



OHIO STATE BOARD OF PHARMACY

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-Equal Opportunity Employer and Service Provider-

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ANNUAL REPORT TO THE OHIO PHARMACISTS ASSOCIATION

APRIL 5, 1997

MISSION OF THE BOARD

The Ohio State Board of Pharmacy shall act efficiently, consistently, and impartially in the public interest to pursue optimal standards of practice through communication, education, legislation, licensing, and enforcement.

GOALS

The goals of the Ohio State Board of Pharmacy are to effectively and efficiently administer and enforce the laws governing the legal distribution of drugs and the practice of pharmacy. The purpose of these laws is to ensure the quality and safety of drugs administered or dispensed to Ohio's citizens; the competency of persons licensed to practice pharmacy in Ohio; and to prevent the diversion of drugs of abuse from the legal channels of distribution for illegal purposes.

INTRODUCTION

The Board is pleased to present this report to the members of the Association at its 117th annual meeting. If you have the opportunity to be around long enough, it is obvious that our society tends to forget the experiences and lessons of the past and the same mistakes are repeated. The Executive Director begins this report by discussing past and present experiences that are similar and have serious implications during the next few years.

DRUGS AND SOCIETY

Phrases and terms commonly seen in today's news include the terms "junk science", "miraculous cure", "drug abuse", "legal drugs", "dietary supplements" and "natural source." One of the most disturbing trends today is the deceptive and dangerous marketing of substances that have the potential to cause adverse effects as safe since they are "natural products", "food," "dietary supplements", and/or "over-the-counter drug products." Even more disturbing is the fact that legislation is readily adopted at both the state and federal level that further legitimizes these concepts to the detriment of society.

Society is becoming more tolerant of “risk taking” on the behalf of individuals and their rights while struggling with increasing health care costs and the provision of quality health care to all of its citizens. This increased tolerance to “risk taking” is marked by the passage of laws such as the “Dietary Supplement Health and Education Act of 1994”, increased efforts on the part of drug manufacturers and marketers to switch more “prescription drugs to over-the-counter status”, and continuing efforts to provide quicker approval of new prescription drugs by the federal Food and Drug Administration. Each of these efforts exposes a greater percentage of the population to “risk” and the potential for death or injury. Only after a significant number of persons have suffered serious harm, and/or a significant number of deaths have occurred, will dangerous drug products, both over-the-counter and prescription, be removed from the marketplace. We tend to forget that drugs not only have the potential to do good but can also cause harm.

Our society is quickly moving away from the precepts that drugs may not be marketed until they have been proven not only safe but also effective. The premise that the risk of harm should be minimal has been replaced with “post marketing” surveillance mechanisms and the removal of a drug product from the market only after a significant number of individuals have been seriously harmed or have died from its adverse effects.

Lessons in the past have included the “non-addictive” drugs marketed in the 1900’s. These include heroin in the form of a cough syrup; the marketing of cocaine-containing products based on their energizing and mood enhancing effects, and cannabis as a calmative.

Cocaine, a significant drug of abuse today, was also a problem in the late 1800’s. Commercially available purified cocaine became available in the United States in 1884 and problems with its abuse and misuse was evident almost immediately. The voices of prominent medical experts promoted the use of cocaine as a “remarkable, harmless stimulant”. William A. Hammond, Surgeon General of the United States and a prominent neurologist, assured the public in print and lectures that it was no more habit-forming than coffee or tea.

Within a year of its availability as a commercially available drug, the Parke-Davis Company marketed cocaine in 15 different forms, including coca cigarettes, cocaine for injection, and cocaine for sniffing. The company promoted cocaine as a drug that “can supply the place of food, make the coward brave, the silent eloquent and ... render the sufferer insensitive to pain.”

Today’s drugs of abuse that have been introduced and marketed as not being habit-forming or addictive are carisoprodol (Soma™), butorphanol (Stadol™), and tramadol (Ultram™). Experience in the marketplace, however, is proving these claims to be wrong.

Ensuring the safety of drug products prior to marketing is no longer a requirement in the present regulatory scheme of F.D.A. This is due to the increasing political pressure being placed on F.D.A. to quickly approve drugs for marketing. This reliance upon post-marketing surveillance to identify any adverse events that are significant is demonstrated by the marketing of the non-steroidal anti-inflammatory drug ketorolac tromethamine (Toradol™). Following several years in the marketplace and a post-marketing surveillance study of approximately 10,000 patients, the manufacturer issued an important drug warning to all doctors in 1995 that stated the following:

WARNING

TORADOL, a nonsteroidal anti-inflammatory drug (NSAID), is indicated for the short-term (up to 5 days) management of moderately severe acute pain, that requires analgesia at the opioid level. It is NOT indicated for minor or chronic painful conditions. TORADOL is a potent NSAID analgesic, and its administration carries many risks. The resulting NSAID-related adverse events can be serious in certain patients for whom TORADOL is indicated, especially when the drug is used inappropriately. Increasing the dose of TORADOL beyond the label recommendations will not provide better efficacy but will result in increasing the risk of developing serious adverse events.

“Hyperbole” seems to be the standard for the promotion and marketing of products without regard for their potential or ability to cause harm or death if consumed by the public. “Junk science” seems to be the order of the day, and a large percentage of the public is willing to accept as fact anything that is published often enough or if published in widely-read publications such as “Readers Digest”. A perfect example of this phenomenon is the “Fen-Phen” treatment for the “serious, debilitating, and life-threatening disease of obesity”. A book titled Thinner At Last has been published by an M.D. and bears the following promotional language on the front flap of the book cover:

For the first time in medical history, truly permanent weight loss is possible through a remarkable news drug program that has already helped thousands of patients nationwide. In Thinner at Last, the eminent New York internist Steven Lamm describes his extraordinary success with a drug program unlike any other available. The combination of two FDA-approved drugs, fenfluramine and phentermine, acts on the brain’s neurotransmitters to regulate the appetite control center, which is responsible for signaling fullness. These totally safe, fully endorsed medications are not amphetamines and are not addictive; they actually enhance the body’s natural inclination to be thin and healthy.

....

Now, at last, we have real and heartening proof that obesity is a chronic medical condition that can be treated pharmacologically – and successfully. This book is leading a powerful new medical movement that can bring relief to the 30 million Americans who are currently overweight and enable them to become thinner at last – not for a month or a year, but for a lifetime.

However, the March 1997 FDA Medical Bulletin reported the following regarding fenfluramine (Pondimin™):

The product labeling for Pondimin (fenfluramine HCl) has been revised to convey the final evaluation of the International Primary Pulmonary Hypertension Study. PONDIMIN IS AN APPETITE SUPPRESSANT, AND APPETITE SUPPRESSANTS INCREASE THE RISK OF DEVELOPING PRIMARY PULMONARY HYPERTENSION (PPH), AN OFTEN FATAL DISORDER. Use of appetite suppressants for longer than 3 months is associated with a 23-fold increase in the risk of developing PPH. Therefore, the risk associated with the long-term use of appetite suppressants is estimated to be about 23 to 46 cases per 1 million persons per year.

In January of this year, the manufacturer who markets Pondimin issued a letter to doctors and pharmacists advising them that “The use of phentermine and fenfluramine concomitantly is not an approved use of Pondimin. The manufacturer’s letter poses a dilemma for both the prescriber of these drugs and the dispensing pharmacist.

Both health professionals have been put on notice by the company that manufactures and markets both Pondimin™ and Redux™ in the United States that the one drug whose patent has or will soon expire (fenfluramine) has not been approved for concomitant use with phentermine. The company marketing these two drugs has just recently been granted five years of marketing exclusivity for Redux since it has been classified by FDA as a new molecular entity (NME). For these reasons, it is hard to determine if the manufacturer's letter is for public health reasons or marketing purposes.

Products now sold as food or dietary supplements that contain drugs that have the potential to cause harm or even death are promoted and marketed to the public without proof that they are safe or effective. The sale of these products cannot be restricted or withdrawn from the marketplace until the F.D.A. has determined that they pose an "imminent hazard" to the public. How many people have to experience a serious adverse event before action may be successfully taken by the FDA to remove a particular product from the market is not known.

Direct Marketing Of Prescription Drugs To The Public

Significantly increasing the public risk is the marketing of prescription drugs directly to the public – especially prescription drugs which have been quickly approved by F.D.A. without assurances that they are safe or effective. Examples are the drugs Oraflex™, Omniflox™, and most recently Seldane™. This is illustrated by the following excerpts from an article appearing in the Wall Street Journal that was written by Dr. Philip R. Alper, a clinical professor of medicine at the University of California at San Francisco.

Who to Trust: Drug Companies or Your Doctor?

Old timers may remember the Eli Lilly Co. as it was before the appearance of modern pharmaceutical marketing. A bastion of the ethical drug industry, Lilly was punctilious in its relations with physicians. Then came Oraflex.

It happened roughly two decades ago, and Oraflex was in the first wave of direct marketing to the public by drug manufacturers. Unfortunately for Lilly, in addition to relieving arthritis, Oraflex had a disconcerting way of causing the fingernails of its users to fall off. Less frequently, but more importantly, serious hepatic toxicity led to several fatalities. Oraflex was withdrawn from the market.

When the Food and Drug Administration approves a drug, usage expands from a few patients in clinical trials to the population at large. As a result, previously unseen drug complications then begin to show up because more patients are exposed.

In the past, new drugs were introduced into physician armamentariums in a gradual way. Doctors read the literature, attended conferences, were "detailed," and checked with colleagues. Some used the new drug sooner than others, but rare complications often became known even before many doctors had introduced it into their own practices.

All this has changed with the rapid pace of new-drug introductions and their accompanying market blitzes. The aim is to create consumer demand even before the doctor would be willing to use the drug spontaneously. Call it an end-run around the doctor, arm-twisting, manipulation or whatever. The result is the same.

....

The marketing of prescription drugs directly to the public where the system relies on post-marketing surveillance studies is a losing proposition for the public. This is especially true if the potential for profits significantly outweighs the liability potential from lawsuits by those patients who have suffered adverse reactions or their survivors.

The recent wave of tort reform regarding product liability throughout the United States has shifted the risk benefit ratio towards the manufacturer and the profit margin resulting from keeping products on the market that have the potential to cause serious adverse actions. It is common business knowledge that it's now likely to be more profitable if the company continues to market the product and settle any law suits later that may result from injuries or death.

Due to tort reform, significant profits can be realized during the time such lawsuits are pending, insignificant out-of-court settlements may be reached with the plaintiffs, or judgments resulting from a trial under tort reform are not likely to offset the profits realized from the continuing marketing of the product.

Caveat emptor.

113 YEARS OF PROFESSIONAL PEER REVIEW (1884-1997)

BOARD MEMBER APPOINTMENTS

Board Members Reappointed *(Term of Office: July 1, 1996 - June 30, 2000)*

Mr. Nicholas Repke, the first public member to be appointed to the Board, was re-appointed for a four-year term by Governor Voinovich. Mr. Repke is a resident of Gahanna, Ohio and holds a B.S. in Mechanical Engineering from the University of Illinois as well as an M.S. in Industrial Management from Purdue University. Mr. Repke has taken a very active role on the Board and was appointed by President Neuber as the Board member responsible for budget issues during this fiscal year.

Mr. Robert B. Cavendish, owner and operator of Lloyd's Drugs in Johnstown, Ohio, was also re-appointed to the Board for a second term. Mr. Cavendish's Board member responsibilities for FY 97 are legislation and rules. This responsibility includes serving as chair of the 1997 Ad Hoc Advisory Committee on Rule Review. Mr. Cavendish has practiced as a community pharmacist in the same pharmacy that he served his apprenticeship since obtaining his license in 1956. Mr. Cavendish purchased the pharmacy in January 1963 from his preceptor - Registered Pharmacist Harry Lloyd.

New Board Member Appointed *(Term of Office - July 1, 1996 - June 30, 2000)*

Mrs. Diane C. Adelman, registered pharmacist from Beachwood, Ohio and manager of a K-Mart Pharmacy, was appointed by Governor Voinovich on July 8, 1996. Mrs. Adelman is a graduate of Ohio Northern University College of Pharmacy and is the daughter of past Board member A. Milton Cohen, also of Beachwood, Ohio. Mrs. Adelman is responsible for Board matters concerning exams, internship, and reciprocity.

SCOPE OF BOARD'S AUTHORITY AND RESPONSIBILITY

Many laws regarding drugs and their legal distribution have been enacted over the last 113 years by the Ohio General Assembly. These laws have provided the Ohio Board of Pharmacy

with the responsibility for administering and enforcing all of the state laws governing the legal distribution of drugs. These laws include the Pharmacy Practice Act; Controlled Substance Act; Dangerous Drug Distribution Act; Pure Food and Drug Act; and the Criminal Code dealing with drugs.

The wide scope of the Board's responsibilities establishes it as the single state agency where the public, health care practitioners and providers, other government agencies, other drug law enforcement agencies, and criminal justice employees may obtain information regarding drugs and the laws or rules governing their distribution in Ohio. These responsibilities result in the Board members having to devote a considerable amount of time conducting Board business.

Board members not only attend and participate in the regularly scheduled business meetings but also participate in special (usually one day) meetings for the purpose of considering a request for a summary suspension of a license, other business items requiring an immediate decision, and meetings regarding specific aspects of the operations of the Board and other health professions or organizations.

Board Member Responsibility Appointments

Each fiscal year, the Board reorganizes by electing a president and vice-president during the April or May Board meeting. The new officers for the next fiscal year are installed at the last meeting of the current fiscal year (June). In August, the Board president assigns the individual members certain areas of responsibility regarding the operations of the Board. The following appointments are in effect for the current fiscal year (97):

Administration/Probationary Reports	Mrs. Plant
Budget/Finance	Mr. Repke
Compliance/Enforcement	Mrs. Neuber
Consumer Affairs/Public Relations	Mr. Lamping
Continuing Education	Mr. Hanna
Exams/Internship/Reciprocity	Mrs. Adelman
Legislation/Rules	Mr. Cavendish
Licensure/Registration	Mr. Repke
Personnel	Mr. Littlejohn

The following Board committees also met as needed this past year and contributed to the workload of the Board members:

Ad Hoc Advisory Committee on Rule Review	Mr. Littlejohn, Mrs. Neuber
Coalition on Pharmacy Practice	Mrs. Neuber
Nurse Practitioner Formulary Committee	Mr. Hanna
Joint Health Regulatory Boards	Mr. Littlejohn, Mrs. Neuber
Ohio Tuberculosis Coalition	Mr. Maslak, Mrs. Plant,
Recruitment Committee	Mrs. Adelman, Mrs. Neuber, Mrs. Plant, and Mr. Repke

The Recruitment Committee was established due to the fact that the Executive Director announced in 1996 that he would leave employment with the State Board of Pharmacy on December 31, 1998. Notice that the Board was accepting applications for the position of Executive Director was posted on the Board's Home Page on the World Wide Web in February of this year and the following notice will be mailed to local, national, and state pharmacist associations as well as national pharmacy publications this month.

Ohio State Board of Pharmacy

Executive Director

The Ohio State Board of Pharmacy is accepting applications for the position of Executive Director. The position will be available January 1, 1999; however, a six-month transition commencing July 1, 1998 is anticipated. The successful candidate must have a current license to practice pharmacy in Ohio or be eligible for licensure by examination or reciprocity. By Ohio law, the Executive Director is the chief administrative officer of the Ohio Board of Pharmacy and is responsible for directing and carrying out its legal responsibilities as a state licensing, regulatory, and drug law enforcement agency.

More detailed information may be obtained regarding this position, the Board, its responsibilities, and operations by accessing the Board's Home Page on the World Wide Web:

<http://www.state.oh.us/pharmacy/>

Interested applicants should submit their current curriculum vitae to the President of the Board with a cover letter expressing their interest **no later than December 31, 1997** (Ohio State Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, Ohio 43266-0320).

