
PHYSICIAN DRUG DISPENSING

AN OVERVIEW OF STATE REGULATION



OFFICE OF INSPECTOR GENERAL
OFFICE OF ANALYSIS AND INSPECTIONS

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OFFICE OF INSPECTOR GENERAL

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This report, entitled "Physician Drug Dispensing: An Overview of State Regulation," offers an exploration of State approaches to regulating physician drug dispensing.

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I. SITUATIONAL RESTRICTIONS

Physician dispensing is permitted only when:

- a. Situation is an emergency to meet the immediate needs of the patient X X X
- b. Pharmacy services are not available (e.g., rural area, specified distance, pharmacy closed) X

II. REQUIREMENTS FOR DISPENSING PRIVILEGE

- c. Dispensing physician must have approval or special permit/license from or must register with a State agency X X
- d. Dispensing physician must meet educational requirements

III. COST & PRICING REQUIREMENTS

- e. Prescription charges must be listed separately from office visit charges on patient bills
- f. Prescription charges or profits are prohibited or restricted X X X X X

IV. PATIENT CHOICE

- g. Written prescriptions provided to patients
- h. Patients must be advised of choice to fill prescription elsewhere
- i. Drug prices must be posted or quoted upon request

V. PROCEDURAL REQUIREMENTS

Prescription drugs dispensed by physicians are subject to:

- j. Labelling requirements X X X X X X X X X
- k. Record keeping requirements for all legend drugs X X X X
- l. Storage requirements X X X
- m. Security requirements for drug inventory X X X
- n. Personal dispensation or supervision by dispensing physician X X X X X X X X
- o. Dispensation is limited to a physician's own patients X X X X X X X X X

VI OTHER REQUIREMENTS (See Appendix II)

X X

Note: Reflects State regulation in effect as of 8/1/88, and excludes Federal requirements for controlled substances and child-resistant

Does not reflect recent statutory changes in MD and VA which are awaiting promulgation of regulations prior to implementation.

* As of 8/1/88 these States do not regulate physician dispensing.

Source: State regulatory boards/agencies as reported to OIG

Prepared by: DHHS/OIG/OAI Region I

8/1/88

EXECUTIVE SUMMARY

PURPOSE

The purpose of this inspection was to promote a better understanding of State regulation of physician drug dispensing. It focused primarily on determining the extent and type of State regulation, and on exploring the effectiveness of State approaches to the practice and the outlook for the future.

BACKGROUND

This inspection grew out of the Inspector General's interest in further understanding the issues surrounding the growing practice of physician dispensing. It is based on three lines of inquiry: (1) telephone discussions with representatives of State regulatory agencies, primarily the boards of medicine and pharmacy, (2) a review of the literature, and (3) discussions with representatives from national organizations and various Federal agencies.

FINDINGS

The Incidence Of Physician Dispensing Across The Country Is Relatively Low But Seems To Be Growing.

- Three-fourths of those regulatory officials offering an estimate believe that 5 percent or less of the physicians in their States are dispensing for profit.
- Half of all respondents thought the practice has been increasing in their States, and most expected this growth to continue.

The States Have Imposed Various Types Of Requirements To Regulate Dispensing By Physicians.

- Nearly all States have some type of regulation governing the dispensing of drugs by physicians.
- Among the States, there are five major types of regulatory requirements governing dispensing by physicians. These include requirements that: (1) permit dispensing only in limited situations, (2) enable State agencies to identify dispensing physicians, (3) limit profits on drugs dispensed by physicians, (4) protect freedom of choice for consumers, and (5) impose procedural controls such as labeling and record keeping.

Overall, State Requirements Regulating Dispensing By Physicians Are Much Less Extensive Than Those Regulating Pharmacists And Have Minimal Impact On The Practice.

- States have extensive regulation governing the dispensing of prescription drugs by pharmacists.
- In a majority of States, the regulation governing the dispensing of prescription drugs is much less restrictive for physicians than for pharmacists.
- The thrust of recent State regulatory activity has been to strengthen controls over dispensing by physicians rather than to prohibit the practice.
- A large majority of respondents considered the enforcement of their States' requirements for physician dispensing as being no more than moderately effective.
- A variety of constraints, especially limited resources and fragmented regulatory responsibilities, have hampered States' efforts to enforce their regulatory requirements for physician dispensing.

Considerable Support Exists Among State Regulatory Officials For Further Regulation Of Dispensing By Physicians.

- Two-thirds of all respondents thought it very important for physician dispensing to be regulated in their States.
- Nearly two-thirds of regulatory board/agency officials contacted reported complaints on physician dispensing during the last 2-3 years. Complaints were reported by at least one board/agency official from three-fourths of all States, including those with and without regulation.
- Many respondents from States with regulation thought stronger requirements were needed.
- Nearly half of all respondents thought Federal action addressing the practice of physician dispensing was not necessary; a third favored it, and nearly 10 percent thought it might be needed.

RECOMMENDATIONS

The State Governments

- STATE GOVERNMENTS SHOULD TAKE INITIATIVES TO PROMOTE STRONGER, MORE EFFECTIVE REGULATION OF PHYSICIAN DISPENSING.

Effective regulation of drug dispensing is important to protect the public and to ensure accountability in the drug distribution system. States have extensively regulated dispensing by pharmacists, but most have minimal requirements governing physician dispensing. States, at the very least, should adopt a basic threshold of regulation for dispensing physicians which includes:

- procedural requirements such as labeling, record keeping, and supervision which are similar to those applicable to pharmacists;
 - registration requirements so States can identify physicians who are actually dispensing; and
 - requirements which protect freedom of choice for patients to buy their prescriptions from either their physician or their pharmacist.
- STATE GOVERNMENTS SHOULD TAKE STEPS TO STRENGTHEN THEIR ENFORCEMENT OF REGULATION GOVERNING PHYSICIAN DISPENSING.

Effective regulation of physician dispensing is hindered by constraints on States' efforts to enforce current requirements. These efforts could be strengthened by such actions as providing more resources to State regulatory agencies and by defining more clearly the authority and responsibilities of these agencies, including their ability to inspect routinely the offices of dispensing physicians.

The National Associations

- THE FEDERATION OF STATE MEDICAL BOARDS AND THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY SHOULD WORK TOGETHER IN HELPING STATES TO PROMOTE STRONGER, MORE EFFECTIVE REGULATION GOVERNING PHYSICIAN DISPENSING.

These associations can provide further leadership to State boards by addressing jointly the respective authorities and responsibilities for regulation of physician drug dispensing which affect both the professions of medicine and pharmacy.

COMMENTS

The Assistant Secretary for Planning and Evaluation, the Health Care Financing Administration, and the Public Health Service (PHS) were all in general agreement with our recommendation that the States should continue to assume primary responsibility for regulating physician drug dispensing. The PHS, however, disagreed with our recommendation for stronger, more effective regulation. Other comments from these agencies, as well as comments from other agencies outside the Department and from national organizations, reflect a range of opinion, pro and con, about our findings and recommendations. A summary of these comments and our response to general issues raised appear at the end of the report. Detailed comments and our responses to them appear in appendix I.

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INTRODUCTION

This inspection grew out of the Inspector General's interest in gaining a better understanding of the issues involved in the current controversy surrounding the practice of physicians dispensing drugs.

Physicians have always dispensed drugs to some degree as part of the practice of medicine.¹ However, this practice has attracted more attention of late because increasing numbers of physicians are dispensing, often at a profit, the drugs they prescribe for their patients. The practice has grown as the nation's health system has become increasingly competitive and cost-conscious, and has been encouraged by the drug repackaging industry which has emerged during the early to mid-1980s. Drug repackagers buy and then repackage commonly prescribed drugs into convenient, unit-of-use sizes ready for physicians to sell directly to patients. They have sought to capitalize on the increasingly competitive health care environment by encouraging physicians to dispense the drugs they prescribe. Repackagers have cited advantages of convenience to patients and improved quality of patient care from office-based dispensing, but some of them have promoted dispensing to physicians as a highly lucrative source of additional income.

No one knows for certain the magnitude of the revenues being realized by physicians as a result of drug dispensing, but industry spokespersons and some financial analysts predict dramatic growth in the industry. Revenues realized by repackagers may increase from an estimated \$25 million last year to as much as \$400 million to \$500 million by 1990 and possibly as much as \$2 billion within 5 to 7 years.²

The prospect of increasing numbers of physicians routinely dispensing drugs for profit has captured the attention of pharmacy, consumer, and medical groups as well as the State and Federal Governments. Heated debate about the practice is being waged at both the State and national levels over a complex variety of ethical, economic, public health, and regulatory issues related to the practice.³ Is it a conflict of interest for physicians to sell the prescription drugs they prescribe? Is the quality of patient care enhanced or harmed by physician dispensing? Does the practice promote or restrain competition? Will consumers pay more or less for prescriptions dispensed by physicians? What kind of regulation of the practice is warranted, and should regulation occur at the State or Federal level?

The Federal Government has become more involved with this issue in recent years. Staff from the Federal Trade Commission (FTC) have sought to discourage the States from prohibiting or unreasonably restricting physician dispensing of prescription drugs. They have suggested that dispensing by physicians enhances competition in the prescription drug market and may lead to lower prices and better services. On the other hand, the U.S. Congress has been moving in a different direction with respect to physician drug dispensing. In the last session, it considered legislation to prohibit licensed practitioners from dispensing drugs for profit except in special situations. This bill, which would have amended the Federal Food, Drug, and Cosmetic Act administered by the FDA, attracted widespread attention from Federal agencies and medical, pharmacy, and consumer groups.

Present Federal requirements affecting dispensing by physicians are limited primarily to controlled substances, the labeling and packaging of drugs, and the distribution of drug samples. Under the terms of legislation administered by the Drug Enforcement Administration of the Department of Justice, those who dispense controlled substances are subject to registration, record-keeping, security/inventory, and certain labeling and packaging requirements. In addition, prescription drugs dispensed by physicians as well as by pharmacists are subject to the child-resistant packaging requirements contained in the Poison Prevention Packaging Act of 1970 administered by the U.S. Consumer Product Safety Commission. The Federal Food, Drug, and Cosmetic Act contains labeling and packaging requirements for prescription drugs, and recent amendments to the Act prohibit the sale of drug samples and impose other requirements involving physicians on the distribution of samples.⁴

Other than the requirements of the Federal Food, Drug, and Cosmetic Act, the dispensing of drugs by physicians has attracted little attention from the Department of Health and Human Services (HHS). According to officials from the Health Care Financing Administration (HCFA), the agency has taken no position on the practice of physician dispensing in its most recent guidelines to the States for the Medicaid program, although some States reimburse physicians for the drugs they dispense to Medicaid recipients. Since we began our study last winter, the Congress enacted the Medicare Catastrophic Coverage Act of 1988. According to congressional and HCFA staff with whom we spoke, physicians as well as pharmacists can participate in the new outpatient prescription drug program provided they meet and/or agree to the criteria specified in the Act.

Over the years, however, the State governments, rather than the Federal Government, have played the major role in regulating the dispensing of prescription drugs by both physicians and pharmacists. Pharmacists are the primary dispensers of prescription drugs in this country. As such, the profession is guided by national standards of practice, and the practice of pharmacy has been highly regulated by the States in order to protect the public and to assure accountability for the distribution of drugs.⁵

Comprehensive information about the States' regulatory approaches to the dispensing of prescription drugs by physicians has not been readily available. Yet better understanding of these approaches is important to Department policymakers as they consider the significance of physician drug dispensing for its programs. Accordingly, we conducted this inspection to examine State approaches to regulating the dispensing of prescription drugs by physicians. (In this inquiry, we were primarily interested in State regulation applicable to dispensing in amounts larger than samples or starter dosages.) We were particularly interested in the extent of regulation among the States, the nature of the regulatory requirements imposed, and perceptions from State regulatory officials about the effectiveness of States' requirements and enforcement efforts.

We gathered information through: (1) telephone discussions with the staffs of boards and agencies involved in regulating physician dispensing (primarily the medical boards and the pharmacy boards), in all 50 States and the District of Columbia; (2) a review of the literature, including congressional hearings, studies and analyses, articles from the popular media and

professional journals, and publications and papers from various private and public organizations; and (3) discussions with the staff of national organizations including the American Medical Association, American Pharmaceutical Association, Competitive Health Care Coalition (representing drug repackaging companies), Federation of State Medical Boards, National Association of Boards of Pharmacy, National Association of Chain Drug Stores, NARD (formerly National Association of Retail Druggists) and from other Federal agencies including FDA and HCFA within the Department as well as with the Federal Trade Commission, Drug Enforcement Administration of the Department of Justice, and the U.S. Congress. (For more information on our methodology, see appendix II.)

This report presents our findings related to State regulation governing the dispensing by physicians of prescription drugs in amounts greater than samples. It begins with an overview of estimates of the incidence of physician dispensing, the extent of regulation among the States and the types of regulatory requirements they impose. It then turns to a consideration of the effectiveness of these regulatory efforts and of the outlook for further government regulation of this practice. It concludes with our recommendations for action addressed to State governments and to the national organizations representing the State boards of medicine and pharmacy.

FINDINGS

The Incidence Of Physician Dispensing Across The Country Is Relatively Low But Seems To Be Growing.

- Three-fourths of those regulatory officials offering an estimate thought that 5 percent or less of the physicians in their States are dispensing for profit.

