



Pills and Solutions

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FDA Inspections and Your Rights

It is no secret that the Food and Drug Administration (FDA), is overreaching its authority to the point many believe it is out of control. There are only so many options available to reign them in. One is for a new administration to appoint a more reasonable head who will follow the law. Good luck with that one. Another option is for Congress to exercise its power of the purse and withhold funding until the agency begins to act within the bounds of law, some laws of which, the FDA agreed to follow then reversed course. The final option is for "We the People" to stand against their unlawful actions. Our Founding Fathers stood against the Crown, paid an enormous price, but gave us the greatest country known to man. In their honor, we should be willing to stand against an agent of our own "crown", to secure the industry known as compounding. The price to pay will not be nearly as great, but the outcome will be immeasurable.

We are aware of several 503A compounding pharmacies who have endured gross violations of the law in the past year. Unfortunately, many do not fully understand their rights or what the FDA has the authority to do, or the restrictions place upon them by law. While we are certainly not legal experts, we have become aware of information that may be of help and we would like to pass it along. There is much you can do to protect yourself, your employees and your business. Some of this you may already know, but some may be new to you. So we offer this to those who are interested. Do with it as you see fit.

1). The first thing you need to do is to secure a copy of the Drug Quality Security Act (DQSA) passed by Congress, agreed to by the FDA and signed into law. It is available on line. It provides a clear definition of a 503A compounding pharmacy and what government agencies have oversight of them. It is tedious to read, but the FDA has provided a single document explaining it. Goggle, "Compounding and the FDA: Questions and Answers". Highlight Section 6. When the FDA comes to call, this is the first thing you show them. You will not win the argument that they have no jurisdiction over you, but at least they will know they can only go so far. Also line up a qualified pharmaceutical attorney. They do not have to be on retainer, just available if you need them.

2). If the FDA shows up and announces an inspection, without a state regulator in tow, politely explain to them that they are in violation of the law, that only a state regulator can announce an

inspection of a 503A facility. Therefore, under advise of counsel, you cannot consent to an illegal inspection. If they object simply say that they would be in violation of the US Constitution guarantee of protection from unlawful search and seizure, in Amendment 4.

The exception is if there is a question of criminal activity or a life threatening situation. Then the FDA may come in for an inspection without the state board of pharmacy regulator. They still must confine the inspection to the issue at hand.

3). If you do not already have a posted sign forbidding photographs, video and recordings in your facility, post one at once.

4). If you do not already have an SOP for inspections write one ASAP. In it state the following:

a) Before an inspection can begin, the FDA inspectors must sign a document agreeing to the terms of the inspection.

b) All inspectors will be accompanied by a designated escort. Inspectors will speak only to the escort, unless the escort or the owner of the facility agrees otherwise. The escort should either be the owner or the manager.

c) All inspectors will observe all safety requirements, protocols, and regulations at all times. Failure to do so will result in immediate removal from the facility. (This is for their protection as well as yours).

d) The inspectors must present documented probable cause for the inspection, specifying such things as a particular drugs, lot numbers, tests, equipment, or logs that they intend to inspect. They may not go beyond those items listed in the documentation. (If they do, that qualifies as a fishing expedition and is illegal.) They can not say they want to see all of your results on a kind of test, for example. It has to be related to a specific patient, drug, date, technician, testing apparatus, or the like.

e) Any reports or information you provide them must be copies, not originals, and customer's names should be redacted.

f) All of the formulas that you develop are proprietary and do not have to be given to them, unless they provide a written statement of their intended use and who will see them. All such formulas or materials must be stamped with "Proprietary". These are considered your intellectual property and are protected under the 4th Amendment of the US Constitution.

g) Do not sign or initial any papers or documents they may hand you. Simply say that on advise of counsel you are not allowed to sign or initial any papers or documents.

h) If they ask to remove anything from your facility, they must provide documented probable cause for doing so, provide the intended reason, tell what tests they will run, if any (be sure to retain some of the substance so you can run parallel tests), and they should sign a document stating these things. Again, failure on their part is a violation of the Search and Seizure clause in the 4th Amendment.

5). They may ask for documentation that you have audited your vendors. It is a good idea to have done this. Audits can be a simple list of questions verifying the vendor follows GMP or ISO or some scrutiny procedures.

6). The FDA agents will most likely try to intimidate you and convince you to do whatever they ask. Do not let them intimidate you. Be polite, but be firm. If they attempt to insist, tell them you would be happy to call the sheriff and let him explain the law to them.

If a state regulatory agent accompanies the FDA agents, you will have to comply to their demands, but the same rules as above apply. Inspectors must agree to an escort as their primary contact, they need to be reminded of the confines of the DQSA law, they must have documented probable cause for specific searches, they may not take photos, videos or make any recordings, they must provide all required documents, and before the inspection they must sign an agreement of the terms of inspection. (This assumes you have such a form already.). Inspectors must follow all safety precautions. They may try to assure you such provisions are not necessary, but you must be firm and insist. Explain that on advise of counsel, you have to take steps for their protection and yours.

Expect to be written up - it's how they justify their job. You have 10 days to challenge their findings in writing if you believe the findings to be in error. The findings are public record. Most people who read them pay little attention to them. Regard them as kind of a rite of passage. You also have 10 days to respond to findings that require action on your part. You should be sure to avoid admitting to anything in your letter, but do state corrective actions you intend to take.

Hopefully, you will find this information useful. It is not intended to be exhaustive and we are not legal experts, but the guidelines given here are based on sound public knowledge.

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