

North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 1046 – Disciplinary Actions

July

Return Goods Hearing: Bayer Corporation. Return goods policy not compliant with Board rule .2901. Order is that Bayer's biological products may not be selected by a pharmacist for use as an equivalent drug product.

August

None

September

Robert Remine Broyles, III, King (DOB November 13, 1963). Consuming an alcohol-containing substance not prescribed for him by a practitioner acting in the ordinary course of medical treatment, violation of Order Reinstating License of October 27, 1997. License suspended indefinitely, stayed for five years with specific conditions including an active suspension of license until January 29, 2000.

Wendy S. Kuo, Chapel Hill (DOB July 22, 1970). Dispensing error. Consent Order entered: License suspended 90 days, stayed two years with conditions.

Jerry R. Parker, Cullowhee (DOB August 28, 1950). Consuming controlled substances from stock of pharmacy where employed without authorization. License suspended indefinitely, stayed five years with conditions.

Michael E. Switzer, Winston-Salem (DOB December 11, 1968). Forged prescriptions for hydrocodone products, and diverted the product from pharmacy where employed for own personal use. License suspended indefinitely.

October

Kenneth R. Holland, Canton (DOB November 19, 1946). Heard by Board Member Overman. Violation of patient counseling rule. Recommendation: License suspended seven days, stayed two years with active suspension of one business day, and other conditions. Accepted by Mr. Holland June 25, 1999. Accepted by Board September 21, 1999.

Roger McCollum, St. Pauls (DOB January 2, 1947). Filled prescriptions and obtained drugs without authorization; Medicaid had been billed for some of the medications obtained pursuant to the unauthorized prescriptions; failure to conduct drug utilization reviews prior to dispensing prescription drugs. License revoked.

Sanjay R. Patel, Huntersville (DOB April 25, 1967). Heard by Board Member Watts. Dispensing Error. Recommendation: Official Board Reprimand. Accepted by Mr. Patel August 31, 1999. Accepted by Board September 21, 1999.

Marilyn F. Rant, Highlands (January 8, 1943). Violation of Consent Order entered January 20, 1998. License suspended indefinitely.

Pre-hearing Conferences for September & October

Ira H. Bomze, Mooresville (DOB January 23, 1936). Heard by Board Member Overman. Manufactured progesterone suppositories without being registered with the federal Food and Drug Administration as a manufacturer of prescription drugs; location where manufacture of products occurred does not hold a pharmacy permit to practice pharmacy by the Board of Pharmacy. Recommendation: License suspended seven days, stayed three years with specific conditions. Accepted by Mr. Bomze September 17, 1999. Accepted by the Board October 19, 1999.

Howard I. Duckworth, Jr., Hickory (DOB January 17, 1951); **Richard D. Williams**, Morganton (DOB May 18, 1943); and **Burke Pharmacy**, Morganton. Heard by Board Member Overman. Violation of patient counseling rule. Recommendation: License suspended seven days, stayed two years with active suspension of three business days for Mr. Duckworth and Mr. Williams; permit suspended seven days, stayed two years with active suspension of the permit for one business day, and other conditions. Accepted by Mr. Duckworth June 21, 1999; Mr. Williams, June 21, 1999; Burke Pharmacy June 21, 1999. Accepted by the Board September 21, 1999.

Charles A. Wrinkle, Hickory (DOB May 24, 1940). Heard by Board Member Overman. Violation of patient counseling rule. Recommendation: License suspended seven days, stayed two years with active three-day suspension and other conditions. Accepted by Mr. Wrinkle June 25, 1999. Accepted by the Board October 19, 1999.

Roxanne Yankee, Advance (DOB September 13, 1963). Heard by Board Member Overman. Dispensing errors committed in practice of pharmacy. Recommendation: Official Board Reprimand, with conditions. Accepted by Ms. Yankee September 28, 1999. Accepted by Board October 19, 1999.



National Pharmacy

(Applicability of the contents of articles in the National Pharmacy is assumed and can only be ascertained by examining the original text.)

Internet Prescribing Site Studies Identify Concerns

Two recent studies, one published in the October 28, 1999 issue of *The New England Journal of Medicine*, and the other published in the December 7, 1999 issue of the *Annals of Internal Medicine*, raise concerns about the quality of care provided by Internet physicians and the potential for serious abuse by purchasers of prescription drug products.

