Search & Destroy Mission Yields Scant Results

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We commented on the Obama Administration's anti-preemption search and destroy mission at the time, back in 2009. To recap, a presidential memorandum directed all federal administrative agencies to seek out, identify, and correct any "unjustified" statements about preemption that took place during the prior ten years (read: during the Bush administration). The FDA was, of course, included in this search and destroy mission. Indeed, it was probably the primary target.

Well, not too long ago the FDA released the results of its search, to almost no publicity. See 76 Fed. Reg. 61565 (FDA Oct. 5, 2011). Even the FDA Law Blog, our usual source for administrative news, didn't bother covering it.

Why?

Because it was basically a non-event. The FDA concluded that "three FDA regulatory preambles contain or refer to statements about preemption that are not legally justified." The primary target, of course, was the FDA's prescription drug preemption preamble of January 24, 2006. However, the FDA's preemption analysis in that preamble had already been nuked by the Supreme Court in Wyeth v. Levine, 129 S.Ct. 1187, 1200-01 (2009), and has pretty much been a dead letter since then (which is pretty much what the FDA said).

So that one's pretty slim pickings – the end of what unfortunately had become a zombie preamble.

The two others were mere references, "two final rules with preambles that referenced the preemption discussion in the [1/24/06] physician labeling rule." Just to be sure, we took a look. One of them involves preemption in the context of FDA-regulated products stored in a "Strategic National Stockpile." 72 Fed. Reg. 73589 (FDA Dec. 8, 2007). It would be hard to find an FDA decision with less relevance to product liability litigation than that, since by definition stockpiled products haven't been used on anybody, at least not yet.

The other preamble, 73 Fed. Reg. 49603, 49605-06 (FDA Aug. 22, 2008), is a little more interesting, since it involves the FDA's amendment of the Agency's Changes Being Effected ("CBE"), which was something we did blog about at the time. Again, the preemption discussion in this preamble appears to have been dealt with in the Levine case, where the Court indicated that this 2008 change didn't affect its view of preemption. 129 S. Ct. at 1196-97.

So that's all the FDA did. It didn't find anything improper about any of the Agency's other preemption-related statements that we detailed in another of our prior posts. Nor did the FDA change the substance of any of the three regulations – only the preambles:

FDA's conclusion about the regulatory preambles, therefore, does not affect the validity or operation of the codified provisions in these three final rules.

The only other stuff in the FDA's search and destroy report, has to do with: (1) OTC drug preemption – that it does not apply to "product liability" – which we already knew; and (2) food preemption, to include references to certain uncodified portions of a 1990 amendatory statute. That's a bit more interesting, but once again it was something that the courts had already figured out.

Thus, all things considered, the FDA Law Blog probably had it right when it didn't bother to cover the rather meager results of the FDA's preemption search and destroy mission. But given that we're preemption wonks, and that we had covered the launch of the mission, we thought our readers would at least like to know about the whimper that resulted.