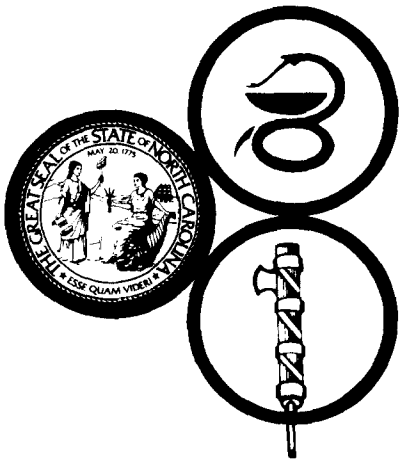
July, 1988



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 573 — Disciplinary Actions

February: *Vance Jefferson Lester*, Madison. Substituting generic products for brand name products without authorization from the prescribing physician; dispensing legend drugs and controlled substances without authorization from the prescribing physician; refilling prescriptions for legend drugs and controlled substances without authority from the prescribing physician. License suspended 90 days, stayed five years with an active suspension of ten days and other conditions.

March: *Richard Vann Kennerly*, Mooresville. Indulgence in the e of drugs to an extent rendering him unfit to practice pharmacy; aking Schedule IV controlled substances for his personal use without a valid prescription. License suspended indefinitely with conditions.

John D. Quick, Jr. Charges dismissed, no action taken.

April: *Anthony B. Cameron*, Sanford. Request for reinstatement heard and granted with conditions.

Item 574 — Election Results

The spring election for two Board positions produced one winner and one run-off election. The results are:

District 1	
Harry Brogden	332
Ken W. Burleson	463
Harold V. Day	636
Ronald Holland	96
Michael Overman	433
District 2	
Loni T. Garcia	740
Jack G. Watts	1180

Jack Watts was declared the winner in District 2 for a three year term to begin in the Spring of 1989. The Board of Pharmacy Elections ruled several years ago that, in the event one candidate does not receive a majority in any election, the candidate with the next largest number of votes has the opportunity to call for a run-off within ten days. In a letter dated May 26, 1988 Ken Burleson requested a run-off election and the ballots are enclosed with this Newsletter. Please use the enclosed small pencil to mark your ballot as instructed. Ballots will be counted on the evening of August 22nd at about 5 p.m. at the Institute of Pharmacy in Chapel Hill. It is an open meeting and anyone may attend.

Item 575 — Revision In Fee Structure

At the last session of the General Assembly the Pharmacy Practice Act was revised to provide for the registration and issuance of a pharmacy permit to physicians who dispense drugs for a fee or charge. The statute change also specified that such physicians must follow the same requirements that pharmacists meet in packaging, labeling and other matters. The Board staff prepared for the issuance of these permits in the same way that permits are issued for the operation of pharmacies by pharmacists. The statute provided that each physician must register and it was the Board's decision that the same fee charged to pharmacists for a permit should apply to dispensing physicians and the 1987-88 Board budget was constructed accordingly.

In November of 1987 a letter was sent to every physician in North Carolina informing them of the change in statute and the procedures planned by the Board which included permit issuing sessions at eight cities around the state to make it easier for physicians to comply. Shortly after that time the Board became a defendant in litigation over the implementation of this statute and an injunction was granted prohibiting the Board from charging fees to physicians for permits or requiring a personal appearance for the issuance of such permits.

The litigation costs are significant and an important indirect effect has been that the anticipated income from physician dispensing permits has not yet materialized. In planning for the Board's budget it was estimated that there would be 300 dispensing physicians registered during the first year for anticipated income of $60,000. This shortfall and the length of time since the last fee increase has made a change in the Board fees necessary.

The last increases occurred in 1981, 1973 and 1965, so an increase at this time is about on schedule with past changes. Increases in expenses are general but some examples might be helpful. Legal fees are four times greater this year than they were in 1981, our postage has tripled and our telephone bill is four times larger than it was at the time of our last fee increase. The proposed new fees will be presented to the general assembly this summer.

continued on page 4

National Pharmacy

(Applicability of the contents of articles in the National ... and can only be ascertained by examini

THE "ORANGE BOOK" — OFTEN ASKED QUESTIONS

The *Approved Drug Products with Therapeutic Equivalence Evaluations* commonly referred to as the "Orange Book," identifies currently marketed drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA). Also included are therapeutic equivalence evaluations for approved multisource prescription drug products that have been prepared to serve as public information and advice to state health agencies and pharmacists in the administration of drug product selection laws. The "Orange Book" also serves to promote public education in the area of drug product selection.

