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# STATE DISCIPLINE OF PHARMACISTS

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**OFFICE OF INSPECTOR GENERAL**  
**OFFICE OF EVALUATION AND INSPECTIONS**

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JULY 1990

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## OFFICE OF EVALUATION AND INSPECTIONS

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This study, entitled "State Discipline of Pharmacists," was conducted to examine the practices of State boards of pharmacy in disciplining pharmacists.

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# STATE DISCIPLINE OF PHARMACISTS

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## EXECUTIVE SUMMARY

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### PURPOSE

The purpose of this inspection was to assess the disciplinary practices of State boards of pharmacy. It examined the strengths and vulnerabilities of the pharmacy boards in attempting to ensure that pharmacy is practiced safely, competently, and in accordance with pharmacy and drug laws.

### BACKGROUND

This is the sixth in a series of Office of Inspector General (OIG) reports on State boards of licensure and discipline. The other reports have focused on boards of medicine, dentistry, podiatry, chiropractic and optometry. In this, as in the other reports, the OIG's interest in the boards' performance is based on the important front line of protection they afford to the public. The inquiry was based on: (1) telephone discussions with representatives from all the State boards of pharmacy, (2) visits to six States for in-depth discussions with board representatives, (3) discussions with representatives from State and national professional organizations and government agencies, and (4) review of pertinent literature and data.

### FINDINGS

*The enforcement responsibilities of State pharmacy boards have become increasingly complex and challenging in recent years because of changes in pharmacy practice and the problem of drug diversion.*

*Many States have taken important steps to strengthen the enforcement capacity of State pharmacy boards.*

- Many States have broadened their regulatory and disciplinary controls through changes in their pharmacy and drug laws.
- Many States have strengthened the boards' capacity to address drug diversion.

*The number of the most serious types of disciplinary actions taken by State pharmacy boards between 1986 and 1988 increased for the nation as a whole. However, virtually all this increase occurred in three States, and the incidence of serious disciplinary actions varied considerably among the States.*

- For the nation as a whole, the most serious types of disciplinary actions taken by State pharmacy boards between 1986 and 1988 increased by slightly more than 20 percent. These actions include revocations, suspensions, probations, and voluntary surrenders of licenses.

- Most of the increase in the most serious disciplinary actions between 1986 and 1988 is attributable to three States. Many pharmacy boards took relatively few such actions during this period.
- Rates of the most serious disciplinary action taken by State pharmacy boards during this period varied widely—from 1.49 actions per 1000 licensees in one State to 45.61 actions per 1000 licensees in another.
- In most States, as in the nation as a whole, the number of revocations and voluntary surrenders did not increase between 1986 and 1988.
- The limited use of peer review by many professional pharmacy associations, particularly in comparison with that in some other professions, makes the disciplinary performance of pharmacy boards all the more significant.

*Pharmacy boards impose the most serious discipline mainly for drug diversion and self-abuse of drugs. They rarely address quality of care issues, despite the increasing emphasis in the profession on the clinical aspects of pharmacy practice.*

*The ability of many State pharmacy boards to protect the public is hampered by limitations in their legal authorities, administrative processes, and resources.*

## **RECOMMENDATIONS**

### *The State Governments*

- State governments should ensure that State pharmacy boards have adequate resources and authority for carrying out their enforcement responsibilities effectively.
- State governments should take steps to streamline the administrative process so that State pharmacy boards are able to process disciplinary cases more efficiently.
- State governments should take steps which enhance the capacity of pharmacy boards to deal with drug diversion and impairment of pharmacists.

### *State Pharmacy Boards*

- State pharmacy boards should review the outcomes of their disciplinary process and evaluate whether they are affording the public the maximum protection possible.

- State pharmacy boards should disseminate more broadly information on the disciplinary actions they have taken.

#### *The National Association Of Boards Of Pharmacy*

- The National Association of Boards of Pharmacy (NABP) should intensify its efforts to help State pharmacy boards address the changing nature of pharmacy practice, particularly with respect to the clinical roles of pharmacists.
- The NABP should work with State pharmacy boards and national professional pharmacy organizations to explore viable approaches to assessing the continued competence of licensed pharmacists.

#### *The American Pharmaceutical Association*

- The American Pharmaceutical Association (APhA) should exercise its leadership in encouraging more peer review of pharmacists' professional performance by national and State professional pharmacy organizations.
- The APhA should work with the NABP and other professional pharmacy organizations to develop appropriate methods for assessing the continued competence of pharmacists.

#### *The U.S. Public Health Service*

- The Public Health Service (PHS) should increase its support to the NABP in its efforts to provide leadership to State pharmacy boards.

### **COMMENTS**

Comments on the draft report were received from the Health Care Financing Administration and the Public Health Service within the Department, and from the Drug Enforcement Administration of the Department of Justice. These comments were in general agreement with the findings and recommendations of the report. Comments were also received from several national organizations including the American Association of Colleges of Pharmacy (AACCP), American Pharmaceutical Association (APhA), American Society of Hospital Pharmacists (ASHP), National Association of Boards of Pharmacy (NABP), and the National Clearinghouse on Licensure, Enforcement and Regulation (CLEAR). These organizations, too, were generally supportive of our recommendations, although the APhA and the NABP expressed some reservations about our recommendation calling for more peer review of pharmacists' professional performance by national and State professional pharmacy organizations. A summary of these comments and our response to issues raised appear at the end of the report. The detailed comments appear in appendix A.

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## INTRODUCTION

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The purpose of this inspection was to assess the disciplinary practices of State boards of pharmacy. It examined the strengths and vulnerabilities of the pharmacy boards in attempting to ensure that pharmacy is practiced safely, competently, and in accordance with pharmacy and drug laws. Specific attention was focussed on the disciplinary authorities of pharmacy boards, on their processes for enforcement and discipline, and on the extent, type, and reasons for their disciplinary actions in recent years.

This report is the sixth in a series of reports issued since 1986 by the Office of Inspector General (OIG) on the various State health professional boards: medicine, dentistry, podiatry, chiropractic, and optometry.

The Federal Government has long recognized the paramount role played by State regulatory boards in setting the standards for the licensure and discipline of health care practitioners. In so doing, it has relied on the States to provide an important front line of protection for the health and safety of the public. In particular, the Department of Health and Human Services (HHS) has relied on State boards to provide overall assurance that the health care services supported by the Medicare and Medicaid programs are provided by health care professionals duly licensed and practicing within the terms of the States' practice acts and other related laws. Although the Department can sanction providers who have abused or defrauded these programs, it continues to depend upon State boards to discipline providers for transgressions unrelated to the Medicare or Medicaid programs.

As expenditures under the Medicare and Medicaid programs have grown to be larger than one-fourth of all expenditures for health care in the United States, the Department's interest in the performance of State regulatory boards for the various health professions has increased. In this context, a report on the performance of State pharmacy boards, particularly in fulfilling their disciplinary responsibilities, is both relevant and timely. For many years, nearly all States have reimbursed pharmacists for services provided to Medicaid recipients. It is possible, too, that Federal health care benefits will be expanded during the 1990s in which case the relevance of the State boards of pharmacy to the Department may become even greater.

The information for this inspection was based on four lines of inquiry: (1) telephone discussions with the chief executives of the State pharmacy boards during the spring of 1988 and the spring of 1989; (2) visits to six States (CA, FL, MA, MI, NY, TX) involving discussions with several pharmacy board representatives; (3) review of pertinent literature and relevant data bases; and (4) discussions with representatives of various major professional associations concerned with disciplinary practices of pharmacy boards. (For more methodological background, see appendix C.)

This report presents our findings on the practices of State pharmacy boards in disciplining pharmacists. It begins with a brief profile description of State boards of pharmacy. It then

turns to a discussion of the disciplinary practices of the boards and concludes with recommendations for action addressed primarily to State governments and State boards of pharmacy.

## STATE BOARDS OF PHARMACY

Pharmacy boards, like other health professional boards, are administrative agencies created by State governments to protect the health, welfare, and safety of the public through the regulation of pharmacy practice.<sup>1</sup> State governments have empowered pharmacy boards to establish the scope of pharmacy practice, to license pharmacists and pharmacies, and to discipline those who violate the legal requirements. In the United States today, approximately 183,000 pharmacists are in active practice in nearly 68,000 pharmacies.<sup>2</sup>

From their early days in the late 1800s, pharmacy boards, like the other health professional boards, were primarily examining boards which emphasized their licensure activities more than their discipline function. They were relatively inconspicuous agencies of State government which functioned largely autonomously and were comprised solely of pharmacists.

Since the 1960s, the environment has changed considerably for State professional boards. With the consumer movement and heightened concern about the quality of health care services, more attention has been focussed on the performance of boards in protecting the public. Demands for greater accountability led many States to bring professional boards into large central agencies, to add public members to complement the professionals, and to place more emphasis on discipline.

Pharmacy boards have, however, developed into entities which vary significantly from other health professional boards. Pharmacy boards do more than define the scope of professional practice and license and discipline the professionals. They also regulate pharmacies as the facilities in which the profession is practiced, and they regulate the distribution of the drug product itself. Thus the purview of pharmacy boards is much broader and in some ways their task is more complex than that of other health professional boards.

Pharmacy boards, too, vary significantly among themselves. Boards differ in the scope of their responsibilities. For many boards these responsibilities extend beyond the practice act and the licensure and discipline of pharmacists and pharmacies. Seventy-five percent of the boards, for example, also license and inspect drug manufacturers and wholesalers.<sup>3</sup> Nearly forty percent of the boards are the State scheduling authorities for controlled substances.<sup>4</sup> Finally, many pharmacy boards have significant responsibilities in administering their States' food and drug laws.<sup>5</sup>

Pharmacy boards differ in the way they are organized. About 50 percent of the pharmacy boards report that they are attached to a larger government department and are not independent. Some boards have sole authority to make rules and regulations; some do not. Most boards, but not all, can both license and discipline. A few boards are advisory to other

entities of State government who make final decisions about rules, licenses, and discipline concerning pharmacy. Pharmacy boards have an average of seven members, although they range from three to 21 members. Seventy percent of the boards have at least one public member. In most States, board members are appointed by the Governor for terms ranging from 3 to 6 years.

Pharmacy boards also vary in the staff and other resources which support them. Although the large majority of boards have full-time directors, a few do not employ directors or have only part-time directors. The number of staff available to boards ranges from one State having one part-time person to another State having 31 staff. These data, however, do not always include the inspectors and investigators available to the boards. Finally, annual board budgets among the reporting 39 States range from a low of \$2,500 in one State to a high of \$2,874,104 in another State.<sup>6</sup>

This widespread variation among the pharmacy boards makes generalizations about them difficult. What boards do and how they do it depend in large part on their responsibilities, organization, and resources. Nonetheless, we believe that our inquiry has yielded important understandings about the strengths and vulnerabilities of the boards as they discipline pharmacists—understandings which are pertinent to most pharmacy boards today.

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## FINDINGS

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*The enforcement responsibilities of State pharmacy boards have become increasingly complex and challenging in recent years because of changes in pharmacy practice and the problem of drug diversion.*

The practice of pharmacy has been undergoing significant and rapid change since World War II. Pharmacy boards, as regulators of pharmacy practice, face a challenging task in keeping up with the complex changes in drug therapies, distribution systems and practice settings, and pharmacists' professional roles and responsibilities.

Rapid technological changes have resulted in the explosive proliferation of new drug products and the development of sophisticated drug therapies and delivery systems. Computerization has affected not only the routine administrative aspects of pharmacy practice such as labeling and record keeping but has enabled various more sophisticated applications such as robotics, fax machines for transmitting prescriptions, and automated drug profiles for more complete monitoring of patients' drug therapies.

Pharmacy practice has also been affected by the concerns of consumers and third-party payers, both public and private, over the rapidly increasing costs of health care. Economic factors have contributed significantly to the emergence of mail order pharmacies as well as drug repackaging companies which are encouraging the dispensing of prescription drugs by physicians and other health care professionals. Cost containment efforts by private insurers and the Federal Government have resulted in greater emphasis on shorter hospital stays and increased reliance on outpatient care. As a result, pharmacy is being practiced more and more in settings other than community pharmacies and hospitals. Practice in nursing homes, ambulatory care facilities, and patients' homes, for example, may require different regulatory approaches by pharmacy boards.

The role of the pharmacist, too, has been experiencing significant change. No longer is the pharmacist primarily the compounder of medicines now that drug products are developed and manufactured by pharmaceutical companies. Gradually, an additional role for pharmacists as therapeutic advisors has been evolving.<sup>7</sup> The nation's pharmacy schools have revised curricula and degree programs to incorporate clinical training to address this new role. And the national standards for pharmacy practice developed by the American Pharmaceutical Association (APhA) and the American Association of Colleges of Pharmacy (AACCP) in 1979 clearly articulated clinical responsibilities for practicing pharmacists.<sup>8</sup> The challenge to pharmacy boards has been, and continues to be, whether and how best to translate these clinical expectations into the States' regulatory requirements governing the practice of pharmacy.<sup>9</sup>

Finally, pharmacy boards have had to cope with the changing regulatory responsibilities imposed on them by the Federal Government. Recent Federal initiatives which significantly affect the regulatory and enforcement efforts of State pharmacy boards include tighter controls

over controlled substances, State licensure of wholesale prescription drug distributors, and the new national practitioner data bank.

According to one pharmacy board official, all these changes in pharmacy practice have been “progressing faster than the boards of pharmacy’s ability to regulate that practice.”<sup>10</sup> Indeed, keeping up with the rapidly changing face of pharmacy was identified recently by pharmacy board executives as the major challenge facing pharmacy boards today.<sup>11</sup>

In addition to the dramatic changes occurring in pharmacy practice, the serious national problem of drug diversion has complicated the enforcement responsibilities of State pharmacy boards. For several years, the diversion of prescription drugs from legitimate distribution channels for illicit use has been most acute at the retail level—practitioners and pharmacies. More than 10 years ago, the General Accounting Office (GAO) estimated that over 200 million dosage units of prescription drugs were being diverted each year at the retail level. More recently, the Drug Enforcement Administration (DEA) has estimated that 80 to 90 percent of the prescription drugs diverted for non-medical use is occurring at the practitioner and pharmacy levels.<sup>12</sup>

Diversion of controlled substances at the pharmacy level occurs in several ways. It can result from direct illegal sales of controlled substances by pharmacists or from outright theft of drugs from pharmacies, either by pharmacists for their own use or by others. Diversion can also result from prescription forms which are counterfeit or have been stolen or altered in some way. And finally, a more subtle form of diversion can occur when pharmacists, either knowingly or unknowingly, dispense controlled substances which have not been issued for legitimate medical purposes. This practice, often referred to as “non-therapeutic dispensing”, can involve controlled substances being dispensed to addicts or to the public for other unapproved clinical indications or for further distribution.<sup>13</sup>

*Many States have taken important steps to strengthen the enforcement capacity of State pharmacy boards.*

- Many States have broadened their regulatory and disciplinary controls through changes in their pharmacy and drug laws.

