



North Carolina Board of Pharmacy

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Item 1033 – Disciplinary Actions Pre-Hearing Conference Recommendations - May 1999

Mildred F. Matthews (DOB November 17, 1939), Asheville. Heard by Board Member Timothy R. Rogers. Numerous dispensing errors made in the practice of pharmacy. Recommendation: License suspended 15 days, stayed three years with conditions which include a four-day active suspension of the license. Accepted by Ms. Matthews May 14, 1999; accepted by the Board May 18, 1999.

Full Board Hearings May

Roger L. Simpson (DOB July 21, 1954), Monroe. Order reinstating license entered. License not eligible to be reinstated until specific conditions are met, including completion of 600 hours of work as a pharmacy apprentice.

Victor M. Sorrell (DOB April 23, 1958) Hickory. Obtaining and consuming controlled substances from pharmacy stock without authorization. License suspended indefinitely, stayed five years with active suspension of one year, October 16, 1998, through October 15, 1999, and other specific conditions.

June

Granville Jones (DOB August 10, 1961), Durham. Order reinstating license entered with conditions.

Allen J. Stalling, (DOB January 30, 1952), Wallace. Order Summarily Suspending License entered effective June 16, 1999.

Ricky D. Trivette, (DOB June 6, 1963), Banner Elk. Obtaining and consuming ketamine, a prescription drug from place of employment without authorization. Consent Order entered: License suspended indefinitely, stayed seven years with conditions.

Harry B. Umphlett, Jr., (DOB June 11, 1933), Goldsboro;
John A. Mitchener, III (DOB September 30, 1941), Edenton and **Mitchener's Pharmacy**, Edenton. Conviction of conspiracy to commit mail fraud and the sale, purchase, and trade of drugs purchased by a public hospital. Mr. Umphlett, Jr.'s license suspended indefinitely; Mr. Mitchener's license suspended seven days, stayed one year

with active suspension of one day and other conditions; pharmacy permit to operate Mitchener's Pharmacy suspended 30 days, stayed five years with active suspension of one day and other conditions.

Item 1034 – Return Goods Compliance

It was reported in the April 1999 issue of this *Newsletter* that Fujisawa Healthcare, Inc. of Deerfield, Illinois, was not in compliance with the Board rule on this issue. This will inform all parties that Fujisawa Healthcare, Inc. is now in compliance with the North Carolina rule on returned goods.

Item 1035 – 12-Hour Maximum, Meal & Rest Breaks

The Board originally proposed a rule more than one year ago, which would have prohibited permit holders from requiring pharmacists to work more than 12-hours per day, required a 30-minute meal break after six hours of filling prescriptions, and a 15-minute rest break after four hours of dispensing prescriptions. The Rules Review Commission objected to the proposal, effectively stopping it in state government.

The Board has filed litigation against the Rules Review Commission, and the matter should be in the process of consideration by the courts as of the arrival of this *Newsletter*. After this proposal became public, some chain stores initiated meal and/or rest breaks for their pharmacists, and the Board believes this is a step in the right direction. The members intend to pursue the matter further, and solidify the concept in state law as a matter of public safety and protection.

With all the responsibilities of pharmacists these days, including patient counseling and drug use review, it is necessary for pharmacists to be rested and alert in order to minimize dispensing errors. You can keep up-to-date on this and other issues by referencing the Board's Web site at www.ncbop.org, and looking for the appropriate category, which often is New Developments.

Item 1036 – Board Newsletters on Web Site

If you think you remember seeing something in the Board's *Newsletter*; but can't recall where it was or the exact wording,

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National Pharmacy

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

NABP Awards First VIPPS™ Seals to On-Line Pharmacies

NABP awarded its first Verified Internet Pharmacy Practice Sites (VIPPS™) seals on September 15, 1999, to three on-line pharmacies, planetRx, Merck-Medco Rx Services, and drugstore.com, each of which is now authorized to display the VIPPS seal on their Web site and maintain a link from the seal to NABP's VIPPS Web site.

