

Internal FDA Memorandum Contradicts Public Statements

FDA contends that it has always held that compounded meds are “new, unapproved drugs” subject to the same requirements as manufactured products under the Food, Drug, and Cosmetic Act of 1938. A memo uncovered during a federal trial shows that the opposite is true: the FDA developed this theory in the late 1980’s and even anticipated backlash from pharmacists and physicians.

The memo was authored by David G. Adams, an associate counsel in the FDA’s Office of the General Counsel. It is dated August 2, 1989, and appears to be written in response to questions from the Center for Drug Evaluation and Research as to whether or not FDA has authority to regulate compounded medications used in radiological exams.

Despite never being authorized by Congress to regulate compounded medications, the FDA began in the 1980’s to seek ways to expand its authority to cover compounded medications. It appears that in 1989 the FDA decided that the only way to justify this authority was to assert the theory that the Food, Drug, and Cosmetic Act of 1938 had always applied to compounded medicines – even though no government agency or piece of legislation proposed this in the 50 years since it was passed. In order to make its argument stick, FDA had to say its theory was not novel. This memo proves it was.

Among other things, the FDA acknowledges in this memo that its theory that compounded medicines are “new, unapproved drugs:”

- “is a departure from the traditional approach we have taken;” (p. 1)
- “will likely face a variety of practical problems, as well as two significant legal issues: (1) whether we have jurisdiction over this aspect of the practice of pharmacy and (2) whether we can regulate intrastate sales of unapproved new drugs;” (p. 1)
- will require “the establishment of new legal precedents;” and (p. 2)
- “may prompt an outcry from the general community of pharmacists and physicians;” (p. 4)
- “leaves pharmacists in the objectional [sic] position of ‘living in sin.’” (p. 4)

The full memo can be viewed by following the link below.

 [FDA Smoking Gun Memo](#)