Controversy Over Conscience Clauses, Must-Fill Laws Fueled by Plan B Decision

The conflict over pharmacists' right of conscience, and how that might be balanced with patients' right to their medications, has not subsided in recent months. If anything, the controversy has increased, fueled by the Food and Drug Administration's (FDA) decision last year to allow pharmacies to sell the Plan B emergency contraception (levonorgestrel) to women 18 and older without a prescription. Some states that do not already have conscience clauses on the books are rushing to add them; others are issuing "must-fill" edicts.

In the vast majority of cases in which a pharmacist is handed a prescription he or she cannot fill because of firmly held ethical, moral, or religious beliefs, the outcome is the same, whether the state laws dictate a firm "must-fill" position or specifically allow the pharmacist to opt out: the pharmacist hands the prescription to a colleague who then dispenses the medication.

Ideally, all situations would end like this, with pharmacists' right of conscience and patients' right to medication both respected. Inevitably, however, conflicts arise, and it is at those times that pharmacists and patients need to know where they stand vis-à-vis the law and regulation by the board of pharmacy.

A Shifting Landscape

In an effort to clarify the situation, particularly in regard to emergency contraception, state legislatures have produced a blizzard of (often competing) bills. Most have disappeared into committees or failed to pass. Many are currently pending.

Of the laws or regulations that have passed, a few conflict with already-existing statutes, confusing the issue further. Illinois provides perhaps the best-known example of this, as recent administrative rules requiring all pharmacies to stock and fill emergency contraception vie with a strong conscience clause that has been on the books since 1977. To date, neither legislative debates nor lawsuits have resolved the conflict.

In the meantime, confusion for pharmacists still exists in Illinois and in other states.

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Conscience Clause
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This confusion may be intensified or alleviated at any time by the passage of a new law, a decision by a court, or the issuance of a new rule. To find out the latest status of bills in state legislatures, consider these resources: The National Conference of State Legislatures is tracking the status of proposed conscience clause and must-fill legislation. Visit www.ncsl.org/programs/health/conscienceclauses.htm for a summary of current and past bills and their status.

Marsha N. Cohen, a law professor at the University of California's Hastings College of Law, has also compiled extensive information on proposed and passed laws and statutes covering conscience clauses and "must-fill" provisions, available at http://sierra.uchastings.edu/cohen/conscience_clause.htm.

Conscience-Clause States
Some states, including Arkansas, Georgia, Mississippi, and South Dakota, have passed laws allowing pharmacists to refuse to dispense emergency contraception. The laws vary by state. Georgia, for example, requires pharmacists to "make reasonable efforts" to find another pharmacist to fill the prescription, or return it to the patient. On the other hand, Mississippi's broad conscience legislation specifically allows health care providers to refuse to advise or refer.

Other states, including Colorado, Florida, Maine, and Tennessee, have relatively broad refusal clauses regarding family planning or contraceptive services that do not specifically mention pharmacists—though pharmacists clearly appear to be covered by the clauses.

Meanwhile, still other states, like Illinois, have general conscience clauses on the books, although these do not specify contraception. As mentioned, it is not always clear how other rules or laws that seem to conflict impact these conscience clauses.

Must-Fill States
At the other end of the spectrum, several states, including some with conscience clauses, specifically require pharmacists or pharmacies to fill all prescriptions, including emergency contraception, in a timely fashion. These states include California, Illinois, Maine, Minnesota, and North Dakota.

Not all of the statutes or regulations specifically mention emergency contraception. North Dakota's regulations, for example, define "[r]efusing to compound and dispense prescriptions that may reasonably be expected to be compounded or dispensed in pharmacies by a pharmacist" as "unprofessional conduct." Some regulations, like Minnesota's, which otherwise reads much like North Dakota's, specifically allow an exemption for pharmacists who refuse to assist or participate in an abortion. While emergency contraception usually works by preventing fertilization of the egg, it may at times prevent a fertilized egg from implanting in the uterus—something some people consider tantamount to abortion.

Maine's conscience clause (mentioned above) coexists with more recent legislation (the Collaborative Practice for Emergency Contraception Act, passed in 2004) that provides that a pharmacist may refuse to fill only in accordance with a "discretion-not-to-fill" statute, which allows refusal when the pharmacist is "unsatisfied as to the legitimacy or appropriateness of any prescription presented."

