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"Parallel Claims And Reporting Requirements": New Motivation For Medical Device And Prescription Drug Manufacturers To Give Adequate Warning.

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I. INTRODUCTION

The United States Supreme Court ("The Supreme Court") has recognized that the Food & Drug Administration ("FDA") has limited resources, and that manufacturers "have superior access to information about their [products], especially in the post-marketing phase as new risks emerge." [2] Indeed, the FDA requires that a manufacturer of medical devices and pharmaceutical products provide updated reports to the FDA related to adverse events. [3] This reporting requirement is critical to monitor safety issues with the product. And it is critical to the FDA process of issuing updated warnings to physicians and patients, so they can make informed decisions related to the risk of the product. Before the reporting requirements were implemented, a 1986 General Accounting Office (GAO) study concluded that less than one percent of device problems occurring in hospitals were actually reported to FDA.[4] While there has been some improvement, one study concluded that less than 10% of the adverse events are still actually reported. [5]

The pre-emption doctrine case law has plowed its way through the state and federal courts often leaving devastated plaintiffs in its path in terms of dismissals and compromised settlements. Compound pre-emption with the heightened pleading requirements, outlined in *Iqbal*[6] & *Twombly*, and plaintiffs have entered an entirely new world of litigation. Fortunately, the pre-emption case law travelled to the Supreme Court for clarification with both medical device and pharmaceutical claims. Plaintiff counsel working in these areas must be familiar with the developing case law in order to appropriately screen new cases, comply with heightened pleading requirements, and to participate in the legislative efforts to change the remaining inconsistencies. This article discusses the key Supreme Court pre-emption decisions as applied to both medical device and generic drug litigation, and discusses the use of specific federal "post marketing reporting regulations" to survive the formidable pre-emption defense.

II. MEDICAL DEVICE REVIEW.

The first step in evaluating any medical device claim is to understand how the product entered the market. The FDA breaks the regulatory process down into three classes of medical

[1] www.thelyonfirm.com
[2] *Wyeth v. Levine*, 555 U.S. 555.
[3] 21 C.F.R.803.1 & 21 C.F.R. 803.50-803.58; 21 C.F.R. 314.80 (C)(2013)
[4] http://www.fda.gov/medicaldevices/safety/reportaproblem/default.htm (See History of MDR Regulation)
[5] See, Katz, Seth. *Put Adverse Events to Good Use.* Trial, Sept. 2013 (Citing, Lorna Hazell, Under-Reporting of Adverse Drug Reactions: A Systematic Review, 29 Drug Safety 385 (2006)(finding a median underreporting rate of 94% across 37 studies)
[6] *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009).

devices. For the purposes of our discussion, it is only important to know that FDA Classification ranges from-- Class I: (Low Risk)(dental floss, crutch, scissors, wire cutter, wrench, wheelchair, powered heating pad, weights, straps, etc); Class II: (Moderate Risk) (powered heating pad); and Class III: (High Risk)(Hip Implants, Cardiac Defibrillators). Assuming the product is not exempted from review, there are two different types of regulatory processes that a company can elect in order to sell a medical device on the U.S. market - (A) Pre-Market Approval ("PMA"), and (B) the 510k process.

A. PMA: Pre-Empted w/ Exceptions

Depending on the Classification and the history of the device, the FDA requires different types of information before a product can be placed on the U.S. market. For new innovative products, that are also Class III devices, the FDA would require significant and detailed testing and data to show the product is safe and effective before it could be sold. This process is known as the Pre-Market Approval Process (PMA). This is the process that most people would expect to see for a medical device --i.e., significant clinical testing and design evaluation submitted before the product is cleared for sale.

