Item 931 – Disciplinary Actions

Full Hearing

Dewey L. Creasman, North Wilkesboro (DOB: May 6, 1940), Richard G. Brame, North Wilkesboro (DOB: December 25, 1942), and Red Cross Pharmacy, North Wilkesboro. Original Final Order of March 31, 1993, appealed through courts. Consent Order Modifying Final Order on Remand entered May 1997. Failure to provide patient counseling as required by law. Licenses of Creasman and Brame suspended three (3) years from date of execution of the Consent Order with conditions, among which are seven consecutive days of suspension of pharmacist Brame’s and Creasman’s license. Permit suspended thirty (30) days, stayed three (3) years with conditions.

February

Ralph Ragan Harper, Kings Mountain (DOB: February 18, 1942). Failure to renew pharmacist license and the pharmacy permit for the year 1996 by December 31, 1995; violated the Consent Order dated May 24, 1995. Suspension of license to practice provided by the Consent Order activated, and the license suspended for a period of twenty-one (21) consecutive working days. The active suspension shall be completed by July 1, 1997, and other conditions.

Mary Markow-Sears, North Wilkesboro (DOB: April 30, 1960). Violations of Board’s Final Order of August 10, 1994; taking and consuming controlled substances without a prescription from the pharmacy where employed. License revoked.


March

Villiard Elmer Gares, Charlotte (DOB: May 18, 1937). Dispensing and consuming prescription drugs without authorization; violation of Board’s April 28, 1994 Final Order; dispensing prescription drugs without serial numbers and failing to maintain accurate records regarding the dispensing of prescription drugs. License suspended indefinitely.

James W. Russell, Flushing, Michigan (DOB: March 1, 1931). Conspiracy to distribute controlled substances; mail fraud. License revoked.

April

David K. Earnhardt, Greensboro (DOB: April 9, 1960). Order reinstating license entered with specific conditions.


Pre-Hearing Conferences

Julian W. Harris, Chapel Hill (DOB: July 18, 1950), and Fearrington Pharmacy, Pittsboro. Consumption of controlled substances without authorization; failure to make and keep adequate records relating to the dispersal of controlled substances and other prescription drugs; indulgence in the use of drugs to an extent that rendered him unfit to practice pharmacy. Recommendation: License of Mr. Harris revoked. Permit: suspended for thirty (30) days, stayed five (5) years with conditions. Accepted by Mr. Harris, March 4, 1997. Accepted by Mrs. Harris on behalf of pharmacy, March 20, 1997. Accepted by Board, March 18, 1997 and April 15, 1997.

Terry L. Littke, Rocky Mount (DOB: March 27, 1948). Creating false prescriptions and filing false insurance billings; failure to maintain records of transactions involving Schedule V controlled substances. Recommendation: License suspended thirty (30) days, stayed five (5) years with conditions. Accepted by Littke, February 28, 1997; accepted by Board, March 18, 1997.

Gordon B. Johnson, Charlotte (DOB: October 3, 1954). Ingesting controlled substances and other prescription drugs without authorization of a physician to an extent that rendered him unfit to practice pharmacy; failure to maintain a current license with the Board during a period when he

Continued on page 4
**DEA Amends Controlled Substance Regulations**

The Drug Enforcement Administration (DEA) published a final rule in the March 24, 1997 Federal Register that consolidates, eliminates, and clarifies portions of Title 21, Code of Federal Regulations, Parts 1300 through 1316. These regulations fall under the federal Controlled Substances Act and other controlled substance-related statutes enacted to control diversion.

**Section 1304.04** (Pharmacy controlled substance recordkeeping requirements)

**New Requirement:** Pharmacies with automatic data processing systems are permitted to file Schedule III, IV, and V prescriptions without stamping them in the lower right corner with a one-inch high letter “C.”

**Previous:** Under Section 1304.04(h), all pharmacies had to maintain controlled substance prescriptions either in a separate prescription file reserved only for Schedules III-V substances or in a “readily retrievable” form. Prescriptions are deemed “readily retrievable” if, when initially filed, they are marked with the red “C.”

**Section 1304.11** (Controlled substance inventory regulations)

**New Requirement:** Permits the biennial controlled substance inventory to be taken on any date within two years of the previous biennial inventory.