Other laws, like California's, seek to accommodate pharmacists who object to emergency contraception by allowing pharmacists to refuse to fill a prescription on ethical, moral, or religious grounds—but only if they previously notify employers in advance and in writing which drugs they object to dispensing, and the employer is able to accommodate them without undue hardship. At the same time, pharmacies must ensure patients' timely access to their prescription medications, and they must have protocols in place to ensure access despite pharmacist refusal.
Board of Pharmacy Actions

The duty to clarify acceptable actions by pharmacists, of course, does not always rest with the state legislature. Some boards of pharmacy have issued statements that spell out how existing rules apply to the emergency contraception issue, while others have created new regulations that specifically address rights of conscience versus medication access.

At times, this has drawn boards of pharmacy into the crossfire as they create new rules or interpret existing ones in a highly charged atmosphere. The Washington State Board of Pharmacy garnered national headlines in April of this year when, after advisement from the state’s governor, it issued a rule change requiring all pharmacies to fill emergency contraception prescriptions. Individual pharmacists may opt out of filling a particular prescription – but only if another pharmacist is available at the time to fill it. Moreover, pharmacies must order new supplies of a medication, if a patient asks for something that is not in stock. The Board also amended its pharmacy regulations to specify certain actions as unprofessional conduct: destroying an unfilled, lawful prescription; refusing to return an unfilled, lawful prescription; violating a patient’s privacy; and intimidating or harassing a patient.

Other boards of pharmacy, while not issuing new regulations, have either made explicit statements letting pharmacists understand how the board interprets existing rules or have made rulings that indicate where the board stands on the issue. Most attempt to straddle the line between respecting pharmacists’ moral values and ensuring patient rights. North Carolina, for example, issued a statement on the subject:

“The Board notes that although pharmacists have a right to avoid moral or ethical conflict, they do not have a right to obstruct otherwise legitimate prescription dispensing or delivery solely on the basis of conscientious objection.

“Board of Pharmacy staff interprets this policy to mean that if a pharmacist refuses to fill a prescription for emergency contraception then that pharmacist has an obligation to get the patient and the prescription to a pharmacist who will dispense that prescription in a timely manner.”

The Texas State Board of Pharmacy also provides guidance to pharmacists. A statement on the Board’s Web site notes, “If a pharmacist is unable to sell a medication or fill a particular prescription for any reason, he/she should refer the patient to another pharmacist at the pharmacy, if possible, or refer the patient to a pharmacy where the patient may obtain the medication.”

Similarly, the Oregon State Board of Pharmacy publicly posts its position statement, “Considering Moral Ethical Objections.” “Interference with a patient’s right to receive timely, professional prescription services and information... may be considered unprofessional conduct and could result in disciplinary action by the Board,” the Board states. It adds, as an example, that “the Board would consider it unprofessional conduct for a pharmacist to lecture a patient about the pharmacist’s moral or religious beliefs, to violate the patient’s privacy or to destroy, confiscate, or otherwise tamper with the patient’s prescription.”

The Board recommends that pharmacists who feel unable to dispense certain types of drugs should notify the pharmacist-in-charge in writing, and that protocols should be established to ensure patients’ rights. The New York State Board of Pharmacy has issued a similar statement to help guide pharmacists.

And Next . . .

Most states have not yet fully tackled the right-of-conscience issues raised by Plan B’s switch to over-the-counter “behind the counter” status. Will pharmacies be required to stock emergency

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Legal Briefs

nabp newsletter

From Soho Down to Brighton . . .

By Dale J. Atkinson, JD

The regulatory issues impacting the Internet and ultimate public protection mandates placed upon the boards of pharmacy continue to stimulate complex legal debates. At the heart of many of the issues is the use of online questionnaires as a basis for establishing physician/prescribing practitioner-patient relationships to substantiate the prescription that will ultimately be presented to the pharmacist. Of course, pharmacists must use professional judgment in assessing the legitimacy of a particular script prior to dispensing the medications.

Because the interests of the public do not always coincide with the interests of business, there may be times that "regulation" of the profession in the form of statutes, regulations, and/or rules must be enacted to ensure the interests of the consumers is paramount. Consider the following:

In July 2005, the Colorado State Board of Pharmacy held a rulemaking hearing to consider a rule prohibiting pharmacists from dispensing prescription drugs resulting from Internet-based questionnaires, Internet-based consultations, or telephonic consultations without a valid preexisting patient-practitioner relationship. As ultimately adopted, the rule states:

A pharmacist shall make every reasonable effort to ensure that any order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.

After its adoption, the rule was challenged by a pharmacy and pharmacist (referred to as appellants) alleging several substantive and procedural violations including that the Board failed to provide a complying statement of basis and purpose as required by the Administrative Procedures Act (APA), failed to maintain adequate and appropriate records of the rulemaking hearing proceedings, exceeded its statutory authority, and that the language in the rule was impermissibly vague and overbroad. The matter was heard by the Colorado Court of Appeals.

