January 1999

North Carolina Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Item 986 – Disciplinary Actions

September

Julian Walter Harris, Chapel Hill (DOB July 18, 1950). License reinstated with specific conditions.

Morgan Lewis Williams, Thomasville (DOB February 28, 1948). License reinstated with specific conditions.

October Pre-Hearing Conference Recommendations

Amy Dianne Boyce, Winston-Salem (DOB September 20, 1962). Heard by Board Member Crocker. Admission to abuse of alcohol and prescription medications. Consent Order entered: License suspended five years, stayed indefinitely with specific conditions. Accepted by Ms. Boyce October 7, 1998; accepted by the Board October 27, 1998.

Henry Donald Hamilton, Washington (DOB May 17, 1949). Heard by Board Member Crocker. Admission of selling or otherwise diverting 2,115 dosage units of the Schedule III controlled substance Vicodin ES without authorization of a legal prescriber; placing 25 fraudulent documents on file at pharmacies in order to account for the diversion of the Vicodin ES. Consent Order entered: License suspended indefinitely, stayed indefinitely with a 90-day active suspension of the license and other specific conditions. Accepted by Mr. Hamilton October 7, 1998; accepted by the Board October 27, 1998.

Raymond Gerald Mizelle, Rocky Mount (DOB October 21, 1956). Heard by Board Member Crocker. Fraudulently, knowingly, and willfully misapplied or diverted to his own use or other unauthorized or illegal use prescription drugs that he had access to by virtue of his employment; placing 15 fraudulent prescriptions on file at his place of employment to cover the diversion of 295 dosage units of prescription drugs. Consent Order entered: License suspended three years, stayed three years with specific conditions. Accepted by Mr. Mizelle October 19, 1998; accepted by the Board October 27, 1998.

Continuing Education Audit Results

Prehearing conferences resulting from discrepancies found during the 1998 continuing education (CE) random audit were held in September and heard by Board members Watts and Lockamy. (See Item 980 in the October 1998 newsletter). After reviewing each case, a proposal was made to require an additional five contact hours of CE from deficient pharmacists during the calendar year 1999, to be included on the renewal application for the year 2000. Proposals were accepted by all the pharmacists involved and by the Board members on October 27, 1998. The pharmacists' names appear below:

Karen Early Adams, Morganton; Douglas Terry Corwin, Charlotte; Alan Percy Cunningham, Burnsville; Yvonne B. Daugherty, Fuquay Varina; Lisa Beth Ezzell, Wilmington; Ralph Ragan Harper, Jr., Kings Mountain; Lisa M. Harris, Lillington; Richard T. Holder, Boone; Diane M. Ignar, Cary; James Lewis Inabinet, Pfafftown; Irvin Crispin Kepner, Jr., Wilmington; Renee Haney Laton, Havelock; Andrew Craig Lewis, Monroe.

Item 987 – PRN Agreement

At its September meeting, the Board of Pharmacy agreed to enter into a Memorandum of Understanding (MOU) with the North Carolina Pharmacist Recovery Network, Inc. (NCPRN). This document will, among other things, stipulate the terms and conditions on which NCPRN and the Board will work together to protect the public and aid the impaired pharmacist.

One item of particular interest to pharmacists is the deferred program stipulation in the MOU. Essentially, if a pharmacist with an impairment problem is being investigated by the Board, he or she will be offered participation in the deferred program pursuant to specific qualifications. If he or she agrees to participate and immediately surrender his or her license, formal disciplinary action will be deferred and the pharmacist's name will not appear in the Board's newsletter. This information will remain in the person's file and will be available to the public.

Certain members of the Board and NCPRN felt this will help get the impaired person out of practice quicker, thereby protecting the public, and will also encourage the pharmacist to seek treatment. NCPRN will still be able to take cases anonymously prior to any Board action.

