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Reasons the FDA Should Not Be Involved in Pharmacy Compounding

In the past, Compounding Was Pharmacy! Throughout history, pharmacists compounded drugs for patients as they were prescribed by physicians.

- In 1820, the U.S. Pharmacopeia established monographs for pharmacy compounding for the U.S.
- In 1906, the U.S. Pure Food and Drug Act established the *U.S. Pharmacopoeia* and *National Formulary* as two of the official compendia of standards for pharmaceuticals in the U.S.
- In the early 1900s, however, the pharmaceutical industry began manufacturing most drugs and dosage forms for patients.
- The U.S. Food and Drug Administration (FDA) was established with the passage of the Federal Food, Drug and Cosmetic Act of 1938 to develop and enforce standards for manufactured drugs.

During the mid-1900s with the large effort by the pharmaceutical industry in providing numerous strengths and dosage forms for drugs, the need for compounding diminished. Since the late 1900s, however, a lot has changed and the pharmaceutical industry no longer supplies all the medications needed by patients and pharmacy compounding has experienced tremendous growth. It has not, however, been without its detractors demanding that the FDA control compounding. However, the FDA recognizes the importance of, and need for, pharmacy compounding. This is also true of the Supreme Court and the U.S. Congress; all recognize the contribution of pharmacy compounding to modern health care today.

The individual states enact laws establishing the various professions and their requirements. The State Boards of Pharmacy are established to enforce the components of these acts as they relate to pharmacy. *Pharmacy compounding is addressed in state boards of pharmacy regulations or the laws within the states.* This should be adequate and places the control and enforcement at the state level, not at the federal level. The FDA was created to enforce requirements on the pharmaceutical industry and not on the practice of pharmacy. However, the FDA has expanded its "reach" in recent years due to a blurring of the line where some pharmacists are practicing in a "gray area" between compounding and manufacturing. This gray area needs to be clarified for all involved through the state boards of pharmacy. This presentation does not necessarily address this gray area but does address compounding involving the relationship between a physician, patient and pharmacist.

The FDA should not be involved in pharmacy compounding for the following reasons:

1. The FDA's definition of a "New Drug" requires that all compounded formulations and any manipulation of a commercially manufactured product outside its officially, approved labeling, is an unapproved new drug. In fact, a significant percent of drugs are used for indications other than what their official labeling states.

2. It is *impractical* to require that each and every one of the thousands and thousands of formulations prescribed by physicians and compounded every day be submitted to the FDA as an Investigational New Drug with accompanying documentation, this includes hospital intravenous admixtures, etc. The current cost to get a single drug to market is from 200 to 500 million dollars.

3. No entity would be interested in financing all the clinical trials to support each and every one of the compounded formulations as there would be insufficient income from these compounded preparations to pay for the research and clinical studies. Already, many FDA-approved drugs are discontinued by the pharmaceutical manufacturers for "economic reasons" when a sufficient profit is not gained from them.

4. With the variations within each formula, physicians may prescribe a change that would result in another "New Drug" that has not been tested. Why should a physician be denied the right to prescribe a change in strength or delivery route and a patient denied the right to adequate health care and treatment that could be cost-saving, because the FDA views it as another "New Drug"?

5. The time requirement and logistics of studies for these compounded formulations would be difficult, if not impossible. As an example, providing patient populations for these thousands of studies would be a formidable, if not an impossible task.

6. A change in the vehicle, due to the preferences of different physicians, would again require additional New Drug applications.

7. There is no patent protection for these formulas as they are prescribed by physicians for individual patients so there is no incentive to do it.

8. The FDA is a large, complex governmental agency where communication between departments seems somewhat limited.

9. As is apparent in recent years, the FDA is not really charged with the responsibility of keeping the pharmaceutical supply intact in the U.S., as they have closed down manufacturing facilities that eliminated the availability of numerous drugs; the physicians then have no alternative source of the drugs without prescribing medications that need compounding.

10. FDA approval of a drug is no guarantee that adverse events, even deaths, will not occur.

11. The current mechanism(s) related to single patient INDs, orphan drugs, and compassionate use are not feasible for physicians to initiate, as many patients are "one of a kind" and the time required for the current mechanism(s) are unrealistic.