Failures of the FDA to Follow Through Since the Food and Drug Administration Modernization Act (FDAMA) of 1997

Overview

If enacted, PCCA believes that FDA oversight of the pharmacy profession will result from S.959, the Pharmaceutical Compounding Quality and Accountability Act – with the unintended consequence of restricting access to compounded medications for hundreds of thousands, if not, millions of patients each year.

While the goal of the bill was to originally provide oversight of those compounding sterile products, dispensed interstate for non-patient specific situations, S.959 allows sweeping intrusions into the practice of compounding, while it excludes key areas such as compounding in hospitals.

We believe that inserting the FDA into a state controlled profession will not result in higher quality, as some have suggested. We base this assertion on the FDA’s track record since the introduction of the last major compounding regulation, the Food and Drug Administration Modernization Act (FDAMA) of 1997. Here are a few examples of the FDA’s track record:

Example 1: CPG issued May 29, 2002 in light of Supreme Court Ruling.

Within the CPG:

“In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:

2. Compounding drugs that were withdrawn or removed from the market for safety reasons. Appendix A provides a list of such drugs that will be updated in the future, as appropriate.”

FDA Failure:

Appendix A has not been updated since March 1, 1999

Also, the CPG was issued on 05/29/02 and a notice of availability was published in the Federal Register but no consultation occurred with any committee outside of the FDA, which could be interpreted as direct violation of FDAMA of 1997 503A - (d)(1).

“...if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d),...”

FDA Failure:

Since the bill was passed, no such “positive list” was ever developed.

Example 3: FDAMA Section 503A–(b)(1)(C)

“...does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and...”

FDA Failure:

Since the bill was passed, only one such list was published and has never been updated since the original publication.

Example 4: FDAMA Section 503A–(b)(3)(A)

“...such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and...”

FDA Failure:

Since the bill was passed, no such identification occurred by the FDA.

Example 5: FDAMA Section 503A–(b)(3)(B)(i)

“...that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State;...”

FDA Failure:

Since the bill was passed, no State was ever approached about entering into a memorandum of understanding.
Example 6: FDAMA Section 503A–(b)(3)(B)

“The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).”

FDA Failure:

Since the bill was passed, no standard memorandum of understanding was developed.

Example 7: FDAMA Section 503A–(d)(1)

“IN GENERAL.—The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.”

FDA Failure:

Since the bill was passed, no advisory committee was ever convened.

Example 8: FDAMA Section 503A – (d)(2)

“LIMITING COMPOUNDING.—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

FDA Failure:

Since the bill was passed, no such public consultation with the USP occurred, nor did the FDA promulgate any “criteria.”