Information Technology - Shaping The Future

One of the biggest challenges facing the Ohio Board of Pharmacy is ensuring that it is able to effectively carry out its responsibilities in the future. An important aspect of the "information technology" revolution and the Board's ability to attain its goals and mission is how effectively and efficiently the Board obtains, manages, and disseminates information to the public, licensees, registrants, and other government agencies.

Information technology is not only shaping the future of healthcare, it is also shaping the future of federal, state, and local government agencies - emphasizing their role as effective gatherer, analyzer, and disseminator of information. This information is not only invaluable to policy makers, legislators, and government agencies, but also to the public in making good decisions about their health and well being.

Information is defined as timely or specific knowledge. Today, vast amounts of real-time information are readily available on every topic imaginable to anyone with a computer and a modem. The problem, however, is the quality or factual basis of the information provided. In a society that emphasizes free speech and encourages entrepreneurs in the marketplace, a significant amount of the information made available to the public is what can be referred to as "advocacy", "promotional", or "marketing" literature. The major goal of such literature is to promote the use and sale of a product - not to provide factual information that may reflect adversely on the product or service.

Included in this report are many indicators of "The Information Age" and its impact on the State Board of Pharmacy. The Ohio Board of Pharmacy's "Home Page" on the World Wide Web went live on March 1, 1996 and has been accessed 2,613 times as of March 31, 1997. The Board is also connected through the "Electronic Licensure Network Program" with the other members of the National Association of Boards of Pharmacy and maintains a Local Area Network (LAN). The Board is presently implementing a wide area network that will provide each of its field agents with on-line access to current information maintained by the licensing and registration department.

The Board is also participating in the development and implementation of a community health management information system that would link already-existing regional and enterprise networks. This system is being developed and implemented by the Ohio Corporation for Health Information (OCHI).

In September 1994, the Board was contacted by the Executive Director of the Ohio Corporation for Health Information (OCHI) to meet with him and the Executive Director of the Ohio Health Care Board. The purpose of the meeting was to discuss the development of the " 'electronic script' within appropriate processes of control and confidentiality as an effective technology enabler for both a higher quality of healthcare delivered and a more efficient delivery infrastructure".

OCHI was established in 1994, as an impartial non-profit [501(c)(3)] data intermediary for the Ohio healthcare community. The Board of Trustees membership at the time of its inception included representatives of employers, providers, and the public sector. The stated mission at that time was "to facilitate the exchange of comparative information among those decision-makers who can best influence the improvement in the quality of healthcare delivered while effective overall cost-effectiveness".

The Ohio Health Care Board was established by the Ohio General Assembly in 1993 by the enactment of H.B. 478. The mission statement for this board was "to develop a comprehensive health care system that organizes health resources to assure access for all Ohioans to high quality, cost-effective health care". The OCHI system is expected to begin transmitting administrative health care data between providers and third-party payers this spring. An "electronic script" program is in the planning stage and may be implemented before the end of this calendar year.

BOARD OF PHARMACY PERSONNEL

MEMBERS OF THE BOARD

Diane C. Adelman, R.Ph.; Beachwood [Term Expires 06/30/2000]
Robert B. Cavendish, R.Ph.; Johnstown [Second Term Expires 06/30/2000]
John L. Hanna, R.Ph.; Hillsboro [Term Expires 06/30/1998]
Paul F. Lamping, R.Ph.; Cincinnati [Second Term Expires 06/30/1999]
Amonte B. Littlejohn, R.Ph.; Cleveland Heights [Term Expires 06/30/1997]
Joseph J. Maslak, R.Ph.; Canal Winchester [Term Expires 06/30/1998]
Suzanne L. Neuber, R.Ph.; Sylvania [Term Expires 06/30/1997]
Ruth A. Plant, R.Ph.; Hudson [Second Term Expires 06/30/1999]
Nicholas R. Repke, Public Member; Gahanna [Second Term Expires 06/30/2000]

ADMINISTRATIVE SECTION

EXECUTIVE DIRECTOR

Franklin Z. Wickham, R.Ph.

ASSISTANT EXECUTIVE DIRECTOR / DIRECTOR OF INTERNSHIP

William T. Winsley, R.Ph.

ADMINISTRATIVE ASSISTANT

Sandra Butler

FISCAL SPECIALIST

Karen Prather

LICENSING SECTION

LICENSING ADMINISTRATOR / COMPUTER SYSTEMS MANAGER

Nancy L. Little, R.Ph.

PROGRAMMER/ANALYST

Matthew Cooke

CERTIFICATION/LICENSING EXAMINERS

Internship and Licensure Exams Coordinator

Mary Flovin

Pharmacists and Reciprocity Coordinator

Yolanda Ferguson

Continuing Pharmacy Education Coordinator

Michelle McGee

Dangerous Drug Distributors Coordinators

Erika Curtis

Sharon Prentice

OFFICE ASSISTANT / RECEPTIONIST

Vacant

LEGAL AFFAIRS SECTION

LEGAL AFFAIRS ADMINISTRATOR

David L. Rowland, J.D.

OFFICE ASSISTANTS

Legal Affairs Secretary

Susan Orr

Drug Identification Coordinator

Debra Smith

COMPLIANCE SECTION

COMPLIANCE ADMINISTRATOR

Timothy J. Benedict, R.Ph.

COMPLIANCE SUPERVISOR

Robert L. Cole

COMPLIANCE SPECIALISTS

Robert Amiet, R.Ph.

Elaine Jones, R.Ph.

Mark Keeley, R.Ph.

Paul Kover, R.Ph.

Louis Mandi, R.Ph.

William McMillen, R.Ph.

Joann Predina, R.Ph.

COMPLIANCE AGENTS

David Avery

Lynn Mudra

Frank Bodi

William Padgett

Michael Cluxton

George Pavlich

Dale Fritz

Christopher Reed

David Gallagher

James Reye

Joseph Holliday

Fred Williams

Kevin Kinneer

(One Vacancy)

OFFICE ASSISTANTS

Compliance Secretaries

Kathi Baker

Laurie Sturtz

BOARD COUNSEL - OFFICE OF THE ATTORNEY GENERAL

ASSISTANT ATTORNEY GENERAL

Mary L. Hollern, Esq.

BOARD MEETINGS

Fiscal Year 96 (July 1, 1995 - June 30, 1996) Meetings

The Board held 12 regularly scheduled meetings of the full Board in FY 96 for a total of 40 days. Board members attended 338 days of official meetings in FY 96. Two special one-day Board meetings were held in FY 96 for the purpose of considering evidence regarding the summary suspension of pharmacists' licenses whose continued practice or method of distributing controlled substances presented a danger of immediate and serious harm to others. Seven of the 19 summary suspensions issued by the Board in FY 96 were issued following a special one-day meeting of at least five voting members (*see Summary Suspensions - Page 52*).

Fiscal Year 97 (July 1, 1996 - June 30, 1997) Meetings

Six meetings of the full Board have been held to date for the purpose of conducting official Board business and conducting Chapter 119. Adjudication hearings. Four of these meetings were five days in length (Monday - 10 a.m. through Friday Noon) while the remaining two were four-day meetings (Monday - 10 a.m. through Thursday - 5 p.m.). A special one-day meeting of five voting members was held for the purpose of considering evidence and testimony regarding whether or not a pharmacist's license that was summarily suspended due to a felony drug abuse conviction should be reinstated. The license was reinstated by the Board following the hearing and the license to practice placed on probation for one year.

Two more regular business meetings are scheduled for the remainder of this fiscal year (April and June). The two remaining business meetings for this year, and those tentatively scheduled for FY 98, are three days in length (Monday - 8 a.m. through Wednesday - 5 p.m.).

The Board has scheduled three-day meetings each month for FY 98 (July 1, 1997 - June 30, 1998) in order to improve attendance and insure that a quorum is present to conduct official business. The five-day Board meetings conducted these past two fiscal years has made it difficult for some Board members to attend and participate in the entire meeting. FY 96 was the first year since the number of Board members was increased to eight that the Board was not able to conduct official business as scheduled due to a quorum of voting members not being present.

<u>FY</u>	<u>Number of Meetings</u>	<u>Meeting Days</u>	<u>Days of Per Diem</u>	<u>Hearings Held</u>	<u>Notices Considered</u>	<u>Hearings Pending</u>
90	8	37	306	98	NA	33
91	8	33	272	37 [15]	38	10
92	9	38	321	61	7	19
93	13	38	341	38	6	47
94	11	40	401	46 [2]	9	33
95	14	43	409	51	8	16
96	12	40	338	49	7	22
97 TD	6	28	225	30	5	18

[Hearings held by one member serving as Hearing Officer]
 NA - not available TD - (to date) as of 03/10/97

Each meeting of the Board is open to the public and the following is a tentative schedule of the meetings through the end of FY 98:

TENTATIVE BOARD MEETING SCHEDULE

<u>Date</u>	<u>Time</u>	<u>Location</u>	<u>Purpose</u>
04/21/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
04/22/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
04/22/97	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
04/22/97	1:30pm-3pm	65 S. Front Street, Room C-5	Rules Hearing
04/23/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
06/16/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
06/17/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
06/17/97	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
06/18/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
07/14/97	8am-5pm	77 S. High Street, Room 1914	Board Meeting
07/15/97	8am-5pm	77 S. High Street, Room 1914	Board Meeting
07/15/97	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
07/16/97	8am-5pm	77 S. High Street, Room 1914	Board Meeting
08/11/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
08/12/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
08/12/97	1pm-3pm	77 S. High Street, Room 1952	Reciprocity Hearing
08/13/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
09/08/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
09/09/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
09/09/97	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
09/10/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
10/06/97	8am-5pm	77 S. High Street, Room 1952	Board Meeting
10/07/97	8am-5pm	77 S. High Street, Room 1952	Board Meeting
10/07/97	1pm-3pm	77 S. High Street, Room 1914	Reciprocity Hearing
10/08/97	8am-5pm	77 S. High Street, Room 1952	Board Meeting
11/17/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
11/18/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
11/18/97	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
11/19/97	8am-5pm	65 S. Front Street, Room C-5	Board Meeting
12/08/97	8am-5pm	77 S. High Street, Room 1914	Board Meeting
12/08/97	1pm-3pm	77 S. High Street, Room 1919	Rules Hearing
12/09/97	8am-5pm	77 S. High Street, Room 1914	Board Meeting
12/09/97	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
12/10/97	8am-5pm	77 S. High Street, Room 1914	Board Meeting
01/12/98	8am-5pm	77 S. High Street	Board Meeting
01/13/98	8am-5pm	77 S. High Street	Board Meeting
01/13/98	1pm-3pm	77 S. High Street	Reciprocity Hearing
01/14/98	8am-5pm	77 S. High Street	Board Meeting
02/09/98	8am-5pm	77 S. High Street	Board Meeting

02/10/98	8am-5pm	77 S. High Street	Board Meeting
02/10/98	1pm-3pm	77 S. High Street	Reciprocity Hearing
02/11/98	8am-5pm	77 S. High Street	Board Meeting
03/09/98	8am-5pm	77 S. High Street	Board Meeting
03/10/98	8am-5pm	77 S. High Street	Board Meeting
03/10/98	1pm-3pm	77 S. High Street	Reciprocity Hearing
03/11/98	8am-5pm	77 S. High Street	Board Meeting
04/06/98	8am-5pm	77 S. High Street	Board Meeting
04/07/98	8am-5pm	77 S. High Street	Board Meeting
04/07/98	1pm-3pm	77 S. High Street	Reciprocity Hearing
04/08/98	8am-5pm	77 S. High Street	Board Meeting
05/04/98	8am-5pm	77 S. High Street	Board Meeting
05/05/98	8am-5pm	77 S. High Street	Board Meeting
05/05/98	1pm-3pm	77 S. High Street	Reciprocity Hearing
05/06/98	8am-5pm	77 S. High Street	Board Meeting
06/08/98	8am-5pm	77 S. High Street	Board Meeting
06/09/98	8am-5pm	77 S. High Street	Board Meeting
06/09/98	1pm-3pm	77 S. High Street	Reciprocity Hearing
06/10/98	8am-5pm	77 S. High Street	Board Meeting

The only meeting dates that do not appear on this tentative schedule are those needed to consider the results of an investigation regarding an impaired pharmacist or pharmacy intern, or special meetings called to consider an important matter that needs to be decided before the next regularly scheduled Board meeting. Notice of these meetings are mailed at least 24 hours prior to the meeting to those individuals and organizations that subscribe to the "Sunshine Notice" service of the Board. This service presently costs \$25.00 per fiscal year and includes not only notices of meetings but also notices of Chapter 119. Public Rules Hearings, State Board Newsletters, Compliance Bulletins, and News Releases. Subscriptions must be renewed annually on the first day of July of each fiscal year.

Anyone planning to attend a Board meeting should contact the Board office at least two weeks prior to the tentative published date to confirm the date, time, and location. All of the meetings are held in the Vern Riffe Center for Government and the Arts, 77 South High Street or the State Departments Building at 65 South Front Street, Columbus, Ohio.

WORKLOAD

The workload of the Ohio Board of Pharmacy continues to grow with increasing exposure to and recognition by the public, businesses providing health care, law enforcement agencies, news sources (television, newspapers, magazines, trade publications), law firms representing health care businesses, and health care professionals throughout the United States. The number of inquiries for information, consumer complaints, and reports of alleged illegal activity involving drugs and health care professionals continue to increase in number.

The Board office received over 33,000 incoming telephone calls through the switchboard during FY 96. Eighteen thousand six hundred thirty-seven (18,637) incoming telephone calls were

received during the first six months of this fiscal year. Forty percent (13,336) of the persons calling the Board office in FY 96 asked to speak to a pharmacist.

In order to continue to decrease operating costs while increasing the efficiency and effectiveness of the Board in communicating with its customers, a FAX machine capable of receiving and transmitting requested documents as needed on a 24-hour basis was purchased. Since obtaining the FAX machine in July 1992, the number of pages scanned (sent) and printed (received) remained relatively constant at approximately 12,000 pages per calendar year until 1996. The number scanned and received during 1996 totaled 17,081 pages. The number of pages scanned and received each calendar year are approximately the same. During calendar year 1996, 8,613 were scanned and 8,468 were received.

In an effort to further improve communications and service to its customers, the Board established a Home Page on the World Wide Web on March 6, 1996. Information and documents commonly requested by many persons calling the Board office are being posted on the Home Page and callers instructed to access the documents and download them if they wish. The purchase of the FAX machine and the establishment of the Home Page have helped prevent increased costs due to the copying and mailing of requested information. The ability of the FAX machine and the Home Page to disseminate information immediately also provides those persons needing such information when they need it.

One of the most significant factors contributing to the increasing workload of the Board is the impact of health care reform and the continual evolution of the health care delivery system being driven by economic factors. The activities of the Board in the past affected mostly citizens of the state of Ohio and bordering states. Today, the impact of the Board's activities affects not only Ohio citizens but citizens throughout the United States.

Citizens of Ohio are also impacted by health care providers or wholesalers located in other states. The Board presently licenses 555 wholesalers from 42 other states, the District of Columbia, and Puerto Rico. One hundred two (102) out-of-state terminal distributors located in 33 different states are also licensed with the Board as of March 24, 1997. Twelve (12) are located in Florida, 15 in Pennsylvania, four in California, seven in Kentucky, and seven in Texas.

Ohio's geographical location and business climate has made it a popular location for wholesale and terminal drug distributors who provide dangerous drugs via interstate commerce throughout the United States. These facilities are much larger than in the past due to consolidation and the use of new distributive technology. An example of one of these larger facilities engaged in the wholesale distribution of drugs is one built by Foxmeyer Drug Company in Washington Court House, Ohio in 1995 and sold to McKesson in 1996. This modern and technologically-advanced distribution facility was located near Wilmington, Ohio in order to take advantage of the large air freight facility there and the quick access to interstate highways.

The Board now has 17 mail order pharmacies located in the state of Ohio and 95 located in other states. Many of the mail order pharmacies located in Ohio are filling prescriptions for patients throughout the United States and its territories. Each year, the Board must certify to the other states where they are licensed as out-of-state pharmacies that their licenses are current and in good standing. An increasing number of these states are also requiring these pharmacies to submit a copy of their most recent inspection report in order to renew their states' licenses.