The court first addressed the fact that administrative rules are presumed valid and the challenging party has a heavy burden to establish a rule's invalidity. Invalidity of a rule may be established by demonstrating that a rulemaking body either (1) acted in an unconstitutional manner; (2) exceeded its statutory authority; or (3) acted in a manner contrary to statutory rulemaking requirements. Addressing the overall arguments of procedural defects asserted by the appellants, the court held that the APA requires "substantial compliance" with the statutory rulemaking requirements. That is, strict or absolute compliance is not expected of the rulemaking entity.

Specifically, the appellants argue that the board did not provide a complying statement of basis and purpose as required by the APA. The APA requires a prehearing statement of basis and purpose, and after
consideration of the relevant matter presented, the agency shall incorporate by reference on the rules adopted a written concise general statement of their basis, specific statutory authority, and purpose. The reason for the former requirement is to provide public notice of what the agency is considering, and the latter requirement is to assist in appellate review.

In the current matter, the Board included the following statement of basis and purpose:

**Basis and Purpose:** Proposed Rule regarding Dispensing of Orders resulting from Internet-based questionnaires, Internet-based consultation, or a telephonic consultation without a valid preexisting patient-practitioner relationship.

In upholding compliance with the APA, the court held that the statement of basis and purpose and the underlying rule was based almost entirely on policy considerations, rather than findings of fact obtained from hearings related to the rule. Thus, the statement did not need to identify the presence of factual support for the Board's determination of need. Indeed, the court held that the regulation was "self-explanatory" and its basis and purpose were obvious.

Next, the appellants argued that the Board has not maintained adequate and appropriate records of the rulemaking proceedings. Again, the court disagreed with the appellants. The court noted that the records must contain "[a]ny official transcript of oral presentations made in the proceeding upon which the rule is based on, if not transcribed, any tape recording or stenographic record of those presentations and any memorandum prepared by a presiding official summarizing the contents of those presentations." In the current matter, the hearing was tape recorded and subsequently transcribed. While the transcriptions contain numerous omissions because portions of the tapes were inaudible, many representatives of the Board (at the request of the appellants) reviewed the transcripts and filed in missing statements and identified many of the speakers.

Appellants argued that there remained many inaudible and unreconstructed portions of the proceedings rendering the record inadequate and not in compliance with the APA. Not persuaded, the court held that the substance and core testimony were apparent, sufficient, and ready for public inspection and appellate review. It also noted that numerous written comments were included in the record further identifying relevant arguments and authorities.

Relevant to the record, the appellants argued that the record did not reflect a quorum of board members present and how such members voted when adopting the rule. The court rejected this argument stating that the record indicated a quorum present and a unanimous vote in favor of adoption.

The appellants argued that the Board exceeded its authority in promulgating the rule in that the determination of whether there is a "valid preexisting patient-practitioner relationship" necessarily involves knowledge of the Medical Practice Act and, thus, is outside the scope of the authority of the Board of Pharmacy. Illustrating the importance of the "declaration" contained in the pharmacy practice act, the court liberally construed the authority of the statute and the power of the Board of Pharmacy to adopt rules deemed necessary by the Board for the proper administration and enforcement of the responsibilities and duties delegated to the Board. The court recognized the technical (continued on page 122)
More States Adopt Pedigree Laws to Protect Medication Supply Chain from Counterfeiters

In the first half of 2007, state legislatures and boards of pharmacy continued to address the dangers that counterfeit drugs present to the nation’s drug distribution system by adopting pedigree legislation or regulations.

Most prescription medications manufactured in the United States go directly from the manufacturer to the wholesaler, to the pharmacies, allowing little opportunity for counterfeit drugs to enter the supply chain. When medications go through one or more secondary wholesalers, however, the supply chain becomes more vulnerable to counterfeit infiltration. By providing documentation to identify each sale, purchase, or trade of a drug, pedigree requirements reduce the opportunity for counterfeit drugs to enter the medication supply chain.

The original Prescription Drug Marketing Act (PDMA), which came into effect in 1988, requires states to adopt certain minimum standards for the licensing of wholesale drug distributors. Technically, its intention was to address the counterfeit drug issue, which it did, but it also created a patchwork regulatory structure across the country, which made licensure easier to come by for counterfeiters.

Although the regulations implementing the PDMA have been stayed since 1999, the fundamental statutory requirement to pass a pedigree has been in effect since PDMA was enacted. The regulations primarily serve to clarify who is an authorized distributor of record and what information a pedigree must contain.

Many states have moved forward with their own pedigree requirements, which are often more stringent than what the PDMA would require even if all the provisions were in place. Since 2004, 23 states have passed their own pedigree laws to protect their borders from counterfeit drugs.

