One Shoe Drops

Friday, September 02, 2011

Wyeth v. Levine, 555 U.S. 555 (2009), was decided more than two years ago, now. Even though its anti-preemption rationale hinged on an the Court's interpretation of an exception in an FDA regulation that was in no way required by the FDCA itself, we are unaware of any move by anyone in the industry, or by the regulatory types aligned our side, to seek amendment of that regulation in such a way that would reverse the result in Levine.

PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), was decided little more than two months ago. Like Levine, its preemption rationale – favoring preemption, this time – hinged on the Court's interpretation of there **not** being exception in an FDA regulation that was in no way required by the FDCA itself. Showing none of the reticence (if that's what it should be called) of the defense side, the other side, through its catspaw, Public Citizen, has filed a Citizen Petition requesting that the FDA alter its treatment of generic drugs so as to reverse the preemption result in Mensing. For all the administrative ins and outs of the petition, we recommend the FDA Law Blog's discussion here.

We can't say we're surprised at all that the other side did what it did. Preemption is the most powerful defense there is, since it operates without regard to the facts or merit of the underlying litigation. Changing the composition of the Supreme Court is entirely speculative at this juncture. Any attempt to change the FDCA would probably get bogged down in the current partisan squabbling that has paralyzed Congress with respect to anything remotely connected to health care. So the administrative option is all that the plaintiffs (or anybody else) have available.

However, we don't think Public Citizen has gone about it the right way, perhaps because that's impossible, or perhaps because they want the whole loaf rather than just a half. Public Citizen's problem, however, is the FDCA itself, which in the Hatch Waxman Amendments, mandates that generic and branded labels be the "same." Congress said so twice. 21 U.S.C. §§355(j)(2)(A)(v); 355(j)(4)(G). However, Public Citizen's approach, which would allow ANDA holders to amend CBE-style at will, inevitably results in labeling that at times is not the "same" – contrary to the governing statute. The FDA has a lot of leeway, but probably not that much.

It might be argued – and probably will be – that the Hatch-Waxman provisions mandating identity only apply to the application itself. Under that view, generic labels could diverge from branded ones after approval. But to us, that proves just a bit too much. If the statute's identity requirements somehow vanish at the moment of approval, then is there really bioequivalency any more? Theoretically, a plaintiff could argue that one day after approval, before a single generic pill is ever sold to anyone, some legal duty to vary the generic label arises. Such a result would both nullify the language Congress used, and in light of the bioequivalency basis for allowing abbreviated generic applications in the first place lead, would lead to an absurd result. We don't think that kind of approach would get the FDA out of *ultra vires*-land.

Also, consider Mensing. It, of course, was a post-approval case. Every product liability case is post-approval, since any drug (branded or generic) has to be approved before it can be marketed. Thus, in Mensing, the Court had to presume that the "same" language of Hatch Waxman didn't burst like a bubble and disappear the moment the generic drug in that case was approved. A one-minute-after-approval argument probably wouldn't impress the Court very much (at least the majority), given their rejection of "approach[es] to pre-emption that render[] conflict pre-emption all but meaningless." 131 S. Ct. at 2579.

There's no way that a CBE-style label change by a generic drugmaker can force the branded manufacturer to adopt the same label, much less do it instantaneously, which would be required to maintain the statute's "same" mandate. Thus, were the FDA to go the route Public Citizen requests, it would probably end up losing in court, as having contradicted the black letter of the governing statute.

That's not to say that nothing could be done, but since Public Citizen is more concerned about preemption than public safety, it doesn't propose anything that's consistent with the statute's sameness requirement.

We can envision a regulatory change – that logically should be adopted for both branded and generic drugs (we share the general discomfort at the preemption rules being different between the two categories) – whereby more limited types of new evidence (statistical significance, say, rather than the current mere "reasonable evidence" standard) about a more limited set of risks (death or permanent serious injury) could be submitted CBE-style, and if the FDA didn't veto it, everybody (branded and generic) would on short notice have to change their

labels in the interim, pending full investigation. In essence, a proper preliminary showing would shift the usual regulatory burden of proof post-approval. But any system of that nature would leave preemption intact in a lot of cases, and extend it to branded drugs if we had our way, so Public Citizen can't be expected to propose anything like that.

Maybe somebody else could.

In a less cosmic vein, we also see that, when Public Citizen wants something from the FDA, it asserts a "shared responsibility" between the FDA and drug manufacturers to keep labeling up to date. PCCP at 3. We don't really disagree, but that's a far cry from the language in Wyeth v. Levine, that "primary responsibility" for labeling rests with the manufacturer. We'll keep that in mind for the next time Public Citizen swings back the other way when it's in court rather than before the FDA.

Finally, maybe we should be flattered, as we note that Public Citizen, when looking for authority for the proposition that "[u]nder the product liability law of many states, the brand-name company cannot be held liable drug for harm caused by inadequate labeling where the injured patient took a generic form of the drug," PCCP at 6, they cited the scorecard on that issue maintained by this blog (although it messed up the link (no space before ".html")). Evidently, even the other side thinks that, on this issue anyway, we're the most reliable and comprehensive source around. And on Public Citizen's proposition, we and PC are in rare agreement – except for the rogue Conte decision, and a stray federal district court thumbing its nose at Erie federalism, the score's on the order of 55-2. If this were something else than the law, where plaintiffs get unlimited bites at the apple, somebody would have applied a "mercy rule."

We'll be doing our best to keep it that way, because if – as Public Citizen seems to argue – branded drugs subject to CBE label modification are "safer" than generic drugs lacking that procedure, then it serves no public health function at all to penalize safer branded drugs with liability for injuries caused by less safe generics. That would stand 50 years of product liability on its head.