"Each of these three on-line pharmacy operations were able to satisfy VIPPS' rigorous 17-point Internet pharmacy practice criteria, demonstrate appropriate licensure, and pass an on-site visit from VIPPS inspection teams at the applicants' headquarters and fulfillment centers to review and verify compliance with VIPPS criteria," said NABP President Dyke Anderson. "These pharmacies have demonstrated consumers can use their Internet services with confidence."

The VIPPS certification process begins with the submission of a completed VIPPS Application Form and supporting documentation. Submitted materials include essential information such as the applicant's business name, ownership, address and phone number, Web site address, and documentation of adherence to VIPPS criteria. Such criteria include maintaining and following written policies and procedures for drug utilization review, patient counseling, patient confidentiality, and quality improvement programs.

After an evaluation of the applicant's submitted materials, a written evaluation is issued to the applicant, and a site inspection is scheduled.

During a site inspection, VIPPS inspectors:

- ◆ Investigate issues arising from the evaluation of the applicant's submitted information;
- ◆ Confirm that policies and procedures reviewed during evaluation of the VIPPS application are available to, and used by, members of the on-line pharmacy staff, and that staff members are trained to use them;
- ◆ Collect new, revised, or additional policies and procedures supporting VIPPS criteria;
- ◆ Probe and test problem resolution and contingency plans; and
- ◆ Identify strong and weak areas or departments for internal monitoring.

Upon completion of the site visit, inspectors submit a report of their findings to NABP, including deficiencies and recommended corrective actions. A written report is then issued to the applicant. If deficiencies are noted, the report includes recommendations for VIPPS criteria compliance. If the review is satisfactory, the report confirms VIPPS certification.

"VIPPS applications continue to be received at NABP headquarters," said NABP Executive Director Carmen A. Catzone.

PlanetRx, is headquartered in South San Francisco, California. Merck-Medco is based in Las Vegas, Nevada. Drugstore.com, inc. is located in Bellevue, Washington.

ISMP Survey Reveals Pharmacy Computer System Flaws

Concerns regarding the ability of computerized pharmacy systems to detect and correct prescription errors were brought to the forefront when the results of a recent computer field test and survey performed by the Institute for Safe Medication Practices (ISMP) were published earlier this year.

The ISMP tested pharmacy computer systems with specific questions to assess their ability to detect serious or fatal errors, including serious drug interactions, and found that many systems performed poorly.

A majority of the computer systems were unable to detect orders that exceeded a set maximum dose. Only 38 percent of systems detected lethal overdoses of both cisplatin and vincristine, 34 percent detected lethal colchicine doses, and 87 percent did not detect an excessive tobramycin dose for a patient with renal impairment. Although 88 percent detected a ketorolac and aspirin cross-allergy, and 85 percent a drug interaction between ketoconazole and cisapride, only 35 percent detected a drug ingredient duplication with acetaminophen and Percocet, and only 39 percent detected a problem with an oral suspension ordered intravenously.

The survey also revealed that only 42 percent of the respondents' systems are linked between the pharmacy and laboratory. Of those with linked systems, only 41 percent automatically screen orders against current laboratory values.

"Standards of care, and most board laws, require pharmacists to perform prospective drug utilization reviews when filling prescriptions," said Kevin E. Kinkade, Chairman of the Executive Committee for the National Association of Boards of Pharmacy (NABP). "With the vast majority of pharmacists using computerized systems to assist them in performing these reviews, the boards of pharmacy have reason to be concerned about the results of this study."

ISMP recommends that pharmacists not rely on pharmacy computer systems alone to support effective drug therapy monitoring.

"Vendors may market systems by promoting the detection of unsafe orders. Yet it is clear that, in practice, complex self-programming and the unrealistic time commitment necessary to achieve desired results may prohibit full use of the sys-

Compliance News

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tems' capabilities," the ISMP report states. "Thus, such vendor claims are meaningless unless the system applications are user friendly, allow maximum capabilities to easily be achieved, and are not cost prohibitive."