**Previous:** The biennial inventory had to be taken on either 1) “the day of the year on which the initial inventory was taken,” 2) “on the registrant’s regular general physical inventory date which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply,” 3) “on any other fixed date which does not vary by more than six months from the biennial date that would otherwise apply,” or 4) “on a date that is within four days of his biennial inventory date” if a local DEA special-agent-in-charge is notified in advance of when the inventory will be taken.

**Section 1305.12(b)** (Reporting requirements for lost or stolen DEA Form 222 order forms)

**New Requirement:** The purchaser or supplier who discovers the loss of DEA 222 order forms must report it to the special agent-in-charge at the local DEA divisional office.

**Previous:** Such losses were reported to the DEA registration unit in Washington, DC.

**Part 1306.11** (Specific regulatory requirements for the issuance, filling, and filing of prescriptions)

**New Requirement:** Section 1306.11(d) has extended the length of time a pharmacy has to obtain a written prescription that covers an emergency Schedule II oral prescription to seven days.

**Previous:** Length of time was 72 hours.

**Section 1306.11(e), (f), and (g)** (Faxing of Schedule II prescriptions)

**New Requirement:** Section 1306.11(g) allows a Schedule II narcotic prescription to be filled by any pharmacy “for a patient residing in a hospice certified by Medicare under Title XVIII or licensed by the state,” pursuant to a facsimile prescription. The facsimile serves as the original written prescription as long as the practitioner or agent notes on the prescription that the patient is a hospice patient.

**Previous:** Only Sections 1306.11(e) and (f) provided exceptions to the Controlled Substance Act requirement that a Schedule II drug be dispensed only pursuant to a written prescription. These sections allow the filling/compounding of a Schedule II narcotic prescription for parenteral use by a home infusion pharmacy and the filling of a Schedule II substance prescription by any pharmacy for a long-term care facility (LTCF) resident pursuant to a facsimile prescription. The facsimile serves as the original written prescription.

**Section 1306.13(b)** (Requirements for partial filling of Schedule II substance prescriptions)

**New Requirement:** Eliminates the requirement that the pharmacist determine whether additional partial fillings are necessary for those prescriptions written for LTCF residents or patients with a documented terminal illness.

**Previous:** Prescriptions written for such patients could be filled in partial quantities, including individual dosage units, as long as the pharmacist determined the additional partial fillings were necessary prior to any subsequent partial filling.

**Section 1306.26** (Rules for the transfer between pharmacies of Schedule III, IV, and V drug prescription refill information)

**New Requirement:** Redesignated Section 1306.25(a) permits pharmacies that share a real-time, on-line electronic database to transfer prescription refill information for Schedule III, IV, and V substances as often as refills are authorized by law and the original prescription.

**Previous:** Section 1306.26(a) allowed the transfer of prescription information to occur only once.

**Section 1306.26(b)(2)** (Information a pharmacist must obtain when receiving a transferred prescription)

**New Requirement:** Redesignated Section 1306.25(b)(2) requires the receiving pharmacist to obtain not only the last refill date, but the dates and locations of all previous refills.

**Previous:** The receiving pharmacist had to obtain, among other things, the number of valid refills remaining and the last refill date.

For further information, contact G. Thomas Gitchel, chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; 202/307-7297.

State laws regarding these requirements may vary from federal law. Check with your state board of pharmacy for details.

**FDA Declares “Morning After” Pills Safe and Effective**

In the February 25, 1997 Federal Register, the Food and Drug Administration (FDA) announced its conclusion that certain combined oral contraceptives containing ethinyl estradiol and norgestrel or levonorgestrel are safe and effective for use as a postcoital emergency contraceptive. The FDA encouraged manufacturers to make this additional contraceptive option available.

According to the FDA, estrogens and progestins, either separately or combined, have been used for several decades to prevent pregnancy in women who have unprotected intercourse as a result of rape, contraceptive failure, or lack of planning. The FDA's Advisory Committee for Reproductive Health Drugs recently confirmed the safety and effectiveness of combined oral contracept...
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Premarin because the active ingredients

1997, the Food and Drug Administration (FDA)

one therapeutically equivalent drug is substituted for an­

evaluation initiatives include warfarin, levothyroxine, digoxin, pheny­

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facturers’ formulations of NTI drugs. They maintain the FDA’s

and patient monitoring for the safe and effective use of the drug.