States are adopting model legislation, such as the language provided in the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy, and they are also recognizing accreditation programs such as the NABP Verified-Accredited Wholesale Distributors program, both of which help build uniformity and standardization.

The following is an overview of states that have passed pedigree legislation in 2007:

- **Georgia:** Senate Bill (SB) 205, the Prescription Medication Integrity Act, was signed by the governor on May 24. The bill requires wholesale distributors to establish and maintain inventories and records of all transactions regarding the receipt and distribution of prescription drugs. These records must include pedigrees, documenting “all necessary identifying information on each sale from the manufacturer to the sale to the pharmacists,” for all prescription drugs that leave or have ever left the normal distribution channel. Additionally, the bill states that, by July 1, 2009, the Georgia State Board of Pharmacy must establish an implementation deadline for electronic pedigrees.

- **Idaho:** SB 1184, the Idaho Wholesale Drug Distribution Act, was signed by the governor on March 30. The act requires wholesale distributors of prescription drugs, “including repackagers, but excluding the original manufacturer of the finished form of the prescription drug,” that leave, or have
ever left, the normal distribution channel, to provide a pedigree to the person who receives the drug. Pedigrees must include "all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, or the manufacturer's third party logistics provider, colicensed product partner, or manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug." Additionally, the legislation notes that, by July 1, 2009, the Idaho Board of Pharmacy must determine a targeted implementation date for electronic track and trace pedigree technology.

- **Maryland:** House Bill (HB) 1030, SB 759, Wholesale Distributor Permitting and Prescription Drug Integrity Act, was approved by the governor on May 8, 2007. The legislation strengthens wholesale distributor requirements in Maryland by requiring surety bonding, routine inspections, pedigrees, and criminal background checks, and revises wholesaler requirements to include inspection and bond. The legislation also requires a prescription drug distributed outside the normal distribution channel to have a pedigree that records each distribution. The Maryland Board of Pharmacy must adopt regulations to implement the bill by January 1, 2008.

- **Montana:** HB 536, which would have created the Wholesale Licensure and Prescription Medication Integrity Act, was vetoed by the governor on May 3. The proposed legislation was intended to tighten licensing requirements for wholesale distributors and would have required a pedigree documenting the chain of custody of prescription medications from manufacturer to pharmacy.

- **North Dakota:** HB 1455 was signed by the governor on March 29. The legislation requires wholesale distributors of prescription drugs, including repackagers but excluding the original manufacturer, which leave or have ever left the normal distribution channel, to provide a pedigree to the person who receives the drug. Further, the North Dakota State Board of Pharmacy must determine, by July 1, 2009, a targeted implementation date for electronic track and trace pedigree technology.

- **South Dakota:** HB 1155 was signed by the governor on March 26 and mirrors the pedigree legislation passed in North Dakota. The following states passed legislation that addresses pedigrees prior to 2007:

  - Arizona
  - California
  - Colorado
  - Florida
  - Indiana
  - Mississippi
  - Nebraska
  - Nevada
  - New Jersey
  - New Mexico: clean-up bill passed in 2007
  - Oklahoma
  - Texas
  - Vermont
  - Virginia: clean-up bill passed in 2007
  - Oregon: adopted rules to address pedigrees in regulation.

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Fall Legislative Conference Program

September 16-18, 2007

Hyatt Regency Crystal City
Arlington, VA

Sunday, September 16
7:30 AM - 5 PM
Registration/Information Desk Open

9 - 9:15 AM
Welcome Remarks

9:15 - 10:15 AM
Keynote Speaker

10:30 AM - Noon
Legislative and Regulatory Update
Program #205-000-07-006-L03P
(0.15 CEUs – 1.5 contact hours)

Noon - 1:15 PM
Buffet Luncheon

1:15 - 2:45 PM
The Federal Legislative Process: Understanding the Beltway

3 - 4:30 PM
Meeting Your Congressional Leadership: Tools for a Successful Encounter

6:30 - 8:30 PM
Welcome Reception
(Buffet dinner will be served.)

Monday, September 17
7 - 9 AM
Registration/Information Desk Open

7 - 8 AM
Continental Breakfast

9 - 11 AM
Roundtable Discussion: Political Platforms Meet Current Issues in Pharmacy Regulation
Program #205-000-07-007-L03P
(0.2 CEUs – 2 contact hours)

11 AM - 5 PM
Open time to meet with Congressional Leadership

Tuesday, September 18
7 - 8 AM
Registration/Information Desk Open

7 - 8 AM
Continental Breakfast

8:45 - 9:45 AM
Building the Infrastructure for Health Information Exchange
Program #205-000-07-008-L03P
(0.1 CEUs – 1 contact hour)

10 - 11 AM
111th Congress and the New Administration: What to Expect

11 - 11:15 AM
Closing Remarks

11:15 AM - 5 PM
Open time to meet with Congressional Leadership

NABP staff will be available to assist attendees on an individual basis to apply for CLE credit for attending conference CE sessions. To apply for CLE credit, attendees must initiate the program approval process in their own states by completing and submitting the appropriate application materials and forms. NABP will provide documentation as necessary.

