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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
NEW YORK REGIONAL OFFICE

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April 11, 1991

Jeffrey W. Moran
Ranking Republican Member,
Assembly Commerce and Regulated Professions Committee
GENERAL ASSEMBLY OF NEW JERSEY, Assembly Republican Office
2nd Floor, State House Annex, CN-098
Trenton, New Jersey 08625

Dear Assemblyman Moran:

The staffs of the New York Regional Office and the Bureau of Competition of the Federal Trade Commission are pleased to respond to your request for our views on Senate Bill No. 2051, which would prohibit a physician from dispensing more than a 72-hour supply of drugs or medicines to any patient, unless the drugs or medicines are dispensed at no charge.[1] The provision of ancillary services or products to patients by physicians, which includes the dispensing of drugs or medicines, raises difficult issues because it offers potential benefits and poses certain risks.

Congress has empowered the Federal Trade Commission to prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. 15 U.S.C. § 41, et seq. Pursuant to this statutory mandate, the Commission and its staff encourage members of licensed professions to compete to the extent competition is compatible with other legitimate goals. The Commission and its staff, through law enforcement proceedings[2]

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[1] These comments are the views of the staffs of the New York Regional Office and the Bureau of Competition of the Federal Trade Commission. They are not necessarily the views of the Commission or of any individual Commissioner.

[2] Massachusetts Board of Registration in Optometry, 110 F.T.C. 549, 600 (1988); Rhode Island Board of Accountancy, 107 F.T.C. 293 (1986) (consent order); Louisiana State Board of Dentistry, 106 F.T.C. 65 (1985) (consent order); American Medical Association, 94 F.T.C. 701, aff'd, 638 F.2d 442 (2d Cir. 1980), aff'd mem. by equally divided Court, 455 U.S. 676 (1982); American Institute of Certified Public Accountants, C-3297 (July 26, 1990) (consent order).

and studies,[3] have been evaluating the competitive effects of public and private restrictions on the business practices of lawyers, dentists, optometrists, physicians, and other state-licensed professionals. The aim of the Commission and its staff has been to identify restrictions that impede competition or increase costs without providing countervailing benefits to consumers.

The Commission has authorized its staff to submit comments to governmental bodies that have been considering restrictions on the practice of physicians providing patients with ancillary services or products. Our goal has been to help to ensure that these governmental bodies are aware of the possible competitive effects of physicians providing ancillary services or products to their patients.[4]

The original draft of Senate Bill No. 2051 is accompanied by a memorandum which gives the rationale behind the bill's proposed prohibition on a physician's for-profit dispensing of more than a 72-hour supply of drugs or medicines to a patient. Although acknowledging that physicians have traditionally dispensed limited quantities of medication for the convenience of their patients or as part of an emergency treatment, the memorandum maintains that the practices of medicine and pharmacy are separate and distinct professions that have different educational and training requirements. Further, in your request for our views, you noted that Senate Bill No. 2051 raises certain concerns that include the issue of competition between physicians and pharmacists. In addition, you stated that although only 3 percent of physicians in New Jersey dispense drugs or medicines,

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[3] E.g., C. Cox & S. Foster, The Costs and Benefits of Occupational Regulation (FTC Staff Report 1990); W. Jacobs, et al., Improving Consumer Access to Legal Services: The Case for Removing Restrictions on Truthful Advertising (FTC Staff Report 1984).

[4] See, e.g., Letter to Jack B. Carson, Executive Director, Virginia Board of Pharmacy (Nov. 27, 1989) (regarding proposed regulation of the dispensing and sale of prescription drugs by physicians); Letter to The Honorable Ray Hamlett, Missouri House of Representatives (February 27, 1989) (regarding proposed legislation to prohibit employment of, and payment of referral fees to, physical therapists); Comments to the Department of Health and Human Services (Dec. 18, 1987) (regarding regulations pursuant to the Medicare and Medicaid anti-kickback statute); Letter to H. Fred Varn, Executive Director, Florida Board of Dentistry (Nov. 6, 1985) (regarding dentists who refer patients to other dental practices in which the referring dentists have a financial interest).

the Assembly Commerce and Regulated Professions Committee is concerned with the potential of more physicians providing the service.

