July 1999

North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 1016 – Disciplinary Actions

Pre-Hearing Conference Recommendations – February, March, April 1999

Julia Della-Mea, Rowland (DOB February 25, 1965); **Bryan Monroe**, Hope Mills (DOB February 16, 1974); **Jason M. Foil,** Lumberton (DOB July 24, 1971); **Drugs America,** 103 E. 24th Street, Lumberton. Heard by Board Member Crocker. Violation of Patient Counseling Rule, 21 NCAC 46.2504. Recommendation: Permit and license of Ms. Della-Mea suspended seven days, stayed two years with active suspension of the permit for one business day and other conditions; license of Pharmacists Foil & Monroe suspended seven days, stayed two years with active three-day suspension of the license and other conditions. Accepted by Della-Mea and Drugs America April 6, 1999; accepted by Monroe April 6, 1999; accepted by Foil April 7, 1999. Accepted by Board April 21, 1999.

David John Hauser, Advance (DOB December 8, 1949). Heard by Board Member Watts. Dispensed chlorpromazine on an order for chlorpropamide. Recommendation: Official Board Reprimand. Accepted by Hauser January 27, 1999. Accepted by Board February 16, 1999.

William Timothy Bratton, Roanoke Rapids (DOB March 1, 1961) & **Drugco Pharmacy,** 107 Smith Church Road, Roanoke Rapids. Heard by Board Member Watts. Dispensing prescription drugs to a patient without authorization of a physician; pharmacy's automated data processing system did not correctly record the pharmacist responsible for individual dispensations of drugs. Recommendation: License issued to Pharmacist Bratton suspended 30 days, stayed three years with conditions; Permit issued to Drugco Pharmacy suspended seven days, stayed three years with conditions. Accepted by Bratton and Drugco January 29, 1999. Accepted by Board February 16, 1999.

David Alexander Ayers, Surf City (DOB September 6, 1947). Heard by Board Member Watts. Dispensing controlled substance prescriptions more frequently than the prescribed dosage, in excess of normal therapeutic use, and without the authorization of a physician. Recommendation: License suspended 30 days, stayed two years with conditions. Accepted by Ayers January 29, 1999. Accepted by Board February 16, 1999.

Joseph Finnan, Rutherfordton (DOB April 1, 1941). Heard by Board Member Rogers. Numerous dispensing errors in the practice of pharmacy. Recommendation: License revoked, stayed five years with active 10-day suspension and other specific conditions. Accepted by Finnan March 2, 1999. Accepted by Board March 16, 1999.

Pre-Hearing Recommendations Pursuant to CE Audit

Proposal was made to add an additional five contact hours of continuing education during the calendar year 1999, to be included on the renewal application for the year 2000. Accepted by the following pharmacists: Ms. Shannon Booth, Kernersville; Mr. Alan P. Cunningham, Burnsville; and Ms. Maureen E. Burns, Madison. Accepted by the Board on March 16, 1999.

February Return Goods Hearing

The Board held a hearing for Taylor Pharmaceuticals, Decatur, Illinois, whose company policy was not in compliance with Board Rule .2901. It is the Order of the Board that Taylor Pharmaceuticals' products are ineligible for use in product selection in North Carolina.

[PLEASE NOTE: It was reported in the April issue of this newsletter that Baxter Healthcare Corporation was not in compliance with Board rule on this issue. This will inform all parties that Baxter Healthcare Corporation, Deerfield, Illinois, is now in compliance with the North Carolina rule on returned goods.]

April

Dwight Oxendine, Raeford (DOB May 21, 1960) & **Healthcare Connection,** Raeford. Consent Order entered: License suspended 90 days, stayed three years with active 10-day suspension and other conditions; permit suspended 90 days, stayed three years with conditions.

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National Pharmacy

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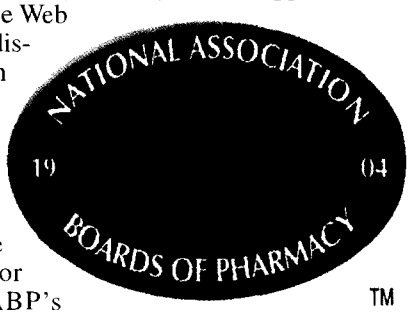
and can only be ascertained by examining

VIPPS Program to Provide Consumers with Information about Internet Pharmacies

As an increasing number of Internet pharmacies begin to introduce their services to the public, the National Association of Boards of Pharmacy (NABP) is completing development of its voluntary Verified Internet Pharmacy Practice Sites (VIPPS) program. Accessible through NABP's Web site at www.nabp.net, the VIPPS program will provide consumers with useful information about those on-line companies that are providing pharmacy services and have met the Association's criteria and requirements for program participation.

