



# North Carolina Board of Pharmacy

P.O. Box 459, 620H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

## **Item 670: Board Member Election**

Enclosed with this *Newsletter* you will find a ballot, biographies, and a return envelope to cast your vote in the Board member election. There are two seats up for selection, and they are for the western and north central parts of the state. Please cast your vote for one candidate in each district and submit your ballots prior to May 20, 1991. The ballots will be counted in the Board office in Carrboro during an open meeting beginning at approximately 5:00 p.m. on May 20. Observers are welcome to attend. This is a valuable opportunity for you to participate in selecting your Board members, and we urge you to submit your ballots without delay.

## **Item 671: Disciplinary Actions**

### **November:**

**James Dallas Neal, Liberty.** Indulgence in the use of drugs to an extent that renders him unfit to practice pharmacy; dispensing prescription drugs without authorization including unauthorized generic substitutions. License revoked.

**Steven Lance Morris, Greensboro.** Indulgence in the use of drugs and alcohol to an extent that renders him unfit to practice pharmacy; appropriating controlled substances for his own use without proper authorization from a physician. License suspended indefinitely with specific conditions placed upon reinstatement request.

**Noah Michael Sites, Raleigh.** License restored with conditions: License suspended two years, stayed five years with specific conditions set forth.

### **January:**

**Sandra Brown White, Rural Hall.** License reinstated, active suspension of license terminated, stayed for five years with specific conditions of reinstatement which must be followed.

**Julian Walter Harris, Chapel Hill.** Appropriating Schedules II and IV controlled substances for his own use without obtaining authorization from a physician. Because of a successful period of rehabilitation and participation in an aftercare program, Board delays imposition of any disciplinary sanctions against license until successful completion of PRN con-

tract or information received concerning unsuccessful completion of the conditions of the contract.

**James Ralph Hamilton, Jr., Pollocksville.** Appropriating Schedules III, IV, and V controlled substances for own use without obtaining authorization from a physician. License suspended indefinitely, stayed for five years with specific conditions.

**Roger L. Simpson, Marshville.** Appropriating and consuming Schedules III and IV controlled substances without authorization from a physician. License suspended indefinitely, stayed for five years with active suspension until specific conditions set forth are met.

## **Item 672: Interns' Impressions**

During the last year, the Board office has served as a rotation site for some pharmacy students completing their undergraduate degrees. As part of each student's assignment, they were asked to list positive and negative activities noted by pharmacist preceptors during their experience. Examples of the good news elicited from these students are found in the next paragraph.

Positive activities including helpful advice to a traveling husband and wife, including arranging an appointment with a local physician and checking back with the couple the following morning to make sure they were making good progress. Another pharmacist contacted an out-of-state physician to obtain a new prescription for a visitor and later checked the patient's blood pressure several times the following week to make sure that no further problems had developed. Two preceptors noted an outreach effort by pharmacists to make home visits when they were not required and checking back to make sure that the patient was following the proper directions. Another preceptor took time out from his schedule to play checkers with a 94-year old gentleman whose "checker buddy" had recently passed away. Other exemplary activities included a preceptor who grieved with a family who had recently lost a child of similar age to his own son.

The bad news concerning the preceptors seems to have one common element. All noted that they had seen preceptors

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# National Pharmacy

(Applicability of the contents of articles in the National Pharmacy, Com and can only be ascertained by examining

## Q and A from Rx Legend (part two)

In the last issue of this *Newsletter*, we printed some of the questions and answers that were omitted from *An Introduction to FDA Drug Regulation - A Manual for Pharmacists*, the revised and renamed version of the *Rx Legend*, FDA's guide to statutes and regulations governing the practice of pharmacy. In response to our readers' requests, we will continue to publish the more pertinent questions in the next several issues of the "National News Section."

Responses to the questions should not be construed as an interpretation of any state or local pharmacy law. Such comment should be obtained from the authorities charged with their enforcement.

**Q** Frequently a physician asks that the name of a medicine be put on the prescription package that is dispensed to the patient. Is this permissible?

**A** Yes. Federal law requires the label of a prescription package to carry certain information (the name and address of the dispenser; a serial number; the date of the prescription or of its filling; the name of the prescriber; and if stated in the prescription, the name of the patient; and the directions for use and cautionary statements, if any, contained in such prescriptions). However, the law does not forbid the addition of other truthful information. Some states also require the pharmacist, when actually compounding a drug, to list all the ingredients and their quantities.

**Q** Can I give a copy of a prescription? Can I fill or refill a copy of a prescription?

**A** You can give a copy of a prescription. It should be clearly marked as a copy, and it has no legal status as a valid prescription that can be filled or refilled by a pharmacist. A copy of a prescription may be useful for information purposes. This is the only purpose a copy of a prescription can serve.