There is considerable uncertainty about the incidence of physicians who are dispensing for profit across the country. Estimates most frequently appearing in the media are that 5 percent of physicians are dispensing for profit.⁶ In an effort to determine the incidence more precisely, we asked regulatory officials about the proportion of physicians dispensing for profit in their States.⁷

Of those regulatory board/agency officials offering an opinion, three-fourths thought that no more than 5 percent of the physicians in their States are dispensing for profit. In fact, a third gave the figure of less than 1 percent. Only 15 percent of these officials thought the prevalence of dispensing for profit is greater than 10 percent in their States.

On the other hand, nearly half the officials with whom we spoke would not estimate the proportion of physicians dispensing for profit in their States. Even respondents from the 13 States with requirements for registration were sometimes uncertain about the prevalence of the practice because their registration requirements do not distinguish between those physicians who register thinking they might dispense and those who actually do dispense, nor do they distinguish among those who dispense for profit, at cost, or without charge. Moreover, none of the officials was aware of any analyses or surveys related to the incidence of the practice in their States.

- Half of the respondents thought the practice has been increasing in their States, and most of them expected this growth to continue.

Nevertheless, despite the uncertainty about the exact number of dispensing physicians, half of all the officials with whom we spoke thought the number of physicians dispensing for profit in their States has been increasing during the last 2 or 3 years. This opinion was offered by at least one respondent from nearly three-fourths of the States. Nearly three-fourths of these officials expected this growth to continue in the future. They offered as reasons economic pressures facing physicians practicing in an increasingly competitive environment and the aggressive marketing efforts of the drug repackaging companies.

The States Have Imposed Various Types Of Requirements To Regulate Dispensing By Physicians.

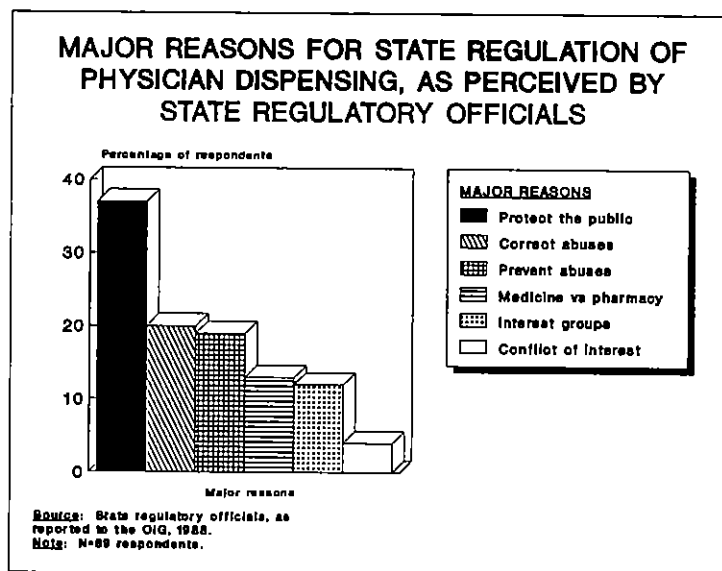
- Nearly all States have some type of regulation governing the dispensing of drugs by physicians.

Forty-five States, including the District of Columbia, reported having some type of regulation governing the practice of physicians dispensing drugs from their offices. Only six States reported no regulation governing the dispensing of both controlled and non-controlled drugs.⁸

Although most States began regulating physician dispensing a number of years ago, their regulatory activity has increased considerably within the past 2 or 3 years. During this time, over half the States have considered regulatory changes. Twelve States have instituted regulation for the first time, and eight States have modified existing requirements. In nine States, proposed changes are currently awaiting action by legislatures, regulatory boards, or the courts.

The States have regulated physician dispensing primarily to safeguard the health of the public. Respondents to our inquiries mentioned public health concerns almost twice as often as any other reason for their States having instituted regulation originally (see figure I).

FIGURE I



Other factors included problems and abuses associated with physician dispensing such as drug diversion and improper labeling. Some States regulated the practice on the premise that dispensing by physicians constitutes a conflict of interest; others wanted to preserve the traditional responsibilities of medicine and pharmacy: physicians prescribe for patients, and pharmacists dispense the prescriptions.

Recent regulatory activity in the States seems to have been triggered by many of these same concerns as well as, in some States, by uneasiness over the promotional efforts of drug repackaging companies. Although staff from the FTC have sought to discourage some States from prohibiting or unreasonably restricting physician dispensing, respondents from all but a few States thought that their efforts had had little, if any, effect on their States' attitudes toward

regulation. State pharmacy associations and boards, more often than medical associations and boards, were mentioned by respondents as having been the driving forces behind State regulation of the practice.

- Among the States, there are five major types of regulatory requirements governing dispensing by physicians.

The States have imposed a wide variety of regulatory requirements on physicians who are dispensing drugs. We have grouped these regulatory requirements into five major types of regulation (see figure II) as follows:⁹

Type I: *SITUATIONAL RESTRICTIONS*

Regulation of this type permits dispensing by physicians only in limited situations, such as medical emergencies or occasions when pharmacy services are unavailable or the physician is filling the patient's immediate needs. Five States have requirements of this type.

Type II: *REQUIREMENTS FOR DISPENSING PRIVILEGE*

Regulation of this type mandates that dispensing physicians identify themselves to State regulatory boards/agencies.¹⁰ Although 13 States have this type of regulation, the specific requirements vary considerably among them. Three States require the physician to receive prior approval from the medical board or, in one case, to apply for a permit from the pharmacy board if the dispensing will be for profit or will be more than an occasional practice. The remaining 10 States simply require dispensing physicians either to register with the medical boards when renewing their medical licenses or to register with or obtain permits from the pharmacy boards or other State agencies. Two of these States reportedly have fees associated with the registration/permit requirement. One State requires dispensing physicians, in addition to registering, to complete 6 hours of continuing education each year to learn about their legal responsibilities and the State's regulatory requirements.

Type III: *COST AND PRICING REQUIREMENTS*

Regulation of this type limits the amount physicians may charge for the drugs they dispense. Of the seven States with this type of regulation, five prohibit physicians from dispensing for profit. One State permits rural physicians only to charge for the cost of the drugs, and one State prohibits physicians from charging "excessive" fees.

The requirement that prescription charges be listed separately from other medical charges on patients' bills was not reported to be part of any State's current regulation of physician dispensing.

Type IV: *PATIENT CHOICE*

Regulation of this type includes requirements designed to protect freedom of choice for consumers in deciding whether to purchase their prescriptions from their physicians or from pharmacies. Four States require physicians to provide or offer to provide patients with written prescriptions and/or to advise them that they can fill their prescriptions elsewhere if they wish. Two States require physicians to post or quote prescription prices.

Type V: *PROCEDURAL REQUIREMENTS*

Regulation of this type limits dispensing to the physicians' own patients and also extends to dispensing physicians some of the same regulatory controls mandated by the States for pharmacists. Although virtually all States have at least one requirement within this type, only about one-fourth of them mandate all or even most of these requirements for physicians who are dispensing.

Most States have requirements for labeling drugs dispensed by physicians and requirements which specify who may legally dispense drugs within the physician's office. Slightly more than half the States have record keeping requirements and limit dispensing to the physician's own patients. Fewer than half the States have requirements addressing the storage of drugs and the security of the inventory within the office.

According to the regulatory board/agency officials with whom we spoke, the most crucial of their regulatory requirements are the procedural requirements (Type V regulation). Among these, respondents most frequently mentioned as especially important the labeling and record keeping requirements and those that authorize dispensing only by the physicians themselves, not by other office personnel. Many respondents also identified regulation requiring some kind of registration (Type II regulation) as critical so that boards/agencies can identify who is dispensing in order to monitor compliance with State regulation.

We found, finally, that the regulatory requirements governing the practice are, in almost all States, based in statutes and/or rules (regulations) that specifically address dispensing by physicians or practitioners. In a majority of States, the regulation that applies to dispensing by physicians also applies to other practitioners, such as dentists, who are licensed to prescribe drugs.

Overall, State Requirements Regulating Dispensing By Physicians Are Much Less Extensive Than Those Regulating Pharmacists And Have Minimal Impact On The Practice.

- States have extensive regulation governing the dispensing of prescription drugs by pharmacists.

Through laws administered by the boards of pharmacy, the States have imposed requirements regulating the licensure and discipline of pharmacists and the practice of pharmacy itself. All States require, as conditions of licensure, that pharmacists be graduates of accredited colleges of pharmacy, that they have practical or internship experience, and that they pass examinations given by the pharmacy boards. Most States also impose continuing education requirements for relicensure of pharmacists. In addition, pharmacies must be registered with State pharmacy boards, and they are subject to inspections by State authorities. Moreover, State pharmacy laws detail a variety of requirements governing the practice of pharmacy, including availability of approved reference materials and equipment, the supervision of the dispensing process, as well as the labeling, record-keeping, and storage of prescription drugs.

- In a majority of States, the regulation governing the dispensing of prescription drugs is much less restrictive for physicians than for pharmacists.

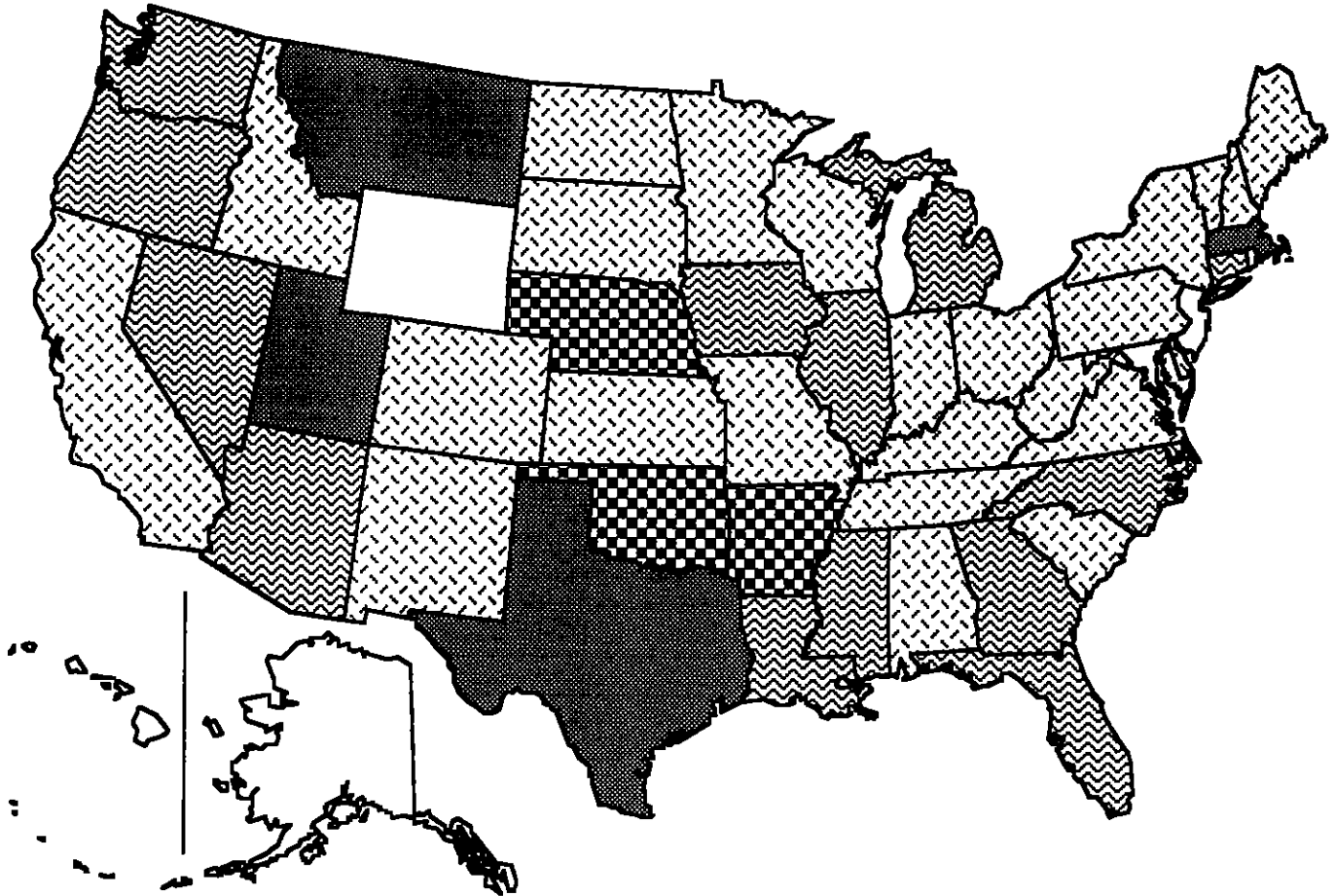
Although, as we have seen, most States have imposed various requirements on the dispensing of prescription drugs by physicians, overall these requirements in most States are much less far-reaching than those for pharmacists. In virtually all States, physicians are permitted to dispense drugs without being licensed as pharmacists, and therefore are not bound by most of the specific requirements governing the practice of pharmacy.

Indeed, as indicated in figure II, six States reportedly imposed no regulation on dispensing by physicians. Of the remaining 45 States reporting regulation of dispensing by physicians, our analysis suggests that over 50 percent, or 25 States, have requirements which exert only minimal restrictions on the practice (see figure III). In these States the regulation governing dispensing by physicians is limited to the procedural requirements (Type V) only. Although these States vary in which and how many of the procedural requirements they impose, none has mandated any other type of regulatory requirement in order to control more tightly the practice of dispensing by physicians. Interestingly, three of the four States with the largest number of practicing physicians are among those with minimal restrictions.






