

newsletter

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NABP, APhA to Create “e-home” for Pharmacy Practice

Against a backdrop of ever-increasing sophistication of Internet communications, NABP and the American Pharmaceutical Association (APhA) announced the launch of a premier Web portal that promises to be “home” for pharmacists. NABP Chairman Jerry Moore announced the joint venture during NABP’s 97th Annual Meeting in Seattle on May 6, 2001. Moore portrayed the site as a portal that will provide visitors quick and easy access to timely information with a broad-based interactive engine that will improve efficiency, speed, and the availability of information. The site, which is scheduled to debut this fall, will also serve as a gateway to the individual NABP and APhA Web sites.

On January 12, 2001, NABP and APhA joined forces to create this one-stop source of information. Both organizations will manage and update the site to ensure that it continues to serve the public and the pharmacy practice community. Two representatives from each organization sit on the management board and will oversee the site and ensure that it continues to serve the public and pharmacy community.

“We can advance patient care when pharmacy associations work together,” adds Moore. “NABP is pleased to be partnering with APhA in the development of this significant new online community.”

When completely implemented, the NABP/APhA Web site will provide pharmacists and boards of pharmacies with:

- a re-licensure facility for pharmacists;
- online practice exams for NABP-produced competency assessment exams;
- access to breaking pharmacy news;
- a suite of continuing education (CE) services;
- comprehensive drug information services;
- an online store providing access to reference books and registration for live educational programs;
- a career center with Web-based career information tools and job postings; and
- online registration for NABP and APhA activities and meetings.

The Continuing Education component, provided by the APhA, will be activated first.

Pharmacists will be able to complete CE programs online and receive real-time scoring. APhA’s online drug information center will allow pharmacists access to drug database information as well as provide real-time advice regarding breaking drug issues.

NABP will provide the re-licensure facility allowing pharmacists and pharmacies to renew their licenses with their state boards of pharmacy. NABP will also contribute practice exams for its competency assessment programs. Students will find them helpful in evaluating their knowledge, skills, and areas of interest.

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Internet Pharmacies: Separating the Good from the Bad

The Internet has opened a wealth of information for the public. Consumers can now easily purchase their prescriptions online with the click of a mouse. To assure consumers that the Web site they are using is safe and legitimate, NABP developed the Verified Internet Pharmacy Practice Sites™ (VIPPS™) certification program. Consumers know that the VIPPS seal is only posted on online pharmacies that have met NABP's rigorous 17-point criteria review.

Online pharmacies continue to attract consumers who are seeking privacy, convenience, and cost savings when they purchase health care products and prescription medications. Unfortunately, consumers, especially those who are bargain hunting, may be duped into patronizing e-pharmacies that have the appearance of legitimately operating pharmacies, but in reality are engaging in unethical or illegal practices. In other instances, consumers knowingly search for and utilize Internet pharmacies because the pharmacies offer to ship prescription medications, including controlled substances, without the benefit of a valid prescription.

Since the 1999 explosion of state prosecutions of illegitimate Internet pharmacies and their prescribers, both state and federal authorities continue their assault on illegally operating e-pharmacies. State attorneys general and state pharmacy boards have investi-

gated and prosecuted online pharmacies and their pharmacists on such grounds as unprofessional conduct, pharmacists' failure to address

Since the 1999 explosion of state prosecutions of illegitimate Internet pharmacies and their prescribers, both state and federal authorities continue their assault on illegally operating e-pharmacies.

patients' possible dependencies on drugs dispensed from the online pharmacy and illegally advertising the distribution of prescription drugs via the Internet, and deceptive practices.

Most notably, in March 2001, the Oklahoma State Board of Pharmacy revoked and fined the pharmacy license of Mainstreet Pharmacy as well as the pharmacist license of the manager/owner. Mainstreet Pharmacy operated under the Web site nationpharmacy.com.

The Oklahoma Board concluded, among other things, that the pharmacist owner had charged unfair professional fees for dispensing prescriptions (\$110 - \$240 fees were initially charged for every new Internet customer); failure to establish effective controls

against diversion of prescription drugs (in a seven-day period in November 2000, the pharmacy shipped 151,000 units of controlled dangerous drugs); failure to address the possible addiction of a patient to a drug he dispensed, and regularly dispensing controlled dangerous substances through the mail when the ultimate user was not personally known to the practitioner. (See *Compliance News: Nine Counts Filed Against Oklahoma Internet Pharmacy* on pg 86.)

Pennsylvania began prosecuting e-pharmacies. In November 2000, the Pennsylvania attorney general barred two online pharmacies from advertising, selling, and delivering prescription medica-
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HHS Privacy Regulations Take Effect

The US Department of Health and Human Services' (HHS) privacy regulations, which are the first comprehensive federal standards for medical privacy, took effect on April 14. In an April 13 HHS press release, HHS Secretary Tommy G. Thompson stated that these rules give patients greater access to their medical records and more control over how their personal information will be used and disclosed.

The HHS rules have been the subject of considerable debate since they were published in the December 28, 2000 *Federal Register*. According to an April 13 *New York Times* article, "Bush Accepts Rules to Protect Privacy of Medical Records," the Bush administration had considered delaying the release of the rules in order to review objections from the health care industry, which said the standards would impose costly administrative burdens. Instead, Bush allowed the rules to take effect on schedule but asked Thompson to suggest "appropriate modifications" to address "legitimate concerns" from the health care industry.