Effects or ineffective therapy.

as more accurately termed by the FDA, is defined as a drug which


drug for another can result in ineffective therapy or toxic effects
due to differences in bioequivalence. The Health Alliance for NTI

Patient Safety (NTI Alliance), a primary advocate of the proposed

anti-substitution laws whose initial funding was provided by

DuPont Merck Pharmaceuticals, believes individual states should

ensure that NTI drugs are substituted “only with the express

knowledge and consent of the patient and the treating physi­

Ovral white 4 4

Levlen yellow 4 4

Tri-Levlen yellow 4 4

For further information, contact Lisa D. Rarick, Center for Drug Evaluation and Research (HFD-580), Food and Drug Administra­

5600 Fishers Lane, Rockville, MD 20857, 301/827-4260.

Pharmacy Debates Substitution of Narrow Therapeutic Index Drugs

Recent legislative initiatives introduced in Colorado, Missouri, New Jersey, Ohio, Tennessee, Texas, and Virginia could amend state
drug product selection laws by imposing restrictions on pharmacists’ ability to substitute generic products for brand-name

products that have a narrow therapeutic index (NTI).

These initiatives have prompted debate within the pharmacy

profession. At issue is the fact that substitution with nonbio­
equivalent NTI drugs may cause drug levels to rise above or fall

below the desired therapeutic range, which can result in toxic

effects or ineffective therapy.

According to the Food and Drug Administration (FDA), a drug

with a “narrow therapeutic index,” or “narrow therapeutic ratio”
as more accurately termed by the FDA, is defined as a drug which has:

1) less than a two-fold difference in median lethal dose (LD50)

and median effective dose (ED50) values; 2) less than a two-fold
difference in the minimum toxic concentrations and minimum

effective concentrations in the blood; or 3) requires careful titration

and patient monitoring for the safe and effective use of the drug.

[21 CFR 320.33(c)]

Drugs classified as NTI drugs within the proposed state legis­
lative initiatives include warfarin, levothyroxine, digoxin, pheny­
toin, theophylline, carbamazepine, conjugated estrogens, valproic

acid, and lithium.

Opponents of the state initiatives insist the FDA accurately

assesses and compares the bioavailability of the various manu­
facturers’ formulations of NTI drugs. They maintain the FDA’s

determination regarding therapeutic equivalence found in the

FDA’s Approved Drug Products with Therapeutic Equivalence

Evaluated (the “Orange Book”), including those for NTI drugs,
sufficiently demonstrates that substitution of NTI drugs is safe.

Supporters of the proposed regulations argue that pharma­
cists’ substitution of one manufacturer’s formulation of an NTI
drug for another can result in ineffective therapy or toxic effects
due to differences in bioequivalence. The Health Alliance for NTI

Patient Safety (NTI Alliance), a primary advocate of the proposed

anti-substitution laws whose initial funding was provided by

DuPont Merck Pharmaceuticals, believes individual states should

ensure that NTI drugs are substituted “only with the express

knowledge and consent of the patient and the treating physi­

Opponents of the NTI Alliance initiatives contend state ge­
neric substitution laws already require physician approval for drug

product substitution, and additional documentation of such

approval would place an unnecessary burden on the pharmacist.

In an April 16, 1997 letter to the National Association of Boards

of Pharmacy (NABP), the FDA responded to an NABP request

for clarification of the agency’s position on the NTI drug sub­

stitution issue. As stated by Roger L. Williams, deputy center direc­
tor of pharmaceutical science for FDA’s Center for Drug Evalua­
tion and Research, “FDA is aware of the NTI initiatives that are

occurring at the state level . . . To date, we [FDA] have not seen
data to support such proposed changes.” He continued by not­
ing, “If one therapeutically equivalent drug is substituted for an­
other [as indicated in the “Orange Book”], the physician, pharma­
cist, and patient have FDA’s assurance that the physician should

see the same clinical results and safety profile. Any differences

that could exist should be not greater than one would expect if one

lot of the innovator’s product was substituted for another.”