As Commission staff pointed out in previous comments on this subject, we do not endorse physician dispensing as preferable to pharmacist dispensing. Rather, we support consumer choice among qualified providers of drugs or medicines. Physician dispensing may increase consumers' options in the purchasing of prescription drugs or medicines, and we believe it may increase competition among physicians and between physicians and pharmacists and lead to lower prices and better services.

The dispensing of drugs or medicines by physicians is a traditional part of medical practice that was once quite common and is currently authorized in all but a few states. Some consumers may value the option of obtaining drugs or medicines prescribed by their physician without having to make a separate trip to a pharmacy. Indeed, the same patient may have different preferences at different times. For example, a parent with a two-year old child suffering the pain of an ear infection may desire one-stop shopping, whereas the same parent may prefer to purchase prescription vitamins for the child at a pharmacy.[5] Moreover, there are a number of innovative providers of medical services that are increasing consumer demand for physician provided drugs and medicines. For example, outpatient surgeries have grown in the last decade in part due to the emergence of innovative forms of practice, such as freestanding outpatient surgical centers, "emergicenters," walk-in clinics, and even individual physicians who employ new technology to provide patient services outside of the traditional hospital setting. This trend may not only be increasing physicians' desire to prescribe from their offices, but may also be increasing consumers' demand to obtain prescription drugs in these non-traditional settings.[6]

Although physician dispensing of drugs or medicines to patients for profit offers potential benefits, the practice may also pose certain risks. Specifically, some opponents of the practice claim that physicians who dispense for profit may be led by their own financial interests to harm patients by

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[5] Although Senate Bill No. 2051 would permit physicians to dispense a 72-hour supply of drugs or medicines to patients at a charge, a substantial number of prescriptions are for more than a 3-day supply of drugs or medications.

[6] H.J. Anderson, Ambulatory Care Growth Changes CEO Priorities, Hospitals, February 5, 1991, at 44.

overprescribing or prescribing inappropriately.[7] Of course, some protection against these abuses already exists. For example, licensing boards could discipline physicians who prescribe inappropriately. We support efforts to ensure that both physicians and pharmacists adhere to health and safety regulations that have a net positive effect. For example, some may argue that physicians who dispense drugs should be subject to the same sanitation, recordkeeping, and other requirements that apply to pharmacists. To the extent that such regulations are cost-effective and reasonably related to public health and safety, their imposition may advance public welfare without limiting consumer choice among qualified providers of prescription drugs or medicines. Determining whether physician dispensing should be further restricted requires balancing the risk of abuse against the potential pro-competitive benefits of the practice.

Some risk of over-utilization probably exists whenever the same person both recommends a service and then provides it. Yet this practice is common in the health care industry and indeed throughout the economy--from the physician who recommends an appendectomy and then performs the operation to the auto mechanic who recommends engine rebuilding and then does the work. Indeed, pharmacists face this potential conflict when they recommend vitamins or other non-prescription drugs. If only the potential abuses inherent in this kind of practice are considered, and the attendant efficiencies are ignored, some very useful and ordinary business practices would be suspect.

Physician dispensing raises over-utilization issues similar to those posed by the practice of physicians referring patients for ancillary services or products to entities in which such physicians have financial interests.[8] Namely, the risk of referrals for unnecessary or inappropriate care may increase when a physician has a financial interest in the provision of the recommended ancillary service. HHS Inspector General and General

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[7] There may also be a risk that patients will be deceived if they incorrectly assume that a dispensing physician does not have a financial interest in the drug he or she dispenses to them. To the extent that misimpressions are common and injure consumers, some type of disclosure to patients of the physician's financial interest or of alternative sources of the prescribed drug may be appropriate.