According to Thompson, HHS "will make it clear through guidelines or recommend modifications [to the privacy regulations] that:

- Doctors and hospitals will have access to necessary information about a patient they are treating, and they will be able to consult with other physicians and

specialists regarding a patient's care.

- Parents will have access to information about the health and well-being of their children, including information about mental health, substance abuse, or abortion."
- And, patient care will be delivered in a timely and efficient manner and not unduly hampered by the confusing requirements surrounding consent forms.

Many pharmacists have been concerned about the rules' consent requirements, noting they would be hard-pressed to obtain a patient's consent to allow a neighbor or relative to pick up a medication if a patient's physician called in a

prescription to the pharmacy. Thompson has said that guidelines or revisions to the rules will allow pharmacists to "fill phoned-in prescriptions and serve their customers in a timely manner."

Health care providers and insurers have two years to comply with these rules. After April 14, 2003, anyone who violates the rules will be subject to civil and criminal penalties, including a \$250,000 fine and 10 years in prison for the most extreme violations.

For additional information about the HHS privacy rules, see "HHS Releases Final Privacy Rules" on page 22 of the February 2001 *NABP Newsletter*. **NABP**

New Computers Provide State Boards with Faster Service



Thomas Buedel, information technology manager of the North Carolina Board of Pharmacy, and from left, Melanie Hawn, reciprocity coordinator, and Deborah Stump, exam coordinator, sit in front of a new Dell computer, one of the 36 computers NABP provided to state boards of pharmacy earlier this year. The new computers were sent to provide faster service and to prepare for NABP's upcoming Internet-based communication system. Participating states and territories are: Alabama, Alaska, Arizona, Colorado, Connecticut, District of Columbia, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Hawaii, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Washington, and West Virginia. All of these states have already received and installed NABP's software, which allows database replication and other forms of communication.

By John F. Atkinson



Last year in the Report of Counsel, we posed the following fact situation:

Patient A, an Illinois resident, called her physician, Dr X,

and complained about premenstrual cramps. The physician phoned a prescription for Toradol to the patient's pharmacy, which had served her over the years and maintained her drug profile. Accordingly, the pharmacy was familiar with her other medications and the fact that she was allergic to NSAID drugs. The prescription was entered into the computer by the pharmacist and was blocked because of Patient A's allergies and the potential interaction with Toradol. The pharmacist, without consulting the physician, bypassed the computer block and filled the prescription.

When Patient A's husband obtained the drug on behalf of his wife, he asked the pharmacist whether he was familiar with his wife's allergies and further inquired as to whether there would be any problem by reason of the allergies and the drug which had been prescribed. He was advised that it was safe for his wife to take

Toradol. An insert was placed in the bag containing the prescription which warned against taking Toradol with "... aspirin, ibuprofen and many prescription drugs." It also warned against taking the drug "... if you have had an allergic reaction to it...." The patient began taking Toradol as instructed and called the pharmacy immediately upon incurring side effects. She was advised by the pharmacist to continue to take the medication. When the side effects increased substantially, she called a pharmacist friend in Texas who advised her to stop taking the drug and immediately go to the closest emergency room.

These were the basic facts before the Illinois Court of Appeals in *Happel v. Wal-Mart Stores, Inc.*, 737 N.E.2d 650 (2000). The trial court had granted summary judgment in favor of Wal-Mart based on the learned intermediary doctrine, which thrusts upon the physician the primary responsibility for advising patients as to adverse reactions and side effects of drugs. The doctrine has been used to shield the pharmacist and pharmacy from liability due to injuries caused by drug interactions or side effects as long as the prescription is correctly filled. NABP filed an amicus curiae (friend of the court) brief in support of the plaintiff, Heidi Happel.

In reversing the trial court decision and overturning the summary judgment, the court of appeals was influenced by NABP's argument that the pharmacist is educated, examined, and licensed as a professional with expertise in the health care field and, as such, is required to engage in patient counseling, and prospective drug review, and to undertake pharmaceutical care pursuant to existing standards of practice. Basically, all of the above are established in the practice act.

In its opinion the court states:

Additionally, the NABP also suggests that defendant had a duty to warn in this case. The NABP notes that pharmacy is a profession, with certain universal standards and practices. The NABP observes that the duty to warn in this case is consonant with the professional practices and standards expected of a pharmacist. Thus, the NABP suggests that the recognition of a duty in this case is commensurate with the status of pharmacy as a profession and with the pharmacist's professional responsibilities. We find the NABP's advocacy to be persuasive: that the professional association for pharmacists demands that pharmacists be held to a duty to warn in this case strongly supports our conclusion. Accordingly, we

hold that, under the circumstances, where defendant knew of Heidi's allergies, where defendant knew that Toradol was contraindicated for a person with Ms Happel's allergies, and where defendant knew that injury or death was substantially certain to result, defendant had an affirmative duty to disclose, either to Dr Lorenc or to Ms Happel, the information that Heidi should not take Toradol.

Wal-Mart sought to appeal the court of appeals decision to the Illinois Supreme Court, which request was initially denied but later allowed.

Accordingly, the *Happel* case will ultimately be determined by the Illinois Supreme Court.