Pharmacy is often described as the most highly regulated of all health professions. In recent years, many State legislatures and pharmacy boards have been moving to address the changes occurring in pharmacy by further expanding their regulatory control. Slightly more than two-thirds of the States, for example, have separate regulations governing the practice of pharmacy in institutional settings or requiring computerized storage of prescription records. Nearly one-half have regulations governing nuclear pharmacies where radioactive drugs and devices are handled. A growing number of States now require pharmacists to keep patient profile records and to provide counseling to their patients.<sup>14</sup> Controversial regulatory issues such as the use of pharmacy technicians, mail order pharmacies, and the dispensing of

prescription drugs by health professionals other than pharmacists are currently under debate in many States.

The National Association of Boards of Pharmacy (NABP) has provided important leadership to States in their efforts to stay abreast of the rapid changes in pharmacy practice. In 1977, the NABP developed a Model State Pharmacy Act as well as model regulations for institutional pharmacy, nuclear pharmacy, and pharmacy computerization to serve as guidelines to State boards. Over the last 3 years alone, the NABP has developed guidelines and model laws or regulations on issues such as wholesale drug distribution, anabolic steroids, use of sterile pharmaceuticals in home health care, mail order pharmacies, patient counseling, and impaired pharmacists.

During the past 3 or 4 years, at least one-fourth of the States have also been strengthening their boards' authority to discipline pharmacists.<sup>15</sup> At present, every board reported having authority to revoke and suspend licenses and most, but not all, have authority to place licensees on probation or to deny the renewal of licenses. However, only approximately two-thirds of the boards have authority to impose fines for violations, and only about one-third of the boards reported having written guidelines for their use in deciding which penalties to impose.

Disciplinary penalties may be imposed by pharmacy boards only for reasons (or grounds) specified in the States' pharmacy practice acts. These grounds vary somewhat from State to State. However, the majority of States have adopted those grounds recommended in the NABP Model Act. These include unprofessional conduct; incapacity which prevents a pharmacist from practicing with reasonable skill, competence and safety to the public; court convictions for acts involving gross immorality or moral turpitude; fraud, deceit, or misrepresentation; and violations of State and Federal pharmacy or drug laws.<sup>16</sup>

- Many States have strengthened the boards' capacity to address drug diversion.

Nine States have now adopted a multiple copy prescription program which enables State authorities, including pharmacy boards, to monitor the distribution of Schedule II controlled substances from the prescriber to the dispenser to the consumer. The experience of several States suggests that these programs can result in a 30 to 50 percent reduction in Schedule II prescriptions. They have been effective in combatting problems with forged prescriptions and in reducing theft of controlled substances from pharmacies. These programs, too, have enhanced the efficiency of State regulators, including pharmacy board inspectors and other law enforcement personnel, by facilitating their review of prescription data through aggregated reports as opposed to the time-consuming review of individual scripts on site.<sup>17</sup>

Nearly half the States have adopted requirements for separate registration of all practitioners, including pharmacists, who handle controlled substances. This registration is different from the pharmacist's license to practice and separate from the DEA registration which is issued to the pharmacy rather than the pharmacist. Such a registration can be used by the boards to



restrict or deny the pharmacist's privileges to dispense controlled substances while still retaining the basic privilege to practice. The registration can also be a source of additional revenues for investigating drug diversion.<sup>18</sup>

Finally, several States have established Task Forces of local, State, and sometimes Federal agencies concerned with drug diversion to improve coordination and communication among them.

In efforts such as these, many States have recognized the critical and unique role which can be played by pharmacy boards in combatting drug diversion by pharmacists and pharmacies. Among all the agencies combatting drug diversion, only the pharmacy boards have the legal authority to revoke the licenses of pharmacists and pharmacies and thereby to terminate their legal rights to practice.

*The number of the most serious types of disciplinary actions taken by State pharmacy boards between 1986 and 1988 increased for the nation as a whole. However, virtually all this increase occurred in three States, and the incidence of serious disciplinary actions varied considerably among the States.*

- For the nation as a whole, the most serious types of disciplinary actions taken by State pharmacy boards between 1986 and 1988 increased by slightly more than 20 percent. These actions include revocations, suspensions, probations, and voluntary surrenders of licenses.

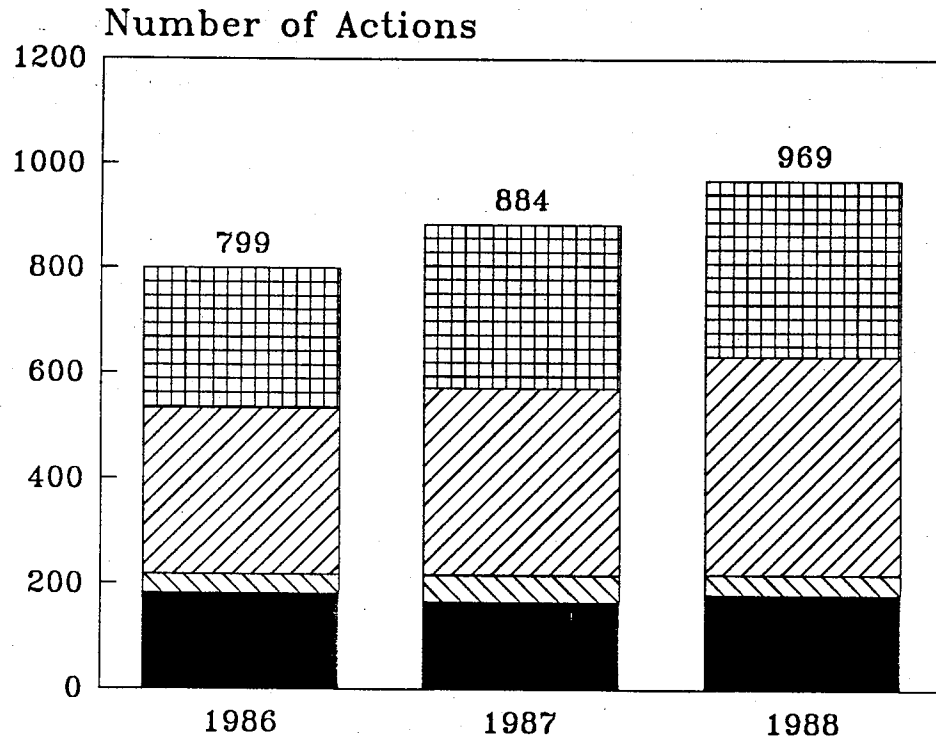
Because comprehensive disciplinary data was not available from any existing sources, we asked the board executives in all 50 States plus the District of Columbia to provide us with information on the number and type of serious disciplinary actions taken by their boards in 1986, 1987, and 1988. We received information for all 3 years from all but four States. Nevada and New York were unable to provide data for all 3 years. Oklahoma provided data only for revocations, and Kentucky provided no data for 1988. (See appendix B for a state-by-state breakdown of serious disciplinary actions reported for the period 1986-1988 and appendix C for a more detailed description of our methodology.)

We found that the number of the most serious disciplinary actions—revocations, suspensions, probations, and voluntary surrenders—imposed by pharmacy boards on pharmacists and pharmacies increased by slightly more than 20 percent during this 3-year period. These actions increased from 799 in 1986 to 969 in 1988.<sup>19</sup> Suspensions accounted for nearly 60 percent of this increase and were approximately 40 percent of all the most serious actions imposed during this period (see figure I).

As noted earlier, pharmacy boards also take other kinds of formal disciplinary actions such as reprimands and fines. These other kinds of penalties are important disciplinary tools and can be used effectively by boards. We did not include these other types of actions in our analysis

Figure I

# Serious State Disciplinary Actions Against Pharmacists and Pharmacies, 1986-1988



	1986	1987	1988
Probations	266	312	336
Suspensions	315	355	414
Vol. Surrenders	36	51	38
Revocations	182	166	181

Revocations
  Vol. Surrenders  
 Suspensions
  Probations

Source: 49 State Boards of Pharmacy as reported to the Office of Inspector General, HHS, May 1989.

summarized here. This is not because we considered them unimportant, but because we considered the data available to us on these actions too imprecise for reliable analysis.<sup>20</sup>

- Most of the increase in the most serious disciplinary actions between 1986 and 1988 is attributable to three States. Many pharmacy boards took relatively few such actions during this period.

About 97 percent of the overall increase in the most serious disciplinary actions resulted from the actions of three States. In fact, one State alone accounts for 57 percent of this increase.

Our analysis indicates that many pharmacy boards imposed these most serious penalties infrequently during the 3-year period between 1986 and 1988. The median rate of discipline among the States was approximately eight of these most serious actions per 1000 licensees during this time<sup>21</sup>. Further, 15 States reported taking 10 or fewer of these most serious actions during this entire period. In fact, seven States reported fewer than 5 such actions. All these States were those we categorized as small or extra-small except for one medium-sized State. Seven States, all small or extra-small, took no serious actions at all for one of these 3 years. (See appendix C for a more detailed description of our typology.)

- Rates of the most serious disciplinary action taken by State pharmacy boards during this period varied widely—from 1.49 actions per 1000 licensees in one State to 45.61 actions per 1000 licensees in another.

In addition, considerable variation is also apparent when disciplinary actions are correlated with location and size. States in the Midwest disciplined at the highest rate of 15.55 actions per 1000 licensees—nearly twice as often as those in the West and nearly three times as often as those in the Northeast. The large States disciplined most frequently—at a rate of 15.57 actions per 1000 licensees. This rate was more than one and one-half times the rate of the extra-small and the extra-large States, both of which disciplined least frequently and at nearly equal rates.

How are we to account for these wide variations in the performance of the boards? Perhaps some boards are more committed to aggressive discipline than others. It could be that those boards with fewer actions are dealing with more complicated cases or resolving informally types of cases which other boards might bring to hearings. Finally, these variations might result to some degree from differences in the administrative process or in the resources available to the boards. It is likely that each of these factors to some extent affects the disciplinary performance of the boards.

- In most States, as in the nation as a whole, the number of revocations and voluntary surrenders did not increase between 1986 and 1988.

Revocations and voluntary surrenders of licenses are the most serious of all disciplinary penalties imposed by the boards. Yet we found that the use of these penalties did not change much overall and accounted for only 25 percent of all the serious actions taken during the entire period.

We think it is important to note, too, that the number of revocations summarized here may overstate the severity of the boards' disciplinary activity. Although revocations are the ultimate penalty available to boards, they are often neither as permanent nor as serious as the public may think. Boards can, for instance, reinstate the licenses they once revoked. In fact, at least 243 licenses were reinstated in 1987.<sup>22</sup> Boards also may impose revocations, only to stay them and effect a lesser penalty. The boards reported to us only the most serious penalty for those actions involving multiple penalties. Thus our data on the number of revocations does not reflect the actions actually effected.

We recognize also that the disciplinary practices of State pharmacy boards encompass significant activity which is not captured through analysis of the most serious disciplinary actions they impose. As we shall see, the majority of complaints and problems are handled by administrative staff through a variety of informal interventions. Nevertheless, we think serious disciplinary actions are an important indicator of the rigor of pharmacy boards in fulfilling their responsibilities to the public.

- The limited use of peer review by many professional pharmacy associations, particularly in comparison with that in some other professions, makes the disciplinary performance of pharmacy boards all the more significant.

We found that the APhA and most State professional associations of pharmacists have been largely inactive in monitoring the performance of their members in recent years. The APhA as well as some State professional associations have formalized processes in their bylaws for review of their members' conduct. However, fears of antitrust litigation have dampened the peer review efforts of most associations with which we had contact. Peer review by professional associations has been less limited in other professions such as medicine, dentistry, and podiatry.

To be sure, the performance of pharmacists is monitored to some extent by other government agencies. The States' Medicaid Fraud Control Units as well as the DEA and other State agencies with responsibilities for controlled substances laws can punish wrongdoing by pharmacists. The Office of Inspector General can exclude pharmacists and pharmacies from participation in the Medicare and Medicaid programs. Data from our case study States showed that these pharmacy boards had, for the most part, imposed serious disciplinary penalties against those pharmacists and pharmacies sanctioned by the OIG between 1984 and 1988.<sup>23</sup>

Nonetheless, perhaps to a greater extent than other health regulatory boards, pharmacy boards are the primary protectors of the public in relation to the practice of their licensees. Other

mechanisms useful in monitoring the performance of other health professionals, such as mandatory reporting laws and hospital peer review committees, are not as prominent in monitoring the performance of pharmacists.

*Pharmacy boards impose the most serious discipline mainly for drug diversion and self-abuse of drugs. They rarely address quality of care issues, despite the increasing emphasis in the profession on the clinical aspects of pharmacy practice.*

Approximately half of all the formal disciplinary actions reported to us by pharmacy board executives for the period 1986-1988 were for reasons of diversion and impairment. These officials estimated that nearly one-fourth of these actions were the result of diversion by the pharmacist for economic gain; nearly three-fourths of them primarily for impairment of the pharmacists due to self-abuse of drugs. Analysis of the those disciplinary actions reported to the NABP's Disciplinary Clearinghouse confirmed these reports. Slightly more than half the violations reported to the Clearinghouse for the years 1986, 1987, and 1988 involved drug diversion and self-abuse of drugs.

### **Drug Diversion**

For many pharmacy boards, drug diversion cases consume considerable time and effort from both administrative staff and board members. Discussions with board officials in our case study States confirmed that drug diversion cases are among those having top priority for investigation and prosecution and for receiving the most severe disciplinary sanctions.