The difficulty faced by a pharmacist who wishes to refill a prescription on the basis of a copy is that no matter what kind of refill instructions are marked on the copy, the pharmacist who receives it has no way of knowing whether or to what extent that prescription has been refilled by the pharmacy where it was originally filled. Indeed, he cannot ascertain whether copies have been given to other pharmacies. His only entirely safe course is to call the prescribing physician; and then, in practical effect, he is getting a new prescription.

**Q** Can I sell a prescription drug for human use as an over-the-counter veterinary drug?

**A** It is not permissible for a pharmacist to sell a prescription drug intended for human use over-the-counter for veterinary purposes. If a pharmacist wishes to sell drugs for veterinary use, it is recommended that he or she purchase such drugs already labeled by the manufacturer for veterinary use with labeling that gives complete directions for such use.

Certain drugs, even when offered for veterinary use, are restricted to prescription dispensing. Some drugs labeled for veterinary use bear the legend: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian, or on his prescription order."

**Q** Can a pharmacist accept and return to stock the unused portion of a prescription that a customer may return with a request for a refund?

**A** It is a very dangerous practice to accept and return to stock unused portions of prescriptions (or for that matter, unused portions of over-the-counter drugs) that are returned by patrons. Many state boards of pharmacy have issued regulations specifically forbidding this practice and FDA endorses the actions of these boards as being in the interest of the public health. Some boards permit return of drugs in unit dose containers which meet USP Class A or B requirements.

There is no doubt that the pharmacist is legally responsible for any hazards of contamination or adulteration that arise from mixing returned portions of drugs with shelf stock.

## Act Places Anabolic Steroids in Schedule III

After months of intense discussion and deliberation, the Anabolic Steroids Control Act of 1990 (S 3266), one of several pieces of legislation included in the voluminous Omnibus Crime Control Bill [now P.L. No. 101-647], was passed and signed into law by President Bush on November 29, 1990. The new law amends the federal Controlled Substance Act (CSA) [21 U.S.C. 812(c)] by placing anabolic steroids into Schedule III.

The Act defines "anabolic steroids" as:

... any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth...

Although human growth hormone is not placed in Schedule III, the Act states that:

# Compliance News



Compliance news to a particular state or jurisdiction should not be assumed to be the law of such state or jurisdiction.)

... whoever knowingly distributes or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or recognized medical condition . . . is guilty of an offense punishable by not more than five years in prison, such fines as authorized by title 18, United States Code, or both.

To date, 40 states have adopted or enacted anabolic steroid laws or regulations. Of these states, 19, or 48 percent, have placed anabolic steroids under their Controlled Substances Act.

The movement to Schedule III places the enforcement responsibility for the Anabolic Steroids Control Act under the Drug Enforcement Administration (DEA) umbrella. Some areas involving counterfeit drugs are under discussion with the Food and Drug Administration (FDA).

During the deliberations that preceded the final draft of the new Act it was evident that, although the FDA and DEA were concerned about the diversion and abuse of anabolic steroids and were working hard to control or stop these activities, neither agency felt they had the manpower or the resources to assume the enforcement responsibility for this unique class of drugs. Policing the diversion and abuse of anabolic steroids is a significant problem that requires the appropriation and commitment of significant resources.

In its final form, the Act complies with the requirements of the Controlled Substance Act, which provides that any person who manufactures, distributes, or dispenses any controlled substance, or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, must obtain a registration with the DEA to meet certain security requirements, take an inventory of the stocks of controlled substances on hand, and maintain retrievable records for two years (state law may vary and require records to be maintained for longer than two years).

For the practicing pharmacist this means, aside from the registration requirements, that on or before February 27, 1991 (as defined by the Act) an inventory should have been taken of the pharmacy's anabolic steroid stock. This action may have caught many pharmacists by surprise, since the Act was part of a large legislative package and little time was available for public notice.

Pharmacies that are not registered with the DEA, or elected not to obtain a Schedule III registration, or are not entitled to receive such registrations should have surrendered all quantities of currently held anabolic steroids on or before February 27, 1991, in accordance with the procedures outlined by the federal CSA conditions [21 CFR 1307.21, Disposal of Controlled Substances], or transferred the drugs to a CSA registrant authorized

to possess a Schedule III controlled substance. Anabolic steroids surrendered to the DEA must be listed on DEA Form 41, "Inventory of Controlled Substances Surrendered for Destruction." Of course, any surrender or transfer of controlled substances must also follow state pharmacy laws.

When disposing of controlled substances, 21 CFR 1307.21 allows that

any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance.

The Special Agent in Charge authorizes and instructs the applicant to dispose of the controlled substance in one of the following manners:

- (1) By transfer to persons registered under the Act and authorized to possess the substance;
- (2) By delivery to an agent of the Administration or to the nearest office of the Administration;
- (3) By destruction in the presence of an agent of the Administration or other authorized person; or
- (4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

Individuals who wish to destroy such substance but are not CSA registrants must submit a letter to the Special Agent in Charge stating:

- (i) The name and address of the person;
- (ii) The name and quantity of each controlled substance to be disposed of;
- (iii) How the applicant obtained the substance, if known; and
- (iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant.