In its brief requesting the supreme court to accept the case, Wal-Mart turns back the clock to the "count, pour, lick, stick" mentality by treating the pharmacists in the same category as a sub-professional urging that the sole duty of the pharmacist is to correctly fill the prescription. Wal-Mart states:

The American medical system is effective because there is a distinct and well-defined chain of command among health care practitioners, which is of the utmost benefit to the patient. The physician is the captain of the

medical ship. The physician is in the position of control, and nurses, technicians and **pharmacists** fall within the chain of command, **carrying out the physician's orders**. When a physician decides to prescribe a particular drug, the physician relies upon his education, experience, and knowledge of the patient's condition and medical history. Based on this chain of command, the physician is the sole person who is in a position to prescribe medications that are appropriate for specific patients. A pharmacist is not in a position to make the determinations a physician has to make, and should not be placed in such a position. The physician may have selected a drug with full knowledge that the patient will suffer an adverse reaction but, based upon the patient's history and condition, there may be no alternative. **[Emphasis added.]**

It is this type of reasoning that demeans the pharmacy profession and poses a very substantial threat to the public health. Pharmaceutical care can be accomplished if the pharmacist assumes the professional role for which he or she is trained, including acting as a check and balance on the "omniscient" prescribing physician. The medical profession and the

courts should willingly accept this role if the public health is to be more effectively protected.

It is understandable that Wal-Mart should seek to protect its economic base by attempting to avoid liability under the learned intermediary doctrine. However, persons familiar with the profession know that pharmacists generally have a greater knowledge and understanding about drugs and their characteristics than any other professional including most physicians. In our opinion, to advocate that the only duty of a pharmacist is to correctly fill a prescription is to irresponsibly ignore the ultimate goal of health care regulatory boards, which is the protection of public health.

It is interesting to note that in its brief in support of Wal-Mart, the National Association of Chain Drug Stores (NACDS) states:

NABP has a vision of pharmaceutical care, in which pharmacists have the time and opportunity to have privileged discussions with consumers about all aspects of their drugs. NACDS supports that vision of the practice of pharmacy. However, that vision of pharmacy practice does not require the imposition of new tort liability against pharmacists.

Is not the pharmacists' education geared toward this vision? Does not the clinical program

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The Academic Perspective

Reinterpreting “Unable to Supply”

By David B. Brushwood, JD, RPh



For many years, some pharmacists have misconstrued the “unable to supply” language that appears in US Drug Enforcement Administration (DEA) regulation 21 C.F.R. § 1306.13(a). The familiar regulation states that a pharmacist may partially fill a Schedule II prescription if the pharmacist is “unable to supply” the full quantity called for, as long as the pharmacist makes a notation of the quantity supplied on the face of the prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescriber. No further quantity may be supplied beyond 72 hours without a new prescription. (Partial filling for a patient who is “terminally ill” or who is a long-term care facility [LTCF] patient is permissible over 60 days, under the next subsection of the regulation.)

Some pharmacists, as well as some pharmacy law teachers and some pharmacy regulators, have thought that the only circumstance under which “unable to supply” would be pertinent was lack of drug stock in the pharmacy. In other words, this narrow interpreta-

tion has been said to mean that if the patient simply wanted a small initial supply (due to convenience or finances), with the balance filled inside 72 hours, then the patient was out of luck. If the pharmacy possessed the full supply, then the patient had to take all or none of the prescription, under this interpretation of the regulation.

The response to a recent letter I wrote to Ms Patricia M. Good, chief of the Liaison and Policy Section of the DEA, clarifies the appropriateness of a less restrictive interpretation of the rule. In that letter, I posed two hypothetical questions. The first question was as follows:

A pharmacist receives a prescription for a Schedule II opioid analgesic. The pharmacist makes a good faith effort to determine the legitimacy of the prescription by examining it personally, by talking with the prescriber, and by talking with the person presenting it. Obviously, if the pharmacist concludes with certainty that what has been presented is not a valid prescription, the pharmacist must refuse it. Equally obvious, if the pharmacist concludes with certainty that what has been presented is a legitimate prescription, the pharmacist may dispense it. However, despite the best efforts to determine the legitimacy of this prescription, doubts may linger. If the pharmacist believes the prescription to be legitimate,

but needs additional time to confirm legitimacy, may the pharmacist dispense a partial (for example, 24-hour) supply of the Schedule II controlled substance and then fill the prescription for the balance within 72 hours of the first partial filling, while using the intervening period to fully explore the legitimacy of the prescription? This question assumes that, during the intervening period, the results of additional investigations have confirmed with certainty the legitimacy of the prescription. Should those additional investigations not result in certain clarification of legitimacy, then the pharmacist would have no choice but to refuse the balance of the prescription.

Ms Good's response:

In the first scenario described in your letter, a pharmacist needs additional time to determine the legitimacy of a prescription for a Schedule II controlled substance. You have asked if the pharmacist can dispense a partial quantity of the prescribed controlled substance and then dispense the remaining balance upon confirmation of the prescription's legitimacy. It appears that the phrase “unable to supply” would apply in this situation. Therefore, the pharmacist would be in compliance with the partial-filling regulation. The pharmacist's actions, includ-

ing that of dispensing a limited quantity initially, are reasonable and appropriate under the described circumstances.

