

# North Carolina Board of Pharmacy

P.O. Box H, Chapel Hill—Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

## ITEM 444 BOARD DISCIPLINARY ACTIONS

**September:** A pharmacist-manager from Salisbury appeared to respond to charges of dispensing prescription drugs and controlled substances without a prescription. The investigation resulted from complaints regarding this activity and disclosed other violations such as altered prescriptions for controlled substances. The pharmacist admitted certain violations and, by way of explanation, stated that he was trying to run a very busy prescription department without adequate help. After hearing the case it was the decision of the Board to issue a 45 day active suspension of the pharmacist's license with reinstatement only after passing a pharmacy jurisprudence examination and a 5 year probation under other conditions.

A hearing was held for the former Director of Pharmacy at a hospital in Gastonia who was charged with pleading guilty in Federal Court to a felony charge of distribution of controlled substances outside the course of legitimate business. The pharmacist did not appear due to his incarceration in the federal prison system for 2-1/2 years and his attorney spoke in his behalf. An undercover operation was conducted by the FBI and involved transactions and negotiations at a massage parlor and restaurant in Charlotte. One purchase of Dilaudid<sup>®</sup> was documented and an audit of the pharmacy revealed significant shortages of other drugs including over 800 dosage units of morphine, at least 500 of which were believed to have arrived on the illicit market. In the pharmacist's defense, the lawyer stated that this was his first offense and these events were the product of a bad marriage which has since dissolved. It was the Order of the Board that the pharmacist's license be suspended for the period of incarceration plus an additional 90 days with the license reinstated only after successful completion of a jurisprudence examination.

**October:** A pharmacist-manager from Plymouth appeared before the Board to respond to charges of personal use of drugs. The Board Inspector arrived on a regular inspection visit to his pharmacy and noticed some erratic movement including slurred speech, dry mouth and unsteady movement. After some questioning and an audit, the pharmacist admitted that both he and his wife had used drugs without a prescriber's authorization on many occasions. The audit revealed a shortage of over 2000 Percodan<sup>®</sup> and more than 150 grams of Cocaine over an 18 month period. The pharmacist explained that he had drifted into drug abuse and had not realized that things were "that far along". He stated that he did not now use drugs and had "seen the light". It was the decision of the Board to suspend the pharmacist's license and that it can be returned only after he enrolls in a drug treatment program, has at least 30 days of treatment with

reports to the Board and that there be at least 4 consecutive negative drug screen results. An additional 5 years probation was also instituted.

A pharmacist from Morehead City appeared, after some delay, to respond to charges of personal use of drugs while he was employed at a pharmacy in another town in the Southeastern part of the state. Testimony indicated a shortage of 300 Trintabs and the pharmacist admitted consuming up to 5 of these per day. It was the Order of the Board that there be an active suspension of the pharmacist's license for 15 days and the Board also issued a 1 year probation.

**November:** A pharmacist-manager from Charlotte appeared in response to charges that he had plead guilty to felony charges of the illegal distribution of drugs and for failure to comply with the law governing the distribution of drugs. Testimony was introduced regarding an audit of more than 10 controlled substances which revealed a shortage of in excess of 100,000 dosage units. Other testimony indicated that prescription drugs (antibiotics) were being dispensed without a prescription and that some Schedule V OTC drugs were being dispensed without adequate labeling. The pharmacist offered in his defense that he had inherited a bad situation from a prior owner, that this was his first offense and also offered numerous affidavits and a petition on his behalf. It was the Board's decision to issue an active suspension on his license for 1 year, to be returned only on the successful completion of the jurisprudence examination and obtaining a minimum of 20 hours of continuing education in pharmacy practice and also issued 5 years probation.