Through NABP's VIPPS seal (shown below), Internet users will be able to immediately identify VIPPS-approved on-line pharmacy sites. These Web sites will be required to display the seal and establish a hyperlink to the VIPPS screen, from which users will be able to view specific information about the site. Internet users can also log on to the VIPPS site to search for data about all of NABP's VIPPS-approved sites.



"Consumers are encouraged to look for the VIPPS seal when browsing on-line pharmacy Web sites, and to click on the seal to verify its authenticity through an established link to the VIPPS site," said NABP President Dyke F. Anderson.

In June, the Association began accepting applications from on-line pharmacy companies for admission to the VIPPS program. Since then, NABP has been verifying the data provided by applicants and conducting inspections of their operations to ensure adherence with the program's established criteria and requirements.

"As the first VIPPS seals are awarded, the VIPPS Web section will go live. Time projections indicate that the first seals will be awarded in August," Anderson said. "However, consumers should keep in mind that VIPPS is an evolving program. On-line pharmacy sites will be constantly added to the program as they are approved for participation."

Data gathered during the VIPPS application process includes licensure information for the on-line pharmacy; the types of services offered (e.g., dispense prescription medications and/or over-the-counter medications); and the company's written policies and procedures regarding drug utilization review, patient counseling, patient confidentiality, and quality improvement programs.

If the results from the application review are satisfactory, the on-line pharmacy enters into an agreement with the Association in which the pharmacy agrees to:

- adhere to the VIPPS criteria and program requirements;
- maintain all appropriate state and federal licenses in good standing;
- provide and allow certain information about the pharmacy to be posted and maintained for public access on the VIPPS Web site;
- facilitate and allow inspections of its operations, given reasonable notice and accommodation; and
- display and maintain the VIPPS seal, with a hyperlink on the pharmacy's Web site.

More information about the VIPPS program can be found at www.nabp.net. Questions should be directed via e-mail to vipps@nabp.net, or by calling Glenn Detweiler, NABP's licensure programs director, at 847/698-6227.

FDA Dietary Supplement Labeling Rule Goes into Effect

A new Food and Drug Administration (FDA) regulation implementing some of the major provisions of the Dietary Supplement Health and Education Act of 1994, went into effect March 23, 1999. The new regulation, intended to give consumers the information they need to make informed purchasing choices, requires consistent and more thorough labeling of dietary supplements.

Manufacturers are now required to include on labels a "Supplement Facts" panel, a clear identity statement, and a complete list of ingredients. The "Supplement Facts" panel must state the following:

- The manufacturer's suggested serving size;
- Information on nutrients (e.g., Vitamins A and C, calcium, and iron) when they are present in significant levels, and the percent Daily Value where a reference has been established – similar to nutrients listed on the "Nutrition Facts" panel on food labels;
- All other dietary ingredients present in the product, including botanicals and amino acids – those for which no Daily Value has been established.

A statement of identity must appear on the front panel of the product label and must use the terms "dietary supplement" or a term identifying the contents of the product, such as "Vitamin C supplement" or "Herbal supplement." Herbal products must be identified by the common or usual name and the part of the plant used to make the supplement (i.e., root, stem, or leaf).

The FDA plans to survey dietary supplements on the market for compliance with the new labeling requirements.

Warning Issued for Products Containing GBL

Reports of potentially life-threatening problems associated with the use of gamma butyrolactone (GBL) have led to a warning issued by the Food and Drug Administration (FDA) for a voluntary manufacturer recall of products containing GBL. Although labeled as dietary supplements, GBL-containing products are actually unapproved new drugs illegally marketed under various brand names, including Renewtrient; Revivarant or Revivarant G; Blue Nitro or Blue Nitro Vitality;

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he law of such state or jurisdiction.)

GH Revitalizer; Gamma G; and Remforce. These products claim to build muscles, improve physical performance, enhance sex, reduce stress, and induce sleep.

When taken orally, GBL is converted in the body to gamma hydroxybutyrate, also known as GHB, an unapproved drug which has also been illicitly distributed as a body-building, dietary supplement.

GBL-containing products have been associated with at least 55 reports of adverse effects, including one death. In 19 of those cases, patients became unconscious or comatose and several required intubation. Other reported effects included seizures, vomiting, and bradycardia.

GBL has been sold in both liquid and powder forms in health food stores, gymnasiums and fitness centers, and via the Internet. Consumers are advised to dispose of any GBL-containing products and to contact a physician if they experience any adverse effects. The FDA asks that adverse events be reported to MEDWATCH at 800/332-1088.

