35). It is proposed for several reasons:

- First, the level of treatment given this controversial cause of action is excessive, given that the ALI has never adopted medical monitoring as a cause of action in any Restatement or other project voted on by the membership, and state law is extremely divided on both the existence and scope of medical monitoring. Several of the current illustrations (Nos. 3-4, 6, 9) concern the legal or factual merits of the underlying claim, rather than aggregation.
- Second, whether and to what extent medical monitoring should be a recognized cause of action lies properly with the ongoing Third Restatement project concerning Economic Torts and Related Wrongs, and the extensive treatment here encroaches on that project.
- Third, the illustrations that remain should be reordered to reflect the most common legal outcome in the medical monitoring area, particularly under current legal trends, which is that the cause of action is not amenable to classwide determination due to individualized issues related to exposure and susceptibility.

#### **I. AMENDMENT TO ILLUSTRATIONS**

**[Proposed Revision to 116:16-120:9]**

##### **Illustration:**

2. Multiple consumers 1-100 allege that each of them is at a significantly elevated risk of future disease as a proximate result of wrongful exposure in excess of background exposure levels to a toxic substance for which Defendant is legally responsible. As relief, all consumers seek the establishment and funding by Defendant of a court-supervised program whereby all exposed consumers will receive medical monitoring for the future disease. Whether applicable substantive law requires present physical injury, or alternatively permits such an action in the

absence of physical injury, the aggregation decision is dependent upon an intermediate inquiry. That inquiry, however, turns on the individual circumstances of particular consumers – for instance, the magnitude of the exposure, the warnings (if any) provided to a given consumer, or whether the consumer bears some degree of legal responsibility for the exposure under principles of comparative fault. Where the intermediate inquiry is individualized, even if the requested remedy in fact respects the substantive law of the jurisdiction, the relief sought is not indivisible, nor would aggregate treatment be warranted. Due to the need for individualized inquiry, determining the existence of the remedy would not materially advance the resolution of consumers’ claims.

The availability of medical monitoring as a remedy, or as an independent claim, in the absence of other manifest injury, is controversial, with courts deeply divided. Initial acceptance of medical monitoring has waned, and the last decade has seen more states decline to recognize this new tort than adopt it. The ALI has never taken a position on whether recovery for medical monitoring should be permitted in these circumstances. These Principles take no position on medical monitoring as a matter of substantive law, except that adjudications should be conducted with fidelity to the law of the relevant jurisdiction as provided in §1.03(b).

Illustration 2 represents the most common outcome when class certification has been sought for medical monitoring claims, as many of the factors responsible for class actions falling into disfavor in mass-tort personal injury cases tend also to be present in litigation involving risk of personal injury.

**Illustration:**

3. Same situation as in Illustration 2, except: (1) the evidence to be offered by consumers in support of this allegation consists of epidemiological,

regulatory or other aggregate proof applicable to all consumers so exposed to the disputed toxic substance, (2) the connection between the elevated risk of future disease and exposure to the substance for which Defendant is legally responsible does not involve individualized inquiry into the circumstances of particular consumers, (3) all consumers allege that, in light of such exposure, a reasonable physician would prescribe a medical-monitoring regime above and beyond the medical services that such a physician otherwise would recommend, and (4) such monitoring will be instrumental in guiding medical intervention to mitigate the effects of disease manifestation, should disease ultimately occur. On these facts, if the requested remedy in fact respects the substantive law of the jurisdiction, then the court should find that the requested relief demands a form of performance other than the distribution of money to individual claimants. Medical monitoring with the capacity to guide medical intervention to mitigate the effects of disease differs from the distribution of money to compensate claimants for past harm where, as a practical matter the required program could not be administered so as to provide the specified medical monitoring only to some of the exposed consumers among those situated similarly. In accordance with §1.03, the court has discretion to characterize such a remedy as indivisible and, hence, capable of treatment on an aggregate basis. This characterization is irrespective of whether applicable substantive law treats medical monitoring as analogous to an injunction or to conventional damages.

Court supervision underscores the binding quality of the program vis-à-vis consumers, who receive the indicated additional medical services, not an award in the nature of damages that consumers may use as they choose. Judicial discretion is appropriate in this situation given the

almost limitless variations in underlying facts and in the details of requested medical monitoring programs.

**Illustration:**

4. Same situation as in Illustration 3, except that the requested remedy amounts to creation of a fund with a fixed amount of money equivalent to the anticipated cost of appropriate medical services, and ongoing court supervision to ensure that customers actually obtain the indicated medical services is minimal. If the court considers the relief sought to be fundamentally monetary in nature, it should characterize the remedy as divisible and thus not suitable for aggregate treatment under this Section. Though nominally cast as a demand for medical monitoring, the requested relief operates in practice in the manner of conventional damages. The limitation that any remedy be used exclusively to fund a medical-monitoring program is missing here, by comparison to the relief sought in Illustration 3.

As in Illustration 3 the basis of the court's action is framed in discretionary ("should") terms, reflecting the recognition that requested remedies, particularly in light of the court's evaluation of their importance in the overall scheme of relief sought, are subject to almost infinite variation.

**[Renumber current Illustration 10 as Illustration 5]**

**II. CORRESPONDING CHANGES TO REPORTERS' NOTES**

**[Proposed Revision to 122:19-124:35]**

Illustration 2 addresses the most common outcome in class certification decisions involving medical monitoring. The most frequent result, certainly in recent years, is for aggregation of medical monitoring claims to be denied on the ground that entitlement to such

monitoring is dependent upon individualized inquiry into the extent of class members' exposure to the substance, their susceptibility to relevant medical conditions, alternative causes for their increased risk, or individualized defenses such as comparative fault. Thus, the same individualized issues responsible for class actions generally "falling into disfavor" in mass-tort litigation frequently preclude class certification by making the resultant medical monitoring class insufficiently "cohesive" to justify the elimination of class members' right to opt out. See Reporters Notes to §1.02, at page 26 (lines 12-17).

In medical monitoring cases involving individualized issues, the remedy, assuming the cause of action exists under the law of the relevant jurisdiction, cannot be considered "indivisible" where its availability turns upon plaintiff-specific factors not common to the class. As a leading medical monitoring opinion described the problem:

While 23(b)(2) class actions have no predominance or superiority requirements, it is well established that the class claims must be cohesive. . . . [B]y its very nature, a (b)(2) class must be cohesive as to those claims tried in the class action. Because of the cohesive nature of the class, Rule 23(c)(3) contemplates that all members of the class will be bound. Any resultant unfairness to the members of the class was thought to be outweighed by the purposes behind class actions: eliminating the possibility of repetitious litigation and providing small claimants with a means of obtaining redress for claims too small to justify individual litigation. . . . We believe that addiction, causation, the defenses of comparative and contributory negligence, the need for medical monitoring and the statute of limitations present too many individual issues to permit certification. . . . These disparate issues make class treatment inappropriate.

Barnes v. American Tobacco Co., 161 F.3d 127, 143 (3d Cir. 1998) (internal citations and quotation marks omitted) (applying Pennsylvania law). This "cohesiveness" requirement is similar to but "more stringent" than the equivalent requirements of Rule 23(b)(3), given the Due Process implications of eliminating class members' opt out rights. E.g., Lienhart v. Dryvit Systems, Inc., 255 F.3d 138, 147 n.4 (4th Cir. 2001); Barnes, 161 F.3d at 142-43.

Similarly, the court in In re Welding Fume Products Liability Litigation, 245 F.R.D. 279, 311 (N.D. Ohio 2007), explained:

[I]n medical monitoring cases stemming from toxic spills or radioactive releases, the question of increased risk of injury . . . is virtually the same as the question of exposure – if the plaintiffs were exposed to a toxic material released by the defendant, then their risk of illness is higher. . . .

In this case, however, the allegedly hazardous substance to which the plaintiffs were exposed (manganese fumes) is released by a commonly-used and extremely useful product (welding rods), the sale and use of which requires no governmental dispensation. The parties experts agree, moreover, that not every exposure to manganese fumes is toxic; the level of exposure is critical to the question of whether an increased risk of illness occurs. And, the product came with warnings. Thus, whether the defendants were negligent . . . depends not simply on whether any given plaintiff suffered exposure, but on whether the warning supplied by the defendant sufficiently apprised the plaintiff of the risk of exposure. Similarly, whether a given plaintiff suffers an increased risk of illness . . . depends not simply on the fact of welding fume exposure, but on *the degree* of exposure, and whether there was more exposure than might have otherwise occurred *due to the failure of the warning*. These circumstances change dramatically the degree of typicality of evidence and issues among plaintiffs in this case, because of the great variety of products, manufacturers, warnings, employers, and workplaces involved.

Id. at 309-10 (footnote omitted) (emphasis original).