Any NCPRN correspondence, questions, or comments can be directed to the Board or to Dave Marley, RPh, Executive Director, North Carolina Pharmacist Recovery Network, Inc.,

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NABP to Conduct Study on Dissemination of Drug Information to Patients

The Food and Drug Administration (FDA) has awarded the National Association of Boards of Pharmacy (NABP) a grant to determine whether pharmacists are disseminating prescription drug information to patients. The study is being conducted to monitor pharmacy's progress in meeting the goals of the FDA's "Prescription Drug Product Labeling; Medication Guide Requirements," commonly referred to as "MedGuide."

Published in the August 24, 1996 *Federal Register*, the MedGuide legislative proposal urged private sector initiatives to "meet the goal of distributing useful patient information to 75 percent of individuals receiving new prescriptions by the year 2000, and 95 percent of individuals receiving new prescriptions by the year 2006."

NABP will be working with Professor Bonnie Svarstad of the University of Wisconsin, Madison, School of Pharmacy, to implement the study, which will be completed by July 1999. In collaboration with the FDA, a sample of pharmacies in 10 representative states will be selected for participation in the study.

The objectives of NABP's study are to collect a sample of written materials currently being distributed to patients with the receipt of a new prescription for selected drugs, to evaluate the materials according to a protocol developed from the criteria outlined in the legislation's Action Plan, and to report the results to the FDA and the public. The Action Plan can be found in the *Federal Register* or viewed on the Internet at http://library.nyam.org/keystone/final.html.

As mandated in the MedGuide legislation, a review of private sector initiatives must be conducted by January 1, 2001, to determine their progress in meeting information distribution goals. If the initiatives do not meet the specified goals, the legislation states that "FDA would either: 1) implement a mandatory comprehensive Medication Guide program, or 2) seek public comment on whether the comprehensive program should be implemented, or whether and what other steps should be taken to meet patient information goals."

New Prescribed Uses Approved for Aspirin

In the October 23, 1998 *Federal Register*, the Food and Drug Administration (FDA) announced the approval of a new rule that broadens the recommended prescribed uses of aspirin for patients with cardiovascular, cerebrovascular, and rheumatologic conditions. The rule was enacted in response to multiple scientific studies that support the use of aspirin for these disease states.

Under the new rule, aspirin is recommended for use in both men and women for the treatment of transient ischemic attacks (TIA) or ischemic stroke. Cardiovascular indications of aspirin include unstable and chronic stable angina pectoris, acute myocardial infarction (MI), and recurrent MI. Additionally, patients who have undergone specific revascularization procedures, such as angioplasty and coronary bypass operations, **and** have a vascular condition for which aspirin is already indicated are included in the rule. The doses recommended for these cerebrovascular and cardiovascular conditions are lower (50-325mg) than those previously prescribed. Lastly, aspirin is recommended for rheumatologic diseases, such as rheumatoid arthritis, osteoarthritis, spondylarthropathies, and arthritis and pleurisy associated with systemic lupus erythmatosus.

The rule applies to over-the-counter aspirin, buffered aspirin, and aspirin/antacid combination products. The revised labeling will go into effect within a year and will be provided directly to licensed prescribers. Aspirin manufacturers will be required to use the specified labeling if they desire to distribute labeling regarding the professional uses of aspirin to physicians and health care professionals.

The FDA emphasizes that consumers should not self-medicate with aspirin for these serious conditions. Consumers need to make sure that aspirin is their best treatment. They should also be informed of important risks, such as bleeding, that can be incurred through the new uses of aspirin. According to the FDA, these expanded uses of aspirin can be lifesaving when used upon the recommendation and under the supervision of a physician.

For further information, contact Ida I. Yoder of the FDA at 301/827-2222, or log on to the Center for Drug Evaluation and Research's Web site at www.fda.gov/cder/new/aspirin/aspirin_QA.htm.

