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Please Watch Me to See If I Ever Get Sick

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Class claims for medical monitoring pose challenges for courts and drug companies.

BY SEAN P. WAJERT

Drug manufacturers are facing potentially high-dollar claims in class actions for "medical monitoring." Although this claim evolved in cases involving environmental exposure to toxic chemicals, the theory has migrated to prescription drugs, leaving both companies and courts to struggle with the resulting doctrinal and policy issues.

Traditionally, product liability claims over drug sales involve plaintiffs alleging current injury from the product. The necessary emphasis on family medical history, pre-existing conditions, individual lifestyles, and variations among patients in the warnings seen, heard, or relied upon often preclude class certification.

Food & Drug
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Medical-monitoring claims, in contrast, are brought by plaintiffs who allege that they have been exposed to a harmful substance or product and are at an increased risk of contracting a future, latent injury because of that exposure. In cases involving phen-fen, Vioxx, Bextra, hormone-replacement therapy, Viagra, Lipitor, OxyContin, Fosamax, Meridia, and several other drugs, claimants have alleged that their past use of prescription medications has put them at an increased risk of future harm.

Such plaintiffs do not suffer any current injury in the traditional sense. Rather, they seek medical testing to detect a future injury at the earliest possible moment and maximize the chances of receiving a beneficial treatment or cure.

Although several jurisdictions do not recognize claims for medical monitoring, those that do typically impose some version of the following requirements: significant exposure to a proven hazardous substance, a causal link with the tortious conduct of the defendant, significantly increased risk of contracting a serious latent disease, a reasonable necessity for periodic diagnostic testing different from that normally recommended in the absence of the exposure, and the existence of monitoring procedures that make the early detection of the disease possible.

Substantial variation among jurisdictions exists on other elements and on the application of several elements, such as whether there must be a proven cure or beneficial treatment that will result from early detection of the disease.

From Chemicals to Drugs

Medical monitoring was developed largely in the area of environmental exposure to toxic chemicals such as polychlorinated biphenyls, known as PCBs. Nonetheless, plaintiffs have increasingly sought to apply the concept to pharmaceuticals. This expands the pool of plaintiffs in a mass tort, from those actually injured to those who are merely allegedly at risk of future injury.

Yet as an examination of the elements of a monitoring claim and the policy behind the recognition of the theory shows, medical monitoring does not easily apply to prescription drugs.

In an effort to create a medical-monitoring claim, plaintiffs in these cases allege that the drug in question is the proven "toxic" substance, the voluntary ingestion through a prescription is the "significant exposure," and the potential future side effects of the drug constitute the increased risk of disease.

But legal prescription drugs, by definition, have been found safe and effective by the Food and Drug Administration, and use of such medications occurs only after the intercession of a learned intermediary (typically a doctor) who has balanced the benefits and risks of the drug for the particular patient.

Thus, it is questionable whether a drug should be considered a proven hazardous substance. Significant exposure is often measured by comparison with normal background levels in the environment, yet a medical patient would normally have had no background exposure to a medication (unless the patient had been prescribed a competitive drug in the same class). Accordingly, there may be no significantly increased exposure to that class of drugs.

The prescribed, voluntary use of a medicine is far removed from the original medical-monitoring notion of involuntary exposure to a toxic chemical in the environment.

Policy-level distinctions exist as well, as was noted in a recent case involving hormone replacement therapy. In *Vitanza v.*

Wyeth Inc. (2006), plaintiffs failed to obtain class certification of a group defined as all persons in New Jersey who had taken the drug Prempro and were not ill but wanted medical monitoring for an alleged increased risk of future breast cancer.

In this case, the New Jersey state court noted that recognition of medical monitoring came in the "unique" context of toxic substances in environmental tort actions and is to be "applied sparingly." The policy reasons applicable to the environmental-exposure context—including the difficulty in proving exposure levels and duration, and even the identity of the chemicals at issue—are not present in the prescription-drug context, where plaintiffs have access to relevant information through the label, pharmacy records, and their prescribing physician.

Although medical-monitoring claims are problematic even in individual cases, aggregation of a significant number of cases arguably poses the greater threat to pharmaceutical makers.

An individual seeking medical monitoring for a future side effect he or she may never have typically may not raise the specter of significant damages. But the cost of periodic medical testing over the course of thousands of claimants' expected life spans can generate huge claims for damages. The possible transition from individual claims to class actions fundamentally alters the litigation and dramatically raises the stakes.

