



# North Carolina Board of Pharmacy

P.O. Box H, 602H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

## Item 534 — Disciplinary Actions

December: *Wallace Allen Johnson, Wallace Allen Johnson, Jr. and Wally's Pharmacy*, Mount Airy: Substituting generic products for brand name products when the prescribing physician indicated to dispense as written; refilling prescriptions for legend drugs without authorization from the prescribing physician; violation of June, 1984 Order of the Board of Pharmacy (Johnson, Sr.); (Johnson, Jr.): substituting generic products for brand name products when the prescribing physician indicated dispense as written; dispensing controlled substances without a valid prescription; refilling a prescription vial for legend drugs without authorization from the prescribing physician; violation of June, 1984 Order of the Board of Pharmacy. Appealed from an earlier decision in June. Net Result: Johnson Sr., 45 days active suspension; Johnson, Jr. 5 months active suspension; Wally's Pharmacy, 10 days active suspension.

January: *John William Gray, Jr., Charlotte*: Violations of Board's Order of July, 1986. License revoked.

## Item 535 — Policy on Impaired Pharmacists

With disturbing frequency the Board sees impaired pharmacists in disciplinary hearings. In an effort to make its position known on this subject, the Members have adopted a policy which is reprinted below. This policy was adopted prior to the existence of an organized impaired pharmacists program which is now being formed.

### *The Impaired Pharmacist*

The North Carolina Board of Pharmacy has the gravest concern regarding the problem of the impaired pharmacist. The Board feels that steps should be taken to provide counselling, professional advice, as well as guidance and information for pharmacists with drug and alcohol problems. It is axiomatic to any type of treatment or informational program that the anonymity of the individuals seeking assistance be maintained. Dealing with this problem is not a responsibility of the Board of Pharmacy. The Board can only consider the impaired pharmacist on a case by case basis when there has been an alleged violation of law or regulation. The Board feels that this is an appropriate problem for the North Carolina Pharmaceutical Association. It notes that other professional associations provide a mechanism for rendering assistance to its members.

The Board, on the other hand, is confronted with the impaired

pharmacist who is alleged to have violated a law or regulation. Assuming that the competent evidence introduced at the hearing satisfied the Board that the pharmacist is guilty as charged, there are a number of factors which the Board may consider in reaching a decision. The Board feels that the pharmacy profession and the general public are entitled to know what those general factors are, and why the Board considers them to be significant in reaching a decision in an individual case.

There are certain *mitigating* factors: 1) whether this is the first time the pharmacist has been charged; 2) the gravity of the offense, such as insignificant shortages of drugs which are diverted for the sole use of the pharmacist; 3) the pharmacist acknowledged his responsibility for the shortages at an early stage in the investigation and assisted the investigating officers thereafter; 4) the pharmacist is aware of, and acknowledges, his drug or alcohol problem, or dependency, and has independently sought effective assistance prior to the hearing and the positive attitude the pharmacist has towards recognizing the problem and rehabilitation ; 5) there is evidence that the pharmacist is taking positive steps to control the problem and there is no substantial likelihood that the offense, or violations, will be repeated in the future; 6) the history of the pharmacist including his activities in his profession and community; and 7) the psychological harm which might result from a revocation or long term suspension of the pharmacist's license.

These are not all but some of the major mitigating factors which the Board considers in reaching a decision.

Some of the *aggravating* factors which the Board considers are as follows: 1) the severity of the offense. This includes, but is not limited to, whether there are substantial shortages over a long period of time, falsifying records or concealing an offense; 2) whether the drugs illegally obtained by the pharmacist were diverted not only to his use but to the use of any third person; 3) whether there is a history of prior offenses; 4) the refusal of the pharmacist to acknowledge that a problem exists and past unwillingness to seek effective help or assistance; 5) the likelihood that the pharmacist will in the future continue to violate the law and regulations of the Board; and 6) the likelihood that the pharmacist will continue to be a hazard to the general public health.

The presence of one or more mitigating factors and the absence of any aggravating factors usually results in a stay of the suspen-

*continued on page 4*



# National Pharmacy

(Applicability of the contents of articles in the National Pharmacy, and can only be ascertained by examining the original article.)