FDA Recognizes Pharmacists in New OTC Labeling Regulations

A final rule recently issued by the Food and Drug Administration (FDA) recognizes pharmacists' knowledge and contributions to patient care when it comes to over-the-counter (OTC) drug products. Published in the March 17, 1999 *Federal Register*, the rule establishes standardized format and content requirements for the labeling of over-the-counter (OTC) drug products, and is intended to assist consumers in reading and understanding OTC product labeling so they may safely and effectively use these products.

In the rule, the FDA recognizes that "pharmacists are knowledgeable about OTC drug products" and "are a valuable resource" for consumers. It is for these reasons that the new rule requires manufacturers to include on OTC product labeling the phrase, "Ask a doctor or pharmacist before use if you are ...," when addressing drug/drug or drug/food interaction warnings.

"The recognition of pharmacists as competent providers of OTC drug information has been a long time coming," said NABP President Dyke F. Anderson. "This regulation acknowledges the pharmacist's role as an integral member of the health care team."

The regulation also goes a long way towards providing understandable information to patients. A new "Drug Facts" box on each product will state the "Active ingredients," "Purpose" (pharmacological category), "Uses," "Warnings," "Directions," "Other information" (when appropriate), and "Inactive ingredients." The regulation also addresses minimum type sizes and other graphic features, including options for modifying the format for various package sizes and shapes.

Most OTC product manufacturers must comply with the new regulations within two years. All of the more than 100,000 OTC products must have compliant labeling within the next six years.

Risk Management Program Accompanies Approval of Fentanyl "Lollipop"

Accompanying the release earlier this year of a new fentanyl product developed specifically for breakthrough cancer pain was the requirement by the Food and Drug Administration (FDA) that a comprehensive risk management program be in place to prevent potentially dangerous misuse or abuse. The new product, oral transmucosal fentanyl citrate (Actiq®), comes as a flavored sugar lozenge that dissolves in the mouth while held by an attached handle.

The areas of potential misuse and abuse are three-fold, according to Anesta Corp., the product's developer, and Abbott Laboratories, its manufacturer and distributor. Concerns regarding accidental ingestion by children, diversion and abuse, and inappropriate prescribing for and use by patients who are not tolerant to the effects of opioids, have resulted in a risk management program that focuses on the safe storage, use, and disposal of Actiq, and instructs health professionals regarding proper patient selection and education.

For patients, a "Patient Leaflet" is available with detailed use, storage, and disposal information, as well as an "Actiq Welcome Kit," containing a child-resistant lock (for the home storage compartment), a child-resistant temporary storage bottle (to store partially used Actiq units), a portable locking pouch, and a demonstration video. For pharmacists, a dispensing checklist appears on the shelf carton, which directs the pharmacist to ensure that the patient is a chronic opioid user, and to counsel the patient on the safe use, storage, and disposal of Actiq, as well as its risks to children.

For more information about the Actiq risk management program, log on to the Actiq Web site at www.abbotthosp.com/PROD/PAIN/actiqprod/act001.htm or call 1-888/818-4113.

Web Site Offers Pain Management Policy Information

For those interested in pain management and the effects of government regulation on the practice, the University of Wisconsin's Pain & Policies Studies Group (PPSG) Web site offers a wealth of information. Dedicated to facilitating public access to information about pain relief and public policy, the site features pain-related laws, regulations, and medical board guidelines for each state; articles about trends in pain policy; policy alerts; and a large section on international policy and opioid consumption trends. The PPSG's Web site can be found at www.medsch.wisc.edu/painpolicy/.

The PPSG studies the extent to which the regulation (or the perception of regulation) of drugs and professional practice affects pain management. Much of its work focuses on identifying and addressing the barriers to medical use of opioid analgesics essential to chronic pain management and palliative care, and the effects of prescription monitoring and health insurance on pain management.

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Item 1017 – Election Results

The election results for two positions on the Board of Pharmacy were tabulated in the Board offices on May 17, 1999. The results of the election are as follows:

District 3

Brent Clevenger	377
David Cox	453
Judy Gunnarson	302
Stan Haywood	918
Christina Nall	255
Ron Small	728

District 4

Charles Branton	530
Tom D'Andrea	204
Jimmy Jackson	756
Wallace Nelson	1,456

Mr. Wallace Nelson was declared the winner for District 4, representing the northeastern part of the state. Mr. Ron Small called for a run-off in District 3, and the ballots will be counted on the evening of July 19, in the Board offices in Carrboro.