In the *New England Journal of Medicine* study, Katrina Armstrong, MD, J. Sanford Schwartz, MD, of the University of Pennsylvania School of Medicine, and David A. Asch, MD, of the Philadelphia Veterans Affairs Medical Center, set out to evaluate the availability of Viagra® (sildenafil) on the Internet.

In mid-April 1999, these investigators identified 86 sites that offered to provide Viagra to patients without a physician's visit. They evaluated only 77 sites, since nine sites ceased operations during the 10-day interval between the identification of sites and their evaluation.

Of the 77 sites evaluated, 71 percent (51 sites) were located in the United States, 14 percent (11 sites) in the United Kingdom, four percent (three sites) in Germany, three percent (two sites) in New Zealand, and eight percent (six sites) in "other" locations.

Fifty-five percent of sites (42 sites) required the patient to complete an online medical evaluation (questionnaire). Five percent (four sites) offered an online evaluation, but did not require it, while 40 percent (31 site) did not offer one. Thirty-five percent (27 sites) assured consumers that the online evaluation would be reviewed by a physician, but none provided any specific information regarding physicians' qualifications.

Regarding the information requested about patients' medical history, 57 percent (44 sites) asked about the use of nitrates, 52 percent (40 sites) inquired as to whether the patient had been diagnosed with angina or coronary heart disease, 49 percent (38 sites) asked about the presence of erectile dysfunction, 45 percent (35 sites) asked about prior evaluations for impotence, and 43 percent (33 sites) inquired about symptoms of heart disease.

Regarding the types of information provided to Viagra consumers about the drug, 55 percent (42 sites) provided information on contraindications (i.e., concomitant use of nitrates), 47 percent (36 sites) discussed efficacy, 45 percent (35 sites) referred to the product's indications, 44 percent (34 sites) mentioned "other risk factors," and 42 percent (32 sites) gave instructions for product use.

On the issue of liability, sixty-eight percent of the sites (52 sites) required patients to consent to release the site from any

liability, and 16 percent (12 sites) required patients to specifically agree to waive the need for a physical exam.

"Our findings document that sildenafil is readily obtainable over the Internet without the need for a visit to a physician or review by a pharmacist," the investigators concluded. They maintained that the wide availability of Viagra "highlights the need for effective regulation of Internet prescribing in the public interest," and that "state licensing boards for physicians and pharmacists should move quickly to establish and enforce guidelines for the involvement of US clinicians in prescribing drugs over the Internet." They further concluded that "effective strategies to address sites outside the United States may require cooperative efforts of customs authorities, the pharmaceutical industry, and national and international regulatory agencies."

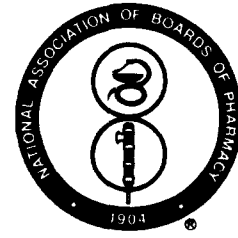
In the *Annals of Internal Medicine* study, researchers Bernard S. Bloom, PhD, and Ronald C. Iannacone, BS, from the University of Pennsylvania School of Medicine, set out to describe the Internet availability and cost of prescription drugs to the public. They collected data on the sites' requirements for obtaining a medication, prescription and shipping costs, availability and cost of the Internet physician consultation, the geographic location of the company and its consulting physicians, and the medications available through the site.

Researchers identified 46 Web sites that provided prescription drugs via the Internet. Of these 46 sites, 80.4 percent, or 37 sites (33 US-based and four internationally-based), required a prescription from a personal physician or from an Internet physician consultation, while nine (all internationally-based) did not require a prescription or physician consultation.

Those that offered Internet consultations focused on general and diagnosis-specific medical histories and medication use. Consultations were said to be with a physician, although disclaimers stated that the physician may not reside in the same country as the patient or the online pharmacy, and no information was available regarding physician name, specialty, location, or qualifications. Online consultations also included a waiver stating that the patient agreed not to hold the company liable for adverse outcomes.

Each company notified the patient by e-mail of the results of the consultation, and confirmed whether the desired medication could be purchased. Prescriptions received from US-based sites could be used to purchase medications from the Web site or from a pharmacy of the patient's choice, and allowed for two refills, after which another physician consultation was required. All sites waived the consultation fee if the patient was denied a prescription for the requested medication.

