No Stand Up Comity In New York

Thursday, July 07, 2011

A friend of ours, we'll call him "Anonymous," let us know about the recent decision in Forman v. Novartis Pharmaceuticals Corp., ___ F. Supp.2d ___, 2011 WL 2559386 (E.D.N.Y. June 27, 2011). We reviewed it, and were somewhat taken aback that – after the court in Desiano v. Warner–Lambert & Co., 467 F.3d 85 (2d Cir. 2007), presumed to know more about Michigan law than either the Michigan courts (Taylor v. Smithkline Beecham Corp., 658 N.W.2d 127 (Mich. 2003)) or the Sixth Circuit (Garcia v. Wyeth-Ayerst Laboratories, 385 F.3d 961 (6th Cir. 2004)), with jurisdiction over Michigan – yet another court out of New York now presumes to know New Jersey law better than the New Jersey courts (McDarby v. Merck & Co., 949 A.2d 223 (N.J. App. Div.2008)), and the New Jersey federal courts, which have followed McDarby. See Stanger v. APP Pharmaceuticals, LLC, 2010 WL 4941451, at *4 (D.N.J. Nov. 30, 2010); Baker v. APP Pharmaceuticals, LLC, 2010 WL 4941454, at *4 (D.N.J. Nov. 30, 2010); Haggerty v. Novartis Pharmaceuticals Corp., 2009 WL 5064779, at *4 n.4 (D.N.J. Dec. 15, 2009).

We made that point to our friend.

His response?

"Hey, its New York! You're looking for humility?"

We wouldn't dream of going that far. After all, we know more than a few Yankees fans.

We'd just like to see a little comity every now and then.

That would preferable to the current, absurd situation where, in a prescription drug case in Michigan, or in a punitive damages case involving drugs in New Jersey, the plaintiffs lose under those states' application of the fraud-on-the-FDA preemption rule of Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), to their own law. But if plaintiffs can somehow wheedle their way into court in New York, then the same claims survive.

We made this last point in our initial discussion of Desiano way back in 2006, where we urged federal courts to "remember federalism" and not construe state causes of action differently from the courts of those states. With New York courts continuing to boldly go where no courts

have gone before (or since), and forum-shopping plaintiffs following them, we think it's time to review this issue.

First, Buckman (with the caveat that Bexis' role in that case gives us more than the usual defense interest in its correct application).

Buckman, at the Supreme Court level, involved a separate claim for fraud on the FDA – because that was the only thing appealable at the time. The original orders, In re Orthopedic Bone Screw Products Liability Litigation, 1995 WL 273600, at *2-3 (E.D. Pa. March 2, 1995) (PTO 12), and In re Orthopedic Bone Screw Products Liability Litigation, 1997 WL 305257, at *2-3 (E.D. Pa. March 28, 1997) (reaffirming PTO 12 in light of Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)), rev'd, 159 F.3d 817 (3d Cir. 1998), rev'd, 531 U.S. 341 (2001), dismissed not only separate causes of action for fraud on the FDA, but also claims dependent upon allegations that either asserted fraud on the FDA or sought private enforcement of the FDCA.

> "In the instant case, plaintiffs' fraud-on-the-FDA claim is not interchangeable with the Lohrs' negligence claim. This is so not because a state common-law fraud claim is preempted by the MDA, but because the fraud claim at issue here has as its object the FDA and not plaintiffs. That object transforms an otherwise simple fraud claim that would not be preempted by the MDA according to the reasoning of Lohr into one that is precluded by virtue of the fact that the MDA does not provide for a private right of action."

1997 WL 305257, at *3.

However, the requirements of the federal rules allow only (with irrelevant exceptions) final judgments, and not partial dismissals, to be appealed. Compare that to, say, the New York rule. The major players in the Bone Screw litigation faced many other claims and allegations. Only the FDA consultant – Buckman – had an appealable order. Thus, that the Supreme Court in Buckman considered only a stand-alone claim, was simply the happenstance of the procedural background.

Let's look – once again – at the reasons why the Supreme Court in Buckman (without dissent) found preemption:

- First of all, "the relationship between a federal agency and the entity it regulates is inherently federal in character." Buckman, 531 U.S. at 347. That means, among other things, that there's no presumption against preemption, id., because such a

presumption (assuming it exists at all) is enjoyed only by "traditional state tort law principles" and not "any sort of fraud-on-the-agency theory." Id. at 352 (distinguishing Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984)).