My second question:

A patient visits an emergency room of a hospital for the treatment of a minor trauma and receives a legitimate prescription for a large number of dosage units of a Schedule II opioid analgesic. The patient does not realize the large quantity is being prescribed, nor does the patient understand the high cost of the large quantity. The emergency room physician has prescribed the large quantity to prevent the patient from returning to the emergency room several days later solely to be given an additional prescription. At the pharmacy, the patient is surprised that the large quantity has been prescribed and is surprised at the expense. The patient does not know whether the trauma will be painful beyond a 72-hour period and does not want to be dispensed unnecessary and expensive controlled substance medications. May the pharmacist dispense a partial supply of the Schedule II controlled substance and then fill the prescription for the balance within 72 hours of the first partial filling, while permitting the patient during the intervening period to discover whether the pain warrants acquisition of the balance of the prescription?

Ms Good's response:

In the second scenario, a patient receives a prescription for a Schedule II controlled substance and the patient is not prepared to pay the costs associated with filling the large quantity prescribed or is not sure the total prescribed quantity is necessary. You have asked if the pharmacist can dispense a partial supply and then dispense the remaining balance within 72 hours if requested by the patient. Again, it appears the phrase "unable to supply" would apply in this situation. Therefore, the pharmacist would be in compliance with the partial-filling regulation. Initially, the patient is not aware of the need to obtain the total prescribed quantity of medication or is unable to obtain the entire quantity. Federal regulations are not intended to prevent a patient from obtaining medications that have been appropriately prescribed by an authorized practitioner.

These responses open up possibilities for pharmacists in their efforts to meet patients' needs and to also deter controlled substance diversion. The response to the first hypothetical question permits a pharmacist to partially fill a seemingly valid Schedule II prescription for which attempts at verification have not been completely successful. Chances are good that legitimate pain patients will return to receive

the balance of the prescribed quantity within the 72-hour period (after verification by the pharmacist – such as talking with other prescribers or with other pharmacists). Drug addicts or drug dealers will probably choose not to accept a partial supply.

The response to the second hypothetical question makes it possible for a pharmacist to dispense only the quantity the patient needs of a Schedule II medication prescribed in high quantities. This reduces the likelihood that the patient will keep the unneeded balance on hand, where it can be stolen from a medicine chest by either a family member or a friend who has no legitimate need for it.

Pharmacists have responsibilities to both help patients in pain and to restrict controlled substance diversion. Regulation flexibility is a key factor in the enablement of pharmacists to meet these responsibilities. The interpretation of DEA Regulation 21 C.F.R. § 1306.13(a), within the responses provided by Ms Good, provides pharmacists with additional flexibility so that they can meet their dual responsibilities. **NABP**

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A Dose of *Humor*

Reimporting Trouble

By Phil D. Script

Pharmacy school wasn't easy for my former student Al Buterol. He took the NAPLEX® (North American Pharmacist Licensure Examination™) so many times he was getting to know the test administrator at his local Prometric Testing Center on a first name basis. I paid him a visit recently at the pharmacy where he worked in the very southern part of Arizona to see how he was doing and ask an interesting question that came to me.

"Why, Mr Script, my old pharmacy school teacher," said a surprised Al as I came through the back door.

"I hope the 'old' refers to 'former,' rather than my age," I said.

"It just means you have a lot more experience than I," he said, making up for his slip.

"Experience that has kept you out of some real trouble," I reminded him. "By the way, I notice your back door is open – I'm surprised. Any character can come in and steal your stock."

"That's left open for my mother, who comes in about now and brings my lunch," replied an apologetic Al.

"Say, Mr Script, I've got this problem – " Just then Al was called to the counter by the ringing of the customer bell.

"I need some help," a woman's voice said. "Is someone here?"

Peering over the counter was a short elderly lady.

"I just bought this from another pharmacy, and the pills look funny. Is this OK?"

"Where did you get this?" Al asked, holding the container of pills.

"From a pharmacy just across the border in Tijuana," the lady replied. "It's the same as my blood pressure medication, and it was a really great deal. It's \$38 in the US, but these pills are only \$3.60."

"I can't guarantee that this is OK to use," Al replied. "The pills are discolored. I don't know if they have been stored properly, or how old they are."

Al seemed to know what he was doing. I guess he must have absorbed something between the naps I caught him taking during my lectures.

Just then an elderly man appeared in the counseling area, "I have a question, sir," he said, twisting his hearing aid till a loud squeal caused everyone to cover their ears. "If I forget to take my Glucophage, should I take a double dose in the evening?"

"That's not a good idea," Al said.

"I would have asked the pharmacist in Mexico, but he

couldn't speak English," he said. "Sure got a good deal, though – only one-sixth the price I pay here."

After helping the man, Al turned to me and whispered, "That's my problem; all these people come here from Mexico where they buy drugs cheaply. But then they come to me with their problems."

The phone rang and Al picked it up, listened for a while, then turned to me, holding the phone aside. "This man says he lives in the neighborhood, bought 30 tablets of Claritin from an Internet pharmacy that he later found out was located in southeast Asia. When the box arrived, it was mangled, with some damage to the pill container. Now he says the label looks different from what he's used to, and he's afraid it's counterfeit."

"I really can't tell you anything without seeing it, sir," Al told the man. "Why don't you bring it in?" After Al hung up he said, "Of course, he paid \$43 for it in the states, and to the rogue Web site he only dished out \$4.70 plus shipping. How can pharmacies in other countries sell these drugs so cheaply?"