ISMP plans to use the results of its survey to promote improved pharmacy computer technology for more effective recognition of drug therapy problems. The complete results of this survey can be found on ISMP's web site at www.ismp.org/ISMP/MSAarticles/Computer.html.

Y2K Guidance for Rx Medication Users Issued

In response to concerns about the possible effects of the Year 2000 (Y2K) transition on the nation's prescription drug supply, the President's Council on Year 2000 Conversion recently released a guidance for users of prescription drugs to follow when refilling medications as the country approaches the new year.

The guidance was developed by a working group composed of manufacturers, wholesalers, distributors, retailers, hospitals, health care professionals, health maintenance organizations, insurance companies, patient advocate organizations, and government agencies, who reviewed pharmaceutical supply system operations and efforts to ensure the system is equipped to handle the Y2K transition.

The guidance assures consumers a continued supply of medications, and maintains companies within the medication distribution system are testing critical computer systems and refining contingency plans. The guidance confirms that local pharmacists will be within easy access of a substantial supply of pharmaceuticals, since the industry typically operates with a 90-day inventory on hand and maintains readiness for emergencies. It is recommended that patients refill prescriptions when they have a five to seven day supply of medication remaining.

For further information, visit the President's Council on Year 2000 Conversion Web site at www.y2k.gov.

DEA Publishes Methamphetamine Control Act Special Surveillance List

Pursuant to a mandate by the Comprehensive Methamphetamine Control Act of 1996 (CMCA), which broadened controls on products used in the production of methamphetamine and other controlled substances, the US Drug Enforcement Administration (DEA) published its "Special Surveillance List," a list of "laboratory supplies" subject to CMCA controls. The CMCA makes it unlawful to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply

to manufacture a controlled substance or a listed chemical with reckless disregard for the illegal uses to which such laboratory supply will be put. Violations of this provision can result in fines of up to \$250,000.

The Special Surveillance List, which was published in the May 13, 1999 *Federal Register*, includes all listed chemicals found in Title 21 of the Code of Federal Regulations, Section 1310.02(a) or (b) (those which, in addition to having legitimate uses, are used in the illegal manufacturing of controlled substances), other chemicals such as ammonia gas, formic acid, and lithium and sodium metals, and equipment, such as tableting machines and 22-liter heating mantles.

The complete list can be viewed on the DEA home page at www.usdoj.gov/dea/. For further information, contact Frank Sapienza, chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, 202/307-7183.

DEA Takes Action on Ketamine, Marinol®

Recent actions by the US Drug Enforcement Administration (DEA) have placed ketamine (Ketalar[®]) into Schedule III, and have transferred synthetic dronabinol (Marinol[®]) from Schedule II to Schedule III of the federal Controlled Substances Act (CSA).

As of July 2, 1999, prescriptions for Marinol, used for the treatment of nausea and vomiting associated with cancer chemotherapy, and anorexia associated with weight loss in patients with AIDS, were subject to the less stringent recordkeeping requirements and distribution restrictions of those drugs included in Schedule III, including the allowance of up to five refills within six months. This action was taken based upon the DEA finding that Marinol has less potential for abuse than other drugs in Schedule II. The final rule announcing this change was published in the July 2, 1999 *Federal Register*.

August 12, 1999, was the effective date for increased restrictions on ketamine, a general anesthetic indicated for both human and veterinary use. DEA findings of a wide geographic distribution and prevalence of diversion and abuse, and the spreading notoriety among teenagers and young adults of ketamine as a party drug, resulted in the DEA's decision to make ketamine a Schedule III drug. The final rule announcing this change was published in the July 13, 1999 *Federal Register*.

For further information, contact Frank Sapienza, chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, 202/307-7183.

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you may be able to find the text on our Web site. Newsletters from January 1997 to present are now available on the homepage at "Newsletter on the Web." An index is also available on the home page.