FDA Mandates Alcohol Warning on OTC Analgesics

The Food and Drug Administration (FDA) published a final rule in the October 23, 1998 *Federal Register* that would require alcohol warning labels for all over-the-counter (OTC) internal analgesic/antipyretic products that are labeled for adult use and contain aspirin, other salicylates, acetaminophen, ibuprofen, naproxen sodium, and ketoprofen. The rule is specifically targeted to advise people who drink three or more alcoholic drinks per day to consult their physicians before

using these drugs, due to the increased risk of gastric bleeding and/or liver damage.

"Consumers need to know that chronic use of alcohol while taking pain relievers or fever reducers can be hazardous to their health," said Dr. Michael A. Friedman, acting FDA commissioner. "FDA urges people with a history of alcohol use to seek a doctor's advice about their risk of side effects before taking these medications."

The final rule was issued based on recommendations provided by the Nonprescription Drugs Advisory Committee and the Arthritis Drugs Advisory Committee, which concluded that chronic alcohol ingestion and OTC analgesic/antipyretic use may lead to increased risk of liver damage or gastric bleeding.

The warnings mandated by the rule include:

- Acetaminophen: "Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage."
- Aspirin, carbaspirin calcium, choline salicylate, ibuprofen, ketoprofen , magnesium salicylate, naproxen sodium, and sodium salicylate: "Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take [ingredient] or other pain relievers/fever reducers. [Ingredient] may cause stomach bleeding."
- Combination of acetaminophen with other analgesic/antipyretic ingredients: "Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take [insert ingredients] or other pain relievers/fever reducers. [Insert ingredients] may cause liver damage or stomach bleeding."

Manufacturers have six months to add this warning to the labeling for OTC products and combination products that are intended for adult use and contain these analgesic/antipyretic agents.

For further information, contact Debbie L. Lumpkins, Center for Drug Evaluation and Research (HFD-560), FDA, 5600 Fishers Lane, Rockville, MD 20857; 301/827-2241.

Twenty-Four States Allow Collaborative Practice Agreements

A recent search of state pharmacy practice acts and board of pharmacy regulations conducted by the National Association of Boards of Pharmacy (NABP) revealed that six more U.S. jurisdictions have enacted legislation or promulgated regulations to provide pharmacists with some degree of collaborative practice and/or prescriptive authority. The number of jurisdictions granting such authority now totals 24, compared to 18 reported in this "National Pharmacy Compliance News" in late 1997.

Idaho, Louisiana, Nebraska, Ohio, and Tennessee, as well as the U.S. territory of Guam, join the growing number of jurisdictions that permit their pharmacists to develop collaborative practice agreements with prescribers. Such agreements generally allow pharmacists to initiate and/or modify patients' medication regimens pursuant to an approved protocol.

The chart below provides an updated listing of U.S. jurisdictions that currently permit pharmacists collaborative practice or prescriptive authority.

States with Enacted Provisions Allowing Pharmacist Collaborative Practice and/or Prescriptive Authority

Arkansas	Mississippi
California	Nebraska
Florida	Nevada
Guam	New Mexico
Hawaii	North Dakota
Idaho	Ohio
Indiana	Oregon
Iowa	South Dakota
Kansas	Tennessee
Kentucky	Texas
Louisiana	Vermont
Michigan	Washington

Continuing Education Articles Included with State Board Newsletters

Continuing a collaborative effort that produced two successful series of continuing education (CE) articles on patient counseling and medication errors, the National Association of Boards of Pharmacy (NABP) Foundation, *U.S. Pharmacist*, and Glaxo Wellcome Inc. have again joined forces to develop and distribute a CE article series through your state board of pharmacy newsletters. This new series will address various topics of interest to pharmacy practitioners, beginning with the article in this issue that discusses pain management and controlled substances.

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3500 Vest Mill Road, Suite #9, Winston-Salem, NC 27103; 336/774-6555; fax 336/774-9010; e-mail NCPRN@msn.com, www.ncprn.org.