All prescriptions for products containing anabolic steroids must follow the provisions of federal and state controlled substance laws. In particular, all prescriptions for products containing anabolic steroids that were issued on or before February 27, 1991 and are authorized for refilling shall be limited to five refills and shall not be refillable after six months from the date of issue.

Pharmacists also need to be aware that any activity with respect to anabolic steroids that violates the CSA, or is not authorized by the Act, shall be unlawful and subject to the actions and penalties set forth in the law.

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dispensing out-of-date drugs without informing the recipient of that fact. One student noted that a preceptor counted tablets and capsules in his hand rather than use a manual device which was in the pharmacy. The interns noted numerous occasions when prescriptions were refilled without authorization. In one other case, a mother was directed by the Poison Control Center to obtain Syrup of Ipecac without explaining to the mother that she could expect the child to vomit vigorously shortly after administration. Once student stated, without naming names, that a preceptor she had worked for customarily consumed liquor during the last hour of the business day.

Just when you thought pharmacy was making progress.

### **Item 673: Board Position on the PharmD**

Speaking of progress, you should be aware by now that the American Council on Pharmaceutical Education (ACPE), national accreditation agency for schools and colleges of pharmacy, has announced plans to modify accreditation standards to only accredit the PharmD degree by the year 2000. With over 95 percent of the pharmacists in this state possessing only a BS degree, this issue is of some significance to North Carolina licensees. Because of the impact of this plan on licensees in this state, the North Carolina Board of Pharmacy adopted the following position at its February 1991 meeting:

The North Carolina Board of Pharmacy recognizes the vital importance of the accreditation process and the activities of the American Council on Pharmaceutical Education. Their proposal leading to the Doctor of Pharmacy degree as the standard by the year 2000, therefore, deserves close scrutiny. Current educational models for the PharmD vary with an experiential component comprising a substantial portion of the additional time required beyond the BS degree.

With this in mind, and noting that over 90 percent of pharmacists are holders of BS degrees and are apprehensive of a proposal that could unjustifiably relegate them to a second-class status, the Board makes the following statement which is intended in its entirety and is not to be taken out of context.

The Board would look favorably on the proposal with the following conditions:

- I. That the Standards of Practice adopted in 1978 be revised.
- II. That the Competencies used in the NABPLEX examination be reviewed and modified to reflect the new standards.
- III. That current holders of BS degrees be eligible to obtain PharmD degrees from each accredited school in a reasonable process such as:
  - A. A degree exchange program, similar to what occurred in the legal profession, where a bachelor's degree can be traded for a more contemporary professional doctorate. Please note that this is not a "grandfathering," but a quid pro quo in an updating procedure; or
  - B. A reasonable add-on PharmD that would not interrupt the pharmacist's current employment and recognize ex-

perience through passing competency exams or crediting years of practice to satisfy some requirements.

- IV. That no fixed length of time be set, direct or indirect, to complete the degree for undergraduate students. In other words, let the education market operate to find its own optimum level with a goal of decreasing rather than increasing the time required.

### **Item 674: Literacy Video Available**

The North Carolina Pharmaceutical Association, with assistance from a grant from the Upjohn Company, has produced a video which is helpful to pharmacists dealing with patients who have low literacy skills. To obtain a copy of this valuable and important learning tool, contact the North Carolina Pharmaceutical Association at 1-800-852-7343.

### **Item 675: Pharmacy Computers and Signing the Daily Printout**

One of the recordkeeping options for computers provides for a printout of each day's prescription information. Board and federal rules require that each day's printout be signed by the pharmacist(s) on duty. Please check your procedures to be sure that you are in compliance with the rules on this issue.

### **Item 676: Health Careers**

From time to time, pharmacists get inquiries from students or their parents about careers in pharmacy or other health professions. One reference source is the *Comprehensive Guide to Careers in the Health Professions*, which is now available from the Area Health Education Centers throughout the state. The Centers and their telephone numbers are Asheville, 704/257-4467; Charlotte, 704/355-3863; Fayetteville, 919/678-7258; Greensboro, 919/379-4400; Greenville, 919/551-2587; Raleigh, 919/250-8018; Rocky Mount, 919/972-6958; Wilmington, 919/343-0161; and Winston-Salem, 919/748-3649.

### **Item 677: Inventory May 1, 1991**

This is a reminder that your controlled substances inventory is due as of the beginning or close of business on May 1, 1991. If you want a form for this purpose, they are available from the Board office at a cost of \$3.15.

The *North Carolina Board of Pharmacy News* is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc., to promote the voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

David R. Work, JD, RPh – State News Editor  
Carmen A. Catizone, MS, RPh – National News Editor &  
Executive Editor

Janice Teplitz – Editorial Manager

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