Compliance News



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The researchers concluded that although the Internet offers improved access to health care, it comes at a significant cost. Patients obtaining Propecia through a physician consultation pay 40 percent more (before shipping costs) than those using traditional methods. Of particular concern was the potential for patients to provide false or incorrect information to obtain a prescription. Researchers noted that although giving incorrect or false information was not encouraged, it was indirectly facilitated through the use of preselected click-off choices. "For example," they said, "a medical history question asking whether the patient had had a complete physical examination and blood tests in the past year would already have a preselected answer of 'yes.'"

Also of concern was the quality of Internet consulting physicians and the appropriateness of medical services provided. Researchers noted that although no information is provided to patients about consulting physicians, 21.4 percent of the sites (10 sites) offered detailed information on how physicians could become consultants. Bloom and Iannacone also emphasized the dangers of international freelance sites that "were willing to sell any medication, no matter how dangerous or potentially open to abuse by purchasers, without a physician consultation or prescription." They emphasized that such sites "may inadvertently put the patient in jeopardy of contravening US or another country's laws in addition to putting their health at risk."

In a related editorial published in the same *Annals of Internal Medicine* issue, Food and Drug Administration (FDA) representatives, Jane E. Henney, MD, Jeffrey E. Shuren, MD, JD, Stuart L. Nightingale, MD, and Thomas J. McGinnis, RPh, reiterated the dangers of obtaining prescription medications via the Internet. "Before buying a prescription drug over the Internet," they recommended, "patients should check with the National Association of Boards of Pharmacy (NABP) to see if the pharmacy has a valid license and has met state practice standards." They also encouraged practitioners and patients to report potentially illegal Web sites to the FDA or NABP.

Appropriate Disposal of Rx Containers and Confidential Information

State boards of pharmacy are taking a closer look at the appropriate disposal of prescription containers and handling of confidential patient information. The issue received national attention when Fox News' "The Fox Files" aired a segment featuring program investigators digging through pharmacy dumpsters and finding patient information in the trash. The

investigators used some of the scavenged patient information to determine if they could obtain refills and informed some of the affected patients that their confidential information had been found in the trash.

Pharmacies often discard empty prescription medication vials, unused labels, faxed and telephoned messages, notes, and receipts containing confidential patient information in unsecured dumpsters. If accessed by unauthorized individuals, this practice may violate patient confidentiality. In addition, prescription drug abusers may use such sensitive information as a label or receipt showing that refills are available for a controlled substance to obtain controlled substances.

If prescription drug abusers find a prescriber's Drug Enforcement Administration (DEA) number in the garbage, they could use that number to impersonate a doctor and order prescription drugs to sell on the street.

Many boards of pharmacy are alerting the pharmacists in their jurisdictions of the disposal problem, and are recommending the following procedures developed by NABP's Task Force on Recycling Safety Closure Prescription Containers:

- ◆ Shred all paper documents and black out information on prescription container labels prior to disposal;
- ◆ Give empty prescription containers back to patients;
- ◆ Implement a system whereby pharmacy garbage is held in a secure area until transferred to a disposal firm for destruction.

NABP hopes that through awareness, pharmacists and pharmacies will change their procedures to prevent the release of confidential information when the intention is to dispose of it.

NABP Seeking DSM Item Writers

Pharmacy practitioners, educators, and regulators interested in becoming involved with the test item writing process for NABP's disease state management (DSM) examinations in anticoagulation, asthma, diabetes, and dyslipidemia, should mail, fax, or e-mail a letter of interest and a current resume or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone at 700 Busse Highway, Park Ridge, IL 60068; fax to 847/698-0124; e-mail to ceo@nabp.net.

If selected, item writers will receive training materials describing the skills necessary to write items for the examinations, and may be asked to attend a workshop. Applicable expenses will be paid by NABP. Once trained, item writers will receive periodic requests to develop new test items that will be considered for inclusion in the DSM exams.