1. *Riegel v Medtronic (2008)*

In *Riegel v. Medtronic*,[7] the Supreme Court, essentially, held that products marketed in a form that received PMA are immune from state law tort claims. The decision makes several key points: (1) the FDA PMA establishes federal "requirements"; (2) the PMA is a "rigorous" process where the FDA "weighs any probable benefit of the device against any probable risk of injury or illness from such use; (3) once the device is approved, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling or any other attribute that would affect the safety or effectiveness;" [8] and, importantly, (4) claims based on " a violation of FDA regulation" may be "parallel" claims and are not pre-empted. [9]

B. 510K Process: Not Pre-Empted:

On the other hand, devices that have long histories and carry a Class I or Class II classification, the FDA only requires what is known as the 510(K)[10]or "substantially equivalent"

[7] 128 S. Ct. 999 (2008).
[8] 360e (d) (96); 21 CFR 814(b) (2): The manufacturer may submit an application for supplemental market approval.
[9] 128 S.Ct. 999.

[10] See, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm#510k (A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to PMA. A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable. Submitters must compare their device to one or more similar legally marketed devices

approval. A device submitted under a 510K review is not required to undergo clinical testing to demonstrate it is safe and effective. Rather, this process includes submitting some forms with basic information to otherwise notify the FDA of the intent to sell the product. This process allows the FDA a chance to review the application to determine whether the device is "substantially equivalent" to previously approved devices. The determination is usually made within 90 days of submission. [11]

1. *Medtronic v. Lohr (1996)*

The holding in *Medtronic v. Lohr*, [12] is well recognized and held that state law claims based on defective design, manufacturing or labeling are not pre-empted where the device was approved through the 510k process.

III. PRESCRIPTION DRUG REVIEW.

The starting point in whether a drug claim is pre-empted is also based on the classification of the product and how it enters the market. The FDA's pre-market approval process for a new drug (brand) application is as, if not more, "rigorous" than a PMA and includes the approval of the text of the proposed label. With respect to generics, in 1984, Congress passed the Hatch -Waxman Amendments that created an expedited process for generic drugs. The law allows a generic drug manufacturer to gain FDA approval by showing that the proposed generic drug is "equivalent" to an existing brand name drug. The process requires the safety, efficacy, and labeling to all be the same. [13] While generic drug process appears to be similar to the "510K" process for devices, the analysis is under a different statute with different regulations, and unfortunately, for plaintiffs, renders a different result.

1. *Wyeth v. Levine (2009)*

In January, 2006, under the Bush Administration, without public notice or opportunity to be heard or comment on the issue, the FDA issued a Federal Regulation "Preamble" that reversed the FDA's historical position on pre-emption and was intended to provide immunity to pharmaceutical manufacturers. Incredibly, the Supreme Court provided the " Preamble" little deference[14] and held that federal law does not preempt state law strict liability "failure to warn" claims with respect to brand name products.

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and make and support their substantial equivalency claims. Until the submitter receives an order declaring a device SE, the submitter may not proceed to market the device.)

[11] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm#510k
[12] 518 U.S. 470.
[13] *Pliva v. Mensing*, 131 S. Ct. 2567 (2011)
[14] Indeed, the Court noted that: "It is inherently suspect in light of the FDA's failure to offer interested parties notice or opportunity to comment on the pre-emption question....and it reverses the FDA's own longstanding positions that state law is a complementary form of drug regulation without explanation." 555 U.S. at 559.

In reaching the decision, the Court made a number of notable observations: (1) Manufacturers bear the primary responsibility for drug labeling changes; (2) The history of the Food, Drug and Cosmetic Act ("FDCA") shows that Congress did not intend to pre-empt state law "failure to warn" claims; (3) there was no evidence the FDA prevented the defendant from strengthening its label; (4) there is an FDA regulation[15] that permits the manufacturer to make certain changes before receiving the agency's approval; (5) Wyeth could have revised its label accordance with the final FDA Rule[16] which allows revision of the label to "reflect newly acquired information"; and (6) "The [Final] Rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent development." [17]

2. *Pliva v Mensing (2011)*

The Court held that the generic manufacturers could not independently comply with both federal and state requirements, rendering the claims pre-empted under the "impossibility" standard.[18] While the decision was seen as a death knell to all generic drug claims, the decision, however, had some gaps, as the dissent notes: "Two main points remain undisputed. First, [generic manufacturers] do have a duty under federal law to monitor the safety of their products. And, second, they may approach the FDA to propose a label change when they believe a change is required. " [19] The next question is whether these duties translate into a viable cause of action.