Item 988 – Delivery Rule Nullified

The Board of Pharmacy considered a rule in 1998 that would have required the signature of any person receiving a delivered prescription. Much publicity ensued over this proposal, and the General Assembly included a provision in the state budget that, essentially, prohibited the Board from adopting it. As a result, the Board's efforts in this area are null and void.

Inspiration for the rule came from a tragedy in New England, where some teenagers managed to divert prescription drugs that had been sent to a patient by mail. The youngsters needed emergency care at the hospital as a result of the lax delivery system. The Board's intent was to prevent such an occurrence from harming North Carolina citizens. We all hope a similar event does not occur here.

Attention Pharmacists!

Board rules require that address changes for pharmacists, including pharmacist-manager changes, be reported within **30 DAYS** of the change. If the Board office is not notified, the pharmacist/pharmacy is in violation of the Rules of the Board.

Item 989 – Technician/Pharmacist Ratio

The Board of Pharmacy's rule on the ratio of technicians to pharmacists, .1601(a)(2), is now in effect. This rule provides that no more than two unlicensed personnel who spend the majority of their time performing functions constituting dispensing shall be on duty in the pharmacy per pharmacist per day.

Inspectors will review practice sites for compliance during regular inspection visits.

Item 990 – Emergency Refill Rules

In October, the Board of Pharmacy took action on two different rules involving emergency dispensing of prescriptions. One is a modification of existing rule .1809, which allows the dispensing of a limited quantity of prescription drugs when the pharmacist is unable to contact the prescriber for refill authorization. Until the Board's action, the limit was a 72-hour supply. That was changed to a 30-day supply, with a proposed effective date of April 1, 1999.

A different emergency rule has attracted media attention and applies to a situation different than that described above. In situations in which a prescriber is unable to provide medical services to the patient, such as the case involving bankruptcy of a medical practice similar to that which occurred in Raleigh, the pharmacist may, under certain circumstances, dispense a one-time, emergency 90-day supply. The text of the rule, .1815, can be found in the New Developments section of the Board's Web site at www.ncbop.org. Please note that this rule would also apply when a physician dies unexpectedly or retires.

Ordinarily, pharmacists do not want more rules, but nearly everyone agrees that these are good changes and in the public interest.

Item 991 – Voluntary Credentialing Exams

In 1999, the Board will offer examinations for pharmacists who voluntarily wish to be credentialed for treating diabetes, asthma, dyslipidemia, and anticoagulation. Any person who has a license to practice pharmacy in North Carolina that is current and in good standing may take the examinations. The first administration will be held in February. Space is limited for these exams, and applications will only be accepted while space is available.

Applications may be requested from the Board office at P.O. Box 459, Carrboro, NC 27510; 919/942-4454; or by e-mail at csmith@ncbop.org. The deadline for February exam applications to be received in the Board office is February 5. Each exam costs $25. A check made payable to the National Association of Boards of Pharmacy should be submitted with the application to the Board office. Successful candidates on each exam may obtain a certificate.

Examinations will be held at the Carolina Club, Alumni Hall, in Chapel Hill at the following times: February 24, asthma 9 a.m., diabetes 1 p.m.; February 25, dyslipidemia 9 a.m., anticoagulation 1 p.m. Exams are also scheduled for June and September. See the Board's Web site at www.ncbop.org for more information.

While the examination will be given several times a year, at this point it is up to individual pharmacists as to how often they choose to be recertified.

Item 992 – Pharmacist Work Conditions

As of the press deadline for this newsletter, the Board of Pharmacy had approved a rule which states that owners shall not require a pharmacist to work longer than 12 hours a day, with other provisions for meal and rest breaks. The Rules Review Commission was scheduled to consider this rule in December, and a favorable vote would keep this proposal on track. A suggested effective date for the rule is April 1. However, the General Assembly could take action on the matter prior to that time. You can keep up-to-date on this and other important issues by visiting the New Developments section of the Board's Web site, www.ncbop.org.

