# On the Banks of the Stream of Commerce: Why There Should Be No Individual "Product" Liability of Corporate Officers, Directors and Employees

**By Gerald P. Schneeweis**

Much attention has been given recently to high-profile civil administrative proceedings and lawsuits by state and local governmental entities against pharmaceutical and medical device company executives. There have also been occasional attempts by counsel for non-governmental/personal injury plaintiffs to name corporate officers, directors and employees as individual defendants in litigation stemming from the sale and use of a prescription drug or device, under the theory that they individually committed fraud in the marketing and promotion of a drug or device to the plaintiff's prescribing physician.

It is one thing to allege that an individual corporate officer, director or employee intentionally and personally made actionable misrepresentations amounting to fraud about, for example, a prescription medical device product's safety, efficacy or its FDA-approved or cleared uses to the plaintiff's physician. Such claims would typically survive a pleading challenge and, depending on the facts established during discovery, possibly summary judgment.

But what about a "pure" product liability claim against such individuals that is *not* founded upon allegations of fraud or other intentional harm, but instead, on the notion that the individual defendant is separately liable, under strict liability and/or negligence principles, for personal injuries caused by their own individual role in the defective design, manufacturing or warnings about the company's product?

It may seem a self-evident proposition that a third-party personal injury plaintiff cannot maintain a separate claim for garden variety "product liability" (under either a strict liability or negligence theory) against *individual* employees, officers or directors of, for example, a *company* that designs, manufactures, and/or distributes a medical product.

However, in some circumstances, plaintiff's counsel may try to do just that, by blurring the distinction between the company that makes a product and the individual who works for, or is/was otherwise formally affiliated with it. Thus, there are some situations in which a plaintiff may try to assert "typical" product liability claims against an individual defendant that are based on principles of strict liability and negligence, *i.e.*, not solely based on fraud or intentional conduct directed at the plaintiff or their medical provider.

Why would they bother with this?

If, for example, the company has gone out of business and had only a relatively small liability policy that provides insufficient protection against multiple claims stemming from the former company's product, plaintiff's counsel might argue that the individuals' own assets should provide a fund for the third party-plaintiff's recovery. In other instances, plaintiff's counsel may resort to naming individual defendants to increase the cost of the litigation to the main corporate defendant or its insurer and/or to exert additional pressure to settle in situations in which a fraud case would be difficult to plead or prove under heightened pleading and evidentiary standards. Naming individual defendants under a strict liability and negligence-based product liability theory might also be done to attempt to destroy federal diversity jurisdiction by inclusion of non-diverse defendants.

While there seems to be precious little law on the specific subject of whether individuals are separately liable to a third party plaintiff for injuries allegedly caused by their company's (or former company's) product the author believes that courts should not apply the doctrine of *strict liability* against them. The actual "enterprise" to which the doctrine of strict liability applies should arguably only be the *company*, which puts *its* product in the "stream of com-

merce" that is essential to the application of strict products liability. It would seem to follow that the individual defendants—corporate officers, directors and employees—should be entitled to a dismissal of such claims upon a showing that they acted at all relevant times on behalf of the company, that they were not "market participants" individually, and were not separately engaged in the stream of commerce for purposes of applying strict liability.

If the plaintiff also asserts a "simple" *negligence* product liability claim against an individual defendant by claiming that he or she was individually negligent in the design, manufacturing or warnings about the product, the defendant can make the same arguments as with a strict liability claim (they are not an "enterprise"; it is the company's sale of the product, not theirs, etc.) but would also likely have to convince the court that they owe no separate tort duty to the plaintiff because the applicable policy factors weigh heavily against such a separate, individualized duty. With some variations, courts confronted with a challenge to the existence of a general tort duty of care to a third party would be expected to consider the following factors:

- foreseeability of harm to the plaintiff by the defendant's acts;
- the degree of certainty that the plaintiff suffered injury;
- the moral blame attached to the defendant's conduct;
- the policy of preventing future harm;
- the extent of the burden of to the individual defendant;
- the social utility of the defendant's conduct;
- the consequences to the community of imposing a duty to exercise care with resulting liability for breach; and
- the availability, cost and prevalence of insurance for the risk involved.

Thus, an individual defendant could offer some basic facts to persuade the court to dismiss a product liability claim based on strict liability or negligence:

- the individual is not separately in the business (as an individual enterprise) of designing, manufacturing, distributing or selling a medical product;
- while the individual may have had some role in the product's design, manufacturing or warnings, they could not individually and unilaterally change the product's characteristics;
- to the extent that they had any control over some aspect of the product, it was solely in their capacity as an employee, officer or director of the company;
- the individual defendant had no pre-existing, individual contact with the particular plaintiff or their medical provider in which they can be said to have assumed a separate tort duty toward them; and
- that while the company may have product liability insurance, the individual is not typically able to procure his or her own liability insurance against third-party bodily injury claims attributed to a product the *company* sells, as such claims would probably be subject to the "business pursuits" exclusion in a homeowner's or renter's liability policy and the "personal injury" exclusion under the company's own D&O policy.

Litigation is stressful enough for company employees or ex-employees who need to work with in-house and outside counsel to provide the facts necessary for the company's defense. The burden on individuals who are also named separately as defendants in such litigation is much more substantial. Individuals named individually in such a lawsuit obviously prefer to have the litigation resolved as quickly as possible, rather than having to participate as individual, separate defendants in a jury trial over injuries allegedly caused by the *company's* product. By the same token, they probably will not expect to have to contribute their own funds to a settlement based on the threat of a jury trial over a product that is the *company's*, not theirs.

