Hospital Pharmacy and the CGMP

Doctor Feldmann's editorial in the May issue[1] charges FDA with requiring hospital pharmacists to comply with the revised current Good Manufacturing Practice Regulations (CGMP).

Not so.

The quotation in this editorial comes from paragraph 43 of the preamble to the CGMP's[2] in which FDA responded to the general comments received from the public on the proposed amendments. Retrospectively, it is apparent that paragraph 43 is not as clear as it should be. Nevertheless, we can state unequivocally that FDA is not interested in, and has *never* asserted jurisdiction over, a hospital pharmacy that limits its activities to serving the hospital of which it is a part. We would only consider the hospital pharmacy to be a repacker if the unit dose packages that it prepares are marketed outside the hospital. Even then, if it shares its unit dose services with other hospitals, we have special, separate guidelines covering such services.

FDA's position is best expressed by the Commissioner's endorsement of the unit dose repackaging guidelines prepared by The American Society of Hospital Pharmacists and published in the December 1977 issue of the *American Journal of Hospital Pharmacy*. Dr. Kennedy said:

> *"We applaud the American Society of Hospital Pharmacists for preparing this important guide to a better quality control system for drugs repackaged by hospital pharmacists for use in a unit dose drug distribution system. We recognize it as a major step forward in assuring that patients receive safe and efficacious drugs. In our judgment it is an excellent example of what a professional society can do to improve patient care in hospitals."*

It is FDA's view that the ASHP guidelines are suitable equivalents to our CGMP's for normal hospital pharmacy practice.

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[1] E. G. Feldmann, *J. Pharm. Sci.*, **68** (5), I (1979).
[2] *Fed. Regist.* (Sept. 29, 1978).

Hospital Pharmacy and the CGMP: A Response

We appreciate this response from Mr. Belson and Mr. Loftus and their effort to clarify the FDA intent of the current GMP regulations.

Our May editorial was originally stimulated by a series of discussions between APhA (and ASHP) staff on the one side and FDA staff on the other side during the 1977–1978 period. The background facts, as we were told them, differ from those described in the Belson–Loftus letter.

Specifically, FDA *did* attempt to assert jurisdiction over hospital pharmacy *via* challenges to certain operating procedures pertaining to unit dose repackaging. These challenges took several forms, one of which was directed at an arrangement whereby a "contract repackager" would bring unit dose repackaging equipment to the hospital and operate it to fulfill the current repackaging needs of the hospital. Under these arrangements, the operation (*a*) took place at the pertinent hospital, (*b*) functioned under the direct supervision of the hospital pharmacist, and (*c*) was limited to producing unit dose packages exclusively for use within that hospital. But, nevertheless, FDA did assert jurisdiction in at least several such instances, thereby causing significant problems and generally hassling the various parties involved.

After considerable skirmishing, an unwritten "truce" eventually emerged, and both sides appeared content to leave the matter rest—although basically unresolved, the issue was not actively pursued further.

But the wording of the September 1978 *Federal Register* preamble—plus pharmacist West's correspondence—made it appear to us that FDA was again preparing to flex its muscle.

Upon receipt of the Belson–Loftus letter, we checked once more to ensure that we had correctly stated our recollection of the situation and its past history. One of the APhA staff members familiar with the situation stated that: "FDA is now trying to do a disappearing act." And an ASHP staff member pointed out that in this letter the operable word is "asserted"; that is, even here, FDA is not conceding any lack of jurisdiction over such pharmacy practice in the hospital setting, but only that it is not presently asserting such jurisdiction.

Nevertheless, both of these staff members also added that this Belson–Loftus letter was far less equivocating than past FDA statements on this issue. Furthermore, had FDA actually followed the policy described in this letter in the past, the entire controversy would never have arisen in the first place!

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Amphetamine Analogs

The recent article on "Heterocyclic Analogs of Amphetamine . . ." by W. O. Foye and S. Tovivich[1] listed two pyridine compounds without reference to previous work. β-(6-Methyl-2-pyridyl)-isopropylamine was reported by A. Burger and G. E. Ullyot [*J. Org. Chem.*, **12**, 342 (1947)], and β-(3-pyridyl)isopropylamine was reported by A. Burger and C. R. Walter, Jr. [*J. Am. Chem. Soc.*, **72**, 1988 (1950)].

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[1] W. O. Foye and S. Tovivich, *J. Pharm. Sci.*, **68**, 591 (1979).