

COLD IRON TRUTH

Coldiron Truth: Beware the state pharmacy board

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What does the pharmacy board have to do with me? I'm a physician, regulated by the state medical board. Well heads up. If regulations coming your way are adopted, you will have the additional privilege of being licensed, inspected by, and financially supporting your state pharmacy board.

How did all this happen? In 2012 <http://www.cdc.gov/hai/outbreaks/meningitis.html> , a compounding pharmacy inadequately sterilized multiple lots of methylprednisolone, which were sold around the country and used for intrathecal injections. As a result, [753 http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html#casecount_table](http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html#casecount_table) patients developed fungal infections, including 386 cases of meningitis, and 64 of them died. The owner of the pharmacy and the head pharmacist are up on second degree murder charges.



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After a media bonfire, a congressional hearing complete with the taking of the fifth amendment, and a major rewrite of pharmacy regulations with increased scrutiny and oversight, the State of Ohio Board of Pharmacy rushed to [adopt rules <https://pharmacy.ohio.gov/Documents/Pubs/Special/Compounding/Hazardous%20Drug%20Compounding%20by%20Prescribers.pdf>](https://pharmacy.ohio.gov/Documents/Pubs/Special/Compounding/Hazardous%20Drug%20Compounding%20by%20Prescribers.pdf) before reasonable regulations could be worked out by the Food and Drug Administration, the American Medical Association, and the Federation of State Medical Boards. The Ohio board of pharmacy adopted the U.S. Pharmacopeial Convention ([USP <http://www.usp.org/>](http://www.usp.org/)) regulations, written for compounding pharmacies, and applied them to physicians' offices.

In an overreaching bureaucratic coup de grace, any practitioners who reconstitute any drug in their offices is considered to be a compounding pharmacy, ordered to pay compounding pharmacy registration fees (\$112 yearly), and to undergo the same inspections as compounding pharmacies. You can't be too safe, you know, and all those registration fees (totaling about \$2 million per year in Ohio alone) will decrease what would have been an onerous registration and inspection expense for true compounding pharmacies.

This is the reality we are facing in Ohio, and this situation may soon be "coming to a theater near you." I understand that several pharmacy boards in other states are preparing to roll out similar regulations.

As a kicker, if the product you reconstitute is preservative free (botulinum toxin anyone?), you must use it or dispose of it within one hour. Yes, one hour. If you dilute bleomycin or 5-fluorouracil (5-FU), you must install an outside vented laminar flow hood, and wear level 5 hazmat gear while drawing it up.

patients, doctors now need more regulations, licensing, inspections, and fees?

The real problem here, of course, is not the \$112 fee. It will be the loss of many drugs and therapies that can be used inexpensively in the office, but will now either be unavailable to patients or available at a greatly increased cost. I pointed this situation out at a pharmacy board meeting, and they helpfully responded that I can have my friendly local pharmacist compound any drug I need in a specific strength and unit dose. Who is going to pay for this? I can make diclofenac or 5-FU cream in my office for less than \$20. Instead, it will cost over \$700 at the pharmacy! Further, making something fiscally impossible, like installing a laminar flow hood, is not different than denying it outright. I consider this to be restraint of trade.

Don't allow yourselves to be compromised as Ohio physicians have been. You must be vigilant. Attend the public hearings and testify. In Ohio, the hearings were held over the Christmas holidays. Guess what? No one came to the hearings! You must show up and complain. Loudly. You must point out how patients are going to be hurt, not helped, by these rules. You must point out the superb safety record of physicians when using in-office pharmaceuticals. You must alert your neurology, ophthalmology, gynecology, and urology colleagues to the problem since they all use neurotoxins, too. The primary care doctors all reconstitute drugs (think antibiotics) for office use, too.

These efforts are also part of a larger campaign to give pharmacists a larger clinical role in patient care. If pharmacists license you, if they inspect your office, how can you oppose them when they want clinical privileges?

is a legislative change that instructs that physicians, not pharmacists, will define what is considered to be a dangerous drug.

It is time to be alert, vigilant, and outspoken. You must do this to preserve your ability to do what is best for patients, to be able to deliver care in an expeditious, efficient, and cost-effective manner. This is what being physician is all about! Keep your state board of pharmacy off your license and out of your office.

Dr. Coldiron is a past president of the American Academy of Dermatology. He is currently in private practice, but maintains a clinical assistant professorship at the University of Cincinnati. He cares for patients, teaches medical students and residents, and has several active clinical research projects. Dr. Coldiron is the author of more than 80 scientific letters, papers, and several book chapters, and he speaks frequently on a variety of topics. Reach him at dermnews@frontlinemedcom.com.

References

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