As time goes by, we will add to and improve this section of our Web site as a service to pharmacists and the public.

Item 1037- 1999 General Assembly Actions Significant Pharmacy Legislation – 1999 Session

I. House Bill 1095 – Clinical Pharmacist Practitioner.

Under this legislation, a joint committee of the North Carolina Medical Board and the North Carolina Board of Pharmacy will develop rules to govern the performance of medical acts by clinical pharmacist practitioners. An approved clinical pharmacist practitioner may be authorized to implement predetermined drug therapy, modify, and prescribe drug dosages, dosage forms, and dosage schedules, and order laboratory tests pursuant to a drug therapy management agreement. The drug therapy management agreement must be physician, pharmacist, patient, and disease-specific. Fees for registration as a clinical pharmacist practitioner shall not exceed \$100, and for renewal, not exceed \$50. The act becomes effective July 1, 2000, with the exception of the provisions relating to the development and adoption of regulations, which are effective now. *The above legislation was the only effort by the Association this year, and they deserve congratulations for their success. It will make more programs like the Asheville Project possible. Call 1-800/852-7343 for more information.*

II. Senate Bill 951 – Health Workers ID Badge.

This legislation requires health care practitioners, including doctors, nurses, dentists, and pharmacists to wear a badge, or other form of identification, displaying the practitioner's name and the type of license, certification, or registration held by the practitioner. The identification badge need not be worn if the patient is being seen in the practitioner's office and the information can be obtained from a posted license, sign, or brochure provided to the patient. The Board is authorized to adopt rules regarding the use of these identification badges. This act became effective October 1, 1999.

III. Senate Bill 513 – Prescription Drug ID Card.

Pursuant to this bill, every health benefit plan that provides coverage for prescription drugs or devices and issues a prescription drug card, shall issue to its insureds a uniform prescription drug identification card. The act sets out nine requirements for the card and requires, by January 1, 2003, the card to contain a magnetic strip, bar code, or other technology for electronic processing of claims. The act applies to health benefit plans that are delivered, issued for delivery, or renewed on and after July 1, 2000.

IV. Senate Bill 59 – Mobile Pharmacies. This bill amends G.S. § 90-85.3 to allow a mobile pharmacy to register with the Board as a single pharmacy rather than registering each location from which dispensing occurs. In order to be eligible for the single registration, the mobile pharmacy must meet the following conditions:

- (1) It is either self-propelled or movable by another vehicle.
- (2) It is operated by a non-profit corporation.
- (3) It dispenses drugs at no charge, or at a reduced charge, to persons whose family income is less than 200 percent of the federal poverty level, and who do not receive reimbursement from Medicare, Medicaid, private insurance, or governmental unit. This act became effective July 2, 1999.

Item 1038 – Patient Counseling

The Board continues its emphasis on patient counseling, and has written letters to more than 20 pharmacists with specifics on how their practices could be improved. Several Board members have noted that dispensing errors can be caught by the pharmacist at the time of patient counseling when reviewing the product with the patient. It is a good opportunity to discover dispensing errors before they reach the patient.

Item 1039 – Orange Book On-Line

The Food and Drug Administration's (FDA) *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book," is now available on-line at the following Web site: www.fda.gov/cder/ob/. The Board requires every pharmacy to have a current drug equivalency reference. Pharmacies that have Internet access may now fulfill this requirement by utilizing FDA's Web site.

Item 1040 - Dentists Prescribing Zyban

The Board office has received an inquiry as to the appropriateness of a dentist prescribing Zyban for smoking cessation. After discussion at a Board meeting, it was the consensus of Board members and staff that prescribing Zyban for smoking cessation is within the practice of dentistry.

Item 1041 - DME Subcommittee Suggestions

(This item is submitted by Teresa Gregory, DME Subcommittee Member, who operates Medi-Home Care in Statesville)

The Durable Medical Equipment (DME) Subcommittee for the North Carolina Board of Pharmacy is again asking the state's DME industry for some feedback on the amount of backup oxygen that should be required to be left in the patient's home.