A pharmacist-manager from Old Fort appeared before the Board in response to charges of personal use of drugs. Testimony indicated a shortage of over 6 ounces of cocaine, nearly 5,000 dosage units of Percodan<sup>®</sup> and more than 1,000 dosage units of Tylox over a 26 month period. The investigation was the result of a complaint which was confirmed on visits by the Board Inspector on at least two occasions. The hearing had originally been scheduled for September, postponed to November on request of Counsel in order that the pharmacist might straighten out business affairs and enter a drug treatment program. At the time of the hearing the pharmacist had not yet entered a treatment program and his business had not improved. It was the decision of the Board to suspend the pharmacist's license indefinitely as of December 1st and to revoke the permit to operate the pharmacy as of January 1, 1984. The pharmacist may obtain his license only after enrollment in a substance abuse treatment program, remain in the program until discharged and then appear before the Board to request reinstatement.

*Contd. on page 4*



# National Pharmacy

## FDA ACTS ON OTC CAFFEINE/ PHENYLPROPANOLAMINE COMBINATIONS

FDA issued an "advisory opinion" in the November 18 *Federal Register* indicating that OTC Caffeine/Phenylpropanolamine combinations are "new drugs" requiring approved NDA's for marketing. In its "advisory opinion" FDA indicated that it intends to regulate as "new drugs" all products labeled as stimulants which contain caffeine in combination with any other active ingredient and all products, regardless of their labeled indication, that contain as their sole active ingredient caffeine and phenylpropanolamine, caffeine and ephedrine or pseudoephedrine, or phenylpropanolamine with ephedrine or pseudoephedrine.

The caffeine/phenylpropanolamine combination products have been classified as Generally Recognized as Safe as an "anorectic/stimulant" in the FDA OTC Drug Review. Because of this classification and in order to provide for a transitional period that will allow for inventory reductions at the retail, wholesale, and manufacturing levels, FDA has indicated that no immediate enforcement of action will be taken. FDA did indicate, however, that it will monitor marketing of these combination products and may, at some time in the future, establish a specific date in order to cut off the marketing of these products.

In publishing the "advisory opinion" FDA explained that the position was necessary "because of the wide spread abuse of these products intended to produce effects similar to those produced by substances subject to the Controlled Substances Act. The intended affect of this action is to eliminate misuse and abuse of these products."

A few of the larger ethical manufacturers of diet aid caffeine/phenylpropanolamine products have recently reformulated their products to remove the caffeine. The other manufacturers of combination products will now have to follow suit. It is unlikely that this action by FDA will, in itself, spell the end to abuse of the various OTC stimulant products but it is certainly a step in the right direction.

## WHAT TO DO WHEN THE DOCTOR DIES

The issue of how to handle refill requests from patients when the prescriber has died or retired from practice is one that pharmacists face with some regularity. The following response to the question was recently provided to the South Dakota Board of Pharmacy and to the National Association of Boards of Pharmacy by the Office of Drugs, National Center for Drugs and Biologics, FDA.

"It is well established that a prescription of a practitioner given to a patient signifies generally, that a physician/patient relationship exists. This relationship also connotes that during the "life" of that prescription the patient is under the practitioners professional care and includes the number of authorized refills.

It is our opinion that once a physician/patient relationship is broken the prescription loses its validity since the physician is no longer available to treat the patient and oversee his/her use of the prescribed drug(s).

Accordingly, when a doctor leaves the community, or dies, the doctor/patient relationship is disjoined and the pharmacist, if he is

aware of the situation, should instruct the patient to seek out a new physician. In short, "the prescription dies with the physician."

Prudence counsels that the patient should be able to obtain a sufficient amount of prescribed drug of an unexpired prescription to carry him/her over until the services of a physician is obtained. In such cases, the pharmacist must use professional judgement to protect the interest of the patient, and, for that matter, him/herself.

The FDA has, as a practical matter, deferred to the states the regulatory overview of such prescription transactions and we believe that states should clarify, by regulation if necessary, the legal status of a prescription under the cited circumstances."