Several of these states are also requiring mail order pharmacies located in Ohio to certify that the licenses of their pharmacists are current and in good standing.

The Board is also receiving an increasing number of complaints from citizens located in other states regarding prescriptions that they have obtained by mail from pharmacies located in Ohio. These complaints are being filed with the Ohio Board directly by the patients or the Board of Pharmacy in the state where the patient resides. Consequently, the Board is being asked by the other states to investigate such complaints and inform them of the results of the investigation.

It is expected that the workload of the Board will continue to increase due to even greater exposure and interaction with the public and other concerned entities through the Board's Home Page on the World Wide Web and E-mail. The greatest challenge facing the Ohio Board of Pharmacy during the next two years is the successful and effective management of information related to the Board's responsibilities and activities in both printed and electronic form. The Board needs to increase the public's access to information maintained by the Board as well as respond in a timely manner to requests for information.

To meet this challenge, the job responsibilities of the Board's present administrative staff will be revised and one additional pharmacist position will be created during FY 98. The present Licensing Administrator's job responsibilities will be divided and an Information Systems Administrator position created. The pharmacist currently holding the position of Licensing Administrator is presently responsible for both the licensing activities of the Board as well as managing the Board's information systems. It is no longer possible for one person to do both jobs due to the increasing complexity of the Board's information systems and the increasing workload regarding licensing.

The job responsibilities for the revised position of Licensing Administrator will include the processing of all applications (new and renewal) for licenses issued by the Board. Other duties and responsibilities will be added to this pharmacist position to provide for more effective follow-up regarding discontinued licenses; information regarding entities that are not licensed and are in violation of Ohio's drug laws; and conducting more thorough background checks for applicants when warranted.

The new position – Pharmacy Board Information Systems Administrator – will be responsible for the six different computer networks that the Board presently uses in carrying out its responsibilities and communicating with licensees, registrants, and the public. Four of these networks are operational and are being used on a daily basis by the Board employees in carrying out their job responsibilities. These four systems include the Board's Licensure and Dangerous Drug Information System; the National Association of Boards of Pharmacy's Electronic Licensure Transfer Program; the State's Central Accounting System; and the State Data Network system (Board Home Page and E-mail). Two new computer networks that the Board is involved with are in the process of development and implementation (Ohio Corporation Health Information enterprise network and the Licensing/Regulatory Board's Public Information Access network). This person will also be responsible for training Board employees to effectively use their personal computers in order to carry out their job responsibilities.

REVENUE/APPROPRIATIONS

The Ohio Board of Pharmacy generates revenue through licensing and registration fees, examination fees, fees for services, imposing monetary penalties, and the collection of fines levied by the courts of Ohio for drug law violations. The Board also generates funds for drug law enforcement purposes through its investigation and criminal prosecution of violations of Chapter 2925. of the Ohio Revised Code. These funds are derived from mandatory fines levied by the Ohio courts in cases involving the Board staff as well as asset forfeitures in state and federal cases.

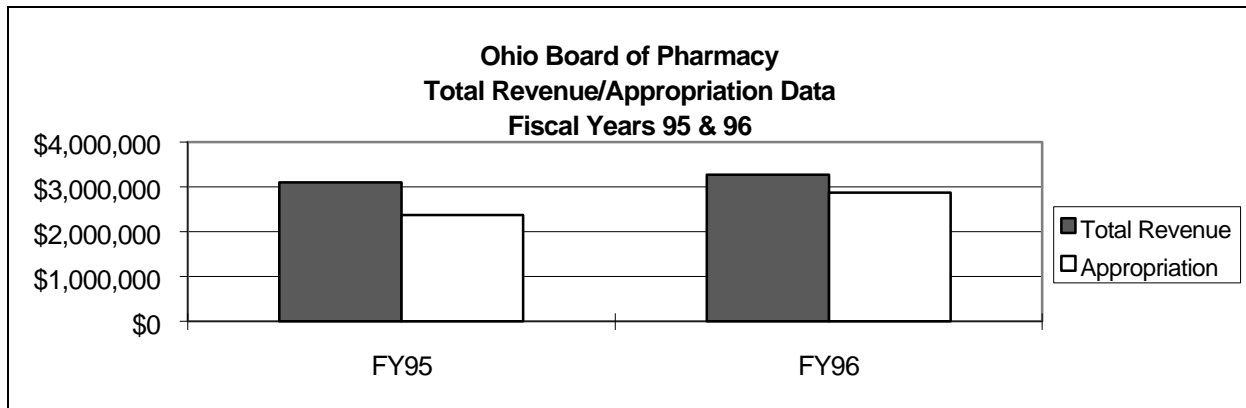
Sixty-eight percent (68%) of the revenue generated by the Board of Pharmacy during FY 95 and 65% during FY 96 came from licensing and registration fees and service fees. The following table indicates the percentage generated by the different sources of revenue for FYs 95 and 96. Monetary penalties are imposed by the Board as the result of a disciplinary hearing or consent agreements while fines and bond forfeitures are imposed by the criminal courts in Ohio.

SOURCES OF REVENUE - FISCAL YEARS 95 & 96				
<u>Revenue Sources</u>	<u>FY 95</u>	%	<u>FY 96</u>	%
Licensing/Service Fees	\$2,111,485	68.1	\$2,113,637	64.7
Monetary Penalties	38,075	1.2	63,700	2.0
Fines	953,781	30.7	1,087,266	33.3
Total Revenue	\$3,103,341		\$3,264,603	

The total amount of revenue (licensing/registration fees & fines) collected by the Board of Pharmacy has exceeded the amount appropriated by the Legislature for use by the Board in carrying out its responsibilities as indicated in the following table with the exception of FY 92. The total amount of revenue collected by the Board in FY 92 was less than the reduced appropriation by \$15,560 (0.9%). Due to cost-cutting measures implemented by Board staff, however, the actual expenditures for FY 92 were \$16,407 less than the reduced appropriation (\$1,721,836).

TOTAL REVENUE/APPROPRIATION DATA				
<u>FY</u>	<u>Total Revenue</u>	<u>Appropriation</u>	<u>Difference</u>	<u>%</u>
96	\$3,264,603	\$2,862,792	\$401,811	12.3
95	3,103,341	2,374,296	729,045	23.5
94	2,676,469	2,205,761	470,708	21.3
93*	2,022,500	1,757,366	265,134	13.1
92*	1,722,683	1,738,243	(15,560)	(0.9)

**Appropriation was cut by \$35,474 for FY 1992 and \$54,352 for FY 1993 in January 1992.*



The following table indicates the amount of the Board's appropriation for FYs 92 through 96 that is covered by drug fines. Approximately 69% (\$749,155) of the drug fines collected in FY 96 were used by the Board of Pharmacy in carrying out its drug law enforcement responsibilities.

<u>FY</u>	<u>Fine Revenue</u>	<u>Amount of Appropriation Covered By Fine Revenue</u>	<u>% of Fine Revenue</u>
96	\$1,087,266	\$749,155	68.9
95	953,781	262,811	27.6
94	882,601	474,492	53.8
93	689,170	424,036	61.5
92	630,116	630,116	100.0

All fines imposed by courts for violations under Ohio Revised Code Section 2925.03 have been divided among the law enforcement agencies responsible for the case since November 20, 1990 (effective date of H.B. 258). Only 50% of fines imposed by the courts for violations of all other sections of Ohio Revised Code Chapter 2925. (Drug Crimes) were deposited into the treasury of the state of Ohio. The remaining 50% was divided among the law enforcement agencies responsible for the case according to the extent of their involvement and deposited with the appropriate government agency (e.g.-city or county treasurer, etc.).

Recognizing the decreasing amount of revenue that the State would realize from drug fines due to H.B. 258 when it was enacted by the Legislature, and the fact that the Board of Pharmacy is involved in many cases involving drug law violations, the Legislature amended O.R.C. Section 4729.65 (S.B. 218 effective 10/11/91) to provide the Board of Pharmacy with the ability to qualify for moneys realized from mandatory fines levied by the courts of Ohio and asset forfeitures. Accordingly, the Board is receiving its share of the mandatory fines and asset forfeitures resulting in prosecution of individuals violating both state and federal law (S.B. 218). The law restricts the use of these funds and they may only be used to subsidize the drug law enforcement efforts of the Board.

O.R.C. § 4729.65 (B)(1)(a): *There is hereby created in the state treasury the board of pharmacy drug law enforcement fund. All moneys that are derived from any mandatory fines or forfeited bail to which the board may be entitled under [divisions (J) and (K) of section 2925.03] or division (B)(5) of section 2925.42 of the Revised Code and all moneys that are derived from forfeitures of property to which the board may be entitled pursuant to Chapter 2925. of the Revised Code, section 2923.32, 2923.35, or 2933.43 of the Revised Code, any other section of the Revised Code, or federal law shall be deposited into the fund. The moneys in the fund shall be used solely to subsidize the drug law enforcement efforts of the board.*

The Board's Drug Law Enforcement Fund received \$36,827 during FY 96. Federal and state laws restrict the use of these funds. The Total Revenue Data table on Page 22 includes only those funds which may be used to cover expenses associated with the operation of the Board (i.e.- expenses such as rent, travel, and payroll).

BOARD OF PHARMACY DRUG LAW ENFORCEMENT FUND			
FY	Amount Collected	Difference	% Change
91	\$ 375.00		
92	44,237.76	\$ 43,862.76	99.1
93	154,028.99	109,791.23	71.2
94	68,678.96	(85,350.03)	(55.4)
95	91,838.24	23,159.28	33.7
96	36,826.75	(55,011.49)	(59.9)

In order to insure that the Board continues to generate sufficient revenue to cover its cost of operations and continue to improve services, the Board is seeking authority to recover the costs of conducting investigations of licensees and registrants guilty of violating state and federal drug laws. Legislation will be introduced in the near future to amend Sections 4729.16, 4729.56, and 4729.57 of the Ohio Revised Code for this purpose.

HISTORICAL FINE/BOND FORFEITURE DATA (Funds Deposited in General Revenue Fund)			
<u>Fiscal Year</u>	<u>Amount Collected</u>	<u>Difference</u>	<u>% Change</u>
80	\$ 435,219	+ \$168,496	63% increase
81	513,913	+ 78,698	18% increase
82*	646,408 ¹	+ 132,491	26% increase
83	631,092 ²	- 15,316	2% decrease
84	590,948 ³	- 40,144	6% decrease
85	688,323 ⁴	+ 97,375	16% increase
86	667,143 ⁵	- 21,180	3% decrease
87	784,885 ⁶	+ 117,742	18% increase
88	788,229 ⁷	+ 3,344	0.4% increase
89	842,921 ⁸	+ 54,692	7% increase
90**	819,639 ⁹	- 23,282	3% decrease
91	667,388 ¹⁰	- 152,251	19% decrease
92	630,116 ¹¹	- 37,272	5.6% decrease
93	764,427 ¹²	+ 134,311	17.5% increase
94	821,790 ¹³	+ 57,363	6.9% increase
95	991,856 ¹⁴	+ 170,066	20.7% increase
96	1,150,966 ¹⁵	+ 159,110	16.0% increase

* Am. H.B. 135 enacted (effective 10/6/81)
 ** S.B. 258 (effective 11/20/90) decreased the amount of drug crime fines deposited into the General Revenue fund due to mandatory drug crime fines and their distribution to local and state drug law enforcement agencies rather than the State's General Revenue fund.
 Monetary penalties imposed by the Board (included in totals above).

1 \$2,350	6 \$152,050	11 \$21,432
2 \$2,375	7 \$74,033	12 \$75,257
3 \$11,700	8 \$86,261	13 \$31,533
4 \$28,150	9 \$63,639	14 \$38,075
5 \$30,850	10 \$33,650	15 \$64,800

The licensing and regulatory boards are expected to generate sufficient revenue from licensing fees and fees for services in order to cover operating expenses. The Board of Pharmacy, however, collects fines levied by the courts in Ohio for drug law violations and this revenue is included in the total revenue estimates of the Board for appropriation purposes. This is due to the fact that the Board has drug law enforcement responsibilities as well as the licensing and regulation of the practice of pharmacy and the legal distribution of drugs in Ohio.

The amount of revenue that the Board will receive from this source will significantly decrease during FY 98 due to the enactment of Sub. S.B. 2 by the 121st General Assembly (Criminal Sentencing/Criminal Law changes) on June 29, 1995. Sub. S.B. 2 made further changes in the distribution of drug fines effective July 1, 1996, the beginning of FY 97.

It is anticipated that the provisions of this legislation will eventually decrease the drug fine revenue collected by the Board of Pharmacy by approximately 85 to 90 percent. The full impact of Sub. S.B. 2 will not be fully realized until FY 98 (July 1, 1997 – June 30, 1998).

In order to assess the impact of the legislation on the Board's revenue, Board staff created the following table that identifies the sections of the Ohio Revised Code that will continue to be paid to the Board of Pharmacy as of July 1, 1996 and the amount collected pursuant to these sections during FYs 94, 95, and 96. The table also provides the total amount of fine revenue that would have been distributed to the local law enforcement agencies under the provisions of Sub. S.B. 2 had it been in effect during FYs 94, 95, and 96.

SUB. S.B. 2 IMPACT ON BOARD REVENUE				
	<u>FY 94</u>	<u>FY 95</u>	<u>FY 96</u>	<u>FY 97 TD</u>
Total Fines Received	\$ 778,191	\$ 956,233	\$ 1,086,116	\$ 485,155
Sections Continued				
2925.12	\$ 3,637	\$ 4,876	\$ 4,129	\$ 1,886
2925.14	59,193	128,507	115,233	101,064
2925.31	1,021	2,010	2,171	725
2925.32	0	50	10	0
3715.65	0	250	250	0
3719.08	0	0	820	0
3719.16	285	365	470	70
3719.21	267	0	0	500
3719.41	0	200	0	0
3719.81	300	0	0	0
4507.02	0	20	0	0
4511.19	50	75	0	0
4729.28	530	34	0	300
4729.51	181	2,125	13	183
Total To Board	\$ 65,464	\$ 138,512	\$ 123,096	\$ 104,728
Total* To Local Law Enforcement	\$ 712,727	\$ 817,721	\$ 963,020	\$ 380,427
		<i>*For crimes committed after 07/01/96</i>		<i>TD - as of 12/17/96</i>

The following table illustrates the amount of revenue generated from licensing fees and fees for services for FYs 84 through 96. This revenue source generated \$2,113,637 in FY 96 or approximately \$2,152 (0.1%) more than the amount collected in FY 95.

FEE REVENUE / APPROPRIATION DATA				
<u>FY</u>	<u>Fee Revenue</u>	<u>Appropriation</u>	<u>Difference</u>	<u>%</u>
96	\$2,113,637	\$2,862,792	\$(749,155)	(26.2)
95	2,111,485	2,374,296	(262,811)	(11.1)
94	1,762,335	2,205,761	(443,426)	(20.1)
93	1,258,073	1,757,366	(499,293)	(28.4)
92	1,092,567	1,738,243	(645,709)	(37.1)
91	1,319,067	1,661,904	(342,837)	(20.6)
90	1,194,025	1,581,579	(387,554)	(24.5)
89	926,008	1,426,895	(500,887)	(35.1)
88	837,628	1,498,011	(660,383)	(44.1)

87	739,535	1,127,172	(387,637)	(34.4)
86	741,635	1,177,192	(435,557)	(37.0)

The increase in revenue from licensing fees and fees for services was not significant during FY 96. In order to generate sufficient revenue to cover operating expenses and improve services provided by the Board, licensing fees and fees for services will have to be increased during the next biennium. The only alternative is to find new funding sources. One potential source of new funds is to require all entities involved in the purchase and legal distribution of dangerous drugs to be licensed as a terminal distributor.

