I've been reading a lengthy history of the FDA by Harvard political scientist Dan Carpenter. I'm planning to post later about some his observations regarding the political dynamics of drug regulation. But I was also struck by the implications of his description of drug regulation with regard to preemption of state torts claims.

At first impression, the argument for preemption seems very plausible. The FDA has much more expertise than any jury. If the FDA considers a drug to be safe and effective, why should a jury be allowed to second-guess that in a torts action?

On closer examination of how the FDA works, the argument becomes less plausible. When the FDA is approving a new drug, it is not a simple matter of determining that studies were properly conducted and provide the right statistical information. It also depends on 30 day rehab Los Angeles There are many judgment calls: what "end point" to use to measure success (sometimes immediate lifesaving but sometimes changes in blood chemicals or in symptomatic relief), when to terminate a trial if initial results are sufficiently promising, how to deal with "red flag" cases and outliers, and so forth.

Rather than second-guessing the FDA's scientific judgment, state tort law may simply be balancing risk and benefit differently. This may be legitimate just as a matter of federalism, but it may also reflect the difference between a prior restraint, where FDA keeps a drug off the market completely, and compensation for harm done after the drug is available.

In addition, by the time a tort case is brought, much more evidence may be available. FDA has much more power to control new drugs than existing drugs. Once drugs are on the markets, collecting information about safety and efficacy is harder, and FDA's tools for removing a drug are weak. In addition, once the drug is approved, it may be prescribed for other uses that have not been subject to careful study. A drug company may say that this simply reflects the prescribing decisions of individual doctors, but companies have been known to encourage such uses, and even when they do not do so, they may profit handsomely. In short, a drug that looked good to FDA may turn out to have fewer benefits and create more risks than FDA ever expected.

The argument for federal preemption with regard to prescription drug safety seems stronger than for other products, because FDA is a more systematic regulator of new drugs with a deserved reputation for quality decisions. Of course, there are other arguments for preemption relating to national uniformity or encouraging innovation . But arguments based simply on the expertise and policy-making responsibilities of federal agencies may have less merit than they seem.