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New rules: Differences between suing medical-device and pharmaceutical drug manufacturers

New court decisions and different approval processes change the litigation landscape

In the last three and a half years, the landscape of medical device and pharmaceutical litigation has developed to reveal opposite implications for manufacturers of products in those industries. Although in both areas there exist expedited processes for obtaining approval of a product to enter the market, Supreme Court decisions have determined that in one area, using that process shields companies from product liability lawsuits while in the other it exposes companies to them.

Medical devices

The story of this dichotomy begins with the Supreme Court's decisions in *Medtronic Inc., v. Lohr et al* (1996) 518 U.S. 470 and *Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312.

Because of growing public health and safety concerns about medical devices, Congress enacted the Medical Device Amendments of 1976 (MDA), which established three regulatory classes for medical devices. The three classes

indicate the level of control needed to ensure that the device is safe and effective. (21 U.S.C. § 360(c).) The higher the class, the more risk the device posed and the more control needed to ensure its safety.

Class I devices include items such as bandages and gloves, Class II devices include things such as wheelchairs, and Class III devices include things such as pacemakers and heart valves. Class III devices receive the most oversight since

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they pose the highest safety risk. This oversight includes a rigorous approval process called premarket approval (PMA). This process includes providing the FDA with full reports of information that is known or should be known to the applicant regarding the safety of the device, statements about the components and operation of the device, a full description of the methods and controls used in the manufacture of the device, and a copy of the proposed label, among other things. (21 U.S.C. § 360e(c)1.) Once these reports are submitted, the FDA reviews them, and may or may not approve the device. If it is approved, the MDA prohibits changes to the device that affect the safety or manufacture of the device without FDA approval. (*Id.*, § 360e(d)(6)(A)(i).)

Surprisingly, most Class III devices on the market today have never gone through this process. Instead, they received FDA approval through two exceptions. First, devices that were on the market prior to the enactment of the MDA were not taken off the market. Rather, they have remained on the market until the FDA completes the PMA process. Second, Class III devices that are substantially equivalent can enter the market without having to go through the PMA process. Instead, they go through an expedited Section 510(k) process which involves providing the FDA with a premarket notification identifying the device(s) that are on the market that are substantially equivalent to the one for which the manufacturer is seeking approval. The focus in this process is on sameness, not safety. (Food, Drug and Cosmetics Act § 510(k), 21 U.S.C. § 360(k).)

With those regulations in place, it was only a matter of time before the legal implications were tested. What specifically would be tested was a provision in the MDA that stated that no state could impose a requirement related to safety or effectiveness on any medical device that is different or in addition to the requirements outlined in the MDA. (21 U.S.C. § 360(a).)

In 1996, the Supreme Court considered whether state law causes of action

against a manufacturer whose device entered the market through the expedited Section 510(k) process were preempted. (*Medtronic Inc., v. Lohr, et al* (1996) 518 U.S. 470.) The Supreme Court held that they were not. Included in its reasoning was the fact that preemption would provide immunity to an industry that Congress felt, with the enactment of the MDA, needed more regulation for public safety. Emphasizing Congress's desire for public safety, the Court also rejected Medtronic's argument that approval through the Section 510(k) process meant the design could not be changed and therefore design claims were preempted, by pointing out that the Section 510(k) process is focused on equivalence, not safety and as such it provides little protection to the public. (*Id.* at p. 493.) In addition to the public safety issue, the Court made it clear that the Section 510(k) process did not impose requirements on medical device manufacturers; therefore, state tort law was not adding to or differing from any existing requirement. (*Ibid.*)

Subsequently, in 2008, the Supreme Court considered another preemption case in the medical device arena, *Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312. This time, the issue before the court was whether state law claims against medical device manufacturers whose devices were approved through the more rigorous PMA process were preempted. This time, the Supreme Court held that they were. The Court distinguished this case from *Lohr* by explaining that the Section 510(k) process at issue there was focused on equivalence, whereas the PMA process at issue in *Riegel* focused on safety. (*Id.* at p. 323.) The relevance of this distinction was clarified by the Court's reasoning that the PMA process imposes requirements on medical device manufacturers and that state tort claims would impose contrary requirements. As such, the Court determined that such claims are barred by the express terms of the MDA, which prohibits states from imposing requirements on medical device manufacturers that are different or in addition to the ones provided for in the MDA. (*Id.* at pp. 323-324; 21 U.S.C. § 360k(a)(1).)

A look at the two cases suggests that the Court's preemption decision hinged on the approval process for each device. The slower, more rigorous PMA process creates safety and effectiveness requirements which cannot be altered, preempting state law tort claims. The faster "substantially equivalent" Section 510(k) process imposes no requirements other than equivalence, and therefore does not preempt state law tort claims. As a result of these two decisions by the Court, medical device manufacturers were faced with the decision either to get their products on the market quickly through the expedited Section 510(k) process and leave themselves open to state tort claims, or to go through the more rigorous PMA process and essentially ensure immunity from such claims.