Ohio State Board of Pharmacy LICENSING/REGISTRATION REVENUE DATA (includes fees for services/publications)			
<u>Fiscal Year</u>	<u>Amount Collected</u>	<u>Difference</u>	<u>% Change</u>
70	\$ 174,862		
71	\$ 192,605	+ \$ 17,743	10% increase
72	\$ 283,743	+ \$ 91,138	47% increase
73	\$ 270,573	- \$ 13,170	5% decrease
74	\$ 285,115	+ \$ 14,542	5% increase
75 ¹	\$ 296,231	+ \$ 11,116	4% increase
76	\$ 368,927	+ \$ 72,696	25% increase
77	\$ 374,242	+ \$ 5,315	1% increase
78	\$ 403,032	+ \$ 28,790	8% increase
79	\$ 422,788	+ \$ 19,756	5% increase
80	\$ 449,009	+ \$ 26,977	6% increase
81	\$ 492,358	+ \$ 43,349	10% increase
82 ²	\$ 516,494	+ \$ 24,136	5% increase
83	\$ 719,498	+ \$ 203,000	39% increase
84	\$ 692,896	- \$ 26,602	4% decrease
85	\$ 686,323	- \$ 6,573	1% decrease
86	\$ 741,635	+ \$ 55,042	8% increase
87	\$ 739,535	- \$ 2,100	3% decrease
88 ³	\$ 837,628	+ \$ 98,093	13% increase
89	\$ 926,008	+ \$ 88,380	11% increase
90 ⁴	\$1,194,025	+ \$ 268,017	29% increase
91	\$1,319,067	+ \$ 125,042	11% increase
92 ⁵	\$1,092,567	- \$ 226,500	17% decrease
93 ⁶	\$1,258,073	+ \$ 165,506	13% increase
94	\$1,762,335	+ \$ 504,262	40% increase
95 ⁷	\$2,111,485	+ \$ 349,150	20% increase
96	\$2,113,637	+ \$ 2,152	0.1% increase

1 - Am. Sub. H.B. 300 enacted (1975 Drug Abuse and Controlled Substance Act)
 2 - Am. Sub. S.B. 4 enacted (Emergency Medical Systems - three categories of dangerous drugs/differing fees/free satellite licenses/practitioner corporations & partnerships exempted from licensure)
 3 - R.Ph. (07/01/88) and Dangerous Drug Distributor (08/10/87) license and registration fees increased to implement provisions of FY 88 appropriation to provide for an Administrative Assistant for Legal Affairs and clerical-technical support
 4 - Licensing fees increased by Legislature (07/01/89) and Board (09/01/89)

5 - Revenue decreased due to fewer takeovers and licensing of same sites during the fiscal year
 6 - The Drug Laws of Ohio publication has been granted to the Banks-Baldwin Law Publishing Company for handling and distribution
 7 - Sub. H.B. 391 and S.B. 88 enacted (Retail sellers of Oxygen, food processors, and animal shelters)

Ohio State Board of Pharmacy
 TOTAL REVENUE DATA

Fiscal Year	Licensing Fees	Drug Fines/ Bond Forfeitures	Total Collected	Difference	% Change
70	\$ 174,862	\$ 18,686	\$ 193,548		
71	\$ 192,605	\$ 67,341	\$ 259,946	+ \$ 66,398	34% increase
72	\$ 283,743	\$105,894	\$ 389,637	+ \$129,691	50% increase
73	\$ 270,573	\$192,937	\$ 463,510	+ \$ 73,873	19% increase
74	\$ 285,115	\$288,485	\$ 573,600	+ \$110,090	24% increase
75	\$ 296,231	\$383,438 ¹	\$ 679,669	+ \$106,069	18% increase
76	\$ 368,927	\$271,306	\$ 640,233	- \$ 39,436	6% decrease
77	\$ 374,242	\$207,028	\$ 581,270	- \$ 58,963	9% decrease
78	\$ 403,032	\$229,699	\$ 632,731	+ \$ 51,461	9% increase
79	\$ 422,788	\$266,723	\$ 689,504	+ \$ 56,773	9% increase
80	\$ 449,009	\$435,219	\$ 884,228	+ \$194,724	28% increase
81	\$ 492,358	\$513,917	\$1,006,275	+ \$122,047	14% increase
82	\$ 516,494 ²	\$646,408	\$1,162,902	+ \$156,627	16% increase
83	\$ 719,498	\$631,092	\$1,350,590	+ \$187,688	16% increase
84	\$ 692,896	\$590,948	\$1,283,844	- \$ 66,746	5% decrease
85	\$ 686,323	\$688,323	\$1,374,646	+ \$ 90,802	7% increase
86	\$ 741,635	\$667,143	\$1,408,778	+ \$ 34,132	3% increase
87	\$ 739,535	\$784,885	\$1,524,420	+ \$115,642	8% increase
88	\$ 837,628 ³	\$788,229	\$1,625,857	+ \$101,437	7% increase
89	\$ 926,008	\$842,921	\$1,768,929	+ \$143,072	9% increase
90	\$1,194,025 ⁴	\$819,639 ⁵	\$2,013,644	+ \$244,715	14% increase
91	\$1,224,250	\$667,388	\$1,891,639	- \$ 122,005	6% decrease
92	\$1,092,567	\$630,116	\$1,722,683	- \$ 168,956	9% decrease
93	\$1,258,073	\$764,427	\$2,022,500	+ \$299,817	15% increase
94	\$1,762,335	\$914,134	\$2,676,469	+ \$653,969	32% increase
95	\$2,111,485 ⁶	\$991,856	\$3,103,341	+ \$426,872	16% increase
96	\$ 2,113,637	\$1,150,966 ⁷	3,264,603+ \$	161,2625% increase	

1 - Am. Sub. H.B. 300 enacted (1975 Drug Abuse and Controlled Substance Act)
 2 - Am. Sub. S.B. 4 enacted (Emergency Medical Systems - three categories of dangerous drugs/differing fees/free satellite licenses/practitioner corporations & partnerships exempted from licensure)
 3 - R.Ph. (07/01/88) and Dangerous Drug Distributor (08/10/87) license fees increased to implement provisions of FY 1988 appropriation to hire Administrative Assistant for Legal Affairs and clerical support
 4 - Licensure fees increased to cover greater percentage of appropriation (Budget Bill and Controlling Board action)
 5 - H.B. 258 was enacted by the General Assembly in Calendar Year 1990 and will decrease the amount of drug crime fines deposited into the General Revenue fund due to mandatory drug crime fines and their distribution to drug law enforcement agencies
 6 - Sub H.B. 391 (07/21/94)& S.B. 88 (06/29/94)enacted (retail sellers of Oxygen, food processors, non-territorial pharmacies, animal shelters)
 7 - Sub. S.B. 2 (07/01/96) resulted in larger percentage of drug fines being distributed to local law enforcement agencies.

LICENSING

The licensing of individuals to practice pharmacy is one of the mechanisms for protecting the public by ensuring that candidates are qualified to practice pursuant to the provisions of the Pharmacy Practice Act.

PHARMACY INTERNS

College students who are pursuing an entry-level degree in Pharmacy may obtain a license to practice pharmacy under the personal supervision of a pharmacist if they meet the following qualifications:

1. Are of good moral character and habits;
2. Are not addicted to or abusing drugs or liquor; and
3. Have successfully completed forty-eight semester or seventy-two quarter hours of college and have been accepted into a school or college of pharmacy recognized and approved by the board, or
4. Have obtained a first professional degree in pharmacy from a program which has been recognized and approved by the board, or
5. Have established education equivalency by obtaining a Foreign Pharmacy Graduate Examination Commission certificate, and have established proficiency in spoken English by successfully completing the Test of Spoken English (TSE) or its equivalent.

PHARMACISTS

Licensure by Examination - Competency is determined initially through the use of examinations. In order to qualify to sit for an examination for licensure as a pharmacist, individuals must:

1. Be of good moral character;
2. Be a graduate of an accredited program in pharmacy or if a graduate of a foreign college of pharmacy have obtained a Foreign Pharmacy Graduate Examination Committee certificate;
3. Have successfully obtained 1500 hours of practical experience in a pharmacy; and
4. If a foreign pharmacy college graduate, demonstrate his/her proficiency in the English language (written and spoken).

Foreign Pharmacy Graduate Equivalency Examination (FPGEE)

The Ohio Board of Pharmacy utilizes the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) in order to determine whether or not a foreign pharmacy graduate's education is equivalent to a graduate from a college of pharmacy in the United States. This examination is a comprehensive measure of the foreign pharmacy graduate's knowledge of pharmacy. It is a written examination that includes between 300 and 400 multiple-choice questions and is given in English. The exam is comprised of the following five major content areas: pre-clinical sciences, pharmaceutical sciences, biomedical sciences, social and behavioral sciences, and pharmaceutical services management.

Foreign pharmacy graduates qualify to sit for the licensure examination in Ohio by successfully completing the Foreign Pharmacy Graduate Equivalency Examination, the Test of English as a Foreign Language (TOEFL), the Test of Spoken English (TSE), and obtaining 1500 hours of internship following registration as a pharmacy intern.

National Association of Boards of Pharmacy Licensure Examination (NABPLEX) Federal Drug Law Examination (FDLE)

The national examinations known as NABPLEX and FDLE were used to determine whether or not an individual initially qualified to practice pharmacy in Ohio. The NABPLEX exam was administered as a paper-and-pencil examination until January 1997 and was a straightforward, unambiguous, and relevant test of pharmaceutical knowledge requisite to the safe dispensing and use of drugs, drug products, and devices. The exam was used by all states (with the exception of California), and by the District of Columbia and the Commonwealth of Puerto Rico.

The Board discontinued the administration of the FDLE in September of 1996 to test a candidate's knowledge of federal laws. The Jurisprudence exam presently used by the Board is compiled by Board staff and tests the candidate's knowledge on both federal and state law. Several states require candidates for licensure by reciprocity to take and pass the FDLE examination. Ohio pharmacists licensed by examination must take and pass FDLE in order to qualify for licensure by reciprocity in Pennsylvania if originally licensed by examination after April 1, 1983.

North American Pharmacist Licensure Examination (NAPLEX)

The National Association of Boards of Pharmacy (NABP) and its member states began using the new computer-adaptive North American Pharmacist Licensure Examination (NAPLEX) in March of this year. The computerized examination utilizes state-of-the-art technology to assess whether a candidate can competently practice as an entry-level pharmacist.

Computer-adaptive tests select questions that target a candidate's ability level. The computer programmed test continuously estimates each candidate's ability level based on responses to the test questions and then selects the most appropriate questions for the individual.

In order to pass the exam, the candidate's ability must meet or exceed a pre-determined level of minimum competence as established by a diverse national panel of practitioners, educators, and regulators. The process of selecting questions tailored to the candidate's ability level allows fewer questions to be administered on the exam. The NAPLEX exam consists of 185 test items compared to the 350 questions included on the paper-and-pencil NABPLEX. Consequently, testing time is less. The NAPLEX administration takes only four hours and fifteen minutes compared to the eight-hour time required for the NABPLEX.

The computer-adaptive examination also provides the opportunity to administer the licensure examination more often than three times a year and at many different sites. The NAPLEX will be administered in one- or two-week testing windows that are presently scheduled about every three months. Candidates will no longer have to come to one central location in order to take the examination since the NAPLEX will be administered by Sylvan Technology Centers which are located throughout the United States and its territories.

The NAPLEX's development was based on competency statements that were validated by pharmacists in the United States and Canada. Licensing authority representatives from both countries are now discussing the possible future recognition of the North American Pharmacist Licensure Examination as the uniform licensing exam that will be used by the U.S. states and Canadian provinces.

Jurisprudence Examination

The third mechanism used to assess a candidate's ability to practice in Ohio is a Jurisprudence Examination compiled by the Board. This exam tests the candidate's knowledge regarding laws and regulations governing the legal distribution of drugs. This exam consists of 70 questions and candidates have 90 minutes to complete the exam.

Multistate Pharmacy Jurisprudence Examination (MSPJ)

The member boards of the NABP are in the process of developing and implementing a computerized adaptive test (CAT) known as the Multistate Pharmacy Jurisprudence Examination. Advanced computer technology now provides NABP with the ability to develop a program that will automatically select test questions according to the requirements of an individual state and without conflicting with existing federal laws. The examination will be available for use by the boards in October 1998.

The following table provides data concerning the number of candidates sitting for the licensure examinations in Ohio since FY 86, the number of candidates who were successful in all required examinations, and the number who were not. The figures for FY 97 are current through March 1, 1997 (includes September 1996 & January 1997 exams).

PHARMACY PRACTICE ACT LICENSURE EXAMINATION STATISTICS				
<u>FY</u>	<u>Number of Candidates</u>	<u>Number Successful</u>	<u>Number Failing</u>	<u>Per Cent Failing</u>
86	338	304	34	10.0 %
87	337	315	22	6.5 %
88	328	303	25	7.6 %
89	369	346	23	6.2 %
90	401	373	28	7.0 %
91	391	356	35	9.0 %
92	358	323	35	9.8 %
93	437	353	84	19.2 %
94	510	424	86	20.3 %
95	496	408	88	17.7 %
96	549	442	107	19.5 %
97 TD	192	162	30	15.6 %

TD - as of 03/04/97

Testing for Competency To Practice (License Reinstatement)

Through June 1996, the Board used the NABPLEX, FDLE, and a state Jurisprudence exam whenever a pharmacist's competency to continue in the practice of pharmacy was in doubt due to substance abuse, mental impairment, repeated violations of federal and state laws, or when a pharmacist has not continuously practiced pharmacy in another state and let his/her license lapse for a period longer than three years. Since September 1996, the Board has used the NAPLEX and/or the Jurisprudence exams for this purpose.

Five State Jurisprudence exams were administered in FY 96 and four State Jurisprudence exams to date in FY 97 pursuant to adjudication orders issued by the Board.

Licensure by Reciprocity (Licensure Transfer)

One of the major purposes of the National Association of Boards of Pharmacy is to facilitate the transfer of pharmacists' licenses between active members of the association. At the present time, pharmacists may freely and quickly transfer their licenses to practice between all of the states, Washington D.C., and Puerto Rico with the exceptions being the states of California and Florida.

One hundred sixty-three (163) pharmacists transferred their licenses to Ohio in FY 96 and 117 pharmacists have transferred their licenses to practice in Ohio to date in FY 97. Pennsylvania has had the largest number of pharmacists transferring their licenses to Ohio for the last three fiscal years (FY 94 - 23; FY 95 - 44; and FY 96 - 35). Pharmacists transferred their licenses from 27 different states in FY 94; 35 in FY 95; and 28 in FY 96.

Reciprocity hearings are held during regularly scheduled Board meetings. Two more reciprocity hearings are scheduled for FY 97.

The Board proposed to deny one applicant for licensure by reciprocity in FY 96. A public hearing was held during the January 1996 meeting and the candidate was permitted to transfer his license to Ohio.

The Boards, through the National Association of Boards of Pharmacy, have implemented the Electronic Licensure Transfer Program (ELTP) computer network to decrease the amount of time required to transfer a license between states. The state boards are presently using the system to verify the current status of pharmacists wishing to transfer their license to another state. Full implementation of the system will not only decrease the amount of time required to reciprocate but also simplify the application process for licensure transfer.

The National Association of Boards of Pharmacy (NABP)

The Ohio Board of Pharmacy was instrumental in the founding of the National Association of Boards of Pharmacy in 1904. The purpose for establishing this organization was to facilitate the transfer of licenses to practice pharmacy between the states by developing uniform standards regarding the education and practical experience obtained by pharmacy students in the different states.

Uniformity has been established through the efforts of NABP and pharmacists are the only health professional that can easily and quickly transfer their licenses to practice between the states that are active members of the association. California and Florida are the only two states that do not reciprocate with the other states at this time.

National standards for the education of pharmacists were established through the formation of the American Council on Pharmaceutical Education (ACPE) in 1932. The organizations establishing ACPE were the American Pharmaceutical Association, The American Association of Colleges of Pharmacy, and the National Association of Boards of Pharmacy.

In 1968, NABP took steps to further facilitate the transfer of licenses between the states with the development of a national standardized licensure examination in pharmacy. The exam was first known as the national "Blue Ribbon Exam" and eventually became known as "NABPLEX".