During this past year, the Committee asked for input. Only two responses were received, and of those two responses, only one letter gave a rationale for its recommendations. The DME Subcommittee has recommended that 48 hours be the minimum standard. Several providers complained that 48 hours was either too much (costs would increase considerably), or that it would not be enough (as in the case of a severe ice storm, hurricane, etc.). So, please submit your recommendations in writing to the North Carolina Board of Pharmacy, PO Box 459, Carrboro, NC 27510, to the attention of Steve Hudson, by October 31, 1999.

Your input is greatly wanted and appreciated. If no response is received, the current standard of 48 hours of backup of oxygen will remain in effect.

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Item 1042 – Division of Facility Services Meeting

(The information below is submitted by Wayne Link, chairman of the Durable Medical Equipment Subcommittee)

Since the inclusion of durable medical equipment in the Pharmacy Practice Act, a question has remained about the registration and regulation of dealers who are registered with the Division of Facility Services (DFS), but handle durable medical equipment.

On August 19, 1999, the Board of Pharmacy's Durable Medical Equipment Subcommittee members, Wayne Link and Teresa Gregory, along with members of the Board staff, met with Dr. David Bruton, secretary,

Department of Health and Human Services, and Lynda McDaniel, director, Division of Facility Services, to develop a plan for the registration and regulation of the companies affected by the uncertainty. It is anticipated that a positive outcome will result from the coordination between the two agencies. The results will be published in a future addition of the *Newsletter*.

Item 1043 - PharmD Student - An Inside Look

(This item was written by Melissa Durkee, a North Carolina registered pharmacist who is a student in the PharmD Program at Campbell University and served a two-week rotation in the Pharmacy Board office in July, 1999.)

I have been a registered pharmacist for three years, and am aware of the plethora of pharmaceutical associations and state boards of pharmacy for some time. I've even been a member of a few of those associations -- I've paid annual dues, attended an occasional CE dinner, even a convention or two. Luckily, or so I thought, my only relationship with the Board of Pharmacy has been to renew my registration and call David R. Work, executive director, with an occasional law question.

The sad fact is that I never really understood the organizations. Sure, I had heard the North Carolina Association of



Durable Medical Equipment Subcommittee members for 1999 are, seated, Chairman Wayne Link, Lynn; and, standing left to right, Teresa Gregory, Statesville; Larry Lankford, Durham; Tim Rogers, Raleigh. Not pictured is Wm. Whitaker Moose, Mt. Pleasant.

Pharmacists (NCAP) was working to get some type of collaborative practice bill passed (which they successfully did), and read that the North Carolina Board of Pharmacy was striving for better working conditions for pharmacists (which they are currently fighting for). But how do these organizations work? What do they do? Who are "they"?

I am presently attending Campbell University to earn the Doctor of Pharmacy degree. In addition to expanding my clinical skills, this experience has afforded me several unique opportunities. My most recent experience was spending two weeks at NCAP, and two weeks at the North Carolina Board of Pharmacy. Here's an inside look.

At NCAP, I spent the majority of my time working with Beth Williams on the Diabetes Community Health Project, a statewide initiative to provide pharmaceutical care to diabetics in the state. It was inspiring to see that what people in other states are talking about, North Carolina is doing!

I also had the opportunity to see, first hand, how professional organizations work to advance the profession and assist their members. Dan Garrett, the executive director of NCAP, invited me to accompany him to several meetings throughout the week. I saw how the pharmaceutical association interacts with the Medical Society, the State Legislature, and the pharmaceutical industry. The two weeks opened my eyes to how much local pharmaceutical associations do for the profession and how every pharmacist can contribute if he/she takes the time to get involved. It truly is inspirational and exciting to see where pharmacy is going and to have a voice in how it's getting there. I have joined three committees, and I'm looking forward to my first meeting on August 23.