In identifying and developing drug diversion cases, pharmacy boards typically work with officials from local and State law enforcement agencies as well as from the DEA. Approximately two-thirds of the boards reportedly utilize the DEA's ARCOS reports to identify potential diversion.<sup>24</sup> However, less than 20 percent of the boards reported that they rely primarily on ARCOS, because its reports are considered too untimely and not always readily available to pharmacy inspectors. Most pharmacy boards identify potential diversion cases primarily through pharmacy inspections and from information received from other government agencies. Several boards reportedly have instituted their own systems for tracking the distribution of controlled substances by manufacturers and wholesalers.

In several States, the pharmacy boards have focussed particular attention on the problem of non-therapeutic dispensing by pharmacists. Federal controlled substances legislation allows prescribers to write prescriptions only for legitimate medical purposes in the usual course of their professional practice. The law defines a corresponding responsibility for pharmacists to fill only legitimate prescriptions and makes them accountable for the prescriptions they dispense.<sup>25</sup> The pharmacy boards in California, Michigan, and Texas, for example, have widely publicized the corresponding responsibility of pharmacists and have imposed discipline on those who violate these legal requirements.

## Impairment

In recent years, many pharmacy boards have come to recognize the importance of therapeutic interventions when dealing with pharmacists impaired by the abuse of alcohol or other drugs. Although the extent of chemical dependence among pharmacists is not known for sure, the APhA has suggested that chemical dependency affects a "substantial" number of pharmacists and pharmacy students.<sup>26</sup>

With the leadership of organizations such as the AACP, APhA, and NABP and some State pharmacy associations and pharmacy boards, the number of education and treatment programs for impaired pharmacists has increased dramatically since the early 1980s. Approximately 80 percent of the States now have programs to assist impaired pharmacists. These programs are usually operated by the State pharmacy associations or by private, non-profit agencies under contract to State government agencies. The NABP has encouraged pharmacy boards to establish cooperative relationships with rehabilitation programs and to offer rehabilitation as either adjuncts or alternatives to formal discipline.

In five of our six case study States, the pharmacy boards had official connections with treatment programs. Three of the boards usually direct impaired pharmacists into these programs, sometimes in conjunction with action against the license but sometimes not. The other two pharmacy boards have had only one option when dealing with impaired pharmacists: mandatory revocation of license in one State; surrender of the license during treatment in the other. In both States, however, recent or pending legislation will grant the boards more latitude in the actions they can take. In all these States, impaired pharmacists who enter these programs voluntarily are not reported to the boards unless they are considered by program staff to be of danger to the public or drop out of the programs prematurely. Considerable variation exists among these boards in the extent to which they monitor the progress of pharmacists they have ordered into treatment and the degree to which they rely on the programs to determine when treatment has been completed successfully.

## Quality of Care

With pharmacy boards devoting so much of their time and effort to problems of diversion, impairment, and technical violations, one might ask how much attention boards focus on pharmacists who may be incompetent. The answer is that boards seem to be doing very little either to identify pharmacists who may be incompetent or to ensure that practicing pharmacists have maintained at least minimal levels of competence.

During the 3-year period 1986-1988, the States reported to the NABP fewer than two dozen disciplinary actions for reasons they described as incompetence. Moreover, board representatives from our case study States reported that although their practice acts included incompetence as one grounds for discipline, their boards had rarely, if ever, disciplined pharmacists for incompetence.<sup>27</sup>

Why is this the case? The explanations seem to be that competence is difficult to define and the profession of pharmacy does not appear to have achieved consensus on standards of competence. We found striking contradiction among the board officials with whom we spoke about competency issues. These officials variously defined competence as "We have no definition" to "Competence is following the rules." Many officials thought that standards for judging competence did not exist. Some thought the standards of competence were the requirements of the practice acts. Another official said the standards for competence were his "own gut feelings."<sup>28</sup>

Without consensus on definitions and standards, it is not surprising that no mechanisms have been widely instituted for assessing the continued competence of practicing pharmacists. Like other health licensing boards, pharmacy boards do not require periodic reexamination of licensees and, with the exception of mandatory continuing education, have not adopted other approaches helpful in assuring continued competence, such as peer review, practice audits, or self-assessment procedures. Although pharmacy inspectors do scrutinize pharmacists' practice sites through routine inspections, this process focuses on the pharmacists' compliance with the technical requirements of pharmacy law rather than on the quality of his or her performance. As a result, pharmacists who may be incompetent can continue to practice as long as they do not come to the attention of the boards and as long as they renew their licenses periodically by filing a form and paying a fee. Although continuing education is mandatory for pharmacists in most States and can be effective in improving knowledge and skills,<sup>29</sup> the system does not require pharmacists to demonstrate periodically that their skills and knowledge continue to meet minimum levels of competence.

Concerns about the capacity of health licensing boards to assure the continued competence of professionals reflect the increasing attention being focussed today on the quality of health care services generally. Pharmacy boards have only begun to address quality of care issues. As the executive from a large pharmacy board observed during one of our discussions:

*We don't get into quality of care. Our statute doesn't really address the clinical role of pharmacists or the practice of pharmacy outside the pharmacy. It's time for us to begin to address standards of practice for this.*

Progress has been slow and uneven among the States in defining scope of practice requirements for the emerging clinical roles of pharmacists. Similarly, the oversight process of most boards does not address the performance of pharmacists in clinical settings. Thus, disciplinary actions for inadequate clinical performance have been few. The task is complex and, as we have seen, presents a major challenge to the pharmacy boards.

*The ability of many State pharmacy boards to protect the public is hampered by limitations in their legal authorities, administrative processes, and resources.*

### **Insufficient Legal Authorities**

Many pharmacy boards still do not have adequate legal authority to discipline pharmacists and pharmacies. The grounds for discipline contained in the pharmacy practice acts are sometimes vaguely defined. This is particularly true for the complex grounds such as incompetence or unprofessional conduct. Moreover, some boards lack authority to discipline pharmacists without full evidentiary hearings, even when they have been convicted in criminal courts or disciplined by other State boards or government agencies.

Many pharmacy boards do not have a full complement of penalties at their disposal. As we have seen, all boards can revoke or suspend the licenses of pharmacists and pharmacies. However, five boards lack authority to impose probation; eight cannot issue reprimands; and 11 are not able to impose restrictions on licenses. At least 15 boards cannot impose fines for infractions of pharmacy law. Of those boards which can, some are able to impose only small fines or can fine only for violations of controlled substances laws. Many board representatives with whom we spoke said fines were an effective intermediate penalty for disciplining pharmacists and an effective sanction to impose on pharmacies which, because they are businesses, can be difficult for boards to close down even temporarily. Finally, many boards lack the authority to require mental, physical, or knowledge-based examinations of pharmacists as part of the disciplinary process.<sup>30</sup>

Pharmacy boards are also hampered in their ability to act quickly when they identify pharmacists (or pharmacies) who pose an immediate danger to the public's welfare. A few pharmacy boards have no authority to suspend licenses on an emergency basis. A few others have the authority but only for violations of controlled substances laws. Even boards which are empowered to take emergency suspensions can have difficulty using this authority. We encountered several States in which boards impose these suspensions very rarely. This is not because the boards have no need but because these actions are very time-consuming to prepare and must meet the very high standards of proof required by the courts or the States' Attorneys General. Board representatives from one State we visited said emergency suspensions in their State can take as long as 2 years to obtain.

This inability of boards to act quickly in emergency situations can pose dangers to the health and welfare of the public. One pharmacy inspector shared with us his concerns about a pharmacist he knows well who is alcoholic. "I don't have the time it would take to spend with him to document what I would need. All I can do is try to persuade his wife to make him stop practicing." An inspector from another State described his efforts with an elderly pharmacist who continues to practice in his own store despite serious memory problems. In this case, the inspector feels his only recourse is to convince the pharmacist to retire. In the meantime, he has been encouraging other staff from the store to watch him closely and the local pharmacy association to provide some relief assistance so he does not practice as frequently.



## Administrative Barriers

- The ability of many pharmacy boards to protect the public is also jeopardized by their limited exchange of information with other entities.

We found that potentially rich sources of information about possible wrongdoing by pharmacists remain largely untapped by pharmacy boards. In our case study States, board officials reported their States had no comprehensive laws requiring the reporting to them of potential or actual wrongdoing by pharmacists. Consequently, they receive few, if any, referrals from hospitals, nursing homes, insurance companies, or the courts. Individual pharmacists make few referrals to the boards as do the professional associations of pharmacists in these States. As a result, pharmacy boards most often learn about potential cases from consumers, other law enforcement agencies including the DEA, and from pharmacy inspectors through their inspections of pharmacies or reviews of controlled substances records and reports.

Moreover, many pharmacy boards have not been sharing information with each other on the disciplinary actions they have taken. We found that during the period 1986 through 1988, more than one-fourth of all boards never reported any of their disciplinary actions to the voluntary Disciplinary Clearinghouse maintained by NABP. In fact, two-thirds of the boards did not report any actions for at least 1 of these 3 years. Similarly, since 1985 only one-fourth of the States reported any disciplinary actions to the clearinghouse maintained by National Clearinghouse on Licensure, Enforcement, and Regulation (CLEAR). This failure of so many pharmacy boards to regularly share important disciplinary information with each other increases the vulnerability of the public to wrongdoers who are licensed to practice in more than one State or who transfer their licensure to other States to avoid discipline.

Not only do many pharmacy boards not share information with each other, but a sizeable number do not publicize their disciplinary actions even to the professional pharmacy community in their States or to the general public. Only slightly more than half the pharmacy boards were participating in NABP's newsletter project in 1988. Funded primarily by NABP's Bureau of Voluntary Compliance, these State newsletters contain both national news and State-specific information, including summaries of disciplinary actions, in an effort to enhance pharmacists' voluntary compliance with State and Federal pharmacy laws.

- The ability of pharmacy boards to protect the public by assuring prompt discipline for serious offenses is hampered by the time-consuming nature of the disciplinary process itself. This process can be very elaborate and often unwieldy for dealing with detailed pharmacy law and for adjudicating the serious, often very complex, disciplinary cases.

Pharmacy boards vary considerably in the specifics of their disciplinary processes and in the latitude given to administrative staff for resolving complaints and dealing with violations. Nevertheless, we found that most boards have tried to maximize resources by prioritizing the

cases they pursue and by adopting multiple levels of intervention for dealing with different kinds of violations.

The enforcement process is swiftest and simplest for the least serious violations. Minor infractions, frequently those discovered during routine pharmacy inspections, are often dealt with by the inspectors immediately with written or verbal warnings. More serious violations, or repeated or uncorrected minor violations, are typically dealt with through meetings between the pharmacist and a supervisory inspector or an informal committee which includes some board members. This strategy of prioritization seems to serve the boards well. It permits the administrative staff to resolve the majority of complaints and violations through various informal mechanisms so that only the most serious cases are considered by the entire board for formal discipline. In recent years, these kinds of cases have primarily involved drug diversion, impairment of pharmacists due to abuse of alcohol or drugs, and serious fraud.

The irony, however, is that the most serious cases, including those which presumably pose the greatest threat to the public's welfare, are those cases which can take the longest time for boards to deal with. These cases are often complex ones requiring time-consuming investigation and legal preparation. These cases can also take a very long time to process because of the multiple reviews and clearances required as part of the disciplinary process. These reviews often involve staff from different State agencies which usually have competing priorities. Many pharmacy boards, for example, must share inspectors and investigators with other licensing boards or must rely on staff from offices of attorney general for their legal assistance.

Furthermore, long delays can result from the hearing process itself. Representatives from several boards complained to us about the long delays which result in their States from the frequent continuances granted to defendants. One board has no regularly scheduled meetings for considering disciplinary cases. Long delays thus result from the logistical difficulties of arranging members' schedules. To make matters worse, if the case is not concluded in 1 day or a last minute continuance is granted, the lengthy process of rescheduling the hearing must begin anew. Finally, delays can occur after the hearing process is concluded due to stays granted during the appeals process or, in those States with boards which are advisory, from further deliberations by other State officials.

Some States have taken steps to expedite their disciplinary process. Some do not require the full judicial process or evidentiary hearings for certain kinds of cases. Others are making increased use of stipulated settlements negotiated by staff for subsequent approval by board members or are relying on Administrative Law Judges rather than evidentiary hearings of the boards for those cases which cannot be stipulated.

Despite measures such as these, the investigation and adjudication processes can take a long time. Several board officials from our case study States told us of cases taking a year, 2 years, or even longer before the board had concluded its deliberations. Barriers which hamper more timely resolution of the most serious cases exist in many States. Nearly one-third of the board executives with whom we spoke singled out administrative bottlenecks in their States'

administrative processes as major factors hindering their boards' efforts to assure prompt discipline.

### **Inadequate Resources**

Nearly 60 percent of the pharmacy board executives with whom we spoke thought their ability to enforce pharmacy laws and to discipline effectively has been hampered by insufficient resources.<sup>31</sup> The fees boards charge their licensees are one indicator of resources available to boards as the budgets for two-thirds of the pharmacy boards reportedly depend on the amount of receipts they collect. We examined the renewal fees for both pharmacists and pharmacies and found them to be quite low. This was the case even though 20 percent of the States increased their renewal fees for pharmacists and 25 percent of the States increased the renewal fees for pharmacies between 1987 and 1988. The average annual cost of a pharmacist's license was \$43.12 in 1988, an increase of less than \$4 since 1987. The average annual cost of a pharmacy permit was \$84.33 in 1988, a decrease of slightly more than \$5 since 1987.<sup>32</sup>

Insufficient resources hinder the ability of pharmacy boards to enforce the laws and discipline pharmacists in several important ways. First, the number of staff available to do the job promptly and thoroughly may be insufficient. Although representatives from several boards mentioned they had had small increases in staff in the last few years, many more indicated a need for additional legal expertise and for more pharmacy inspectors. The staff of many boards are stretched thin. On the average, pharmacy boards have five inspectors for conducting inspections and investigating reports of potential wrongdoing. In many States, these inspectors are shared with other boards.<sup>33</sup> In consequence, fewer and fewer pharmacy boards have been conducting routine inspections of pharmacies once a year, a process important for educating pharmacists as well as for identifying violations. Only one of our case study States reported being able to conduct routine inspections annually. Another rarely, if ever, performs them.