Williams also noted that the FDA does not formally designate

NTI drugs in its Approved Drug Products with Therapeutic

Equivalence Evaluations or elsewhere, and that in the future,

appropriate guidance could be developed based on the criterion

specified in 21 CFR 320.33(c) to provide assistance in assessing

bioequivalence, potentially including a listing of drug products.

FDA Refuses to Approve Generic Premarin Products

On May 5, 1997, the Food and Drug Administration (FDA) announced it would not approve synthetic generic forms of Wyeth­

Ayerst Laboratories’ Premarin® because the active ingredients

have not yet been confidently defined.

Premarin contains a number of different estrogens. Precisely

how each of these estrogens contribute to the drug’s overall ef­
ficacy is by treating menopausal symptoms and osteoporosis has not been definitively determined.

“Based on currently available data, there is no way to assure

synthetic generic forms of Premarin have the same active ingredi­
teins as the brand-name drug. This is essential for determining

beauty, and is also a legal requirement for

their approval,” said Janet Woodcock, director of the FDA’s Cen­
ter for Drug Evaluation and Research.

The FDA is encouraging studies that will scientifically deter­
mine Premarin’s active ingredients and provide a potential for

approval of generic versions of the drug.
was practicing pharmacy in the state and failure to obtain continuing education credits required. Recommendation: License revoked. Accepted by Mr. Johnson, February 26, 1997; accepted by Board, March 18, 1997.


Rebecca B. Styron, Pine Level (DOB: February 5, 1954). Admitted use of following drugs without a prescription: Tenuate; Lorazepam; Pondimin; Xanax; Alprazolam; Ionamin-15; Phentermine; Diethylpropion; Ionamin-30; Isollyl Improved; Adipex-P; Fastin; Tenuate Dospan. Recommendation: License suspended indefinitely. Accepted by Ms. Styron, March 18, 1997. Accepted by Board, April 15, 1997.

Item 932 – Board Schedule
July 14  Reciprocity, 3:30 p.m. Board Office, Carrboro
July 15  Board Meeting, 9 a.m. Board Office, Carrboro
September 15  Reciprocity, 3:30 p.m. Board Office, Carrboro
September 16  Board Meeting, 9 a.m. Board Office, Carrboro
October 21  Board Meeting, 9 a.m. Campbell University, Buies Creek
November 24  Reciprocity, 3:30 p.m. Board Office, Carrboro
November 25  Board Meeting, 9 a.m. Board Office, Carrboro

Ordinarily, permits are issued on the first and third Mondays of the month at 2 p.m. This is sometimes rescheduled and should be confirmed with Rachel Paris at 919/942-4454, ext. 27, before you make arrangements to be present.

Item 933 – New Rules Affect Pharmacy Practice
Section .1703 sets out new rules for dispensing by physician assistants (PAs) and nurse practitioners (NPs). It provides for a pharmacy permit at any location where PAs or NPs dispense drugs and requires a consulting pharmacist to be part of this practice. Pharmacists should review with the physician and mid-level practitioner their use of pharmaceuticals for drug interactions, optimal patient therapy, and cost effectiveness. A copy of the Board’s rule on this subject is available from the Board office.

A new section was added to the Board’s rule, Section .1812, which provides that pharmacists must disclose any business relationships when they ask a prescriber to change a drug from one entity to another. This applies to what would ordinarily be called “therapeutic interchange” and does not apply to the customary product selection law currently in the Board rules. This is intended to provide full disclosure to the prescriber regarding who is benefiting from the requested change in therapy.

Item 934 – USP Posters
The U.S. Pharmacopeia (USP) is offering a set of three posters that describes confusion between drug names, dangerous abbreviations, and opioid (narcotic) analgesics equivalent analgesic doses. Single copies are available from USP at 12601 Twinbrook Parkway, Rockville, MD 20852.

Item 935 – Prescription Error Policy
At the regular March meeting of the North Carolina Board of Pharmacy, the members discussed the Board’s policy on dispensing errors in relation to pharmacist workload. By consensus, the members decided to handle prescription dispensing errors in the following manner.

Reports of prescription dispensing errors will be investigated in due course and, if probable cause is determined, a hearing or pre-hearing conference will be scheduled. If the error occurred at a location where more than 150 prescriptions per pharmacist per day were filled on the date of the error, both the pharmacist and the permit will be cited for the disciplinary proceeding. Each case would be considered individually on the facts involved.

