

Bad feds, deadly meds: Column

Rena Steinzor 9:06 a.m. EST February 28, 2015

FDA must be equipped to regulate compounding pharmacies.

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In December, the [Department of Justice indicted 14 people](http://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis) (<http://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis>) who worked at the New England Compounding Center. The company manufactured drugs in insanitary conditions that produced a fungal meningitis outbreak that killed 64 people and made 751 gravely ill in 2012. One of the owners and a senior pharmacist face charges of racketeering and second-degree murder.

This [small compounding company mixed](#)

http://www.help.senate.gov/imo/media/doc/11_15_12%20HELP%20Staff%20Report%20on%20Meningitis%20Outbreak.pdf) steroid injections in a so-called clean room where the air conditioning was shut down (<http://www.nytimes.com/2012/10/27/health/fda-finds-unsanitary-conditions-at-new-england-compounding-center.html?pagewanted=all>) at night, technicians wore gloves with holes (http://www.help.senate.gov/imo/media/doc/11_15_12%20HELP%20Staff%20Report%20on%20Meningitis%20Outbreak.pdf) in them and the ventilation system absorbed fragments from a recycling operation located nearby (<http://www.nytimes.com/2012/10/27/health/fda-finds-unsanitary-conditions-at-new-england-compounding-center.html?pagewanted=all>) and owned by the same individuals. When employees complained about unsanitary conditions, managers said (<http://www.nytimes.com/2012/10/13/us/workers-cite-concerns-at-firms-tied-to-meningitis.html?pagewanted=all>), "This line is worth more than all your lives combined, so don't stop it." Countless vials of the contaminated steroid drugs were shipped [out to hospitals and other treatment centers in 20 states](http://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis) (<http://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis>).

The indictments are good news. If convictions are obtained, they will serve as some deterrent to further misconduct within an industry that continues to be virtually unregulated.

At the time the drugs were shipped, primary responsibility for policing the compounding industry lay with state pharmacy boards. In Massachusetts, one member of the [state board was a top executive of a company](http://www.reuters.com/article/2012/10/29/us-usa-health-meningitis-closure-idUSBRE89R0LR20121029) (<http://www.reuters.com/article/2012/10/29/us-usa-health-meningitis-closure-idUSBRE89R0LR20121029>) owned by the same people as the New England Pharmacy Center. The Food and Drug Administration, which is underfunded, overworked and subject to constant litigation that garbled its legal authority over the compounding industry, decided it could not systematically monitor such operations. Of course, members of Congress were unsympathetic to these excuses and FDA chief Dr. Margaret Hamburg was [dragged before committees and excoriated](http://www.npr.org/blogs/health/2012/11/14/165156555/congressmen-clash-with-fda-over-meningitis-outbreak) (<http://www.npr.org/blogs/health/2012/11/14/165156555/congressmen-clash-with-fda-over-meningitis-outbreak>).

In March 2013, [Congress passed bipartisan legislation](http://www.hlregulation.com/2013/11/18/drug-compounding-bill-to-clarify-fdas-role-introduce-new-regulatory-limits-2/) (<http://www.hlregulation.com/2013/11/18/drug-compounding-bill-to-clarify-fdas-role-introduce-new-regulatory-limits-2/>) to fix the problem. Incredibly, though, it allowed compounding pharmacists to decide whether to volunteer to be regulated. Unless they register with the FDA, the agency has no way of knowing about them except through patient and medical professional complaints, a reporting method that in many cases comes far too late. The rationale? Market forces will take care of the problem because no hospital or treatment center will want to deal with an unregistered company.

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In January, the Office of the Inspector General at the Department of Health and Human Services [issued a report regarding Medicare's oversight](https://oig.hhs.gov/oei/reports/oei-01-13-00400.asp) (<https://oig.hhs.gov/oei/reports/oei-01-13-00400.asp>) of compounding pharmacies that supply hospitals. Contrary to the optimism of Congress, the report found that as of January 1, 2015, [just 26 compounding pharmacies](https://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf) (<https://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf>) had registered with the FDA. According to the industry's main trade association, [7,500 community-based pharmacies](http://www.iacprx.org/?277) (<http://www.iacprx.org/?277>) operate around the country, and 3,000 of that number make sterile preparations. The Inspector General also found that Medicare auditors [did barely anything to review](https://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf) (<https://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf>) how hospitals choose and scrutinize manufacturers of compounded sterile preparations, again because of resource shortfalls and lack of training. So much for Congress's half-baked fix for the problem.

The criminal law is a blunt tool to deal with routine industrial practices — even in cases as egregious as the New England one — and its remedies come too late for past victims of abuses. But until opportunistic politicians stop characterizing regulations as "red tape" that "kills jobs" and following Grover Norquist's promise to reduce health and safety agencies to a size where they can be [drowned in the bathtub](http://www.thenation.com/article/grover) (<http://www.thenation.com/article/grover>

norquist-field-marshal-bush-plan), public health will continue to be compromised. Until and unless we restore the vitality of the agencies created to deliver these safeguards, prosecutors must continue to lower the boom on industry scofflaws, especially the individuals who cut corners and kill or injure people.

Hamburg has announced her departure (http://www.washingtonpost.com/national/health-science/fda-head-margaret-hamburg-to-resign-in-march-ostroff-to-be-acting-chief/2015/02/05/0f05de26-ad3a-11e4-abe8-e1ef60ca26de_story.html) after six years on the job. Her experience at the FDA is a testament to the culture of blame that constantly threatens to ensnare public servants. At the rate we are going, we will reach the point where no outstanding candidates will ever want these jobs. That sad circumstance provides a tragic coda to the deaths of those scores of fungal meningitis victims.

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