Salaries which are not competitive is a second major consequence of limited resources. Several board representatives complained to us about the inability of their States to attract and retain experienced legal staff to work with them in the development and prosecution of cases. Others mentioned the difficulties of recruiting pharmacists to work as inspectors given the higher salaries available to them elsewhere. Even the level of compensation offered to board members is low in most States: an average per diem of \$49.58 plus expenses last year.<sup>34</sup>

Finally, pharmacy boards faced with insufficient resources sometimes do not have the support services critical to their overall performance. Orientation for board members and training for staff, essential given the scope and dynamism of boards' regulatory responsibilities, is limited in some States. Computerization, vital for keeping current records on licensees and tracking disciplinary actions, has lagged for some as well. We witnessed the deliberations of one pharmacy board, for example, which had to rely on the defendant for information about previous disciplinary actions.

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## RECOMMENDATIONS

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Given the situation described in the previous pages, we offer several recommendations with respect to the enforcement and disciplinary practices of State pharmacy boards. Our central recommendations are directed to State governments and to State boards of pharmacy. We address several other important recommendations to the National Association of Boards of Pharmacy, the American Pharmaceutical Association, and the U.S. Public Health Service.

### THE STATE GOVERNMENTS

- State governments should ensure that State pharmacy boards have adequate resources and authority for carrying out their enforcement responsibilities effectively.

If boards are to protect the public, they need adequate resources. They need a sufficient number of well-qualified, adequately paid staff and board members. They need computer systems and training for both staff and board members.

Resources available to the boards need not be limited by overall constraints on State budgets. States should ensure that the fees for pharmacy licenses and permits generate revenues sufficient for the boards' needs and that the revenues generated be available for use by the boards. Other mechanisms for generating revenues also exist. We learned of one board which has authority to recover from defendants the costs of the time incurred by the board's investigators and lawyers.

Boards need a full range of disciplinary options at their disposal—options which are effective and flexible for both pharmacists and pharmacies. States ought to have written disciplinary guidelines for imposing penalties. Although each case is unique, guidelines which describe ranges of penalties for various offenses are important for assuring fairness and consistency in board decisions and useful for practitioners.

Pharmacy practice acts should state clearly and specifically the grounds for discipline so that both regulators and pharmacists understand what is and is not acceptable. Practice acts too should empower boards to require physical, mental, or knowledge-based examinations of pharmacists when necessary.

States should ensure that boards have authority to act promptly in order to protect the public's welfare. In certain cases, boards should be able to take action against licensees without full evidentiary hearings. They should be held to standards of proof which protect the rights of pharmacists but are not so burdensome as to jeopardize the rights of the public. It is imperative that boards have both the authority and a workable process for suspending immediately the licenses of those who threaten the health and safety of the public. This is not the case now in most States.

- State governments should take steps to streamline the administrative process so that State pharmacy boards are able to process disciplinary cases more efficiently.

The time-consuming nature of the disciplinary process in many States coupled with the inability of most boards to effect emergency actions jeopardizes the protection afforded by boards to the public. States should streamline their processes as much as possible and rid them of unnecessary reviews and other time-consuming procedures.

- State governments should take steps which enhance the capacity of pharmacy boards to deal with drug diversion and impairment of pharmacists.

By strengthening their overall efforts to address drug diversion and impairment, States can enhance the capacity of pharmacy boards, as well as other health professional boards, for dealing more effectively with these serious problems. State governments might consider, for example, supporting treatment programs for all health professionals including pharmacists who come to the attention of their licensing boards.

States should consider adopting stronger measures for combatting drug diversion such as separate registrations for controlled substances and multiple copy prescription programs. Such approaches have enhanced the enforcement efforts of pharmacy boards as well as those of other agencies. They have been strongly supported by the DEA over the years and more recently by The White House Conference for a Drug Free America.<sup>35</sup>

## **STATE PHARMACY BOARDS**

- State pharmacy boards should review the outcomes of their disciplinary process and evaluate whether they are affording the public the maximum protection possible.

It is imperative that pharmacy boards carry out their disciplinary responsibilities forcefully. The disciplinary data on serious actions suggest that too many boards have not been imposing rigorous discipline over the last few years. To be sure, many boards discipline wrongdoers in less formal ways, and many boards too have been hindered by constraints of various kinds. Nonetheless, that so many boards imposed so few of these most serious actions during the last 3 years suggests a need for greater intensity in their disciplinary efforts.

- State pharmacy boards should disseminate more broadly information on the disciplinary actions they have taken.

Pharmacy boards should do a better job of sharing with each other information on the serious disciplinary actions they take. Failure to report completely and timely on serious actions to CLEAR and to the NABP Disciplinary Clearinghouse limits the ability of boards to protect the public from pharmacists who escape discipline in one State by moving to another State where they are also licensed. It also undermines the effectiveness of NABP's process for

verifying the credentials of those pharmacists wishing to transfer their licensure from one State to another. State boards should take immediate steps to improve their voluntary reporting through these existing mechanisms. They should not delay until implementation of the new practitioner databank, authorized under Section V of the Medicare and Medicaid Patient and Program Protection Act of 1987, when reporting of disciplinary actions becomes mandatory.

## **NATIONAL ASSOCIATION OF BOARDS OF PHARMACY**

For many years, the National Association of Boards of Pharmacy (NABP) has provided important leadership to State pharmacy officials in the areas of licensure, discipline, and regulation of pharmacy practice. As pharmacy practice continues to change and the demands on boards continue to grow, we urge the NABP to continue to provide this leadership to State boards. In so doing, we encourage the NABP to broaden and increase its financial base so it can continue these important efforts independent of any financial association with pharmacy organizations which may be regulated by its membership. We offer the following specific recommendations:

- The NABP should intensify its efforts to help State pharmacy boards address the changing nature of pharmacy practice, particularly with respect to the clinical roles of pharmacists.

The NABP should focus particular attention on assisting boards in developing regulatory requirements and oversight procedures which address patient care responsibilities of pharmacists. In so doing, the NABP should work with other professional pharmacy organizations, especially the APhA, the AACP, the American Council on Pharmaceutical Education (ACPE), the American Society of Consultant Pharmacists (ASCP), and the American Society of Hospital Pharmacists (ASHP).

The NABP should also help boards identify useful strategies for dealing with drug diversion.

- The NABP should work with State pharmacy boards and national professional pharmacy organizations to explore viable approaches to assessing the continued competence of licensed pharmacists.

We agree with the conclusions of the 1975 AACP/APhA Task Force on Continuing Competency<sup>36</sup> that pharmacists should be required to demonstrate continued professional competence to State licensing boards as a condition of relicensure. Most boards have adopted mandatory continuing education as a mechanism for assuring continued competence. Boards now need to explore and experiment with various mechanisms for assessing periodically the professional competence of practicing pharmacists. The task is complex and controversial. The NABP has a vital role to play in charting the direction for this effort involving State boards and the professional pharmacy organizations.

## THE AMERICAN PHARMACEUTICAL ASSOCIATION

- The American Pharmaceutical Association (APhA) should exercise its leadership in encouraging more peer review of pharmacists' professional performance by national and State professional pharmacy organizations.

The relative lack of peer review by professional pharmacy organizations is unfortunate. Without a process to permit review of professional performance by peers, the profession abdicates responsibility for policing itself and undermines the confidence of the public in its professionalism. It is important that the professional pharmacy organizations renew these efforts and be guided less by the threat of antitrust litigation than by the examples of the few State pharmacy associations and the associations of other professions such as medicine, dentistry and podiatry which have more active peer review programs. As the most broadly based professional organization of pharmacists, the APhA should take the lead in this effort which should also include its affiliated State associations as well as other national professional organizations such as the ASCP and the ASHP.

- The APhA should work with the NABP and other professional pharmacy organizations to develop appropriate methods for assessing the continued competence of pharmacists.

Ten years ago, the APhA and the AACCP pioneered the development of the professional practice standards for pharmacy<sup>37</sup>—the first order of business recommended in 1975 by the Task Force on Continuing Competence. The second order of business charted by the Task Force was the development and implementation of mechanisms for assessing performance based on the standards. Little has been accomplished in this arena during the last 10 years. We urge the APhA to work with other professional and regulatory organizations to experiment with approaches such as self-assessment tests, peer review, and practice audits. The task is difficult and complex but, as the experience of several medical specialty boards suggests, is nonetheless possible.<sup>38</sup>

## THE U.S. PUBLIC HEALTH SERVICE

- The Public Health Service (PHS) should increase its support to the NABP in its efforts to provide leadership to State pharmacy boards.

The PHS has provided financial assistance to other professional organizations but has had little involvement over the years with the NABP. We encourage the PHS to explore ways to support the NABP in its efforts to assist the boards. The PHS, for example, might consider working with the NABP in developing and piloting mechanisms for assessing the continued competence of pharmacists. The PHS with its broad purview is well positioned to encourage broad interdisciplinary efforts toward this end.

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## COMMENTS ON THE DRAFT REPORT AND OIG RESPONSE TO COMMENTS

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We received comments on the draft report from the Health Care Financing Administration and the Public Health Service within the Department of Health and Human Services and from the Drug Enforcement Administration in the Department of Justice. Comments were also received from the American Association of Colleges of Pharmacy (AACCP), American Pharmaceutical Association (APhA), American Society of Hospital Pharmacists (ASHP), National Association of Boards of Pharmacy (NABP), and the National Clearinghouse on Licensure, Enforcement and Regulation (CLEAR).

The OIG response to the major issues raised in these comments from these government agencies and national organizations are contained below. The detailed comments from these agencies and organizations appear in appendix A.

Overall, no one disagreed with our recommendations that State governments should ensure that State boards of pharmacy have adequate resources and authorities and should streamline administrative processes to enhance efficiency. Our recommendations that State pharmacy boards review the outcomes of their disciplinary processes and disseminate more broadly the outcomes of disciplinary action to assure maximum protection of the public were also generally supported. Further, no one disagreed with our recommendation that the APhA, the NABP, other professional pharmacy organizations, and the State boards should work together to explore and develop viable approaches for assessing the continued competence of licensed pharmacists.

The APhA and the NABP both had concerns about our recommendation calling for more peer review of pharmacists' professional performance by national and State professional pharmacy organizations. The NABP was concerned that our call for stronger peer review suggested a weakening or replacing of the disciplinary responsibilities of the pharmacy boards. The APhA was concerned about professional associations having adequate resources to undertake peer review efforts and about the possibility of antitrust litigation.

In our view, peer review of pharmacists' professional performance by the professional organizations need not, and indeed should not, duplicate or replace the legal responsibilities of the State pharmacy boards for licensure and discipline. We recognize that peer review, too, has both cost and legal implications for professional associations. Nonetheless, we think that as professional organizations, the pharmacy associations have the responsibility and the opportunity to play an important role in identifying and assisting practitioners whose performance falls below acceptable standards and in referring to the State boards those whose performance has violated legal requirements.

### **Health Care Financing Administration**

The HCFA was generally supportive of our recommendations.



## **Public Health Service**

We are pleased with PHS' concurrence with our recommendation to provide increased support to NABP in its efforts to provide leadership to State pharmacy boards. We recognize that PHS has worked collaboratively with NABP over the years and encourage PHS to consider some financial assistance for specific undertakings as it has provided in the past to other national organizations of the various State health professional boards.

The PHS observes that the estimates of active pharmacists used in the report are overstated. We, too, have recognized the discrepancy between the PHS projected estimates and the manpower estimates available from the NABP and the State boards. The rationale for the estimates we used is explained in appendix C and, we believe, remains valid.

## **Drug Enforcement Administration**

We are pleased with DEA's positive response to our findings and recommendations. As noted in the report, DEA has frequent interactions with State boards of pharmacy involving their respective responsibilities for regulating the distribution of controlled substances.

## **American Association of Colleges of Pharmacy**

We appreciate the positive comments from the AACCP on our report and its support, in particular, of increased professional peer review.

## **American Pharmaceutical Association**

We are pleased that APhA agrees generally with our recommendations to the State governments and the State pharmacy boards.

As noted above, APhA has concerns about our recommendation that it encourage more peer review by professional pharmacy associations. We recognize the important leadership exercised by the APhA over the years in addressing issues such as pharmacist impairment and in developing standards of practice and a Code of Ethics for the profession. While the difficulties associated with peer review efforts are significant, as the APhA points out, we are pleased that it plans to consider carefully this recommendation.

We regret that the APhA did not comment specifically on our recommendation that it work with the NABP and other professional pharmacy organizations to develop appropriate methods for assessing the continued competence of pharmacists. We continue to regard this effort as a high priority which warrants the attention and leadership of the APhA.

## **American Society of Hospital Pharmacists**

We appreciate the response from ASHP, which, while not addressing specifically the findings and recommendations of the report, offers more general comments about our inquiry as it relates to the practice of pharmacy today.

The ASHP suggests that the report should have addressed more completely the public health hazards of pharmacist incompetence and the role of boards in regulating non-pharmacist and mail order dispensing of prescription drugs. We believe an in-depth examination of these issues was beyond the purview of this particular inquiry which focussed on an assessment of the disciplinary practices of the State boards of pharmacy.

We strongly disagree with the ASHP comment that regulation of both the dispensing and clinical aspects of pharmacy practice by State pharmacy boards would be "highly unrealistic and unwise." On the contrary, we believe regulation of the entire spectrum of pharmacy practice is essential to the responsibilities and mandates of State boards to protect the public by assuring safe, competent practice of pharmacy regardless of practice setting. As we noted in the report, a major challenge facing the boards today is the need to address the changing nature of pharmacy practice in which increasing numbers of practitioners are assuming responsibilities for patient care and well as for prescription dispensing.

## **National Association of Boards of Pharmacy**

We appreciate the overall positive response of the NABP to the findings and recommendations of the report. Our comments on particular issues raised by the NABP follow.

The NABP asks that we include in the report the actual disciplinary data collected from the States to support our findings regarding the incidence and rates of serious discipline imposed by the boards in recent years. These State-specific data were not included in the draft of the report because the focus of our inquiry emphasized a national picture of the disciplinary practices of the State boards. In response to this particular request, we have included as part of the final report (see appendix B) the State-specific data we collected. These data were gathered through telephone discussions with pharmacy board officials in all States in order that we might have for our analysis the most comprehensive, up-to-date data available. In those few instances where data are missing, the State officials were unable to provide us with numbers of serious disciplinary actions for their boards. A detailed explanation of our methodology appears in appendix C.