Thirteen States have regulation that places moderate restrictions on physicians who dispense. Regulation in these States includes some or all of the procedural requirements (Type V). In addition, these States impose other types of regulation which exert more control over the practice, such as requirements that dispensing physicians identify themselves to regulatory boards/agencies (Type II), limit fees and profits (Type III), and/or protect patient choice (Type IV).

FIGURE III

RESTRICTIVENESS OF STATE REGULATION OF PHYSICIANS DISPENSING DRUGS
A STATE-BY-STATE OVERVIEW



LEGEND

- Extremely Restrictive Regulation (4) 
- Very Restrictive Regulation (3) 
- Moderately Restrictive Regulation (13) 
- Minimally Restrictive Regulation (25) 
- No Regulation (6) 

NOTE

Based on types of State regulation reported to the OIG
by State regulatory boards/agencies.

August 1988

Only seven States have regulatory requirements that significantly restrict the practice of physician dispensing. Three of these States permit dispensing but use the registration requirement to limit the number of physicians engaging in the practice (Type II). In these States, physicians wishing to dispense must have prior approval of the medical or pharmacy boards which reportedly seldom grant permission. Finally, four States have regulation that is extremely restrictive--they allow dispensing by physicians only in very limited situations (Type I). The regulation process in these States is looked upon as a way to prohibit the practice. (See appendix II for a more detailed description of our typology.)

- The thrust of recent State regulatory activity has been to strengthen controls over dispensing by physicians rather than to prohibit the practice.

Twenty States implemented new regulatory requirements governing dispensing by physicians during the last 3 years. In all these States, the changes strengthened controls placed on dispensing physicians. No State reported having reduced existing requirements or having prohibited dispensing by physicians. The four States which virtually prohibit the practice adopted this regulatory approach many years ago. Within the past 3 years, only five States reportedly have considered prohibiting physician dispensing. Four of them decided against it, and one is still considering a legislative proposal to prohibit the practice.

In moving to strengthen controls over dispensing by physicians, nearly three-fourths of these States have added some of the procedural requirements, and half have imposed registration requirements. Five of the seven States with patient choice requirements added them during this period.

- A large majority of respondents considered the enforcement of their States' requirements for physician dispensing as being no more than moderately effective.

The States' efforts to enforce their regulation governing physician dispensing were viewed as being no more than moderately effective by three-fourths of all respondents from State regulatory boards/agencies. Pharmacy board respondents were much more critical of enforcement efforts than were medical board respondents (see figure IV). Nearly 50 percent of the pharmacy board respondents thought enforcement has been minimally or not effective compared with only 8 percent of medical board respondents. Although one-third of the medical board respondents rated enforcement as very effective, it is interesting to note that nearly an equal number said they did not know how effective their States' efforts have been.

Perceptions about the effectiveness of a State's enforcement efforts corresponded directly with the restrictiveness of its regulation (see figure V). Respondents from those States with less restrictive regulation were more critical of their States' enforcement efforts than were respondents from more highly restrictive States. Only respondents from the minimally or moderately restrictive States thought their enforcement has been minimally or not effective. On the other hand, every respondent from the seven most restrictive States thought that enforcement has been either moderately or very effective in their States; in fact, nearly 70 percent gave "very effective" as their response.

FIGURE IV

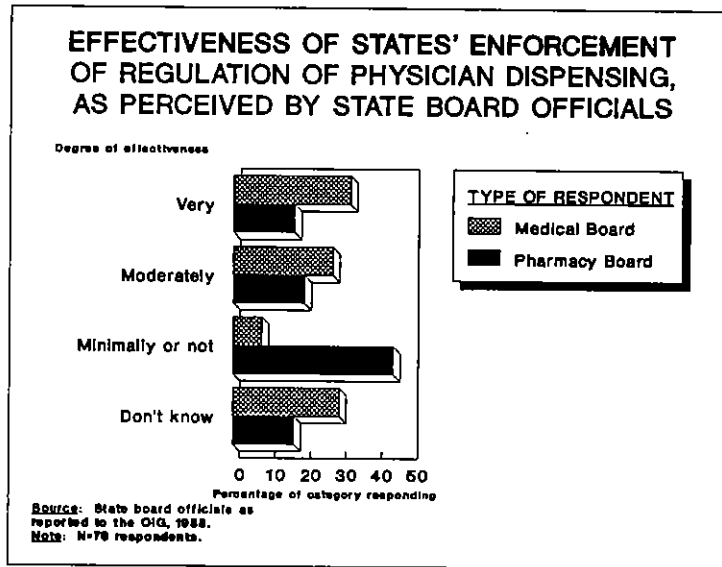
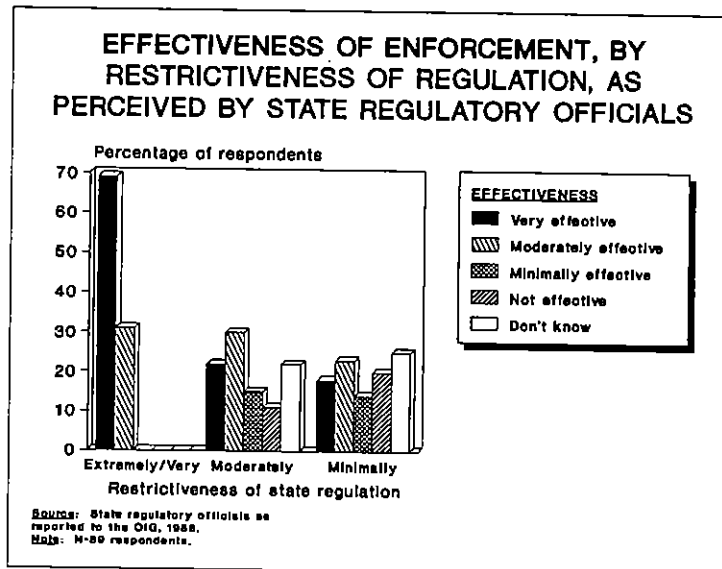


FIGURE V



Most of the States' enforcement efforts have focused on responding to complaints and taking disciplinary actions against physicians. Most respondents thought their boards/agencies were responsive to complaints, but very few States reportedly inspect the offices of dispensing physicians on a routine basis to ensure compliance with State requirements. Within the last 3 years, about one-third of the States have taken disciplinary action against physicians for abuses associated with dispensing. Most frequently these actions have been for improper labeling or various kinds of inappropriate dispensing like overprescribing. In an equal number of States, disciplinary cases are either pending or under investigation.

Respondents from a few regulatory boards specifically mentioned their efforts to familiarize physicians with the requirements for dispensing through mailings, newsletters, and seminars.

Despite these efforts, enforcement of regulatory requirements governing physician dispensing was considered to be of relatively low priority according to respondents from many States. In fact, a few respondents said their States made no effort at all to enforce their requirements.

- A variety of constraints, especially limited resources and fragmented regulatory responsibilities, have hampered States' efforts to enforce their regulatory requirements for physician dispensing.

The States' efforts to enforce their regulatory requirements governing physician dispensing have been constrained by several factors: inadequate resources for regulatory boards/agencies, limited ability to inspect dispensing physicians' offices, ambiguous regulatory requirements, and diffuse responsibility for enforcement within some States.

The major constraint seemed to be insufficient resources. By a wide margin, respondents indicated that this factor, more than any other, diminished their effectiveness. The effects of financial constraints on regulatory boards was described in a 1986 study of State medical boards by the Office of Inspector General (HHS):

In nearly all States, medical board revenues derive entirely from fees imposed on physicians. In response to their expanded responsibilities and workloads, nearly all boards have raised their fees in recent years. Yet, if one takes inflation into account, there is hardly any net increase. This, added to the fact that boards aren't necessarily allowed to spend all the money they collect from fees, has left many of them in an extremely vulnerable position, with investigatory and administrative resources well below the level necessary to handle the job before them.¹¹

Second, limited ability to inspect the offices of dispensing physicians on a routine basis was also frequently mentioned by respondents as a constraint to more effective enforcement. Many of the regulatory requirements imposed on dispensing physicians, such as requirements to ensure patient choice, to restrict profits, and to follow certain procedural stipulations, are difficult to enforce without on-site inspections similar to those conducted in pharmacies by State authorities. Respondents from only half a dozen States mentioned that their States conduct routine, proactive inspections of the offices of dispensing physicians. In some instances, the lack of a routine inspection program results from insufficient resources. Yet, other factors

come into play as well. Respondents from several States mentioned they lack adequate authority to conduct routine inspections of physicians' offices. Other States are not able to identify readily those physicians who are dispensing. Only 13 States reportedly require registration of dispensing physicians. In several of these States, the registration process does not distinguish between physicians actually dispensing and those who register because they might dispense at some future time.

Third, imprecise regulatory language has served as a constraint to effective enforcement in a few States. Two States, for example, have requirements that prohibit physicians' selling drugs at retail or supplementing their incomes by dispensing drugs. But the language of this regulation is so imprecise that enforcement has not been possible. One of these States recently eliminated this type of restriction because of the difficulty of interpretation.

Finally, enforcement efforts in some States may have been hampered because the regulation governing dispensing by physicians and all responsibility for enforcement are not entirely within the purview of the medical boards. In fact, we encountered only a very few States in which the medical boards have, within the body of law they administer, all the regulation governing dispensing by physicians, and, at the same time, have responsibility for all aspects of enforcement.

The States' regulatory requirements for physician dispensing are often not part of the body of law administered by the medical boards although they have the legal responsibility for taking disciplinary action against the licenses of physicians. In fact, very few States have all the regulatory requirements for dispensing by physicians entirely within medical law. In nearly half the States, the requirements governing physician dispensing are based solely in pharmacy law, and in the others, they are contained in various combinations of statutes and other regulation, for example, medical and pharmacy practice acts, opinions of States' attorneys general, or consumer protection laws.

Moreover, although the medical boards in virtually all States reportedly have responsibility to enforce requirements through disciplinary actions, in only about a dozen States are they also responsible for all other aspects of enforcement such as investigating complaints, inspecting physicians' offices, and educating physicians about State requirements. In most States, these enforcement responsibilities are shared among medical boards, pharmacy boards, other State agencies (e.g., offices of attorney general, the departments of health or consumer protection), and/or, occasionally, components of a larger umbrella regulatory agency.

We found that this diffusion of authority and responsibility sometimes resulted in contradictory regulation and confusion over agency roles or even over the requirements themselves. In one State, for example, the pharmacy practice act prohibits physicians from dispensing drugs except in emergencies, whereas the medical practice act allows them to dispense without this restriction. In another State, the medical board told us that responsibility for disciplining physicians rests with the pharmacy board because the dispensing requirements are contained in pharmacy law. The pharmacy board, on the other hand, maintained not only that it has no authority to discipline physicians but that the provisions of the pharmacy practice act do not apply to dispensing by physicians. We found too that in nearly half the States, the regulatory

board/agency officials with whom we spoke disagreed with one another or with the regulation itself regarding their States' requirements. In many instances, respondents had to refer to other staff members or to other agencies to learn what requirements were in place.

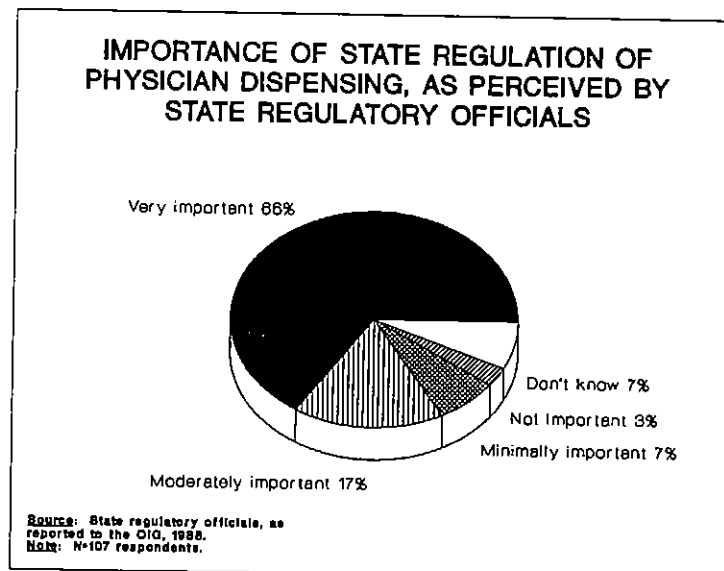
Considerable Support Exists Among State Regulatory Officials For Further Regulation Of Dispensing By Physicians.

- Two-thirds of all respondents thought it is very important for physician dispensing to be regulated in their States.

Two-thirds of all respondents, from States with and without regulation, thought regulation of physician dispensing is very important for their States; only 10 percent thought it minimally or not important (see figure VI). Pharmacy boards attached much greater importance to regulation than did medical boards. Over 80 percent of the respondents from pharmacy boards considered regulation as very important for their State compared with 40 percent of medical board respondents. Nevertheless, nearly three-fourths of the medical board respondents thought it was either very or moderately important for their States to regulate the practice.

We found a direct correlation between the importance attached to regulation by respondents and the restrictiveness of their States' regulation. Whereas nearly all the respondents from the seven most restrictive States considered regulation very important, only half of those from States with no regulation thought so.

FIGURE VI



In general, respondents thought that regulation of dispensing by physicians is necessary primarily to protect the health of the public. Other major reasons included the need for ensuring accountability and for strengthening controls in the nation's drug distribution system in order to reduce the possibilities for diversion. This position is supported by the number of regulatory board/agency officials reporting increases in the number of complaints on physician dispensing.