Following are answers to some often asked questions about the "Orange Book" that were discussed in a presentation at the 84th Annual Meeting of the National Association of Boards of Pharmacy (NABP) by Donald B. Hare, special assistant to the director Office of Drug Standards, Center for Drug Evaluation & Research, FDA.

• **Question:** Can ampicillin suspensions be substituted for ampicillin capsules?

Answer: Scientifically ampicillin suspension 250mg/5ml could be formulated to be bioequivalent to ampicillin capsules 250mg. However, this circumstance cannot be displayed in the "Orange Book" as being substitutable and these two drug products could not meet FDA's standard for therapeutic equivalence since we require substitutable drug products to be pharmaceutical equivalents. We would need to see studies comparing the bioavailability of the products before we would comment on this question.

• **Question:** How does FDA revise its evaluation of a product based on adverse reports?

Answer: Adverse events, including therapeutic failures are reported for all drugs. Therapeutic failures occur even when the drug product is not changed, as is evident from the reports we receive. Blood pressures can rise on previously effective therapy; heart failure can worsen on a stable digoxin/diuretic regimen, seizures can break through, etc. We would not consider changing our therapeutic equivalent evaluations unless evidence exists that the adverse reports (e.g., therapeutic failures) were due to the specific drug product rather than a patient or drug substance problem. If such data were presented to us, we would change the code to therapeutically inequivalent.

• **Question:** How long does it take for a drug to appear in the "Orange Book"?

Answer: The "Orange Book" is updated monthly.

• **Question:** Is the "Orange Book" an official national compendium, an authoritative source which can be used to provide protection in civil suits? Does it have force of law?

Answer: The "Orange Book" is not an official national compendium. The "Orange Book" displays FDA's therapeutic equivalence recommendations on approved multiple source drug products. FDA's evaluation of therapeutic equivalence is a scientific judgment based upon data submitted to FDA. Generic substitution is a social and enconomic policy administered at the state level intended to minimize the cost of drugs to consumers. The programs are administered by the states, because the practices of pharmacy and medicine are state functions. The question of liability is not one in FDA's area of expertise. We suggest that counsel in your state be consulted. The "Orange Book" does not have force of law. The preface of the "Orange Book" addresses this issue.

• **Question:** Provide tips on how to explain to physicians that drugs that are bioequivalent are indeed therapeutic equivalent. Many believe that drugs are not necessarily therapeutic equivalent, just because they are bioequivalent.

Answer: 1. The FDA is not aware of one prospective clinical study that compared two bioequivalent/therapeutic equivalent drug products that demonstrate therapeutic inequivalence. 2. In the majority of cases the marketed innovator's product is not the formulation that was tested in clinical trials. The marketed innovator's drug products was shown to be therapeutic equivalent to the formulation that was used in the clinical trials by a bioavailability/bioequivalence study. Therefore a generic drug product and the innovator's drug product stand in the same relationship to formulation that was originally tested for safety and effectiveness.

• **Question:** How does the "Orange Book" relate to and/or impact on state formularies?

Answer: It became apparent to FDA soon after the repeal of the anti-substitution laws by the states that it could not serve the needs of each state on an individual basis in the preparation of their formularies. In 1978 the Commissioner of Food and Drugs notified appropriate officials of all states of FDA's intentions to provide a list of all prescription drug products that are approved by FDA for safety and effectiveness with therapeutic equivalence recommendations being made on all multiple source drug products in the list. This list could be used by each state in implementing its law, and would relieve FDA of appropriating an enormous amount of resources that would be required to provide individualized service to all states.

Three copies of the "Orange Book" are sent to state officials for their use in implementing their respective state laws. The states are under no mandate to accept the therapeutic recommendations in the "Orange Book".

