Sixth Circuit Court of Appeals Rejects Old Approach to Michigan's Drug Immunity Defense

By Jason J. Thompson

Thanks to the U.S. Court of Appeals for the Sixth Circuit, Michigan residents now enjoy greater protection from dangerous drugs and defective devices. A recent ruling in *Miller v Mylan Incorporated*[1] denied drug manufacturers a free pass in certain defective prescription drug lawsuits.

Beth Ann Kelly was prescribed a medicated patch for her pain. She suffered a fatal overdose of fentanyl—the active drug in the device. Her estate brought a wrongful death lawsuit against Mylan, Inc., the patch's manufacturer.

In its defense, Mylan raised Michigan's drug immunity statute as a complete bar to the case. The trial court found that the fentanyl patch was covered by Michigan's drug immunity law and dismissed the case.[2] On appeal, the Sixth Circuit disagreed, holding that the trial court's analysis was wrong and incomplete.

The case is important to Michigan residents because it calls attention to the fact that modern healthcare treatment is not limited to just drugs or just devices. Today, there are combination products—medical devices that use drugs in their mode of action. In fact, Congress recognized this fact as far back as 1990 when it amended Food and Drug Administration (FDA) regulations and the Food, Drug, and Cosmetic Act to specifically address "combination products."[3] The Sixth Circuit acknowledged this reality in the *Miller* case and held that Michigan's immunity does not cover combination products.

Legal background

Michigan's drug immunity statute expressly restricts immunity to suits based on "a product that is a drug" (i.e., if it is *defined* as a drug) *and* "if the drug was approved for safety and efficacy by the United States food and drug administration" (i.e., if it is *regulated* by the FDA as a drug).[4] Furthermore, the statute adopts the

federal definition of a drug, specifically referencing "section 201 of the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 321."[5] Finally, the statute expressly provides that a medical device is not a drug.[6] Thus, immunity is extended to manufacturers of FDA-regulated products that meet the federal definition of a drug, but does not include medical devices.

Congress's amendment of the federal Food, Drug, and Cosmetic Act in 1990 created a third category of product—the combination product. Simultaneously, Congress deleted language in the definition of "drug" which stated that drugs do not "include devices or their components, parts, or accessories." The deletion reflected the replacement of the binary scheme with a tripartite scheme. While Congress did not explicitly define a "combination product," it did say that such products "constitute a combination of a drug, device, or biological product."[7] FDA regulations more thoroughly define "combination products" to include "product[s] comprised of two or more regulated components, i.e., drug/device… that are physically, chemically, or otherwise combined or mixed and produced as a single entity."[8]

However, when the Michigan legislature passed the immunity statute in 1995, it seemingly failed to account for the fact that Congress had expanded the FDA definitions and regulations five years earlier to include combination products. Whether by ambiguity or intent, the legislature tied immunity of drug manufacturers to the federal definition of a drug. This fact was critical to the Sixth Circuit's analysis of whether Michigan's immunity statute applied to the fentanyl patch.

The *Miller* case

The trial court in *Miller* assumed the fentanyl patch was a drug. It held that "there is no factual or legal basis to disassociate the pharmacologically active and inactive components of the [fentanyl patch], and that the fentanyl patch, including all its system components, is an FDA-approved drug."[9] The court posited that the patch was no different from medication in a time-release capsule. The Sixth Circuit, however, recognized that a fentanyl patch was not just a drug, but also a device for delivering a drug, and thus, could be a combination product under the federal law.

The problem with the trial court's analysis was that the judge never analyzed whether the fentanyl patch was a combination product under federal law. To fix that problem, the Sixth Circuit sent the case back to the trial court with instructions to decide whether the fentanyl patch was a combination product.

The Sixth Circuit next turned to the question of whether combination products are the type of products covered by Michigan's immunity statute. When interpreting statutes, courts assume they are written with knowledge of existing laws. Moreover, accepted canons of statutory construction require an ambiguity to work against immunity for defendants. The Sixth Circuit panel recognized that the Michigan law makes no reference to combination products and, unlike drugs, does not cloak combination product manufacturers with immunity. The Sixth Circuit held, "In light of the Michigan legislature's failure to clearly immunize manufacturers of 'combination products,' the statute should not be construed to exempt those manufacturers from suit."

FAST FACTS

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The effect on Michigan residents

The *Miller* decision represents a game changer for Michigan residents injured by defective drugs. It rejected the old mode of analysis that simply assumed any product involving a prescription drug was in fact a drug for purposes of applying Michigan's immunity statute. Second, it instructed trial courts to determine if devices that use drugs are indeed combination products, devices, or drugs under the federal definitions. The Sixth Circuit said that *a combination product is not defined as a drug under federal law.* After *Miller*, Michigan residents cannot be denied access to the courts for personal injury claims involving defective medical devices and combination products. ■

Jason J. Thompson is chair of the Sommers Schwartz Complex Litigation Department and concentrates in state and national class actions and multidistrict litigation in federal courts. He is board-certified in civil trial litigation by the National Board of Trial Advocacy and has been selected as a Michigan Super Lawyer. His class-action practice includes a variety of areas, including wage and hour violations.

ENDNOTES

1. *Miller v Mylan Inc*, 741 F3d 674 (CA 6, 2014).
2. See MCL 600.2946(5).
3. 21 USC 353(g).
4. MCL 600.2946(5).
5. MCL 600.2945(b).
6. MCL 600.2945(b).
7. 21 USC 353(g)(1).
8. 21 CFR 3.2(e)(1).
9. *Miller*, 741 F3d at 676–677.