Everyone should be aware that the Board would presume under these circumstances that if a sanction is issued, both the pharmacist and the permit should receive the same penalty. For example, if the Board issued a seven-day active suspension of the pharmacist’s license to practice, then a seven-day suspension of the permit would also be issued.

In arriving at the 150-prescriptions-per-pharmacist-per-day threshold, the Board used information presented at the National Association of Boards of Pharmacy (NABP) Health Law Officers Conference in Savannah, Georgia in November 1996. Experts on this program gave a range of not more than 10 to 20 prescriptions per pharmacist per day were filled on the date of the error, both the pharmacist and the permit will be cited for the disciplinary proceeding. Each case would be considered individually on the facts involved.

Application of this data to work schedules leads to the derivation of the 150-prescription threshold. It is common for pharmacists to split a 12-hour schedule, with one pharmacist working 9 a.m. to 3 p.m. and another from 3 to 9 p.m. This is a relatively short shift and, using the lower number of 10 prescriptions per hour (6 hours x 10 prescriptions per hour), produces a 60-prescription figure. Other pharmacists work a 12-hour shift and, using the higher number of 20 prescriptions per hour (12 hours x 20 prescriptions per hour), yields a 240-prescription figure. Averaging these two results (60+240)/2 produces the 150-prescription threshold.

This is a further delineation of the Board’s intent in adopting rule .1811, which states: “Pharmacists shall not dispense
and permit holders shall not allow a pharmacist to dispense prescription drugs at such a rate per hour or per day as to pose a danger to the public health or safety.” Input from pharmacists was obtained from Item 895 in the October 1996 Board Newsletter. Almost 40 responses were obtained from this item and the 150-prescriptions-per-day figure was often mentioned.

Permit holders should note this 150-prescription-per-pharmacist threshold. It is not a limit or a quota. Pharmacists should not adopt the attitude that they will walk away from their responsibilities once this level is achieved. This policy is intended to address the health and safety issues inherent in high-volume dispensing and to signal management to re-examine its situation as workloads increase. It also sends a message to ownership that it has a responsibility for reasonable employee scheduling and can share in the consequences of high-volume dispensing which produces errors.

**Item 936 – NABP Resolution on Prescription Errors**

At its 93rd Annual Meeting in May 1997, the National Association of Boards of Pharmacy (NABP) adopted a resolution approving the report of the National Coordinating Council for Medication Error Reporting and Prevention. The report contained a number of important recommendations, including a section on prescription writing. The Council recommends the following for prescribers when preparing medication orders and prescriptions:

- All prescription documents must be legible. Prescribers should move to a direct, computerized, order-entry system.
- All prescription orders should be written using the metric system, except therapies that use standard units, such as insulin and vitamins. The term “units” should be spelled out rather than abbreviated as “U.”
- The medication order should include the drug name, the exact metric weight or concentration, and the dosage form.
- A leading zero should always precede a decimal expression of less than one. A terminal or trailing zero should never be used after a decimal.
- Prescription orders should include a brief notation of purpose (e.g., “for cough”), unless considered inappropriate by the prescriber.
- Prescribers should include the age and, when appropriate, the weight of the patient on the prescription or medication order.
- Prescribers should not use vague instructions, such as “Take as directed,” as the sole direction for use.
- Prescribers should avoid use of abbreviations and Latin directions for use.

**Item 937 – Narrow Therapeutic Index Drugs**

The General Assembly adopted a change in the Pharmacy Practice Act that provides for the publication of a list of narrow therapeutic index drugs. Patients who use these products should be maintained on the same product. Changes to another manufacturer’s product should be discussed with the prescriber and the patient. A list of the drugs involved will be published in the January 1998 issue of the Board Newsletter.

**Item 938 – Optometrists’ Prescribing Rights**

The General Assembly changed the North Carolina statute on the practice of optometry to allow optometrists unlimited prescribing rights providing they are treating the eye or the adnexa, which is the orb surrounding the eye. It is no longer necessary for optometrists to communicate and collaborate with physicians in this prescribing. Many optometrists now have Drug Enforcement Administration (DEA) registrations that would also allow them to prescribe controlled substances. Please guide your conduct accordingly.

