International Academy of Compounding Pharmacists

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June 30, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: FDA Final Rule on New Policies, Requirements and Procedures Pertaining to the Prescription Drug Marketing Act of 1987 and Prescription Drug Amendments of 1992. 64 Fed. Reg. 67720 (December 3, 1999). [Dockets Nos. 92N-0297 and 88N-0258]

Dear Sir/Madam:

The International Academy of Compounding Pharmacists ("IACP") respectfully submits these comments in response to the Food and Drug Administration's ("FDA's") final rule, published December 3, 1999, which implements the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293, 102 Stat. 95 (1988)) (the "PDMA"), as modified by the Prescription Drug Amendments of 1992 (the "PDA"). 64 Fed. Reg. 67720 (Dec. 3, 1999)("the final rule")[1]. IACP submits these comments on behalf of compounding pharmacists and their patients who benefit from compounded medications.

[1] These comments are filed pursuant to a recent Federal Register notice which delayed the effective date of December 3, 1999 final rule and reopened the administrative record for submission of comments addressing the impact of the final rule on the wholesale distribution system. 65 Fed. Reg. 25639, 25641 (May 3, 2000).

92N-0297 C109

IACP is specifically concerned that FDA's application of the PDMA's pedigree requirements to the wholesale distribution of bulk pharmaceutical substances and FDA's requirement of a written agreement to demonstrate an "on-going relationship" between distributors will greatly restrict pharmacists' access to bulk drug substances used to compound individualized medications. These two elements of the final rule constitute a significant and unwarranted departure from 12 years of FDA and industry practice. In addition, the rule harms public health by disrupting the availability of bulk drugs to pharmacists who compound medications for patients.

BACKGROUND

The PDMA was enacted to prevent the diversion of prescription drugs outside of the normal channels of distribution. It was intended to protect American consumers from "mislabeled, subpotent, adulterated, expired and counterfeit pharmaceuticals," and to "restore the competitive balance in the marketplace" by preventing the anticompetitive effects of such diversion against wholesale distributors and retail pharmacies. See, S. Rep. No. 100-303, at 57; H. R. Rep. 100-76, at 6 (1987). The PDMA establishes a number of restrictions and requirements regarding the marketing and distribution of human prescription drugs to increase accountability in the chain of distribution of these drugs.

On March 14, 1994, the FDA issued a proposed rule to implement the PDMA, as modified under the PDA. 59 Fed. Reg. 11842 (1994). These regulations were not finalized until December 3, 1999. FDA's final rule, if implemented as it now stands, will apply the PDMA's accountability requirements to distributors of bulk pharmaceutical substances despite Congressional intent that the

PDMA was enacted to address concerns about the chain of distribution of finished dosage form prescription drugs. The final rule constitutes a significant departure from FDA's own guidance documents, and from the language, intent and spirit of the PDMA. In addition, FDA's final rule will significantly increase drug costs for pharmacists and patients and will have a severely negative impact on the health and well-being on patients who depend on compounded medications.

The need for, and benefit of, compounded drugs to patient health is well documented. Through the patient-physician-pharmacist relationship, patient needs are determined and decisions are made about treatment regimens that may include a compounded medication. There are a number of compelling reasons to compound medications, including but not limited to:

Medications that are not commercially available:

Manufacturers must be assured that there will be a return on their investment when entering the market place with a drug product. Therefore, using manufacturers' formulations allows physicians to prescribe and pharmacists to dispense only limited chemical forms, dosage forms, strengths, flavors and packaging. Compounding allows the physician to prescribe a custom-tailored medication that is not available commercially to meet the patient's own needs.

Modified commercially available medications:

Physicians prescribe a commercially available medication in a different dosage form to meet a specific patient need and ensure patient compliance. For example, if a patient is allergic to a preservative or dye in a manufactured product, the compounding pharmacist can prepare a dye-free or preservative-free dosage form. Similarly, patients who have difficulty swallowing a capsule can instead be prescribed a compounded lozenge.

In 1997, Congress recognized the important health benefits of compounded therapies and passed legislation that formally recognized the benefit that compounded medications play in treating unique medical needs of patients. The legislation also set forth the legal requirements for compounded medications. This legislation specifically acknowledged that pharmacists will use bulk drugs in compounding. Without bulk drugs, most compounding is not possible.

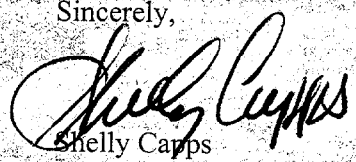
The vast majority of bulk drug substances purchased by pharmacies come from small repackagers who in turn purchase the bulk drugs from small distributors—not manufacturers. These small distributors of bulk pharmaceuticals would be forced to provide detailed pedigree information even if the distributor purchased the bulk drug from an authorized distributor. However, FDA's final rule does not require authorized distributors to provide the pedigree information to secondary wholesale distributors. Although FDA urges authorized manufacturers to provide this information, it is entirely optional. The sale of bulk chemicals to compounding pharmacists is typically a miniscule component of the typical "authorized distributor's" business. Under FDA's rule, an authorized distributor who chooses not to furnish this information can effectively put its secondary distributors out of business. The inability of these distributors to purchase many drugs that are available today would cause a health and safety risk to patients whose access to vital compounded medications would be seriously disrupted.

The distributors of bulk chemicals are left entirely at the mercy of manufacturers and major wholesalers. These manufacturers and wholesalers have no direct economic interest in ensuring that pharmacists continue to have access to bulk drug substances to compound medications. Since these sales represent a very small fraction of total sales, the small distributors to compounding

pharmacists would be the first to be cut off. They would not be deemed authorized distributors by the manufacturer, and the authorized distributor would have no obligation to give them the required pedigree information.

We strongly urge FDA to reconsider the PDMA regulations to exclude bulk pharmaceuticals from PDMA regulations. Congress did not intend for PDMA to apply to bulk drug substances, only finished products. Imposing pedigree requirements on bulk drugs will not improve the quality of health care. Rather, by thwarting compounding, it will have the opposite effect.

Sincerely,



Shelly Capps
Executive Director, International Academy of Compounding Pharmacists

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