Particularly after Barnes, large numbers of medical monitoring class actions have failed the test of class certification because the presence of individualized issues as discussed in Illustration 2. See Wilson v. Brush Wellman, Inc., 817 N.E.2d 59, 66 (Ohio 2004) (class decertified; medical monitoring claim not cohesive due to “multiple individual questions of fact requiring examination for different plaintiffs”); Lockheed Martin Corp. v. Superior Court, 63 P.3d 913, 921-22 (Cal. 2003) (class decertified; due to “actual dosages and variations in individual response,” “causation and damages issues. . . must be counted among those that would be litigated individually”); Baker v. Wyeth-Ayerst Laboratories, 992 S.W.2d 797, 802 (Ark. 1999) (denial of certification of medical monitoring class affirmed; “common issues will depend upon individual differences among the plaintiffs such as when they took the drug, the duration of

use, the quantity taken, the combination used, their medical history and condition at the time of use, and the state of the art at the time the drugs were marketed”); Buynie v. Airco, Inc., 2007 WL 2275013, at \*6 (N.J. Super. A.D. Aug 10, 2007) (denial of certification affirmed; medical monitoring “depends on. . .the likelihood of disease, the significance and extent of exposure to a toxic substance, the toxicity of the substance, the seriousness of the diseases associated with exposure to the substances, and the value of early diagnosis”); Wyeth, Inc. v. Gottlieb, 930 So.2d 635, 640-41 (Fla. App. 2006) (denial of class certification affirmed; “causation is a highly individualistic determination that depends on the individual characteristics of a putative class member, the duration of. . .ingestion, and whether that member was taking other medication”); Goasdone v. American Cyanamid Corp., 808 A.2d 159, 170 (N.J. Super. L.D. 2002) (medical monitoring claim could not be certified due to “the significance and extent of exposure by each class member to defendants' products, and whether medical monitoring is reasonable and necessary for each class member based on the class member's unique medical history”); In re St. Jude Medical, Inc., 522 F.3d 836, 840 (8th Cir. 2005) (class decertified; “plaintiffs request the highly individualized remedy of medical monitoring”); In re St. Jude Medical, Inc., 425 F.3d 1116, 1121-22 (8th Cir. 2005) (class decertified; need for medical monitoring is necessarily an “individualized inquiry depending on that patient’s medical history, the condition of the patient’s heart valves at the time of implantation, the patient’s risk factors for heart valve complications, the patient’s general health, the patient’s personal choice, and other factors”); Ball v. Union Carbide Inc., 385 F.3d 713, 726-28 (6th Cir. 2004) (denial of class certification affirmed; claims too individualized given differences in “total exposure time, exposure period, medical history, diet, sex, age, and a myriad of other factors”); Zinser v. Accufix Research Institute, Inc., 253 F.3d 1180, 1192 (9th Cir. 2001) (denial of class certification affirmed; “it may be difficult to establish a common cause of injury because many factors may contribute to [the alleged defect],

including manufacturing and shipping history and handling of the lead by physicians or staff”), amended, 273 F.3d 1266 (9th Cir. 2001); Rhodes v. E.I. du Pont de Nemours & Co., 253 F.R.D. 365, 375-80 (S.D.W. Va. 2008) (class certification denied; exposure, significantly increased risk, and need for monitoring cannot be proven on a class-wide basis); In re Fosamax Products Liability Litigation, 248 F.R.D. 389, 400 (S.D.N.Y. 2008) (denying certification; liability turns on each “user’s unique medical history and the circumstances surrounding his or her use, the Court is not satisfied that the need for the proposed monitoring program could be proven on a class-wide basis”); Rowe v. E.I. duPont de Nemours & Co., 2008 WL 5412912, at \*17-20 (D.N.J. Dec. 23, 2008) (medical monitoring class could not be certified due to “the plethora of individualized issues underlying the risk of disease issue”); Leib v. Rex Energy Operating Corp., 2008 WL 5377792, at \*12 (S.D. Ill. Dec. 19, 2008) (“[t]he level of individualized inquiry is far greater in a medical monitoring cause of action”); Welding Fume, 245 F.R.D. at 311 (denying certification because “[i]n light of the different welding products, warnings, employers, work environments, and so on,” “there is ultimately no single course of conduct by all of the defendants”); In re Aredia & Zometa Products Liability Litigation, 2007 WL 3012972, at \*5 (M.D. Tenn. Oct. 10, 2007) (“individual issues, such as causation or individual defenses,. . . preclude class certification” of medical monitoring claims); In re Prempro Products Liability Litigation, 230 F.R.D. 555, 570-73 (E.D. Ark. 2005) (certification denied because “[n]o matter how you cut it, cube it, or slice it, Plaintiffs cannot overcome the problems with individual issues of law and fact, which eclipse any possible common questions or cohesion among their claims”); Perez v. Metabolife International, Inc., 218 F.R.D. 262, 270-73 (S.D. Fla. 2003) (certification denied because “individualized inquiries would still be required to assure that the medical monitoring elements were met with respect to each class member”); In re Baycol Products Litigation, 218 F.R.D. 197, 212 (D. Minn. 2003) (“a finding of negligence is

inextricably intertwined with individual issues”; “individual issues will undermine the cohesion of the medical monitoring class”); Zehel-Miller, 223 F.R.D. at 664 (certification denied due to “individual questions concerning patient characteristics and medical history, physician involvement, dosage, causation and comparative or contributory negligence”); Harris v. Purdue Pharma, L.P., 218 F.R.D. 590, 597 (S.D. Ohio 2003) (class certification denied; “case is riddled with individual issues concerning how the alleged marketing affected the judgment of physicians, how resulting prescriptions affected patients, how some patients allegedly used the drug improperly, and how, at the very least, some eighty-percent of those prescribed the drug have not had nor will have an adverse reaction”); In re Baycol Products Liability Litigation, 218 F.R.D. 197, 213 (D. Minn. 2003) (“class members took [the product] at different times, in different amounts, with different co-prescriptions and with different medical backgrounds”); In re Paxil Litigation, 212 F.R.D. 539, 548 (C.D. Cal. 2003) (certification of medical monitoring and other subclasses denied; product taken at “various times, with different dosages, and for different underlying ailments”; “the symptoms and injuries allegedly suffered by the plaintiffs vary from individual to individual”); In re Rezulin Products Liability Litigation, 210 F.R.D. 61, 75 (S.D.N.Y. 2002) (medical monitoring class not cohesive where “it’s up to each clinician to decide whether he wants to put his patients through a monitoring program or not”); In re Propulsid Products Liability Litigation, 208 F.R.D. 133, 147 (E.D. La. 2002) (certification denied because “variations involving proof of causation, the effect of warnings, the significance of the defendants’ direct marketing to consumers, and other similar issues may swamp any common issues and defeat cohesiveness”); In re Methyl Tertiary Butyl Ether (“MTBE”) Products Liability Litigation, 209 F.R.D. 323, 343-44 (S.D.N.Y. 2002) (differences in individual sensitivity, level of contamination, and proximity to contamination “would require even more far-ranging investigation to determine appropriate remediation”); Lewallen v. Medtronic USA,

Inc., 2002 WL 31300899, at \*4 (N.D. Cal. Aug 28, 2002) (medical monitoring class not certified; “Each patient’s medical history is different, as are each patient’s risk factors. Each treating physician's determination is different.”); Duncan v. Northwest Airlines, Inc., 203 F.R.D. 601, 612-13 (W.D. Wash. 2001) (certification denied where putative class members “worked. . .for different time periods, who may have smoked, who may have immediate family members who smoke, and who have different medical backgrounds”); Rink v. Cheminova, Inc., 203 F.R.D. 648, 659, 665 (M.D. Fla. 2001) (certification denied; medical monitoring is “fraught with individualized issues that dictate the member’s entitlement to and the need of monitoring”), app. dismissed, 400 F.3d 1286 (11th Cir. 2004); O’Connor v. Boeing North American, Inc., 197 F.R.D. 404, 413 (C.D. Cal. 2000) (monitoring class decertified; “individual variances could require substantial litigation about whether, or to what extent, each of the class members could participate in the medical-monitoring program”); Thompson v. American Tobacco Co., 189 F.R.D. 544, 557 (D. Minn. 1999) (the “‘cohesiveness’ requirement. . .precludes certification when individual issues abound”); Blaz v. Galen Hospital, Inc., 168 F.R.D. 621, 625 (N.D. Ill. 1996) (certification denied; “variations among individuals with respect to exposure and effects can vitiate a finding of typicality”); Hurd v. Monsanto Co., 164 F.R.D. 234, 239-41 (S.D. Ind. 1995) (certification denied; “no single happening or accident occurred at [the plant] causing identical harms to each putative class member. Rather, each plaintiff was exposed to different levels of [the toxic substance] for different amounts of time in different areas of the plant. Each putative class member’s susceptibility to injury from [the toxic substance] will vary. Thus, no single proximate cause inquiry applies equally to each putative class member; no one set of operative facts establishes liability.”); Thomas v. FAG Bearings Corp., Inc., 846 F. Supp. 1400, 1404 (W.D. Mo. 1994) (certification denied; “individual issues of causation and damage. . .will require individualized proof for each plaintiff”); Brown v. SEPTA, 1987 WL 9273, at \*13 (E.D.

Pa. April 9, 1987) (“entitlement to this type of relief will depend on individualized questions of causation and personal medical history”).

Illustration 3 recognizes that there are cases holding that medical monitoring classes can be certified where individualized issues are not salient, often because the standards for relevant medical monitoring are undisputed. These cases find that the position of the medical monitoring remedy along the law-equity divide, while important for other purposes, does not by itself change the characterization of that remedy for purposes of a court’s aggregation decision. Instead, courts look to the relief that is actually being sought and how that relief would function. Relief dependent upon classwide determinations, rather than individual circumstances can be characterized as “indivisible”:

The principal fallacy in the defendants’ position is the failure to recognize the important distinction between a common unitary claim by a class as a whole for the establishment of a single unitary fund or program, and the aggregated actions of several different, distinct claims of individuals for individualized damage awards. Pursuant to the jury’s verdict, no specific judgment or allocation for . . .any individual class member was made. The only claim that any of the remaining plaintiffs have is the right to apply for participation in [the] program from the established fund.