The National Association of Boards of Pharmacy has now taken another major step towards not only facilitating the transfer of licenses between the states but also the United States and Canada. The National Association of Boards of Pharmacy administered the North American Pharmacist Licensure Examination (NAPLEX), a computer-assisted test, for the first time in March of this year. See Page 24 for additional information regarding this examination. Twenty-two (22) candidates took the exam for licensure in Ohio at Sylvan Testing Centers during the March 24 - 29, 1997 testing window.

NAPLEX TESTING WINDOWS	
<u>1997</u>	<u>1998</u>
March 24 - 29, 1997	January 26 - 31, 1998
June 9 - 21, 1997	June 8 - 20, 1998
July 7 - 19, 1997	July 6 - 18, 1998
October 6 - 11, 1997	October 5 - 10, 1998

Sylvan Examination Testing Centers are located in the following Ohio cities: Akron, Cincinnati, Columbus, Dayton, Mentor, Niles, Reynoldsburg, Solon, Strongsville, and Toledo.

NABP continues to work towards the goal of providing its members with the tools to conduct fair, valid, and reliable competency examinations, and is presently developing a multi-state jurisprudence computer adaptive examination for use by 1998. Computer Adaptive Examinations provide the member boards with the ability to test candidates more frequently and at many locations throughout the United States. The use of Sylvan Test Centers throughout the U.S. provides exam candidates with the opportunity to take the exams near home and avoid the expense and time to travel to a centralized location. Providing both the NAPLEX and MSPJ exams in this format will also enable candidates to complete all exams on the same day if they wish.

Another major step in facilitating the transfer of licenses between the member states of NABP was the establishment and implementation of the "Electronic Licensure Transfer Program" (ELTP) in March of 1996. The ELTP is a computerized communication network connecting the member boards for the purpose of streamlining procedures for licensure transfer between the states and thereby decreasing the amount of time necessary to transfer a license.

LICENSE RENEWAL

Pharmacy Interns/Pharmacists

The Board is continually modifying its licensing system and procedures for the purposes of renewing and issuing licenses in the shortest time possible, as well as enforcing the laws regulating the practice of pharmacy in a cost-effective manner. Twelve thousand five hundred twenty-two (12,522) applications for renewal were mailed to pharmacists in July of 1995 for the 1995-1996 licensure year (3,422 were required to report continuing pharmacy education) and 1,337 were mailed to pharmacy interns. Also, 47 interns who did not pass the June 1995 licensure exam were sent renewal applications to renew their intern license. This fiscal year (97), 12,877 applications were mailed to pharmacists in July of 1996. Of these, 4,122 also received continuing pharmacy education report forms. Applications for renewal were also mailed the same week to 1,429 pharmacy interns and, 59 interns who did not pass the June 1996 licensure exam were sent renewal applications to renew their intern license.

The timeliness of issuing the licenses each year is directly related to the submission of a completed application form for renewal with the required fee and, if appropriate, other required documents. Applications that have not been completed or have not been submitted with the

correct fee are returned to the applicant and the renewal license not issued until the problem has been corrected.

1995-1996 Licensure Year (09/15/95 - 09/15/96)

The Board office mailed licenses (identification cards) for the 1995-1996 licensure year to pharmacists and pharmacy interns as follows:

LICENSES ISSUED 1995 STANDARD RENEWAL			
<u>Date Issued</u>	<u>Total Number Licenses Issued</u>	<u>RPh</u>	<u>Interns</u>
06/28/95	1813	1813	0
07/12/95	812	812	0
07/24/95	1492	1492	0
07/26/95	2481	1908	573
08/08/95	1458	1340	118
08/22/95	2760	2537	223
08/27/95	265	229	36
08/28/95	615	557	59
09/06/95	737	631	106
09/08/95	382	306	76
09/11/95	344	291	53
09/12/95	161	112	49
09/13/95	70	53	16
09/13/95	43	42	1
09/14/95	55	44	11
09/15/95	<u>29</u>	<u>22</u>	<u>7</u>
SUB-TOTAL	13518 (97.2%)	12189 (97.3%)	1328 (96%)
09/18/95	25	17	8
09/20/95	35	29	6
09/25/95	38	26	12
09/27/95	27	24	3
10/02/95	38	35	3
10/03/95	11	6	5
10/06/95	28	27	1
10/16/95	<u>26</u>	<u>22</u>	<u>4</u>
SUB-TOTAL	228	186	42
TOTAL	13746	12375	1370
% RENEWED	98.8 %	98.8%	99%
% LAPSED	1.2%	1.2%	1%

1996-1997 Licensure Year (09/15/96 - 09/15/97)

The Board office mailed licenses (identification cards) for the 1996-1997 licensure year to pharmacists and pharmacy interns as follows:

LICENSES ISSUED 1996 STANDARD RENEWAL			
<u>Date Issued</u>	<u>Total Number Licenses Issued</u>	<u>RPh</u>	<u>Interns</u>
07/29/96	3109	2747	362
08/02/96	1880	1880	0
08/06/96	790	445	345
08/23/96	3745	3445	300
08/29/96	1843	1748	95
08/30/96	603	602	1
09/05/96	473	426	47
09/10/96	425	364	61
09/12/96	281	261	20
09/13/96	<u>168</u>	<u>150</u>	<u>18</u>
SUB-TOTAL	13317 (92.7%)	12068 (93.7%)	1249 (83.9%)
09/16/96	64	57	7
09/17/96	54	47	7
09/18/96	18	15	3
09/23/96	72	61	11
09/30/96	39	36	3
10/04/96	39	34	5
10/16/96	61	52	9
10/18/96	69	64	5
10/18/96	<u>13</u>	<u>13</u> (in audit)	<u>0</u>
SUB-TOTAL	429	379	50
TOTAL	13746	12447	1299
% RENEWED	95.7%	96.7%	87.3%
% LAPSED	4.3%	3.3%	12.7%

Continuing Pharmacy Education

Continued competency is ensured through license renewal. Ohio pharmacists and pharmacy interns are required to submit evidence that they are continuing their pharmacy education in order to qualify for renewal.

Pharmacy Interns

Pharmacy interns must be enrolled in a college of pharmacy in order to qualify for renewal. Two hundred nineteen (219) pharmacy interns were required to obtain and return Certificates of Acceptance forms verifying that they were either enrolled in a college of pharmacy or

that they had been accepted for enrollment with their renewal applications for the 1996-1997 licensure year. These pharmacy interns did not appear on the enrollment lists submitted to the Board by the four Ohio Colleges of Pharmacy at the beginning of the 1996-1997 academic year. If they were previously enrolled in one of the Ohio Colleges of Pharmacy, the Board needs to know whether or not they have transferred to a college of pharmacy in another state or if they have decided to not pursue a career in pharmacy.

Pharmacists

One-third of the pharmacists holding current licenses to practice in Ohio must submit evidence of successfully completing 45 hours of continuing pharmacy education every three years. Continuing pharmacy education must be obtained from providers who have been approved by the Board. Approved providers include national providers who have been approved by the American Council on Pharmaceutical Education and individuals or organizations located in Ohio who have submitted applications to the Board and have been approved as an in-state provider.

The Board approved 28 new in-state providers and re-approved 22 in-state providers of continuing pharmacy education for another three years during FY 96.

Continuing Pharmacy Education Requirement - Jurisprudence

Pharmacists who must report continuing pharmacy education towards renewal of their licenses for the 1997-1998 licensure year must have obtained 0.2 CEU by participating in a jurisprudence program approved by the Board. Paragraph (A) of O.A.C. Rule 4729-7-02 (Requirements for renewal of a pharmacist identification card) was amended by the Board on February 15, 1995 and reads as follows:

Evidence of four and one-half C.E.U.s of approved continuing education shall be submitted with the application for renewal of a pharmacist identification card at intervals not to exceed three years. At least 0.3 C.E.U.s of the total required 4.5 C.E.U.s must be obtained from board approved programs in jurisprudence. Pharmacists required to report continuing education in 1996 must show evidence of 0.1 C.E.U. of jurisprudence. Pharmacists required to report continuing education in 1997 must show evidence of 0.2 C.E.U.s of jurisprudence. Pharmacists required to report continuing education in 1998 and after must show evidence of 0.3 C.E.U.s of jurisprudence. *[emphasis added]*

The jurisprudence requirement applies to:

- all pharmacists who hold a current license to practice pharmacy in Ohio and who reside and practice in the state; and
- those pharmacists who hold a current license to practice pharmacy in Ohio and are not practicing pharmacy in another state that requires continuing education in order to renew their license.

Pharmacists who are actively practicing pharmacy in another state where continuing education is required for renewal of their license to practice in that state may renew their Ohio identification card (license to practice) by using the following statement on their continuing pharmacy education report form:

"I declare under penalties of falsification that I hold a current and valid pharmacist license, number (insert license number), in the state of (insert name of state), and that I have met the continuing education requirements of this state and I do not presently reside or practice pharmacy in the state of Ohio. I hereby agree to immediately notify the board of pharmacy if I return and commence the practice of pharmacy in the state of Ohio."

[Note: Do NOT Insert Your Ohio License Number In This Statement. DO Insert An Out-Of-State License Number And State Name Or The Report Form Will Be Rejected.]

The February 1997 State Board Newsletter contained the second Jurisprudence Quiz for continuing education credit. Pharmacists successfully completing the quiz according to the instructions included in the February issues of the State Board Newsletter receive 0.1 C.E.U. in jurisprudence towards renewal of their license. A continuing education quiz in Jurisprudence is included by the Board in each February issue of the Newsletter and covers material appearing not only in the current February issue but also the material appearing in the previous three issues - May, August, and November. The continuing education report form has been modified to include a separate area for reporting approved jurisprudence courses.

Three thousand forty (3,040) pharmacists obtained 0.1 C.E.U. in Jurisprudence by successfully completing the February 1996 State Board Newsletter quiz. Forty-two (42) Jurisprudence programs were presented by Board staff to local associations and pharmacists throughout the state in FY 96 and 27 to date this fiscal year. All areas of the state have had jurisprudence programs presented by Board staff.

Continuing Pharmacy Education Audit

In order to spread out the administrative workload, the Board's continuing pharmacy education program requires that one-third of the registered pharmacists who hold current licenses to practice (identification cards) report the continuing pharmacy education that they have obtained in order to qualify for renewal. Consequently, 4,122 pharmacists reported continuing pharmacy education towards renewal of the licenses to practice for the 1996-1997 licensure year, and approximately 10% of those reporting were audited (440).

CONTINUING PHARMACY EDUCATION AUDIT					
FY	Date of Notice	Total Audited	Total PTD	Total Cleared Post-PTD	Total Denied (mon.pen.)
90	12/08/89	324	NA	NA	NA
91	11/05/90	332	6	4	2
92	10/16/91	330	2	0	1*(1)
93	10/21/92	367	3	2	1
94	10/08/93	399	4	1	2 (1)
95	10/07/94	346	2	0	1 (2)
96	upon receipt	361	0	0	0
97	upon receipt	440	0	0	0

(mon.pen. = monetary penalty of \$100 imposed)

*NA-not available PTD-proposed to deny *-one withdrew application*

The procedure for conducting the continuing pharmacy education audit was changed during the 1995-1996 licensure year. Board staff now conducts the continuing pharmacy education audits prior to issuing the license to practice. Identification cards are not issued until the pharmacists required to report continuing education credit have cleared the audit.

DANGEROUS DRUG DISTRIBUTORS

Licensing of sites engaged in the legal distribution of dangerous drugs is the foundation of drug law compliance and enforcement programs. Licensing requires a determination that those individuals wishing to engage in such activity meet certain qualifications. Those that do not qualify are not licensed by the Board.

This determination is made administratively by a careful review of the application and a background check of the applicant, their agents, officers, and employees. If the site being licensed is located in another state, the agency licensing the applicant in that state is contacted to verify if they are currently licensed in that state and whether or not their license is in good standing. If the applicant is licensed or registered with any federal drug law enforcement agency, a check is also made with that agency to verify licensure and determine the standing of such license.

New sites located in Ohio are licensed only after a Board compliance agent has visited the site and determined that they qualify. A continuing review of the licensee's qualifications for licensure is made during routine, unannounced compliance inspections. Renewal applications are also carefully reviewed each year to determine whether or not the license should be renewed.

The Board proposed to deny two applicants for licensure as wholesalers of dangerous drugs and one applicant for licensure as a wholesaler of controlled substances in FY 96. All three applications were denied following Chapter 119. hearings.

Wholesale Distributors of Dangerous Drugs Manufacturers and Wholesalers of Controlled Substances

The Dangerous Drug Distribution Act provides that all firms or businesses distributing dangerous drugs at wholesale in Ohio register with the Board of Pharmacy as a wholesale distributor of dangerous drugs. These firms register with the Ohio Board even if their place of business is located in another state. If the wholesale distributor of dangerous drugs is also engaged in the manufacture or wholesale distribution of controlled substances, they are licensed with the Board to engage in such activity. The following table illustrates the number of wholesale distributors (in-state and out-of-state) registered with the Board of Pharmacy as of June 30, 1996 and who hold manufacturer or wholesale licenses to also distribute controlled substances at wholesale in Ohio. The number registered as of February 18, 1997 appears in parentheses.

WHOLESALE DANGEROUS DRUG DISTRIBUTORS				
FY 96 (FY 97 TD)				
	Number [MCS]	Number [WCS]	Total [MCS&WCS]	Number [WDDD]
In-state	8 (8)	209 (217)	217 (225)	468 (531)
Out-of-state	29 (36)	224 (270)	253 (306)	441 (543)
Totals	37 (44)	433 (587)	470 (531)	909 (1074)

KEY: [MCS] - manufacturer of controlled substances TD - as of 02/18/97
 [WCS] - wholesaler of controlled substances
 [WDDD] - wholesale dangerous drug distributor

Terminal Distributors of Dangerous Drugs

Ohio's Dangerous Drug Distribution Act provides for the licensing of most of the sites where dangerous drugs are stored in the state of Ohio for legal purposes. These purposes include the administration or dispensing of the drugs to patients (humans or animals) when diagnosing and/or treating illnesses or injuries. The drugs may also be used for purposes of teaching or in conducting research or drug analysis.

The sites where the dangerous drugs are stored for these purposes are licensed as terminal distributors of dangerous drugs. The Board has established 49 different classifications of terminal dangerous drug distributors for licensing and regulatory purposes. The table on Page 36 lists the different classifications and the number of licenses in each classification of terminal distributors as of February 1997.

The following table indicates the trends occurring among different categories of terminal distributors of dangerous drugs operating pharmacies in Ohio:

	FY 94	%	FY 95	%	FY 96	%	FY 97 TD	%
Retail Pharmacies	2209	83%	2229	84%	2211	83%	2200	83%
<i>Independent (1 outlet)</i>	642	29%	606	27%	562	25%	527	24%
<i>Small Chain (2-11 outlets)</i>	381	17%	370	17%	337	15%	326	15%
<i>Large Chain (12 or more)</i>	1186	54%	1258	56%	1312	59%	1347	61%
Hospital Pharmacies	236	9%	231	9%	231	9%	224	9%
Pharmacy serv. LTCF	42	2%	48	1%	52	2%	53	2%
Fluid Ther/HHC Pharmacy	88	3%	83	3%	79	3%	75	3%
Clinic Pharmacy	24	1%	25	1%	28	1%	36	1%
HMO Pharmacy	18	1%	22	1%	24	1%	20	1%
Mail Order Pharmacy	17	1%	18	1%	15	1%	16	1%
Nuclear Pharmacy	12	0%	12	1%	13	1%	13	1%
Non-Territorial Pharmacy					76	3%	95	4%
Non-Territorial Phar Svc LTCF					5	0.2%	6	0.2%
Totals	2646		2668		2653		2738 TD	

TD - as of 02/18/97

Ohio's Dangerous Drug Distribution Act was amended in 1984 to provide for three different categories of dangerous drugs. The categories indicate those drugs which the licensed terminal distributor is permitted to purchase and possess for distribution or use in Ohio. The license may also be limited to certain drugs within a category of dangerous drugs. In these instances, the drugs are listed on the license addendum. The three categories of dangerous drugs are as follows:

CATEGORY I - Single dose injections of intravenous fluids, including saline, Ringer's lactate, five percent dextrose and distilled water, and other intravenous fluids or parenteral solutions included in this category by rule of the board of pharmacy, that have a volume of one hundred milliliters or more and that contain no added substances, or single-dose injections of epinephrine to be administered pursuant to division (B) of section 3303.08 of the Revised Code.