[8] Besides the dispensing of drugs or medicines, physicians provide patients with a wide variety of ancillary services or products, including clinical laboratory services, imaging services, physical therapy services, and durable medical equipment.

Accounting Office studies found that the impact of physician referral to affiliated entities varied with the type of service provided.[9] Because each type of ancillary service offers different benefits to consumers and poses different risks of abuse, determining the desirability of restrictions on self-referral requires careful scrutiny of individual services.[10]

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[9] Office of Inspector General, Department of Health and Human Services, Financial Arrangements Between Physicians and Health Care Businesses (May 1989); General Accounting Office, Medicare: Referring Physicians' Ownership of Laboratories and Imaging Centers (June 1989). The HHS Inspector General's report did not find a positive relationship between physician ownership of durable medical equipment businesses and the extent to which physicians refer patients for such services. Consequently, restrictions on referrals to affiliated entities for this equipment are probably unnecessary. See generally Issues Related to Physician "Self-Referrals," Hearings on H.R. 939 Before the Subcommittee on Health and the Subcommittee on Oversight of the House Ways and Means Committee, 101st Cong., 1st Sess. 126 (1989) (statement of Richard P. Kusserow, Inspector General, U.S. Department of Health and Human Services).

In contrast, although only limited empirical data are available, the HHS Inspector General and the General Accounting Office studies suggest that physicians refer patients to affiliated entities for clinical laboratory services more often than physicians refer patients to independent entities for the same services. Another study, supported by the American College of Radiology and recently reported in the New England Journal of Medicine, compared the frequency and costs of imaging examinations as performed by primary physicians who used imaging equipment in their offices (self-referring) and as ordered by physicians who always referred patients to radiologists (radiologist-referring). The study's results indicate that the self-referring physicians obtained imaging examinations more often, and usually charged more per referral, than the radiologist-referring physicians. The article noted, however, that from the study's results it is not possible to determine which group of physicians uses imaging more appropriately. See B. Hillman, M.D., et al., Frequency and Costs of Diagnostic Imaging in Office Practice--A Comparison of Self-Referring and Radiologist-Referring Physicians, The New England Journal of Medicine, December 6, 1990, at 1604.

[10] Physician investment and referral procedures, as with physician dispensing, can offer a number of pro-competitive benefits. For example, a physician who refers patients for further care to an affiliated entity may be better able to ensure

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This disparity in impact suggests that evidence demonstrating inappropriate referral should be obtained before referrals to affiliated entities are regulated. For example, as noted above, physician dispensing of drugs or medicines may offer patients the distinctly valuable option of obtaining medical care and prescription drugs at a single location. Before enacting Senate Bill No. 2051, the legislature may wish to consider whether the risk of potential overprescribing requires that consumers forego the benefits of increased convenience and possibly increased competition.

In sum, restrictions or prohibitions on the practice of physicians providing patients with ancillary services or products may be justified on an empirical basis in some circumstances. The possible effect, however, of any legislation that restricts physician dispensing unnecessarily may be to deprive consumers of the benefits of choice, convenience, and price competition. We suggest that consumers not be deprived of these potential benefits unless the legislature determines that physician dispensing has harmed or is likely to harm public health and safety. The legislature may also wish to consider whether less restrictive health and safety standards are sufficient to protect the public.

Sincerely,

Michael Joel Bloom
Regional Director

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[10](...continued)
the quality of that care for those patients. An investment interest may lead to a closer and more permanent working relationship between the referring physician and the entity providing the follow-up care.

We note that HHS has proposed but not implemented certain "safe harbor" regulations, some of which would protect certain physician ancillary business arrangements such as preferred provider and managed care networks. However, certain other ancillary arrangements such as physicians referring people to laboratories in which they have an ownership interest may not be protected under these "safe harbor" regulations. 54 Fed. Reg. 3088 (1989).