- Nearly two-thirds of regulatory board/agency officials contacted reported complaints on physician dispensing during the last 2-3 years. Complaints were reported by at least one board/agency official from three-fourths of all States, including those with and without regulation.

Nearly two-thirds of all the regulatory board/agency officials with whom we spoke reported having received complaints during the last 2 or 3 years. These officials represented over half the medical boards, nearly two-thirds of the pharmacy boards, and more than three-fourths of the separate enforcement agencies. Overall, complaints were reported by at least one board/agency official from three-fourths of all States, including those with and without regulation. Moreover, nearly 30 percent of these officials thought the number of complaints was increasing during this time. The most frequent complaints concerned improper labeling and packaging of drugs as well as what these officials described as various kinds of inappropriate dispensing, such as overprescribing, unnecessary prescribing, and dispensing outdated or inappropriate drugs. Officials also reported having received, to a lesser extent, complaints about physicians overcharging for drugs, improperly supervising the dispensing process, and making patients feel they could not buy their prescriptions elsewhere.

- Many respondents from States with regulation thought stronger requirements were needed.

About half the officials with whom we spoke from States with regulation favored changes to clarify and strengthen further their States' regulatory control over physician dispensing. This view was shared by nearly equal proportions of respondents from medical boards and pharmacy boards. Support for change was strongest among respondents from those States with moderately or minimally restrictive regulation. Respondents from these States most favored regulatory changes to require registration of dispensing physicians, to impose more procedural requirements, and to clarify regulatory language. Overall, only a very few respondents considered any of their States' requirements too restrictive, and no one suggested eliminating regulation completely.

In contrast, about a third of the respondents from States with regulation thought no regulatory changes were needed in their States. Some indicated that dispensing by physicians did not pose a problem, and others thought their regulation was adequate. A few respondents thought their States had not had sufficient experience with recent regulatory changes to consider any further action soon.

- Nearly half of all respondents thought Federal action addressing the practice of physician dispensing was not necessary; a third favored it, and nearly 10 percent thought it might be needed.

Nearly half the State officials with whom we spoke did not favor any Federal action related to physician dispensing. Opposition to Federal action was expressed by more medical board officials than pharmacy board officials (by a margin of more than two to one). A larger proportion of respondents from the seven most restrictive States were opposed to Federal action than those from less restrictive States. A few respondents thought Federal action was unnecessary because physician dispensing was not a problem in their States. A few others felt that Federal regulation would be difficult to implement or enforce. Most of the respondents, however, were opposed simply because they considered regulation of the practice to be more appropriate for the States than the Federal Government. And, indeed, nearly a third of the respondents, including at least one official from half the States, expected additional regulation to be proposed or implemented in their States within the next year or so. These States include those nine States where changes are currently pending, as well as 18 other States.

On the other hand, over a third of the regulatory board/agency officials thought Federal action was needed. And another 10 percent favored some role for the Federal Government if efforts by the States to address the practice should prove to be insufficient. Support for Federal action was strongest among pharmacy board officials and among respondents from those States with moderately or minimally restrictive regulation.

Most proponents of Federal action thought the Federal Government should establish standards governing the practice of dispensing by physicians. They supported federally imposed standards in order to ensure uniform requirements among the States and to provide stronger controls over the drug distribution system nationwide. About a third of those in favor of Federal action, primarily pharmacy board officials, thought the Federal Government should prohibit the practice altogether. A few respondents, all from medical boards, wanted the Federal Government to study further various issues related to the practice of physician dispensing.

When asked specifically about the pending Federal legislation to prohibit practitioners from dispensing for profit, nearly two-thirds of all respondents were familiar with the proposed legislation, but less than half of these favored Federal prohibition. Slightly less than 25 percent of all regulatory board/agency officials with whom we spoke were both familiar with the bill and in favor of it.

More pharmacy board officials were familiar with the legislation than were medical board officials by a margin of nearly two to one. And of all respondents both familiar with and in favor of the legislation, 85 percent were from pharmacy boards. We found no correlation between respondents' opinions about this legislation and the restrictiveness of their States' regulation.

RECOMMENDATIONS

Based on the situation described in the previous pages, we offer the following recommendations with respect to regulation of physicians who dispense drugs to patients beyond the provision of samples. We address these recommendations to State governments and to the national associations of the boards of medicine and pharmacy.

THE STATE GOVERNMENTS

In our view, the public's health and welfare as well as the integrity of the distribution system for prescription drugs are crucial considerations in government regulation of physician drug dispensing. The focus of our inquiry did not include an in-depth analysis of either the incidence or consequences of physician dispensing. However, in examining State regulatory approaches to the practice, we believe we acquired sufficient understanding of the concerns about public health and accountability associated with physician dispensing to support the following recommendations:

- State governments should take initiatives to promote stronger, more effective regulation of physician dispensing.

We believe that the States should continue to exercise primary responsibility for regulating the terms and conditions under which physicians may dispense prescription drugs. State governments are more attuned to local situations than the Federal Government. States have traditionally regulated the practices of both medicine and pharmacy, and thus States have both considerable experience upon which to base further regulation and administrative structures for enforcement already in place. As we have seen, not only have a large majority of States already imposed some requirements on the practice, but there has been considerable activity to strengthen regulation of physician dispensing in recent years. More seems likely to occur in the near future.

Effective regulation of drug dispensing is important to protect the health and welfare of the public and to ensure accountability and adequate controls in the drug distribution system. State governments have recognized the importance of these concerns as they have extensively regulated the dispensing of prescription drugs by pharmacists. For these reasons, most States have also mandated at least some requirements for dispensing by physicians.

Nevertheless, as we have seen, the regulatory requirements imposed by the States on dispensing physicians vary widely across the country, and the large majority of States either have minimal regulation governing the practice or have no regulation at all. Further, many State regulatory boards/agencies reported having received complaints about the practice and having taken disciplinary action of various kinds against physicians for abuses associated with dispensing. These complaints and disciplinary actions have been related primarily to public health and safety issues. Although the incidence of physician dispensing is relatively low in

most States, it appears to be increasing in many States. The practice seems likely to increase further in view of both the economic pressures facing many physicians and the possibility that physicians will participate in the new Medicare outpatient prescription drug program.

Based on what we have learned about the States' current regulatory approaches, the regulation governing dispensing by physicians in most States is significantly less extensive than the regulation governing dispensing by pharmacists. This discrepancy suggests vulnerabilities for both the public's health and for accountability in the drug distribution system.

Should States choose not to prohibit physicians from routinely dispensing drugs, it seems reasonable that they at least adopt requirements sufficient to ensure more adequate protection for the public and heightened accountability for drug distribution. We think the States, at the very least, should adopt a basic threshold of regulatory requirements to govern dispensing by physicians. We suggest this threshold of regulation consist, at a minimum, of the following requirements:

1. The procedural requirements (Type V regulation) such as labeling, record-keeping, storage, security, and supervision of the dispenser should be as applicable to dispensing physicians as they are to pharmacists.
2. A requirement for registration of dispensing physicians with a designated State agency (Type II regulation) is needed so the States can identify those physicians who are actually dispensing for purposes of inspection and monitoring.
3. Requirements to protect freedom of choice (Type IV regulation) for patients.

The procedural and registration requirements we propose as components of this threshold were frequently identified by the State regulatory boards/agencies with whom we spoke as crucial to effective regulation of the practice. And requirements promoting freedom of choice would help to address concerns that the public be able to decide freely whether to obtain prescriptions from their physician or from their pharmacist.

- State governments should take steps to strengthen their enforcement of regulation governing physician dispensing.

Appropriate regulatory controls governing the practice of physician dispensing is only one component of effective regulation. Equally crucial to effective regulation is adequate enforcement of the legal requirements. As we have seen, State regulatory boards/agencies face a number of constraints as they seek to enforce requirements governing physicians who are dispensing. These efforts could be strengthened by State governments through such actions as the following:

- providing more resources to State agencies for enforcement, possibly through fees associated with a registration requirement for physicians who dispense;
- clarifying ambiguous regulatory language, as appropriate;

- delineating clearly the authority and responsibilities of those State agencies involved in enforcement of regulatory requirements;
- improving the ability of State agencies to inspect routinely the offices of dispensing physicians through such measures as assuring adequate legal authority for inspections and mandating registration of dispensing physicians; and
- ensuring that dispensing physicians are knowledgeable about the regulatory requirements governing the practice in their States.

THE NATIONAL ASSOCIATIONS

The Federation of State Medical Boards (FSMB) and the National Association of Boards of Pharmacy (NABP) have an opportunity to provide further leadership to the States in the area of physician drug dispensing. We therefore direct the following recommendation to these associations:

- The FSMB and the NABP should work together in helping States to promote stronger, more effective regulation governing physician dispensing.

Physician dispensing is a controversial practice which affects both the professions of medicine and pharmacy. It seems likely that many State boards of medicine and pharmacy will be under increasing pressure to address safety and accountability concerns associated with the practice in the years ahead. The FSMB and the NABP could provide further leadership to State boards by working together to consider respective authorities and responsibilities for regulation in this area. The associations could also provide valuable assistance to States by developing and incorporating into their respective model practice acts guidelines which are consistent and acceptable to both professions. In so doing, the associations could work out together the specifics of the regulatory threshold described above for consideration by the States as they seek to strengthen regulatory controls over the practice.

COMMENTS ON THE DRAFT AND OIG RESPONSE

Within the Department of Health and Human Services, we received comments on the draft report from the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Health Care Financing Administration (HCFA), and the Public Health Service (PHS). We also received comments from the Drug Enforcement Administration (DEA) and the Federal Trade Commission (FTC). In addition, we received comments from a number of organizations outside the Federal Government: the American Medical Association (AMA), the Competitive Health Care Coalition (CHCC) representing several drug repackaging companies, the National Association of Chain Drug Stores (NACDS), the American Pharmaceutical Association (APhA), the Federation of State Medical Boards (FSMB), and the National Association of Boards of Pharmacy (NABP).

The comments of these government agencies and national organizations are contained below and are followed, in each instance, by the OIG response. We have chosen to include these comments in their entirety (except for attachments and references thereto) because we believe they offer important perspectives on physician drug dispensing and contribute helpful clarifying information. After considering all these comments, we offer several overall observations in response to issues raised by several agencies and organizations.

A few organizations challenged the validity of some findings and recommendations based on criticism of the limited scope of our inquiry and the methodology we used. With respect to the scope of our study, we acknowledge in the report that physician drug dispensing involves complicated, controversial issues of ethics, economics, public health, and regulation. We deliberately chose to focus our attention primarily on the issue of regulation of the practice by the States. We believe that further understanding of the extent and nature of regulation among the States and of the impact and effectiveness of their regulatory approaches would be useful to both Federal and State policymakers. Thus, in so doing, we did not examine other dimensions of the practice, such as conflict of interest concerns, cost implications, and issues of competition which nonetheless seem to us to be important considerations and legitimate issues for further study.

With respect to our methodology, some agencies and organizations criticize the report for being subjective and biased, for relying too heavily on perceptual information from interviews and not heavily enough on objective documentation. We believe our methodology was valid and the conclusions and recommendations of the report are sound and credible. In order to understand State regulation of this practice, we chose to survey every State, not a sample of States, and in so doing, include representatives of both medicine and pharmacy and, in some cases, separate drug enforcement agencies. We chose to survey, in particular, executive directors of the State boards of medicine and pharmacy which are charged with enforcing States' laws governing the practices of medicine and pharmacy. These directors are close to the State regulatory scene and are, in our view, in a very good position to identify the States' regulatory requirements and to comment on their States' enforcement efforts.

We do not deny that bias can affect the judgments of respondents, whether from medical boards or pharmacy boards. However, our major finding outlining the disparity in regulation of dispensing by pharmacists and by physicians is not a matter of perception but a situation documented in State law and regulation. Our major recommendation urging stronger, more effective State regulation to reduce this disparity hinges on this basic fact.

Moreover, the recommendation for stronger regulation is further supported by the information on the extent and nature of complaints and disciplinary actions handled by these boards which was reported to us by board officials. We acknowledge that we did not perform a State-by-State review of board records in order to document complaints and disciplinary actions, but we did rely on data reported to us by State officials we consider to be knowledgeable and reliable. Many of these boards did provide us with numbers of complaints and disciplinary actions related to dispensing by physicians which we summarize in the report. We acknowledge we did not learn of dramatic horror stories attributable to dispensing by physicians. However, the nature of complaints and disciplinary actions reported by the boards suggest to us abuses of the practice such as improper labeling and inappropriate dispensing which are not insignificant for the health and safety of the public. That State boards reported as many complaints and disciplinary actions related to physician dispensing as they did seems to us to be significant given the minimal degree of regulation in many States, the other priorities competing for the attention of State boards, and the fact that many aspects of safe dispensing, such as record-keeping, proper storage, and security, are not readily apparent to patients and are infrequently, if ever, the object of inspections in most States.

Overall, no one disagreed with our conclusion that State regulation governing dispensing of prescription drugs is, for most States, much less extensive for physicians than for pharmacists and that efforts to enforce requirements have been hampered by a variety of constraints. Similarly, although some disagreed with our overall recommendation for stronger regulation, no one took issue with our call for a specific threshold of regulatory requirements for physicians who are dispensing prescription drugs.

APPENDIX I

DETAILED COMMENTS ON THE DRAFT REPORT AND OIG RESPONSES

ASSISTANT SECRETARY FOR PLANNING AND EVALUATION COMMENTS

Thank you for sending me your draft report on physician dispensing for comment. It's a good status report on the extent of state regulatory activity in this area. I agree with your basic recommendations, namely, that regulation of physician dispensing should remain the responsibility of states and that stronger regulatory oversight of the practice of physician dispensing is needed in many states and should be encouraged by HHS. I would add, however, that the extent of physician dispensing of prescription drugs bears continued watching so that we are prepared to assess any problems or political pressures that develop with the growth of this practice.

