FOURTEEN DEAD AND 170 INFECTED: POOR REGULATION BUILT THAT

The latest figures indicate that fourteen people have died and at least 170 have been sickened by fungal meningitis arising from an injectable form of the steroid drug methylprednisolone. The bulk of the cases have occurred from patients receiving spinal injections for back pain but there is now at least one documented case of an infection arising from injection of an ankle. At a time when Republicans running for office all across the country routinely deride “job killing regulations”, we now have a sadly perfect example of how lack of regulation kills people.

The tainted drug causing the infections in these cases comes from a single compounding pharmacy in Massacusetts. Compounding pharmacies exist in a regulatory gray area and have pushed further and further away from their original form due to an absence of regulatory push-back. The FDA strictly regulates the manufacturing of pharmaceuticals and assures that they are produced without risk of contaminating microorganisms that could cause infection upon use of the drug. However, compounding pharmacies are regulated only at the state level, mostly because their original role was to provide unique mixtures of drugs produced in response to prescriptions for individual patients. Sensing opportunity to operate in a regulatory gray area, “the free market” has moved in and compounding operations now openly flaunt the single patient idea. In the current case, CNN reports a CDC estimate that as many as 13,000 patients may have been injected with the tainted drug compounded by New England Compounding Center in Framingham, Massachusetts.

The CNN article describes that the regulatory gaps are well-known but Congress has refused to

act:

> If Sarah Sellers' warnings had been taken seriously 10 years ago, 12 people might be alive today.
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> Sellers, a pharmacist and expert on the sterile compounding of drugs, testified to Congress in 2003 about non-sterile conditions she'd witnessed.
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> "Professional standards for sterile compounding have not been consistently applied," she told the Senate Committee on Health, Education, Labor, and Pensions. "The absence of federal compounding regulations has created vulnerability in our gold standard system for pharmaceutical regulation."
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> Nearly 10 years later, there are still no federal sterility guidelines for compounding pharmacies that make and distribute drugs all over the country.

Further, we see that the court system has acted to weaken the poor regulations that previously existed:

> In the 1990s, FDA regulators began to more closely scrutinize the industry, as some compounding pharmacies grew into larger operations that resembled small pharmaceutical companies.
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> In 1997, Congress passed a law bringing compounded drugs under FDA oversight, requiring that they meet certain standards for production, labeling and advertising. Specifically, the law banned compounding pharmacies from advertising their products.
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> A 9th Circuit court ruled that this last requirement was unconstitutional, and the Supreme Court upheld the decision in 2002. The court did not rule on the other portions of the law, though the FDA has not actively enforced them.

We learn from USA Today that problems from compounding pharmacies lowering safety standards while chasing higher profits through high-volume compounding have led to many known cases of infections and other medical complications over the last ten years or so:

> Thousands of these pharmacies play a critical role in providing custom drug mixtures and hard-to-find compounds that might otherwise be unavailable to doctors and their patients. But a proliferation of compounding operations in recent years and the growth of some into de facto manufacturing enterprises that produce and ship thousands of doses of medication all over the country have paved the way for serious problems.
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> Since 2001, records show that the FDA has issued more than 40 warning letters to compounding pharmacies for sanitary violations and failure to take proper steps to prevent the sale of dangerous or ineffective drugs.
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> /snip/
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> If the NECC drug is implicated in the ongoing meningitis episode, it would be the worst recorded U.S. outbreak of illness associated with medication produced by a compounding pharmacy. But it would be far from the first.
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> More than two dozen deaths since 2001 have been linked to contaminated or mismeasured doses of medications produced by compounding pharmacies, according to USA TODAY's review of state and federal records, academic journals, and industry reports. Scores more patients have been badly injured, sometimes resulting in permanent disability.

There also was a highly publicized incident in 2009 when a pharmacy compounding veterinary

drugs made an error that led to the deaths of 21 polo horses in Florida.

When it comes to the business of compounding, free marketeers who seek to exploit the poor regulatory environment have demonstrated exactly why strict oversight is needed when it comes to pharmaceuticals. In a bit of irony, though, rather than the regulations being the job killers, in this case it would seem that the thirst for high volumes of sales of compounded materials from large-scale operations most likely squeezed out smaller pharmacies who probably would have been more scrupulous in preparing materials for injection in response to prescriptions for individual patients. By massively inflating the scale of an operation that was designed to work for individual patients, thousands of people who already were suffering from severe pain now have been put at risk for fatal complications arising directly from putting profits over safety.