PHARMACEUTICAL PRODUCT LIABILITIES AND THE ROLE OF PREEMPTION

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1. Introduction

Pharmaceutical manufacturers can be subject to product liability claims resulting from various allegations including: (1) design defect, (2) manufacturing defect, and (3) failure to warn. Design defect claims allege that the design of a product is inherently dangerous (even when manufactured perfectly) while manufacturing defect claims allege that a mistake was made in the manufacturing of an inherently safe product. Failure-to-warn claims allege that adequate warnings were not provided to the user even though in most cases there was not a problem with the design or manufacturing of the product.

Significant legal decisions and other changes in the legal environment can directly impact the amount of reserves a pharmaceutical company should accrue to cover the costs necessary to resolve product liability claims. Pharmaceutical manufacturers of all types of drugs (e.g. brand name, generic, biosimilar) have argued that their exposure to product liability claims should be minimal due to the rigorous Food and Drug Administration (FDA) approval process. These arguments, based on the theory of preemption, have had varying degrees of success in the United States legal system.

2. Preemption for Pharmaceutical Manufacturers

The Supremacy Clause of the United States Constitution states that federal law is the supreme law of the land and state laws that are contrary to federal law are invalid (i.e. state law is preempted by federal law). For pharmaceutical manufacturers, a federal law – the Food, Drug and Cosmetic Act (FDCA) – requires that brand name, generic, and biosimilar drugs be approved by the FDA for safety and efficacy prior to being sold to the public. The approval process includes a detailed review of warning labels. Because of this approval process, pharmaceutical manufacturers have argued that failure-to-warn and design defect tort claims filed under state law should be preempted due to the approval process required by the FDCA; however, states typically allow claimants to proceed with these cases against a pharmaceutical manufacturer when an alleged injury occurs.

3. Significant Supreme Court Decisions

Recent US Supreme Court rulings have addressed the preemption of failure-to-warn and design defect claims as it relates to manufacturers of brand name and generic drugs, and the rulings can significantly impact the product liability claim costs of pharmaceutical manufacturers.

In 2009, the Supreme Court ruled in Wyeth v. Levine that failure-to-warn claims against brand name manufacturers are not preempted because brand name manufacturers can alert the public about a proposed warning label through the “changes being effected” provision before the FDA has completed a review. In other words, brand name manufacturers can warn consumers about risks associated with a product before issuing an updated approved warning label. Therefore, the Supreme Court ruled that brand name manufacturers can provide adequate warnings to consumers without violating federal law mandating the approval of warning labels.
For generic manufacturers, the “changes being effected” provision is not applicable. As a result, in 2011, the Supreme Court ruled in PLIVA, Inc. v. Mensing (Mensing) that generic manufacturers cannot be held liable for inadequate warning labels, assuming they are updated in a timely manner, because federal law mandates that generic labels be identical to their brand-name equivalents. Furthermore, in the 2013 case of Mutual Pharmaceutical Co. v. Bartlett (Bartlett), the Supreme Court refuted the argument that generic manufacturers should stop selling a drug if the warning label is inadequate and ruled that federal law preempts design defect claims against generic manufacturers as well.

The Mensing and Bartlett decisions have significantly reduced product liability costs for generic pharmaceutical manufacturers. However, as plaintiffs with alleged injuries resulting from products sold by generic manufacturers look to recover damages but find their options limited, some have attempted to hold brand name manufacturers liable despite not using their product (this is known as “innovator liability”).

4. Implications of Preemption on Product Liabilities

4.1. Brand Name Manufacturers

- Since Wyeth v. Levine, cases where brand name manufacturers have prevailed with a preemption defense are relatively rare. There have been occasional cases where brand name manufacturers have successfully applied a form of the preemption defense (for instance, design defect claims in certain state courts). Recent examples of these cases include Amos v. Biogen Idec in New York (2014), Shah v. Forest Laboratories in Illinois (2015), Rheinfrank v. Abbott Laboratories in Ohio (2015), Batoh v. McNeil-PPC in Connecticut (2016), Cerveny v. Aventis in Utah (2016), and Barcal v. EMD Serono in Alabama (2016). However, given the relatively few cases where a preemption defense has been successful, such rulings have not had a significant impact on total product liability costs for brand name manufacturers.

- The majority of courts across the country that have ruled on innovator liability have rejected it. However, innovator liability was affirmed by California courts in Conte v. Wyeth, Vermont courts in Kellog v. Wyeth, and by the Alabama Supreme Court in Wyeth v. Weeks, and a number of state courts have not yet addressed the topic. In general, innovator liability has not resulted in significant increases in product liability costs for brand name manufacturers.

4.2. Generic Manufacturers

- Failure-to-warn claims are generally preempted on the basis of Mensing and Bartlett; however, generic manufacturers continue to incur legal expense related to defense of claims and, depending on the jurisdiction, these legal expenses can be significant as generic manufacturers may not win a dismissal until a case is heard on appeal.

- Plaintiffs have had success with failure to warn claims against generic manufacturers when the manufacturer does not update labeling in a timely manner to match warning label changes made by the brand name manufacturer (for instance, Reglan litigation in the New Jersey Supreme Court in 2014). In addition, generic manufacturers generally do not have a preemption defense against claims of manufacturing defect.
4.3. Biosimilar Drug Manufacturers

- FDA guidance released in 2016 related to labeling for biosimilar products suggests that the preemption defense may not apply (note, the active ingredients of biosimilars are similar but not identical to brand name drugs, unlike generic drugs where the active ingredients are identical). The guidance states, “…when new information becomes available that causes information in labeling to be inaccurate, the application holder must take steps to change the content of its product labelling [and has] an ongoing obligation to ensure their labeling is accurate and up to date.” Therefore, biosimilar manufacturers likely need to defend against failure-to-warn product liability claims similar to brand name manufacturers as both have an obligation to ensure adequate labeling (in contrast to generic manufacturers that are currently required to follow brand name labeling and are unable to update unilaterally, though must update in a timely manner).

5. Regulatory Response to Preemption

In November 2013, the FDA proposed a new rule that would give generic drug companies the ability to unilaterally update the warning label on their drugs and therefore remove the requirement that they have an identical warning label to the brand name manufacturer. The FDA states that if the proposed regulatory change is adopted, “… it may eliminate the preemption of certain failure-to-warn claims with respects to generic drugs.” This regulatory change could significantly increase product liability exposure for generic manufacturers while potentially mitigating the likelihood of innovator liability claims against brand name manufacturers. However, members of Congress and the pharmaceutical industry have expressed concern that the proposed FDA regulation is in conflict with the Hatch-Waxman Act of 1984 which effectively created the FDA approval process for generic drugs. If the proposed rule is eventually finalized it would likely be subject to legal challenges that would significantly delay or terminate its implementation. In May 2016, the FDA extended the comment period on the proposed rule until April 2017 meaning a final decision on implementation has once again been delayed.

6. Additional Information

Estimating product liability costs for pharmaceutical manufacturers requires a clear understanding of the legal environment and the implications of ongoing developments. Oliver Wyman actuaries have deep and specialized expertise in the estimation of pharmaceutical product liability costs, including mass torts on specific products, and provide actuarial consulting services to many of the world’s largest brand name and generic pharmaceutical companies (and to many of the world’s largest medical device and medical testing companies as well). For additional information on the contents of this article or our services related to product liability claim cost estimation, please contact:

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