CATEGORY II - Any dangerous drug that is not included in category I or III.

CATEGORY III - Any controlled substance that is contained in schedule I, II, III, IV, or V.

The Category III license authorizes the person to possess, have custody or control of, and distribute Category I, II, and III dangerous drugs.

The following table lists the number of the six different categories of terminal distributor of dangerous drugs licensed by the Board.

CATEGORY OF TERMINAL DISTRIBUTOR LICENSES				
<i>(TD - as of 02/18/97)</i>				
	<u>FY 94</u>	<u>FY 95</u>	<u>FY 96</u>	<u>FY 97 TD</u>
Category I	4	3	1	1

Limited Category I	238	11	10	10
Category II	265	228	261	249
Limited Category II	326	769	1545	1557
Category III	5474	5575	5685	5620
Limited Category III	1304	1441	1438	1422
Total	7611	8027	8940	8859

Very few Category I terminal distributor licenses are issued each year due to an increasing number of emergency medical systems qualifying for Limited Category II licenses. Emergency Medical Technicians are now authorized to administer epinephrine, a Category II dangerous drug provided they have obtained the training required by the Emergency Medical Services Board (O.R.C. Section 4765.02).

TERMINAL DISTRIBUTORS <u>Classification</u>	NUMBER LICENSED			
	<u>FY 94</u>	<u>FY 95</u>	<u>FY 96</u>	<u>FY 97 TD</u>
Retail Pharmacy	2209	2229	2211	2200
<i>Independent (1 outlet)</i>	642	606	562	527
<i>Small Chain (2-11 outlets)</i>	381	370	337	326
<i>Large Chain (12 or more outlets)</i>	1186	1253	1312	1347
Hospitals	236	235	236	232
Fluid Therapy/Home Health Care	88	78	80	77
Pharmacy serving LTCF	42	47	54	55
Clinic Pharmacy	24	24	25	24
HMO	18	19	24	23
Mail Order Pharmacy-Located in Ohio	17	18	17	17
Nuclear Pharmacy	12	13	14	15
Specialty Pharmacy	7	6	5	4
Pharmacy/employees only	3	5	6	5
Non-territorial Pharmacy	NA	46	76	95
Non-territorial Pharmacy serving LTCF/institutions	NA	2	2	3
Health Care Facility Pharmacy	1297	1343	1375	1310
Pharmacy (contingency stock - LTCF)	5	4	5	4
Custodial Care	5	8	9	9
First Aid Dept.	312	324	324	318
Convalescent/rest/nursing home	14	11	9	9
DME (Medical Equipment) Pharmacy	6	2	3	5
Practitioner Corporation	232	245	246	234
Private Practitioners	19	22	23	24
Clinic	997	1008	1048	1058
Home Health Care Agency	106	119	134	151
Correctional Institution	70	83	92	86
Mobile Clinic	1	1	1	1
Emergency Medical Systems	1341	1405	1452	1442
<i>Headquarters</i>	804	827	849	839
<i>Satellites</i>	537	578	603	603
Animal Euthanasia	NA	14	22	23
Animal Control (dog wardns/humane soc. shltrs)	39	44	40	38
Veterinary Facilities (includes zoos)	124	122	125	121
Laboratories/research	206	201	194	185
Teaching Institution	66	65	70	69
Sports Training Facility	12	11	10	10
Incinerators (Waste disposal)	10	8	10	9
Dog Trainer	19	21	25	26
Hospice	3	8	10	11
Corporate Headquarters	1	1	1	1
Physical Therapy	55	76	80	81
Retail Seller of Medical Oxygen	8	136	486	503
Oxygen Reseller - Contingency Stock	NA	NA	354	347
Other	6	23	16*	15**
TOTAL LICENSED	7611	8027	8940	8890

TD – as of 02/24/97 NA - not applicable

* The Other classification of terminal distributors of dangerous drugs for FY 96 includes manufacturer-process use (4), food processors licensed to purchase nitrous oxide (10), SWAT EMS (1), group home drug use supervision (3), chemical treatment facility (2), blood banks (9), consulting pharmacies (1), non-emergency transport only (1), helicopters-physicians (2), and miscellaneous (14).

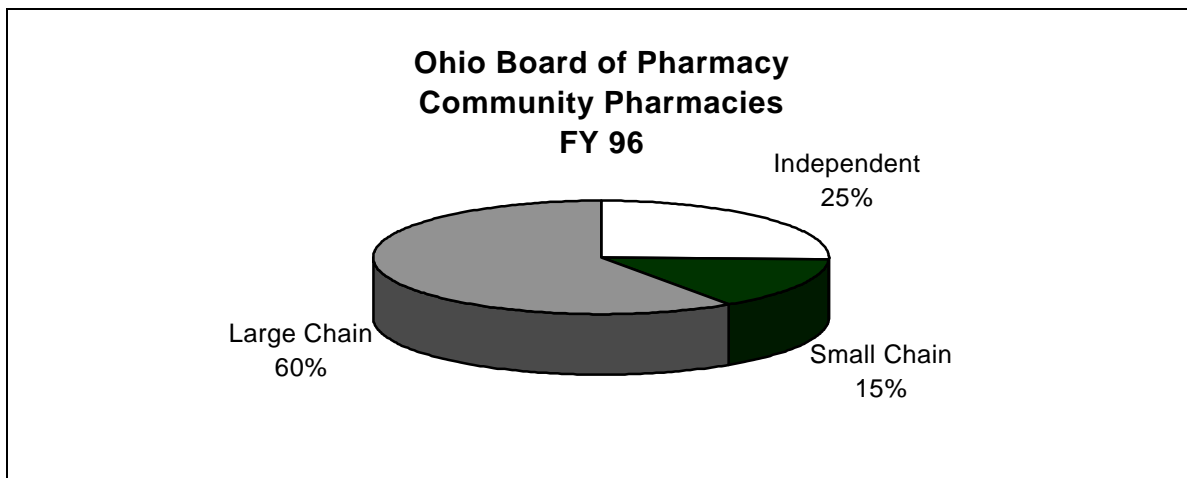
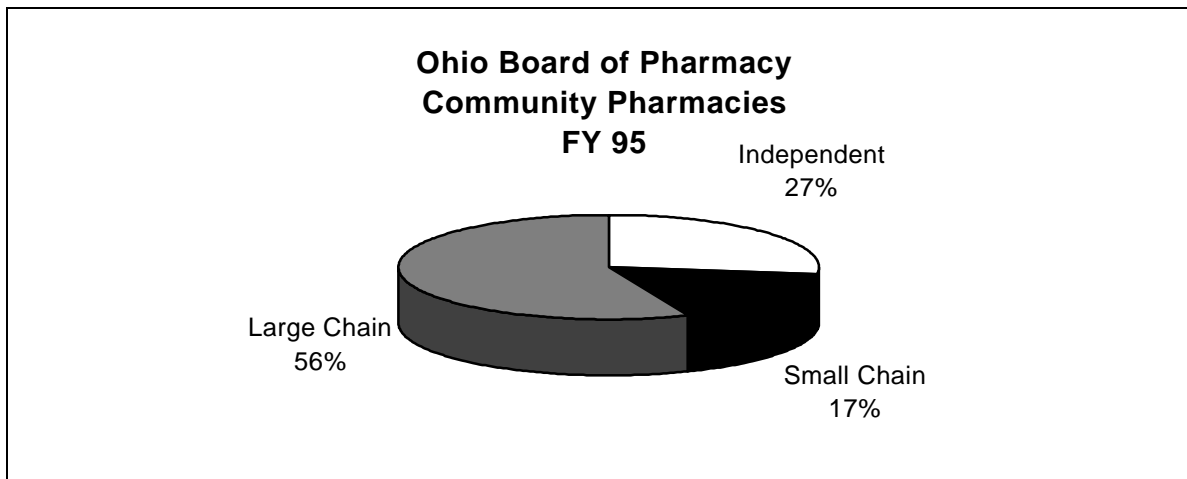
** The Other classification of terminal distributors of dangerous drugs for FY 97 to date includes manufacturer-process use (4), SWAT EMS (1), group home drug use supervision (2), chemical treatment

facility (3), blood banks (8), consulting pharmacies (1), non-emergency transport only (1), helicopters-physicians (2).

Data concerning practice sites continues to document the decrease in the number of hospital, independent, and small chain pharmacies licensed with the Board. In FYs 93, 94, and 95, the total number of independent pharmacies has decreased by 188. Forty-four (44) independent pharmacies discontinued business during FY 96, and 35 have discontinued business to date in FY 97 (as of February 25, 1997).

Further demonstrating a concentration of pharmacy ownership is the decrease in number of sites licensed as small chain pharmacies. One hundred seventeen (117) small chain pharmacies have discontinued business in Ohio since FY 91. Thirty-three (33) small chain pharmacy sites discontinued business in FY 96, and 11 to date in FY 97.

Large chains showed the largest increase in the number of licensed practice sites. The number of retail pharmacies operated in the state of Ohio by large chains (12 or more outlets) has increased every fiscal year since FY 91. The largest increase occurred during FY 93 when 76 large chain sites were licensed by the Board. Sixty-one percent (61%) of all retail pharmacies located in Ohio are presently operated by large chains.



At the end of FY 94, there were 236 hospital pharmacies in Ohio. As of February 25, 1997, there were 232.

As is occurring in other industries and businesses in the United States, the ownership in pharmacies is being concentrated due to purchases of independent proprietors, mergers, and take-overs of corporations. This is occurring not only in the retail operations but also in the wholesale industry. Another major phenomenon is the increasing vertical integration occurring in the pharmaceutical industry. Large chain pharmacies in Ohio have experienced a significant concentration in ownership over the past five years. The most recent large chain pharmacy acquisition having a significant impact in Ohio is the purchase of Revco Drug Stores, Inc. by C.V.S. Revco was the largest chain pharmacy having its corporate headquarters located in Ohio. At one time, Ohio was the corporate headquarters for the following large chains: Gray Drug Stores, Inc.; Lane Drug Stores, Inc.; People's Drug Stores, Inc.; SupeRx Drug Stores, Inc.; as well as Revco Drug Stores, Inc.

The following table consists of information generated by the Board's licensing system. "Active practice" includes pharmacists who are working full-time (40 hours or more per week) and those working part-time (less than 40 hours per week).

<u>REGISTRANTS AND PRACTICE SITE DATA</u>						
(As of February 18, 1997)						
<u>PHARMACY PRACTICE ACT</u>	<u>Total</u>	<u>%</u>	<u>Female</u>	<u>%</u>	<u>Male</u>	<u>%</u>
<u>REGISTERED PHARMACISTS</u>	13033	100%	5408	41.5%	7625	58.5%
<u>Active Practice</u>						
In Ohio	8447	100%	3581	42.4%	4866	57.6%
Out-of-state	2713	100%	1183	43.6%	1530	56.4%
<u>Active Practice Site In Ohio</u>						
Large chain (12+ outlets)	3458	100%	1449	41.9%	2009	58.1%
Private hospital	1610	100%	803	49.9%	807	50.1%
Independent (1 outlet)	1098	100%	293	26.7%	805	73.3%
Small chain (2-11 outlets)	444	100%	151	34.0%	293	66.0%
Government hospital (fed/state/local)	331	100%	158	47.7%	173	52.3%
Mail order pharmacy	374	100%	192	51.3%	182	48.7%
Clinic/Medical Bldg.	173	100%	74	42.8%	99	57.2%
Long-term care pharmacy	205	100%	94	45.9%	111	54.1%
HMO	132	100%	76	57.6%	56	42.4%
Military/V.A. hospital	107	100%	49	45.8%	58	54.2%
Fluid therapy pharmacy	89	100%	42	47.2%	47	52.8%
Nuclear pharmacy	41	100%	8	19.5%	33	80.5%
Pharmacy servicing nursing home(s)	138	100%	71	51.4%	67	48.6%
Nursing home	22	100%	13	59.1%	9	40.9%
<u>Pharmacy-related practice sites</u>						
Pharmaceutical manufacturer	100	100%	35	35.0%	65	65.0%

Pharmaceutical wholesaler	6	100%	1	16.7%	5	83.3%
<u>PHARMACY INTERNS</u>	1491	100%	952	63.8%	539	36.2%

The following tables provide "age by gender" data for the four main sites of practice in Ohio. These four practice sites account for 81% or 6,846 of the pharmacists engaged in active practice in Ohio. The numbers in the brackets indicate the number of practice sites in each of the four classifications of dangerous drug distributors.

Independent Pharmacy [562] (1 outlet)			
<u>Age By Gender Data as of June 30, 1996</u> (in-state only)			
<u>Age (years)</u>	<u>Female</u>	<u>Male</u>	<u>Total</u>
24 yrs or less	22	15	37
25 - 29	45	37	82
30 - 34	53	39	92
35 - 39	43	77	120
40 - 44	58	113	171
45 - 49	25	101	126
50 - 54	26	89	115
55 - 59	5	92	97
60 - 64	15	100	115
65 - 69	11	109	120
70 - 74	5	37	42
75 - 79	1	26	27
80 or greater	2	13	15
TOTALS	311 (26.8%)	848 (73.2%)	1159

Large Chain Pharmacy [1312] (12 or more outlets)			
<u>Age By Gender Data as of June 30, 1996</u> (in-state only)			
<u>Age (years)</u>	<u>Female</u>	<u>Male</u>	<u>Total</u>
24 yrs or less	121	57	178
25 - 29	513	285	798
30 - 34	302	239	541
35 - 39	226	231	457
40 - 44	168	288	456
45 - 49	64	279	343
50 - 54	27	165	192
55 - 59	33	192	225
60 - 64	13	172	185
65 - 69	9	103	112
70 - 74	4	43	47
75 - 79	1	13	14

80 or greater	0	4	4
TOTALS	1481 (41.7 %)	2071 (58.3%)	3552

Small Chain Pharmacy [337] (2 to 11 outlets) <u>Age By Gender Data as of June 30, 1996</u> (in-state only)			
<u>Age (years)</u>	<u>Female</u>	<u>Male</u>	<u>Total</u>
24 yrs or less	7	5	12
25 - 29	28	16	44
30 - 34	32	22	54
35 - 39	31	42	73
40 - 44	25	44	69
45 - 49	18	40	58
50 - 54	3	32	35
55 - 59	10	28	38
60 - 64	2	32	34
65 - 69	4	28	32
70 - 74	0	12	12
75 - 79	0	6	6
80 or greater	0	0	0
TOTALS	160 (34.3%)	307 (65.7%)	467

Private Hospital [236] <u>Age By Gender Data as of June 30, 1996</u> (in-state only)			
<u>Age (years)</u>	<u>Female</u>	<u>Male</u>	<u>Total</u>
24 yrs or less	67	34	101
25 - 29	171	84	255
30 - 34	171	104	275
35 - 39	194	138	332
40 - 44	141	194	335
45 - 49	55	136	191
50 - 54	20	65	85
55 - 59	12	27	39
60 - 64	10	20	30
65 - 69	2	13	15
70 - 74	1	7	8
75 - 79	0	2	2
80 or greater	0	0	0
TOTALS	844 (50.6%)	824 (49.4%)	1668

Sixty-nine percent (69%) of the pharmacists actively practicing in retail pharmacies are employed by the large chains. Twenty-two percent (22%) are actively practicing in independent pharmacies and nine percent (9%) in small chain pharmacies. The number of female pharmacists actively practicing in hospitals now exceeds the number of male pharmacists.