OIG RESPONSE TO ASPE COMMENTS

We agree with ASPE's comments and particularly endorse the need for the Department to monitor the growth of this practice, to remain alert to State regulatory activities, and to reassess the implications of the practice for its various health programs in the not too distant future.

HEALTH CARE FINANCING ADMINISTRATION COMMENTS

We have reviewed the subject report and concur with the OIG's recommendations regarding the regulation of physicians who dispense drugs to patients beyond the provisions of samples. We especially agree that States should continue to exercise primary responsibility (as they do with pharmacies) for regulating the terms and conditions under which physicians may dispense prescription drugs.

It is clear from the report that States have attempted, with only minimal impact, to issue regulatory requirements on dispensing physicians. States need to establish more effective regulation of these physicians which conforms more closely with State requirements that govern pharmacies.

The OIG report indicates that in many States physicians are permitted to dispense drugs without being licensed. It should be noted that with respect to the expanded coverage of outpatient drugs under the Medicare Catastrophic Coverage Act of 1988, a provider must be authorized by State law to dispense covered drugs in order to receive payment on an assignment-claims basis. Since physicians will have to be authorized by the State to dispense drugs in order to receive payment for the drugs on an assignment basis, this may give an impetus to more State regulation of physicians who dispense drugs.

Thank you for the opportunity to comment on this report.

OIG RESPONSE TO HCFA COMMENTS

We agree with the thrust of HCFA's comments. However, we wish to comment on HCFA's point that physician participation in the new Medicare outpatient prescription drug program may encourage more State regulation of dispensing by physicians. Whether or not this proves to be true in the long run, in the immediate future, providers are eligible for participation as long as they agree with certain stipulations of the Act and are authorized by State law to dispense covered drugs. The implications of this situation are, it seems to us, that physicians from most States are eligible to participate in this program as they are authorized to dispense prescription drugs under the terms of their medical licensure. However, these physicians will, as we have seen, be dispensing prescription drugs with far less regulation and control than exists for pharmacists.

PUBLIC HEALTH SERVICES COMMENTS

We agree with the report's statement that ". . . States should continue to exercise primary responsibility for regulating the terms and conditions under which physicians may dispense prescription drugs." We agree in part that State medical boards and pharmacy boards need to provide greater leadership to States and to their constituencies in the area of physician drug dispensing.

The report does not contain any objective evidence of the presence or absence of a major public health problem with physician drug dispensing. We believe this is due to the report's reliance on perceptual information obtained primarily from interviews. We recommend that objective data be used to support the report's recommendations for stronger State regulation and enforcement with respect to physician drug dispensing.

We believe it may be useful to provide some clarification of FDA's policy on physician drug dispensing. Although 503(b) of the Federal Food, Drug, and Cosmetic Act is applicable to physicians, we have long considered physicians who dispense drugs to patients pursuant to a bona fide doctor-patient relationship to be exempt from strict compliance with the labeling requirements for prescription drugs under Section 503(b)(2).

We believe that physicians who dispense drugs to patients pursuant to a bona fide doctor-patient relationship are engaged in the practice of medicine which is under the jurisdiction of the individual States. Consequently, FDA has not initiated any action to discipline physicians for failure to comply with the labeling requirements of Section 503 of the Act when involved in the bona fide prescribing and dispensing of prescription drugs. In this regard, we are not aware of any specific complaints received by FDA advising that the labeling practices of dispensing physicians have resulted in a public health or safety problem requiring Federal intervention.

If such complaints were received, FDA would refer these to State drug officials for appropriate action. Should a situation arise where a dispensing physician's labeling practices result in a safety or health problem not amenable to State remedial action, FDA would consider appropriate steps to correct any violation.

OIG RESPONSE TO PHS COMMENTS

The PHS criticizes the report for relying on perceptual information from interviews. As we noted earlier, the disparity we point out in most States' requirements for dispensing by physicians and pharmacists is not a matter of perception but is based in State law and regulation. We did rely heavily on information supplied by the State boards of medicine and pharmacy who are, we believe, the State agencies most knowledgeable about this subject and who are, at the same time, among the major State agencies upon which the FDA relies for implementation and enforcement of various drug related legislation.

We are pleased that the PHS included in its comments clarification of the labeling requirements for prescription drugs contained in the Federal Food, Drug, and Cosmetic Act (FFDCA), Section 502, and the applicability to physicians of the exemptions from these requirements described in Section 503(b) of the Act. We were alerted during our study to questions raised by pharmacy officials about the applicability of the FFDCA labeling requirements to drugs dispensed by physicians, and we sought to clarify current FDA policy from several agency staff.

Section 503(b)(2) requires that:

Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if state in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, as to a drug dispensed in violation of paragraph (1) of this subsection.

As stated in the PHS comments above, the agency maintains that this Section of the Act is applicable to prescription drugs dispensed by pharmacists and physicians. Yet, at the same time, agency policy exempts physicians, but not pharmacists, from "strict" compliance with these labeling requirements. In its view, the FDA considers dispensing of prescription drugs by physicians part of the practice of medicine and therefore under the regulatory jurisdiction of the States rather than the Federal Government.

In our view, this interpretation reinforces at the Federal level the inequitable disparity that exists at the State level in the regulation of dispensing by physicians and by pharmacists. Further, it seems to us inconsistent to suggest that these Federal requirements do not apply to drugs when dispensed by physicians but do apply to drugs when dispensed by pharmacists. Regulation of the practice of pharmacy has, no less than the practice of medicine, fallen primarily under the jurisdiction of the States. This interpretation suggests a double standard

which raises our concern, particularly as State board officials identified improper labeling of drugs dispensed by physicians as a major reason both for complaints to boards and for the disciplinary actions they have taken.

DRUG ENFORCEMENT ADMINISTRATION COMMENTS

Thank you for providing a copy of the draft report "Physician Drug Dispensing: An Overview of State Regulation" and for soliciting the Drug Enforcement Administration's (DEA) comments on the report.

First, I should point out that this agency's concern in this matter is regarding controlled substances, while the report is addressing physician dispensing of all prescription drugs. Any practitioner dispensing controlled substances must comply with the Federal regulations contained in 21 CFR Part 1300-End, whether or not additional state regulations for this activity exist. These Federal regulations include record-keeping and inventory requirements.

Although over the years there have been instances of physicians prosecuted for dispensing large quantities of controlled substances for illicit profit (especially amphetamines), DEA has no information that this is any more prevalent than doctors who divert by prescribing, or that diversion by dispensing is increasing. On the contrary, Schedule II dispensing doctors are more readily identified through DEA's ARCOS reporting system than are those writing prescriptions.

However, based upon our experiences and monitoring of the states' action (or inaction) and effectiveness in monitoring such practices, it appears to DEA that the findings in your report and the recommendations are sound.

I would like to add that I found this report thorough and informative. Thank you once again for the opportunity to comment on this matter affecting DEA's areas of responsibility.

OIG RESPONSE TO DEA COMMENTS

We are pleased with DEA's positive response to our findings and recommendations. As noted in the report, the Federal requirements implemented and enforced by the DEA with respect to controlled substances are applicable to all dispensing, whether by pharmacists or by physicians.

FEDERAL TRADE COMMISSION COMMENTS

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").¹ The Report recommends that states enact more stringent regulation of physician dispensing of prescription drugs by (1) imposing procedural requirements for supervision, labeling, record-keeping, 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 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. For example, we have submitted comments to regulatory boards in Georgia² and Maryland³ and to a legislative committee in California⁴ concerning physician dispensing...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 consumers. We have not, however, opposed efforts to insure that both physicians and pharmacists adhere to regulations that may promote public welfare.

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 anti-competitive effects when incorporated into a specific regulation or statute or when added to an existing regulatory scheme. For example, while record-keeping 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 competition. Similarly, a state may adopt the recommendation 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.

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.

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- 1 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.
 - 2 See Letter from Jeffrey I. Zuckerman, Director, Bureau of Competition, to William G. Miller, Jr., Joint Secretary, State Examining Boards (November 26, 1986).
 - 3 See 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 See Letter from Jeffrey I. Zuckerman, Director, Bureau of Competition, to The Honorable Tim Leslie, California Assembly (May 1, 1987).
 - 5 See Letter from Jeffrey I. Zuckerman, Director, Bureau of Competition, to William G. Miller, Jr., Joint Secretary, State Examining Boards (June 26, 1987).

OIG RESPONSE TO FTC COMMENTS

We appreciate the FTC's clarification of its current views on physician dispensing and have revised the narrative of the report accordingly.

We, too, share the concern expressed by the FTC that dispensing of prescription drugs, whether by pharmacists or by physicians, be conducted in accordance with adequate health and safety standards to protect the public. The thrust of our recommendation is not to impose a regulatory framework which is more restrictive for dispensing by physicians than by pharmacists. Rather, we recommend that for States which choose not to prohibit or otherwise severely restrict dispensing by physicians a minimum threshold of regulatory requirements should be adopted to achieve greater parity and to protect the health and safety of the public. However, it is important to note that even in adopting our suggested regulatory threshold, we think certain vulnerabilities may remain with the practice in that physicians will be dispensing prescription drugs, albeit in accordance with stricter regulation, but without being required to meet the educational and experiential requirements of licensure which States have chosen to require of pharmacists who dispense.

AMERICAN MEDICAL ASSOCIATION COMMENTS

The American Medical Association has reviewed the draft report of the Office of the Inspector General entitled, "Physician Dispensing: An Overview of State Regulation." The stated purpose of this report was to determine "the extent and type of state regulation" and to explore "the effectiveness of state approaches" regulating physician dispensing. The AMA supports physicians' right to dispense drugs and devices when it is in the best interest of the patient and consistent with our ethical guidelines...

The AMA concurs with the report in its view that the proper place for any regulation of physician dispensing is at the state level. We strongly believe that the regulation of the practice of medicine, including physician dispensing practices, is the role of the states. As noted in the draft report, states are more attuned to local situations than the Federal Government and have traditionally regulated both the practice of medicine and the practice of pharmacy.

The AMA, however, strongly disagrees with the conclusions drawn in the draft report. We cannot support the report's recommendation that there is a need for "stronger, more effective regulation of physician dispensing." The report fails to document any abuses related to physician dispensing, any examples where individual patients or the public health have been endangered, or any instances where current regulations have been ineffective.

The findings and recommendations presented in this draft report are based heavily on a telephone survey of representatives of state regulatory agencies, primarily the boards of medicine and pharmacy. In the absence of documented evidence to confirm the subjective impressions of the respondents, it is virtually impossible to rule out bias in such a study. For example, nearly 50% of the pharmacy board respondents perceived their states' enforcement of regulation of physician dispensing as only minimally effective. In contrast, the majority of medical board respondents perceived their states' enforcement of regulation of physician dis-

dispensing as very or moderately effective; only 8% perceived enforcement as minimally effective. It appears that pharmacy board officials may have a preferential interest in protecting the pharmacy profession and, therefore, there may be a bias against physician dispensing for economic reasons. In the absence of confirmatory data, the conclusion that pharmacy board staffs are biased is just as valid a conclusion as the draft report's conclusion that there is inadequate enforcement of dispensing regulations.

We also question what is meant by "effective regulation." It is notable that the states where regulations are viewed as "most effective" are those that virtually prohibit dispensing. We cannot support stronger regulation of physician dispensing where the goal of the regulation (stated or otherwise) is to impede the legitimate practice of physician dispensing. The Federal Trade Commission has recognized that physician dispensing is a traditional part of medical practice and has urged states to minimize regulatory impediments to physician dispensing. Without any empirical data as to the number and types of complaints occurring in the states, it is premature to recommend "stronger, more effective regulations."

In conclusion, the AMA supports the draft report in its recognition of the states as the proper governmental entities for regulation of physician dispensing practices. The AMA, however, cannot support the call for all states to pass stronger dispensing regulations. The report fails to produce any data supporting a broad call for stronger regulation. The report's survey results show that the concerns regarding physician dispensing are not uniform from state-to-state and, in some instances, are not uniform within the states. The AMA believes that the need for any regulation of physician dispensing must be determined by each state separately, based upon the situation within the state.

OIG RESPONSE TO AMA COMMENTS

We are pleased that the AMA agrees with our view that primary responsibility for regulating the dispensing of prescription drugs by physicians rests with the States.

We are concerned, however, with the thrust of the AMA comments on two counts. First, the AMA suggests that the goal of our recommendation for stronger, more effective State regulation is an effort on our part to "impede the legitimate practice of physician dispensing." On the contrary, the goal of regulation is to assure protection of the public's health and integrity of the distribution system for prescription drugs whether the dispensing is by pharmacists or by physicians. As this report makes clear, in the large majority of States, the regulatory requirements governing dispensing by physicians are far less stringent than those governing dispensing by pharmacists. The arguments justifying the need for regulation of dispensing when practiced by pharmacists are no less valid for dispensing by physicians.

Moreover, as stated earlier, we believe the in-depth telephone discussions with State regulatory officials contributed valuable insights and perspectives which ought not to be dismissed as bias. The information State officials shared on regulatory requirements are detailed

in State law and regulation. Information about the disciplinary actions are a matter of public record in each State, and we have every reason to believe that these responsible State officials provided us with good faith estimates of disciplinary actions and complaints.