Item 1047 – Clinical Pharmacists Progress

By Tuyet Le, PharmD Candidate,

University of North Carolina – Chapel Hill

Pharmacists have been working with physicians for optimum patient therapy for many years through pharmacy and therapeutic committees. On July 14, 1999, the approval of House Bill 1095 authorized the North Carolina Medical Board and the Board of Pharmacy to adopt rules to regulate clinical pharmacist practitioners. This bill acknowledged the need for clinical pharmacist practitioners, as well as the important role that pharmacists have in patient care. The Clinical Pharmacist Practitioner (CPP) Act will entitle pharmacists who have advanced training to work with licensed physicians to implement predetermined agreements for drug therapy such as an aminoglycoside dosing, anticoagulation management, asthma, or diabetes care.

On November 17, 1999, a subcommittee of the North Carolina Medical Board and the Board of Pharmacy met for the first time to discuss the CPP Act. Members representing the Medical Board were Dr. Ken Chambers, Dr. John Dees, Dr. John Foust, and Dr. Stephen Herring. Representing the Board of Pharmacy were Albert Lockamy, Robert Crocker, and Jack Watts. Others present included David Work (executive director of the Board of Pharmacy), Dan Garrett (executive director of North Carolina Association of Pharmacists), Diane Meelheim (Medical Board), Denise Stanford (Board of Pharmacy attorney), Jim Wilson (Medical Board attorney), and Tuyet Le.

The issues presented during this meeting included the qualifications for clinical pharmacist practitioners, North Carolina Center for Pharmaceutical Care- (NCCPC) approved certificate programs, liability and malpractice, and the role and number of supervising physicians. It was decided the attorneys for the Medical Board and the Board of Pharmacy would work together to

draft Clinical Pharmacist Practitioner Regulations by utilizing the Nurse Practitioner Regulations as the starting template. This draft will be reviewed at a joint meeting between committees of the Medical Board and the Board of Pharmacy on January 19, 2000. It is hoped that temporary regulations will be issued in time for the July 1, 2000, effective date.

The initial meeting of the two Boards was positive, and represents a milestone for pharmacy due to the impact it will have on the future of pharmacy and patient care.

Note: For further information about the Clinical Pharmacist Practitioner Act, contact Dan Garrett, North Carolina Association of Pharmacists, 919/967-2237.

Item 1048 – North Carolina Drug Information Centers

Campbell University

Drug Information Center

P.O. Box 1090

Buies Creek, NC 27506

Telephone: 1-800/327-5467 (in-state), 910/893-1478

Fax: 910/893-1476

Contact Person: Connie Barnes

e-mail address: barnes@mailcenter.campbell.edu

Duke University Medical Center North

Drug Information Center Service

Duke University, Box 3089

Durham, NC 27710

Telephone: 919/684-5125

Fax: 919/681-3895

Contact Person: Beth McLendon

e-mail address: mclen005@mc.duke.edu

Eastern Carolina Drug Information Center

c/o Pitt County Memorial Hospital

Department of Pharmacy Services

2100 Stantonsburg Road

Greenville, NC 27835-6028

Telephone: 252/816-4257

Fax: 252/816-7425

Contact Person: Jim Worden

e-mail: jworden@pcmh.com

University of North Carolina Hospitals

Drug Information Center

101 Manning Drive

Chapel Hill, NC 27514

Telephone: 919/966-2373

Fax: 919/966-1791

Contact person: Maryann Oertel

e-mail: moertel@unch.unc.edu

Wake Forest Baptist University Medical Center

Drug Information Service Center

Medical Center Blvd.

Winston Salem, NC 27157

Telephone: 336/716-2037

Fax: 336/716-2186

Contact person: Kelly Verzino or Kathy Phelps

e-mail: kphelps@wfbumc.edu

kverzino@wfbumc.edu

Item 1049 – North Carolina General Assembly Adopts Pharmacist Peer Review Legislation

Under this new legislation, the Board is authorized to enter into agreements with special impaired pharmacist peer review organizations.

These organizations shall establish and maintain a program for impaired pharmacists licensed by the Board for the purpose of identifying, reviewing, and evaluating the ability of those pharmacists to function as pharmacists, and to provide programs for their treatment and rehabilitation.

The agreements shall include provisions for the impaired pharmacists peer review organizations to receive relevant information from the Board and other sources, conduct investigations and review and conduct evaluations in an expeditious manner. These organizations will assure the confidentiality of non-public information and of the peer review processes, and will conduct other related activities for operating and promoting coordinated and effective peer review processes. The Board is authorized to adopt rules for the operation of impaired pharmacist peer review programs.

