



New Sharkey Preemption Article

Wednesday, May 18, 2011

Catherine Sharkey, one of the leading academic commentators on preemption in the administrative context, has released a new article on the subject, entitled "Inside Agency Preemption." Here's a <u>link</u> to an online copy of the article. The Sharkey article has a broad scope, and includes a proposal for a state notification procedure for preemption similar to that process outlined for AG notification in the Class Action Fairness Act, and coordinating agency-state consultation about preemption issues through the little-known Office of Information and Regulatory Affairs ("OIRA"). Here's the description from the Article's <u>Abstract</u>:

[T]he Article addresses possibilities for reform, including a novel attorney general preemption notification provision and a blueprint for external review of newly proposed internal oversight procedures. The specific reform measures are guided by the twin overarching goals of (1) creating a "home" within agencies for consideration of the federalism values at stake in preemptive rulemaking and ensuring participation in the rulemaking process by suitable representatives of the state regulatory interests; and (2) establishing a system of internal agency policing of the empirical and factual predicates to arguments for preemption, coupled with external oversight. This journey inside agency preemption charts preemption's future path.

Good luck. Unless the next election brings about a reversal of the current political deadlock in Washington, we question whether anything of significance will get done in that (or a lot of other) context.

Being the preemption nerds that we are, however, we were interested in the presentation in the article of the response of major federal agencies - including the FDA - to President Obama's "search and destroy" preemption directive of May 20, 2009, which we covered here. We haven't seen anything like this anywhere else. Prof. Sharkey put down the pen and picked up the phone and extracted progress reports of a sort from seven major federal agencies (including NHTSA, EPA, and the CPSC in addition to FDA) on their response to the Obama memorandum.

That alone makes the Sharkey article worth the read. We won't steal Prof. Sharkey's thunder (not that we could), but we note her description of the FDA as "less forthcoming," "opaque," "close to the vest." Sharkey Article at 12, 27. Sound familiar? The article discusses the FDA's





recent preemption provisions, not only in high-profile areas such as the Mensing generic drug implied preemption case, but also on less traveled roads such as OTC drugs and bottled water. Article at 25-26. The FDA's continuing reliance on, at least, express preemption contrasts markedly to the more thoroughly domesticated response to the Obama Memorandum that Prof. Sharkey describes for NHTSA. Article at 16-24.

Anyway, if you're interested in this sort of preemption inside baseball, by all means give the latest Sharkey Article a read. You won't be disappointed.