Medical-monitoring class actions have been brought under Federal Rule 23(b)(2) to obtain court-established monitoring as injunctive relief. They also have been brought under Rule 23(b)(3) and its state counterpart, with the assertion that "common" issues predominate over any questions affecting only individual class members. Among these common issues are, supposedly, the defendant's conduct, the significant exposure of class members, the product's hazardous nature, and the increased risk of future disease each class member faces.

Perhaps reflecting the wide distribution of some drugs, claimants have attempted to seek certification of national and even international classes. One suit filed in the Northern District of Illinois sought a worldwide class of all persons to whom Bextra was prescribed. A suit filed in January in the Eastern District of Louisiana proposes a class of all those prescribed Vioxx in the United Kingdom. Such putative classes raise significant issues concerning the feasibility of certification and the appropriateness of monitoring remedies involving citizens of foreign countries, including questions about jurisdiction and the appropriate forum.

In the Vioxx multidistrict litigation, plaintiffs filed a proposed nationwide class action seeking medical monitoring for all Vioxx users who have not been diagnosed with any injury. Such proposed class actions must inevitably confront the choice-of-law issue and the fact that a class involving claimants from different states would require application of the tort law of those different states. The elements of a medical-monitoring claim are not uniform, and some states do not even recognize such a claim. Those distinctions may preclude the administration of a national class.

Class Problems

Several elements of the typical medical-monitoring claim also present potential hurdles for claimants seeking to obtain class certification, which requires establishing the requisite typicality, coherence, and/or predominance of common issues.

A useful pharmaceutical example is the litigation over hormone-replacement therapy. Claimants in several jurisdictions have sought certification of a class of persons who were allegedly at increased risk of breast cancer from the ingestion of certain hormone-replacement-therapy drugs. In *Wyeth Inc. v. Gottlieb* (2006), for example, the Florida appellate court reversed the decision of the trial court to certify a statewide medical-monitoring class of approximately 300,000 women who took Prempro.

Among the issues typically present in hormone-therapy litigation are the following:

Hazardous substance: Even assuming that a pharmaceutical may ever be a proven toxic substance, estrogen therapy is, according to the FDA, useful for some women who may fit the class definition. Plaintiffs' listed experts even continue to prescribe it for some patients. Because of these factors, it cannot be established on a common basis that the drug is a hazardous substance.

Monitoring regime: In the hormone-replacement-therapy litigation, the proposed monitoring plan for the proposed classes often overlaps the medical testing recommended for all postmenopausal women. A person seeking medical monitoring must show that, *given her own unique medical history,* the exposure caused by the defendant significantly increased her risk and required the monitoring recommended for her. Typically, plaintiffs' monitoring schemes are not programs specific to drug users at increased risk but are applicable to any woman who has any breast-cancer risk factor, including age, family history, weight, and alcohol use.

Causation: Some courts articulate the causation issue as whether the exposure caused the need for medical monitoring. If a putative class member already needs the medical testing because of other risk factors, the defendants' conduct did not cause the need for that medical monitoring. Family medical history, age when having children, obesity, alcohol usage, and other factors affecting the risk of latent disease may preclude a finding of this element on a classwide basis.

Conduct: Class action claimants argue that it is enough that their common use of the defendant's product caused the need for medical surveillance. In one West Virginia drug case, the court found no individual issues surrounding conduct because the marketing of the drug "was directed toward the public as a whole, not to any individual claimant." But plaintiffs are required to show that their need for medical monitoring was caused by the defendant's allegedly common conduct. Where the plaintiffs allege a failure to warn, the fact that the drug was prescribed by many different doctors at many different times over many years—with changing scientific knowledge available to plaintiffs, their doctors, and the drug maker—means that this conduct is not common.

Risk: If putative class members experienced different levels, types, or durations of exposure to the drug (which can occur, for example, because of variances in prescriptions and dosages), their resulting risk levels may also vary significantly. This raises the issue about whether each individual class member's risk has significantly increased due to exposure.

A decision from the Eastern District of Arkansas, *In re Prempro Products Liability Litigation* (2005), noted that plaintiffs must do more than establish merely that a drug generally causes an increased risk in people who take it. Rather, plaintiffs must prove that the drug increased the risk of future disease in each particular plaintiff seeking medical monitoring. This is a crucial distinction. It requires more than an epidemiological, population-based analysis, entailing instead a plaintiff-particular showing akin to specific causation in traditional torts.

Nevertheless, the battle is nowhere near over. Despite arguments about the lack of cohesiveness and absence of predominating common issues, it seems likely that drug makers will continue to confront putative class actions that seek an award of medical monitoring. The claim's absence of the traditional current-injury element of a tort and the uncertain application of causation principles will continue to encourage plaintiffs seeking certification of medical-monitoring classes. Drug manufacturers thus have significant fights ahead of them.

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