3. *Mutual Pharmaceutical Co. Inc. v Bartlett (2013)*[20]

In a 5-4 opinion, the Court found that State-law design-defect claims that turn on the adequacy of a drug's warning are pre-empted. The Court again applied the "impossibility" standard finding that the generic manufactured could not independently act in a manner to comply with both State and Federal duties.

IV. "PARALLEL CLAIMS"

Assuming the product was a PMA device or a generic drug, the general rule is the state law tort claims would be barred. The exception to rule is if the claims are based on "parallel" federal laws. [21] "The idea that Congress would have granted immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter intuitive." [22] In order to satisfy the "parallel claims" exception, the state court claim must seek to

[15] 314.709c)(6)(iii)(A),(C): The "changes being effected" regulation allows a company to make changes that "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product."
[16] 73 Fed Reg 49609.
[17] 518. U.S. 470.
[18] Id.
[19] *Mensing*, 131 S. Ct. 2567.
[20] *Mutual Pharmaceutical Co., Inc. v. Bartlett*, Slip Copy. No 12-142 (2013).
[21] *Lohr*, 518 U.S. 470; *Riegel*, 128 S. Ct. 999.
[22] *Bausch v. Stryker Corp*., 630 F.3d 546 (7th Cir. 2010)

enforce the same standard or duty as federal law. [23] For example, if the product is manufactured to different specifications as required by a PMA, then the state law claim would be "parallel" to the extent the claim is based on the fact that the product didn't comply with the PMA specifications. However, the "parallel claims" do not need to be this product specific to survive. [24] There is no pre-emption where the state law claim is parallel to even general requirements under Quality System Regulations and Current Good Manufacturing Practices-that is, the failure to comply with any applicable provision "renders a device adulterated." [25] But the claim must be supported by both state and federal Law.

V. PRODUCT LIABILITY CLAIMS BASED ON "POST-MARKETING REPORTING VIOLATIONS" ARE PARALLEL UNDER OHIO LAW.

A. Ohio State Law Requires All Manufactures of Devices and Drugs to Provide Sufficient "Post-Marketing" Warning.

The Ohio Product Liability Statute specifically provides that a manufacturer should not sell unreasonably dangerous products. Available causes of action include failure to warn or inadequate instruction claims arising in a "post marketing" setting, where:

> (1)The manufacturer knew, or in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which claimant seeks to recover compensatory damages;
>
> (2) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm. [26]

B. *PMA Devices*: Federal Law Requires All Manufactures of Medical Devices to Provide Post-Marketing Warnings.

The Federal Regulations provide the same requirement for post market surveillance. Once the FDA approves a device, the manufacturer is required to report any information that reasonably suggests that the device: (1) may have caused or contributed to a death or serious

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[23] *Id.*

[24] *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) (addressed the issue of "general" requirements versus "product specific" finding that there isn't a "sound legal basis for defendants' proposal to distinguish between general requirements and 'concrete, device specific' requirements-- and further notes, that "The FDA regulations contain many requirements that are not concrete or product specific, yet were obviously vital to producing safe and effective medical devices."

[25] *Id.*

[26] R.C. 23076.76

injury or (2) has malfunctioned and that any recurring malfunction would likely cause or contribute to death or serious injury." [27]

In response to the "pre-emption defense" and "parallel claims" common law, plaintiffs have included new state law claims that are based on the manufacturer's "failure to report adverse events" and are citing federal regulations.[28] Both the Ninth and the Fifth have held that failure to warn claims based on a manufacturer's failure to comply with its post-surveillance duties established under the federal regulations are not pre-empted. [29]

2. *Generic Drugs*: Federal Law Requires all Manufactures of Generic to Provide Post-Marketing Warnings.