- Claims asserting fraud on the FDA inherently "conflict with, and are therefore impliedly pre-empted by" the "ample" powers the FDA has to combat fraud itself. 351 U.S. at 348.
- Conflict preemption also arises because the "balance" among the regulatory objectives that the FDA seeks "can be skewed by allowing fraud-on-the-FDA claims under state tort law." Id.
- How does this skewing take place? One way the "balance" can be upset, is for tort claims to encourage regulated entities to supply more information than the FDA decides that it wants. Id. at 348-49. The FDA's "flexibility is a critical component of the statutory and regulatory framework." Id. at 349.
- "State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA's] judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA and the MDA." Id. at 350.
- The increased administrative burden of particular concern to in Buckman was "fear" of an entity's FDA submissions being second-guessed ("judged insufficient") by state juries, which creates "an incentive to submit a deluge of information that the Administration neither wants nor needs." Id. at 351.
- Buckman found "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." Id. at 352 (citing 21 U.S.C. §337(a)).
- "[F]raud claims [that] exist solely by virtue of the FDCA disclosure requirements" are different from claims involving "alleged failure to use reasonable care" that only happen to "parallel federal safety requirements." 351 U.S. at 353. "[T]he sort of litigation" where "the existence of these federal enactments is a critical element in [plaintiffs'] case . . . would exert an extraneous pull on the [FDCA], and it is therefore pre-empted." Id.

Thus, in Buckman preemption was directed at "any sort of fraud-on-the-agency theory" because: (1) the relationship of a federally regulated entity with its federal regulator is none of the states' business, (2) state-law second-guessing of submissions to the FDA "inevitably"

encourages a “deluge” of unnecessary information that the FDA neither wants nor needs, and (3) state-law claims with FDCA violations as a "critical element" violate the FDCA's express provision for "exclusive" federal enforcement.

Then along comes Desiano, completely ignoring the substance of the Buckman preemption decision while focusing on the form of action. A duly enacted Michigan statute, as construed by that state’s highest court (see Taylor, supra), precluded all tort claims involving FDA-approved drugs – “traditional” or not. That statute had a fraud-on-the-FDA exception that predicated any and all state tort liability on a finding of agency fraud. The Sixth Circuit, held that just like the Buckman plaintiffs, Michigan was butting into an “inherently federal” regulatory relationship, and that this exception also put state juries in the position of second-guessing the sufficiency of submissions to the FDA. See Garcia, 385 F.3d at 965-67 (e.g., statute “raise[d] the same inter-branch-meddling concerns that animated Buckman”).

Desiano refused to give comity to the Sixth Circuit’s judgment concerning the law of a Sixth Circuit state. 467 F.3d at 89-92.

Fresh from deciding to ignore the Sixth Circuit, Desiano also looked past the fraud-on-the-FDA-related floodgate holding back the possible torrent of state liability, and saw only that liability itself. That’s the only way that the Second Circuit could fly in the face of the unanimous contrary holding in Buckman and find any sort of presumption against preemption. Id. at 94 (the statute “did not invent new causes of action premised on fraud against the FDA” but “rather [] regulate[s] and restrict[s] when victims could continue to recover under preexisting state products liability law”).

That’s both completely true – and completely specious. The Michigan statute – unlike a single claim – made **everything** hinge upon a state-law jury’s determination that an FDA-regulated entity had defrauded its regulator. In Buckman-speak, it made the FDCA violation a "critical element" of every state cause of action. Thus, in terms of Buckman's rationale for implied preemption, the Michigan statutory exception isn’t better, it’s worse. **All** liability becomes predicated on a finding of agency fraud. Not only is the state’s intrusion into an “inherently federal” regulatory relationship indistinguishable from Buckman, but the statutory exception makes practical stakes much higher. The higher the stakes, the more “fear” potential defendants will have of an adverse outcome, and with that fear comes a correspondingly greater “incentive” to “deluge” the FDA with stuff it doesn’t want or need.