The North Carolina Pharmacist Recovery Network was responsible for the development of the legislation, and is currently contracted by the Board of Pharmacy as its pharmacist peer review organization. The act was sponsored by State Representative Martha Alexander (D-Mecklenburg), ratified on May 13, 1999, and signed by the governor on May 21, 1999.

Item 1050 – Inspector Wilkins Receives Award

Board of Pharmacy Inspector **Ken Wilkins** was recognized by the North Carolina Pharmacist Recovery Network as their Board Inspector of the Year for 1999. Mr. Wilkins was recognized for his "professionalism and compassion in dealing with the impaired pharmacists of North Carolina."

The award was presented at the 6th Annual Seminar on Chemical Dependency in the Profession of Pharmacy, held November 7, 1999, in Greensboro.

Item 1051 – Web Site Addresses

Listed below are the web site addresses for the North Carolina Medical Board, Dental Board and Nursing Board:

Medical Board: www.docboard.org/nc

Nursing Board: www.ncbon.com

Dental Board: www.ncdentalboard.org

Item 1052 – Dispensing Errors

A rule adopted by the Board, effective April 1999, provides that dispensing errors which reach the patient be reported to the pharmacist-manager at each location. The purpose of this rule is to implement a quality assurance program as this information is not otherwise available except under provisions of state law.

Item 1053 – Results Summary From Death Reporting Rule

Another summary of reports related to the Board's Death Reporting Rule has been completed, digesting the reports submitted over the last seven years. A total of 162 reports were filed, and some surprises were revealed.

The first unexpected discovery was that between 80 and 90 percent of the reports were filed on drugs that are not controlled substances. From this, it appears that we are not giving non-controlled prescription drugs the attention they deserve.

The other new trend is that deaths are rising due to drugs on the narrow therapeutic index list published as part of the Board's product selection law. A list of these drugs can be found on the Board's Web site located at www.ncbop.org.

Recent reports categorized by therapeutic class included nine involving anticoagulation drugs, eight involving opiate analgesics, six involving thrombolytics, six involving antibiotics, and five involving antidepressants.

Single copies of the summary are available from the Board office.

Item 1054 – Medical, Nursing, and Pharmacy Boards Agree on Pain Statement

In the fall of 1999, the boards of medicine, nursing, and pharmacy adopted this common statement regarding treatment of pain:

Joint Statement on Pain Management in End-of-Life Care

Through dialogue with members of the health care community and consumers, a number of perceived regulatory barriers to adequate pain management in end-of-life care have been expressed to the Boards of Medicine, Nursing, and Pharmacy. The following statement attempts to address these misperceptions by outlining practice expectations for physicians and other health care professionals authorized to prescribe medications, as well as nurses and pharmacists involved in this aspect of end-of-life care. The statement is based on:

- ◆ The legal scope of practice for each of these licensed health professionals;
- ◆ Professional collaboration and communication among health professionals providing palliative care; and
- ◆ A standard of care that assures on-going pain assessment, a therapeutic plan for pain management interventions, and evidence of adequate symptom management for the dying patient.

It is the position of all three boards that patients and their families should be assured of competent, comprehen-

sive, palliative care at the end of their lives. Physicians, nurses, and pharmacists should be knowledgeable regarding effective and compassionate pain relief, and patients and their families should be assured such relief will be provided.

Because of the overwhelming concern of patients about pain relief, the physician needs to give special attention to the effective assessment of pain. It is particularly important that the physician frankly, but sensitively, discuss with the patient and the family their concerns and choices at the end of life. As part of this discussion, the physician should make clear that, in some end-of-life care situations, there are inherent risks associated with effective pain relief. The Medical Board will assume opioid use in such patients is appropriate if the responsible physician is familiar with, and abides by, acceptable medical guidelines regarding such use, is knowledgeable about effective and compassionate pain relief, and maintains an appropriate medical record that details a pain management plan. Because the Board is aware of the inherent risks associated with effective pain relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.

