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POLITICS

How a Shadow Drug Industry Tries to Avoid Regulation

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Last year an outbreak of meningitis killed 53 people in 20 states and sickened more than 720 nationwide. As many as 14,000 patients may have been exposed to the deadly drug.

This was not a natural disaster but a human-made and preventable tragedy. It was caused by a tainted steroid distributed by the New England Compounding Center (NECC), which is part of an obscure \$2 billion-a-year niche of the pharmaceutical industry called "compounding pharmacies." At doctors' request, these firms make customized medications for individual patients, but some have morphed into large manufacturers outside the federal Food and Drug Administration's regulatory reach. Instead, compounding pharmacies are overseen by a state agencies that have a crazy-quilt of different standards, resources, and expertise.

Now some members of Congress are trying to reign in this shadow drug industry by giving the FDA the authority to regulate these firms. But the industry is fighting back, using its political clout to resist federal standards. Like most industries in this situation, they claim that stronger government oversight will hamper their ability to operate profitably. And, like those other industries, the compounding pharmacies are crying wolf.

Under pressure from Cong. Ed Markey (D-MA), the House Energy and Commerce subcommittee is holding hearings Tuesday to bring this issue to public attention. Last week he issued a report documenting that state authorities charged with overseeing compounding pharmacies lack the most basic information about the companies they are supposed to regulate. According to Markey's report, state boards of pharmacy often don't know which pharmacies in their state engage in compounding, how much medication they make, how much of it is sterile or whether any products are sold across state lines. Only Mississippi and Missouri routinely keep track of the number of compounding pharmacies in their states.

State boards don't consistently inform each other, or the FDA, when problem emerge with pharmacies producing dangerous products. Concerned about this lack of transparency, the Iowa pharmacy board is now inspecting over 600 out-of-state pharmacies that ship medications into Iowa. The inspections have already led Iowa to issue charges against five compounding pharmacies, including failure to comply with regulations that require compounders to have prescriptions for specific patients. But no other states have followed Iowa's example.

"In states from coast to coast, compounding pharmacies are going untracked, unregulated and under-inspected, exposing patients everywhere to tainted drugs, disease and death," Markey said in a statement.

Over the years, Republicans have sought to weaken the FDA's authority to regulate corporations -- not only drug companies but also the tobacco industry. At Tuesday's hearing, GOP members are expected to question FDA Commissioner Margaret Hamburg over whether the FDA could have prevented the meningitis outbreak with better policing of the compounding pharmacies.

But Hamburg and other FDA officials insist that federal law limits the agency's authority to regulate the compounders.

"Because they don't register with us, we don't know who they are, we don't have a list of what products they produce," Howard Sklamberg, director of the office of compliance for the FDA's drug division, told the *New York Times* last week.

The problem is hardly new. In 1996, FDA Commissioner David Kessler warned Congress about what he called this "shadow industry." Their activities -- mixing drugs to create new ones -- is comparable to what pharmaceutical manufacturers do. The FDA sets tough sterility standards. Drug firms can't market their products without FDA approval. Without adequate federal standards and regulations, he said, the drugs produced by these firms "could result in serious adverse effects, including death."

In 2007, Senators Edward Kennedy (D, Mass.), Pat Roberts (R, Kan.), and Richard Burr (R, N.C.) proposed the Safe Compounding Drug Act to bring these drug makers within the FDA's authority and set standards, inspect facilities, and regulate interstate sales. Industry groups inundated Capitol Hill with campaign contributions and lobbyists, voicing the familiar predictions of disaster. They denied there was a problem that required federal regulation since "state boards of pharmacy have done a great job," according to L.D. King, executive director of the International Academy of Compounding Pharmacists (IACP), the lobby group for this wing of the drug industry. Another IACP official, David Miller, warned that FDA regulations would "strangle the industry."