So Desiano looked everywhere except at the fraud-on-the-FDA claim itself:

"[Plaingiffs] here are not pressing "fraud-on-the-FDA" claims, as the plaintiffs in Buckman, [but] are, rather, asserting claims that sound in traditional state tort law. In Buckman, the Supreme Court mentioned two characteristics of preempted "fraud-on-the-FDA" claims that distinguish them from claims sounding in preexisting common law. The Buckman Court suggested that the source and "vintage" of the duty the drug maker is accused of breaching in "fraud-on-the-FDA" claims is different from the source and "vintage" of the duty that obtains in traditional tort claims. On this basis, the Buckman Court distinguished the plaintiff's unpreempted claims in Silkwood. . . ."

467 F.3d at 94.

But the defendants in Desiano weren't asking the court for preemption of the underlying state-law claims. They didn't have to. The Michigan legislature had already decided to restrict those claims as a matter of state (not federal) law. Desiano raised the state-law claims as a strawman, despite Buckman involving only the state-law trigger for liability.
Moreover, Buckman distinguished Silkwood because the latter case's claims were "not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles." 351 U.S. 352 (emphasis added). The statutory trigger in Desiano was anything but "traditional" - that's why it took a statute to create it.

And the distinction of Silkwood encompassed "any sort of fraud-on-the-agency theory" – Buckman's reasoning wasn't limited to "causes of action."

Ignoring that point was the next way that Desiano went astray:

"The second difference between common law actions and "fraud-on-the-FDA" claims, suggested in Buckman, is that in FDA-fraud cases, proof of fraud against the FDA is alone sufficient to impose liability. In Buckman, there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements. And Buckman explicitly distinguished Medtronic [which we call Lohr] on this ground. Medtronic, the Buckman Court said, involved a "common-law negligence action against the manufacturer of an allegedly defective" product."

467 F.3d at 95. However, the statutory trigger in Desiano involved an explicit fraud-on-the-FDA trigger.

Via a smoke-and-mirrors analysis that looked past Michigan's fraud-on-the-FDA trigger to the "traditional" claims restricted by state (not federal) law, Desiano thus stood Buckman on its head – converting that Court's intensely practical concerns about the inherent effects of a particular "theory" into a pedantic concern limited to "freestanding" claims.

Then, what of Buckman's declaration that a federal regulator-regulatee relationship is "inherently federal" and thus off-limits to state tort law? What of the practical concern over the consequences of "fear" of state second guessing?

In effect, Desiano held that Buckman didn't really mean what it said:

> "[T]hese worries, if deemed controlling, would prove too much. They would result in preemption of a scope that no one is contemplating, let alone advocating. . . . So long as a court or jury is allowed to consider evidence of fraud against the FDA in an ordinary common law tort suit . . ., there will be substantial inducements on the pharmaceutical industry to provide the federal agency with just the kind of information that troubled the Buckman and Garcia Courts. . . . [U]nless a state barred the submission of evidence of fraud against the FDA in run of the mill tort cases, the policy concerns that Buckman expressed in a very narrow context would seemingly justify invalidating any product liability suit brought against a drugmaker. We do not believe Buckman meant to go anywhere near so far."

467 F.3d at 97. In other words, because we don't think the problems are as serious as the Supreme Court did, we're ignoring the Supreme Court.

For one thing, exclusion of fraud on the FDA evidence is exactly what most courts have done. We've collected those cases here (and there are more since then).

For another thing, the Supreme Court recently gave the back of its hand to this sort of "you couldn't have meant what you said" argument as a ground for limiting preemption. That's not a court's job; that function lies with the legislature:

"[I]t is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre. . . . [D]ifferent federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. As always, Congress and the FDA retain the authority to change the law and regulations if they so desire."

PLIVA, Inc. v. Mensing, ___ U.S. ___, 2011 WL 2472790, at *12 (U.S. June 23, 2011).

Same here.

If the Michigan legislature objects to the way that preemption interacts with its statute, it could change the statute. If Congress objects, it could modify §337 to allow certain private enforcement actions with respect to prescription drugs as it has with food. Judicial predilections that preemption might somehow "prove too much," Desiano, 467 F.3d at 97, aren't substitutes for legislative (or regulatory) fixes – assuming any fix is needed.