As noted and discussed above, the NABP is concerned with our call for strengthened peer review by the professional pharmacy associations. In our view, such an effort would not duplicate or replace the responsibilities of the State boards but would be complementary to their efforts to protect the public.

The NABP makes note of our comment in the report about the “corresponding responsibility” of pharmacists for the legitimacy of the prescriptions they dispense for controlled substances. This responsibility is clearly articulated in Federal law (Title 21, Code of Federal Regulations, Section 1306.4), and, as noted in the report, is being aggressively enforced by some pharmacy boards, including three of our six case study States, as a critical strategy for curtailing drug diversion.

We are concerned with the thrust of the NABP comments about emergency suspensions of licenses. We reiterate the importance to the public of boards having adequate authorities and workable processes for suspending, on an emergency basis, the licenses of pharmacists who threaten the health and safety of the public. Whatever the reasons, the situations described in the report are, in our view, simply not defensible.

### **National Clearinghouse on Licensure, Enforcement and Regulation**

The comments from CLEAR were generally positive. However, with respect to our analysis of the incidence of serious disciplinary actions imposed by the boards between 1986 and 1988, CLEAR comments that further explanation for the increases or lack of increases in these actions would have been helpful. We agree that such an explanation is important. In response, we suggest that the value of our inquiry was to document the disparity that exists nationally in the rate of serious discipline imposed by the boards based on our collection and analysis of the most recent, most comprehensive disciplinary data available at present from State pharmacy boards. Although we suggest possible reasons for this disparity in our report, further exploration was beyond the purview of this particular inquiry and is, we believe, more properly the responsibility of the State governments and their respective boards of pharmacy.



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## APPENDIX A

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### ***COMMENTS ON THE DRAFT REPORT***

We received comments on the draft report from the Health Care Financing Administration and the Public Health Service within the Department of Health and Human Services and from the Drug Enforcement Administration in the Department of Justice. Comments were also received from several national organizations including the American Association of Colleges of Pharmacy (AACCP), American Pharmaceutical Association (APhA), American Society of Hospital Pharmacists (ASHP), National Association of Boards of Pharmacy (NABP), and the National Clearinghouse on Licensure, Enforcement and Regulation (CLEAR). The actual comments received follow in this appendix.

# Memorandum

MAR 12 1990

Date

From

Gail R. Wilensky, Ph.D. *grw*  
Administrator

Subject

OIG Draft Report: "State Discipline of Pharmacists" (OAI-01-89-89020)

To

The Inspector General  
Office of the Secretary

We are responding to your request for comments on the subject report.

While no recommendations were made directly to HCFA, we believe that those made to the other entities are reasonable. We appreciate the opportunity to review the results of this study.



## Memorandum

MAR 20 1990

Date

From Assistant Secretary for Health

Subject Comments on Office of Inspector General (OIG) Draft Report "State Discipline of Pharmacists," OAI-01-89-89020, January 1990

To Inspector General, OS

As requested, we have reviewed the subject draft report and have the following comments on the recommendation addressed to PHS and statistical data cited in the report.

OIG Recommendation

The Public Health Service (PHS) should increase its support to the NABP in its efforts to provide leadership to State pharmacy boards.

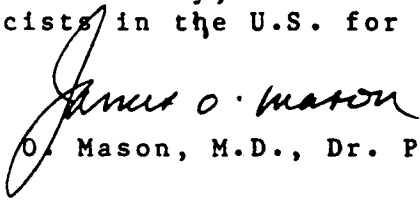
PHS Comment

We concur. PHS is collaborating with the National Association of Boards of Pharmacy (NABP) in its efforts to provide leadership to State pharmacy boards through informal meetings and by its participation on the Pharmacy Manpower Steering Committee which NABP co-chairs along with the American Association of Colleges of Pharmacy. However, PHS does not provide financial or technical assistance to the NABP due to unavailability of funds.

The Health Resources and Services Administration through its Bureau of Health Professions, is pursuing non-financial collaborative efforts with other Government components (Health Care Financing Administration and National Institutes of Health), to identify ways and means to provide technical assistance to NABP.

Technical Comment

The draft report on pages 2 and A2 noted the estimated number of active pharmacists in the U.S. as being approximately 183,000. This number is overstated according to data compiled by the Health Resources and Services Administration's Bureau of Health Professions. Based on the 1978 federally funded Pharmacy Inventory, which is updated annually, the Bureau's Supply Model Estimate of active pharmacists in the U.S. for 1989 was 157,900.

  
James O. Mason, M.D., Dr. P.H.

Washington, D.C. 20537

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

Dear Mr. Kusserow:

This is in response to your draft report "State Discipline of Pharmacists" dated January 1990. I commend your office and those involved for this excellent evaluation of the pharmacy disciplinary process. The Drug Enforcement Administration's (DEA) concern in this matter pertains to controlled substances, while the report is addressing the discipline of pharmacists by state pharmacy boards for infractions dealing with all phases of pharmacy practice. Specific areas of study in the report agree with recommendations that have been made in the past by state officials at DEA national conferences.

The section of the report dealing with Multiple Copy Prescription Programs (MCPP) on page 6 is supportive of a program which has been endorsed by the DEA. MCPP is an effective deterrent to pharmaceutical diversion. Data compiled from states who have instituted the program document a 30 to 50 percent reduction in Schedule II prescriptions. In addition, agencies responsible for investigating diversion of controlled substances have successfully applied MCPP intelligence information in targeting illegal activities. At the present time, nine states have enacted MCPP with 40 percent of the physicians and pharmacists in the United States operating under the program.

The DEA concurs with your recommendation for separate registration for controlled substances. This recommendation responds favorably to the finding that many boards do not have adequate legal authority to discipline pharmacists. The separate registration creates an avenue through which the judicial and administrative processes can take appropriate action against individuals responsible for the diversion of controlled substances.

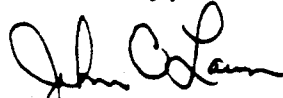


The DEA recognizes that inadequate resources, administrative barriers and insufficient legal authorities reduce the ability of pharmacy boards to enforce pharmacy laws and to discipline effectively. In response to this situation, the United States Code was amended in 1984 to enhance the DEA's authority to revoke or suspend DEA controlled substance registrations issued to registrants that are inconsistent with the public interest. This amendment to the Code has enabled the DEA to work in tandem with the states and has filled a void created when states have been unable to effectively discipline violative registrants.

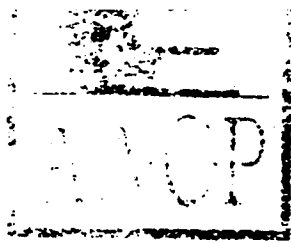
The DEA has enjoyed a close working relationship with the National Association of Boards of Pharmacy (NABP) and I was pleased to see the recommendation that the NABP continue to provide leadership to the state boards.

I feel the findings and recommendations in the report are justified, and the information and methodology of research was thorough. I thank you for providing me with the opportunity to comment on a subject that is important to the DEA.

Sincerely,



John C. Lawn  
Administrator



**AMERICAN ASSOCIATION  
OF COLLEGES OF PHARMACY**

February 27, 1990

Mr. Richard P. Kusserow  
Inspector General  
Department of Health and Human Services  
Washington, DC 20201

Dear Mr. Kusserow:

Thank you for the opportunity to comment on your draft report, "State Discipline of Pharmacists." You and the Boston Regional Office are to be congratulated on the timeliness and accuracy of your observations and recommendations.

After careful review, we offer several observations:

- o The Report refers to quality of health care in several places. We observe that it is difficult for regulatory boards, including those in pharmacy, to assess and/or ensure quality. For example, Boards mandate requirements to enter practice (i.e. education, experience, licensure) and have implemented procedural requirements (i.e. continuing education, patient profiles, patient consultation) with little objective evidence that these affect the quality of pharmaceutical services. Perhaps research and demonstration projects in the area of outcome measures/assessments are needed.

It also follows that standards, as the Report has acknowledged, exist within the profession. Specifically, the APhA/AACP Standards of Practice, published over a decade ago, are currently undergoing review for revision/revalidation. These Standards are used by colleges of pharmacy in curriculum development and assessment, state boards of pharmacy and as a foundation for the NABP's national licensing examination. Additionally, ASHP has a comprehensive set of facility, personnel and process standards for various types of institutional practices. The ASHP's standards are excellent examples of the profession's attempt to ensure the quality of pharmaceutical services. It is essential that efforts in standard development and refinement continue.

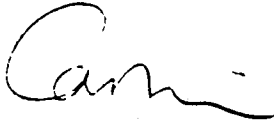
- o Clearly pharmacy practice (and health care) is changing at a rapid pace. If we assume that such change is basically in the best interest of the public health, then pharmacy boards should attempt to stimulate change rather than impede it. There is a thin line between reality and perception and between boards serving in the public interest (as they are charged) and in the interest of the

profession. However, pharmacists are professionals and need to be held responsible for their actions. Pharmacy boards should revise their pharmacy practice acts so as to enable pharmacists to expand the scope of their practices to the limit as defined by the profession, not restrict practice.

- o The Report's observation about the lack of peer review by the profession is a valid and powerful one. In the face of this void, all the public has to rely on is the state regulatory agencies. The recent articulation of the concept of pharmaceutical care (*Pharmacy in the 21st Century*, copy enclosed) which focuses on the outcomes of drug therapy, suggests that pharmacy needs to be responsive to calls for peer review.

If you have any questions or require additional clarification, please feel free to call on us.

Sincerely,



Carl E. Trinca, Ph.D.  
Executive Director

CET:pp

enclosure



**APhA**

March 6, 1990

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

Dear Mr. Kusserow:

The American Pharmaceutical Association is pleased to respond to the draft report of the Office of the Inspector General entitled "State Discipline of Pharmacists". As the national professional society of pharmacists, we are gratified by the substantial analysis that our profession has received in recent reports from your office. More importantly, we are pleased that the critical role that pharmacists play in providing quality health services to patients is finally becoming better understood at the federal level. We appreciate the department's recognition of APhA's leadership role for the profession on these issues.

Our comments include both general reflection on the report, its findings and recommendations, as well as specific responses to the recommendations addressed directly to APhA. We ask that they be carefully considered in the preparation of the final report on this subject.

#### RESPONSE TO FINDINGS AND THE OVERALL REPORT

In general, the draft report's findings appear to have been developed in a fair and reasonable manner, and are presented in a balanced fashion. We particularly commend the IG staff for making on-site visits to examine first hand the workings of several boards of pharmacy.

The draft report identifies several related issues regarding pharmacy boards' capabilities and resources. APhA certainly agrees that boards of pharmacy should be provided with the financial, material and human resources necessary to accomplish their work. While these needs obviously vary from state to state, it is clear that no board of pharmacy, such as one cited in the report, can be expected to effectively accomplish its mission with a budget of \$2500 and one part-time staff person. We hope that the final report will stimulate states to provide boards of pharmacy with the resources they require.

The draft report identifies two other substantial general factors that impact on the capabilities of boards of pharmacy:

- o the greater complexity of the tasks and responsibilities of pharmacy boards compared to their counterparts in other professional disciplines; and,

- o the dramatic changes in the nature and scope of pharmacy practice in recent years, with increased emphasis on patient care and educational activities of pharmacists in many different types of practice settings.

The former issue is not easily resolved. Pharmacy is unique in that both its practitioners and the settings in which they practice are regulated by the same governmental entity. Pharmacists are responsible for the proper control and provision of both powerful and potentially dangerous medications and important patient and information services. This unique mix of services and products places on pharmacists, and theoretically requires of the boards which regulate their practice, levels of regulatory control that are the most demanding and detailed in the health professional regulatory arena.

As mentioned in the draft report, control efforts to date have been focused on structural and procedural components (i.e. equipment and plumbing requirements within pharmacies, restrictions on which pharmacy personnel may remove or place medication containers on pharmacy shelves, controlled substances classification and tracking) rather than on outcome measures of the pharmacy services provided. APhA agrees that measuring the quality of care outcomes is the desired goal. Nevertheless, as the entire health care field is learning, the shift from measuring process to measuring outcome in delivery of care is a very complex task which will require both additional resources and fundamental re-evaluation of regulatory and accreditation activities.

The ability of pharmacy boards to keep up with the rapid changes in pharmacy practice is, in our view, less problematic. Although much remains to be done, APhA has been encouraged in recent years by changes in a few state pharmacy practice acts which have articulated substantial patient care and education functions in addition to traditional medication distribution and control activities. Often, these changes have been a result of effective collaboration between state pharmacy associations, the National Association of Boards of Pharmacy (NABP), and the state boards of pharmacy, using the APhA/AACP Standards of Practice and components of NABP's Model Practice Act. Some state boards have also either expanded or modified their membership to include practitioners from the many varied types and settings of pharmacy practice now in existence. This trend should be encouraged, in order to assist pharmacy boards in their understanding of the full scope of pharmacy practice now and for the future.

The draft report notes the emphasis currently placed on drug diversion and pharmacist impairment by boards of pharmacy. These issues, reflective of perhaps our society's greatest social problem, must be addressed by all of us. APhA does support the role of boards of pharmacy in monitoring compliance by pharmacists with all laws and regulations governing drug diversion. It is important to point out, however, that arrest records for DEA controlled substance violations in the most recent years indicate pharmacist involvement in less than one-tenth of one percent of cases.

The draft report is correct in its identification of impairment and the accompaniment of drug diversion for self-use as a problem which the state boards of pharmacy, along with the profession as a whole, have the responsibility to address. In fact, the profession--through APhA's singular leadership--and the boards of pharmacy have undertaken an aggressive program to do just that.

That program involves the establishment of Pharmacist Recovery Programs in 46 states over the past eight years. Established in cooperation with state boards of pharmacy, such programs are designed to identify, evaluate, treat, and rehabilitate impaired pharmacists and to successfully return them to practice. We therefore take substantial pride in the draft report's mentioning that state boards' activities include reinstatement of licenses. This is at least as much a reflection of successful pharmacist recovery programs as it is a reflection of any "...overstate[ment] [of] the severity of boards' disciplinary activity."