Pedigree Legislation
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Quoted in a June 5, 2007 Drug Topics article, California State Board of Pharmacy Executive Officer Virginia Herold calls e-pedigrees the “most important health mandate” for the Board and a powerful weapon against counterfeit medications. “We think this is the best way to combat counterfeit drugs.”

NABP provides educational assistance to the state boards of pharmacy in developing rules to regulate the wholesale distribution of prescription medications and other pharmacy regulatory issues in order to protect the public health. NABP assisted the Maryland and Wyoming boards of pharmacy by providing draft language, participating in conference calls, and attending stakeholders meetings, as the boards drafted pedigree legislation for consideration during the 2007 legislative session. More information on obtaining assistance from NABP is available by contacting Customer Service at custserv@nabp.net.
NABP Fall Legislative Conference Prepares Attendees to Meet with US Congressional Legislators

Attendees will have the opportunity to discuss important issues with their Congressional representatives and learn the latest on pharmacy regulation during the 2007 NABP Fall Legislative Conference, to be held September 16-18, 2007, at the Hyatt Regency Crystal City in Arlington, VA. In addition, Legislative Conference participants may earn up to 4.5 contact hours (0.45 CEUs) of Accreditation Council for Pharmacy Education (ACPE)-approved continuing education (CE) credit.

Held every four years, the Legislative Conference focuses on current legislative issues relating to the protection of public health and prepares attendees for a successful meeting with their Congressional representatives at Capitol Hill. Attendees will have the afternoons of September 17 and September 18 open to allow for time to meet with their Congressional representatives and are encouraged to schedule appointments in advance of the Conference. State senator contact information can be located on the United States Senate Web site at www.senate.gov and local representatives can be found on the US House of Representatives Web site at www.house.gov.

Conference Programming

To further equip attendees with the tools and knowledge to have successful meetings with lawmakers, NABP has developed three sessions that will focus on how to effectively speak with members of the Senate and the US House of Representatives. These sessions include “The Federal Legislative Process: Understanding the Beltway”; “Meeting Your Congressional Leadership: Tools for a Successful Encounter”; and “111th Congress and the New Administration: What to Expect.”

In addition, the ACPE-approved CE sessions led by educators, regulators, and other pharmacy regulatory experts will provide attendees with an understanding of current health care related and regulatory efforts. These sessions include “Legislative and Regulatory Update”; “Roundtable Discussion: Political Platforms Meet Current Issues in Pharmacy Regulation”; and “Building the Infrastructure for Health Information Exchange.”

NABP staff will be available to assist attendees on an individual basis to apply for CLE credit for attending conference CE sessions. To apply for CLE credit, attendees must initiate the program approval process in their own states by completing and submitting the appropriate application materials and forms. NABP will provide documentation as necessary.

Hotel and Transportation

NABP has confirmed a special meeting rate at the Hyatt Regency Crystal City of $197 single/double occupancy plus applicable state and local taxes per night. Room reservations may be made by contacting the Hyatt Regency Crystal City at 703/418-1234; utilizing the hotel’s central reservations number at 1-888/591-1234; or online through the group room reservation rate link, which is located on the NABP Web site under Meetings. Be sure to mention that you will be attending the NABP Fall Legislative Conference. To ensure accommodations, the Hyatt Regency Crystal City must receive reservations no later than Friday, August 17, 2007.

For airfare and car rental rates, registrants may contact the NABP official travel agency, Options Travel, at 1-800/544-8785. It is recommended that callers identify themselves as registrants for the NABP Fall Legislative Conference, making certain to mention the NABP meeting code number, FLC07.