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## APPROVED PRESCRIPTION DRUG PRODUCTS 4TH ED NOW AVAILABLE

The fourth edition of FDA's *Approved Prescription Drug Products with Therapeutic Equivalence Evaluations* is now available from the Superintendent of Documents. This FDA publication lists currently marketed drug products which have been approved for both safety and effectiveness by the Food and Drug Administration. The publication is of significant value to large purchasers of and to community pharmacists who are concerned regarding the therapeutic equivalence evaluations of the various generic products available.

The therapeutic equivalence evaluation for multiple source drugs have been prepared primarily to serve the various states in the administration of their drug product selection laws.

The list is updated on a regular basis and is republished in October of each year and is available from:

Superintendent of Documents, US Government Printing Office, Washington, DC 20402. The cost of the publication is \$67.00 and includes new monthly cumulative supplements. No government stock number has been assigned to the publication so pharmacists interested in ordering this publication should request it by name.

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## FINAL OTC DRUG REVIEW COMPLETED

In mid October the Food and Drug Administration released the 58th, and last, report of the seventeen advisory panels which have reviewed the safety and effectiveness of all of the thousands of non-prescription drugs sold in the United States.

HHS Secretary Margaret M. Heckler stated "the completion of this last report on the effectiveness and safety of over-the-counter drugs is a milestone in drug history. All American consumers will greatly benefit from the information consolidated in these reports."

In a recent press release, FDA acting commissioner Mark Novitch, M.D., said, "much work remains converting the panels' recommendations into regulatory action but consumers can see results already in improved products, greater safety and reduced medical costs."

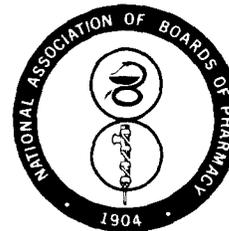
Novitch said that:

"Many manufacturers have reformulated products to take advantage of the panels' judgements of the effectiveness of the various ingredients.

Products containing hydrocortisone for topical use that were

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# Compliance News



once available only by prescription have been judged safe enough for less expensive non-prescription sale.

Safety questions have led to the removal from the non-prescription market of seven once popular ingredients such as camphorated oil and hexachlorophene.

Improved directions, warnings or consumer information have appeared on many labels as a result of the recommendations by the panels.

A mini industry in consumer books, whose authors used the panel reports as background, has been spawned."

The FDA appointed non-government experts on the panel began their work in 1972. Each panel included medically and scientifically qualified experts as voting members while consumer and drug industry representatives sat as non-voting liaison members of the panel.

Under instructions from FDA, the panels concentrated on active ingredients, rather than individual products. The panels has reviewed more than 700 different ingredients, many of them on several different occasions due to the ingredients various uses in different kinds of products.

The panels found about 1/3 of the ingredients reviewed to be of uneven effectiveness, as well as safety, for their intended uses. The rest of the ingredients, the panels said, required additional proof if the manufacturers were to continue to use them. As a result of the panels' work a number of products that were previously restricted to prescription use only can now be purchased over-the-counter and a number of non-effective or potentially unsafe ingredients have been removed from well-known OTC products.

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## FEDERAL "IMITATION CONTROLLED SUBSTANCE" BILL IN THE MAKING

The U.S. Senate Subcommittee on Alcoholism and Drug Abuse chaired by Senator Gordon J. Humphrey (R/N.H.) recently began work on "the Imitation Controlled Substances Act of 1983" (S.503, Humphrey). This new piece of proposed federal legislation would amend the federal Food, Drug and Cosmetic Act by making it a federal crime to manufacture, distribute or advertise an "imitation controlled substance." The bill defines "imitation controlled substances" as products which, by representation or appearance (including color, size, shape, and markings), would lead a reasonable person to believe that they are, in fact, controlled substances. Pharmacists are encouraged to contact their senators regarding support for this piece of legislation.

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## FDA CONTINUES RX TO OTC SWITCHES

The Food and Drug Administration recently proposed switching more previously Rx only products to OTC use. These two products are two cough suppressant drugs that have, according to FDA, been used safely for more than twenty years. The drugs are Benzonatate and Chlophedianol.