"I'm glad to shed some light, my young protégé," I replied. "In Mexico, as in many other countries, production costs are

lower, there are government subsidies, and there are price controls. In the US, the pharmaceutical companies say they need to keep the prices up to pay for the research needed to produce new drugs.”

“You’re not kidding!” replied Al. “One of my patients told me that she lives on Social Security and spends about \$325 a month for her prescriptions. Medicare doesn’t cover them. She can add them into her coverage but that raises her premiums even higher.”

“It’s true,” I said, “that seniors and those without insurance are getting hit hard. Many seniors cross into Mexico or Canada on sold-out bus trips from nearby states in what they jokingly call ‘drug runs.’ Some doctors have no qualms about having prescriptions filled in Mexico. They just tell the patients to be careful and read the labels. The same is true in Canada. A prescription there must be signed by a Canadian doctor, but it has been reported that some pharmacies look the other way. Some US doctors have ‘border licenses’ to prescribe in both the US and Canada. Canadian medication is also sometimes quasi-legally ordered by fax. I’ve read that Maine, New

Hampshire, and Vermont are forming a co-op to bring cheaper pharmaceuticals to their elderly residents.”

“You sure know a lot – I didn’t think you were old enough to be forced to order it for yourself,” Al snickered.

Rather than tell this young whippersnapper where to go, I decided that silence was the better part of discretion.

“And what about the Web?” my quick-thinking student asked. “Is there a Napster equivalent for prescription medications?”

“Well, it’s not free like the music was, but sometimes it’s less costly. Last year about 100 physicians helped a nonprofit health alliance launch a Web site to assist doctors in getting drugs from Canada for patients.”

“But some of the cyberspace activity is outright illegal,” I added. “Whether it’s getting prescription drugs without a prescription from Web sites in foreign countries or engaging in all kinds of private drug sales on Internet chat rooms, it’s the equivalent of selling drugs on the street.”

“Can’t something be done to lower costs?”

“There have been various proposals,” I said. “For ex-

ample, there is an effort in Congress to include drug coverage under Medicare as an entitlement for all seniors. And in October 2000, a law was passed that would allow pharmacies and wholesalers to reimport Food and Drug Administration-approved drugs that were manufactured in the US and other countries, including Australia, Japan, New Zealand, Switzerland, South Africa, the European Union, the European Economic Area, and other areas designated by the US Department of Health and Human Services (HHS). Former HHS Secretary Donna Shalala, however, refused to implement the law, citing flaws and loopholes that would make it impractical.”

Just then the elderly lady who was still standing by the prescription counter proudly held out a plastic bottle.

“You’ve been so nice to me, sonny,” she said to Al, “that I’m buying my hair dressing from your store.”

“You must be making these people happy, Al. Out the window I can see a tour bus pulling up.” **NABP**

Nine Counts Filed Against Oklahoma Internet Pharmacy

On March 5, 2001, agents from at least six federal and state agencies including the Drug Enforcement Administration, the Oklahoma Bureau of Narcotics, the US Post Office, the Internal Revenue Service, the Oklahoma State Medical Board, and the Oklahoma State Board of Pharmacy, raided Mainstreet Pharmacy, operator of the Internet pharmacy, www.nationpharmacy.com.

After receiving complaints from patients across the country, Oklahoma State Board of Pharmacy Compliance Officer Cindy Hamilton discovered that Mainstreet Pharmacy was dispensing excessive quantities of controlled dangerous substances (CDS). Two physicians were writing nearly all of the prescriptions dispensed without seeing the patients.

A formal complaint filed with the Oklahoma State Board of Pharmacy listed nine counts against owner Clayton Fuchs, RPh, and Mainstreet Pharmacy. These counts were:

- 1) Fuchs and Mainstreet Pharmacy conducted themselves in a disrespectful manner, which may lower the public esteem and confidence in the pharmacy community.
- 2) Prices for CDS sold by Fuchs and Mainstreet Pharmacy through nationpharmacy.com were grossly disproportionate compared to the price of CDS sold elsewhere. Fuchs and Mainstreet Pharmacy violated Board rules by charging unfair professional fees for dispensing prescriptions. For example, Mainstreet would purchase 100 hydrocodone/apap 10/500 for \$18 and charge its customers \$240. In another example, Mainstreet would pay \$102.51 for a pint of Tussionex and sell it to customers for \$285.
- 3) A secret agreement was established between Fuchs, the pharmacist owner/manager of Mainstreet Pharmacy, and a physician, whereby the physician would keep \$45 of the initial fee of \$240.
- 4) Fuchs and Mainstreet Pharmacy dispensed CDS prescriptions written by "employee physicians," which were not issued for legitimate purposes. False identities were used to improperly obtain controlled substances. The Oklahoma Board knows of at least two cases where suicidal persons obtained CDS. Unfortunately, in one of these cases the person died.
- 5) Fuchs and Mainstreet Pharmacy failed to hire an adequate number of pharmacists to perform the practice of pharmacy with reasonable safety.
- 6) Fuchs and Mainstreet Pharmacy allowed employee pharmacists to dispense prescriptions written by Dr Ricky Jo Nelson through January 29, 2001, even though his authorization was withdrawn on December 14, 2000.
- 7) Fuchs and Mainstreet Pharmacy violated Board rules by failure to comply with all federal and state laws in their pharmacy business.
- 8) Fuchs and Mainstreet Pharmacy did not attempt to address the possible addiction of patients. Numerous facts and circumstances surrounding the operation of Mainstreet Pharmacy should have suggested the likelihood that there were addiction or dependency problems with their customers.
- 9) Fuchs and Mainstreet Pharmacy regularly dispensed CDS through the mail when the practitioner did not personally know the ultimate user, a violation of Oklahoma narcotic rules.