To register for additional information on the Fall Legislative Conference please visit the Meetings page on the NABP Web site located at www.nabp.net.
NEWLY ACCREDITED VAWD FACILITIES

The following facilities were recently accredited through the NABP Verified-Accredited Wholesale Distributors® (VAWD®) program:

- Agen USA, Inc
  - Louisville, KY
  - Accredited April 26, 2007
- Cardinal Health 105, Inc dba Specialty Pharmaceutical Services
  - La Vergne, TN
  - Accredited April 26, 2007
- Cardinal Health 110 dba Cardinal Health
  - St Charles, MO
  - Accredited May 10, 2007
- Corporate Services, Inc
  - South Bend, IN
  - Accredited May 24, 2007
- CVS Conroe TX Distribution, LP
  - Conroe, TX
  - Accredited May 10, 2007
- CVS Texas Distribution, LP
  - Ennis, TX
  - Accredited May 8, 2007
- Durby Dental Supply, LLC
  - Reno, NV
  - Accredited May 24, 2007
- Express Scripts Specialty Distribution Services, Inc
  - Maryland Heights, MO
  - Accredited May 10, 2007
- Kenco Knoxville
  - Knoxville, TN
  - Accredited May 15, 2007
- Kenco Logistics, Inc
  - Durham, NC
  - Accredited May 10, 2007
- Masters Pharmaceutical, Inc
  - Cincinnati, OH
  - Accredited May 10, 2007
- McKesson Medical-Surgical, Inc
  - Glendale Heights, IL
  - Accredited April 12, 2007
- McKesson Medical-Surgical Minnesota Supply, Inc
  - Grove City, OH
  - Accredited May 8, 2007
- MWI Veterinary Supply Co
  - Holland, MI
  - Accredited May 15, 2007
  - Aurora, CO
  - Accredited May 8, 2007
- Miami-Luken, Inc
  - Springboro, OH
  - Accredited May 24, 2007
- Midwest Med Specialties, Inc
  - Loogootee, IN
  - Accredited May 8, 2007
- MD Logistics, Inc
  - Plainfield, IN
  - Accredited April 26, 2007
- Ortho-McNeil Pharmaceutical Inc dba JOM Pharmaceutical Services
  - Bridgewater, NJ
  - Somerset, NJ
  - Accredited May 8, 2007
- Ozburn-Hessey Logistics, LLC
  - Plainfield, IN
  - Accredited May 10, 2007
- Pharmacy Buying Association
  - Riverside, MO
  - Accredited May 24, 2007
- Phoenix Marketing Group, LLC dba Phoenix Sampling Group
  - Lincoln Park, NJ
  - Towaco, NJ
  - Accredited May 8, 2007
- Redi-L Corporation dba Redi-Mail Direct Marketing
  - Fairfield, NJ
  - Accredited May 15, 2007
- SmithKline Beecham Corporation dba GlaxoSmithKline
  - Durham, NC
  - Knoxville, TN
  - Accredited May 15, 2007
- South Pointe Wholesale, Inc
  - Glasgow, KY
  - Accredited May 10, 2007
- Stericycle, Inc
  - Conyers, GA
  - Accredited April 19, 2007
- Walgreen Company
  - Jupiter, FL
  - Accredited May 10, 2007

A full listing of accredited VAWD facilities can be found on the NABP Web site at www.nabp.net.

Legal Briefs

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The expertise of the Board of Pharmacy in identifying appropriate relationships between prescribing practitioners and patients as related to pharmacy practice.

Substantiating the validity of the rule and the authority of the Board of Pharmacy, the court noted the existence of a rule adopted by the medical board establishing that it is unprofessional conduct to issue a prescription without a valid preexisting patient-practitioner relationship as further buttressing its opinion.

Finally, the court held that the language in the rule was not vague in that it clearly identifies expectations in terms understandable to trained professionals involved in the prescribing and dispensing of dangerous drugs. The court rejected arguments that “valid preexisting patient-practitioner relationship” and “Internet based questionnaire, Internet based consultation, and telephonic consultation” were impermissibly vague. Thus, the court held that the rule promulgated by the board was valid.

This case illustrates the numerous procedural issues involved in board promulgation of a rule, layered on top of the complexities of regulating pharmacy practice in an evolving technological society. Boards of pharmacy are encouraged to understand the procedural aspects of undertaking board operations and encouraged to aggressively pursue regulatory issues involving Internet activities.

NCC MERP Wins APhA Pinnacle Award for Contributions to Health Care Quality through Medication Use Process

The American Pharmacists Association (APhA) Foundation named the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) the winner of its 2007 Pinnacle Awards in the agency/association category for its contributions to health care quality through the medication use process.

The Pinnacle Awards recognize individuals and organizations for pioneering innovative ways to improve the medication use process, reduce medication errors, improve patient outcomes, and increase communication among all members of the health care team. The award was presented on June 12, 2007, at the Andrew W. Mellon Auditorium in Washington, DC.