As the AMA noted, pharmacy and medical boards have different perspectives with respect to some aspects of physician drug dispensing. However, particularly significant, we believe, is the perspective, shared by equal proportions of respondents from medical and pharmacy boards, that further strengthening of their State's regulation of drug dispensing by physicians is warranted.

COMPETITIVE HEALTH CARE COALITION COMMENTS

In response to your letter of November 1, the following comments are submitted on behalf of companies in the drug repackaging industry on the draft report entitled, "Physician Drug Dispensing: An Overview of State Regulation." While we have several concerns regarding the draft, overall we share your view that any regulation of prescription drug dispensing is appropriately within the purview of the states.

As the draft report states, physician dispensing of prescription drugs raises issues as to whether the practice promotes or restrains competition and whether consumers pay more or less for drugs dispensed by physicians. Nevertheless, the draft lacks any discussion of the effect of physician dispensing upon the market price of prescription drugs. We believe that physician dispensing has brought new competition into the prescription drug market, forcing others in the market to offer a better product, more convenient service and lower prices. Omission of discussion and analysis of these fundamental benefits to consumers is a serious deficiency of the draft report.

We also believe the draft to be deficient in its methodology, failing to meet the objective standard necessary to give credibility to its findings. Rather, the report accepts and treats public perceptions as a methodological premise. It cites no studies or statistics revealing actual documented abuse by physicians who dispense drugs. While those who oppose physician dispensing have claimed that the practice has resulted in higher prices, improper supervision, improper labeling and packaging, overprescribing, unnecessary prescribing, outdated dispensing and lack of choice by patients, we are aware of no actual documentation of these allegations. Indeed, the draft report itself states (page 4) that none of the state officials contacted was aware of any analyses or surveys of physician dispensing in any of the states. As your own remarks at the October 6 National Institute on Clinical Laboratory Reimbursement and Policy proceedings recognized, public policy made in the absence of "good solid data" frequently results in very flawed policy decisions.

The draft report appears to be largely based upon telephone conversations eliciting opinions of representatives of organizations, government agencies and state regulatory boards. These opinions describe the industry in general terms, leading to a tenuous basis for the findings of the report. Examples include:

- References to "industry spokespersons" who are uncertain as to the amount of revenues involved in the practice of physician dispensing but who "predict dramatic growth in the industry" without identifying who these "industry spokespersons" are, the interests they represent, nor the basis for their "predictions."
- An overview of *estimates* of the incidence of physician dispensing without identification of relevant and statistically sound facts from which these estimates are made.
- References to complaints received by state regulatory boards regarding physician dispensing without stating the number of complaints received, from whom these complaints were received, nor the content of the complaints received. It would also be useful to know how these complaints were resolved.
- Continued references to state regulatory board officials who *thought* the number of complaints had been increasing. Again, the report's reliance on perceptions is demeaning both to the legal and political significance of your effort.
- References to disciplinary action taken by states against physicians without a comparison with actions taken against pharmacists during the same period, leaving a negative impression concerning disciplinary problems with physicians who dispense drugs, when in fact the number of actions taken against physicians may be minimal.

Reliance upon generalities and opinions as the basis for formulating conclusions jeopardizes the objectivity a report of this nature should possess. Many of those whose opinions were solicited were pharmacists or their advocates. Many state regulatory boards having jurisdiction in this area are largely composed of pharmacists. Such persons may reasonably be expected to have a bias against physician drug dispensing. A report based upon biased opinions cannot help but reflect such bias.

We agree that any regulation of physician dispensing should remain within the states' purview. They are best positioned to make reasonable and informed decisions as to whether and what regulations are needed.

Yet, in making recommendation to the states, the draft report is again deficient in that it ignores an important distinction for states to consider when promulgating regulations. The report should emphasize that states contemplating regulation of physician drug dispensing must recognize the difference between dispensing repackaged drugs and dispensing drugs "in bulk." Dispensers of drugs "in bulk" purchase drugs in large quantities; when a patient needs the drug, the required quantity is taken from a large container and sold "as is." Little attention is given to such important quality and safety factors as proper packaging, labeling, and expiration dates of the bulk drugs. In contrast, physicians who dispense prepackaged drugs sell only drugs purchased from a prepackager licensed by the Food and Drug Administration which requires the prepackager to adhere to strict federal manufacturing standards, Drug Enforcement Administration regulations (which meet or exceed state-mandated pharmacy regulations), and applicable state regulations.¹ Moreover, dispensing of prepackaged drugs eliminates essential-

ly all of the risks of handling associated with traditional dispensing by pharmacists. These critical distinctions substantially reduce the need for state concern for many potential abuses in the dispensing of prepackaged drugs.²

Another deficiency of the report concerns statements of fact which we believe fail to reflect the complete picture. Examples include:

- The statement that revenues realized by repackagers may increase from an estimated \$25 million last year to as much as \$400 million to \$500 million by 1990 and possibly as much as \$2 billion within 5 to 7 years. These estimates seem dubious in light of the fact that the largest companies in the drug repackaging industry, ISP (Stat-Pak) and PPS are barely increasing sales. A minimum of a tripling of sales would be required by every company each year in order to realize the revenue increase estimates stated in the Report.
- A conclusion in the report stating that physician drug dispensing across the country seems to be growing. Yet, the report does not note that much of the growth in physician dispensing is due to the conversion of bulk dispensers of drugs to the safer practice of dispensing of prepackaged drugs.

It would be helpful and important if the report would update the several changes in state laws as follows:

- In Illinois, written prescriptions do not have to be provided to patients; rather, the patient must be advised of the choice of receiving a written prescription.
- In California, patients are advised of their choice to fill prescriptions elsewhere.
- In Oklahoma and Washington, prescription charges or profits are not prohibited. The same prohibition has been overturned by the West Virginia Attorney General and is under review in Virginia.
- Appendix I should delete Nebraska and Oklahoma from the list of states with "very restrictive" regulations. The report states that in these states the "required board approval reportedly has been given very sparingly," when, in fact, the required board approvals in these states is granted regularly.
- Appendix II should note that this year the Florida legislature removed its restriction requiring six hours annually of continuing medical education and replaced it with a simple registration requirement.

Finally, the report only superficially presents its "findings." For example, the report establishes a major conclusion in the face of facts to the contrary. On page 17 a "finding" of the report highlights the fact that "many respondents from States with regulation thought stronger

requirements are needed," despite the fact that the text of the report asserts that "a third of the respondents from States with regulation thought *no* regulatory changes were needed in their States" while still others "thought their States had not had sufficient experience with recent regulatory changes to consider any further activities soon." (Emphasis added.) More consideration should be given to these statements due to the significant number of respondents who advocate that either no regulations are needed at all or that no regulations are needed in the near future.

Another example can be found on page 19. There the report recommends that "State governments . . . take initiatives to promote stronger, more effective regulation of physician dispensing." The report should include an appendix identifying states which have recently struck down regulations for being too restrictive in order to remind states of the danger of over-regulation.

We are pleased to have had the opportunity to submit the foregoing comments and trust that you will let us know if we can provide further information or assist you in any way in finalizing the report.

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- 1 For example, page 9 of the report refers to the fact that state regulatory board officials are of the view that states should implement regulations authorizing dispensing only by the physicians themselves. In the case of a physician who dispenses prepackaged drugs-as opposed to dispensers of drugs "in bulk"-there is little need for such a regulation.
 - 2 In support of this proposition, the Annual Schering Report IX prepared by Schering Laboratories in Kenilworth, New Jersey (1987), concludes that consumers get better instructions from physicians than from a typical drug store where the patient is likely to receive prescriptions from a cashier.

The report shows that 92% of the patients surveyed were given detailed instructions on dosage by their physician at the time they received a prescription. This compares to 43% who received instructions from a pharmacy.

OIG RESPONSE TO CHCC COMMENTS

With respect to the CHCC's comments on the scope of our report, we reiterate that the focus of our inquiry was primarily directed at gaining further understanding of the States' regulatory approaches to drug dispensing by physicians. That an examination of economic issues involved in physician dispensing was beyond the scope of this inquiry diminishes neither the significance of the economic issues nor of the regulatory issues which we did examine.

The CHCC believes our methodology was deficient and suggests the report contains insufficient data to justify our recommendations for stronger, more effective regulation. As noted earlier, we believe our approach was reasoned and credible given the purpose and scope of the inquiry and that it balanced the perspectives of both medicine and pharmacy. We acknowledge we did not compare disciplinary actions taken by State boards against physicians with those taken against pharmacists. We question the significance of such a comparison given the disparity in State regulation of the practice between the two professions and given that the dispensing of prescription drugs is at the core of pharmacy practice and closely monitored by regulatory officials. For all the reasons detailed above, we believe our data on regulatory requirements provides a solid basis for our policy recommendations.

The CHCC takes issue with our finding summarizing the views of regulatory board officials with respect to the need for stronger regulation of the practice. We believe the interpretation and emphasis we give to the supporting data is correct. As stated in the report, one-third of the officials from States with regulation thought no further *changes* were currently needed, not that "no regulations are needed at all or that no regulations are needed in the near future."

The CHCC suggests we include an appendix to the report in which we identify those States "which have recently struck down regulations for being too restrictive..." We would welcome further information in this regard. Our research for this study yielded no examples of States having rescinded any requirements for dispensing by physicians once they had been implemented. We have learned of only one State, after our research had been completed, which repealed an existing requirement but did so while adding other requirements to strengthen the State's overall control over the practice.

We appreciate the comments on the accuracy of current State requirements and of estimated revenues of repackagers. We have modified the data for some States; for others we made no changes because we believe our descriptions are correct. Our statement regarding revenues of the repackaging industry are based on published estimates from the sources we reference in appendix IV.

We accept the distinction made by the CHCC between dispensing drugs "in bulk" and dispensing prepackaged drugs. The Coalition maintains that prepackaged drugs are safer. We acknowledge that repackaged drugs may have important differences from drugs "in bulk." However, that fact does not, in our view, obviate the need for stronger State regulatory control of the type we recommend. Regardless of whether drugs are dispensed "in bulk" or in smaller quantities from repackaging companies, we think State governments need to be able to iden-

tify dispensing physicians, to assure that patients have freedom of choice in filling prescriptions, and to assure compliance with all the procedural requirements we suggest in order to protect the public and the integrity of the drug distribution system.

NATIONAL ASSOCIATION OF CHAIN DRUG STORES COMMENTS

The National Association of Chain Drug Stores, Inc. (NACDS) appreciates the opportunity to comment on the draft report entitled, "Physician Drug Dispensing: An Overview of State Regulation." NACDS represents 173 chain drug corporations operating in excess of 21,000 retail pharmacies nationwide that dispense 40 percent of the nation's prescription drug products. As a long-standing integral component of the health care delivery system, we applaud your initiative in this area, as you have clearly recognized the serious implication for the safety and welfare of the American consumer.

Based upon the conclusions reached in the report, it is apparent that the Inspector General believes that a conflict of interest exists when a physician both prescribes and dispenses prescription drugs. With increasing cost containment pressures on physicians, the oversupply of physicians, and the resultant reduction in their annual incomes, it can be expected that this practice will only increase since the only incentive to dispense prescription drugs is an opportunity for supplemental income. Additionally, recent passage of the Medicare Catastrophic Coverage Act, expanding the Federal Government's involvement with outpatient prescription drug programs, may further this practice and its related abuses. Thus, physician dispensing has nothing to do with better health care, but is encouraged and driven by a growing drug repackaging industry promising increased profits to physicians.

While we agree with the conclusions of the report that there is a basic and compelling need for a closer scrutiny of physician dispensing, we recommend that the practice be prohibited altogether except for those situations in which a medical emergency arises or the physician is fulfilling a patient's immediate needs. Only by a stringent control on this practice can the public health be served.

It is well established that the pharmacist is the primary source of information on prescription drugs not only for the consumer but also to the physician. The pharmacist is the only member of the health care delivery system educated and licensed for this important function.

As is clearly shown by your study, physicians have not and will not tolerate regulation of themselves. Absent any credible justification, NACDS encourages the Inspector General not to give credence to a system that does not serve or benefit the health needs of the consumer.

In conclusion, NACDS appreciates this opportunity to comment on the draft report.

OIG RESPONSE TO NACDS COMMENTS

We are pleased with the positive response of the NACDS to our inquiry. It is important to note, however, that in stating our conclusions we do not intend to suggest that physician drug dispensing represents a conflict of interest. On the contrary, the focus of our inquiry and the

resultant findings do not permit our taking a position on the question of whether physicians should or should not dispense prescription drugs. Rather, the findings of our inquiry support our recommendations, namely, that should States choose to permit dispensing by physicians, they should impose adequate regulatory controls over the practice to assure the protection of public health and the integrity of the drug distribution system.

AMERICAN PHARMACEUTICAL ASSOCIATION COMMENTS

We are pleased to submit our comments on the draft report entitled "Physician Drug Dispensing: An Overview of State Regulation." APhA is the national professional society of pharmacists, representing the third largest health profession, comprising more than 150,000 pharmacy practitioners, pharmaceutical scientists and pharmacy students. Your office and staff are to be commended for their attention to a serious problem facing the American public. The representatives of the State agencies that you surveyed for this report are very knowledgeable about the laws you sought to review. Because our member pharmacists are so directly affected by these laws, we trust you will give our comments the weight we believe they deserve.

We have circulated the report among our leadership and staff, as well as all of the state pharmacy association executives, in an effort to provide you with comments that are truly representative of pharmacists' views. As you know, we worked closely with Dr. Yessian and Ms. Kvaal to assist them whenever possible.