Approval of pharmaceutical drugs

A look at the availability of state tort claims against pharmaceutical drug manufacturers reveals a different scenario than the one pertaining to medical device manufacturers. Like medical devices, the growing concern over public safety due to unsafe drugs and fraudulent marketing prompted Congress to enact the Federal Food, Drug and Cosmetic Act (FDCA) in the 1930s. The FDCA contained a provision, similar to the MDA, for premarket approval of new drugs which required a drug manufacturer to submit to the FDA an application which contained reports and investigations along with proposed labeling.

At that time, a drug application was denied only if the FDA was able to prove that it was harmful. In 1962, Congress shifted the burden from the FDA to the drug manufacturers by amending the FDCA to require that the drug manufacturers (1) demonstrate that their drug was safe when used in the manner prescribed in the proposed labeling and (2) prove that their drug was effective in the manner prescribed in the proposed labeling. (21 U.S.C. § 355(b).) In 2007, Congress once again amended the FDCA to authorize the FDA to require drug manufacturers to update their drug labels to reflect safety information that

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becomes available after a drug's initial approval, thereby creating a duty for drug manufacturers to update their labels. As a matter of fact, there is regulation known as the "changes being effected" (CBE) that allows a drug manufacturer to add to or strengthen its label without prior approval by the FDA. (21 C.F.R. § 314.70.)

This is the general evolution of pharmaceutical drug regulations. These regulations applied to all drugs until 1984, when Congress passed what is commonly known as the Hatch-Waxman Amendments, allowing generic drugs to be approved simply by showing that they were equivalent to a brand name drug already approved by the FDA. (21 U.S.C. 355(j).) No clinical trials or studies were required in order to get generic drugs approved and out into the market. This expedited approval process parallels Section 510(k)'s "substantially equivalent" process, in that equivalence was the key factor for approval. As with medical devices, after the creation of these regulations, it was only a matter of time before the legal implications were tested in this industry.

In 2009, the Supreme Court was poised to issue yet another preemption decision. This one would resolve the issue of whether FDA approval of a drug preempted state law tort claims against the drug manufacturer. The Supreme Court held that it did not. (*Wyeth v. Levine* (2009) 555 U.S. 555.) In its decision, the Court rejected the drug manufacturer's impossibility and obstruction-of-purpose arguments.

The drug manufacturer argued that it was impossible for it to comply with both state and federal regulations because (1) FDA approval is required in order to change the text of a warning label; (2) any change in label needs to reflect newly acquired information; and (3) unilateral changing of the warning label is in violation of federal distribution and branding. (*Wyeth v. Levine*, 2006 U.S. Briefs 1249, 26-27 (U.S. May 27, 2008).) The Court rejected this argument. Specifically, the Court held that (1) through the CBE regulations, a drug manufacturer can change its label

without approval; (2) newly acquired data also means new analysis and interpretation of old data; and (3) the FDA does not find a drug misbranded simply because the label has changed, but rather when the label is inadequate. (*Levine, supra*, 129 S.Ct. at pp. 1196-1197.)

Similarly, the Court rejected the manufacturer's argument that state tort law claims obstruct the purpose of the FDCA, which was to entrust an expert agency to make labeling decisions. The Court explained that concern for public safety and the history of the FDCA and its amendments made it very clear that it was the drug manufacturer – not the FDA – that was responsible for the labeling of drugs. (*Levine, supra*, 129 S.Ct. at p. 1202.) In the end, the Court concluded that FDA approval of a drug does not protect the manufacturer from state tort law claims. (*Id.* at p. 1204.)

Most recently, in June 2011, the Supreme Court yet again issued opinion-based preemption. This time, the issue before the Court was whether state law tort claims against a generic drug manufacturer were preempted. This time, the Court decided that they were. (*Pliva Inc., et al v. Mensing* (2011) 131 S.Ct. 2567). Although the Court stated in *Levine* that the history of the FDCA makes it clear that a drug manufacturer is responsible for its own drug labeling (*Levine, supra*, 129 S.Ct. at p. 1202), the Court now carved out an exception for generic drug manufacturers. The reasoning of the Court was primarily that there are different duties or requirements for brand-name and generic drug manufacturers such that when a generic drug is being approved, the manufacturer must only show how it is equivalent to an already approved drug. (*Mensing, supra*, 131 S.Ct. at p. 2571.) This equivalence analysis involves the generic drug having the same label as the brand name drug. In other words, the Court determined that the options available to drugs approved through the premarket approval process, such as changing the label through CBE regulations, were not available to generic drugs whose labels had to be the same as the brand name drug. (*Id.* at p. 2575.)

Unlike the *Lohr* case, the manufacturers in *Mensing* were successful in their argument that the expedited approval process for generic drugs imposed requirements on the drug that that label must be identical to that of the brand name drug, and any deviation from that would violate the federal regulation. The Court's reasoning in *Lohr* – that because the expedited process was focused on *equivalence* and not *safety*, preemption would afford little protection to the public, and was inconsistent with the public safety goals of the MDA – was not adopted in *Mensing*, even though the history of the FDCA and its amendments revolved around public safety. (*Mensing, supra*, 131 S.Ct. at pp. 2577-2578.)