## ***SURVEY OF PHARMACY LAW AVAILABLE***

The 1986-87 *Survey of Pharmacy Law* is now available from the National Association of Boards of Pharmacy. This survey of the 50 state boards plus Washington D.C. and Puerto Rico includes information on organizational, licensing, internship and drug law. The NABP Census of Pharmacy has been included in this year's *Survey*, detailing:

- total number of licensed pharmacists by state
- number practicing in community or hospital pharmacies
- manufacturer or wholesaler, teaching and government
- number of female pharmacists in each state
- total number of licenses suspended, revoked, reinstated
- total number of licensed hospital, community and chain pharmacies, and
- number of dealers licensed to sell OTC drugs

Pharmacists contemplating reciprocating to other states and who are interested in learning the licensure requirements in various states will find the publication useful. Copies are being provided to all last year pharmacy students free of charge by A.H. Robins.

The 1986-87 *Survey of Pharmacy Law* can be ordered through the NABP Publications Desk, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068, at a cost of \$20 per copy. Please send a check with your order.

## ***SOFTGELS***

The November-December 1986 issue of *Pharmacopeial Forum* contains two items which may be of particular interest to pharmacists and state boards of pharmacy.

One of these is the creation of a new dosage form entitled, "Soft-gel." Recent unfortunate tampering incidents have prompted suppliers of soft capsules to urge the adoption of nomenclature to distinguish them from hard capsules. Softgels are defined as solid dosage forms in which the drug is enclosed in a soft soluble container or 'shell' of a suitable form of gelatin. The term, capsule, would continue to denote articles marketed as "hard" capsules.

A copy of the proposed text describing softgels follows:

"Softgels are solid dosage forms in which the drug is enclosed in a soft, soluble container or "shell" of a suitable form of gelatin.

"Softgels generally require large-scale production methods. The gelatin shell is somewhat thicker than that of capsules and is plasticized by the addition of some polyol, such as glycerin or sorbitol. The shell may contain a preservative to prevent growth of fungi.

"Classically, softgels have been filled with active ingredients dissolved or suspended in an oleaginous vehicle such as a vegetable oil. However, as a result of the recognition of bioavailability problems, it is more common to use nonaqueous but water-miscible vehicles, such as the liquid polyethylene glycols, as carriers for the drug. Liquids are metered into the shell just prior to sealing.

Because of the possibility of leakage of the liquid contained therein, it is sometimes advisable to package such softgels in single-unit containers. Softgels can be filled also with powders or granules."

## ***PRESCRIPTION TO OTC STATUS CHANGES***

### ***Prescription Drugs***

What are prescription drugs? Prescription drugs, also defined as legend, are subject to the requirements of Section 503 (a) and (b) of the Food, Drug and Cosmetic Act. The Section defines "drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed... and determined to be habit forming, toxic or has a potential for harm or is limited by an approved application to use under the professional supervision of a practitioner licensed by law to administer such a drug."

A prescription drug can only be dispensed "upon a written prescription of a practitioner licensed by law to administer such drug, upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or by refilling any such written or oral prescription or by oral order which is reduced promptly to writing and filed by the pharmacist." Prescription drugs include on their packaging label a statement to the effect of "Caution: Federal law prohibits dispensing without a prescription."

### ***OTC Drugs***

Nonprescription or OTC drugs are defined as drugs generally recognized among qualified experts as safe and effective, made in accordance with "good manufacturing standards," and labeled with "directions under which the layman can use a drug safely and for the purposes for which it was intended." (22 CFR 330.10)

### ***Dispensing Prescription Drugs***

The Durham-Humphrey Amendment (1952) outlines federal laws governing the dispensing of prescription drugs. In summary, it prohibits the sale of legend drugs without a prescription and prohibits unauthorized refilling of legend drugs. Pharmacy Law Digest notes that the Durham-Humphrey Amendment is the drug control law most likely to be violated.

