FDA TRIALS: WHY EXEMPTIONS ARE A BIG DEAL*

The FDA trials process for new drugs can take years and are very expensive. The following is a high-level snapshot of the process, as defined by the FDA. I say high-level because the journey to FDA approval for every new drug may have a path all its own.

1. Investigational new drug application. The pharmaceutical drug company and its partners may perform preclinical testing on animals and how the drug will be used with humans. The FDA will decide, based on the results submitted to it, if the new drug is reasonably safe to start testing on humans.
2. Phases 1 and 2 testing. Phase 1 testing is performed on healthy volunteers. Phase 2 testing begins if Phase 1 testing does not result in unacceptable toxicity. The number of Phase 2 volunteers is limited to approximately 300.
3. Phase 3 testing. If the results of Phase 2 are positive, Phase 3 begins. The number of Phase 3 subjects ranges from a few hundred to 3,000. At the end of Phase 3, the FDA will conduct a review to assess the new product's safety, efficacy, or optimal use.
4. New drug application (NDA). Assuming the FDA's review is positive, the pharmaceutical drug company (or a drug sponsor) will initiate a new drug application (NDA). This includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured. Assuming the application is complete, the average response time by the FDA to the NDA is 10 months, or 6 months for priority drugs.[7]

For pharmacies compounding drugs, the FDA trials process for every compounded drug would be so expensive and so time-consuming that only the highest-volume and highest-valued drugs would end up going through the process. A number of compounding pharmacies would elect to exit the business, and drug shortages would result for patients in need of medication. This is the opposite result that both the lawmakers and the FDA hope for from the Drug Quality and Safety Act. Thus, the

* The above description of the FDA trials process is a high-level snapshot. For a detailed review of the process itself, I urge my readers to visit the FDA website at http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm or call the FDA and speak to one of the FDA trials specialists.