Scott v. American Tobacco Co., 949 So.2d 1266, 1285 (La. App. 2007). While Scott was not technically about medical monitoring, but rather involved relief in the form a smoking cessation program, the principle is the same. As described, the relief in Scott functioned in an indivisible fashion, as it was not dependent upon the individual circumstances of class members.

Whether a proposed medical monitoring remedy is “indivisible” has often turned on “the fine distinction between a medical monitoring claim that seeks monetary relief in the form of compensatory damages and a medical monitoring claim that seeks injunctive relief in the form of a court-supervised medical monitoring program. Arch v. American Tobacco Co., 175 F.R.D. 469, 483 (E.D. Pa. 1997). As one court explained through a series of examples:

Relief in the form of medical monitoring may be by a number of means. First, a court may simply order a defendant to pay a plaintiff a certain sum of money. The plaintiff may or may not choose to use that money to have his medical condition monitored. Second, a court may order the defendants to pay the plaintiffs' medical expenses directly so that a plaintiff may be monitored by the physician of his choice. Neither of these forms of relief constitute[s] injunctive relief. . . .

However, a court may also establish an elaborate medical monitoring program of its own, managed by court-appointed court-supervised trustees, pursuant to which a plaintiff is monitored by particular physicians and the medical data produced utilized for group studies. In this situation, a defendant, of course, would finance the program as well as being required by the court to address issues as they develop during program administration. Under these circumstances, the relief constitutes injunctive relief. . . .

Day v. NLO, Inc., 144 F.R.D. 330, 335-36 (S.D. Ohio 1992), rev'd on other grounds, 5 F.3d 154 (6th Cir. 1993). A number of courts have reached similar results: Meyer v. Fluor Corp., 220 S.W.3d 712, 719 (Mo. 2007) (“the common fact of exposure to a set of toxins from a single source that is the common and overriding issue” where theory of “liability is premised upon the exposure to toxins from a single source during a specified age range”); In re West Virginia Rezulin Litigation, 585 S.E.2d 52, 72-73 (W.Va. 2003) (allowing certification of monitoring claims involving “idiosyncratic reaction[s]” that were “not related to the dose taken by each patient”); Olden v. LaFarge Corp., 383 F.3d 495, 508 (6th Cir. 2004) (medical monitoring certification affirmed; individual medical and property damage issues were “minor” and no alternative exposure sources established); Mejdrech v. Met-Coil Systems Corp., 319 F.3d 910, 911-12 (7th Cir. 2003) (medical monitoring issue certification affirmed; the “first question is particularly straightforward” and “the second only slightly less so”); Gasperoni v. Metabolife, International, Inc., 2000 WL 33365948, at \*7 (E.D. Mich. Sept. 27, 2000) (medical monitoring “does not create individualized issues in the present case”); Josephat v. St. Croix Alumina, LLC, 2000 WL 1679502, at \*11 (D.V.I. Aug. 7, 2000) (“individual issues in this case will not interfere with the proof required by the above medical monitoring elements”); Elliott v. Chicago Housing

Authority, 2000 WL 263730, at \*15-16 (N.D. Ill. Feb. 28, 2000) (defendant allegedly failed to comply with regulatory monitoring standards; “a court-supervised medical monitoring program through which class members will receive periodic examinations may be properly characterized as seeking injunctive relief”); In re Diet Drugs Products Liability Litigation, 1999 WL 673066, at \*6, \*11 (E.D. Pa. Aug. 26, 1999) (monitoring program that included notification and statistical analysis in addition to testing was “equitable in nature”; monitoring recommendations from independent medical societies provided cohesiveness); In re Telectronics Pacing Systems, Inc., 172 F.R.D. 271, 285-86 (S.D. Ohio 1997) (defendant conceded necessity of monitoring for entire class; medical monitoring properly considered injunctive where administratively-imposed relief might conflict and a “research program is a uniform benefit to the class”), decertified on reconsideration, 168 F.R.D. 203 (S.D. Ohio 1996); German v. Federal Home Loan Mortgage Corp., 885 F. Supp. 537, 554, 560 (S.D.N.Y. 1995) (medical monitoring class conditionally certified; “specific types of situations can be resolved by the designation of sub-classes” or decertification; “plaintiffs have presented a colorable claim for medical monitoring as injunctive relief”), reargument granted on other grounds, 896 F. Supp. 1385 (S.D.N.Y. 1995); Gibbs v. E.I. duPont de Nemours & Co., 876 F. Supp. 475, 477, 481 (W.D.N.Y. 1995) (adequacy of defendant’s existing medical monitoring program at issue; remedy “extended beyond individual monitoring to data compilation and analysis and other pooling of resources”; postponing consideration of individualized issues); Day v. NLO, Inc., 851 F. Supp. 869, 884 (S.D. Ohio 1994) (“No matter how individualized the issue of damages may be, these issues may be reserved for individual treatment”; certification of non-opt-out class “most appropriate” as “use of the Court’s injunctive powers to oversee and direct medical surveillance is vastly superior to a lump sum monetary payment”); Yslava v. Hughes Aircraft Co., 845 F. Supp. 705, 712-13 (D. Ariz. 1993) (“factual commonality exists” due to geographically specific subclasses; “court-

supervised program requiring ongoing, elaborate medical monitoring” held indivisible); Boggs v. Divested Atomic Corp., 141 F.R.D. 58, 67 (S.D. Ohio 1991) (“need for medical monitoring...would be virtually identical”); medical monitoring claim certified as “an entitlement to injunctive relief, [that] would undoubtedly be in the form of a complex order, addressing many specific features”); Barth v. Firestone Tire & Rubber Co., 673 F. Supp. 1466, 1478 (N.D. Cal. 1987) (medical monitoring fund to gather and disseminate information about diagnosis and treatment of diseases possibly linked to toxin with unknown effects was only available in equity); cf. In re Copley Pharmaceutical, Inc., 158 F.R.D. 485, 492 (D. Wyo. 1994) (certifying individual legal issues related to medical monitoring as limited class).

Illustration 3 also specifies that the characterization of medical monitoring relief as “indivisible” is discretionary, rather than mandatory. Judicial discretion is consistent with the general principles recognized in §1.03 and §202(a). E.g. §2.02, comment a (recognizing “the bedrock point that aggregate treatment in litigation is a matter of judicial discretion that flows from the general authority of courts to exercise early and effective supervision of litigation”). Discretion is appropriate in light of the gradations in medical monitoring remedies described in the cases, from little more than a mandatory injunction to pay money to “elaborate” plans envisioning ongoing judicial supervision, and in evaluating if the background facts justify such certification, as successfully certified medical monitoring class actions have often involved situations where, for one reason or another, the standards for monitoring are not in dispute.

At present there is case law in both directions on the certification of class actions for medical monitoring. Surveying the case law, the court observed in Welding Fume:

[T]here is no common set of factual circumstances predictive of whether a court will certify a medical monitoring class. It is easy to find cases, for example, where a court *granted* class certification to plaintiffs in a limited geographic region who sought medical monitoring after suffering single-source exposure to a toxin in their drinking water, and just as easy to find cases where a court *denied*

certification under similar conditions – and there is no obvious or simple way to reconcile the two different results. Similarly, courts have ruled oppositely in different cases involving plaintiff classes seeking medical monitoring for illnesses allegedly caused by: (1) addiction to nicotine in the same brands of cigarette; and (2) adverse side effects of the same prescription drug.

245 F.R.D. at 304 (citing illustrative cases) (emphasis original).

Illustration 4 represents those cases in which courts have concluded that the non-monetary aspects of claimed medical monitoring remedies were essentially window dressing for what were, at bottom, claims for money damages. Numerous cases address situations in which a claim ostensibly for medical monitoring does not actually seek indivisible relief, but is instead “essentially a suit for damages” that is not properly certified as a mandatory class action, if at all. Building & Construction Department, AFL-CIO v. Rockwell International Corp., 7 F.3d 1487, 1492 (10th Cir. 1993). The characterization of a remedy as “indivisible” has significant Due Process implications, because if a medical monitoring claim is little more than a disguised request for monetary damages, treating it as indivisible relief would deprive putative class members of constitutional rights to opt out of aggregated litigation.