As a result of these two decisions, brand name drug manufacturers who go through the lengthy process of premarket approval leave themselves open to state law tort claims while generic drug manufacturers can get their drugs out on the market quickly and with immunity from state law tort claims, simply by showing that they are equivalent to a previously approved brand name drug. This decision seems at odds with the safety concerns that prompted the FDCA in the first place. Now, patients who, unbeknownst to them, have their prescriptions filled with a generic drug by their pharmacists, have no ability to seek justice if they are injured by that drug.

Contrasting outcomes, and what to expect

As a result of these four decisions, there is now an inconsistent landscape with regard to the availability of state law claims against manufacturers of medical devices versus those of pharmaceutical drugs. For patients who have been injured by a medical device, they can only bring claims against manufacturers who went through the expedited Section 510(k) approval process, and not against those who went through the more rigorous PMA process. Conversely, patients injured by a pharmaceutical drug cannot bring claims against generic manufacturers who went through the expedited approval process. Yet, brand

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name manufacturers, who went through the rigorous premarket approval process, are open to liability.

Even though the purpose of the enactment of both the MDA and the FDCA by Congress was public safety, the Court reasoned its way into opposite decisions. It makes no sense to immunize generic drug manufacturers for the same reasons it made no sense to immunize device manufacturers that availed themselves of the expedited “substantially equivalent” process. Both situations involve a product that was approved for human use without testing, investigations, studies, etc., and solely on the basis of equivalence to a product already on the market, not safety.

That “substantial equivalence” only means equivalence, not safety, has become painfully apparent over the past decade. In fact, with medical devices, the Section 510(k) process is currently under comprehensive review by the FDA because of the number of recalls within the group of devices approved in that manner. (“Medical Device Recalls and the FDA Approval Process” (2011), <http://www.510k.net/resources/Zuckerman%2C+2011.pdf>.) This comprehensive review included 25 action items that work groups and task forces within the FDA’s Center for Devices and Radiological Health (CDRH) developed to better the Section 510(k) process, which they planned on implementing in 2011 after the Institute of Medicine had a chance to review seven of those action items. (“Plan of Action for Implementation of 510(k) and Science Recommendations” (2011), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf>.) On July 29, 2011, the Institute of Medicine issued its report recommending that the FDA replace the Section 510(k) process with a new regulatory framework. (“Medical Devices and the Public’s Health: The FDA 510(k)

Clearance Process at 35 Years” (2011), <http://www.iom.edu/~media/Files/Report%20Files/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years/510k%20Clearance%20Process%202011%20Report%20Brief.pdf> at p. 3.) In its report, the Institute of Medicine mirrored the Supreme Court’s views regarding safety, saying that the Section 510(k) process was focused on equivalence and not safety and that a new premarket and post-market regulatory scheme needed to be developed that focused on safety. (*Id.* at p. 2.) Whether or not the FDA or Congress will be influenced by this report, and what changes to the §510(k) process will be made are yet to be seen.

Similar to devices, generic drugs approved through the FDCA’s expedited approval process have been no model for safety. One example is the drug at the center of the *Mensing* decision. Reglan was approved in the U.S. in 1983 for the treatment of GERD. Only five years later, generic manufacturers began producing the generic version, Metoclopramide. Although Reglan/Metoclopramide was only approved for short term use, four to 12 weeks, it has consistently been promoted and prescribed for longer use. Long term use of Reglan/Metoclopramide has been linked to a serious movement disorder called Tardive Dyskinesia. So for over 20 years, generic manufacturers have been filling pharmacies with a drug that has been causing consumers serious injuries. Another example is the well known acne drug, Accutane. Accutane was approved in 1984 and has been shown to cause serious health problems, such as irritable bowel syndrome, Crohn’s disease and ulcerative colitis. What is particularly interesting about this drug is that the brand name version is no longer even available; however, three generic versions are.

The one thing that we can be sure about is that the preemption issue regarding devices approved through the Section 510(k) process will most likely be challenged again if changes are made to that process. If a new process focuses more on safety and post-market obligations, the Supreme Court’s analysis may well change and the ultimate decision may not be a favorable one to consumers.

The recent decision preempting state law claims against generic drugs will probably fuel proliferation of generic drugs once the patents have expired on the brand-name drug – even by brand-name drug manufacturers. Post-patent marketing of the very same medication now comes with complete immunity. Notably, generics make up a significant majority of the drugs dispensed in the U.S. In 2009, 75 percent of all drugs dispensed were generic, and if the brand name has a generic available, the generic is dispensed 90 percent of the time. (See “Expanding the Use of Generic Drugs” (Dec. 2010), <http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.pdf>.)

In the end, the divergent decisions of the Supreme Court may ultimately result in a win/win situation for both medical device and pharmaceutical drug manufacturers at the expense of injured victims.

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