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Dodgy compounded-drug makers must be monitored better

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Going to a cancer-treatment facility is not supposed to produce fungal infections in patients. Nor is routine cataract surgery expected to result in blindness.

Unfortunately, that's exactly what happened to dozens of oncology patients in New York last year and dozens more ophthalmic patients in Texas earlier this year. In each case, and in all too many cases across the country, Americans are being treated with poorly regulated "compounded drugs," which are made from combining two or more medications to address a particular patient's condition. The worst incident to date occurred in 2012, when 64 people died from meningitis and about 700 others were sickened after receiving tainted steroid injections made by the New England Compounding Center, a now-defunct Massachusetts compounder. Unscrupulous compounders, like one in Broward County, have also been charged with defrauding the government and insurance companies.

Compounded drugs are legal and beneficial for many patients. Except when they aren't.

Some compounders licensed only to make individually prescribed drugs see big dollar signs and secretly make compounded drugs in large quantities to sell wholesale. These are sterile compounds either injected into one's skin or infused into one's eyes. While the Food and Drug Administration (FDA) regulates drug manufacturers and outsourcing facilities, only states have jurisdiction over compounding pharmacies, and they have a patchwork of laws and enforcement capabilities to monitor them.

Yet, a recent report by the Pew Charitable Trusts found that barely half of the states monitor the number of compounders in their state, and only a few keep track of violations. The study found revealed that many states have too few inspectors and that their inspections are irregular and brief. Only Minnesota, Washington state, and Washington, D.C. reported that their inspections lasted between one and three days.

Some bad actors, seeing that the odds of being inspected and cited for violations are low, produce contaminated compounded drugs that they illegally sell to online pharmacies, clinics and doctors. As this gray-market manufacturing expands, so do the risks to patients. Although the FDA lacks regulatory powers over these pharmacies, a study by the agency found that one-third of samples failed quality and safety tests.

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Coalition Against Insurance Fraud

Capitalizing on the opioid epidemic and justifiable fears of prescribing opiates, some compounders also have developed expensive pain-killing creams that work no better than over-the-counter products like Bengay, according to the Coalition Against Insurance Fraud. Charging exorbitant prices, these skin-cream compounders are gouging consumers, government, and insurers.

"Dodgy companies peddling pricey compound pharmaceuticals have fleeced the Tricare program," the federal military health-insurance program, by $1.7 billion in the first nine months of 2015, Stars & Stripes reported. Meanwhile, an Inspector General's report revealed that Medicare Part D spending on drugs sold by compounding pharmacies rose from $70 million in 2006 to more than half a billion dollars in 2015. In the particularly egregious Broward County case, compounders were charged with defrauding insurers and Tricare to the tune of $175 million.

How do we rein in this "dodgy" new type of essentially unregulated drug manufacturer? Lawsuits have been filed, prosecutors have gone after some compounding pharmacies, and compounders have pled guilty to fraud in New Jersey, Colorado, Mississippi, and other states in

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