The Federal Regulations also require that a generic manufacturer "develop written procedures for the surveillance, receipt, evaluation, and reporting of post-marketing adverse drug experiences to the FDA." [30] If a manufacturer receives a report of an adverse event, it must report the event to the FDA within 15 days and investigate the event;[31] Generic manufacturers must also submit a year end analysis summarizing data that may affect the safety and labeling of the product. [32] *Bartlett* provides what almost appear as jury instructions for a parallel "post-market claim" -- In a footnote, the Court states:

> We do not address the state-design defect claims that parallel the federal misbranding statute. The federal misbranding statute requires the manufacturer to pull even an FDA approved drug from the market when it is "dangerous to health" even if used in the dosage, or manner, or with the frequency or duration-prescribed, recommended, or suggested in the labelling thereof. [33]
>
> The parties and the Government appear to agree that a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA. Because the jury was not asked to find whether new evidence concerning sulindac that had not been available to the FDA rendered suldinac so dangerous as to be misbranded under the federal misbranding statute, the misbranding provision is not applicable here. [34]

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[27] 21 C.F.R. 803.50(a); See 21 U.S.C. 360i(a)

[28] *Stengel v. Medtronic, Inc.* , 704 F.3d 1224; *Hughes v Boston Scientific*, 631 F.3d 762 (5th Cir. 2011); Medtronic's writ of certiorari is pending before the Supreme Court, *Medtronic Inc. v Stengel*, No. 12-1351.

[29] The court only addressed the issue of duty and "parallel claims" and did not weigh in on whether the Plaintiff could ultimately prove causation. Importantly, the Opinion also distinguished the case from *Buckman v. Plaintiff's Legal Comm*., 531 U.S. 341 (2001) because *Buckman* addressed the pre-market approval process as opposed to the post-market duties.

[30] *Mensing* citing, 21 C.F.R. 314.80-(b), 314.98 and 314.80 making it applicable to generics.

[31] 314.80(c)(9)(i)-(ii)

[32] *Id*.

[33] *Bartlett*, at 14 citing 21 U.S.C. 352(j); *Bates v Dow Agrosciences, LLC*, 544 U.S. 431 (2005).

[34] Id.

While the current case law has not developed on this issue, the rational has been laid out in the decisions discussed herein. The Supreme Court, in *Mensing* and *Bartlett*, based its decisions on the "impossibility" of the manufacturer actually changing the label or design of the drug. While the FDA carried the ultimate authority on changing label, the same analysis wouldn't hold up if the claim is based on the post-market duties of "reporting adverse events" or "removing misbranded products". Both acts are within the independent control of the company and are found as an independent duties under both Ohio and Federal law. While the causation analysis, and the complexity of bringing such a claim, is beyond the scope of this article, should the causes of action survive, it would naturally follow that where generic manufacturers in possession of important safety information adequately report such data, certain steps would be taken by the FDA to update the warnings, if necessary.

VI. CONCLUSION

The current state of the law doesn't protect the majority of the public. In 2011, brand name drugs only accounted for 18% of the market. [35] Given the Supreme Court precedent and recent medical device decisions on "parallel" claims, a state law tort action based on federal reporting requirements may be a viable (and only potential) claim in both PMA medical device and generic drug claims. While the Supreme Court recognizes that Congress historically believed "state law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and give adequate warning"[36], the current Congress has yet to show they have the same belief. In the meanwhile, counsel may want to consider such "parallel" claims, and others, should Congress not take the appropriate steps to cure these gaps in this important public health law. [37]

[35] http://www.nytimes.com/2013/03/25/business/generic-brand-name-drug-case-goes-to-supreme-court.html?pagewanted=all&_r=0

[36] 555.U.S. at 568.

[37] See, *Bartlett*, at 20. The Supreme Court implicitly asked for assistance form Congress in *Bartlett*, noting: " Suffice to say, the Court would welcome Congress' ' explicit' resolution of the difficult pre-emption questions that arise in prescription drug context."