**Item 939 – Top Ten**

Recent press reports indicate the Food and Drug Administration (FDA) has designated 10 drugs as the most frequently reported for drug interactions. They are Aleve, Norplant, Prozac, Depo-Provera, Risperdal, Today contraceptive sponge (now off the market), Rogaine, Humulin, Mevacor, and Biaxin. When dispensing these items, an extra effort to counsel the patient should be made so the patient knows what to expect.

**Item 940 – PRN Refills**

The Board office has received several inquiries lately regarding PRN refills. It was suggested that an item be included in this Newsletter on the subject.

The Pharmacy Practice Act deals with this subject by stating that prescriptions marked “PRN” cannot be refilled for more than one year unless marked otherwise. This means the letters “PRN” or “AD LIB,” or similar statements, allow a prescription to be refilled for one year only.

Prescriptions marked for specific numbers of refills, providing they are not controlled substances in Schedules III or IV, of course, can be refilled for the specific amount and beyond one year. It is also theoretically possible for a prescriber to indicate they want a prescription filled “PRN for three years” and have that order be valid for three years of refills. All of this is dependent upon the pharmacist’s judgment as noted in rule .180 I, which provides that a pharmacist may refuse to fill or refill a prescription if he or she believes it would be harmful to the patient, if there is a question about its validity, or if it is not in the patient’s best interest.

**Item 941 – Oxygen Survey**

With hurricane season rapidly approaching and the recent years of unpredictable weather throughout the country, a reassurance for a sufficient amount of back-up oxygen supply kept in the patient’s home is necessary for the interruption of therapy. The ice storm during the winter of 1996 and the more recent fury of Hurricane Fran led the Durable Medical Equipment Subcommittee of the North...
Carolina Board of Pharmacy to conduct a survey on the amount of back-up oxygen supply being provided to patients.

To date, approximately 20 to 25 percent of the permitted DME suppliers were surveyed. The average number of patients being supplied with oxygen by each company is 130.3, with five patients being the minimum and 578 patients the maximum. Both the minimum and the maximum come from the state’s largest city, Charlotte.

The average amount of oxygen back-up provided is approximately 25 hours at two liters per minute, with one “E” cylinder being the minimum amount and an “H” cylinder or a liquid oxygen system the maximum amount provided to the patient. Of those surveyed, 63 percent of the suppliers had an emergency disaster plan in place.

Twenty percent of those surveyed are licensed by the Food and Drug Administration (FDA) and the North Carolina Department of Agriculture to transfill oxygen. The average number of delivery vehicles used by suppliers was 2.3. These vehicles ranged from vans, box trucks, and pickup trucks to four-wheel-drive station wagons. The average number of miles to the location of the outermost oxygen patient was approximately 44 miles with a drive time of 53 minutes.

The survey consisted of about 50 percent national suppliers and the other half independent suppliers. Oxygen suppliers from each region of the state were surveyed.

The survey will continue to gain more input from other oxygen suppliers throughout the state. The ultimate goal is the safety of the people of North Carolina.

**Item 942 – Prescription Delivery**

Earlier this year, there was much publicity about a prescription mailed to a patient in the northeast that was intercepted by teenagers. The teenagers apparently had a “party” with this prescription drug, which brought law enforcement to their home.

Pharmacists are reminded that home prescription delivery poses the same risk unless the prescription is specifically handed to an adult. It is always best to obtain a signature on this type of prescription delivery and, of course, patient counseling can occur by telephone.

**Item 943 – Request for Input**

The editor requests input from pharmacists regarding what items they would like included in the Board’s Newsletter. We try to offer information about significant practice matters and want to have optimum communication. This includes feedback from individual pharmacists on what they think is useful or not, and what would be helpful information for the Board.

We also want input on specific items. For example, if you approve of the Board’s adoption of the 150-prescription-per-day threshold, please let us know by writing to the Board office at P.O. Box 459, Carrboro, NC 27510.

**Item 944 – DME Elections**

Board of Pharmacy durable medical equipment (DME) registrants elected Larry Lankford, representing rehabilitation, to the vacant position on the DME Subcommittee. Mr. Lankford will serve a three-year term beginning immediately.