With regard to pharmacy practice, North Carolina has no quantity restrictions on dispensing controlled substances, including those in Schedule II. This is significant when utilizing the federal rule that allows the partial filling of Schedule II prescriptions for up to 60 days. In these situations, it would minimize expenses and unnecessary waste of drugs if the prescriber would note on the prescription that the patient is terminally ill, and specify the largest anticipated quantity that could be needed for the next two months. The pharmacist could then dispense smaller quantities of the prescription to meet the patient's needs up to the total quantity authorized. Government-approved labeling for dosage level and frequency can be useful as guidance for patient care. Health professionals may, on occasion, determine that higher levels are justified in specific cases. However, these occasions would be exceptions to general practice, and would need to be properly documented to establish informed consent of the patient and family.

Federal and state rules allow the fax transmittal of an original prescription for Schedule II drugs for hospice patients. If the prescriber notes the hospice status of the patient on the faxed document, it serves as the original. Pharmacy rules also allow the emergency refilling of prescriptions on Schedules III, IV, and V. While this does not apply to Schedule II drugs, it can be useful in situations where the patient is using drugs such as Vicodin for pain, or Xanax for anxiety.

The nurse is often the health professional most involved in on-going pain assessment, implementing the prescribed pain management plan, evaluating the patient's response to such interventions, and adjusting medication levels based on patient status. In order to achieve adequate pain management, the prescription must provide dosage ranges and frequency parameters within which the nurse may adjust (titrate) medication in order to achieve adequate pain control. Consistent with the licensee's scope of practice, the RN or LPN is accountable for implementing the pain management plan utilizing his/her knowledge base and documented assessment of the patient's needs. The nurse has the authority to adjust medication levels within the dosage and frequency ranges stipulated by the prescriber and according to the agency's established protocols. However,

Continued from page 5

the nurse does not have the authority to change the medical pain management plan. When adequate pain management is not achieved under the currently prescribed treatment plan, the nurse is responsible for reporting such findings to the prescriber and documenting this communication. Only the physician or other health professional with authority to prescribe may change the medical pain management plan.

Communication and collaboration between members of the health care team and the patient and family are essential in achieving adequate pain management in end-of-life care. Within this interdisciplinary framework for end-of-life care, effective pain management should include:

- ◆ Thorough documentation of all aspects of the patient's assessment and care;
- ◆ A working diagnosis and therapeutic treatment plan including pharmacological and non-pharmacologic interventions;
- ◆ Regular and documented evaluation of response to the interventions and, as appropriate, revisions to the treatment plan;
- ◆ Evidence of communication among care providers;
- ◆ Education of the patient and family; and,
- ◆ A clear understanding by the patient, the family, and health care team of the treatment goals.

It is important to remind health professionals that licensing boards hold each licensee accountable for providing safe, effective care. Exercising this standard of care requires the applications of knowledge, skills, as well as ethical principles focused on optimum patient care while taking all appropriate measures to relieve suffering. The health care team should give primary importance to the expressed desires of the patient, tempered by the judgement and legal responsibilities of each licensed health professional as to what is in the patient's best interest.

Approved by:

North Carolina Board of Nursing, September 24, 1999

North Carolina Board of Pharmacy, September 21, 1999

North Carolina Medical Board, September 22, 1999

Item 1055 – Percocet Changes

Endo Laboratories has recently announced several changes involving their product, Percocet. Products are now available containing 2.5 mg of oxycodone and 325 mg of acetaminophen in a football-shaped pink color. The old product, which is the standard Percocet, consists of 5 mg of oxycodone and 325 mg of acetaminophen, and is now a round tablet and is colored light blue.

Another product is now available with 7.5 mg of oxycodone and 500 mg of acetaminophen in an oblong peach-colored tablet. The last new product contains 10 mg oxycodone with 650 mg of acetaminophen in an oblong yellow tablet.

All of these changes will, no doubt, cause some confusion and pharmacists should be alert to this possibility. If a pharmacist receives a prescription for Percocet and is unsure of which strength to dispense, a telephone call should be made to the prescriber to clarify the situation. A note should be made on the prescription document to verify this contact, and the pharmacist can dispense the desired product without returning the prescription to the prescriber to be rewritten.

Pharmacists should also be careful to note that each of these colors is a pastel color, and older patients are likely to have difficulty perceiving the different shapes and colors. The fact that there are now a total of four products with three different shapes could further confuse the issue. Please use care when dispensing such prescriptions, and give the patient a thorough counseling on the usual issues.

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