DON'T BE LEFT HANGING WITH DRUG PRODUCT PROBLEMS!

Drug product quality is as important to us as it is to you. The *USP Drug Product Problem Reporting Program* is relying on your observations of poor product quality, therapeutic ineffectiveness packaging and labeling problems, and possible product tampering to improve the quality of prescription and OTC drug products in the marketplace. The USP program is a private, non-governmental program designed to immediately inform participating product

' Compliance News

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ng the law of such state or jurisdiction.)

manufacturers and the FDA of potential health hazards and defective products based on the report *you* submit.

Reports may be submitted in writing using the USP report form or by calling USP toll free at 1-800-638-6725. The manufacturer or the FDA may contact you directly to discuss your concerns and USP will forward to you any information it receives.

Problem reports received will be computerized and correlated with reports from other health professionals. This will allow for trend analysis of medical products on the market. Your input is needed to help provide a complete picture of current trends for a more accurate evaluation of these products. Reports of problems experienced in your practice will help to provide practical input into the improvement of compendial standards in the USP/NF or drug information monographs in the USP DI.

ORAL LIQUIDS: ADOPTION OF THE TERMS ORAL SOLUTION AND ORAL SUSPENSION AND EVENTUAL ELIMINATION OF TERMS SUCH AS SYRUP, ELIXIR, ETC.

As pharmacists, I'm sure we each have a conception of what ·vrup or an elixir is. But a survey of the United States Pharma-:ial Convention, Inc. (USP) Advisory Panels revealed that ..nsumers and the other health professions may not. We think of syrups as concentrated solutions of sugar, usually sucrose, intended for oral administration; and elixirs are commonly thought of as clear, sweetened hydroalcoholic liquids intended for oral use. But the fact of the matter is that the terms have been eroded to the extent that they may be meaningless as descriptors for products on the market. For example, we now have on the market oral solutions designated as elixirs, but having no alcohol content; and syrups with no sugar; and syrups with more alcohol than elixirs; and "oral solutions" with large percentages of alcohol.

The amount of alcohol present in an article is required by the Federal Food, Drug and Cosmetic Act to be indicated on the label. For some time now, the attention of the USP has been directed to the importance of similarly labeling oral preparations with the sugar content, in order that the pharmacist who is concerned about a diabetic patient, for example, would be alerted.

With the labeling containing a list of all inactive ingredients, it becomes less necessary to attempt to alert practitioners to the formulation characteristics by using a limited dosage form term in the product's title. Thus the Drug Nomenclature Committee is considering reducing the titles of oral liquids to two terms: *Oral Solutions* and *Oral Suspensions*. These titles would be applied to newly admitted articles henceforth. And gradually and systematically, such terms as *Elixir* and *Syrup* would be eliminated ·om current monograph titles.

It just may be that eventually these two common terms of today will join the ranks of those other terms such as cordials, decoctions, infusions, honeys, and wines, once thought to be such an integral part of the pharmacists armamentarium. Conversion of the terms is expected to be gradual so as not to cause undue confusion.

DISCONTINUANCE OF HIGH-ESTROGEN ORAL CONTRACEPTIVE PILLS

The three manufacturers of high-estrogen oral contraceptive pills have advised the Food and Drug Administration that they will follow recommendations to discontinue the manufacture and distribution of these high-dose pills.

Three months ago, FDA's Fertility and Maternal Health Drugs Advisory Committee concluded that high-estrogen pills are no more effective than low dose pills and noted that some studies have shown an association between the dosage and the risk of blood clotting disorders. The committee of experts recommended that contraceptive pills with more than 50 micrograms of estrogen be withdrawn from the market.

The manufacturers, G.D. Searle and Company, Ortho Pharmaceutical Corp. and Syntex Corp., are sending letters to doctors informing them that they are phasing out the products which contain more than 50 micrograms (one microgram is one thousandth of a milligram) of estrogen. The letters said that a six-month phase out period will allow doctors to switch patients from a high-estrogen dose to lower estrogen pills — pills that contain between 30 and 50 micrograms of estrogen.