With this in mind, following is an excerpt from a list prepared by the Proprietary Association of ingredients and dosages which have been transferred from Prescription to OTC status since 1982. Pharmacists are responsible for the requirements of both federal and state drug control laws. It is possible, and is often the case, that state practice acts and laws controlling the manufacture, distribution and sale of drugs overlap with federal law. In those instances where an overlap occurs, the more stringent requirements must be followed. If you have any questions about the drug control laws of your state, it is best to consult with your state board of pharmacy.

# Compliance News

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



## Ingredients & Dosages Transferred From Rx to OTC Status as a Consequence of the U.S. Food and Drug Administration's Review of Nonprescription Drugs\* (As of December 3, 1986)

INGREDIENT	ADULT DOSAGE	PRODUCT CATEGORY	DATE OF OTC APPROVAL	PRODUCT EXAMPLES
dexbrompheniramine maleate	2 mg./4-6 hours (oral)	antihistamine	January 15, 1985*	
dexbrompheniramine maleate (pursuant to an approved NDA)	6 mg./12 hours (oral timed-release)	antihistamine	September 3, 1982	Drixoral (Schering)
diphenhydramine hydrochloride	50 mg. single dose only (oral)	sleep-aid	April 23, 1982*	Sominex 2 (J.B. Williams) Sleep-eze 3 (Whitehall)
diphenhydramine hydrochloride	25-50 mg./4-6 hours (oral)	antihistamine	January 15, 1985*	Benadryl 25 (Parke Davis)
diphenhydramine monochloride	76 mg. single dose only (oral)	sleep-aid	April 23, 1982*	
dyclonine hydrochloride	0.05 to 0.1% in rinse, mouthwash gargle or spray, 3-4 times daily 1 to 3 mg. as lozenge	oral anesthetic	May 25, 1982*	Sucrets Maximum Strength Lozenges (Beecham)
haloprogin	1.0% (topical)	antifungal	March 23, 1982*	
ibuprofen (pursuant to approved NDAs)	200 mg./4-6 hours (oral)	internal analgesic/ antipyretic	May 18, 1984	Advil (Whitehall) Nuprin (Bristol-Myers)
miconazole nitrate	2.0% (topical)	antifungal	March 23, 1982*	Micatin (Ortho)
oxymetazoline hydrochloride (pursuant to an approved NDA)	0.025% solution/drops (topical)	ocular vasoconstrictor	May 30, 1986	Ocuclear (Schering)
triprolidine hydrochloride (pursuant to an approved NDA)	2.5 mg./4-6 hours	antihistamine	November 26, 1982	Actifed Capsules (Burroughs Wellcome) Actidil Syrup and Capsules (Burroughs Wellcome)
triprolidine hydrochloride	2.5 mg./6-8 hours	antihistamine	January 15, 1985*	
triprolidine hydrochloride (pursuant to an approved NDA)	5 mg./12 hours (oral timed release)	antihistamine	June 17, 1985	Actifed 12-hour Capsules (Burroughs Wellcome)

\*FDA approval for OTC marketing is on an interim basis pending adoption of a Final Monograph.

sion of a license, thereby producing a period of probation. It is the Board's desire to give an offending pharmacist who has a drug or alcohol problem an opportunity to prove that the problem is being resolved. Often the Board will require unannounced urinalysis tests and have the Board's investigators and inspectors routinely check to see that the pharmacist is abiding by the terms of the Board's judgment, which often includes a direction to continue effective help, counselling or attending AA meetings.

If there are one or more aggravating factors present with the absence of any mitigating factors, the Board generally will impose a more severe judgment, possibly including the revocation of a license.

The Board considers the above approach to be consistent with that mandated by the North Carolina General Assembly and the people of North Carolina in the establishment of the fair sentencing program. The Board feels that it is also consistent with prior decisions of the Board. This is a fair and equitable approach consistent with the maintenance of the Board's duty to protect the public health.