The change is part of a proposed standard for over-the-counter cough relief products under the FDA's OTC drug review program.

FDA has already transferred more than two dozen products previously restricted to prescription use to OTC status and sale. All of these products have had a long history of safe use. In announcing the proposal for Benzonatate and Chlophedianol FDA also concurred with an expert panel that reviewed cough and cold products for the agency that four ingredients already in non-prescription use as cough suppressants are indeed safe and effective. These are two forms of Dextromethorphan and Codeine Phosphate and Codeine Sulfate. (Many states, however, still restrict Codeine Containing products to a prescription only status.) FDA also said that the ingredients Camphor and Menthol have been found to be effective cough drugs. Previously, there was not sufficient evidence to say that these drugs were indeed effective.

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## RECLASSIFIED DRUGS GET CPSC ATTENTION

The Consumer Product Safety Commission (CPSC), the agency that oversees compliance with the Poison Prevention Packaging Act, has begun to be concerned about the recent number of prescription drugs converted to over-the-counter status by FDA. Since sale in child-proof containers is not automatically required for OTC products, CPSC believes that not only will "the number of (poisonings) incidents increase" but also "use of the product will increase since it will be available to more persons."

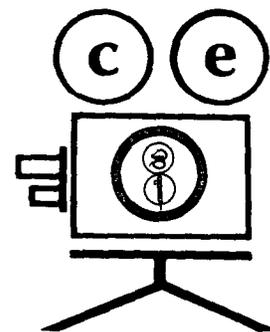
As a result of this concern CPSC has decided to review each Rx to OTC conversion recommended by FDA. Recently, CPSC proposed that all OTC products containing more than 75 milligrams of Diphenhydramine Hydrochloride be sold only in child-resistant packages.

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## VIDEO CE AVAILABLE

The NABP Foundation and the Foundation's Bureau of Voluntary Compliance (the organization which assists 29 boards of pharmacy with the production of this *Newsletter*) announced the availability of the second in a series of video tape presentations on federal drug law. "Professional and Legal Responsibilities in Pharmacy Practice: The Federal Controlled Substances Act" is the title of the new continuing education tape and was produced in cooperation with the Drug Enforcement Administration.

The new tape, like the first tape dealing with the Federal Food, Drug and Cosmetic Act, is designed to meet ACPE Standards of quality for continuing education programming and the Foundation is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. State and local pharmacy groups, schools interested in either video tape should contact their state board of pharmacy. For more information contact NABP Foundation Headquarters.



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A pharmacist from Asheville appeared before the Board in response to charges of personal use of drugs obtained while he was a staff pharmacist at a hospital in Asheville. Drugs used and abused included Meperidine, Morphine, Hydromorphone and perhaps cocaine. Testimony indicated that the pharmacist had entered a drug treatment program, was making progress, and had a reasonable chance of success with diligent effort. The testimony of a former employer, a pharmacist who was part of the treatment program staff and a letter of recommendation all attested to the pharmacist's progress and prognosis. It was the decision of the Board to suspend the pharmacist's license for 60 days to be reinstated only under conditions including continued treatment until discharged and his consent to unannounced drug screens at the Board's request.

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#### ITEM 445—RECOMMENDATION ON CE

The State Tripartite Committee, consisting of representatives from the School of Pharmacy, the North Carolina Pharmaceutical Association and the Board of Pharmacy meet periodically to consider internship questions and other matters of mutual concern. At their meeting on November 14, the Tripartite Committee passed a resolution which recommends to the Board "the implementation of a mandatory continuing education as permitted by current legislation." If any individual pharmacists have any comments about this matter please let us know by writing the Board office.

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#### ITEM 446—QUARTERLY QUERY

Which of the following is or are true regarding a pharmacist's responsibility to refuse to fill or refill a prescription?