Because of the proven success of Pharmacist Recovery Programs, boards of pharmacy now have less need to revert to disciplinary actions to assure the public is protected from pharmacists suffering from impairment. Consequently, the volume of disciplinary actions taken by an individual board of pharmacy should not necessarily be used as a measure of its effectiveness in dealing with pharmacist impairment and resultant drug diversion. In Virginia, for example, it has been reported that when the state's Pharmacist Recovery Program was founded, "more than 40 pharmacists in the state had lost their licenses that year because of drug or alcohol abuse. With the program underway, such disciplinary action is a rarity."

The movement to establish Pharmacist Recovery Programs got its largest boost in 1982, when the APhA House of Delegates adopted the following policy:

1. APhA believes that pharmacists should not practice while subject to physical or mental impairment due to the influence of drugs--including alcohol--or other causes that might adversely affect their abilities to function properly in their professional capacities.
2. APhA supports establishment of detection processes as well as counseling, treatment, prevention, and rehabilitation programs for pharmacists and pharmacy students who are subject to physical or mental impairment due to the influence of drugs--including alcohol--or other causes, when such impairment has potential for adversely affecting their abilities to function properly in their professional capacities.

APhA's strategy from the beginning has been to help establish impairment assistance programs in the states and in the schools. Soon after the 1982 policy on pharmacy impairment was adopted, APhA began a relationship with the University of Utah School on Alcoholism and Other Drug Dependencies. The internationally recognized school, which this year will be holding its 39th session, conducts a one-week, intensive summer course on a broad range of areas related to chemical dependency. In 1983, APhA agreed to become the sponsor of the Pharmacists Section, one of 18 sections of the school and to use that opportunity to help implement the new policy. The session would be used to help foster the development of impaired pharmacist assistance programs at the state level.

Although APhA's involvement goes back to 1982, state level activity had begun even earlier, with the first state impaired pharmacist program established in 1979. In the same year that APhA became involved, two other state programs were established. A recent APhA survey shows that today there are 46 state-level impaired pharmacist programs, largely as a result of APhA's sponsorship of the University of Utah school.

All programs have a close working relationship with the state boards of pharmacy, and APhA has worked closely with the National Association of Boards of Pharmacy to nurture that relationship. The programs serve the needs of the boards and the public well--they provide a mechanism whereby pharmacists who are afflicted with the illness of chemical dependence are identified (or self-identified), voluntarily removed from practice, treated, and rehabilitated. Further, the programs assure that impaired pharmacists entering into the programs do not return to practice until successfully treated and rehabilitated.

#### RESPONSE TO RECOMMENDATIONS

The draft report's recommendations are addressed to state governments, state boards of pharmacy, NABP, APhA and the U.S. Public Health Service. Consistent with the comments made above, APhA supports:

- o the recommendations made to state governments to provide resources, streamline procedures and enhance the capacity of state boards to effectively carry out their responsibilities.
- o the recommendation that state governments consider supporting impairment programs for pharmacists. A major deficiency in many Pharmacist Recovery Programs is a lack of adequate funding, so such state financial support would be welcome. One state, Texas, already accomplishes this by allocating a portion of each pharmacist licensure and relicensure fee to the state pharmacy association to help offset the cost of its Pharmacist Recovery Program. In another state, California, the state legislature has enacted legislation establishing and funding a program to assist impaired health professionals.

- o the recommendations to state pharmacy boards to review the outcomes of their processes and procedures as they relate to the protection of the public, and to make information on disciplinary actions available as appropriate.
- o the recommendation to NABP to assist state boards of pharmacy in addressing the changing nature of pharmacy practice. APhA believes that NABP has made progress in this area in recent years, and will continue to work cooperatively with NABP, as it has done, to facilitate that process.

The recommendation calling on the U.S. Public Health Service to increase its support to NABP requires further study and information. It is unclear to APhA at this stage what benefits would accrue in a strictly bilateral relationship between NABP and USPHS. However, inclusion of USPHS in a broadly participatory process on the subject of state discipline of pharmacists could prove to be valuable.

Finally, but most critically for APhA, are those recommendations made directly to us. The draft report calls on APhA to:

- o exercise its leadership in encouraging more peer review of pharmacists' professional performance by national and State professional pharmacy organizations.
- o work with the NABP and other professional pharmacy organizations to develop appropriate methods for assessing the continued competence of pharmacists.

The draft report describes a "...relative lack of peer review by professional pharmacy organizations [that] is unfortunate." The report further suggests that organizations be less concerned with threats of antitrust litigation than in renewing efforts in this area. APhA's historical commitment to professional practice is clearly evidenced by:

- o the development in 1852, and subsequent refinements of, the profession's only Code of Ethics;
- o the identification and articulation of the profession's Standards of Practice, in conjunction with the American Association of Colleges of Pharmacy (AACP);
- o the establishment within the APhA Bylaws of a Judicial Board (although currently not operational because of concerns about the antitrust posture of the Federal Trade Commission and the Department of Justice);
- o the establishment of, and continued sole financial support for, the Board of Pharmaceutical Specialities, the profession's recognized system for approving and certifying specialties and specialists within the pharmacy profession; and



- o the previously discussed efforts in establishing a nationwide program to address pharmacist impairment.

The level and extent of APhA's efforts in these and other "peer review" activities must continue to be based on the legal, professional and resource constraints of both the organization and the health care system generally. APhA is currently engaged in a project with AACP and NABP to revalidate and, as appropriate, further evolve the profession's Standards of Practice. When originally conducted in 1978, this project was envisioned as the first step in a multi-step process to determine practice standards, define the necessary competencies to practice at the level of the standards, and develop programs to assure pharmacists obtained and maintained those competencies. Our commitment to this activity continues, subject of course to overall staff and budgetary resources.

Similarly, any commitment to an even more comprehensive "peer review" system to assure the quality and competence of pharmacists will require tremendous financial and staff resources to assure both complete and fair investigatory and due process procedures for pharmacists being evaluated. Perhaps most critically, the concept of a national standard for pharmacist performance presupposes a national level of uniformity of resources to deliver pharmacy care, and a national consensus on the part of patients as to what they desire or demand from their pharmacists. Clearly these conditions do not yet exist, and must be developed if any program of peer review is to be successful. We would welcome the opportunity to obtain federal or other grant support to further develop these concepts. APhA will take under advisement and carefully consider this recommendation of the draft report.

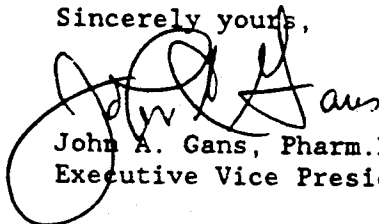
It has also been our personal organizational experience that the concerns about antitrust litigation are in fact substantial and valid. Even when adequate resources are available to assure a sound peer review process, professional organizations are quite vulnerable to lawsuits by both individual and government agencies, such as the Federal Trade Commission and Department of Justice. APhA believes that OIG is aware of the FTC's recent heightened interest in this area, particularly regarding health care associations. We would therefore welcome the input of the OIG in communicating its views on this subject to the other federal regulatory agencies whose views on this subject appear to be substantially different from those of the Inspector General.

Organizationally, APhA remains committed to assisting and encouraging pharmacists in advancing the professionalism, comprehensiveness, and quality of pharmacy care that they provide. We will continue to work in

Richard P. Kusserow  
March 6, 1990  
Page -7-

conjunction with colleagues in pharmacy practice, education, research and regulation to achieve these goals. We appreciate the chance to respond to what we believe is an excellent draft report on this subject and stand ready to work with the Department on behalf of the profession and the patients we serve.

Sincerely yours,



John A. Gans, Pharm.D.  
Executive Vice President

JAG:CEW/mmg

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March 16, 1990

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

Dear Mr. Kusserow:

Thank you for asking the American Society of Hospital Pharmacists (ASHP) to comment on the draft report of "State Discipline of Pharmacists."

The State boards of pharmacy are to ensure that pharmacy is practiced safely, competently, and in accordance with pharmacy and drug laws. The citations and disciplinary actions by the boards of pharmacy are key to insuring the safety of the public. The draft report does not mention any public health hazards related to pharmacist incompetence. Medication errors committed by all health care practitioners contribute to problems in the health care system. The report may be viewed as incomplete without discussion of the public health hazard that an incompetent pharmacist poses to society.

There are some other areas of pharmacy practice in which state boards' of regulatory authority is not yet fully developed. Mail order prescriptions and non-pharmacist dispensing are two such areas. The report should include some analysis of the role of boards of pharmacy in regulating these areas.

We would also like to add our thoughts about the profession as we have seen it evolve. The pharmacy practice area is in a state of transition. At one end of the spectrum, we have practitioners who spend most of their professional time in the mechanics of prescription dispensing. At the other extreme are pharmacists who spend most of their time in direct patient care (clinical). The largest preponderance of practitioners have a mix of both dispensing and clinical activities. State boards are focused on regulating the activities of the dispensing group because that concept of practice is all that is embodied in state pharmacy law and regulations. It would be highly unrealistic and unwise to expect state boards to regulate the entire spectrum of pharmacy practice. This practice may inhibit the further development of the profession along clinical lines by tending to lock in the current state of practice, even if the focus might be on what is currently progressive.

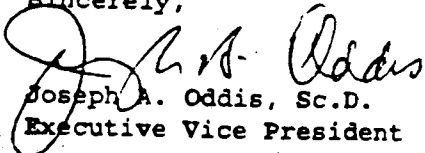
Pharmacy practice has moved toward the promotion of competency with the speciality practice areas and certifying specialists in a variety of practice settings. This recognition fosters the self-assessment and self-development of practitioners. The ASHP is working to meet the needs of these practitioners by the development of the many self-study instructional

materials, ACCRUE: Executive Management Seminar Series, and is committed to the development of a clinical staff development program. The ASHP's Practitioner Recognition Program is designed to foster excellence in practice and provide recognition to those practitioners willing to make the voluntary commitment to self-development. The educational focus of ASHP has been structured to meet the needs of the practitioners in the varied practice settings and encourages them to advance themselves.

Perhaps it should be considered to organize a conference to explore the most appropriate way to regulate pharmacy practice looking specifically at the outcomes of practice rather than the methods of practice. Currently, the possibility of such a conference is being pursued by the Joint Commission of Pharmacy Practitioners (JCPP).

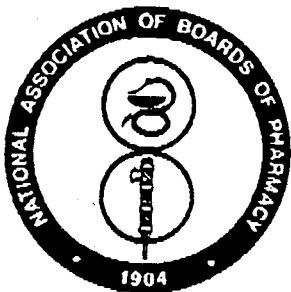
We hope that the staff comments and recommendations will be useful in the preparation of the final report. Call on us again should your office need additional input.

Sincerely,

  
Joseph A. Oddis, Sc.D.  
Executive Vice President

JAO:JB/skr031900w

cc: Board of Directors



nabp

National Association of Boards of Pharmacy

O'Hare Corporate Center • 1300 Higgins Road • Suite 103  
Park Ridge, IL 60068 • 312/698-6227

March 8, 1990

Mr. Richard Kusserow  
Inspector General  
Department Of Health & Human Services  
Office of the Inspector General  
Washington, DC 20201

Dear Inspector General Kusserow:

Thank you for providing the National Association of Boards of Pharmacy (NABP) with this opportunity to comment on the draft report of the "State Discipline of Pharmacists." NABP is the national association that represents the state boards of pharmacy in all 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, some provinces of Canada, and the Pharmacy Board of Victoria, Australia.

We commend the staff of the Boston Regional Inspector General for Evaluation and Inspections office for their careful and detailed analysis of the State pharmacy boards. The report objectively identifies critical issues with a clear understanding of the intricate and delicate nature of pharmacy regulation. The report recognizes the problems imposed on the State pharmacy boards by understaffing and inadequate resources and emphasizes the need for the State pharmacy boards to be empowered with the broadest form of penalties, including the right to reprimand and fine, in order to be fully effective.

NABP appreciates the complimentary remarks made in regard to our efforts to provide the State pharmacy boards with assistance in meeting their responsibility to protect the public health and welfare. We look forward to working with the Office of the Inspector General, the Public Health Service, and other government agencies to accomplish the recommendations outlined in the report.

**SPECIFIC COMMENTS:**

**INTRODUCTION:**

**Page 1 Federal Acknowledgement of the Role of State Boards of Pharmacy.**

NABP concurs that State pharmacy boards serve as the "frontline of protection for the health and safety of the public." It is essential that both federal and state governments increase their support and cooperative efforts with State pharmacy boards in order to keep this "frontline of protection" operable and effective.

**FINDINGS:**

**Page 4 The enforcement responsibilities of State pharmacy boards have become increasingly complex and challenging in recent years because of changes in pharmacy practice and the problem of drug diversion.**

The OIG report accurately recognizes that the practice of pharmacy has changed dramatically in recent years. As noted in the report, the challenge now facing State pharmacy boards is how to effectively regulate this changing practice. At the minimum, NABP agrees with the OIG report that State pharmacy boards must translate clinical pharmacy services into State regulatory requirements for governing the practice of pharmacy. However desirable such a translation may be, it can occur only if State pharmacy boards are empowered by legislative changes to broaden the definition of the practice of pharmacy to encompass more than the mere dispensing of a drug product.

**Page 8 Most of the increase in the most serious disciplinary actions between 1986 and 1988 is attributable to three states.**

On pages A-2 and A-3 of Appendix I, the report notes that the analysis of disciplinary actions may not be "completely accurate or all-inclusive." Recognizing the limits of the study and the incomplete data, it would be useful to clarify the above statement with the actual data. At the minimum, it is necessary to identify the three states responsible for skewing the overall increase in disciplinary actions.

It is important to recognize that, although the number of serious disciplinary actions imposed by a board is a good external evaluator, it is one of many indicators. It has been our experience that State pharmacy boards are much more active in protecting the public health than is indicated by the disciplinary data information contained in the OIG report. As mentioned in the report, educational programs as well as informal and formal interventions by administrative staff also have a dramatic effect on the protection of the public health. Unfortunately, outcome measures examining the overall effect of the total spectrum of State pharmacy board actions have not been defined or analyzed.

State pharmacy boards are taking a more active role in addressing the quality of care and clinical aspects of pharmacy practice. While the progress to date has been slow and, at times, erratic, it can proceed at a faster pace with the assistance of the Office of the Inspector General and other government agencies.