Item 993 – Board Positions Open

This spring, elections will occur for two Board of Pharmacy member positions that will become vacant in 2000. Nominations must be received in the Board office prior to March 10, 1999, along with a petition signed by 10 pharmacists from the region the candidate seeks to represent.

The two positions up for election are the central district, consisting of Mecklenburg, Union, Anson, Richmond, and the counties bordering them on the north; and the northeast district, consisting of Wake, Durham, and Granville counties

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and those east to the ocean. Specific counties are listed in the Board's rule at NCAC 46.2103. Pharmacists must reside in a county within the district which they represent.

Potential candidates should know that Board members are expected to spend at least 50 days per year on Board business and away from their regular place of practice. The responsibilities and time demands of the position are substantial and arrangements need to be made with employers for such service prior to a person seeking election. Ballots will be sent in April for return to the Board office and counting in May.

North Carolina is the only state that elects its pharmacist Board members, and pharmacists need to prudently exercise this responsibility. This fact is one of the primary reasons for the Board's pioneering action in certain areas, such as the rules specified earlier in this newsletter.

Item 994 – No Technician Registration for 1999

The 1998 session of the General Assembly adjourned without approving the registration of technicians by the Board of Pharmacy. Leaders at the North Carolina Pharmaceutical Association have expressed the opinion that the elections in November 1998 produced a climate more receptive to pharmacy issues. If you wish to be active in such matters, contact the North Carolina Pharmaceutical Association at 1-800/852-7343.

Item 995 – Federal Legislation to Create Pain

[Reprint of an article by the state news editor, which appeared in many North Carolina newspapers in September 1998]

With everything that has been happening in Washington, you probably haven't noticed that Congressman Henry Hyde has introduced an amendment to the Federal Controlled Substances Act captioned The Lethal Drug Abuse Prevention Act of 1998 [HR 4006]. This bill provides that the Drug Enforcement Administration (DEA) can act against a physician or pharmacist to permanently exclude them from practice if they prescribe or dispense a controlled substance to assist a dying person and the drug hastened death.

There has been no public outcry about the use of controlled substances at the end of life, so we need to look elsewhere for the source of this initiative.

If the sponsors of this measure succeed, you can expect that the next target will be birth control. These theocracy advocates will certainly press to punish prescribers of contraceptive drugs and devices which they believe are immoral.

This bill is primarily a blunt assault on individual liberties, the cornerstone of our form of government. It cannot be stated better than it was by the late Supreme Court Justice Benjamin Cardozo, who wrote, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." Ethicists call this autonomy, or self-governance by the individual, but anyone can plainly see it is the epitome of liberty.

When a person decides to leave this world should be entirely his or her own decision. A good example can be found in the author James Michener. He had for many years been under dialysis treatment, which is a common therapy for failed kidney function. Earlier this year, he elected to cease such treatments and, within a week or so, went to his reward. Any physician, nurse, or pharmacist who helped him with a controlled substance in his final days could be subject to severe sanctions under the Hyde bill. Is all of this really the province of our Congress? Of course it isn't. It's an individual decision, which should have no interference from Washington.

Eventually, ambitious federal agents, prosecutors, or disgruntled surviving relatives will use this law to ruin the careers of people who are only making the end-of-life comfortable for struggling patients. When this happens to doctors and pharmacists, they will fear federal prosecution and decline to help suffering patients.

I have a standing offer to all pharmacists that says they can have one week to get their pharmacy in order, and if I can't find a violation in three minutes, I will give them five dollars. Over the last 25 years, nobody has accepted that offer. Additional punitive drug laws here will only lead to more suffering for patients as they approach the end of life.

State prosecutors have abundant criminal and controlled substances statutes to use in egregious cases. Nurses, pharmacists, and doctors are also subject to peer judgment by their licensing boards, including expulsion when warranted. This third layer of bureaucratic prosecution is unnecessary and uncalled for.