- I. In his judgment, it would be harmful to the patient.
  - II. In his judgment, it would not be in the patient's best interest.
  - III. If there is a question as to the prescription's validity.
    1. I only.
    2. II only.
    3. I & II only.
    4. II & III only.
    5. I, II, and III.
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#### ITEM 447—DISCIPLINARY ACTIONS OF THE BOARD OF MEDICAL EXAMINERS

The Board of Pharmacy has been informed of activity from the Board of Medical Examiners which effect the prescribing rights of certain physicians. The actions reported to the Pharmacy Board are as follows: License Revoked: William J. Wheeler, M.D., Wilmington; Roger Neal Goodlin, M.D., Fayetteville, 10/26/83; Edwin S. Mize, Jr., M.D., Charlotte, 11/3/83; Archibald Carter Maghee, M.D., Greenville, 3/2/83. Licenses Surrendered: Walter Glenn Lewis, M.D., Gibsonville, 1/1/83; Harry Lee Hinson, M.D., Fayetteville, 1/31/83; Frank Joseph Brown, M.D., Boone, 2/21/83; Clarence Edens, M.D., Rosman, 3/30/83; Winston A.Y. Sargent, M.D., Burnsville, 3/31/83; John C. Young, M.D., Asheville, 7/7/83; Jeffrey R. MacDonald, M.D., Bastrop, TX, 7/7/83. Fred A. Vidal of Franklin surrendered DEA privileges.

These matters are being reported to you for your professional use, no undue publicity is intended nor expected from this item other than its normal meaning within medical practices.

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#### ITEM 448—CLARIFICATION REGARDING PAs/NPs

The Board has received several questions regarding the propriety of physician assistants or nurse practitioners prescribing more than a 30 day supply or 100 dosage units or for the indication of refills on prescriptions. Material submitted from the Board office and by

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the North Carolina Board of Medical Examiners plainly states that these quantities and refills are not permitted.

The intent of that statement is that it should apply only to physician assistants or nurse practitioners and physician assistants cannot authorize refills or quantities in excess of 30 days or 100 dosage if it is on the specific or direct order of the supervising physician. Please note that this also needs to be indicated on the prescription as "on the order of" as in other situations, (see Item 366).

The question has also arisen regarding the prescribing of drugs such as Tedral<sup>®</sup> and other compounds which contain an item which by itself, is a controlled substance. These articles are specifically excluded under federal regulations and are not treated as a controlled substance if they are in combination with at least one other active ingredient and are in sufficiently weak doses. It is the opinion of the Board staff that physician assistants and nurse practitioners can issue prescriptions for these excluded articles or compounds providing, of course, that these drugs are included in the approved standing orders of the physician assistant or nurse practitioner.

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#### ITEM 449—DRUGS FOR VETERINARY USE

It has come to the Board's staff attention that there is a widely held "myth" in this state that prescription legend drugs may be dispensed for veterinary purposes without a prescription. This is not the case. All prescription legend drugs, whether for human use or veterinary use, may only be dispensed on the order of a prescriber authorized by law to issue such an order. Pharmacists who dispense prescription legend drugs for veterinary use without the order of a veterinarian or other qualified individual are risking prosecution. In a recent speech, an official of the federal Food and Drug Administration noted that this would be one of their targets of concern and enforcement for the immediate future. Pharmacists should take note of this situation in order to avoid further problems with the F or proceedings in the court system from law enforcement agencies. The answer to Quarterly Query is 5, (I, II & III).

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#### ITEM 450—DEA CHECK DIGIT

The following is provided as a source for verifying the DEA Check Digit.

1. Add the 1st, 3rd, and 5th digits.
2. Add the 2nd, 4th, and 6th digits and multiply by 2.
3. Add the two results and the last digit will be the same as the last digit of a valid DEA number.

EXAMPLE: DEA Number 1234563

$$1+3+5 = 9$$

$$2+4+6 \times 2 = 24$$

$$\underline{\quad 33 \quad}$$

The last digit is 3 and 1234563 is verified. If the number were 1234-567, it would be erroneous and a pharmacist should be suspicious of the prescription.

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