To amount to an “indivisible” remedy, the degree of ongoing judicial involvement in overseeing a medical monitoring program must be significant, and conversely, monetary relief cannot be the plaintiffs’ “primary” objective. See Wilson, 817 N.E.2d at 65 (medical monitoring class decertified; demand that defendant “pay for a reasonable medical surveillance and screening program” sought monetary remedy; adopting “bright line test” requiring “[c]ourt supervision and participation in medical-monitoring cases”); Philip Morris Inc. v. Angeletti, 752 A.2d 200, 252-53 (Md. 2000) (denial of certification of medical monitoring class affirmed; “[c]alling such payment ‘injunctive relief’ does not change the status of the claim from that of a fundamentally monetary nature”); Jaffee v. United States, 592 F.2d 712, 715 (3d Cir. 1979) (denial of certification of medical monitoring class affirmed; a “request for prompt medical

examinations. . .cannot transform a claim for damages into an equitable action”); Zinser, 253 F.3d at 1196 (denial of certification of medical monitoring class affirmed; medical monitoring claim that merely requested funding for future treatment and damages properly viewed as involving divisible monetary remedy); Mehl v. Canadian Pacific Railway Ltd., 227 F.R.D. 505, 519-20 (D.N.D. 2005); Rezulin, 210 F.R.D. at 72-73 (without evidence of the cost of medical monitoring or “its value to individual class members” the equitable nature of medical monitoring cannot be established); Lewallen, 2002 WL 31300899, at \*3 (non-monetary aspects of medical monitoring claim held “merely incidental to the primary claim for money damages”); Duncan, 203 F.R.D. at 611 (plaintiff’s “seek[ing] individual damages. . .distinguishes the proposed relief from pure monitoring programs”); Dhamer v. Bristol-Myers Squibb Co., 183 F.R.D. 520, 529 (N.D. Ill. 1998) (certification of medical monitoring class denied; “the ultimate relief requested is in the form of money damages which when taken along with plaintiff’s other claims for money, demonstrate that money damages is the predominant relief sought”); Cook v. Rockwell International Corp., 181 F.R.D. 473, 479-80 (D. Colo. 1998) (class decertified; the “crux of the action is for money damages”); Reilly v. Gould Inc., 965 F. Supp. 588, 593-94 (M.D. Pa. 1997) (“constructive trust” for medical monitoring was not common equitable relief where facility had been closed for many years, thereby eliminating need for injunction); O’Connor v. Boeing North American, Inc., 180 F.R.D. 359, 378 (C.D. Cal. 1997) (medical monitoring program that “involve[d] payments by the defendants for treatment of disease” and “also sought compensatory and punitive damages” could not be considered equitable); Smith v. Brown & Williamson Tobacco Corp., 174 F.R.D. 90, 100 (W.D. Mo. 1997) (certification of medical monitoring class denied; “the relief requested is in the form of money which. . .demonstrates that monetary relief is the predominate relief sought”); Harding v. Tambrands, 165 F.R.D. 623, 632 (D. Kan. 1996) (certification of medical monitoring class denied; “the relief sought by plaintiffs is primarily

money damages”); Thomas, 846 F. Supp. at 1404 (certification of medical monitoring class denied; “future costs of medical monitoring” were nothing more than a form of monetary compensation); Copley Pharmaceutical, 158 F.R.D. at 490-91 (refusing to certify non-opt out class; declaratory relief “incidental” to medical monitoring demand for a fund; primary remedy was damages); Abbent v. Eastman Kodak Co., 1992 WL 1472751, at \*13 (D.N.J. Aug. 28, 1992) (certification of medical monitoring class denied; request for fund was “monetary”); Werlein v. United States, 746 F. Supp. 887, 895 (D. Minn. 1990) (medical monitoring claim with “no provisions for anything besides an exchange of money” into a reimbursement fund was divisible monetary remedy; “[p]ayment of cash by one party to reimburse other parties for costs incurred is not injunctive relief”), vacated in part on other grounds, 793 F. Supp. 898 (D. Minn. 1992).

**[Proposed Revision to 124:42]**

Illustration 5 . . . .

**[Proposed Revision to 125:23]**

The approach to aggregation outlined in Illustration 5 . . . .

**[Proposed Revision to 125:31]**

§ 2.03(b). Illustration 5 . . . .

**LEGAL JUSTIFICATION FOR AMENDMENT**

**I. THE INSTITUTE HAS NOT TAKEN A POSITION ON MEDICAL MONITORING CLAIMS.**

The ALI’s only prior treatment of medical monitoring is a reporter’s study, “Enterprise Responsibility for Personal Injury,” at 369-75 (1991), which was never voted on by the membership. Medical monitoring is a subject of the ongoing Restatement Third of Torts project. See Restatement of the Law Third, Economic Torts and Related Wrongs, Preliminary Draft No. 2 §21 (May 15, 2006). Comment a to that draft states:

Several reasons explain why the law typically does not allow recovery of a preventive expense though it would allow recovery for the bodily harm that necessitates the expense should bodily harm become manifest: When an expense provides other material benefits to the claimant allowing recovery of the entire expense would give the plaintiff a windfall. . . . When the claimant has not yet incurred the expense there is a concern that funds recovered will be used for another purpose. . . . Claims for preventive expense sometimes raise the problem of indeterminate liability. This is particularly true when the defendant's conduct exposes a large number of people to a risk of developing serious illness. . . .

## **II. THE EXISTENCE OF CLAIMS FOR MEDICAL MONITORING IN THE ABSENCE OF PRESENT INJURY IS CONTROVERSIAL.**

As the Reporters' Notes to the draft Restatement of the Law Third, Economic Torts and Related Wrongs §21, comment a observed in 2006, "Courts are split on the viability of an action for medical monitoring expenses." That split has only continued to grow wider. Many states do not recognize a medical monitoring cause of action at all, and others do so only in limited situations. See, e.g., Herbert L. Zarov, Sheila Finnegan, Craig A. Woods & Stephen J. Kane, "A Medical Monitoring Claim for Asymptomatic Plaintiffs: Should Illinois Take the Plunge?" 12 DePaul J. Health Care L. 1 (2009); Victor E. Schwartz, Leah Lorber & Emily J. Laird, "Medical Monitoring: The Right Way & the Wrong Way," 70 Mo. L. Rev. 349 (2005); James A. Henderson, Jr. & Aaron D. Twerski, "Asbestos Litigation Gone Mad: Exposure-Based Recovery for Increased Risk, Mental Distress & Medical Monitoring," 53 S.C.L. Rev. 815 (2002); Victor E. Schwartz, Mark A. Behrens, Emma Tubb & Jennifer Groninger, "Medical Monitoring – Should Tort Law Say Yes?," 34 Wake Forest L. Rev. 1057 (1999). The current state of the law is splintered, with 13 jurisdictions recognizing, or predicted to recognize, medical monitoring in the absence of present injury in at least some circumstances;<sup>1</sup> federal common law and 21

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<sup>1</sup> Several sources mention an unavailable Montana trial court opinion as supporting medical monitoring, see Lamping v. American Home Products, Inc., No. DV-97-85786 (Mont. 4th Dist. Feb. 2, 2000).

jurisdictions refusing to recognize, or predicted as refusing to recognize, medical monitoring; and 4 jurisdictions subject to conflicting precedent:

**Federal Common Law:** Medical monitoring is not a viable theory of liability. Metro-North Commuter Railroad Co. v. Buckley, 521 U.S. 424, 441-44 (1997); see Norfolk & Western Railway. Co. v. Ayers, 538 U.S. 135, 156-57 (2003) (*dictum* reaffirming Metro-North).

**Alabama:** Alabama law does not recognize independent claims for medical monitoring. Houston County Health Care Authority v. Williams, 961 So.2d 795, 811 (Ala. 2007); Hinton v. Monsanto Co., 813 So.2d 827, 830-31 (Ala. 2001).

**Arizona:** Arizona law recognizes independent claims for medical monitoring in environmental torts. Burns v. Jaquays Mining Co., 752 P.2d 28, 33-34 (Ariz. App. 1987), review dismissed, 781 P.2d 1373 (Ariz. 1989).

**California:** California law recognizes medical monitoring as a remedy “when liability is established under traditional tort theories of recovery.” Potter v. Firestone Tire & Rubber Co., 863 P.2d 795, 822-23 (Cal. 1993).

**Colorado:** A federal court has predicted that Colorado law would recognize an independent medical-monitoring claim for environmental torts. Cook v. Rockwell International Corp., 755 F. Supp. 1468, 1477 (D. Colo. 1991).

**Connecticut:** Connecticut law has only adopted medical monitoring in Workers Compensation. Doe v. City of Stamford, 699 A.2d 52, 55 & n.8 (Conn. 1997). Otherwise medical monitoring has not been recognized under Connecticut law. Bowerman v. United Illuminating, 1998 WL 910271, at \*10 (Conn. Super. Dec. 15, 1998) (rejecting independent claim for medical monitoring); Martin v. Shell Oil Co., 180 F. Supp.2d 313, 323 (D. Conn. 2002) (open question).

**Delaware:** The Delaware Supreme Court rejected, but did not rule out, medical monitoring in asbestos litigation. Mergenthaler v. Asbestos Corp., 480 A.2d 647, 651 (Del. 1984). Medical monitoring was recently permitted under an estoppel theory (the defendant admitted the need for monitoring) in the absence of any underlying tort. Guinan v. A.I. duPont Hospital for Children, 597 F. Supp.2d 517, 538-40 (E.D. Pa. 2009) (applying Delaware law); Hess v. A.I. Dupont Hospital for Children, 2009 WL 595602, at \*12-13 (E.D. Pa. March 5, 2009) (applying Delaware law).

**District of Columbia:** Federal courts have predicted that District of Columbia law would recognize medical monitoring as an equitable remedy, but not as damages in product liability litigation. Friends for All Children, Inc. v. Lockheed Aircraft Corp., 746 F.2d 816, 837-38 (D.C. Cir. 1984) (equitable remedy); Witherspoon v. Philip Morris Inc., 964 F. Supp. 455, 467 (D.D.C. 1997) (rejecting separate medical monitoring in product liability action).

**Florida:** Florida law allows independent claims for medical monitoring in negligence, but not strict liability. Petito v. A.H. Robins Co., 750 So.2d 103, 106-07 (Fla. App. 1999); Zehel-Miller v. Astrazenaca Pharmaceuticals, LP, 223 F.R.D. 659, 663-64 (M.D. Fla. 2004).