That's enough on Desiano. We won't even go into the opinion's almost singular (we'd certainly never seen it before) resort to the Buckman oral argument **transcript** in its effort to limit what the Buckman **decision** actually held. See 567 F.3d at 95-96 & n.8.

Our friend was indeed right. Don't expect humility – or even adherence to what's supposed to be binding precedent – from New Yorkers, at least those with Article III lifetime appointments. If they can make law there, they'll make law everywhere.

Oh, and it's not just us who look askance at Desiano. So did (and presumably does) the Supreme Court. Presumably because of Desiano's crabbed reading of Buckman (because that's what the defendants argued) the Court granted *certiorari* in Desiano – although by then the lead plaintiff (Desiano was an appeal from an MDL, and individual plaintiffs get treated like cannon fodder in MDLs) was somebody named Kent.

As we of course reported, the result in Kent was a 4-4 tie, resulting in a non-precedential affirmance. Warner-Lambert Co., LLC v. Kent, 552 U.S. 440 (2008) (per curiam order).

But the missing vote on the Court in Kent was Chief Justice Roberts.

And as subsequent events have shown, not just in Mensing, but in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), Wyeth v. Levine, 555 U.S. 555 (2009), and Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068 (2011), too, the Chief is one of preemption's best friends on the Court – particularly in FDCA-related cases.

All that means that Desiano – which wasn't very persuasive (unless you're pro-plaintiff and result-oriented) to start with – is a thin reed indeed to be hanging one's judicial robes on. It's one of the few adverse decisions out there that we can say with some certainty would be reversed if ever brought before the entire Court.

Which brings us – finally – to Forman. New Jersey passed a tort reform bill a while ago that had a couple of provisions relevant to drug/device manufacturers. For one thing it created a rebuttable presumption of adequacy for FDA-approved warnings (N.J.S.A. §2A:58C-4) that ordinarily is "virtually dispositive of such [warning] claims." Perez v. Wyeth Laboratories Inc., 734 A.2d 1245, 1259 (N.J. 1999). For another thing, the statute completely barred punitive damages against makers of FDA-approved products, except upon a showing of fraud on the FDA. N.J.S.A. §2A:58C-5(c).

The Appellate Division of the New Jersey Superior Court took a look at this provision in McDarby v. Merck & Co., 949 A.2d 223 (N.J. App. Div. 2008). Notably, McDarby was decided after Desiano, so the court had the opportunity to consider whether to follow the Second Circuit down the path to perdition. McDarby didn't – and reversed a punitive damages award:

"Although the decision in Buckman must be read in light of the recent affirmance, by an equally divided Court, of the Second Circuit's decision in Desiano, we nonetheless find Buckman to be controlling precedent in this case. We reach this conclusion because we perceive a difference between the purposes of compensatory and punitive damages that renders the distinctions drawn by the Desiano court between the fraud claims before it and those in Buckman inapplicable in the present context. . . . [T]he statutory focus, like that in Buckman, is narrowly drawn upon a defendant's act of knowingly withholding from or misrepresenting to the FDA information material to the harm alleged. This limited claim for punitive damages, focused upon deterring a manufacturer's knowingly inadequate response to FDA informational requirements, thus differs from the common law compensatory claims at issue in Desiano. . . .

Although there are differences between the fraud-on-the-FDA claim asserted in Buckman and [plaintiff's] punitive damage claim premised on the withholding of information . . . we find the single focus upon fraud on the FDA in each to be sufficiently similar to warrant the application of Buckman to this case. . . . Because

the punitive damages provisions of N.J.S.A. 2A:58C-5c impinge upon federal statute and regulation to the same extent that was recognized in Buckman, we find the principles of implied preemption applied by the Court in Buckman to be applicable here."

949 A.2d at 273-76 (we omitted the court's long discussions of both Buckman and Desiano, since we've already inflicted our own on you).

Later, the New Jersey Supreme Court dismissed an appeal it had previously granted in McDarby without comment as improvidently granted. McDarby v. Merck & Co., 979 A.2d 766 (N.J. 2009). That suggests that New Jersey's highest court had no problem the Appellate Division's preemption analysis.