If a court is unwilling to dismiss the claims against the individuals at the pleading stage by way of a motion to dismiss or similar procedural vehicle, summary judgment might still be an option. If actionable fraud or other intentional harm has been pled separately as against individual defendants, they may also want to move, if possible, for summary judgment on those claims at the appropriate time on the grounds that there are no competent facts that would support a jury finding on such claims at trial.

As to "product liability" claims against individual defendants, a motion for summary judgment could argue that the individual defendant cannot be held liable for injuries allegedly caused by the company's product, for at least the following reasons:

- The doctrine of *strict liability* should not apply, as a matter of law, since the *company,* and not the individual employee, officer or director, is the "manufacturer, distributor or retailer" who is in the "stream of commerce" in which the product reaches the consumer;
- there should be no legal basis for a *negligence*-based product liability claim against individual defendants, because in the absence of an individual contact with the plaintiff or physician, there should be no evidentiary

basis to support a finding of a separate legal "duty" owed to the third party by the individual defendant;

- to the extent that an individual has some input into a product's characteristics, it was done (as per the plaintiff's own affirmative allegations in the operative complaint) "within the course and scope" of the individual defendant's capacity as an officer, employee or director of the company who actually sells the product;
- sound public policy considerations require that, absent proof of fraud or a disregard of the formalities inherent in a corporate entity's existence, courts are obligated to recognize the fundamental rule that corporate entities have a separate legal existence apart from the individuals who are officers, directors or employees of the company;
- while the company can be held liable for the negligence of its employees, officers or directors under the doctrine of *respondeat superior*, the reverse is not true—the individual is not responsible for the negligent design, manufacturing or warnings given by the company with respect to *its* product, even though those activities can only be accomplished by individuals who work for the company in some capacity;
- the modern doctrine of "strict product liability" itself is founded in the public policy that in an increasingly complex, industrialized society with mass distribution of a product, an "enterprise" which is a market participant in the "stream of commerce" should fairly bear the cost of injuries that may be suffered by *that enterprise's product's* users;
- if courts were to disregard the fundamental legal distinction between corporate entities who design, manufacture, distribute and sell medical products and the individuals who are affiliated with them, very few people would want to work for or serve on the board of directors for such a company, which would ultimately have a disastrous impact on the healthcare industry, the medical profession and patients;
- as a practical matter, individual defendants sued for bodily injury under a strict liability or negligence theory would be essentially unable to obtain insurance to defend and/or indemnify against it. Such a claim may be excluded under standard language in a third party liability portion of the individual's homeowners or renter's policy (under the "business pursuits" exclusion) and even if such a claim were tendered to the company's D&O insurer, the standard D&O policy language contains an exclusion for claims arising from personal injuries; and
- the FDA licensee for a particular medical product is the *company*, which in turn has to comply with the FDCA, FDA regulations and other laws, even if the company accomplishes this through corporate employees, officers, directors or third parties, who act on behalf of the company and not in their own individual capacity.

Courts presiding over product liability and other tort litigation are often reminded by plaintiff's counsel that, when faced with a tough call on whether a legal "duty" is owed, public policy considerations have long favored the compensation of those injured by a faulty, mass-produced product. "Foreseeability" of harm is a quite elastic concept that is thus routinely argued as a basis for expanding "duty" and resulting tort liability. In the last few years, the highest courts of three states (Alabama, California and Massachusetts) have allowed a suit to go forward against an innovator drug company by a plaintiff who had ingested a generic version of the product that was indisputably made by the innovator's *competitor*. While these state supreme courts termed the basis for the claim as a "misrepresentation" (which in Massachusetts is also required to be "reckless"), the innovator drug company in each case was left to defend a lawsuit *involving a product it didn't make, for which it didn't receive the proceeds of a "sale*." Central to all of these decisions was the idea that, because of a strong preemption defense, the plaintiff would not be able to succeed against the actual (generic) manufacturer of the product, and thus the public policy of compensating personal injury plaintiffs justified a departure from the bedrock product liability principle that a defendant-manufacturer is not responsible for injuries allegedly caused by a product it did not sell.

But, as discussed above, counsel for an individual defendant named in such litigation can raise important public policy considerations, too. Virtually any product-related injury can be characterized, at least at the pleading stage, as "reasonably foreseeable" to anyone at the company who designs, manufactures, tests, markets, sells or deals with adverse event reports about the product, However, it can be argued that this shouldn't be a sufficient basis for imposing separate, individual "product" liability for it on an R&D staff engineer, factory shift supervisor, regulatory affairs director or even chief financial officer. Further, even though individual defendants may be entitled to a defense and indemnification by their employer against such claims, this may be quite insufficient, especially if the company no longer possesses the means to do so because it no

longer exists or had little or no product liability insurance. And if the former company has declared bankruptcy, an automatic stay of product liability lawsuits against it wouldn't extend to claims made against its individual former employees, officers and directors.

Plaintiffs will probably continue to attempt to blur the contours of established principles of "enterprise liability" inherent in the law of *product* liability with "simple negligence" principles. After all, there is a general rule that one remains liable for their own negligence, even though it may be imputed to their employer or principal. However, it is the author's opinion that where the individual defendants/employees are not separate "market participants" and have not acted fraudulently or separately interacted with a plaintiff or their medical provider so as to assume some separate, individualized duty of care, they should ultimately not be subject to individual "product" liability.

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