**Georgia:** A federal court has predicted that Georgia law would not recognize an independent claim for medical monitoring. Parker v. Brush Wellman, Inc., 377 F. Supp.2d 1290, 1302 (N.D. Ga. 2005), aff'd, 230 Fed. Appx. 878, 883 (11th Cir. 2007).

**Guam:** A federal court has predicted that Guam law would recognize an independent claim for medical monitoring. Abuan v. General Electric Co., 3 F.3d 329, 334 (9th Cir. 1993).

**Illinois:** Illinois law is split, with courts both recognizing and rejecting an independent claim for medical monitoring. Compare Stella v. LVMH Perfumes & Cosmetics USA, Inc., 564 F. Supp.2d 833, 836 (N.D. Ill. 2008); Gates v. Rohm & Haas Co., 2007 WL 2155665, at \*4-5 (E.D. Pa. July 26, 2007) (applying Illinois law); Muniz v. Rexnord Corp., 2006 WL 1519571, at \*6-7 (N.D. Ill. May 26, 2006); Carey v. Kerr-McGee Chemical Corp., 999 F. Supp. 1109, 1119 (N.D. Ill. 1998) (all recognizing medical monitoring), with Jensen v. Bayer AG, 862 N.E.2d 1091, 1100-1101 (Ill. App. 2007) (medical monitoring claims “lack merit”); Lewis v. Lead Industries Ass’n, Inc., 793 N.E.2d 869, 877 (Ill. App. 2003) (rejecting medical monitoring as independent equitable remedy); Campbell v. A.C. Equipment Services Corp., Inc., 610 N.E.2d 745, 748 (Ill. App. 1993) (decision “should not be construed as recognizing” medical monitoring); Guillory v. American Tobacco Co., 2001 WL 290603, at \*7 (N.D. Ill. 2001) (rejecting medical monitoring).

**Indiana:** Indiana law is split, with courts both allowing and rejecting an independent claim for medical monitoring. Compare Allgood v. General Motors Corp., 2005 WL 2218371, at \*6-8 (S.D. Ind. Sept. 12, 2005) (denying motion to dismiss medical monitoring claim), with Hunt v. American Wood Preservers Institute, 2002 WL 34447541, at \*1 (S.D. Ind. July 31, 2002); Johnson v. Abbott Laboratories, 2004 WL 3245947 (Ind. Cir. Dec. 31, 2004) (rejecting medical monitoring).

**Kansas:** A federal court has predicted that Kansas law would not recognize an independent claim for medical monitoring in product liability. Burton v R.J. Reynolds Tobacco Co., 884 F. Supp. 1515, 1523 (D. Kan. 1995).

**Kentucky:** Kentucky law does not permit an independent claim for medical monitoring. Wood v. Wyeth-Ayerst Labs, 82 S.W.3d 849, 859 (Ky. 2002).

**Louisiana:** Louisiana law, by statute, prohibits independent claims for medical monitoring, requiring that relief be “directly related to a manifest physical or mental injury or disease.” La. Civ. Code Ann. art. 2315 (1998).

**Michigan:** Michigan law does not recognize independent claims for medical monitoring. Henry v. Dow Chemical Co., 701 N.W.2d 684, 686 (Mich. 2005);

**Minnesota:** Minnesota law does not recognize an independent claim for medical monitoring in product liability. Bryson v. Pillsbury Co., 573 N.W.2d 718, 721 (Minn. App. 1998); Thompson v. American Tobacco Co., 189 F.R.D. 544, 551-52 (D. Minn. 1999); Paulson v. 3M Co., 2009 WL 229667 (Minn. Dist. Jan. 16, 2009); Palmer v. 3M Co., 2005 WL 5891911 (Minn. Dist. April 26, 2005).

**Mississippi:** Mississippi law does not recognize independent claims for medical monitoring. Paz v. Brush Engineered Materials, Inc., 949 So.2d 1, 3-6, 9 (Miss. 2007).

**Missouri:** Missouri law recognizes medical monitoring in environmental actions but not in product liability litigation. Meyer v. Fluor Corp., 220 S.W.3d 712, 717-18 (Mo. 2007) (medical monitoring recognized in environmental action); Ratliff v. Mentor Corp., 569 F. Supp.2d 926, 929 (W.D. Mo. 2008) (medical monitoring not cognizable in product liability actions).

**Nebraska:** Federal courts have predicted that Nebraska law would not recognize an independent claim for medical monitoring. Trimble v. Asarco, Inc., 232 F.3d 946, 962-63 (8th Cir. 2000) (applying Nebraska law)<sup>2</sup>; Schwan v. Cargill Inc., 2007 WL 4570421, at \*1-2 (D. Neb. Dec. 21, 2007); Avila v. CNH America LLC, 2007 WL 2688613, at \*1-2 (D. Neb. Sept. 10, 2007).

**Nevada:** Nevada law does not recognize independent claims for medical monitoring. Badillo v. American Brands, Inc., 16 P.3d 435, 438-39 (Nev. 2001).

**New Jersey:** New Jersey law recognizes medical monitoring in environmental actions, including environmental product liability, Mauro v. Raymark Industries, Inc., 561 A.2d 257, 264 (N.J. 1989) (asbestos product liability); Ayers v. Township of Jackson, 525 A.2d 287, 310-12 (N.J. 1987) (environmental). New Jersey law rejects medical monitoring in other product liability actions. Sinclair v. Merck & Co., 948 A.2d 587, 595 (N.J. 2008).

**New York:** New York law is split. Some courts recognize independent medical monitoring claims. Allen v. General Electric Co., 821 N.Y.S.2d 692, 694-95 (N.Y. A.D. 2006); Askey v. Occidental Chemical Corp., 477 N.Y.S.2d 242, 247 (N.Y. A.D. 1984) (recognizing medical monitoring as a remedy only); Acevedo v. Consolidated Edison Co., 572 N.Y.S.2d 1015, 1018 (N.Y. Sup. 1991); Gerardi v. Nuclear Utility Services, Inc., 566 N.Y.S.2d 1002, 1004 (N.Y. Sup. 1991); Abbatiello v. Monsanto Co., 522 F. Supp.2d 524, 538-39 (S.D.N.Y. 2007); Patton v. General Signal Corp., 984 F. Supp. 666, 674 (W.D.N.Y. 1997); Gibbs v. E.I. duPont de Nemours & Co., 876 F. Supp. 475, 478-790 (W.D.N.Y. 1995). Some

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<sup>2</sup> Abrogated on other grounds, Exxon Mobil Corp. v. Allapattah Services, Inc., 545 U.S. 546, 552 (2005) (supplemental federal jurisdiction).

courts recognize medical monitoring only if there is a “clinically-demonstrable presence of a toxin in the plaintiff’s body, or some other indication of a toxin-induced disease.” DiStefano v. Nabsico, Inc., 767 N.Y.S.2d 891, 891 (N.Y. A.D. 2003); Major v. Astrazeneca, Inc., 2006 WL 2640622, at \*7 (N.D.N.Y. Sept. 13, 2006). Another appellate court rejected independent claims for medical monitoring altogether. Abusio v. Consolidated Edison Co., 656 N.Y.S.2d 371, 372 (N.Y. A.D. 1997).

**North Carolina:** North Carolina does not recognize an independent claim for medical monitoring. Curl v. American Multimedia, Inc., 654 S.E.2d 76, 81 (N.C. App. 2007) (allowance of such a claim is “a task within the purview of the legislature and not the courts”); Carroll v. Litton Systems, Inc., 1990 WL 312969, at \*51 (W.D.N.C. Oct. 29, 1990).

**North Dakota:** A federal court has predicted that North Dakota law would not recognize an independent claim for medical monitoring. Mehl v. Canadian Pacific Railway Ltd., 227 F.R.D. 505, 518 (D.N.D. 2005).

**Ohio:** A federal court has predicted that Ohio law would recognize an independent claim for medical monitoring. Day v. NLO, Inc., 851 F. Supp. 869, 880-81 (S.D. Ohio 1994).

**Oklahoma:** A federal court has predicted that Oklahoma law would not recognize an independent claim for medical monitoring. Cole v. ASARCO, Inc., 2009 WL 920581, at \*4-5 (N.D. Okla. April 2, 2009).

**Oregon:** Oregon law does not recognize an independent claims for medical monitoring. Lowe v. Philip Morris USA Inc., 183 P.3d 181, 186-87 (Or. 2008).

**Pennsylvania:** Pennsylvania law allows independent claims for medical monitoring in negligence, but not strict liability. Redland Soccer Club v. Department of the Army, 696 A.2d 137, 145 (Pa. 1997); Brown v. Dickinson, 2000 WL 33342381, at \*1 (Pa. C.P. March 9, 2000); Barnes v. American Tobacco Co., 989 F. Supp. 661, 664 (E.D. Pa. 1997); (all requiring a “negligent” act); cf., In re Orthopedic Bone Screw Products Liability Litigation, 1995 WL 273597, at \*9-10 (E.D. Pa. Feb. 22, 1995) (medical monitoring inappropriate in product liability action not involving exposure to an environmental toxin).

**South Carolina:** A federal court has predicted that South Carolina law would not recognize an independent claim for medical monitoring. Rosmer v. Pfizer, Inc., 2001 WL 34010613, at \*5 (D.S.C. March 30, 2001).