The limited use of peer review by many professional pharmacy associations, particularly in comparison with that in some other professions, makes the disciplinary performance of pharmacy boards, all the more significant.

We agree that the disciplinary performance of State pharmacy boards is significant, because no other process for review exists. However, we strongly advise against the development of any peer review system by professional organizations for use by the State pharmacy boards.

A review process conducted by organizations like the American Pharmaceutical Association (APhA), internal to its members and goals, is needed and long overdue. The development of such a system could enhance the regulatory efforts of the State pharmacy boards by increasing voluntary compliance with the law. The NABP Foundation's Bureau of Voluntary Compliance (BVC) is charged with exactly this purpose. Over the past ten years, the BVC has developed educational programs, video tape presentations, and seminars to promote voluntary compliance among the nation's pharmacists. Representatives from the Food and Drug Administration, Drug Enforcement Agency, and

(Continued)

Consumer Product Safety Commission participate in the BVC meetings and programs and hold ex-officio member status. NABP would certainly welcome the Office of the Inspector General's participation in the meetings and deliberations of this important committee.

Peer review systems designed with this purpose in mind would better serve the public health. Establishing peer review systems, simply because they presently do not exist, may be detrimental. It would seem more prudent to follow the recommendations of the OIG report and concentrate our resources towards increasing the activity of State pharmacy boards in quality of care issues and in the clinical aspects of pharmacy practice. A peer review system organized through APhA could then be used to baseline the standards of care of the community of practicing pharmacists.

Any violation of the State pharmacy practice act, which would be expanded to meet the changes in practice and include clinical functions, should be reported to, and acted upon, by the State pharmacy board where constitutional authority and due process are already in place. Such authority should not be placed with peer review systems that are organized through the auspices of a professional interest association.

Many of the problems other health professions are currently facing in regard to their disciplinary activity are the result of relying solely upon peer review systems outside the legal authority of their State licensing boards. The National Disciplinary Data Bank was enacted to correct the failed efforts of some professions to discipline incompetent or dangerous practitioners. The peer review systems that other professions rely upon are often rendered ineffective by threatened legal action.

The current structure of the State pharmacy boards and the authority empowered to them by their State pharmacy practice acts is working well. Although many of these pharmacy practice acts may need to be updated in order to meet the challenges of the future, they should not be replaced or circumvented.



Drug Diversion

Protecting the American public from the untoward and dangerous effects of drug diversion is a crucial item on the regulatory agenda of State pharmacy boards. If our nation's drug delivery system is to remain safe, we must prevent and halt drug diversion. The OIG report acknowledges the time and effort that State pharmacy boards devote to combating this scourge and notes that this concentrated effort is diverting attention from other regulatory areas, such as continued competence. State pharmacy boards need additional federal funding and support in order to continue their present efforts in the fight against drug diversion and to expand their responsibilities to meet the future challenges of pharmacy practice.

The Prescription Drug Marketing Act of 1987 provides a framework for State pharmacy boards to curtail drug diversion activities through State licensure of wholesalers and drug distributors. We urge federal agencies to support the efforts of the State pharmacy boards to implement this Act and to develop additional legislation to stop drug diversion.

One particular comment in the report that merits attention, "The law defines a corresponding responsibility for pharmacists to fill only legitimate prescriptions and makes them accountable for the prescriptions they dispense." While this may be the OIG's view of the law, the courts do not follow this concept from either a disciplinary standpoint or from a civil liability standpoint. On several occasions, NABP has emphasized the fact that the courts narrowly construe the pharmacist's professional role, limiting the duty of the pharmacist to appropriately filling legitimate prescriptions. State boards of pharmacy are moving towards defining that corresponding responsibility cited in the OIG report, i.e., defining quality of care and competence standards. Let us hope that the courts will cooperate with this changing concept.

Quality of Care

According to the OIG report, case study States reported, "that although their practice acts included incompetence as grounds for discipline, their boards had rarely, if ever, disciplined

(Continued)

pharmacists for incompetence." Furthermore, the report contends that "no mechanisms have been widely instituted for assessing the continued competence of practicing pharmacists."

State pharmacy boards have difficulty enforcing competency issues for a number of reasons. The report indicates that a primary reason is the fact that no consensus exists regarding definitions or standards. Efforts by the State pharmacy boards to move ahead in this area are vigorously opposed by special interest groups. State pharmacy boards are often defeated by the intensive lobbying efforts of these special interest groups.

The State pharmacy boards would most likely accept this responsibility if the accompanying standards and definitions are also enacted. Unfortunately, in the face of such strong opposition from the special interest groups, passage of such requirements seems impossible unless the OIG report is taken to heart by state governments and legislatures.

The NABP Model Act mentioned in the OIG report does define the practice of pharmacy and addresses standards of practice which can be implemented by appropriate regulation.

Pages 14-15

Insufficient Legal Authorities

We agree with the OIG report that the grounds for discipline contained in the pharmacy practice acts are sometimes vaguely defined. Grounds for discipline are broadly defined in order to provide the board with the widest latitude in which to implement the grounds through appropriate rules and regulations. NABP recommends the continuation of such generalities in order to provide the appropriate latitude for enforcement.

We are concerned with the report's finding that emergency suspensions "can take as long as two years to obtain." Normally, statutes that permit

(Continued)

the suspension of a license on an emergency basis can be quickly implemented. It is the finalization of such an emergency suspension that can take a long period of time. However, once under emergency suspension, a license can only be restored through the courts.

NABP believes that the State pharmacy boards are empowered with more authority than some realize. The problem lies with the inability of some State pharmacy boards to exercise this authority effectively because they are understaffed, lack the resources, or are reluctant to be proactive.

Administrative Barriers

The OIG report's discussion of administrative barriers supports NABP's concept of an effective disciplinary clearinghouse. In fact, NABP must aggressively pursue State pharmacy boards to gain their cooperation to voluntarily submit disciplinary action information to the Association for distribution among the other State pharmacy board members.

Since the completion of the OIG report, the NABP Disciplinary Clearinghouse has been fully computerized. Almost all State pharmacy boards now participate in the NABP Clearinghouse. Additionally, the FDA and NABP have agreed to share disciplinary information concerning wholesalers and manufacturers in order to increase the reporting of such information to the State pharmacy boards and to allow for the more effective resolution of enforcement problems through federal and state cooperation.

The report also recognizes the problems that exist in "...the time consuming nature of the disciplinary process itself." Many times, however, State pharmacy boards cannot control this process. It is a function of how often a State pharmacy board meets, which is often directly related to the resources available to the board. Additionally, the system is slowed by delays permitted by boards and hearing officers and other legal maneuvering of attorneys.

(Continued)

The delay imposed on the disciplinary system by the insufficient resources noted in the OIG report is a serious matter. Some states have dealt with this problem by centralizing licensing boards under one umbrella agency. The information we have collected seems to indicate that centralization often dilutes already scarce resources and decreases regulatory effectiveness.

**RECOMMENDATIONS:**

NABP supports the recommendations of the report that call for increased support and funding for State pharmacy boards. We will continue our efforts to serve a leadership role for the State pharmacy boards as they begin to address the changing nature of pharmacy practice. We caution against the creation of peer review groups unless their purpose is well defined and activities tightly controlled.

In closing, we want to again indicate that NABP is most eager to work with the Office of the Inspector General, the Public Health Service, and other government agencies to ensure that the public health and welfare is protected.

Sincerely,

NATIONAL ASSOCIATION  
OF BOARDS OF PHARMACY

*C. A. Catizone (SS)*

C. A. Catizone  
Executive Director

CC/ps

cc NABP Executive Committee  
State Boards of Pharmacy



# National Clearinghouse on Licensure, Enforcement and Regulation

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WA Dept. of Health

John B. Welsh, Jr.  
Senior Counsel  
WA House of Representatives

March 30, 1990

Martha B. Kvaal  
Deputy Regional Inspector General  
for Evaluation and Inspections  
U.S. Dept. of Health and Human Services  
JFK Federal Building Room 1407  
Boston, Massachusetts 02203

Dear Ms. Kvaal:

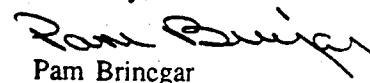
It has been our pleasure to review the January, 1990 draft copy of *State Discipline of Pharmacists*. This is a very thorough document that captures and presents in an informative manner current disciplinary practices among pharmacy boards. There is little doubt that there will be general agreement with the finding that an obvious need exists in many states for more statutory authority before appropriate disciplinary actions can be taken against pharmacists.

With respect to the information we are given that 97% of the recent increase in "most serious disciplinary actions" has occurred in just three states and that further, 15 states took 10 or fewer of these "most serious actions" for the period 1986-88, it would have been helpful to understand what accounted for the increase or lack of increase in such actions. While the correlation made with location and size is interesting, it does not necessarily explain what is going on in these states.

We feel it is particularly important that the report points out the need for the field of pharmacy to address the issues of standards for quality of care and the need to share information on disciplinary actions taken. With regard to the latter, we appreciate that you mention CLEAR as a repository for state board disciplinary actions and agree that reporting to both CLEAR's National Disciplinary Information System (NDIS) and the National Association of Boards of Pharmacy (NABP) Disciplinary Clearinghouse is an extremely important step toward resolving this problem. We also agree that it is not in a health profession's best interest to wait for operation of the National Practitioner Data Bank (NPDB) to begin the practice of reporting information to a central repository. Through delay, valuable disciplinary information is lost that could stop practitioners from crossing state lines to resume practice without challenge simply because appropriate information was not shared. Also, as a practical administrative matter, it will be far simpler for boards that are in the practice of sharing disciplinary information to comply with the requirements of the NPDB.

Thank you for the opportunity to comment on this report.

Sincerely,

  
Pam Brincgar  
Project Director, NDIS



Affiliate Organization of The Council of State Governments

## APPENDIX B

### INCIDENCE AND RATE OF SERIOUS DISCIPLINARY ACTIONS IMPOSED BY STATE BOARDS ON PHARMACISTS AND PHARMACIES BY STATE 1986-1988<sup>1</sup>

State	Licensees (2)	1986		1987		1988		Total	
		Actions	Rate	Actions	Rate	Actions	Rate	Actions	Rate
AK	408	0	0.00	1	2.45	1	2.45	2	4.90
AL	4422	17	3.84	20	4.52	25	5.65	62	14.02
AR	2506	11	4.39	14	5.59	10	3.99	35	13.97
AZ	2989	3	1.00	7	2.34	9	3.01	19	6.36
CA	25912	94	3.63	58	2.24	61	2.35	213	8.22
CO	2643	2	0.76	1	0.38	2	0.76	5	1.89
CT	3278	6	1.83	11	3.36	7	2.14	24	7.32
DC	976	4	4.10	4	4.10	0	0.00	8	8.20
DE	482	1	2.07	6	12.45	1	2.07	8	16.60
FL	12648	42	3.32	65	5.14	69	5.46	176	13.92
GA	7428	46	6.19	56	7.54	52	7.00	154	20.73
HI	952	1	1.05	0	0.00	1	1.05	2	2.10
IA	2928	10	3.42	12	4.10	12	4.10	34	11.61
ID	990	2	2.02	1	1.01	7	7.07	10	10.10
IL	11139	120	10.77	136	12.21	216	19.39	472	42.37
IN	7734	27	3.49	15	1.94	18	2.33	60	7.76
KS	2616	1	0.38	4	1.53	3	1.15	8	3.06
KY	3853	16	4.15	18	4.67			34	8.82
LA	4669	9	1.93	17	3.64	12	2.57	38	8.14
MA	7896	25	3.17	21	2.66	20	2.53	66	8.36
MD	4545	7	1.54	8	1.76	10	2.20	25	5.50
ME	906	1	1.10	1	1.10	4	4.42	6	6.62
MI	9141	18	1.97	36	3.94	42	4.59	96	10.50
MN	4108	22	5.36	29	7.06	21	5.11	72	17.53
MO	5066	22	4.34	33	6.51	41	8.09	96	18.95
MS	2960	47	15.88	61	20.61	27	9.12	135	45.61
MT	1007	2	1.99	0	0.00	1	0.99	3	2.98
NC	6267	16	2.55	17	2.71	11	1.76	44	7.02
ND	918	3	3.27	1	1.09	1	1.09	5	5.45
NE	2262	4	1.77	5	2.21	4	1.77	13	5.75

NH	860	5	5.81	9	10.47	5	5.81	19	22.09
NJ	7185	15	2.09	6	0.84	3	0.42	24	3.34
NM	1986	2	1.01	2	1.01	3	1.51	7	3.52
NV	834								
NY	18193								
OH	10532	40	3.80	16	1.52	23	2.18	79	7.50
OK	6050	3	0.50	3	0.50	3	0.50	9	1.49
OR	2392	12	5.02	15	6.27	11	4.60	38	15.89
PA	13625	1	0.07	11	0.81	24	1.76	36	2.64
RI	991	6	6.05	3	3.03	5	5.05	14	14.13
SC	3478	10	2.88	8	2.30	20	5.75	38	10.93
SD	861	2	2.32	0	0.00	2	2.32	4	4.65
TN	5627	15	2.67	21	3.73	59	10.49	95	16.88
TX	17148	52	3.03	86	5.02	62	3.62	200	11.66
UT	1541	5	3.24	2	1.30	13	8.44	20	12.98
VA	4930	13	2.64	6	1.22	14	2.84	33	6.69
VT	578	3	5.19	3	5.19	0	0.00	6	10.38
WA	4429	27	6.10	18	4.06	16	3.61	61	13.77
WI	4912	4	0.81	13	2.65	12	2.44	29	5.90
WV	1637	1	0.61	2	1.22	0	0.00	3	1.83
WY	455	4	8.79	2	4.40	6	13.19	12	26.37

- (1) As reported by State pharmacy board officials to the Office of Inspector General, HHS, May-June 1989. Actions included in these figures are revocations, suspensions, probations, and voluntary surrenders for both pharmacists and pharmacies. New York and Nevada provided no data; Oklahoma provided figures only for revocations; and Kentucky provided data for 1986 and 1987 only.
- (2) Number of active pharmacists plus number of licensed pharmacies as reported to the National Association of Boards of Pharmacy by States in 1987. For those States not reporting to the NABP, the OIG obtained data by telephone from the state pharmacy boards.