Still later, another panel of the Appellate Division held that punitive damages claims were preempted under McDarby, because they necessarily conflicted with what the FDA actually did. See Cornett v. Johnson & Johnson, 998 A.2d 543, 567 (N.J. Super. App. Div. 2010) (noting that such an award would be regulatorily contrafactual – requiring that "the FDA would have responded differently" than it in fact did). Ignoring what the FDA actually did in favor of what a state-law jury says it should have done seems like a pretty raw conflict to us. (We note that the New Jersey Supreme Court recently accepted an appeal in Cornett, 15 A.3d 325 (N.J. 2011), although we're not sure on what issue – there were a lot of other things going on in the case).

Unlike McDarby, we see the New Jersey statute as quite similar to what was at issue in Desiano – at least in one respect. They were both **worse**, in terms of the reasoning that drove Buckman, than Buckman itself. Like Buckman, the punitive damages statute drove New Jersey law squarely into the inherently federal field of overseeing people's interactions with a federal regulatory agency.

Even more directly than Buckman, punitive damages based upon fraud on the FDA amounts to private enforcement of perceived FDCA violations that is prohibited by §337(a), because the sole function of punitive damages is to punish and/or deter illegal conduct.

And again, the fear factor driving regulated entities to over-submit (and thus gum up the FDA's works) is much worse than Buckman (and, for that matter, worse than Desiano).

Why?

Dollars. Punitive damages can be larger than compensatory damages – potentially much larger. Depending on what court is interpreting what part of State Farm Mutual Auto. Insurance Co. v. Campbell, 538 U.S. 408 (2003), punitive damages can be as large, up to four times as large, or even up to ten times as large, as compensatory damages.

So in a punitive damages case take the "fear" that motivated the Supreme Court to find preemption in Buckman and multiply it several times over. Then you'll have the amount of fear that the prospect of punitive damages for fraud on the FDA can generate.

But nope, that's not how the New York court in Forman read the law. Instead it extended Desiano to New Jersey's punitive damages statute – holding that the New Jersey judges in McDarby (and of the "[n]umerous state and federal courts [that] have relied on McDarby," 2011 WL 2559386, at *6) didn't know what they were doing. See id. at *7 (deciding, like Desiano, not to give comity to New Jersey state and federal court decisions).

A Yankees fan for sure.

But the Forman opinion has several howlers of its own. First, it applied the Levine "clear evidence" standard. 2011 WL 2559386, at *3. That standard in nowhere found in Buckman, and Levine distinguished Buckman – it did not subsume it. Second, Forman adopted Levine's "congressional silence" rationale, 2011 WL 2559386, at *5, when (as Buckman discussed at length) Congress has been anything but silent. From the inception of the FDCA, that statute has prohibited private enforcement actions (and that's all a punitive damages award can be) against purported FDCA violators via §337(a). Third, it suggests an open question about whether "the legislature intended for the NJPDA to still apply to products liability cases against manufacturers involving FDA-approved drugs and warnings if the exception to the statute was satisfied," 2011 WL 2559386, at *8, when the statute also includes the general presumption of adequacy recognized in Perez. Fourth, it states, 2011 WL 2559386, at *11, that Levine applied a presumption against preemption to punitive damages, when in fact punitives were never at issue in the case. See Levine v. Wyeth, 944 A.2d 179, 182-83 (Vt. 2006) (verdict consisted entirely of "economic damages," "noneconomic damages," and "prejudgment interest").

Beyond these assorted errors, Forman is simply Desiano once-removed – even further out on a limb. The court rotely follows Desiano and holds that, because there isn't "a specific cause

of action for fraud-on-the-FDA" and punitive damages aren't "based solely on the wrong of defrauding the FDA," it can't be preempted. 2011 WL 2559386, at *9.

As we've already explained, we say "so what?" to that, since the punitive damages claim puts states in the business of overseeing federal regulatory interactions equally as much as in Buckman, and it's even scarier from an over-submission standpoint, given the larger verdict potential. But logic was never Desiano's strong point. Significantly, Forman doesn't even bother discussing the Supreme Court's reasons why it found preemption in Buckman. Even more than Desiano, this new decision elevates Forman over substance (sorry, couldn't resist).

