Pharmacy Compounding subject to FDA Approval?

The Facts Just Don't Fit

Over the past 15 years, there has been a fundamental disagreement between the U.S. Food & Drug Administration (FDA) and the profession of pharmacy over the legality of compounding.

The view recently espoused by the FDA is that compounding has been illegal ever since the Federal Food, Drug, and Cosmetic (FDC) Act was passed in 1938. The compounding profession disagrees, and the facts concur. The issue is coming to a head in litigation in Texas. There, the courts will decide whether, as FDA says, every pharmacist who has compounded since 1938 has committed a criminal act each time he or she has compounded, or whether Congress never intended to criminalize the act of compounding to fill prescriptions written by physicians.

FDA's lengthy legal briefs can be boiled down to a very simple argument: that every compounded drug is an unapproved new drug. FDA's argument primarily hinges on one statutory provision.

This provision defines a new drug as "any" drug that is not generally recognized as safe and effective by experts. FDA argues that the word "any" is clear, simple, and unambiguous, and precludes examining any historical facts.

The problem with FDA's argument is that the courts have repeatedly rejected it. Just recently, the U.S. Supreme Court reviewed a federal statute that imposed restrictions on individuals who had been convicted by "any" court. The government argued there, as the FDA argues here, that "any" means "every" and there are no exceptions. The Supreme Court rejected the government's argument in that case, ruling that a Japanese court was not "any" court for purposes of interpreting the law. In other words, the Court said that courts should not read the word "any" literally as meaning each and every, and should not ignore, as the government wanted, Congress' objectives and the historical context.

This is not a new concept. The Supreme Court in this decision
This is not a new concept. The Supreme Court in this decision cited another, nearly 200-year-old Supreme Court decision involving the word “any.” Thus, FDA’s central argument about how statutes must be interpreted – that the phrase “any drug” means every single drug, without qualification – flies in the face of judicial precedent going back two centuries.

FDA has cited no facts to support its position. Instead, FDA relies completely on this statutory argument. However, the facts refute FDA’s view.

**FACT:** The legislative history of the FDC Act shows that Congress did not intend to interfere with the practice of medicine. Depriving physicians and patients of access to compounded drugs at a time when there were no alternatives for most diseases would have caused an extraordinary disruption with medical practice, and would have been contrary to Congress’ intent.

**FACT:** There is absolutely no indication from the legislative history that anyone in Congress expected or intended for the FDC Act to turn compounding pharmacists into criminals. FDA says that this silence shows that Congress did not intend to confer an exemption upon pharmacists. In fact, the contrary was true – no expressed exemption was needed because nobody ever contemplated that compounding would be deemed illegal. Compounding had been practiced since the early colonial days. Under FDA’s theory, Congress fundamentally changed the health care delivery system without anyone in Congress saying, or even hinting, that they had just abolished compounding as a lawful activity.

**FACT:** As of 1938, every state permitted compounding. Pharmacists were trained and licensed to compound in every state. These state laws did not change after passage of...
the FDC Act. Compounding remained a state-sanctioned, state-licensed activity. Under FDA's theory, every state was authorizing pharmacists to – and often even requiring pharmacists to – commit illegal acts.

FACT: In 1938, pharmacy schools trained pharmacists to compound. Under FDA's theory, these schools of pharmacy were teaching – and have continued to teach – illegal conduct.

FACT: The pharmacy groups were among the strongest supporters of the FDC Act. The President of the American Pharmacists Association (APhA) was persistent in supporting the bill, and praised Congress for passing the law. In fact, pharmacy groups wanted the law passed because they were already heavily regulated, and their competitors – drug manufacturers – were not. Under FDA's theory, the pharmacy groups were supporting legislation that deemed virtually every pharmacist in the United States criminals.

FACT: The United States Pharmacopeia (USP) contained monographs for compounded drugs in 1938. In fact, Congress gave the USP special status under the FDC Act. Under FDA's theory, the USP monographs for compounded drugs established criteria for illegal products. In fact, since 1938, the USP has added monographs for new compounded drugs, and more recently, standards for compounding. Under FDA's theory, each new monograph has represented another formula for another illegal product.