**Tennessee:** Federal courts have predicted that Tennessee law would not recognize an independent claim for medical monitoring. Bostick v. St. Jude Medical, Inc., 2004 WL 3313614, at \*14 (W.D. Tenn. Aug. 17, 2004); Jones v. Brush Wellman, Inc., 2000 WL 33727733, at \*8 (N.D. Ohio 2000) (applying Tennessee law).

**Texas:** A federal court has predicted that Texas law would not recognize an independent claim for medical monitoring. Norwood v. Raytheon Co., 414 F. Supp.2d 659, 664-68 (W.D. Tex. 2006).

**Utah:** Utah law recognizes independent claims for medical monitoring in negligence. Hansen v. Mountain Fuel Supply Co., 858 P.2d 970, 978-80 (Utah 1993).

**Vermont:** A federal court has predicted that Vermont law would recognize an independent claim for medical monitoring. Stead v. F.E. Myers Co., 785 F. Supp. 56, 57 (D. Vt. 1990).

**Virginia:** A federal court has predicted that Virginia law would not recognize an independent claim for medical monitoring. Ball v. Joy Technologies, Inc., 958 F.2d 36 (4th Cir. 1991) (applying Virginia law).

**Virgin Islands:** Virgin Islands law does not recognize an independent claims for medical monitoring. Louis v. Caneel Bay, Inc., 2008 WL 4372941, at \*5-6 (V.I. Super. July 21, 2008); Purjet v. Hess Oil Virgin Islands Corp., 22 V.I. 147, 153-54 (D.V.I. Jan. 8, 1986).

**Washington:** A federal court has predicted that Washington law would not recognize an independent claim for medical monitoring. Duncan v. Northwest Airlines, Inc., 203 F.R.D. 601, 608-09 (W.D. Wash. 2001).

**West Virginia:** West Virginia law recognizes independent claims for medical monitoring, not limited to negligence. In re West Virginia Rezulin Litigation, 585 S.E.2d 52, 72-73 (W.Va. 2003); Bower v. Westinghouse Electric Co., 522 S.E.2d 424, 427 (1999).<sup>3</sup>

In light of the currently profound divergence in relevant authority, and the ALI's non-recognition of medical monitoring, the number of illustrations devoted to the controversial medical monitoring cause of action in §2.04 – currently eight – should be reduced and the controversial nature of medical monitoring as a cause of action in the absence of present injury should be explicitly noted.

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<sup>3</sup> See also Philip Morris Inc. v. Angeletti, 752 A.2d 200, 251 (Md. 2000) (declining to decide whether “novel tort theory” of medical monitoring should be adopted in Maryland).

**III. THE MOST FREQUENT RESULT WHEN MEDICAL MONITORING CLAIMS ARE SOUGHT TO BE AGGREGATED IS DENIAL OF CLASS CERTIFICATION DUE TO INDIVIDUALIZED FACTUAL ISSUES CONCERNING EXPOSURE, RISK, CAUSATION, AND AFFIRMATIVE DEFENSES.**

In reorganizing and reducing the existing illustrations in §2.04, this amendment places first an illustration (a combination of current Illustrations 7-8) that addresses the most common outcome in class certification decisions involving medical monitoring. The most frequent result, certainly in recent years, is for aggregation of medical monitoring claims to be denied on the ground that entitlement to such monitoring is dependent upon individualized inquiry into the extent of class members' exposure to the substance, their susceptibility to relevant medical conditions, alternative causes for their increased risk, or individualized defenses such as comparative fault. Thus, the same individualized issues responsible for class actions generally "falling into disfavor" in mass-tort litigation frequently preclude class certification by making the resultant medical monitoring class insufficiently "cohesive" to justify the elimination of class members' right to opt out. See Reporters Notes to §1.02, at page 26 (lines 12-17).

In medical monitoring bases involving individualized issues, the remedy, again assuming it exists under the law of the relevant jurisdiction, cannot be considered "indivisible" where its availability turns upon plaintiff-specific factors not common to the class. As a leading medical monitoring opinion described the problem:

While 23(b)(2) class actions have no predominance or superiority requirements, it is well established that the class claims must be cohesive. . . . [B]y its very nature, a (b)(2) class must be cohesive as to those claims tried in the class action. Because of the cohesive nature of the class, Rule 23(c)(3) contemplates that all members of the class will be bound. Any resultant unfairness to the members of the class was thought to be outweighed by the purposes behind class actions: eliminating the possibility of repetitious litigation and providing small claimants with a means of obtaining redress for claims too small to justify individual litigation. . . . We believe that addiction, causation, the defenses of comparative and contributory negligence, the need for medical monitoring and the statute of limitations present too many individual issues to

permit certification. . . . These disparate issues make class treatment inappropriate.

Barnes v. American Tobacco Co., 161 F.3d 127, 143 (3d Cir. 1998) (internal citations and quotation marks omitted) (applying Pennsylvania law). This “cohesiveness” requirement is similar to but “more stringent” than the equivalent requirements of Rule 23(b)(3), given the Due Process implications of eliminating class members’ opt out rights. E.g., Lienhart v. Dryvit Systems, Inc., 255 F.3d 138, 147 n.4 (4th Cir. 2001); Barnes, 161 F.3d at 142-43.

Particularly after Barnes, large numbers of medical monitoring class actions have failed the test of class certification because the presence of individualized issues as discussed in the proposed Illustration 2. See Wilson v. Brush Wellman, Inc., 817 N.E.2d 59, 66 (Ohio 2004) (class decertified; medical monitoring claim not cohesive due to “multiple individual questions of fact requiring examination for different plaintiffs”); Lockheed Martin Corp. v. Superior Court, 63 P.3d 913, 921-22 (Cal. 2003) (class decertified; due to “actual dosages and variations in individual response,” “causation and damages issues. . . must be counted among those that would be litigated individually”); Baker v. Wyeth-Ayerst Laboratories, 992 S.W.2d 797, 802 (Ark. 1999) (denial of certification of medical monitoring class affirmed; “common issues will depend upon individual differences among the plaintiffs such as when they took the drug, the duration of use, the quantity taken, the combination used, their medical history and condition at the time of use, and the state of the art at the time the drugs were marketed”); Buynie v. Airco, Inc., 2007 WL 2275013, at \*6 (N.J. Super. A.D. Aug 10, 2007) (denial of certification affirmed; medical monitoring “depends on. . . the likelihood of disease, the significance and extent of exposure to a toxic substance, the toxicity of the substance, the seriousness of the diseases associated with exposure to the substances, and the value of early diagnosis”); Wyeth, Inc. v. Gottlieb, 930 So.2d 635, 640-41 (Fla. App. 2006) (denial of class certification affirmed; “causation is a highly

individualistic determination that depends on the individual characteristics of a putative class member, the duration of . . . ingestion, and whether that member was taking other medication”); Goasdone v. American Cyanamid Corp., 808 A.2d 159, 170 (N.J. Super. L.D. 2002) (medical monitoring claim could not be certified due to “the significance and extent of exposure by each class member to defendants' products, and whether medical monitoring is reasonable and necessary for each class member based on the class member's unique medical history”); In re St. Jude Medical, Inc., 522 F.3d 836, 840 (8th Cir. 2005) (class decertified; “plaintiffs request the highly individualized remedy of medical monitoring”); In re St. Jude Medical, Inc., 425 F.3d 1116, 1121-22 (8th Cir. 2005) (class decertified; need for medical monitoring is necessarily an “individualized inquiry depending on that patient’s medical history, the condition of the patient’s heart valves at the time of implantation, the patient’s risk factors for heart valve complications, the patient’s general health, the patient’s personal choice, and other factors”); Ball v. Union Carbide Inc., 385 F.3d 713, 726-28 (6th Cir. 2004) (denial of class certification affirmed; claims too individualized given differences in “total exposure time, exposure period, medical history, diet, sex, age, and a myriad of other factors”); Zinser v. Accufix Research Institute, Inc., 253 F.3d 1180, 1192 (9th Cir. 2001) (denial of class certification affirmed; “it may be difficult to establish a common cause of injury because many factors may contribute to [the alleged defect], including manufacturing and shipping history and handling of the lead by physicians or staff”), amended, 273 F.3d 1266 (9th Cir. 2001); Rhodes v. E.I. du Pont de Nemours & Co., 253 F.R.D. 365, 375-80 (S.D.W. Va. 2008) (class certification denied; exposure, significantly increased risk, and need for monitoring cannot be proven on a class-wide basis); In re Fosamax Products Liability Litigation, 248 F.R.D. 389, 400 (S.D.N.Y. 2008) (denying certification; liability turns on each “user’s unique medical history and the circumstances surrounding his or her use, the Court is not satisfied that the need for the proposed monitoring program could be proven on a

class-wide basis”); Rowe v. E.I. duPont de Nemours & Co., 2008 WL 5412912, at \*17-20 (D.N.J. Dec. 23, 2008) (medical monitoring class could not be certified due to “the plethora of individualized issues underlying the risk of disease issue”); Leib v. Rex Energy Operating Corp., 2008 WL 5377792, at \*12 (S.D. Ill. Dec. 19, 2008) (“[t]he level of individualized inquiry is far greater in a medical monitoring cause of action”);<sup>4</sup> In re Welding Fume Products Liability Litigation, 245 F.R.D. 279, 311 (N.D. Ohio 2007) (denying certification because “[i]n light of the different welding products, warnings, employers, work environments, and so on,” “there is ultimately no single course of conduct by all of the defendants”); In re Aredia & Zometa Products Liability Litigation, 2007 WL 3012972, at \*5 (M.D. Tenn. Oct. 10, 2007) (“individual issues, such as causation or individual defenses, . . . preclude class certification” of medical monitoring claims); In re Prempro Products Liability Litigation, 230 F.R.D. 555, 570-73 (E.D. Ark. 2005) (certification denied because “[n]o matter how you cut it, cube it, or slice it, Plaintiffs cannot overcome the problems with individual issues of law and fact, which eclipse any possible common questions or cohesion among their claims”); Perez v. Metabolife International, Inc., 218 F.R.D. 262, 270-73 (S.D. Fla. 2003) (certification denied because “individualized inquiries would still be required to assure that the medical monitoring elements were met with respect to each class member”); In re Baycol Products Litigation, 218 F.R.D. 197, 212 (D. Minn. 2003) (“a finding of negligence is inextricably intertwined with individual issues”; “individual issues will undermine the cohesion of the medical monitoring class”); Zehel-Miller, 223 F.R.D. at 664 (certification denied due to “individual questions concerning patient characteristics and medical history, physician involvement, dosage, causation and comparative or contributory negligence”); Harris v. Purdue Pharma, L.P., 218 F.R.D. 590, 597 (S.D. Ohio 2003) (class certification denied;