The findings of the inspection appear to be fairly collected, accurate, and presented in a balanced fashion. The profiling of state laws by elements is particularly insightful. APhA's own informal research and the findings of the Glassman Oliver Report...corroborate the findings that the incidence of physician dispensing for profit is expanding, that attempts to regulate the practice are increasing, and that attempts to enforce existing laws and regulations have been largely ineffective due to budgetary and political difficulties. It is also true that considerable support exists for further regulation.

Prior to discussing APhA's specific recommendations concerning the inspection report, we want to make it clear that APhA policy opposes any form of nonpharmacist dispensing. The APhA policy on nonpharmacist dispensing, adopted March 31, 1987, states:

1. The American Pharmaceutical Association supports the principle that all patients receiving prescription medications are entitled to comprehensive pharmaceutical services. These services include, but are not limited to, patient counseling, maintaining patient profiles, and providing the check and balance system with other health professionals to help prevent prescriber errors and adverse drug interactions.
2. The American Pharmaceutical Association opposes nonpharmacist dispensing of prescription medications.

Discussion of the APhA House of Delegates recognized that emergency situations occur. Because of the exceptional nature of emergencies and the concern that formal recognition would weaken the language and allow loopholes in legislation to become standard practice, the APhA House of Delegates chose to omit that formal recognition.

APhA supports the recommendations contained in the inspection report. However, our view... that regulation of the practice is a necessary step should not imply that APhA views physician dispensing as acceptable if regulated. Rather, our position is based upon the belief that appropriate regulation of the dangerous practice of physician dispensing is better than no regulation at all.

APhA believes that the Inspector General's recommendations in the final report should:

- A. Support federal legislation. The Inspector General is encouraged to support federal legislation that would limit physician dispensing to emergency situations, e.g., Congressman Wyden's bill (H.R. 2168). In those situations, minimum federal standards similar to those governing pharmacy practice should apply. This bill is likely to be reintroduced in the next Congress.

Three significant factors require swift and uniform federal action to protect the welfare of the American public. They include:

1. Expanded activities of the profit-minded drug repackagers;
2. The intrusion of the FTC in this traditional area of state authority; and
3. The inability of states to effectively enforce laws and regulations concerning the practice.

Many drug repackaging companies have encouraged physicians to sell prescription medication. A national repackaging association has predicted that fifty percent of all practicing physicians could be dispensing within the next five years.

Three states were warned against regulating the practice by letters and public statements made by Federal Trade Commission Chairman Daniel Oliver and his staff. These warnings have inhibited other states from pursuing regulations. Chairman Oliver has taken the position that dispensing physicians add to the pool of competitive outlets, thus making the market more competitive. APhA maintains that physician dispensing is anticompetitive. Patients are unlikely to question a physician when told to "stop at the desk on the way out and pick up your prescription medication."

As the report explains, states have a most difficult time enforcing their laws to limit physician dispensing. Minimum federal laws and regulations would assist the States by sending a clear message that this is a serious issue. Thus, we encourage you to support federal legislation in your final report.

- B. Encourage federal agencies to assist in the enforcement of state laws. The Inspector General should urge the Department of Health and Human Services to insure that any prescriber authorized to participate in any state and/or federally funded prescription drug program meets minimum standards of pharmacy practice.

It is most appropriate that federal agencies begin paying closer attention to the distribution of drug products by physicians. The federal government has established standards for the purity and safety of drug products and safeguards governing drug products with a potential for abuse. While these regulations affect physicians, they are much more stringently applied to pharmacists who are the traditional caretakers of these drug products and for whom the laws were designed. The states have traditionally determined who shall prescribe and who shall dispense drug products. The laws and regulations controlling the highly competitive pharmacy marketplace in the United States have evolved over the past 125 years and include a combination of federal and state laws. State boards of pharmacy control the licensure of pharmacists and pharmacies, but they have little or no authority over physicians who choose to dispense medication.

- C. Investigate dispensing physicians' conflict of interest. The Inspector General should consider an expanded study to investigate the conflict of interest that occurs when a prescriber both chooses the patient's medication and profits from the sale of that medication.

The Congress, in the recent passage of the Medicare Catastrophic Coverage Act, has recognized a conflict of interest when physicians profit from referrals of home IV therapy patients. Severe penalties are to be imposed upon violators of those provisions as a means of deterring such practices. The same condition occurs when a physician selects his own "pharmacy" by dispensing a drug product to a patient and profiting from that sale. Yet this smaller, but equally significant, transaction goes unnoticed in the law.

Dispensing prescribers typically have a limited inventory of drug products which reduces the opportunity for effective drug product selection. If the prescriber carries only one brand of a multi-source product, patients will no longer have the wide range of choices which makes our health care system one of the best in the world.

Dr. Arnold Relman, editor of the *New England Journal of Medicine* echoed our concerns when he said, "[A physician] should not be a business man with an inventory of drugs on his hands that he wants to sell you at a profit. The risk is that a particular drug will be used when it may not be the best drug or when you may not need a drug at all." In another document, he stated, "When doctors profit by selling their patients drugs that they themselves have prescribed, they are attempting to fill two basically incompatible roles--those of fiduciary and vendor. [Federal legislation] is necessary to protect the public from possible abuse resulting from the confusion of these roles and to make clear that we want our doctors to act as protectors of their patients' interest and not as ordinary tradespeople."

- D. Include all prescribers in recommendations to control the practice. While the term "physician dispensing" has become commonplace, the Inspector General is asked to urge Congress and federal agencies to include all prescribers in recommendations to control the practice of prescribers' dispensing for profit.

Many federal and state laws allow various groups of practitioners to prescribe and (either directly or by omission) dispense drug products. These include, but may not be limited to, dentists, osteopaths, podiatrists, optometrists, physicians' assistants, nurse practitioners, and veterinarians. If "physician" dispensing for profit is ill-advised, then other practitioners' dispensing for profit is ill-advised as well.

- E. Urge lawmakers and regulatory agencies to require dispensing prescribers to do so directly to the patient. Special emphasis should be placed upon requirements that prescribers authorized to dispense do so directly to the patient, rather than delegating responsibility or activities in any way.

It is dangerous enough to eliminate the safety net of overlapping responsibilities between physicians and pharmacists by allowing physicians to dispense to patients without pharmacist involvement. The growing practice by dispensing physicians of delegating dispensing functions to nurses or nonprofessionals increases the chances for error and incomplete or inaccurate information.

Every effort must be made to insure that physicians do not delegate this important work.

- F. Update the chart of state laws to reflect recent changes. The chart classifying various elements of state laws should be updated to reflect the enclosed clarifications and recent changes in California, Florida, and Iowa.

Attached for the Inspector's use are letters and supporting documents from the California, Florida, and Iowa Pharmacists Associations. These documents address specific elements of the chart dealing with state laws and should be used to make the chart as up-to-date as possible.

In closing, APhA thanks the Inspector General for the opportunity to comment on a well-researched and well-written inspection report. It is our hope that the recommendations contained in this letter will be considered carefully for inclusion in the final report. In so doing, the American public might be one step closer to protection from the ill effects of a dangerous practice. We are willing to meet with you at any time to discuss these issues, and we look forward to receiving your final report.

OIG RESPONSE TO APHA COMMENTS

We appreciate the positive response of the APhA to our overall report and offer the following comments with respect to their suggestions.

The APhA suggests the report support Federal legislation to limit physician dispensing. We believe any Federal legislation must take into account current State regulation on this subject. We hope this analysis will be useful to government policymakers at all levels as they design a framework for further regulation of this practice.

The APhA encourages Federal agencies to assist in enforcement of State laws and the Department, in particular, to ensure that dispensing prescribers meet minimum standards of pharmacy practice. APhA points out that dispensing standards for pharmacists are more stringent than those for physicians. We have addressed this disparity in our recommendation that a minimum threshold be adopted by States. We would also argue, as we have above, that current FDA policy is inconsistent in applying the prescription drug labeling requirements of the Federal Food, Drug, and Cosmetic Act to drugs dispensed by pharmacists but not to those dispensed by physicians.

The APhA suggests that the OIG evaluate the conflict of interest aspect of physician drug dispensing. Although an examination of this issue was beyond the scope of this study, it may warrant study at a later date.

We agree with the thrust of APhA's concern that our recommendations ought to apply to dispensing by all prescribers rather than only to dispensing by physicians. In fact, we found that in many States, the regulation governing dispensing by physicians also included dispensing by other types of practitioners such as dentists, osteopaths, podiatrists, veterinarians, etc. However, because we limited our inquiry to State requirements for dispensing by physicians, we cannot technically justify inclusion of other types of dispensing providers in the recommendations of this report.

We share the concern of APhA regarding the need for supervisory control over the dispensing process and have suggested, as part of the threshold of regulation we recommend, that States address directly this aspect of dispensing in their regulatory requirements.

Finally, we appreciate the clarification and updating of State laws. We have noted these changes in the report and its appendices.

FEDERATION OF STATE MEDICAL BOARDS COMMENTS

The Federation of State Medical Boards appreciates the opportunity to comment on the draft report entitled "Physician Drug Dispensing: An Overview of State Regulation."

The report is highly informative and presents a thorough examination of State requirements for the dispensing of prescription drugs by physicians. It is important to emphasize, however, that the findings and recommendations of the report address regulation of dispensing by physicians in amounts larger than free samples. Further, in our view, any regulation of this practice should be thoughtfully crafted keeping in mind the best interest of the patient.

The Federation supports the OIG recommendation that we and the National Association of Boards of Pharmacy work together to provide leadership to State boards in the regulation of

drug dispensing by physicians. The FSMB revises its publication, "Guide to the Essentials of a Modern Medical Practice Act," every 3 years and will consider including the topic of drug dispensing by physicians in the next edition in 1991.

We look forward to receiving the final report.

OIG RESPONSE TO FSMB COMMENTS

We appreciate the overall positive response of the FSMB to our report and, in particular, its willingness to address physician drug dispensing in its guidelines to State medical boards as well as in cooperation with the efforts of the National Association of Boards of Pharmacy.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY COMMENTS

I am pleased to comment on behalf of the National Association of Boards of Pharmacy (NABP) in regard to the draft report entitled, "Physician Drug Dispensing: An Overview of State Regulation." The NABP is the national association of the 50 state boards of pharmacy, the District of Columbia, Puerto Rico, the Virgin Islands, some provinces of Canada and, most recently, the Pharmacy Board of Victoria, Australia.

In our view, the report provides an excellent overview of physician drug dispensing. I want to commend Dr. Yessian, Ms. Kvaal and other members of the project team for their thoroughness and objectivity. Without question, the issue of physician drug dispensing is controversial and often elicits emotional and political considerations. The draft report steers clear of these considerations and presents the facts of the issue, clearly and concisely.

The following comments are offered by NABP to provide more insight into the issue and offer suggestions on how better to regulate the practice of physician drug dispensing.

FINDINGS:

The Incidence of Physician Drug Dispensing:

The incidence of physician drug dispensing is extremely difficult to document. Although the majority of respondents to the survey estimated "that 5 percent or less of the physicians in their states are dispensing for profit," it is important to understand that physician drug dispensing is much more commonplace.

The report notes this on page 1, "Physicians have always dispensed drugs to some degree as part of the practice of medicine." The dispensing that occurs as "part of the practice of medicine," because of the myriad of activities it may assume, is a significant threat to the health and welfare of the public by the mere fact that it cannot be documented. However, the physician drug dispensing we are referring to, and examined by the report, is not the one time "administration dose" or "starter dose" occurrences. It is the consistent and repeated dispensing of drugs by the physician directly to his/her patients.

If asked to estimate this percentage, ignoring the qualification of "for profit," and having no hard data to substantiate the estimate, we would offer a percentage approaching 10 percent. We can explain the low estimate in the report as being attributable to the distinction of "for profit." This distinction may have skewed the respondents' estimates.

Although this may seem a minor point, its significance extends beyond the need to establish an accurate estimate. The significance lies in the number of individuals that could possibly be affected by this practice. Even if the report's estimate of 5 percent is correct, millions of people are affected. NABP would encourage the report to provide some explanation of the magnitude of the problem in terms of the number of people affected by this practice.

State Requirements:

We offer several comments in regard to state requirements to regulate dispensing by physicians.

- The primary concern of the state boards in regulating physician dispensing is to protect the public health (page 5). The need for regulation and the concern expressed by the respondents reflects the danger that exists if the practice of physician dispensing is left unregulated or at the mercy of economic forces.
- The requirements imposed by the boards of pharmacy on the regulation of pharmacists practicing pharmacy are more stringent than the requirements on the dispensing of prescription drugs by physicians, (pages 9-10). This disparity is accentuated when one considers that the professional education and experience obtained by physicians in regard to drugs is far less than that of a pharmacist.

At the least, it would seem in the best interest of the public to impose the same requirements for physicians as pharmacists. Theoretically, because the physician lacks the same education and training as a pharmacist, it would seem appropriate to require more stringent requirements for the physician dispensing drugs. Stricter requirements for such practitioners might provide another safeguard to prevent inappropriate or unsafe dispensing by unqualified practitioners.

- The regulation governing physician dispensing must be effectively enforced. The report notes that States' efforts to enforce their regulation is only moderately effective (page 12) because most States lack the resources to enforce their regulatory requirements (page 14), have limited ability to inspect the offices of dispensing physicians (page 14), find that the basis for the regulatory requirements is divided among the medical and pharmacy boards or fall outside of the purview of both of these boards (page 15). These findings illustrate the need to develop, implement and enforce effective legislation. The states need direction and appropriate funding to fulfill their responsibilities. It is quite clear from the information NABP has reviewed that the authority over physician dispensing sometimes falls into a legislative quagmire asking the pharmacy and medical boards to decipher what their responsibilities and enforcement activities are.