Item 1018 – Post Schedule

A new rule adopted by the Board, effective April 1, 1999, requires that each pharmacy post in a conspicuous location specific hours that a pharmacist is on duty in the pharmacy. This does not apply to hospitals, nursing homes, or similar institutions, but does apply to retail pharmacies. The posting notice should specify any breaks for meals or rest. See .1601(a)(3).

Item 1019 – Treating Pain

For the first time in memory, a Medical Board has disciplined a physician for failing to adequately treat pain. An Oregon doctor was disciplined by the Medical Board for refusing a hospice nurse's request for stronger pain drugs and anti-anxiety medication for an elderly man who expired three weeks later of cancer.

While this case did not directly involve a pharmacist, licensees should be aware that the standard for pain treatment has undergone changes over the last several years. The North Carolina Medical Board has a policy on the treatment of pain, which can be found at www.ncmedbrd@interpath.com.

Item 1020 – No "Big Brother" Scrutiny of Prescribing

Physicians and pharmacists may be under the impression that there is some state agency that is scrutinizing prescriptions for controlled substances and other psychotherapeutic drugs. Practitioners should be aware there is no office in this state that is collecting information on all controlled substance prescriptions or those for psychotherapeutic drugs.

Some states capture this information electronically or through required duplicate or triplicate prescription blanks. This is not the case in North Carolina. The Medical Board and Pharmacy Board do investigate complaints or other situations that are brought to their attention, and therapy for Medicaid patients is, of course, subject to peer review. Prescribers and dispensers should not feel that there is any unjustified scrutiny occurring and that normal practice would not involve anyone looking over their shoulder.

Item 1021 – Caution on Names

Vincent Lee from Onslow Memorial Hospital has reported on the possible confusion of several products, which are Cerebyx, Celebrex, Celexa, Ceretec, Ceredase. He references an article on page 28 of the February 1999 issue of *Hospital Pharmacist Report,* to support his concerns.

Item 1022 – Clarification of Prescribing Authority

Item 1011 of the April issue of the Board's newsletter contained information about prescribing by physician assistants and nurse practitioners. One addition to that item should be that prescriptions from nurse practitioners and physician assistants for Schedules II and III drugs may not be refilled. Prescriptions for Schedule IV drugs may be refilled as authorized by the prescriber.

Item 1023 – Board Meetings for 1999

July 20, 1999
No August Meeting
September 21, 1999
October 19, 1999
November 16, 1999
No December Meeting

This and other information can be found at the Board's Web site: www.ncbop.org.

Attention Pharmacists

Board rules require that address changes for pharmacists, including changes in pharmacist-manager, be reported within **30 DAYS** of the change. If the Board office is not notified of the change, the pharmacist/pharmacy is in violation of the rules of the Board.

Item 1024 – Recycling Prescription Containers and Labels

The National Association of Boards of Pharmacy (NABP) recently convened a Task Force on Recycling Safety Closure Prescription Containers. The Task Force's suggestions included measures to ensure that confidential information

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is not inadvertently released. It recommended that pharmacists should:

- Shred all paper documents and black-out information on prescription container labels prior to placing them in the trash.
- Return empty prescription containers to patients.
- Implement a system whereby pharmacy trash is held in a secure area until transferred to a disposal firm for incineration or other method of destruction.

This information is intended to assist you in your practice.

Item 1025 – Emergency Dispensing

The Board now has two rules providing for the dispensing of refills or quantities of prescription drugs in emergency situations. The most commonly applied rule can be found at section .1809, which, under certain circumstances, allows the pharmacist to dispense a 30-day supply of a refill, providing that he or she notify the prescriber or the prescriber's office within 72 hours of such dispensing. This can occur as long as the medication is essential, or to continue therapy in a chronic condition. A written record of such dispensing is made pursuant to the rule and if, in the pharmacist's judgment, the interruption of therapy would produce undesirable health consequences. This also cannot occur for a Schedule II drug.

When medical services are interrupted, such as the problems created with the MedPartners bankruptcy in Raleigh in the fall of 1998, pharmacists may dispense a one-time emergency supply of up to 90 days of the prescribed medication under circumstances similar to that specified in .1809. This also applies to the situation where a prescriber unexpectedly dies or retires. Pharmacists should refer to the specific text in each rule for guidance. This also cannot occur for a Schedule II drug.

These sections can be found on the Board's Web site at www.ncbop.org under Drug Law, section 4600 Rules.

Item 1026 – DME Election

The Durable Medical Equipment (DME) Subcommittee met June 2, 1999, at the Board offices in Carrboro. Among the items of business transacted was that of counting ballots in the election. The results of the election are printed below.