All Ohio R.Ph. <u>Age By Gender Data as of June 30, 1996</u> (in-state only)			
<u>Age (years)</u>	<u>Female</u>	<u>Male</u>	<u>Total</u>
24 yrs or less	269	139	408
25 - 29	958	554	1512
30 - 34	778	553	1331
35 - 39	746	724	1470
40 - 44	618	895	1513
45 - 49	259	762	1021
50 - 54	106	486	592
55 - 59	101	447	548
60 - 64	68	470	538
65 - 69	57	433	490
70 - 74	34	217	251
75 - 79	8	104	112
80 or greater	8	57	65
TOTALS	4010 (40.7%)	5841 (59.3%)	9851

REGULATION

Ad Hoc Advisory Committee on Rule Review

Each calendar year the Board appoints an Ad Hoc Advisory Committee on Rule Review. The members of this committee are volunteers and serve at their own expense. The Board of Pharmacy first established this committee in 1984 due to the enactment of the Regulatory Flexibility Act by the Ohio General Assembly. The sections of law making up this act requires each state agency to review each rule that effects individuals, small businesses, or small organizations at least once every five years.

The purpose of this review is to determine whether a rule should be continued without change, be amended, or rescinded, so as to minimize the economic impact of such rule on such persons. The following questions must be considered in reviewing each of the Board's rules:

- (1) Does the rule effect a "small business" (i.e.-an independently owned and operated business having fewer than 400 employees), or a "small organization (i.e.-an unincorporated association, sheltered workshop, or non-profit enterprise having fewer than 400 employees)?
- (2) Does the rule effect any individual in his or her capacity as an officer or employee of a "small business" or "small organization"?
- (3) Is the rule needed?

- (4) What is the nature of any written complaints or comments regarding the rule?
- (5) Does the rule duplicate, overlap, or conflict with other rules?
- (6) What is the degree of change that has occurred in the area affected by the rule in respect to technology, economic conditions, and other relevant factors?

The committee is appointed by the Board from lists of names submitted by organizations whose members are affected by rules adopted pursuant to the laws governing the practice of pharmacy and the legal distribution of drugs. Sub-committees are appointed in areas where members require a special expertise in addressing the required questions. For example, nuclear pharmacists serve as members of a subcommittee of the Ad Hoc Advisory Committee on Rule Review when the nuclear pharmacy rules are reviewed pursuant to the Regulatory Flexibility Act of 1984.

The following rules were reviewed by the 1996 Ad Hoc Advisory Committee on Rule Review:

<u>RULES REVIEWED</u>	
<u>CALENDAR YEAR 1996</u>	
<u>Rule Number</u>	<u>Title</u>
4729-1-01	Public hearing notice
4729-1-02	Notice of meetings
4729-1-03	Public records
4729-1-05	Advisory committees
4729-3-01	Definitions
4729-3-02	Registration as a pharmacy intern
4729-3-03	Application for registration as a pharmacy intern
4729-3-04	Pharmacy intern identification card renewal
4729-3-05	Internship credit
4729-3-09	Expiration of pharmacy intern registration
4729-5-07	Recognized and approved colleges of pharmacy
4729-5-17	Recordkeeping
4729-5-19	Serial numbering of prescriptions
4729-5-24	Prescription copy
4729-5-25	Dispensing of drugs and compounding of prescriptions
4729-6-01	Definitions; impaired pharmacists
4729-6-02	Applicability
4729-6-04	Approval of treatment providers
4729-6-06	Qualifications of approved treatment providers
4729-6-08	Requirements for approved treatment providers and limited approved treatment providers
4729-6-10	Summary suspension, license of impaired pharmacist
4729-9-01	Definitions
4729-9-04	Returned drugs
4729-9-07	Procedure for discontinuing business as a wholesale or a terminal distributor of dangerous drugs
4729-9-16	Minimum requirements for wholesalers

The first meeting of the 1997 Ad Hoc Advisory Committee on Rule Review will be held this month. Meeting dates are now being finalized. The following rules will be reviewed by the 1997 Ad Hoc Advisory Committee on Rule Review:

<u>RULES FOR REVIEW</u>	
<u>CALENDAR YEAR 1997</u>	
<u>Rule Number</u>	<u>Title</u>
4729-5-01	Definitions
4729-5-02	Identification card, photograph and signature
4729-5-03	Renewal of registration
4729-5-05	Change of name of registrant
4729-5-15	Practitioner
4729-5-18	Patient profiles
4729-5-20	Prospective drug utilization review
4729-5-22	Patient counseling
4729-9-05	Security requirements
4729-9-06	Disposal of dangerous drugs which are controlled substances
4729-9-08	Change in description of terminal dangerous drug facility
4729-9-09	Security of prescription blanks and D.E.A. controlled substance order forms
4729-9-10	Occasional sale
4729-9-13	Distributor of dangerous drug samples
4729-9-17	Storage of adulterated drugs
4729-19-01	Definitions
4729-19-02	Prescriptions for sterile products
4729-19-03	Labeling
4729-19-04	Minimum standards for compounding parenteral or sterile product prescriptions

Thirteen (13) Ohio Administrative Code rules were amended, one was rescinded, and four new rules were adopted by the Board pursuant to the recommendations of the 1996 Ad Hoc Advisory Committee on Rule Review. The rules were effective January 17, 1997 and a copy of the full text may be obtained by contacting the Board office or downloading the "Summary of Rules" titled "Rules Effective 01/17/97" from the Board's Home Page on the World Wide Web:

URL: <http://www.state.oh.us/pharmacy/>

The Board also adopted five new rules pertaining to Peritoneal Dialysis Solutions (new Chapter 4729-27 of the Ohio Administrative Code) as a result of newly enacted legislation. These rules may also be found in the "Rules Effective 01/17/97" Summary of Rules.

The Board has proposed amending Ohio Administrative Code Rules 4729-5-24, 4729-5-31, and 4729-12-09. Rule 4729-5-24 is being amended to clarify ownership of prescription information and provide the owner with the legal authority to require the transfer of a prescription copy from one pharmacy to another pharmacy if unable to receive medication when needed; Rule 4729-5-31 is being amended to update the rule to reflect the licensure exam currently used by the Board;

and Rule 4729-12-09 is being amended to correct language and to add SnoreStop™ which was approved by the Board to be excepted from classification as a Schedule V controlled substance. The public hearing is scheduled for Tuesday, April 22, 1997 at 1:30 p.m. and a copy of the Notice and text of the proposed amendments may be obtained from the Board's Home Page on the World Wide Web.

COMMUNICATIONS

WORLD WIDE WEB

Ohio Board of Pharmacy Home Page
URL: <http://www.state.oh.us/pharmacy/>

The Board's Home Page was placed on the World Wide Web on March 1, 1996. The following outlines the topics presently included under each heading on the Board's Home Page. Information on the Board's Home Page may be downloaded and printed from the World Wide Web.

CONTENTS OF THE BOARD'S HOME PAGE ON MARCH 31, 1997

<p>General</p> <ul style="list-style-type: none"> • Mission Statement • Board Members and Staff • Annual Report – March 1996 	<p>Summaries of Laws/ Rules/Regulations</p> <ul style="list-style-type: none"> • Rules Effective in 1996 • The Legal Practice of Pharmacy • Prescriptions • Faxing Prescriptions • Controlled Substances/ Weight Loss • Samples • Fluid Therapy • Optometry Drugs • Ephedrine • C.S.A. Drug Abuse/ Misuse Report: Ephedrine 	<p>Registration/ Licensing</p> <ul style="list-style-type: none"> • Licensing of Animal Shelters for Euthanasia • Registration As A Pharmacist By Exam • Registration As A Pharmacist By Reciprocity • Continuing Pharmacy Education • Nonresident Terminal Distributor of Dangerous Drugs 	<p>Links to Other WWW Pages</p> <ul style="list-style-type: none"> • NCPDP (National Council for Prescription Drug Programs) • Glaxo Wellcome's HELIX Network • Ohio Northern University College of Pharmacy page • University of Cincinnati College of Pharmacy page
<p>Important Dates/ Sunshine Notice</p> <ul style="list-style-type: none"> • Important Dates (Last Update 03/13/97) • Sunshine Notice (To Be Added) 	<p>FAQ</p> <ul style="list-style-type: none"> • In Progress 	<p>C.P.E. News</p> <ul style="list-style-type: none"> • Jurisprudence C.P.E. Information • Link to Adherence, Inc. page 	<p>In Progress</p>

Board Minutes	What's New	Fees	In Progress
<ul style="list-style-type: none"> • September 16-19, 1996 • October 21-25, 1996 	<ul style="list-style-type: none"> • C.S.A. Drug Abuse/ Misuse Report: Ephedrine • Rules Adopted and Effective 01/17/97 • Notice of Public Rules Hearing on 04/22/97 • Compliance Bulletin 97-001 Regarding Ephedrine Exceptions Effective 03/31/97 • Executive Director Position Opening 	<ul style="list-style-type: none"> • As of 10/31/96 	

The Home Page includes general information about the Board, tentative meeting schedules, the current official Minutes of the Board, Summaries of Laws, Rules, and/or Requirements regarding many topics, Compliance Bulletins, and reports published by the Board. Information about registration as a pharmacy intern, pharmacist, or dangerous drug distributor, and current Newsletters will also be included on the Home Page as the documents are prepared for publication.

COMPLIANCE BULLETINS

The Board's computer system provides the Board with the ability to communicate in a timely and cost-effective manner with those pharmacists or dangerous drug distributors having a "need to know" or whose professional practice/business has been or will be affected by laws, rules, or policy decisions made by state or federal regulatory agencies. Compliance bulletins are issued by the Board on an as-needed basis to those licensees and registrants being affected.

Three compliance bulletins have been issued by the Board since last year's report. Compliance Bulletin 96-003 was mailed on June 17, 1996 to all pharmacists actively practicing pharmacy in Ohio and discussed the Medical Board rules regarding the dispensing of *Redux*TM (dexfenfluramine) – the newly marketed Schedule IV controlled substance for weight loss. The second compliance bulletin (93-004 – Patient Records) was mailed to all Ohio Registered Pharmacists on December 16, 1996. This bulletin discussed the confidentiality of patient prescription records and Ohio Administrative Code Rule 4729-5-17 (Recordkeeping).

The third compliance bulletin (97-001 – OTC Products Containing Ephedrine – Exceptions To Classification As A Schedule V Controlled Substance) was mailed on March 17, 1997 to manufacturers, wholesalers, and pharmacists. This bulletin discussed the provisions of Sub. H.B. 523 which excepted food products and dietary supplements containing natural ephedrine alkaloids from Schedule V of Ohio's Controlled Substance schedules.

COMPLIANCE

Licensing is a process by which government grants permission to engage in a particular business or profession. Licensing is an effective tool for enforcing laws and obtaining compliance in that it ensures that those individuals who are permitted to engage in the

business are qualified. Licensure also provides the licensing agency with the opportunity to effectively monitor compliance with the laws and rules governing the business by conducting compliance inspections.

VOLUNTARY COMPLIANCE

The Ohio Board of Pharmacy continues to educate pharmacists and the individuals responsible for the operation of pharmacies in Ohio regarding the importance of counseling patients and performing prospective drug utilization review when dispensing prescription medications. These efforts have included an annual meeting with the Directors of Pharmacy Operations of chains operating in Ohio; the issuing of written warnings during compliance inspections of outpatient pharmacies; and over 50 presentations by staff to groups of pharmacists and pharmacy students throughout the state of Ohio.

The Board, during its January 1996 business meeting, directed staff to make arrangements for a second meeting of the pharmacists who are responsible for chain pharmacy operations in Ohio. The meeting was held on May 9, 1996. Also invited and attending this meeting was the Executive Director of the Ohio Pharmacists Association, Ernest Boyd. Once again the meeting was well received by those in attendance and it was the consensus of those in attendance that such meetings be continued on at least an annual basis.

COMPLIANCE/ENFORCEMENT ACTIVITIES

Monitoring of compliance with the patient counseling rules has been occurring during routine inspections of pharmacies as instructed by the Board in January, 1995; when investigating complaints or allegations of violations of drug laws and rules; and when investigating reports of dispensing errors. Written warnings are issued by Board agents and specialists for not complying with the rules regarding the maintenance of patient profiles, performing prospective drug utilization review, and patient counseling. Compliance agents and specialists also issue a "written warning" during a compliance inspection or investigation of a complaint if there are certain deficiencies or violations of laws and rules governing the legal distribution of dangerous drugs.

Three "Notices of Opportunity for a Hearing" were issued in 1996 by the Board that include allegations that the pharmacist failed to "counsel patients" and perform "prospective drug utilization review". Two were issued to the responsible pharmacist and one to a pharmacy. These charges were the result of routine inspections conducted by the Board field staff. Two of the Notices were mailed on September 4, 1996 and the adjudication hearing for both the pharmacist and pharmacy were heard on Thursday, March 6, 1997. The third Notice was mailed on January 7, 1997 and a hearing is scheduled June 16, 1997.

Failure To Counsel Patients

FY 95 (January 1 through June 30, 1995) The first written warning (Pink Sheet) that included failure to counsel patients was issued on February 6, 1995. Six hundred eighty-six (686) retail pharmacies were inspected and 111 written warnings were issued by the field staff during the last two quarters of FY 95. Twenty-two (22) of the written warnings issued by the Board field staff during this fiscal year included a "failure to counsel patients".

FY 96 (July 1, 1995 through June 30, 1996) Nine hundred fifty-five (955) retail pharmacies were inspected during FY 96 and 219 written warnings were issued by field staff. Nineteen (19) written warnings issued this fiscal year included a "failure to counsel patients".

FY 97 - first two quarters (July 1, 1996 through December 31, 1996) Three hundred eighty-seven (387) retail pharmacies were inspected during the first two quarters of this fiscal year and 104 written warnings were issued by field staff. Eleven (11) of the written warnings issued during this time period included a "failure to counsel patients".

Failure To Perform Prospective Drug Utilization Review

FY 95 (January 1 through June 30, 1995) Ten (10) investigations were assigned to field staff in FY 95 due to allegations that prospective drug utilization review was not performed by pharmacists.

FY 96 (July 1, 1995 through June 30, 1996) Sixteen (16) investigations were assigned during FY 96 regarding failure to perform prospective DUR. The following table indicates the disposition of these investigations:

<u>Failure To Perform DUR</u> FY 96 (July 1, 1995 - June 30, 1996)	
<u>Cases Closed</u>	<u>Disposition</u>
8	no merit/unfounded*
5	no time to investigate
2	open investigation
1	written warning (Pink Slip) issued

* *Effective prospective drug utilization review could not be performed by the pharmacists in these eight cases due to the fact that they did not have access to the patient's records that existed in other pharmacies nor the prescriber's office.*

The eight cases that were closed as "unfounded" document a fundamental problem that exists in our health care system today - the inability of the practicing pharmacist to obtain and/or access pertinent patient information in order to effectively perform prospective drug utilization review. Board staff determined that had an integrated health care patient information system been in place and the pharmacists had had access to the same information as the State agency paying for the prescriptions, prospective DUR could have been performed with appropriate intervention on behalf of the patient. The information did, however, document possible criminal activity on the part of several of the patients and/or prescribers. Accordingly, new cases have been opened by Board agents and specialists regarding the following potential violations of state law:

1. Deception to obtain dangerous drugs
2. Trafficking in controlled substances
3. Corrupting another with drugs

4. Fraud

The Board issued three "Notices of Opportunity for a Hearing" that included allegations that pharmacists dispensing prescriptions did not perform patient counseling and prospective drug utilization review. The pharmacy and both pharmacists involved in the dispensing of the patient's prescriptions were issued "Notices".

All three of these cases were resolved through settlement agreements with the respondents. One pharmacist paid a monetary penalty of \$950 while the other pharmacist and pharmacy each paid monetary penalties of \$2,500 to the State of Ohio.

FY 97 to date (July 1, 1996 through December 31, 1996)

No allegations have been filed with the Board during this time period regarding the failure of pharmacists to perform prospective drug utilization review. The Board assigned 608 investigations during this time period.