Item 996 – Federal Law May Resurface

[Reprint from Pharmacy Today, *November 1998]*

The political showdown over the Lethal Drug Abuse Prevention Act of 1998 (HR4006/S2151) went on for months, but in the end, the efforts of the American Pharmaceutical Association (APhA) and its partners swayed Congress not to take action.

Sen. Ron Wyden (D-OR), who played a key role in representing the concerns of pharmacists, other health care groups, and terminally ill patients who opposed the bill, said, "Protecting pain management from this ill-considered legislation was an uphill battle. We succeeded in large part because of the efforts of APhA and others, who took on an unpopular cause because they knew it was the best way to serve both their members and the public interest."

Wyden said that he would seek bipartisan action to address pain management and end-of-life care more appropriately in the next session of Congress.

"APhA took a risk in getting involved in this legislative battle – most people thought this bill was about assisted suicide," said John Gans, APhA executive vice president. "APhA's concern with the bill did not relate to assisted suicide, but was a concern shared with a number of other patient and health professional organizations. Our concern was about the impact of the expansion of DEA [Drug Enforcement Administration] authority on the use of controlled substances in the terminally ill. Pharmacists know that pain management is a problem, and that the current regulation of controlled substances contributes to that problem. Increasing regulatory oversight would have further impaired pharmacists' efforts to care for patients."

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Congress began considering the legislation this summer in an attempt to address the debate throughout the country over assisted suicide. The bill would have prohibited pharmacists from dispensing a controlled substance for the purpose of suicide or euthanasia. Consequently, the bill would have increased DEA oversight into pharmacists' dispensing of any long-term pain medication.

A new alliance of health care and patient advocacy groups, the Coalition to Improve Pain Management, joined together to oppose the legislation and its potential negative impact on appropriate management of pain. The coalition included representatives from APhA, the American College of Physicians-American Society of Internal Medicine (ACP-ASIM), the American Society of Pain Management Nurses, and more than 50 other organizations.

"The success of this effort would not have been possible without the strong involvement of APhA and the tremendous turnout by pharmacists across the country," said John Giglio, coalition organizer and general counsel for the National Hospice Organization. "APhA was one of the key leaders of the coalition of 57 health and medical groups in opposing this bill."

Other pharmacy organizations in this effort included the Academy of Managed Care Pharmacy, the American Association of Colleges of Pharmacy, the American Society of Consultant Pharmacists, and the American Society of Health-System Pharmacists.

As the coalition – with support from pharmacists on the grassroots level – spent countless hours lobbying members of Congress, legislators grappled over this bill until the final days of the session.

In late September, the bill passed both the Senate and House Judiciary Committees, with much debate in the Senate. Many senators were concerned with the bill's language and a few specifically mentioned the burdens that would be placed on pharmacists. On the House side, a vote was scheduled for almost a month, but did not make it to the floor due to similar concerns.

Still, supporters of the legislation did not give up, and Sen. Don Nickles (R-OK) tried a new strategy, attempting to attach the legislation to an unrelated budget appropriations package. This move, if successful, would have made it difficult for senators to continue to oppose the legislation. Ultimately, Nickles's attempts to attach language to the appropriations bill were rejected and the bill was removed from budget negotiations.

"The potential for unintended consequences from this bill was far too important for Congress to consider in the absence of full debate," said Harold Sox, ACP-ASIM president. "Including it in the appropriations package would have precluded such debate."

The issue of assisted suicide regulations will almost certainly resurface in Congress next year. Nickles has said that this bill will be one of his top legislative priorities.

"It is unfortunate that we have run out of time this year to have a significant debate on this issue," Nickles said. "But I look forward to working with Senator Wyden and others next year to pass something that will protect states' rights, protect physicians and patients with respect to pain relief, and ensure that no federally regulated drug can be used by physicians for the purpose of assisting in suicide."

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