Position of Respiratory	
Floyd Boyer	29
Grady L. Harbin II	9
Wayne Link	62
Jack Mosley	8
Robert M. Watson	4

Mr. Wayne Link was declared the winner, and will serve another three-year term on the Subcommittee.

Item 1027 – Coordination of DME Services Update

In the last issue of this newsletter, Item 1008 addressed coordinating client services when more than one supplier provides equipment to a beneficiary. The original complaint was forwarded to the Division of Facility Services (DFS). After investigation, DFS deemed it a violation of its standards for a supplier to provide services to a patient who is already being supplied by another provider without informing the patient of the source of all goods and services and coordinating the services with the first supplier before delivery.

The complaint that initiated this investigation involved a provider who supplied BiPap to a patient already using another provider's oxygen system. The Acute and Home Care Branch of DFS made an unannounced visit to the provider to interview the director and staff, and review all medical records. DFS reported that the results allowed them to substantiate the allegations, and the deficiencies were identified as the lack of coordination of services. The provider was required to supply a written plan of correction. Instances like this usually trigger a follow-up visit by DFS staff.

Remember, your voice does make a difference to the Board of Pharmacy Subcommittee on Durable Medical Equipment. Ultimately, the purpose is to provide a high standardized level of patient care administered by health care providers.

Item 1028 – Oxygen Concentrators

The Subcommittee thanks those who responded to the request for statistics on replacement concentrators. From the review of this information, the Subcommittee suggests that a supplier warehouse concentrators at five percent of its total number of concentrators in service. This seems to be a safe number to allow for the exchange of concentrators that fail in the field.

Item 1029 – Newsletter as Official Notice

This newsletter is a publication of the North Carolina Board of Pharmacy and is intended to inform licensees about laws, rules, and pharmacy practice. Please read and keep these newsletters as they are official notification and are used in Board hearings to establish that a pharmacist knew or should have known certain information. Newsletter binders are issued with each new pharmacy permit and should be present at each location.

Item 1030 – Pharmacist Breaks and Technicians

The Board of Pharmacy recently adopted a policy regarding pharmacist breaks and the use of technicians. This policy follows below and became effective March 16, 1999.

Pharmacy Technician Use During Breaks

To facilitate serving the public better, it is the opinion of the Board of Pharmacy that technicians can be used in following ways during pharmacist breaks.

- Prescriptions that have been previously prepared may be picked up by patients or their representatives. A log of

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such transactions is kept with the telephone number at which the patient may be reached and which is available to the pharmacist upon return from break. A telephone call within a reasonable time after prescription pick up shall occur by the pharmacist to review any counseling issues that may be appropriate.

- Prescriptions may be received by technicians and assembly can occur, but pharmacists must check any product and the order before it goes to the patient pursuant to Board rule.
- Pharmacist-managers, at their discretion, may develop a policy for technicians to receive telephone prescription orders.

Item 1031 – Honors for Board Members

In September 1998, Campbell University awarded an honorary doctor of science degree to Jack G. Watts. His many accomplishments include Pharmacist of the Year in North Carolina, president of the North Carolina School Boards Association, and three terms as a trustee of Campbell University.

In May 1999, Campbell University awarded an honorary doctor of science degree to William Whitaker Moose in recognition of his over 40 years of service to pharmacy in his community. He is the current president of the National Community Pharmacists Association (NCPA), and has been a member of the Board of Pharmacy for over 20 years. He is also now serving a six-year term as a representative of the National Association of Boards of Pharmacy (NABP) on the American Council on Pharmaceutical Education (ACPE) Board of Directors, the accreditation group in pharmacy.

In addition, the Board's public member, Tim Rogers, recently received the Dr. Ellen B. Winston Award, which is the highest award given by the Association for Home & Hospice Care of North Carolina. This award was given to Rogers for significant contributions and lifetime achievement in the support and promotion of home care services for the citizens of North Carolina. Dr. Winston was a former U.S. Commissioner of Welfare in the 1960s and Aging Director in North Carolina in the 1970s. She was also a pivotal force in the creation of the Medicare Home Health Benefit.

Item 1032 – Erroneous Report

"The report of my death is premature," is a quotation that is widely attributed to newspaper editor H. L. Mencken. The same is true for a recent report regarding Christopher Dixon, which came originally from the Board office due to a "hic-up" in our record-keeping system. Everyone should know that Christopher Dixon is thriving and well, and practicing pharmacy in New Bern. The Board regrets the error, which was reported in another publication but originally came from this office.

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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