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## APPENDIX C

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### METHODOLOGICAL NOTES

The information for this inspection is based on four lines of inquiry:

- Review of pertinent literature and relevant data bases, including studies, books, articles from professional newsletters and journals, publications and papers from various private and public organizations, and statistical data aggregated by private and public organizations.
- Telephone discussions with representatives of the State pharmacy boards during the spring of 1988 and the spring of 1989. In 1988 we talked with representatives from 42 States and the District of Columbia about the major challenges facing their boards, the major reasons for disciplinary actions, primary sources of information about potential cases, and recent significant changes in authorities. In 1989 we talked with representatives from all 50 States and the District of Columbia to obtain quantitative data on disciplinary actions and discussed drug diversion, foreign-trained pharmacists, exemplary board practices and barriers to effectiveness. In most cases we talked with the chief executives of the boards, but in a few instances we spoke with other staff suggested to us by the executives.
- Visits of 2 to 3 days each to six States (CA, FL, MA, MI, NY, TX) for discussions with pharmacy board representatives which typically included the board president, the public member of the board, the chief executive, an inspector, and an attorney. We deliberately chose States which were among the largest in terms of numbers of pharmacists and pharmacies, of Medicare beneficiaries and Medicaid recipients, and of Medicaid payments for prescription drugs in 1987. These States represented all sections of the country as well as diversity in their organizational structure. Finally, we had shorter personal discussions with staff from nine smaller States during the annual meeting of the NABP in Charleston, South Carolina in May 1989.
- Discussions with representatives of organizations and agencies concerned with issues related to State pharmacy boards. These included staff from the FDA, PHS, and HCFA within the Department of Health and Human Services, the Drug Enforcement Administration, American Association of Colleges of Pharmacy, The American Council on Pharmaceutical Education, American Pharmaceutical Association, National Association of Boards of Pharmacy, National Association of State Controlled Substances Authorities, National Clearinghouse on Licensure, Enforcement and Regulation, the United States Pharmacopeial Convention, Inc., and staff from several State pharmacy associations.



## Numbers of Pharmacists and Pharmacies

There is considerable uncertainty about the number of pharmacists in the United States today. The Public Health Service in its *Sixth Report to the President & Congress on the Status of Health Personnel in the United States* includes pharmacy manpower estimates projected from figures obtained in the 1970s. These projections are considered unreliable by many in the pharmacy profession. Yet the currently available State-specific data on licensed pharmacists double count those pharmacists licensed in more than one State and do not distinguish those in active practice from those who are not currently practicing.

After discussions with representatives from the PHS and the NABP, we decided to use data on the active pharmacists and licensed pharmacies provided by the States to the NABP in 1987. These estimates are published by NABP in its *1988-1989 Survey of Pharmacy Law*. We telephoned the board executives from those few States not included in the NABP report to obtain estimates from them on the number of active pharmacists or pharmacies in their States.

The figure we used for the total number of active pharmacists nationwide is 183,946. The figure we used for the number of licensed pharmacies is 67,947. Our quantitative analysis of disciplinary actions and our size groupings of the States are based on these estimates.

## Analysis of Disciplinary Actions

During May and June 1989 we talked with pharmacy board officials in every State and the District of Columbia for data on the disciplinary actions taken by the boards against both pharmacists and pharmacies in 1986, 1987, and 1988. We asked for the number of revocations, suspensions, probations, voluntary surrenders, or other formal actions they specified.

Forty-seven boards were able to provide us with data for all 3 years, although they could not always provide a separate count for actions against pharmacists and against pharmacies. Two States—Nevada and New York—could not provide the data for any of the 3 years. Oklahoma provided figures only for revocations, and Kentucky could not provide data on 1988 actions.

We cannot confirm that the data on disciplinary actions is completely accurate or all-inclusive. We did try to resolve any questions or inconsistencies with follow-up telephone calls to the board officials who, typically, were very responsive.

We found that some States kept records on disciplinary actions by fiscal year rather than calendar year. For these States, we included in our analysis their 3 most recent and complete years of data. We also analyzed the data for a 3-year period in order to eliminate year-to-year fluctuations and to draw more reliable conclusions. In so doing, we combined disciplinary actions reported for both pharmacists and pharmacies because many States could not separate the two and because oftentimes boards take action against both the pharmacist and the pharmacy in a given case. Finally, we computed a rate of discipline for the 3-year period for

each State. We divided the numbers of actions taken against both pharmacists and pharmacies by the combined number of active pharmacists and licensed pharmacies in each State.

### **Groupings of States by Region and Size**

We analyzed the data on disciplinary actions provided to us by the board executives according to groupings we identified based on size and region of the country. In both these groupings, we omitted Nevada and New York because their data was not available.

With respect to region, we used the U.S. Bureau of the Census categorizations to identify four regions of the country. They are as follows:

- 1 Northeast: CT, MA, ME, NH, NJ, PA, RI, and VT.
- 2 South: AL, AR, DC, DE, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, and WV.
- 3 Midwest: IA, IL, IN, KS, MI, MN, MO, NE, ND, OH, SD, and WI.
- 4 West: AK, AZ, CA, CO, HI, ID, MT, NM, OR, UT, WA, and WY.

With respect to size, we used variance analysis to identify five clusters of States based on the number of active pharmacists and licensed pharmacies. They are as follows:

- 1 Extra-Small: AK, DC, DE, HI, ID, ME, MT, ND, NH, RI, SD, VT, and WY.
- 2 Small: AR, CO, IA, KS, MS, NE, NM, OR, UT, and WV.
- 3 Medium: AL, AZ, CT, KY, LA, MD, MN, MO, NC, OK, SC, TN, VA, WA, and WI.
- 4 Large: GA, IL, IN, MA, MI, NJ, and OH.
- 5 Extra-Large: CA, FL, PA, and TX.

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## APPENDIX D

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### ENDNOTES

1. For a more extensive discussion of State licensing boards, see:

Doug Roederer and Benjamin Shimberg, *Occupational Licensing: Centralizing State Licensure Functions*, Council of State Governments, Lexington, Kentucky, 1980.

Benjamin Shimberg, *Occupational Licensing: A Public Perspective*, Educational Testing Service, 1980.

2. The American Association of Colleges of Pharmacy and the National Association of Boards of Pharmacy are co-managers of the Pharmacy Manpower Project. This project, supported by 13 major pharmacy organizations, is a recent effort to gather more comprehensive data on pharmacists than is currently available. (See appendix C for additional detail about the sources of our manpower estimates.)
3. These responsibilities are being further expanded by the Prescription Drug Marketing Act of 1987 which requires the States to license wholesale prescription drug distributors according to Federal guidelines.
4. *Scheduling Authorities Directory 1988*, National Association of State Controlled Substances Authorities, The Council of State Governments, Lexington, Kentucky.
5. U.S. Department of Human Services, Public Health Service, Food and Drug Administration, *State Law Data*, 1989.
6. *Survey of Pharmacy Law—1988-1989*, National Association of Boards of Pharmacy, Park Ridge, Illinois.  
  
Resources and Responsibilities Survey of all pharmacy board executives by NABP in early 1989.
7. Charles D. Hepler, "The Third Wave in Pharmaceutical Education: The Clinical Movement," *American Journal of Pharmaceutical Education*, Volume 51, Number 4, Winter 1987.  
  
U.S. Department of Health and Human Services, Office of Inspector General, Office of Analysis and Inspections, *Clinical Pharmacy for Ambulatory Patients*, Inspection Number OAI-01-89-89160, draft report, January 1990.
8. Samuel H. Kalman and John F. Schlegel, "Standards of Practice for the Profession of Pharmacy," *American Pharmacy*, Volume NS19, Number 3, March 1979.

9. For elaboration on changes in pharmacy, see:

“The Continuing Competence of Pharmacists, Final Report of the AACP/APhA Task Force on Continuing Competence in Pharmacy,” *Journal of the American Pharmaceutical Association*, Volume NS15, Number 8, August 1975.

“Pharmacy in the 21st Century”, Executive Summaries of Strategic Planning Conferences, March 25-28, 1984 and October 11-14, 1989, American Association of Colleges of Pharmacy.

Nicholas G. Popovich, Ph.D., “Emerging Practice Activities: Specialist and Technician Roles in Pharmacy”, *NABP Newsletter*, Volume 18, Number 3, March 1989.

U.S. Department of Health and Human Services, Public Health Service, *Sixth Report to the President & Congress on the Status of Health Personnel in the United States*, June 1988, pp. 8-1 to 8-17.

10. “State boards up close: How pharmacists rate them”, *Drug Topics*, May 19, 1986, p. 32.

11. Telephone discussions with State pharmacy board executives, Office of Analysis and Inspections, OIG, spring 1988.

12. U.S. General Accounting Office, *Retail Diversion of Legal Drugs—A Major Problem With No Easy Solution*, GGD-78-22, March 1978.

U.S. General Accounting Office, *Comprehensive Approach Needed to Help Control Prescription Drug Abuse*, GGD-83-2, October 1982.

U.S. Department of Justice, Drug Enforcement Administration, *Multiple Copy Prescription Programs Resource Guide*, July 1987.

13. For a more detailed discussion of non-therapeutic dispensing, see Carol E. Fisher, Harvey Dunham, Fred S. Brinkley, Jr., “Controlling Non-Therapeutic Dispensing in the State of Texas,” Texas State Board of Pharmacy, April 1989.

14. *Survey of Pharmacy Law—1988-1989*, op. cit.

U.S. Department of Health and Human Services, Office of Inspector General, *Clinical Pharmacy for Ambulatory Patients*, op. cit.

15. Telephone discussions with State pharmacy board executives, Office of Analysis and Inspections, OIG, Spring 1988.

16. Data on types of penalties and grounds for discipline derive from the 1989 NABP survey of State pharmacy board executives.

17. U.S. Department of Justice, Drug Enforcement Administration, *Multiple Copy Prescription Programs Resource Guide*, op. cit. Information also based on personal interview with staff from the Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.
18. U.S. Department of Justice, Drug Enforcement Administration, "Committee Report on CSA Laws Presented at the 2nd National Conference on the Control and Diversion of Controlled Substances," Tucson, Arizona, 1986.
19. These data include actions for both pharmacists and pharmacies. Although pharmacy boards frequently discipline both as part of the same case, pharmacists are disciplined much more frequently than pharmacies overall. We include actions against both because many boards were unable to provide us with separate data for each.
20. Widespread variation existed in the types of these other formal penalties and in the extent to which the same penalty was considered formal or informal by different boards. Further, the boards reported often imposing these other penalties in combination with the most serious penalties and were often unable to give us unduplicated counts.
21. We aggregated the data reported on revocations, suspensions, probations, and voluntary surrenders for both pharmacists and pharmacies for the entire 3-year period. We computed rates of disciplinary actions per 1000 active pharmacists and pharmacies in each State as reported to the NABP (see appendices B and C).
22. *Survey of Pharmacy Law—1988-1989*, op. cit., p.50.
23. We provided each of our case study States with a listing of those pharmacists and pharmacies sanctioned by OIG since 1984 whose exclusion was still in effect as of October 31, 1988. There were 114 providers among the six States. Our analysis of the States' responses showed that the States had also disciplined three-fourths of these providers and that, in nearly two-thirds of these cases, State action preceded the OIG exclusion notice. The States reported having taken no action against 18 percent of these providers. Approximately 7 percent of these providers had State action pending against them at the time of our inquiry.
24. Telephone discussions with State pharmacy board executives, Office of Analysis and Inspections, OIG, spring 1989. The ARCOS (Automation of Reports and Consolidated Orders System) is a computerized tracking system instituted by the DEA to monitor the distribution of selected controlled substances by drug manufacturers and distributors based on quarterly or monthly reports filed by these companies with the DEA.
25. U.S. Department of Justice, Drug Enforcement Administration, "Pharmacist's Manual," April 1986.

26. *Helping the Impaired Pharmacist, A Handbook for Planning and Implementing State Programs*, American Pharmaceutical Association, Washington, D.C., 1985, p. 1.

For further background information on therapeutic approaches to pharmacists' impairment, see also Ronald L. Williams, "Helping our Impaired Colleagues—We're on a Roll!" American Pharmaceutical Association, Washington, D.C., September 1988.

27. In our discussions, we defined incompetence as a deficiency in minimal skills or knowledge which adversely affect professional judgment.
28. The AACP, APhA and NABP are presently reviewing the 1979 Standards of Practice. The boards must deal with how best to translate these professional standards into regulatory requirements.
29. Daniel A. Nona, W. Robert Kenny and David K. Johnson, "The Effectiveness of Continuing Education as Reflected in the Literature of the Health Professions," *American Journal of Pharmaceutical Education*, Volume 52, Summer 1988.
30. Data on types of penalties and grounds for discipline derive from the 1989 NABP survey of State pharmacy board executives.
31. We attempted to examine the funding levels of pharmacy boards over the last several years but were unable to locate any comprehensive data. The NABP surveys all the boards biannually for updated information on their resources and responsibilities. Although 50 boards responded to the 1989 survey, only 39 provided information on the level of their current budgets. The information available from the last biannual survey was aggregated in a form not useful for comparisons with this year's data.
32. This analysis of fees is based on data included in *Survey of Pharmacy Law*, op. cit., for the years 1988-1989 and 1987-1988.
33. Resources and Responsibilities Survey of all pharmacy board executives by NABP in early 1989. Responses varied from two States having 16 inspectors to one State reporting no inspector because the board executive conducts the inspections. The average number of inspectors among the States responding was 4.7; nearly half the States had no more than three inspectors. In only slightly more than half the States were the inspectors employed directly by the board rather than by another State agency.
34. *Survey of Pharmacy Law 1988-1989*, op.cit., p. 5.
35. White House Conference for a Drug Free America, Final Report, June 1988.
36. "The Continuing Competence of Pharmacists, Final Report of the AACP/APhA Task Force on Continuing Competence," op. cit.

37. Samuel H. Kalman and John F. Schlegel, "Standards of Practice for the Profession of Pharmacy," op. cit.
38. Benjamin Shimberg, "What is Competence? How Can It Be Assessed?" *Power and Conflict in Continuing Professional Education*, edited by Milton R. Stein, Wadsworth, Inc., 1983.