Occasionally board members hear complaints from pharmacists (but rarely from the general public), that the Board should revoke the license of any pharmacist who has been caught illegally using drugs under his supervision and control, and/or being present at a pharmacy while impaired by drugs or alcohol. The Board feels that this would be a harsh, uncompromising and counterproductive approach. Occasionally the Board will have before it a pharmacist who has voluntarily notified the Board of drug or alcohol dependency. While the Board would hope that eventually a course of assistance and information can be established by the Association, in the absence of such a program, the Board is put in the position of having to try to assist such pharmacists and to support them in their efforts to seek a cure or resolution of their personal problem. To automatically revoke that pharmacist's license would be contrary to what is in the best interest of the general public, to the profession and to the individual pharmacist.

### **Item 536 — Biennial Inventory Due Soon**

Federal regulations require an inventory of controlled substances on at least a biennial basis. This is a reminder that the biennial inventory date of May 1st, for many pharmacies, is a short distance away. Inventory forms are available at a charge of \$3.00 from the Board office, P.O. Box H. Carrboro, NC 27510.

### **Item 537 — Pharmacy Fixtures Sought for History Museum**

W.J. Smith is spearheading a committee seeking material for a pharmacy exhibit in the State History Museum in Raleigh. With his long tenure as Executive Director of the North Carolina Pharmaceutical Association, until his retirement in the late '70s, W.J. has many valuable contacts for his venture.

An area has been designated in the new Museum of History Building for a 1925 era pharmacy. The committee is searching for authentic items and store fixtures from the mid 1920's, especially an operating soda fountain for visitors to enjoy the taste of the good old days. If you know of any material which might be appropriate, please contact W.J. Smith, 908 Arrowhead Road, Chapel Hill, 27514, 919/929-2656.

### **Item 538 — Tampering Brochures Available**

The matter of product tampering, although it has not been in the news lately, is of continuing concern to pharmacists and

people in the pharmaceutical industry. If you wish to alert the public about this subject through your pharmacy, there are a number of information sources available. The USP has a brochure, "Tips Against Tampering," which is available at \$15.00 per 100 brochures. If a pharmacist wants to reproduce the copy from this brochure, permission can be obtained by writing Mr. Joseph (Joe) Valentino at the USP, 12601 Twinbrook Parkway, Rockville, Maryland, 20852. The USP also has a free poster which is available for use in your pharmacy and it may be obtained by writing the address above.

The Propriety Association produces another similar version of tips against tampering material and has developed a new publication, "Medicines, Labels and You" published this spring. A packet of both of these publications can be obtained free from the Office of Public Affairs, the Proprietary Association, 1150 Connecticut Avenue, NW, Washington, DC, 20036.

### **Item 539 — Positive Side Effects of Computers**

With the widespread use of computers in pharmacy practice, a number of unintended positive results have been observed. At one time the practice of prescribers writing multiple prescriptions, as many as 6 or 8, on one prescription blank presented problems for pharmacists. Many pharmacists would be reluctant to copy prescriptions and separate them for filing even if it is required when some of the prescriptions contain controlled substances. A computer in the pharmacy requires individual entry and therefore separation of the prescriptions and enormously decreases the chance of errors on prescription refills.

Another secondary effect is that pharmacy students are eager to use computers and are generally enthusiastic about keyboards and CRTs. Consequently they learn such systems with a minimum of objections. The complaint that newly licensed pharmacists can't type hasn't been heard in years. Apparently typing skills are not objectionable to students when they are part of computer literacy.

If you have any other examples of positive side effects of computers, please submit them to the Editor for future editions of the Newsletter.

### **Item 540 — Board Member Election**

Enclosed with this Newsletter is a ballot, biography of candidates and return envelope for the annual Board Member Election. The Board consists of six members, five pharmacists elected from geographic regions of the state by licensed pharmacists and one public member appointed by the governor. This elective position is for a three year term to begin in the Spring of 1988 to be filled from a pharmacist residing in the southeastern part of the state.

A Committee consisting of Sarah Hackney, Hedgpeh Pharmacy, Lumberton; Bill Oakley, Director of Pharmacy, Craven County Hospital, New Bern; Bill Tarr, Kerr Drugs, Fayetteville; and, Tom Thutt, Medical Center Pharmacy, Kinston met on February 24th at the Country Squire Restaurant near Kenansville. The Committee nominated pharmacists whose names appear on the ballot. We appreciate their willingness to serve the profession and the public.

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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 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.

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