Mainstreet Pharmacy has been the subject of criticism in the Oklahoma media as a pharmacy that dispensed and shipped CDS to individuals after only having contact with

that person via the Internet. According to Compliance Officer Hamilton, along with the charges listed above, another “red flag” was the fact that the Mainstreet Pharmacy Web site of nationpharmacy.com did not list significant information for their customers, such as the name of the associated pharmacy; a telephone number or mailing address of the Web site office; the parent corporate name, Millennium Health Service, Inc; the pharmacists names; and associated physicians issuing the prescriptions. Mainstreet Pharmacy sold prescriptions to customers in California, Texas, Illinois, and Virginia without a license to dispense in those states.

“Mainstreet Pharmacy was filling between 300 and 400 CDS prescriptions a day. In one instance approximately 800 CDS prescriptions were prescribed and filled in one day,” Alicia Connolly-Lohr, Oklahoma Assistant Attorney General and counsel for the Oklahoma State Board of Pharmacy explained. Oklahoma Board investigations show that between October 25, 2000 and November 2, 2000, there were 1,684 prescriptions processed; of that number 1,651 were CDS prescriptions.

The CDS prescriptions included, but were not limited to, hydrocodone, diazepam, butalbital, and alprazolam. According to Hamilton, “There was a total of 1.57 million doses of hydrocodone alone

dispensed during the time the Web site was up and running [from December 2000 through the beginning of March 2001.]”

On March 28, 2001, Mainstreet Pharmacy was found guilty on counts one through seven and on count nine with a total fine of \$4,000 (\$500 for each count). Clayton Fuchs was found guilty on all nine counts with a total fine of \$4,500. Both Clayton Fuchs’ pharmacist certificate and Mainstreet Pharmacy’s license have been permanently revoked in Oklahoma.

According to Connolly-Lohr, Clayton Fuchs had operated a similar Internet pharmacy in Texas for a year and a half

before shutting down his operation when he found he was under investigation. This is evidence that NABP’s Verified Internet Pharmacy Practice Sites™ program is needed and perhaps should be a requirement for licensure.

Both Hamilton and Connolly-Lohr agree that more needs to be done about the illegal uses of Internet pharmacies. Due to an increasing concern about Internet pharmacies, NABP, last year, convened the Task Force on Expanded Use of the Internet in Pharmacy Practice and Regulation. The report of the Task Force is available on NABP’s Web site at www.nabp.net. 

Legal Briefs *(continued from page 81)*

of the pharmacist anticipate this vision? Do not the standards of practice support this vision? Does not the licensure process require this vision? Does not the practice act demand this vision? Should not the public health have some input into health care decisions as well as the economic bottom line? Some would think so.

NABP has gained notoriety in this area of duty to warn having received requests for the filing of amicus briefs in *Morgan v. Wal-Mart Stores, Inc*, 30 S.W.3d 455 (Ct. App.810 2000), which has been appealed to the Texas Supreme Court and *Charlisia Moore, et al v. Winn-Dixie, et al*, Harrison

County Circuit Court, Case No. A-2401-98-00564, which will be heard before the Mississippi Supreme Court. Both of these cases are based on issues involving the duty to warn and the learned intermediary doctrine. The ability of NABP to respond to such requests basically depends upon whether facts of a particular case are favorable, the perceived chances of prevailing and, most importantly, the budgetary constraints of the Association.



Attorney John F. Atkinson is a partner in the law firm of Atkinson & Atkinson, counsel for NABP.

Around the Association

Anagnostiadis Named New NISPC Executive Director

On April 30 Eleni Anagnostiadis, RPh, assumed the management and oversight of the daily operations of the National Institute for Standards in Pharmacist Credentialing (NISPC) as its new executive director.

"We at NABP are excited that Eleni has joined NISPC. She brings experience in the development of disease state management programs and coordination of programs to NISPC. Her genuine concern for public health can be seen in her efforts to develop and implement a variety of wellness initiatives," NABP President Richard K. "Mick" Markuson states.

Ms Anagnostiadis started her pharmacy career with Giant Food, a Maryland-based supermarket chain. During her tenure at Giant, she held numerous positions: staff pharmacist, assistant pharmacy manager, assis-

tant pharmaceutical buyer, and her last position as manager of pharmacy support programs. Anagnostiadis has played an important role in the University of Maryland Community Pharmacy Residency Program, which received American Pharmaceutical Association and American Society of Health-System Pharmacists accreditation in November 2000 and the diabetes care program at Giant, which is the first chain-based education program in the country to be recognized by the American Diabetes Association.

In addition to serving on the editorial advisory board of *Pharmacy Today*, Anagnostiadis is a member of the APhA, the Virginia Pharmacists Association, and the Maryland Pharmacists Association. She is a graduate of the University of North Carolina School of Pharmacy.

