Implied Preemption And Medical Devices

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Was anyone else out there struck, like we were, that the Court described the preemptive FDA action it recognized in Pliva, Inc. v. Mensing, ___ U.S. ___, 2011 WL 2472790 (U.S. June 23, 2011), in terms of "equivalence"? Here's what we mean:

> "Under this law [Hatch-Waxman], "generic drugs" can gain FDA approval simply by showing **equivalence** to a reference listed drug that has already been approved by the FDA. This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the **equivalent** brand-name drug."

Id. at *5 (as usual various citations we don't care about omitted) (emphasis added on what we do care about).

Equivalence? Where have we seen that before in preemption cases?

Anybody remember Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)? That case involved a medical device cleared by the FDA under a similar sort of procedure, so-called "510k" "substantial equivalence." Here's how the Court described that process in Lohr:

> "[T]he Act also permits devices that are "substantially equivalent" to pre-existing devices to avoid the PMA process. . . . "[S]ubstantially equivalent" Class III devices may be marketed without the rigorous PMA review [if their manufacturers] submit a "premarket notification" to the FDA. . . . If the FDA concludes on the basis of the §510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis."

518 U.S. at 478.

Mensing recognized that Hatch-Waxman shortened the approval process for generic drugs to make it fast and cheap. 2011 WL 2472790, at *5, see id. at *12 ("bringing more drugs more quickly and cheaply to the public"). The same was true of the substantial equivalence procedure in Lohr. 518 U.S. at 478 (process "ensure[s] that improvements to existing devices can be rapidly introduced").

Mensing found that implied preemption existed against warning (and probably other) claims. Lohr found no express preemption against anything.

In Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), the Court took a look at FDA pre-market approval for medical devices – the long-form ("rigorous") type of medical device approval. PMA approval, the Court held, "is in no sense an exemption from federal safety review – it **is** federal safety review." Id. at 323 (emphasis original). Because of the FDA's "rigorous" review and detailed involvement in PMA, almost any claim (save a violation claim) would be "different from or in addition to" the FDA's requirements, thus leading to broad express preemption.

However, when the Court took a look at the prescription drug equivalent of PMA approval – "new drug" FDA approval – in Wyeth v. Levine, 129 S. Ct. 1187 (2009), it sang a different, discordant tune. The Court cared very little about the overall rigor of the process - that such approval "is federal safety review." Instead, Levine fixated on a narrow exception to FDA pre-approval (the "changes being effected" (CBE) exception), and found that this exception, even though little used, defeated "impossibility" implied preemption. Id. at 1197-98 (CBE gets broad reading because "the manufacturer bears responsibility for the content of its label at all times"), at 1199 (impossibility is a "demanding defense"). As for "purposes and objectives" implied preemption, the Court basically decided that it liked tort plaintiffs better than the FDA. Id. at 1201-02.

So the net result of these four cases – Mensing/Levine for drugs and Lohr/Riegel for devices is that preemption in medical device and in prescription drug product liability litigation are treated bass ackwards from one another. In drugs, the less rigorous "equivalence" based form of FDA review provides more preemption – because of identity requirements – than does the FDA's more rigorous new drug approval process. Conversely, in devices, the less rigorous "equivalence" based form of FDA review leads to less (actually, no) preemption, compared to the extensive preemption provided by the more rigorous PMA process.

What's going on?

Well, aside from the bizarre now-you-see-it-now-you-don't quality of the presumption against preemption, the chief difference between medical device and prescription drug preemption is that, in medical devices, the Court addressed express preemption and in prescription drugs, it

addressed implied preemption.

That's important.

Express preemption, because it is "express" – that is, dependent upon specific statutory language addressing preemption – is inherently limited to the statute containing the express preemption clause at issue (except maybe for cases of identical statutory language, which we're not dealing with today).

Thus, the Court's express preemption medical device decision in Riegel wasn't a lot of help to the prescription drug manufacturer in Levine when the Court was considering the otherwise analogous more rigorous form of prescription drug approval. See Levine, 129 S. Ct. at 1200 (distinguishing Riegel because "Congress has not enacted such a provision for prescription drugs").

The reverse, however, is **not true**. Implied preemption principles cut across statutory lines because they stem directly from the Supremacy Clause itself. Thus the finding that fraud on the FDA claims were impliedly preempted in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), supports preemption against analogous allegations of fraud involving other federal agencies governed by completely different statutes.

So while Riegel isn't going to help much in prescription drug litigation because it's based upon express preemption, there's no reason that Mensing can't come to the rescue of medical device manufacturers who don't enjoy express preemption as a result of Lohr.

Counsel defending product liability litigation involving 510k devices should thus read Mensing and give it close consideration.

Lohr has nothing to do with implied preemption. It doesn't even mention it. Therefore, nothing in Lohr precludes Mensing's implied preemption "sameness" rationale from being applied to "substantially equivalent" medical devices. Abundant Supreme Court precedent, most recently in Mensing itself, establishes the proposition that lack of express preemption doesn't affect the existence of implied (often called "conflict") preemption. See Id. at *8 n.5 ("the absence of express pre-emption is not a reason to find no **conflict** pre-emption") (emphasis original).

The core rationale for impossibility preemption in Mensing was that state tort suits demanding different warnings necessarily conflicted with the federal identity requirement imposed upon generic drugs:

"If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking [plaintiff's] allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic [drug]. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. Thus, **it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same."**

2011 WL 2472790, at *9 (emphasis added).

Is there an analogous "sameness" requirement applicable to 510k medical devices? If a plaintiff argued that a defendant's medical device should have been drastically re-designed to make it safer, would that purported state-law duty conflict with the terms of the device's clearance?

We don't have time to answer these questions in depth, but attorneys with pending 510k cases will. What we can say is that the FDA's regulations delineating the substantial equivalence clearance process at issue in Lohr do appear to impose similarity requirements that, under Mensing, might well give rise to implied preemption. The relevant regulation uses the magic word "same" and several functional equivalents:

"(b) FDA will determine that a device is substantially equivalent to a predicate device using the following criteria:

(1) The device has the **same** intended use as the predicate device; and

(2) The device:

(i) Has the **same** technological characteristics as the predicate device; or

(ii)(A) Has different technological characteristics, such as a significant change in the materials, design,

energy source, or other features of the device from those of the predicate device;

(B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device **is as safe and as effective** as a legally marketed device; and

(C) Does **not raise different** questions of safety and effectiveness than the predicate device."

21 C.F.R. §807.100 (emphasis added). There are undoubtedly Guidance Documents, device-specific clearance letters, and other FDA materials that give flesh to the sameness requirements of §807.100.

Thus, it seems to us – mere bloggers that we are – that any state-law tort claims made against 510k medical devices which either: (1) demand labeling/design changes that would alter the intended use, technological characteristics or safety and effectiveness of the device, or (2) conflict with the FDA's determination that substantial equivalence exists, should be subject to implied preemption under the same rationale recognized by the Supreme Court in Mensing.

Go on ... prove us right (or wrong).