- Physician dispensing should be regulated by the States. The great majority of respondents emphasized the importance of the States regulating physicians dispensing drugs (page 16). Although some respondents favored federal action (page 18), it would appear that the action preferred is not the passage of legislation but the development of uniform standards. Collectively, through organizations like NABP, the States have done an exemplary job of setting uniform standards and sharing information.

We believe that the regulation of physician drug dispensing should be the responsibility of the States. The States should also work together and establish uniform standards. The federal government, if it indeed wants the practice of physician dispensing properly monitored, must realize that the States are the best source for this authority and provide funding and other support.

RECOMMENDATIONS:

We strongly concur with the recommendations set forth in the report. We would like to emphasize particularly that the States need to take the initiative in implementing effective regulation for physician dispensing, that States be empowered and funded to adequately enforce such regulations and that NABP and the FSMB serve as the guiding forces for the development of uniform standards and model regulations.

We would also like to add to the report's recommendations the comments made earlier that, at the very least, physicians should be held accountable to the same requirements that pharmacists are. These requirements include, but are not limited to, the proper labeling, storage and record-keeping for drugs. In essence, if a physician is dispensing drugs he/she must meet the same minimum requirements that a pharmacist must meet. Uniform standards and requirements would protect the public from the dangers of inappropriate dispensing and unqualified practitioners. It would certainly provide the tools to more effectively regulate the practice and provide licensing authorities with the proper record-keeping to monitor the practice.

NABP appreciates the opportunity to comment on this excellent report. If we can be of further assistance to you, please feel free to contact me. Thank you!

OIG RESPONSE TO NABP COMMENTS

We appreciate NABP's comments on the incidence of physicians who are dispensing prescription drugs. As noted elsewhere, our inquiry focussed on dispensing by physicians in amounts larger than samples and starter dosages. We therefore asked regulatory officials to estimate the proportion of physicians dispensing drugs for profit in their States. We agree that although the estimates of incidence vary, a sizeable number of physicians and patients may nonetheless be involved.

We agree with the observations of NABP regarding the States' requirements for dispensing by physicians. As noted previously, the requirements imposed on dispensing by pharmacists in most States are much more stringent than those imposed on dispensing by physicians. This dis-

parity is even more striking in view of the additional requirements for licensure which all States require of pharmacists. Hence, in our recommendations, we state our view that should States choose not to prohibit dispensing by physicians in amounts greater than samples or starter dosages, they then, at the very least, should impose requirements to reduce this inequity in regulation of prescription drug dispensing.

We share the concern of NABP regarding the need for effective enforcement of existing requirements. Accordingly, we included with our recommendation on enforcement specific actions States might consider for strengthening their enforcement efforts.

APPENDIX II

METHODOLOGICAL NOTES

This study focused on State regulation of physicians dispensing prescription drugs from their offices. Our inquiry concentrated specifically on State-imposed requirements for dispensing prescription drugs in amounts greater than samples. Although we are aware that other practitioners such as dentists may also dispense drugs, we chose to limit our inquiry to physicians because they constitute the largest group of medical practitioners in each State.

The information for this study was based on three types of inquiry:

- Review of a wide range of printed materials related to the practice of physician dispensing including congressional hearings, drug repackager marketing materials, studies, consumer surveys, and articles in the public press and in professional and trade association publications.
- Discussions with representatives of organizations and agencies concerned with issues related to physician dispensing. These included staff from the FDA and HCFA within the Department, Federal Trade Commission, Drug Enforcement Administration, U.S. Congress, American Medical Association, American Pharmaceutical Association, Competitive Health Care Coalition, (representing drug repackaging companies), Federation of State Medical Boards, National Association of Boards of Pharmacy, National Association of Chain Drug Stores, and NARD (formerly National Association of Retail Druggists).
- Telephone discussions with staff from 108 State regulatory boards/agencies in all 50 States and the District of Columbia. These included 45 medical boards, 45 pharmacy boards, four centralized umbrella regulatory agencies, and, in 14 States, agencies that are separate from the boards but are involved in enforcement of drug laws. Usually we talked with the executive directors of the boards, but in some instances, we spoke with other staff suggested to us by the executive directors.

Two methodological considerations are important to note with respect to the telephone discussions. First, although we spoke with 108 individuals using a single discussion guide, some questions were asked only of a subset of the total universe. Also, a few individuals had no comment for some questions. Therefore, we have included as respondents in our percentages and figures (N=_) only those individuals who responded to the questions. Second, the guide used in the telephone discussions consisted of both closed and open-ended questions. Because we did not distribute these guides prior to the discussions, the open-ended questions required respondents to answer spontaneously. Thus, the percentages of particular responses to these questions vary more than would have been the case had the respondents been presented with limited response options or had they reviewed the questions prior to the discussions.

Spreadsheet of the States' Regulatory Requirements

The spreadsheet, included as figure II, summarizes regulatory requirements implemented by the States as of August 1, 1988. Information about the requirements was gathered primarily through the telephone discussions with officials from those regulatory boards/agencies having major responsibility for enforcement within each State. We chose this approach for two reasons. First, we could locate no readily accessible, comprehensive, and up-to-date compilation of all the States' statutes and regulations governing the practice of physician dispensing. Second, we found that recent summaries of State regulation prepared by the Arizona Board of Pharmacy (1986), American Medical Association (1987), National Association of Boards of Pharmacy (1987), and the Federation of State Medical Boards (1988) were sometimes in disagreement or were not complete for all States. Therefore, we developed for our own use a checklist which grouped into five types of regulation the requirements most commonly adopted by the States. After refining the checklist according to comments received from selected national organizations and State regulatory boards, we mailed copies to respondents prior to the telephone discussions so they would be familiar with the information we were seeking. By completing the checklist during the telephone discussions, we were able to obtain the comprehensive, up-to-date, specific information we needed.

Because we relied primarily on secondary sources for our information on State requirements, we cannot confirm that the information is completely accurate or all-inclusive. As much as possible, however, we compared the information gathered from all respondents within a State with each other as well as with copies of those States' statutes and regulations available to us. We tried to resolve all inconsistencies with follow-up telephone calls to respondents.

Classification of States by Restrictiveness of Regulation

We classified the States according to the types of regulation in effect on August 1, 1988 as follows:

- *Extremely Restrictive Regulation (4):*

Massachusetts, Montana, Texas, Utah

These States have regulation that limits physician dispensing to emergencies, or to situations in which pharmacy services are unavailable, or the physician is meeting the patient's immediate needs (Type I). Respondents from these States all described their regulation as essentially prohibiting physicians from dispensing. We excluded Arizona from this category because the medical and pharmacy boards reported that their practice acts differ over whether dispensing is allowed or is limited to emergency situations only.

- *Very Restrictive Regulation (3):*

Arkansas, Nebraska, Oklahoma

These States require physicians to receive approval or a permit from a State regulatory board prior to dispensing (Type II). We included only these States in this category because the required board approval reportedly has been given very sparingly.

- *Moderately Restrictive Regulation (13):*

Arizona, Connecticut, Florida*, Georgia, Illinois, Iowa, Louisiana, Michigan, Mississippi, Nevada, North Carolina, Oregon, Washington

These States have some or all of the procedural requirements (Type V) as well as one or more of the requirements from Type II (dispensing physicians must identify themselves to regulatory boards/agencies), from Type III (limitations on fees and profits), and from Type IV (patient choice).

We excluded New Hampshire from this category because its registration requirement applies only to physicians in professional associations or corporations that dispense drugs. Virginia and West Virginia were also excluded because respondents there concurred that the regulation restricting profit is so vague that the restriction, in practice, is meaningless.

- *Minimally Restrictive Regulation (25):*

Alabama, California*, Colorado, Delaware, District of Columbia, Idaho, Indiana, Kansas, Kentucky, Maine, Minnesota, Missouri, New Hampshire, New Mexico, New York, North Dakota, Ohio, Pennsylvania, South Carolina, South Dakota, Tennessee, Vermont, Virginia*, West Virginia, Wisconsin

These States have procedural requirements (Type V) only.

- *No Regulation (6):*

Alaska, Hawaii, Maryland*, New Jersey, Rhode Island, Wyoming

These States reported having implemented no regulation as of August 1, 1988.

* *Both Maryland and Virginia will implement recent statutory changes after regulations have been developed. On the basis of these changes, both States would be considered to have moderately restrictive regulation.*

California implemented the following new additional requirements on January 1, 1989:

- Dispensing physicians must offer a written prescription to patients (IV g) and provide patients with written disclosure regarding choice to obtain prescriptions from a physician or from a pharmacy (IV h);
- Dispensing physicians must store all drugs in a secure area (V l);
- State licensing board shall encourage physicians to take a course in pharmacology/pharmaceuticals as part of continuing education requirements;
- Various requirements were added to handling of complaints and for status reports to the legislature in 1990 and 1991 on complaints.

On the basis of these changes, California's regulation would be considered moderately restrictive.

Florida implemented the following new requirements on October 1, 1988:

- Requirement for continuing education repealed (II d);
- Added to existing registration requirement a fee of \$25;
- Dispensing physicians must provide written prescription to patients (IV g) and orally or in writing advise patients of choice in filling prescriptions (IV h);
- Mandatory inspections of offices of dispensing physicians.

On the basis of these changes, Florida remains a State with moderately restrictive regulation.

APPENDIX III

OTHER REGULATORY REQUIREMENTS FOR PHYSICIAN DISPENSING AS OF AUGUST 1, 1988

CALIFORNIA

- Drugs must be necessary to treatment of the condition for which the patient is under care.
- Use of mechanical dispensing devices is prohibited unless the devices and contents are owned by the physician. Leasing of drug-vending machines is prohibited.
- Dispensing Schedule II controlled substances is prohibited except in an amount necessary for 72 hours.

FLORIDA

- Dispensing physicians must comply with requirements of the Florida Pharmacy Act regarding substitution of drugs.

IOWA

- Upon a physician's authorization, a physician assistant or a registered nurse may supply drugs to patients when pharmacy services are not available or when the supplying of such drugs is in the best interests of the patient. (This has been interpreted to mean rural clinics only.) Additionally, such rural clinics must secure a consultant pharmacist to provide advice regarding the distribution, storage, and appropriate use of drugs.

MONTANA

- Dispensing by physicians "as a usual course of doing business" is prohibited; "dispensing of drugs occasionally" is permitted.

NORTH DAKOTA

- If the amount of drug dispensed is greater than a 72-hour supply, the dispensing is subject to requirements for labeling, record-keeping, patient counselling and patient profile system.

PENNSYLVANIA

- Physicians who dispense sympathomimeticamines must have approval from the medical board and must meet special reporting requirements.

VIRGINIA

- "Permitted" physicians in rural areas are allowed to dispense to their own and other patients.

APPENDIX IV

ENDNOTES

1. For a discussion of the historical background of physician dispensing, see Michael L. Glassman and Donald L. Martin, "Physician Dispensing of Prescription Drugs: An Economic and Policy Analysis," Glassman-Oliver Economic Consultants, Inc., Washington, D.C., 1987.
2. Joy Swiss Thompson, "Opportunities in the Pharmaceutical Repackaging Market, An Industry Study," Wessels, Arnold & Henderson, Minneapolis, Minnesota, October 1987.

"New Investment Market In Dispensing of Pharmaceuticals," *The Stock Market Magazine*, January - February 1987, pp. 4-5.
3. For a discussion of issues surrounding physician dispensing, see "Physician Dispensing of Drugs," Hearing before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, United States House of Representatives, April 22, 1987.
4. The requirements for controlled substances are contained in the Controlled Substances Act of 1970 and the Comprehensive Crime Control Act of 1984. The Prescription Drug Marketing Act of 1987 amended the Federal Food, Drug, and Cosmetic Act to impose restrictions on drug samples.
5. For pharmacy standards of practice, see Samuel H. Kalman and John F. Schlegel, "Standards of Practice for the Profession of Pharmacy," *American Pharmacy*, Vol. NS19, No. 3, March 1979/135, pp. 21-33. For a summary of State pharmacy laws, see *Survey of Pharmacy Law--1987-88*, National Association of Boards of Pharmacy, Park Ridge, Illinois.
6. *The Stock Market Magazine*, op. cit.

"Pharmacists Protest Doctors' Drug Sales," *The New York Times*, September 17, 1987, Section B, p. 1.

"One-Stop Medicine," *Scientific American*, November 1987.

Arnold S. Relman, M.D., "Doctors and the Dispensing of Drugs," *The New England Journal of Medicine*, July 30, 1987, pp. 311-312.
7. Regulatory officials were asked to estimate the proportion of physicians in their States who were dispensing for profit in an effort to distinguish them from those dispensing only samples and starter dosages.

8. We excluded regulation limited exclusively to controlled substances and child-resistant packaging because of Federal requirements applicable to dispensing physicians nationwide.
9. The requirements discussed below and summarized in figure II and figure III are those implemented by the States as of August 1, 1988. We have recently become aware of new requirements implemented since August 1988 in California and Florida. Those changes are noted in appendix II but could not be incorporated here without our having reconfirmed requirements for all the States.
10. This regulation is separate from the registration required by the Drug Enforcement Administration for controlled drugs.
11. Medical Licensure and Discipline: An Overview, Office of Analysis and Inspections, Office of Inspector General, Department of Health and Human Services, June 1986.