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<sup>4</sup> A subsequent decision certified a property damage class that excluded non-owners. Leib v. Rex Energy Operating Corp., 256 F.R.D. 178 (S.D. Ill. 2009).

“case is riddled with individual issues concerning how the alleged marketing affected the judgment of physicians, how resulting prescriptions affected patients, how some patients allegedly used the drug improperly, and how, at the very least, some eighty-percent of those prescribed the drug have not had nor will have an adverse reaction”); In re Baycol Products Liability Litigation, 218 F.R.D. 197, 213 (D. Minn. 2003) (“class members took [the product] at different times, in different amounts, with different co-prescriptions and with different medical backgrounds”); In re Paxil Litigation, 212 F.R.D. 539, 548 (C.D. Cal. 2003) (certification of medical monitoring and other subclasses denied; product taken at “various times, with different dosages, and for different underlying ailments”; “the symptoms and injuries allegedly suffered by the plaintiffs vary from individual to individual”); In re Rezulin Products Liability Litigation, 210 F.R.D. 61, 75 (S.D.N.Y. 2002) (medical monitoring class not cohesive where “it’s up to each clinician to decide whether he wants to put his patients through a monitoring program or not”); In re Propulsid Products Liability Litigation, 208 F.R.D. 133, 147 (E.D. La. 2002) (certification denied because “variations involving proof of causation, the effect of warnings, the significance of the defendants’ direct marketing to consumers, and other similar issues may swamp any common issues and defeat cohesiveness”); In re Methyl Tertiary Butyl Ether (“MTBE”) Products Liability Litigation, 209 F.R.D. 323, 343-44 (S.D.N.Y. 2002) (differences in individual sensitivity, level of contamination, and proximity to contamination “would require even more far-ranging investigation to determine appropriate remediation”); Lewallen v. Medtronic USA, Inc., 2002 WL 31300899, at \*4 (N.D. Cal. Aug 28, 2002) (medical monitoring class not certified; “Each patient’s medical history is different, as are each patient’s risk factors. Each treating physician's determination is different.”); Duncan, 203 F.R.D. at 612-13 (certification denied where putative class members “worked. . .for different time periods, who may have smoked, who may have immediate family members who smoke, and who have

different medical backgrounds”); Rink v. Cheminova, Inc., 203 F.R.D. 648, 659, 665 (M.D. Fla. 2001) (certification denied; medical monitoring is “fraught with individualized issues that dictate the member’s entitlement to and the need of monitoring”), app. dismissed, 400 F.3d 1286 (11th Cir. 2004); O’Connor v. Boeing North American, Inc., 197 F.R.D. 404, 413 (C.D. Cal. 2000) (monitoring class decertified; “individual variances could require substantial litigation about whether, or to what extent, each of the class members could participate in the medical-monitoring program”); Thompson, 189 F.R.D. at 557 (the “‘cohesiveness’ requirement. . .precludes certification when individual issues abound”); Blaz v. Galen Hospital, Inc., 168 F.R.D. 621, 625 (N.D. Ill. 1996) (certification denied; “variations among individuals with respect to exposure and effects can vitiate a finding of typicality”); Hurd v. Monsanto Co., 164 F.R.D. 234, 239-41 (S.D. Ind. 1995) (certification denied; “no single happening or accident occurred at [the plant] causing identical harms to each putative class member. Rather, each plaintiff was exposed to different levels of [the toxic substance] for different amounts of time in different areas of the plant. Each putative class member’s susceptibility to injury from [the toxic substance] will vary. Thus, no single proximate cause inquiry applies equally to each putative class member; no one set of operative facts establishes liability.”); Thomas v. FAG Bearings Corp., Inc., 846 F. Supp. 1400, 1404 (W.D. Mo. 1994) (certification denied; “individual issues of causation and damage. . .will require individualized proof for each plaintiff”); Brown v. SEPTA, 1987 WL 9273, at \*13 (E.D. Pa. April 9, 1987) (“entitlement to this type of relief will depend on individualized questions of causation and personal medical history”).

This section is adapted to serve as “Reporters Notes” to proposed Illustration 2.

**IV. IN THE ABSENCE OF OVERRIDING INDIVIDUALIZED FACTUAL ISSUES, SOME COURTS HAVE CERTIFIED MANDATORY MEDICAL MONITORING CLASSES.**

As Illustration 3 in §2.04, this amendment largely retains the current Illustration 2, somewhat reduced through incorporation by reference. There are cases holding that medical monitoring classes can be certified where individualized issues are not salient, often because the standards for relevant medical monitoring are undisputed. These cases find that the position of the medical monitoring remedy along the law-equity divide, while important for other purposes, does not by itself change the characterization of that remedy for purposes of a court's aggregation decision. Instead, courts look to the relief that is actually being sought and how that relief would function. Relief dependent upon classwide determinations, rather than individual circumstances can be characterized as "indivisible":

The principal fallacy in the defendants' position is the failure to recognize the important distinction between a common unitary claim by a class as a whole for the establishment of a single unitary fund or program, and the aggregated actions of several different, distinct claims of individuals for individualized damage awards. Pursuant to the jury's verdict, no specific judgment or allocation for . . .any individual class member was made. The only claim that any of the remaining plaintiffs have is the right to apply for participation in [the] program from the established fund.

Scott v. American Tobacco Co., 949 So.2d 1266, 1285 (La. App. 2007).<sup>5</sup> Other cases reaching similar results are: Meyer, 220 S.W.3d at 719 ("the common fact of exposure to a set of toxins from a single source that is the common and overriding issue" where theory of "liability is premised upon the exposure to toxins from a single source during a specified age range"); West Virginia Rezulin, 585 S.E.2d at 72-73 (allowing certification of monitoring claims involving

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<sup>5</sup> Scott did not involve medical monitoring claims, which are prohibited in Louisiana, but rather relief in the form a smoking cessation program. As described, the relief in Scott functioned in an indivisible fashion, as it was not dependent upon the individual circumstances of class members.

“idiosyncratic reaction[s]” that were “not related to the dose taken by each patient”); Olden v. LaFarge Corp., 383 F.3d 495, 508 (6th Cir. 2004) (medical monitoring certification affirmed; individual medical and property damage issues were “minor” and no alternative exposure sources established); Mejdrech v. Met-Coil Systems Corp., 319 F.3d 910, 911-12 (7th Cir. 2003) (medical monitoring issue certification affirmed; the “first question is particularly straightforward” and “the second only slightly less so”); Gasperoni v. Metabolife, International, Inc., 2000 WL 33365948, at \*7 (E.D. Mich. Sept. 27, 2000) (medical monitoring “does not create individualized issues in the present case”); Josephat v. St. Croix Alumina, LLC, 2000 WL 1679502, at \*11 (D.V.I. Aug. 7, 2000) (“individual issues in this case will not interfere with the proof required by the above medical monitoring elements”); Elliott v. Chicago Housing Authority, 2000 WL 263730, at \*15-16 (N.D. Ill. Feb. 28, 2000) (defendant allegedly failed to comply with regulatory monitoring standards; “a court-supervised medical monitoring program through which class members will receive periodic examinations may be properly characterized as seeking injunctive relief”); In re Diet Drugs Products Liability Litigation, 1999 WL 673066, at \*6, \*11 (E.D. Pa. Aug. 26, 1999) (monitoring program that included notification and statistical analysis in addition to testing was “equitable in nature”; monitoring recommendations from independent medical societies provided cohesiveness); In re Teletronics Pacing Systems, Inc., 172 F.R.D. 271, 285-86 (S.D. Ohio 1997) (defendant conceded necessity of monitoring for entire class; medical monitoring properly considered injunctive where administratively-imposed relief might conflict and a “research program is a uniform benefit to the class”);<sup>6</sup> German v. Federal Home Loan Mortgage Corp., 885 F. Supp. 537, 554, 560 (S.D.N.Y. 1995) (medical monitoring class conditionally certified; “specific types of situations can be resolved by the designation of

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<sup>6</sup> This class was subsequently decertified on superiority grounds. In re Teletronics Pacing Systems, Inc., 168 F.R.D. 203, 221 (S.D. Ohio 1996).