Immediately following my two weeks at NCAP, I began two weeks at the State Board of Pharmacy. I came with a list of law questions for Mr. Work to answer. My first two days were filled with meetings. I was able to meet each of the current Board members and one future member. After the Board meeting, which all pharmacists are encouraged to attend, I realized the enormous amount of responsibility each Board member has. The Board members, with the assistance of Mr. Work, are the "final word" in pharmacy in this state. Their decisions affect not only thousands of pharmacists, but every citizen of North Carolina who has ever used a prescription drug or durable medical equipment.

Mr. Work, as you can imagine, is extremely busy, but set aside several hours of his schedule to educate me about state Board operations. Perhaps the most important lesson I learned about the State Board was not to fear it. The Board has many rules because it has a tremendous job to do, not because it is on a power trip to punish every person who disobeys the rule of the Board.

At the end of my second week, I realized that the time had gone by so fast that I had forgotten to give my list of law questions to Mr. Work. After spending time at the Board, I now understand the purpose of the State Board. I don't think I need that list anymore!

I truly believe that pharmacists in North Carolina are fortunate to have a Board such as ours. As long as we are honest, abide by the rules, and, above all, act in the best interest of our patients, we will be supported by our Board. As pharma-

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cists, we are often paranoid about breaking a law – who could blame us, there are so many! Unfortunately, the patient often suffers. In this state, we should be proud and take comfort in the fact that we have a Board that truly believes pharmacists should act, first and foremost, in the best interest of their patients.

Perhaps the most important thing I learned while at NCAP and the State Board is that the things we read about, the changes that are made, are all done by people just like me. I know it sounds silly, but often we get too caught up in our busy lives and don't stop to think about just how things happen. If nobody stopped to think about it, nothing would change – we, as pharmacists, and our profession, would not move forward.

Get involved – turn those names you see in print or hear about in pharmacy circles into colleagues and personal friends. Make a difference in the profession. As Mr. Work would say, "Be a participant, not a spectator."

Item 1044 - Y2K Issues

Discussion continues regarding what may, or may not, happen on and after January 1, 2000. Problems may also arise prior to that date due to patients' hoarding of drugs, which could, conceivably, affect the supply of pharmaceuticals.

Practicing pharmacists should understand the Board will be as flexible as possible under the circumstances, and the best advice for pharmacists is to do what you believe is in the patient's best interests. We should all remember that we exist as practicing professionals to serve the public interest and tend to their health and safety. As a baseline, certainly every effort should be made to avoid interrupting maintenance therapy.

Check our Web site, www.ncbop.org, under "New Developments" to keep current on this and other Board matters.

Item 1045 - Hurricane Disaster

Board Rule 21 NCAC 46.2502(i) provides for each pharmacist manager to have a plan to safeguard prescription records and pharmaceuticals in the event of a natural disaster, such as hurricane or flood. Some pharmacists questioned the need or

desirability of this rule, but recent events resulting from Hurricane Floyd reinforced the rule's merit.

While damage was most serious in the eastern part of the state, **all** pharmacists need to make plans in case they are ever faced with such natural disasters. This rule was adopted after Hurricane Hugo, which caused extensive damage in Charlotte and the western Piedmont area. At that time, parts of Charlotte were without electric power for approximately two weeks. Public records also show that more people die inland from hurricanes than at the beach.

Board staff, led by director of investigations Steve Hudson, took an active part in assisting pharmacies and pharmacists during this disaster. This included the emergency delivery of pharmaceuticals to hospitals and community pharmacies at the peak of the storm when common carriers were not operating, and the Highway Patrol and National Guard were otherwise occupied.

Pharmacists are reminded of the rule for emergency dispensing of refills, which allows a pharmacist to dispense up to a 30-day supply of a prescription, providing it is not for a Schedule II drug. This is not necessarily automatic, with the pharmacist's judgment being the key factor.

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