"I am truly excited to be joining NISPC," Anagnostiadis said. "I look forward to the opportunity

to promote the positive outcomes that can be achieved through pharmacist care of patients and third-party payors."

New Board Members

Donna Dagen, public member, Delaware State Board of Pharmacy.

Evelyn Hickman, public member, Illinois State Board of Pharmacy.

Michael R. Hurst, member, Kansas State Board of Pharmacy.

Robert McGinley, RPh, member, New Jersey State Board of Pharmacy.

Merlin L. McFarland, member, Kansas State Board of Pharmacy.

Alison Kay McManus, RPh, vice president, Wyoming State Board of Pharmacy.

Garrison Moreland, RPh, member, Illinois State Board of Pharmacy.

George Roe, RPh, member, Washington State Board of Pharmacy. **NABP**

NABP Awards VIPPS Certification to Savon.com

Savon.com, the drug division of Albertson's, is the most recent online pharmacy to receive Verified Internet Pharmacy Practice Sites™ (VIPPS™) certification from NABP.

Sav-on Drugs continues to operate stand-alone drug stores and combination food/drug

stores under the Sav-on banner, with more than 1,100 pharmacies in its stores. The company filled approximately 80 million prescriptions in 1997.

The voluntary VIPPS program was developed to provide customers with a reliable means to identify those online

pharmacies that have proven their preparedness to meet the unique challenges of pharmacy practice via the Internet.

For more information about the VIPPS program or NABP, please call 847/698-6227 or log on to NABP's Web site at www.nabp.net. **NABP**

NABP Seeks Item Writers for Testing Programs

Pharmacy practitioners, educators, and regulators interested in serving as item writers for the North American Pharmacist Licensure Examination™ (NAPLEX®), Multistate Pharmacy Jurisprudence Examination™ (MPJE™), or the Disease State Management (DSM) examinations should send, fax, or e-mail a letter of

interest and a current resume or curriculum vitae to NABP's Executive Director/Secretary Carmen A. Catizone at 700 Busse Highway, Park Ridge, IL 60068; fax 847/698-0124 e-mail ceo@nabp.net.

Item writers will receive training materials describing the skills necessary for their

designated examination, and may be asked to attend a weekend workshop at NABP headquarters or an area hotel, with applicable expenses paid by NABP. Item writers will receive periodic requests to develop new test items that will be considered for inclusion in NABP's assessment programs.

State board of pharmacy members and staff are particularly encouraged to participate in the item writing process. Questions about item writing should be directed to Carmen A. Catizone at NABP headquarters. **NABP**

2001 NAPLEX/MPJE Item Writing Workshops



The North American Pharmacist Licensure Examination™ (NAPLEX®) Item Writing Workshop was held at the Marriott Suites O'Hare, Rosemont, Ill, February 2-4, 2001. Around the table, from left, are Randy Kupier, Anthony DeFilippo, Melissa Jackson, and Tom Houchens. Others who attended but are not pictured were John Baughman, Mary Chavez, Michael Cockerham, Teresa Hudson, Cynthia Paz Koh-Knox, Mary Laughlin, Gene Martin, Michael Nelson, Donald Ruwe, Virgil Van Dusen, Neal Walker, and Hal Ward.

The Multistate Pharmacy Jurisprudence Examination™ (MPJE™) Item Writing Workshop also met, but is not pictured. The workshop was held on February 9-11, 2001, at NABP Headquarters, Park Ridge, Ill. Attending the workshop were Chris Gassen, Kansas State Board of Pharmacy; Chuck Sauer; Charles Curtis Barr, Nebraska Board of Pharmacy; David Flashover, New York Board of Pharmacy; David Shublak, Indiana Board of Pharmacy; Donald Yee, Maryland Board of Pharmacy; Gary A. Schnabel, Oregon State Board of Pharmacy; LaVerne George Naesea, Maryland Board of Pharmacy; Malcolm J. Broussard, Louisiana Board of Pharmacy; Ann Breakenridge, District of Columbia Board of Pharmacy; Mark Keeley, Ohio State Board of Pharmacy; Michael A. Moné, Kentucky Board of Pharmacy; Richard D. Morrison, Washington State Board of Pharmacy; Rosalie Baran, Michigan Board of Pharmacy; Sharon Demory-Cornish, Maryland Board of Pharmacy; and Steve Morse, Texas State Board of Pharmacy.

NABP Seeks Representatives to ACPE Board

NABP is seeking individuals interested in serving as one of three representatives to the American Council on Pharmaceutical Education (ACPE). On June 30 of every even-numbered year, one representative's six-year term expires. The deadline for letters of interest and resumes is September 15, 2001. [An executive committee subcommittee reviews the letters and presents a recommendation at the November Executive Committee meeting for final approval.] Reminder notices will be sent to the Boards on August 15, 2001. **NABP**

tions to Pennsylvania residents. Online pharmacies Kwikmed and Cymedic Health Group were prosecuted for allegedly selling prescription medications such as Viagra, Xenical, and Propecia without verifying buyers' ages and medical histories and without possessing a license or permit, in violation of the Pennsylvania Consumer Protection Law, Pharmacy Act, and Medical Practice Act. In settling the lawsuit, which was filed in May 2000, the consent agreement requires the pharmacies to refund consultation fees charged to consumers, halt the advertising and selling of prescription medications to Pennsylvania residents, and pay more than \$5,000 in civil penalties and as investigation costs.