United States Pharmacopeia (USP) spearheaded the formation of NCC MERP in 1995, bringing together health care organizations to meet, collaborate, and cooperate to address the interdisciplinary causes of errors and to promote the safe use of medications. Since then, NCC MERP has evolved to become a well-respected partner in patient safety and is credited for several major accomplishments in this arena:

- Development of a standardized definition of “medication error” that has been widely adopted by the Centers for Medicare and Medicaid Services, Food and Drug Administration, USP, and others;
- Development of a taxonomy of medication errors that is widely requested by hospitals and other health care establishments;
- Development of a severity category index of medication errors;
- Issuance of 11 sets of recommendations directed to health professionals in an effort to prevent medication errors and focus on safe prescribing, labeling and packaging, dispensing, administering and reporting of errors;
- Planning and convening two invitational conferences that focused on controversial, important public health issues (standardization of barcodes on medication packages and containers, and standardization of suffix use with drug nomenclature);
- In concert with 93 state and national associations, the council signed on to a set of general principles supporting legislation to uphold as privileged that information submitted to error reporting programs. These principles were incorporated into the Patient Safety and Quality Improvement Act of 2005.
- A founding member of NCC MERP and a current member of its steering committee, NABP helped the council celebrate its 10th anniversary in 2005, offering congratulations and accolades in the NCC MERP 10-year anniversary report, and noting the council’s affinity with the mission of NABP and the state boards of pharmacy.

“Patient safety is a priority that NCC MERP and NABP share. The Association commends NCC MERP for its commitment and dedication in developing many recommendations that have benefited patients and health care communities . . .”

“NCC MERP’s philosophy of examining and evaluating the cause of medication errors, encouraging reporting of those errors, and heightening awareness of reporting systems has an underlying patient safety theme, which is consistent with NABP’s mission of aiding its member boards of pharmacy in developing, implementing, and enforcing uniform standards in the interest of protecting the public health,” NABP states in the anniversary report.

“Patient safety is a priority that NCC MERP and NABP share. The Association commends NCC MERP for its commitment and dedication in developing many recommendations that have benefited patients and health care communities and its efforts to disseminate information to colleges, the medical and pharmacy profession, and professional associations.”

Conscience Clause
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contraception, no matter what the wishes of the pharmacy owner? Are pharmacy technicians covered under existing conscience clauses or Board regulations? Amidst the changing regulatory landscape, one thing is certain: the boards of pharmacy will be kept busy upholding the laws that are passed and providing guidance to the pharmacists they regulate, joining the many stakeholders looking for the proper balance between pharmacists’ rights of conscience and their duty to their patients.
nabp newsletter

FDA Cracks Down on Marketing of Unapproved Timed-Release Guaiifenesin

Food and Drug Administration (FDA) recently announced that it will take action against companies that market unapproved drug products that contain guaiifenesin in timed-release dosage form.

Approximately 20 firms make timed-release products containing guaiifenesin that have not undergone FDA review and as a result are considered by the agency to be unapproved drugs. Timed-release drugs require FDA approval because the FDA must ensure that the product releases its active ingredients safely and effectively, sustaining the intended effect over the entire time in which the product is intended to work.

To date, only Adams Respiratory Therapeutics has obtained FDA approval for timed-release products containing guaiifenesin (600 mg and 1200 mg) under the trade names of Mucinex® and Humibid®. This action does not affect products containing guaiifenesin in immediate release form.

This action is part of a broader initiative that FDA launched in June 2006 targeting marketed unapproved drugs with potential safety risks, that lack evidence of effectiveness, and that constitute health fraud.


Pergolide Ban Worries Veterinarians, Horse Owners

The removal of pergolide drug products from the market due to their potential for cardiac side effects in humans has raised concerns for veterinarians and horse owners.

Aside from managing Parkinson’s disease in humans, pergolide is used to treat Cushing’s syndrome in horses. Veterinarians have been prescribing the drug under the provisions of the Animal Medicinal Drug Use Clarification Act, which allows veterinary practitioners to prescribe approved human drugs for “extralabel” use in animals.

FDA is working to ensure that pergolide remains available to treat Cushing’s syndrome in horses until a new animal drug application is approved for that use. FDA advises that bulk substance used for pharmacy compounding should be labeled for “animal use only,” and that all pharmacy compounding must be done under a valid veterinary prescription to treat an affected horse.

The Center for Veterinary Medicine announced that it will work with sponsors to seek approval of a new animal drug application for the use of pergolide to treat Cushing’s syndrome in horses.

More information is available on the FDA Web site at www.fda.gov. (continued on page 127)

NABP Seeks Item Writers for all Examinations

NABP is seeking item writers for its licensure and certification examination programs. State board of pharmacy members, pharmacists in all areas of practice, and faculty from schools and colleges of pharmacy are encouraged to apply. Pharmacists chosen to serve as item writers must hold active unrestricted licenses in any state or territory of the United States and will have their licenses verified through the NABP Disciplinary Clearinghouse.