A coalition of nine pharmacy organizations -- in reality, drug companies -- claimed that the legislation would "negatively impact patient access to necessary compounded prescription medications."

In the face of that industry mobilization, Kennedy's legislation never made it out of committee and no other legislation has generated much momentum.

Since 2007, The National Community Pharmacists Association (NCPA) has spent about \$2 million on campaign contributions and over \$4.3 million in lobbying, according to the Center for Responsive Politics, a nonprofit watchdog group. During that period, its sister organization, the International Academy of Compounding Pharmacists, has spent over \$1 million on these political influence-peddling activities.

Compounding pharmacies are not legally permitted to produce drugs for the mass market, which require FDA oversight. But a growing number of these outfits do manufacture specialized drugs that they distribute widely, across state lines. NECC, for example, was shipping tens of thousands of vials from its lab outside Boston. This lax regulation has made these firms highly profitable and increasing attractive to investment by private equity firms.

CBS' *60 Minutes* recently broadcast an expose of the NECC's distribution of its "lethal medicine." The show reported that the company was producing products too quickly. One NECC employee told *60 Minutes* that the company "got greedy" and overlooked cleanliness as more orders came in.

Now it is clear that the compounders put their profits over public health and safety. Since last year's meningitis outbreak, compounding pharmacies have been responsible for multiple violations across the country. A team from the FDA recently investigated 31 drug compounding pharmacies in 18 states that produce "high-risk" sterile drugs. The results, announced last week, revealed that 30 or the 31 facilities were served with an inspection report -- a step prior to formal action -- according to the *Los Angeles Times*. The inspectors discovered black particles floating in medication; rust and mold in "clean rooms" where injectable drugs are packaged, and workers handling sterile products with bare hands.

In a prepared statement, FDA Commissioner Hamburg noted that at least four of the targeted firms tried to block the FDA investigators from full access to records or facilities. In at least two cases, investigators had to seek search warrants and were accompanied by U.S. Marshals.

"These challenges and others highlight the need for clearer authorities for FDA to efficiently protect public health," said Dr. Hamburg.

Even in the face of these recent scandals, the industry continues to wield its political clout to resist FDA oversight. The National Community Pharmacists Association (NCPA) said there are already "adequate" regulations in place to protect consumers.

But Hamburg disagrees. She told *60 Minutes* that the agency does not know how many compound pharmacies there are or how many drugs they manufacture, but she is certain that the lack of federal oversight will result in more deaths in the future.

Hamburg has called for legislation to give the agency the authority to "oversee firms engaged in widespread distribution of sterile compounded drug products in advance of or without receiving a prescription."

According to Hamburg, state-level regulation of this nationwide industry isn't enough. Legislation is needed to require compound pharmacies to register with the FDA, comply with federal quality standards, and require them to report serious adverse reactions to their drugs to the FDA.

Two bills have been introduced in the U.S. House of Representative that require more federal oversight and tighter regulations. Markey has introduced the VALID Compounding Act, which would require the FDA to regulate compounding pharmacies that operate as drug manufacturers but preserve states' regulatory authority for traditional small compounding pharmacy activities. Reps. Rosa DeLauro (D-Conn.) and Nita Lowey (D-N.Y.) have sponsored the SAFE Compounded Drugs Act, which would require compounding pharmacies to register with the FDA and require the FDA to set minimum production standards for drugs made by these companies.

It is time for Congress to put the cop on this pharmaceutical beat before more Americans die from the profits-over-safety priorities of this rogue industry.

Peter Dreier teaches politics and chairs the Urban & Environmental Policy Department at Occidental College. His most recent book is *The 100 Greatest Americans of the 20th Century: A Social Justice Hall of Fame* (Nation Books, 2012). Donald Cohen is the chair of In the Public Interest, a national resource center on privatization and responsible contracting. He is also the director of the Cry Wolf Project, a nonprofit research network that identifies and exposes misleading rhetoric about the economy, regulation and government.

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