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UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION WASHINGTON, D.C. 20580

December 15, 1988

COMMISSION AUTHORIZED

Richard P. Kusserow Inspector General Department of Health and Human Services Washington, D.C. 20201

Dear Mr. Kusserow:

We are pleased to respond to your request for our views on the Office of Inspector General's Draft Report entitled "Physician Drug Dispensing: An Overview of State Regulation" ("Report"). The Report recommends that states enact more stringent regulation of physician dispensing of prescription drugs by (1) imposing procedural requirements for supervision, labeling, recordkeeping, storage and security; (2) requiring dispensing physicians to be registered for purposes of inspection and monitoring; and (3) imposing requirements to protect consumers' freedom of choice in determining where to purchase their prescription drugs. The Report also recommends various actions that states should take, including the provision of additional resources, to promote effective enforcement of regulations concerning physician dispensing.

Because the Report's recommendations do not call for the adoption of regulations that would interfere with the ability of consumers to obtain prescription drugs from their physicians, we do not oppose them. We note, however, that we cannot comment definitively on proposals as broad and general as those in the Report, and therefore confine our comments to the major issue raised by the Report -- to what extent physician dispensing of prescription drugs should be regulated.

The Bureau of Competition staff does not endorse physician dispensing as preferable to pharmacist dispensing, or vice versa. Rather, we support consumer choice among qualified providers of prescription drugs. At this time, we are not aware of any justification that supports a total ban on physician dispensing of prescription drugs. Physician dispensing increases consumers' options in the purchasing of prescription drugs, and we believe it may increase competition among physicians and between physicians and pharmacists, and possibly lead to lower prices and

These comments are the views of the staff of the Bureau of Competition of the Federal Trade Commission. They are not necessarily the views of the Commission or of any individual Commissioner.

Richard P. Kusserow Inspector General Department of Health and Human Services

better services. We believe, therefore, that consumers should not be deprived of the potential benefits of physician dispensing unless there is reason to believe that such dispensing has harmed or is likely to harm public health and safety and that less restrictive health and safety standards are insufficient to protect the public.

It is important to clarify the representations made in the Report concerning our views on physician dispensing. The Report states, at pages 1 and 6, that the Federal Trade Commission staff "have sought to discourage" state regulation of physician dispensing on the grounds that physician dispensing enhances competition and that attempts by state governments to regulate the practice "might constitute restraint of trade." This is generally but not entirely accurate. We have opposed only unreasonable restrictions on the ability of physicians to dispense drugs. Moreover, a statute enacted by a state legislature would generally not be subject to the antitrust laws and therefore would not itself constitute an unlawful restraint of trade. Nonetheless, when requested we have submitted comments in opposition to the adoption of what we view as unreasonable restrictions on the ability of physicians to dispense drugs by both state regulatory agencies and state legislatures. example, we have submitted comments to regulatory boards in Georgia² and Maryland³ and to a legislative committee in California concerning physician dispensing. I am enclosing copies of our comments for your information. In those comments, we opposed the adoption of rules or statutes that we believed would unreasonably restrict physician dispensing without providing any countervailing public benefits. It is our belief that restrictions of this nature are likely to be harmful to We have not, however, opposed efforts to insure that both physicians and pharmacists adhere to regulations that may promote public welfare.

See Letter from Jeffrey I. Zuckerman, Director, Bureau of Competition, to William G. Miller, Jr., Joint Secretary, State Examining Boards (November 26, 1986).

^{3 &}lt;u>See</u> Letter from Jeffrey I. Zuckerman, Director, Bureau of Competition, to C. Earl Hill, M.D., President, Maryland State Board of medical Examiners (December 31, 1986).

^{4 &}lt;u>See</u> Letter from Jeffrey I. Zuckerman, Director, Bureau of Competition, to The Honorable Tim Leslie, California Assembly (May 1, 1987).

Richard P. Kusserow Inspector General Department of Health and Human Services

For example, we recently submitted comments to the Georgia State Board of Pharmacy supporting the adoption of rules that would require dispensing physicians to meet health_and safety standards similar to those imposed on pharmacists. 5 In these comments, we stated that the adoption of the proposed rules would not interfere with the ability of physicians to dispense prescription drugs efficiently, and thus would not deprive consumers of the benefits of choice among qualified providers of prescription drugs. We therefore suggest that your office could more accurately state the position of the FTC staff by deleting the second and third sentences of the paragraph bridging pages 1 and 2 of the Report and substituting the following: "Staff from the Federal Trade Commission (FTC) have sought to discourage the states from prohibiting or unreasonably restricting physician dispensing of drugs. The staff has suggested that dispensing by physicians enhances competition in the prescription drug market and may lead to lower prices and better services." Similarly, on page 6, the words "prohibiting or unreasonably restricting" should be substituted for "regulating."

The Report's recommendations do not call for regulations that would interfere with the ability of physicians to dispense prescription drugs, and are therefore consistent with our position. At the same time, however, the Report's regulatory proposals, which appear acceptable in a generalized form, may have anticompetitive effects when incorporated into a specific regulation or statute or when added to an existing regulatory For example, while recordkeeping and security requirements may be desirable in principle, the specific language of a regulation or statute proposed by a state may be so unduly burdensome or restrictive that it unreasonably restricts the ability of physicians to dispense drugs and therefore suppresses Similarly, a state may adopt the recommendation competition. that physicians who dispense be registered and yet may also impose a myriad of other requirements that effectively deny or significantly delay the approval of applications for such registration. While the recommendations offered in the Report appear to call for no more restrictive a scheme of regulation than that which is currently in place for pharmacists, we do not know how each of the states would implement these recommendations. For this reason, we cannot endorse the Report and would prefer to comment on specific rules or statutes as they are proposed by the states.

^{5 &}lt;u>See</u> Letter from Jeffrey I. Zuckerman, Director, Bureau of Competition, to William G. Miller, Jr., Joint Secretary, State Examining Boards (June 26, 1987).

Richard P. Kusserow Inspector General Department of Health and Human Services

In sum, the dispensing of prescription drugs by physicians increases consumers' ability to choose among qualified providers of pharmaceutical services. The resulting competition among physicians and between physicians and pharmacists may produce lower prices and improved services. The recommendations presented in the Report appear to call for regulatory action that would not unreasonably interfere with a physician's ability to provide dispensing services. We do not oppose the concepts embodied in these recommendations, but we cannot comment definitively until we have seen specific proposed regulations.

We appreciate this opportunity to review the Report and give you our comments on this important issue. If you have any questions or would like to discuss our comments, please call Assistant Director Michael D. McNeely at (202) 326-2904.

Sincerely yours,

Affrey I. Zuckerman

Director

Bureau of Competition

Enclosures