Interested individuals should mail or fax letters of interest indicating their current practice/educational settings, specialties/certifications, and years of experience, along with a resume or curriculum vitae to NABP Executive Director/Senator Carmen A. Catizone, at 1600 Beechwood Drive, Mount Prospect, IL 60056; fax 847/391-4502. Applications are accepted on a continual basis and kept on file for a period of five years.

Item writers will be selected based on the specific needs of the programs. Those who are chosen will be asked to attend a workshop at NABP Headquarters with travel and lodging expenses paid by NABP. These workshops occur several times per year and are typically held on a weekend. Attendees will receive detailed instructions and training materials describing the item-writing process and content-related requirements for their designated examination (North American Pharmacist Licensure Examination™, Multistate Pharmacy Jurisprudence Examination®, or Foreign Pharmacy Graduate Equivalency Examination®).

Item writers will then be asked to develop new test items that will be considered for inclusion in NABP licensure and certification examination programs.

For more information about item writing, contact NABP at custserv@nabp.net.
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August 2007

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Current as of July 20, 2007
Professional Affairs Update

(continued from page 124)

site at www.fda.gov/cvm/pergolide.htm.

FDA Nabs Tainted Toothpaste Shipment,
Issues Import Alert

FDA recently warned consumers to avoid using toothpaste made in China and issued an import alert to prevent toothpaste containing diethylene glycol (DEG) from entering the United States.

While FDA is not aware of any US reports of poisonings from toothpaste containing DEG, the agency is concerned about potential risks from chronic exposure to DEG and exposure to DEG in certain populations, such as children and individuals with kidney or liver disease.

FDA has identified the following brands of toothpaste from China that contain DEG and are included in the import alert: Cooldent Fluoride; Cooldent Spearmint; Cooldent ICE; Dr. Cool, Everfresh Toothpaste; Superdent Toothpaste; Clean Rite Toothpaste; Oralmax Extreme; Oral Bright Fresh Spearmint Flavor; Bright Max Peppermint Flavor; ShiR Fresh Mint Fluoride Paste; DentaPro; DentaKleen; and DentaKleen Junior. Manufacturers of these products are Goldcredit International Enterprises Ltd; Goldcredit International Trading Co Ltd; and Suzhou City Jinmao Daily Chemicals Co Ltd.

Based on reports of contaminated toothpaste from China found in several countries, including Panama, FDA increased its scrutiny and began sampling toothpaste and other dental products manufactured in China that were imported into the US. FDA inspectors identified and detained one shipment of toothpaste at the US border, containing approximately 3% DEG by weight.

In addition, FDA inspectors found and tested toothpaste products from China located at a distribution center and a retail store. The highest level found was between 3% and 4%. The product at the retail store was not labeled as containing DEG but was found to contain the substance.

The import alert is posted on the FDA Web site at www.fda.gov/ora/ia/ia6674.html.

FDA Advises Glycerin Testing to Prevent DEG Poisoning

Spurred to action by repeated instances of DEG poisoning, FDA recently issued a guidance for industry entitled “Testing of Glycerin for Diethylene Glycol.”

This guidance provides recommendations on testing that will help pharmaceutical manufacturers, repackers, and other suppliers of glycerin, and pharmacists who engage in drug compounding to avoid the use of glycerin that is contaminated with DEG and prevent incidents of DEG poisoning. DEG contamination of glycerin can be detected by using specific analytical test procedures described in the US Pharmacopeia monograph for glycerin, which quantifies the amount of DEG present at a detection level of 0.1%, as recommended by the interagency Diethylene Glycol Contamination Prevention Workshop of 1997.

The guidance is available on the FDA Web site at www.fda.gov/cder/guidance/7654fnl.htm.

Around the Association

Board Member Appointments:

Karen S. Braman, RPh, MSW, was appointed a member of the Kansas State Board of Pharmacy, replacing Max Heidrick. Braman’s appointment will expire on April 30, 2010.

Frank A. Whitchurch, RPh, was appointed a member of the Kansas State Board of Pharmacy, replacing Merlin McFarland. Whitchurch’s appointment will expire on April 30, 2010.

Karen Bergrud, RPh, was appointed a member of the Minnesota Board of Pharmacy, replacing Vernon A. Kassekert. Bergrud’s appointment will expire on January 1, 2011.

Board Member Reappointment

Alison Kay McManus, RPh, has been reappointed as a member of the Wyoming State Board of Pharmacy. Her term expires March 1, 2013.
Reminder
Visit www.nabp.net to register for the 2007 NABP Fall Legislative Conference to be held September 16-18, 2007, at the Hyatt Regency Crystal City in Arlington, VA.