FDA Commissioner Frank E. Young, MD, Ph.D. said, "I applaud the responsible decision of these manufacturers. Low dose contraceptives are quite safe and, for healthy young women, are considered to be the most effective reversible means of preventing pregnancy."

The most commonly prescribed birth control pills today contain 30 to 35 micrograms of estrogen. The pills being phased out contain 75 to 100 micrograms of estrogen.

NABP FOUNDATION OFFERS SCHOLARSHIPS

The NABP Foundation is pleased to announce the availability of three scholarships to students enrolled in graduate programs in pharmacy administration. The scholarships to be awarded are: First Place — $3,000; Second Place — $2,000; Third Place — $1,000.

Candidates applying for the scholarships must submit a reference paper not to exceed 1,500 words, focusing on a current issue in pharmacy practice and its effect on the regulation of the profession by boards of pharmacy and/or other government agencies.

In addition to the paper, candidates should submit a letter from the Dean of their college of pharmacy verifying their enrollment in a graduate program in pharmacy administration.

All entries must be submitted to the NABP Foundation Scholarship Committee, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068 prior to January 1, 1989. Winners will be announced in the spring of 1989.

continued from page 1

Item 576 — Quarterly Query

How long is a prescription for a Schedule II drug valid?

1. 24 hours.
2. 48 hours.
3. 72 hours.
4. 7 days.
5. There is no time limit.

Item 577 — New Law Book

The Board has published an updated law book which is now available for $5.00 from the Board office. To obtain a copy send $5.00 with your request for a 1988 law book (blue cover) to P.O. Box H. Carrboro, North Carolina, 27510.

Item 578 — New Regulations Adopted

At the April, 1988 meeting of the Board of Pharmacy the members adopted two regulations which provide for significant changes in regulations on prescription delivery and prescriptions by mail. The text of the newly adopted regulations follows below. It is necessary to submit these adopted regulations to the Administrative Rules Review Committee before they are finalized and an effective date established.

.1804 — Prescription: Receiving And Dispensing

In order to assure that the practitioner/pharmacist/patient relationship exists and the safe and secure distribution of drugs and devices and to provide the services specified in G.S. 90-85.3(r) to ultimate users who are not institutionalized:

(1) Any place where prescription orders are dispensed shall have a permit as specified in G.S. 90-85.21 or G.S. 90-85.22 and conform to all pertinent requirements.

(2) Prescription orders may be received for filling and refilling only by a pharmacist or a bona fide employee of the pharmacy. The pharmacist-manager of the pharmacy shall be ultimately responsible for the safe, lawful and secure receipt of prescription orders and delivery of prescription drugs. Notwithstanding the provisions of this rule, prescription drugs also may be delivered by mail in accordance with the provisions of Rule 21 NCAC 46.1601(7).

.1601 — Pharmacy Permits

(7) In addition to the requirements for issuance and renewal of a pharmacy permit imposed by statute and by other rules and regulations of the board, a permit shall not be issued or renew- ' to any person to operate a pharmacy wherein prescriptions compounded or dispensed and distributed when such distribut.. is effected by mail and the practitioner/pharmacist/patient relationship does not exist, until the board is satisfied that:

(a) The pharmacy maintains records of prescriptions compounded or dispensed and distributed in a manner that is readily retrievable;

(b) During the pharmacy's regular hours of operation but not less than six days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed drugs;

(c) The pharmacy complies with all lawful orders, directions, and requests for information from the boards of pharmacy of all states in which it is licensed and all states into which it distributes prescription drugs;

(d) The pharmacy complies with all USP and FDA requirements regarding the storage, packaging, and shipping of prescription medications.

The pharmacist-manager and all other pharmacists employed in pharmacies permitted pursuant to this Paragraph shall be subject to all federal and state statutes and regulations concerning the dispensing of prescription medications including, but not limited to, 21 NCAC 46.1801 and .1805 and 21 C.F.R. 1306.01, 1306.05, and 1306.21. Provided, however, that this Rule shall not apply to the occasional mailing of prescription drugs to bona customers of any pharmacy when the traditional physic. pharmacist/patient relationship is present.

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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