sub-classes” or decertification; “plaintiffs have presented a colorable claim for medical monitoring as injunctive relief”), reargument granted on other grounds, 896 F. Supp. 1385 (S.D.N.Y. 1995); Gibbs, 876 F. Supp. at 477, 481 (adequacy of defendant’s existing medical monitoring program at issue; remedy “extended beyond individual monitoring to data compilation and analysis and other pooling of resources”; postponing consideration of individualized issues); Day, 851 F. Supp. at 884 (“No matter how individualized the issue of damages may be, these issues may be reserved for individual treatment”; certification of non-opt-out class “most appropriate” as “use of the Court’s injunctive powers to oversee and direct medical surveillance is vastly superior to a lump sum monetary payment”); Yslava v. Hughes Aircraft Co., 845 F. Supp. 705, 712-13 (D. Ariz. 1993) (“factual commonality exists” due to geographically specific subclasses; “court-supervised program requiring ongoing, elaborate medical monitoring” held indivisible); Day v. NLO, Inc., 144 F.R.D. 330, 336 (S.D. Ohio 1992) (“elaborate medical monitoring program of its own, managed by court-appointed court-supervised trustees” is an indivisible medical monitoring remedy), mandamus denied in relevant part, 5 F.3d 154, 159 (6th Cir.1993); Boggs v. Divested Atomic Corp., 141 F.R.D. 58, 67 (S.D. Ohio 1991) (“need for medical monitoring. . .would be virtually identical”; medical monitoring claim certified as “an entitlement to injunctive relief, [that] would undoubtedly be in the form of a complex order, addressing many specific features”); Barth v. Firestone Tire & Rubber Co., 673 F. Supp. 1466, 1478 (N.D. Cal. 1987) (medical monitoring fund to gather and disseminate information about diagnosis and treatment of diseases possibly linked to toxin with unknown effects was only available in equity); cf. In re Copley Pharmaceutical, Inc., 158 F.R.D. 485, 492 (D. Wyo. 1994) (certifying individual legal issues related to medical monitoring as limited class).

The amendment specifies that the characterization of medical monitoring relief as “indivisible” is discretionary, rather than mandatory. Judicial discretion is consistent with the

general principles recognized in §1.03 and §202(a),<sup>7</sup> and is more appropriate in light of the gradations in medical monitoring remedies described in the cases, from little more than a mandatory injunction to pay money to “elaborate” plans envisioning ongoing judicial supervision. Judicial discretion is also appropriate in evaluating if the background facts justify such certification, as successfully certified medical monitoring class actions have often involved situations where, for one reason or another, the standards for monitoring are not in dispute.

This section is adapted as “Reporters Notes” to proposed Illustration 3.

**V. WHERE A REQUESTED MEDICAL MONITORING REMEDY IS LITTLE MORE THAN A DISGUISED CLAIM FOR DAMAGES, OR IS OTHERWISE OVERSHADOWED BY DAMAGES CLAIM, COURTS HAVE NOT CERTIFIED MANDATORY MEDICAL MONITORING CLASS ACTIONS.**

The third, and last medical monitoring illustration (Illustration 4) proposed by this amendment is a reworking of the current Illustration 5, addressing the situation where the non-monetary aspects of a claimed medical monitoring remedy are essentially window dressing for what is, at bottom, a claim for money damages. Numerous cases address situations in which a claim ostensibly for medical monitoring does not actually seek indivisible relief, but is instead “essentially a suit for damages” that is not properly certified as a mandatory class action, if at all. Building & Construction Department, AFL-CIO v. Rockwell International Corp., 7 F.3d 1487, 1492 (10th Cir. 1993). The characterization of a remedy as “indivisible” has significant Due Process implications, because if a medical monitoring claim is little more than a disguised request for monetary damages, treating it as indivisible relief would deprive putative class members of constitutional rights to opt out of aggregated litigation.

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<sup>7</sup> See §2.02, comment a (recognizing “the bedrock point that aggregate treatment in litigation is a matter of judicial discretion that flows from the general authority of courts to exercise early and effective supervision of litigation”).

To amount to an “indivisible” remedy, the degree of ongoing judicial involvement in overseeing a medical monitoring program must be significant, and conversely, monetary relief cannot be the plaintiffs’ “primary” objective. See Wilson, 817 N.E.2d at 65 (medical monitoring class decertified; demand that defendant “pay for a reasonable medical surveillance and screening program” sought monetary remedy; adopting “bright line test” requiring “[c]ourt supervision and participation in medical-monitoring cases”); Philip Morris Inc. v. Angeletti, 752 A.2d 200, 252-53 (Md. 2000) (denial of certification of medical monitoring class affirmed; “[c]alling such payment ‘injunctive relief’ does not change the status of the claim from that of a fundamentally monetary nature”); Jaffee v. United States, 592 F.2d 712, 715 (3d Cir. 1979) (denial of certification of medical monitoring class affirmed; a “request for prompt medical examinations. . .cannot transform a claim for damages into an equitable action”); Zinser, 253 F.3d at 1196 (denial of certification of medical monitoring class affirmed; medical monitoring claim that merely requested funding for future treatment and damages properly viewed as involving divisible monetary remedy); Mehl v. Canadian Pacific Railway Ltd., 227 F.R.D. 505, 519-20 (D.N.D. 2005); Rezulin, 210 F.R.D. at 72-73 (without evidence of the cost of medical monitoring or “its value to individual class members” the equitable nature of medical monitoring cannot be established); Lewallen, 2002 WL 31300899, at \*3 (non-monetary aspects of medical monitoring claim held “merely incidental to the primary claim for money damages”); Duncan, 203 F.R.D. at 611 (plaintiff’s “seek[ing] individual damages. . .distinguishes the proposed relief from pure monitoring programs”); Dhamer v. Bristol-Myers Squibb Co., 183 F.R.D. 520, 529 (N.D. Ill. 1998) (certification of medical monitoring class denied; “the ultimate relief requested is in the form of money damages which when taken along with plaintiff’s other claims for money, demonstrate that money damages is the predominant relief sought”); Cook v. Rockwell International Corp., 181 F.R.D. 473, 479-80 (D. Colo. 1998) (class decertified; the “crux of the

action is for money damages”);<sup>8</sup> Reilly v. Gould Inc., 965 F. Supp. 588, 593-94 (M.D. Pa. 1997) (“constructive trust” for medical monitoring was not common equitable relief where facility had been closed for many years, thereby eliminating need for injunction); O’Connor v. Boeing North American, Inc., 180 F.R.D. 359, 378 (C.D. Cal. 1997) (medical monitoring program that “involve[d] payments by the defendants for treatment of disease” and “also sought compensatory and punitive damages” could not be considered equitable); Smith v. Brown & Williamson Tobacco Corp., 174 F.R.D. 90, 100 (W.D. Mo. 1997) (certification of medical monitoring class denied; “the relief requested is in the form of money which. . .demonstrates that monetary relief is the predominate relief sought”); Harding v. Tambrands, 165 F.R.D. 623, 632 (D. Kan. 1996) (certification of medical monitoring class denied; “the relief sought by plaintiffs is primarily money damages”); Thomas, 846 F. Supp. at 1404 (certification of medical monitoring class denied; “future costs of medical monitoring” were nothing more than a form of monetary compensation); Copley Pharmaceutical, 158 F.R.D. at 490-91 (refusing to certify non-opt out class; declaratory relief “incidental” to medical monitoring demand for a fund; primary remedy was damages); Abbent v. Eastman Kodak Co., 1992 WL 1472751, at \*13 (D.N.J. Aug. 28, 1992) (certification of medical monitoring class denied; request for fund was “monetary”); Werlein v. United States, 746 F. Supp. 887, 895 (D. Minn. 1990) (medical monitoring claim with “no provisions for anything besides an exchange of money” into a reimbursement fund was divisible monetary remedy; “[p]ayment of cash by one party to reimburse other parties for costs incurred is not injunctive relief”), vacated in part on other grounds, 793 F. Supp. 898 (D. Minn. 1992).

This section is adapted to serve as “Reporters Notes” to proposed Illustration 4.

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<sup>8</sup> Abrogated on other grounds, Jiron v. City of Lakewood, 392 F.3d 410, 417 (10th Cir. 2004) (effect of guilty pleas). The Cook court decertified a medical monitoring class that it had initially certified in Cook v. Rockwell International Corp., 151 F.R.D. 378 (D. Colo. 1993).

**VI. THE REMAINING ILLUSTRATIONS CONCERNING MEDICAL MONITORING ARE UNNECESSARY.**

This proposed amendment would delete current Illustrations 3 (“applicable substantive law. . .does not authorize medical monitoring as a form of relief”), 4 (“the requested monitoring for consumers does not differ materially from the medical services that a reasonable physician would recommend for persons who lack exposure”), 6 (“no reasonable basis to believe that the requested medical monitoring will serve to guide medical intervention to mitigate disease”), and 9 (“applicable substantive law. . .predicates the availability of the medical-monitoring remedy on. . .present-day injury”). These illustrations are unnecessary and inappropriate in a section on remedy because they involve the merits of medical monitoring claims in general (current Illustrations 3, 9) or whether on hypothetical facts, the substantive elements of a medical monitoring tort exist (Current Illustrations 4, 6), as opposed to than the nature of the remedy as “divisible” or “indivisible.”

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