COMPLIANCE INSPECTIONS

Ideally, each site licensed with the Board should be inspected on an annual basis. This, however, is not feasible due to the increasing number of licensees and registrants, the increasing number and complexity of investigations, and legal problems associated with the enforcement of the drug laws.

The following table illustrates the total number of dangerous drug distributors licensed by the Board for FY 83 through FY 96 and FY 97 to date, number of inspections conducted each fiscal year, and percentage of sites inspected.

Ohio Board of Pharmacy COMPLIANCE INSPECTIONS			
FY	No. of Sites (out-of-state)	No. of Inspections	%
83	6828 (250)	3078	47%
84	6635 (237)	2778	43%
85	6894 (262)	2665	40%
86	7013 (269)	1811	27%
87	6997 (287)	1983	28%
88	7590 (285)	2248	30%
89	7879 (315)	1705	22%
90	7701 (349)	2593	34%
91	7645 (338)	2421	32%
92	8208 (324)	2196	28%
93	8044 (455)	1747	23%
94	8630 (487)	1434	18%
95	8515 (565)	1823	21%
96	8940 (523)	1762	20%
97 TD	8859 (641)	770	0.9%

TD - as of 12/31/96

It is expected that approximately 18% (1480) of the sites licensed with the Board and located in the state of Ohio will be inspected by the close of this fiscal year (June 30, 1997). One new field staff employee was hired this fiscal year - a compliance specialist. The new compliance specialist's responsibilities include the following counties: Adams, Brown, Butler, Clermont, Clinton, Fayette, Hamilton, Highland, and Warren. The compliance agent's position in the Cincinnati area was vacant as of September 1996. Candidates are presently being interviewed for this position.

Other factors influencing the number of inspections conducted each year include an increasing number of summary suspensions of registered pharmacists' licenses each year pursuant to the provisions of Ohio Revised Code Section 3719.12 (Am. Sub. H.B. 615 - effective March 27, 1991); and the complexity and extent of investigations involving drug trafficking or fraud by health professionals and/or employees of dangerous drug distributors. These factors, plus the increasing number of new dangerous drug distributors being licensed by the Board, result in a smaller percentage of licensed sites being inspected each fiscal year.

The following table indicates the top 18 items cited during compliance inspections conducted by the field staff for FYs 95 and 96.

<u>WRITTEN WARNINGS</u> (Pink Sheets)		
<u>DESCRIPTION</u>	FY 95 <u>RANKING (#)</u>	FY 96 <u>RANKING (#)</u>
Drug Accountability	1 (64)	1 (77)

Drug Security	5 (23)	2 (47)
RPh Initials/Date	2 (29)	3 (44)
Library	3 (27)	4 (42)
DEA Inventory (biennial)	4 (24)	5 (32)
Improper Prescription	NA	6 (28)
Improper Dispensing	7 (17)	7 (24)
Outdated Drugs	8 (16)	8 (20)
Patient Counseling	6 (21)	9 (19)
Drug Labels (incomplete)	11 (12)	10 (16)
Rx Information Missing	9 (15)	11 (15)
Illegal Sales	10 (13)	12 (14)
Barricade	NA	13 (12)
I.D. Cards	12 (8)	14 (10)
Rx Copies	14 (6)	15 (9)
Cleanliness	NA	16 (6)
Key Security	15 (3)	17 (5)
OTC/Syringes	12 (8)	18 (4)

NA - Not Available

ENFORCEMENT

INVESTIGATIONS

The following table indicates the number of investigations assigned to the field staff for Calendar Years 1990 through 1996.

INVESTIGATIONS ASSIGNED TO FIELD STAFF						
<u>1990</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>
1073	976	1052	1167	1085	1159	1198
(40%↑)	(9%↓)	(8%↑)	(11%↑)	(7%↓)	(7%↑)	(3%↑)

Incident reports received by the Board from pharmacists, dangerous drug distributors, other health professionals, law enforcement agencies, and the public regarding alleged violations of the federal and state drug laws are classified by subject matter before they are assigned to the field staff for investigation. The following table indicates the top five classifications assigned to the incident reports for FYs 95 and 96.

INCIDENT REPORTS BY CLASSIFICATION [Investigations Assigned To Field Staff]		
	FY 95 Rank (# of reports)	FY 96 Rank (# of reports)
THEFT OF DRUGS	1 (225)	1 (273)
ERROR IN DISPENSING	5 (91)	2 (147)
TRAFFICKING IN DRUGS	3 (131)	3 (138)
DECEPTION TO OBTAIN	2 (184)	4 (127)
FORGERY OF DRUG DOCUMENTS	4 (106)	5 (94)

As indicated in this table, four of the top five classifications of incident reports received by the Board in FYs 95 and 96 allege violations of Ohio Revised Code Chapter 2925. (Drug Crimes). Investigations of these incident reports alleging violations of this chapter are presented to the appropriate prosecutors and often result in the arrest and criminal prosecution of the alleged violators. The following table provides data concerning individuals arrested following investigations conducted by Board of Pharmacy field agents during FYs 95 and 96.

ARRESTS Drug Law Enforcement / Criminal		
	<u>FY95</u>	<u>FY96</u>
PHARMACIST/INTERN	22	16
REGISTERED NURSE	22	23
LPN	7	6
MD/DO	15	7
DDS	0	0
Pharmacy Employee	0	0
Physician Assistant	2	0
Podiatrist	1	1
Sales Representative	1	0
Other	<u>67</u>	<u>41</u>
Total Arrests	137	94

Investigations by the Board resulted in the arrest of 67 health care professionals in FY 95. Fifty-three (53) licensed health care professionals were arrested in FY 96. The results of these investigations were presented to the appropriate prosecutors for criminal prosecution.

SUMMARY SUSPENSIONS WITHOUT A PRIOR HEARING

Division (C) of Ohio Revised Code Section 3719.121, as amended by Am. Sub. H.B. 615 effective 03/27/91, provided that the license or registration of a practitioner, nurse, pharmacist, manufacturer, or wholesaler shall be immediately suspended without a prior hearing by the

appropriate board when a prosecutor has notified the board that the registrant or licensee has:

- (1) pled guilty to, or a judicial finding [has been made] of his guilt of, a felony drug abuse offense;
- (2) a judicial finding [has been made] of eligibility for treatment in lieu of conviction;
- (3) a judicial finding [has been made] of his guilt of an offense in another jurisdiction that is essentially the same as a felony drug abuse offense; or
- (4) a judicial finding [has been made] of his eligibility for treatment in lieu of conviction in another jurisdiction.

The amended statute further provided that the suspension shall remain in effect until a hearing is held by the licensing board. This legislation also provided the Board of Pharmacy and the other health professional licensing boards with the authority to suspend a license without a prior hearing provided there is clear and convincing evidence that continuation of the individual's professional practice or method of distributing controlled substances presents a danger of immediate and serious harm to others.

The Board of Pharmacy has placed a high priority on those cases where the licensee or registrant presents a danger to the public. Accordingly, these cases have first priority among the duties of the field staff and are quickly and thoroughly investigated. As discussed earlier, special one-day meetings of at least five voting Board members are scheduled when substantial and probative evidence has been obtained by the field staff in order to issue a summary suspension order. The Board scheduled special one-day Board meetings during FY 96 and six summary suspensions were issued.

Fiscal Year 1995 (July 1, 1994 - June 30, 1995) Two registered pharmacist licenses were summarily suspended in FY 95 pursuant to notification by a prosecutor of judicial findings of guilt of a felony drug abuse offense. Twenty two (22) pharmacists' licenses were summarily suspended in FY 95 based upon clear and convincing evidence that their continued professional practice presented a danger of immediate and serious harm to others.

Fiscal Year 1996 (July 1, 1995 - June 30, 1996) No registered pharmacist licenses have been summarily suspended in FY 96 pursuant to notification by a prosecutor of judicial findings of guilt of a felony drug abuse offense. Nineteen (19) pharmacists' licenses have been summarily suspended in FY 96 based upon clear and convincing evidence that their continued professional practice presented a danger of immediate and serious harm to others.

SUMMARY SUSPENSIONS (O.R.C. § 3719.121 effective 03/27/91)				
<u>R.Ph.</u>	<u>FY 93</u>	<u>FY 94</u>	<u>FY95</u>	<u>FY 96</u>
Felony Drug Abuse (Prosecutor's notification)	17	9	4	0
Danger To Public	11	19	17	19
TOTAL Summary Suspensions	28	28	21	19

ADJUDICATION ORDERS

(Applications Denied/Disciplinary Orders)

Fiscal Year 1995 (July 1, 1994 through June 30, 1995) Seventy (70) Notices of Opportunity for a Hearing have been issued during FY 95 with two of these being settled by agreements between the respondent and the Board. Fifty-seven (57) Adjudication Orders have been issued to date by the Board in FY 95 of which 51 were the result of hearings before the full Board, and eight were issued by the Board following the consideration of evidence and testimony where the respondents did not request a hearing.

Eleven (11) pharmacists' licenses were revoked by the Board in FY 95. One application for licensure as a pharmacy intern was denied and one was approved by the Board following hearings before the full Board in FY 95. The Board has also approved seven petitions for reinstatement and denied two petitions for reinstatement of suspended pharmacist licenses in FY 95.

Fiscal Year 1996 (July 1, 1995 through June 30, 1996) Sixty-seven (67) Notices of Opportunity for a Hearing were issued during FY 96. The Board issued 45 Adjudication Orders in FY 96 (34 hearings before the full Board, two before a hearing officer(s), and nine following the consideration of evidence and testimony where the respondents did not request a hearing).

The Board revoked 11 pharmacist licenses and two terminal distributor of dangerous drugs licenses in FY 96. Two applications for licensure as a pharmacy intern were approved following a hearing before the full Board, and four applications for registration as a terminal distributor of dangerous drugs were denied by the Board in FY 96. The Board approved three applications to sit for the licensure examination, of which one was a revoked pharmacist, and denied one application to sit for the licensure examination.

The Board denied two pharmacists' petitions for reinstatement of their licenses to practice and approved six pharmacists' petitions for reinstatement in FY 96. The Board also revoked two pharmacists' probation and re-instituted the suspensions following a probation violation hearing.

In FY 96, the Board also entered into five settlement agreements.

PROBATION - IMPAIRED PRACTITIONERS

The license of an impaired pharmacist is immediately suspended by the Board without a prior hearing if continuation of his/her professional practice and/or method of distributing controlled substances presents a danger of immediate and serious harm to others. If requested by the pharmacist, a Chapter 119. public hearing is held to determine whether or not the pharmacist's license will be reinstated and, if so, whether or not limitations will be imposed on his/her professional practice and employment.

A license to practice is reinstated by the Board if the pharmacist has submitted satisfactory evidence at the public hearing that they are no longer impaired and that they will not present a danger of immediate and serious harm to others. Restrictions are often placed on the licenses of these individuals for a period of time as well as certain conditions which they must fulfill during the time stipulated by the Board. The restrictions vary from not being permitted to serve as a preceptor for a pharmacy intern or as the responsible pharmacist for a terminal distributor operating a pharmacy.

Often, the Board also requires that the pharmacist continue to receive counseling; attend regular meetings of support groups; submit written reports to the Board on a monthly or quarterly basis; be monitored by an approved limited treatment provider for a period of time; and submit to random, observed urine screens. The Board also stipulates that the pharmacist not violate any federal or state laws and regulations governing the legal distribution of drugs or the practice of pharmacy.

Thirty-four (34) pharmacists have had their licenses reinstated and are on probation or practicing under certain restrictions as of February 1, 1997.

EMERGING ISSUES

Issues that will be facing the profession and the Board during the next year include the pharmacist's workload, dispensing errors, confidentiality of patient health information, and date-rape drugs.

PHARMACIST WORKLOAD / PHARMACY STAFFING

One of the greatest concerns of the Board is the increasing workload of pharmacists in community pharmacy practice sites and the problems that result from inadequate staffing. The Board is seeking legislation to address the staffing of pharmacies. Legislation will be introduced in the near future to amend Ohio Revised Code (ORC) Section 4729.27 as follows:

Section 4729.27.

- (A) A person not a registered pharmacist, who owns, manages, or conducts a pharmacy ~~as defined in section 4729.02 of the Revised Code~~, shall have in ~~his~~ THE PERSON'S employ, in full and actual charge of such pharmacy, a pharmacist registered under ~~the laws of this state~~ THIS CHAPTER. Any registered pharmacist who owns, manages, or conducts a pharmacy shall be personally in full and actual charge of such pharmacy, or shall have in ~~his~~ THE PHARMACIST'S employ in full and actual charge of such pharmacy, a pharmacist registered under ~~the laws of this state~~ THIS CHAPTER.
- (B) EACH PHARMACY SHALL BE STAFFED AND EQUIPPED IN A MANNER THAT IS APPROPRIATE TO PROVIDE ITS PHARMACISTS WITH THE ABILITY TO PRACTICE PHARMACY IN A SAFE AND EFFECTIVE MANNER.

Inadequate staffing and increasing workloads not only prevent or make it difficult if not impossible to counsel patients and perform prospective drug utilization review but also results in an increasing number of dispensing errors. The proposed legislation will provide the Board of Pharmacy with the ability to address these issues when inspecting pharmacies, investigating complaints, and in taking disciplinary action against the pharmacy and its owners when appropriate.

CONFIDENTIALITY OF PATIENT HEALTH INFORMATION

The confidentiality of patients' health care records continues to be a major concern at the federal level. A "Fair Health Information Practices Act" was re-introduced in Congress this year and the Secretary of the United States Department of Health and Human Resources is presently holding hearings on this subject pursuant to legislation adopted by Congress last year (e.g., Health Insurance Portability and Accountability Act of 1996). Another congressman – Sen. Robert Bennett – has also announced that he intends to re-introduce his "Medical Records Confidentiality Act".

The topic is expected to receive considerable discussion with the advent of integrated computer systems and the use of the Internet in transmitting patient health information. An increasing number of health care businesses are implementing data transmission systems utilizing the Internet.

DATE-RAPE DRUGS

Flunitrazepam and gamma hydroxy butyrate (GHB) are two substances that have been the subject of news reports these past few months.

Rohypnol™ (flunitrazepam) is a Schedule IV controlled substance that is manufactured and sold by Hoffman-La Roche in other countries. The product, however, has not been submitted to the F.D.A. for marketing approval in the United States. If found in the United States, it has been illegally imported. The drug has received considerable press regarding its use by individuals in committing crimes of assault and "date-rape". The drug product is referred to on the street as "roofies". Legislation has been introduced in many states, as well as Congress, to place flunitrazepam in Schedule I of the Controlled Substance Act.

Gamma Hydroxy Butyrate (GHB) is a substance sold in health food stores and has been promoted for sleep, weight control, and for euphoric and anabolic effects. It has been promoted for sale to body builders with the claim that it stimulates growth hormone release. The January 1997 issue of "Drug Utilization Review" reported that GHB has become a popular street drug in certain parts of the United States, and that it is easy to synthesize and is colorless and tasteless when in its liquid form. Law enforcement agencies in other states have reported that GHB is also believed to be involved in some of the "date-rape" cases attributed to "roofies".

The state of Georgia has experienced cases of GHB overdoses or GHB poisonings where the young people were in a coma upon admission to the emergency room. A coma that lasts anywhere from two to ten hours, with residual drowsiness sometimes hanging on for days, is a predominant sign of GHB toxicity. The F.D.A. issued a warning regarding the danger of using GHB for body building and "recreational" uses in February of this year. Legislation to place this substance in Schedule I was introduced in California in November 1996.

Complicating this issue is the fact that, following medical research, GHB may be legally marketed in the near future as an orphan drug for medical purposes by narcoleptics. The company that has approval to market GHB for medical purposes in the United States states that GHB is "particularly effective against cataplexy, a very severe loss of muscle function that can be extremely dangerous to patients". Accordingly, the company has recommended that GHB be placed in Schedule IV of the Controlled Substance Act.