FACT: The United States government has long engaged in the act of compounding. Documents from the early 1940s give military pharmacists instructions on compounding. The Department of Defense has continued to support and utilize compounding. In earlier litigation, we obtained copies of the formulas used by U.S. Army pharmacists for compounding drugs from bulk. Under FDA's theory, every military pharmacist who compounds is breaking federal law. This would create a terrible dilemma for military pharmacists – filling an order to compound a drug would mean to follow an illegal order.

FACT: The federal government provides reimbursement coverage for compounded medications. Under FDA's theory, the U.S. Government is paying for an illegal product.

FACT: The FDA itself did not take the view in 1938 that compounding was illegal. There is no evidence whatsoever that FDA, in the wake of the passage of the law, told pharmacists that their behavior was illegal. In fact, in subsequent publications for pharmacists talking about the FDC Act, FDA described multiple provisions of the law, but did not tell pharmacists that one effect of the law was that compounding had become unlawful.

FACT: There is no contemporaneous evidence that anyone thought that compounded drugs would become illegal new drugs as a result of the 1938 FDC Act. No one in Congress, no one from FDA, no pharmacist, and no witnesses before Congress ever said or suggested such a thing. Under FDA's theory, the U.S. health care system was being transformed, and nobody ever said a word about it. FDA has argued in its brief that Congress passed the law to give FDA the discretion to regulate compounding. In fact,
there is no evidence at all that Congress or anyone else thought it was conferring upon FDA any authority over compounding. Nor is there any evidence that Congress intended for compounding to survive solely at the discretion of FDA.

**FACT:** In 1970, Congress passed a law regulating controlled substances. It gave an exemption for compounding pharmacists under certain circumstances. The U.S. Drug Enforcement Administration’s (DEA) implementing regulations also gave compounding pharmacists an exemption. Under FDA’s theory, Congress outlawed compounding in 1938 and then in 1970 exempted this illegal behavior from certain provisions of the DEA laws. There is no evidence that in 1970 Congress considered compounding to be anything other than a lawful, medically necessary practice.

**FACT:** Compounding remains ubiquitous, in the retail setting, in hospitals, and elsewhere. There is no disputing – even by FDA itself – that compounding remains medically essential. Under FDA’s theory, compounding pharmacists who perform this essential, life-supporting service have been criminals since 1938, protected from prosecution only by FDA’s willingness to exercise its enforcement discretion.

**FACT:** Until relatively recently, FDA did not take the position that all compounded drugs were unapproved new drugs, and therefore illegal. In fact, FDA did not espouse this theory until more than five decades after the law was passed. If, as FDA now argues, the plain language of the statute makes it crystal clear that every compounded drug is illegal, one would have expected FDA to have articulated this theory well before a half century elapsed.

FDA has no facts to support its position. When Congress passed the FDC Act in 1938, nobody – Congress, pharmacists, state legislatures, state Boards of Pharmacy, USP, the U.S. Military, or FDA – thought that Congress had banned compounding. Nobody said a word about this dramatic shift in health policy. It was not until 50 years later that FDA reinterpreted the law to say that a linchpin of the health care system was a criminal act.

The courts have developed principles for interpreting this type of silence. In a less legalistic way, so did Sir Arthur Conan Doyle. In his famous story Silver Blaze, the following exchange took place:

**Colonel Ross:** “Is there any other point to which you would wish to draw my attention?”

**Holmes:** “To the curious incident of the dog in the night-time.”

**Colonel Ross:** “The dog did nothing in the night-time.”

**Holmes:** “That was the curious incident.”

The utter silence regarding any intent to ban compounding, combined with massive accumulation of facts rebutting FDA’s newly minted theory, shows that FDA’s interpretation is simply wrong and would keep millions of patients from receiving essential treatment. For these patients with unique needs that are unmet by off-the-shelf pharmaceuticals, compounded medicines – prescribed or ordered by licensed physicians and mixed by trained, licensed compounding pharmacists – are the safest and most effective way to better health.

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