West Virginia Attorney General Darrell McGraw filed a similar lawsuit in September 2000, accusing Norfolk Pharmacy and Norfolk Men's Clinic of illegally advertising, selling, and prescribing prescription drugs such as Viagra, Celebrex, and Claritin without valid prescriptions from prescribers. Like the Pennsylvania attorney general, McGraw seeks to recover fees charged for doctor consultations. The pharmacy is alleged to have dispensed prescriptions in 1999 and 2000 worth \$54.6 million. Two pharmacists as well as the clinic owners were named in the lawsuit. In July 2000, the clinic owners were also the target of federal criminal charges for conspiracy, mail fraud, money laundering,

obstruction of justice, and violations of the Food Drug and Cosmetic Act. As of the date this article was written, both the state and federal cases were still pending.

West Virginia's prosecution was not Norfolk Pharmacy's only headache. In December 2000, the state of New Jersey filed two multi-defendant lawsuits against Rx Leader and RB Drugstores and their principals, affiliate e-pharmacies, pharmacists, and doctors. One of the named defendants was Norfolk Pharmacy. The lawsuits alleged, among other things, that the defendants engaged in deceptive practices by leading consumers to believe it was safe and acceptable for the defendant online pharmacists and physicians to dispense prescription medications such as phentermine, Ionamin, and Bontril SR, after reviewing consumers' medical questionnaires. New Jersey is seeking to bar the defendants from engaging in the illegal acts, as alleged, and to impose civil penalties and assess costs against the defendants.

In the last 12 months, state medical boards have also been prosecuting physicians who engage in illegal Internet prescribing practices. Alabama, Arkansas, Oklahoma, and Texas have disciplined the licenses of physicians who have prescribed medications based upon online consultations without benefit of a physical examination.

Further, state medical boards have been addressing the issue

of Internet prescribing by physicians. In the last year, numerous medical boards, including those in Colorado, Louisiana, Mississippi, and South Carolina, have adopted various policies that regard the prescribing of medications based solely upon online consultations, without the physician having actually met the patient, as unprofessional conduct, and which state that online consultations are not a valid means to establish patient-physician relationships.

In addition, the Food and Drug Administration (FDA) continues its "cyber letter" campaign to curtail illegal prescription medication shipments to the United States from international Web sites. In March and April 2001, the FDA has sent almost two dozen cyber letters warning registrants and owners of international Web sites that it is illegal for a foreign source to ship foreign versions of FDA-approved drugs into the United States. The online businesses that were the target of these recent cyber letters are located in countries as varied as India, Australia, Panama, China, Germany, New Zealand, and Spain, and sell drugs such as "morning after" pills and oral contraceptives, Prozac, Viagra, anabolic steroids, Accutane, and blood pressure medications, all of which are prescription-only medications in the United States.

For assurance, consumers should make sure that the Web site they are using has the VIPPS™ seal. 

NABP Celebrates "Take Your Child to Work Day"



The children take time out of their busy day to pose with their families on a sunny April afternoon.

It's Annual Meeting time! Some of the children help with the packing of the annual meeting materials.



NABP's guests show off their certificates of participation in "Take Your Child to Work Day."

NABP Meeting Dates

Wednesday-Sunday, July 18-22, 2001

NABP Executive Committee Retreat,
Carmel Valley Ranch, Carmel, Calif

Sunday-Tuesday, August 5-7, 2001

NABP/AACP District III Meeting,
Amelia Island Plantation,
Amelia Island, Fla

Thursday-Saturday, August 16-18, 2001

NABP/AACP District V Meeting,
Rushmore Plaza, Rapid City, SD

Thursday-Sunday, October 4-7, 2001

NABP/AACP District VI Meeting,
Marriott Spring Hill Suites,
Lawrence, Kan

Thursday-Sunday, October 11-14, 2001

NABP/AACP District VII & VIII Meeting,
Sheraton Old Town Hotel, Albuquerque, NM

Thursday-Saturday, November 1-3, 2001

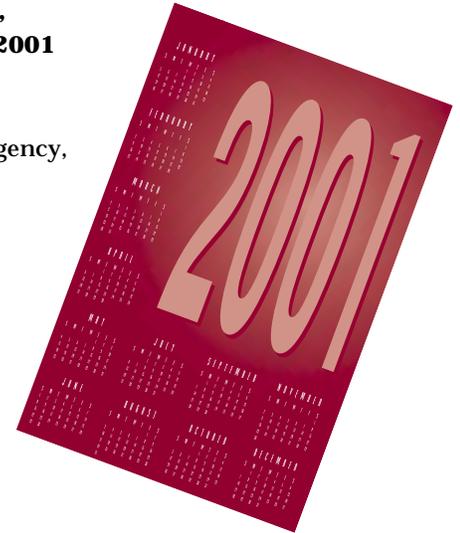
NABP/AACP District I & II Meeting,
Otesaga Hotel & Resort, Cooperstown, NY

Friday-Sunday, November 9-11, 2001

NABP/AACP District IV Meeting, Concourse
Hotel, Madison, Wis

Saturday-Tuesday, November 10-13, 2001

Executive Officer's
Conference
Monterey Hyatt Regency,
Monterey, Calif



newsletter

National Association of Boards of Pharmacy
700 Busse Highway
Park Ridge, Illinois 60068