Thus, there's not even a whisper of Buckman's holding that states have no business intervening in the regulatory relationship between the FDA and the agency's applicants. Forman simply holds that, because Silkwood applied a presumption against preemption, it would, too. 2011 WL 2559386, at *10. But as we've seen, Buckman specifically distinguished Silkwood – and rejected a presumption against preemption – because "any" agency fraud "theory" (not cause of action) overstepped the proper bounds of state law. 531 U.S. at 347, 352.

Instead of following on-point New Jersey precedent, Forman turned instead for support to two Utah District Court cases decided "following Levine." 2011 WL 2559386, at *12. Suffice it to say that those cases aren't very impressive; we looked at them recently, here.

Finally, Forman relied upon the implied preemption analysis in a "very recent" Supreme Court case to find a "high threshold" for implied preemption. 2011 WL 2559386, at *12 (citing Chamber of Commerce of United States v. Whiting, 131 S.Ct. 1968, 1985 (2011). By not citing Buckman, Forman seems to imply that, maybe, Buckman is somehow overruled. Hardly, since Whiting in fact cited Buckman as an example of preemption when states sought to involve themselves in "uniquely federal areas of regulation." 131 S. Ct. at 1983. In fact, Whiting specifically reaffirms the core of Buckman's preemption reasoning:

> "[T]hose cases all concern state actions that directly interfered with the operation of the federal program. In Buckman, for example, the Court determined that allowing a state tort action would cause applicants before a federal agency to submit a deluge of information that the agency neither wants nor needs, resulting in additional burdens on the agency's evaluation of an application, and harmful delays in the agency process."

131 S. Ct. at 1983. From that description, it seems that the Supreme Court, at least, still believes that Buckman meant exactly what it said, and that its policy rationale doesn't prove too much.

Even more tellingly, however, Forman never cited the most recent Supreme Court decision specifically concerning FDCA implied preemption. That's most peculiar, because Mensing was decided on Monday, June 23, while the Forman opinion issued four days later.

As we recall, Mensing was big news. We heard of Mensing on the same day it was decided. We'd hazard a guess that the Internet is equally available in the Eastern District of New York.

What did Mensing have to say about the presumption against preemption that Forman found so important?

Well, the majority gave it the back of its hand – in an FDCA implied preemption case – by not mentioning any such preemption at all:

> "The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." Where state and federal law "directly conflict," state law must give way. We have held that state and federal law conflict where it is "impossible for a private party to comply with both state and federal requirements." We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them."

Mensing, 2011 WL 2472790, at *8-9 (citations, but not quotation marks, omitted).

That's it.

No presumption against preemption necessary to decide an FDCA implied preemption case.

There's more. Four justices (Justice Kennedy did not join this part) hold – for historical reasons dating back to the Framers – that there's no presumption against preemption in any kind of preemption case. Id. at *10-11 (holding that Supremacy Clause is a "non obstante" provision intended to "indicate[] that a court need look no further than the ordinary meaning of federal law, and should not distort federal law to accommodate conflicting state law").

Moreover, Mensing is also substantively bad news for Desiano, Forman, and anybody else looking favorably on fraud on the FDA theories. A fraud on the FDA theory necessarily requires a jury to find that, but for the supposed fraud, the FDA would have done something different than it actually did. Without the FDA doing something different, there can't be causation. Cornett, for example, discussed that point quite recently.

But not as recently as Mensing.

In Mensing, the majority scathingly dismissed contrafactual speculation that maybe the FDA would have done something differently if a defendant done something differently as a "Mouse Trap game." 2011 WL 2472790, at *9. Contrafactual speculation that, if the defendant did something else, so might the FDA, did not obstruct preemption in the least:

> "Accepting [plaintiffs'] argument would render conflict pre-emption largely meaningless. . . . We can often imagine that a third party or the Federal Government might do something that makes it lawful for a private party to accomplish under federal law what state law requires of it. . . . Following [plaintiffs'] argument to its logical conclusion, it is also possible that, by asking, [defendants] could have persuaded the FDA to rewrite its generic drug regulations entirely or talked Congress into amending the [statute].
>
> If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless."

Id. at *10. In light of Mensing, it certainly looks like the Supreme Court is not at all inclined to push a presumption against preemption into the fraud-on-the-FDA sphere – particularly since Buckman specifically held, without dissent, that no such presumption applied.

Our bottom line: In both Michigan and New Jersey, the locals got it right the first time around.