2012

The Meningitis Outbreak: Don't Expect Miracles From the FDA

Joanne Doroshow

In one of this week's most anti-climatic news story, the Center for Disease Control and the Food and Drug Administration (FDA) finally confirmed what everyone knew: The origin of the deadly meningitis outbreak was fungus found in steroid shots produced by the New England Compounding Center (NECC) in Framingham, Mass. With 20 already dead and hundreds sickened so far, no group seems more outraged than members of Congress who are demanding answers from the FDA about how it could have failed so badly to protect the public from this clearly-tainted operation. The FDA? The chronically-underfunded and understaffed agency (check out former FDA Commissioner David Kessler's testimony in 2008), the budget of which is currently threatened thanks to Congress' misplaced obsession with federal deficit cutting? (This reminds me of that VP debate exchange over Libyan embassy security, when Rep. Paul Ryan tried to lecture Vice President Biden over defense cuts while, as Biden pointed out, Ryan's own budget would cut embassy security by $300 million.)

When it comes to "compounding pharmacies," however, money's not the only issue. Following a six-year, million dollar lobbying campaign by the International Academy of

Compounding Pharmacists, Congress in 2007 prohibited the agency from exercising proper authority over these companies. This effort included "hundreds of its pharmacists canvass[ing] Capitol Hill urging lawmakers to abandon the proposed legislation [to increase FDA oversight]." (What a sight that must have been! My mind goes right to that famous Monty Python skit with the pharmacist shouting behind the counter "Who's got the pox? Who's got a boil on the bum?")

As to the legislation they killed,

> *One version would have, among other things, strengthened the FDA's powers to inspect all retail pharmacies that make or dispense compounded medications. It would have required compounded drugs to get the same premarket approval from the FDA as generic drugs, and would require clinical trials in some instances. It also called for steps to restrict distribution of compounded medications beyond state lines. [...] Sarah Sellers, a former FDA official who worked on compliance issues involving compounding at the agency, says that "political pressure from the compounders" ultimately defeated the legislation.*

So while scapegoating the FDA might sound good, the law makes clear that this industry is basically on its own. And in that case, the only thing really holding it accountable is civil litigation. Lawsuits will hold drug companies directly accountable for the harm they cause when the government cannot. And that's essentially what the U.S. Supreme Court acknowledged in one of its rare recent decisions that recognized the value of civil litigation to strengthen corporate accountability even when the government *also* regulates. The

case was *Wyeth v. Levine* (2009), and at issue was the Bush Administration policy of trying to prevent injured victims from holding drug companies accountable in court. The Supreme Court recognized that "the FDA has limited resources to monitor the 11,000 drugs on the market" and therefore, lawsuits "offer an additional, and important, layer of consumer protection that complements FDA regulation." No matter how much blame is heaped on the FDA, the Court confirmed the "central premise of federal drug regulation that the manufacturer bears responsibility."

One of the little-noticed achievements of President Obama, which he accomplished almost as soon as he got into office, was to end that terrible Bush Administration policy. But unfortunately a president can't do everything, for example, when it comes to state laws enacted more than a decade ago. In 1995, Michigan passed a law immunizing drug companies that produce unsafe, government-approved drugs, essentially providing this industry a "get out of jail free" card even where the company is deliberately irresponsible, as long as the drug meets minimal government standards.

Only Michigan residents are blocked from court under this law, but other states are trying to follow Michigan's lead. In part, this is due to the efforts of the American Legislative Exchange Council (ALEC), the secretive group of corporations and conservative lawmakers that draft model bills and push them around to state legislatures. ALEC's model bill provides states with three ALEC-approved legislative choices for establishing drug industry immunity.
Both Wisconsin and North Carolina lawmakers have recently considered legislation to do just that.

The good news for all of these states is that ironically, drug industry immunity only kicks in if the drugs in question are FDA-approved. And thanks to the first-rate influence-peddling and lobbying prowess of compounding pharmacists, the tainted steroid shots at issue today are free and clear of FDA regulation. That has allowed Michigan to become home to one of the very first class action lawsuits filed by victims of the meningitis disaster.

So what's next? There may be a new push in Congress to strengthen FDA oversight of compounding pharmacies. At the same time, the Republican House and Senate "sequestration" bills, H.R. 6389 and S. 3473, (their proposals to avoid mandatory spending cuts), both contain H.R. 5, the House-passed medical malpractice/drug industry/nursing home billthat would weaken the legal rights of sick patients as well as the accountability of negligent drug companies.

As if there weren't enough reasons to worry about this election.