It is hard to believe that 2010 is almost half over, and that ASPL is in its 36th year as a Society! I am honored to have the opportunity to serve as the Society's president, and grateful for all the hard work past officers and board members who served before me, allowing the Society to grow to where we are today. In addition to welcoming the new Board of Directors, I wanted to thank our outgoing President (now Past-President) John Cronin and outgoing Past President Jay Campbell for all their help during my year as President-Elect. I also look forward to working closely this year with our new President-Elect, Frank Palumbo.

I am lucky to step in as President after a financially successful year for ASPL, as reported at the ASPL annual meeting in Washington, DC in March. This success was due to the hard work and commitment of the Board of Directors, our committees, our Executive Director, and of course, all our members. However, the Board realizes we can't take this success for granted – we need to continue to work toward finding additional ways to pursue our Vision of being “The first and best source for information on pharmacy law.”

Over the past year, John Cronin took the lead in developing a new strategic plan for ASPL that identified specific priorities to help the Society continue to grow and remain successful. My main goal this upcoming year is to move a number of these priorities forward, including increasing our exposure with other national pharmacy organizations, and enhancing benefits for our members, especially on our website. To help with this initiative, in addition to the regular standing

The DEA has issued an interim final rule on e-prescribing of controlled substances, which was published in the Federal Register on March 31, 2010. The rule, which is set forth in 21 CFR § 1311, subpart C, will take effect following a 60-day comment period and Congressional review.


### Processing of e-prescriptions for controlled substances

Pharmacies will be able to process electronic prescriptions only if all the following conditions are met:

1. The pharmacy computer application must comply with the requirements of the rule; and
2. The prescription was issued in conformity with the requirements of the rule and all other requirements for prescriptions in the CSA.

All of the pharmacist’s responsibilities to assure the validity of the prescription apply to e-prescriptions as well as to other prescriptions.

The practitioner’s electronic signature must be verified by two of the following forms of authentication: (1) a biometric – something the practitioner is (e.g., iris scan, fingerprint), (2) a knowledge factor – something only the practitioner knows (e.g., password or response to a challenge question), or (3) a device separate from the computer – something the practitioner has (i.e., a hard token).

The rule creates two types of practitioners: individual and institutional. Depending on the category, it details specific requirements by which the practitioner receives the forms of authentication to be used in issuing e-prescriptions, as well as the responsibilities for the clinic or institution in which the practitioner issues e-prescriptions.

### Practitioners must

1. Retain sole possession of the hard token, if used, and must not share the password or biometric information with any other person, and must not allow any other person to use the token or enter the knowledge factor or ID means to sign prescriptions.
2. Notify responsible individuals within the practice or institution within 1 business day of discovery when the hard token has been lost, stolen, or compromised, or when the authorization protocol has otherwise been compromised.
3. If notified that an e-prescription was not successfully received by the intended pharmacy, insure that any replacement paper or oral prescription indicates that the order was originally transmitted to a particular pharmacy and that the transmission failed.
4. Cease using the application if it becomes apparent or known that the application is no longer qualified under the rule or is not fully functional.
5. Notify responsible individuals of any prescriptions discovered to be issued without his or her signature or were not consistent with prescriptions he or she signed.
6. Retain responsibility to assure that prescriptions are issued only for a legitimate medical purpose while acting within the usual course of professional practice. If an agent enters data into the application prior to the practitioner’s digital signing of the prescription, he or she retains responsibility for assuring that the prescription conforms to law and regulations.

Individual practitioners must obtain a two-factor authentication credential from either a government-approved credential service provider, or use a digital certificate from a certification authority that meets requirements of the Federal Bridge Certification Authority.

The credential provider will assure the identity of the practitioner by requiring appropriate identity proofing information. Prescriptions sent digitally to pharmacies will either be digitally signed, or will bear an indication via a digital certificate to have been digitally signed.

**Pharmacies must:**

1. Determine that the pharmacy application has been certified by a third-party auditor or certification organization to accurately and consistently:
   a. Import, store, and display the information required for prescriptions under 21 CFR § 1306.05(a);
   b. Import, store, and display the indication of signing as required by the e-prescribing rule;
   c. Import, store and display the number of refills as required by 21 CFR § 1306.22;
   d. Import, store, and verify the practitioner’s digital signature, as provided in the rule, when applicable.
2. Discontinue processing of e-prescriptions for controlled substances if the auditor or certification organization has found that the application does not function as required or no longer qualifies, or if notified that the application is not in compliance.
3. When notified by an auditor or certification organization that the application is not in compliance, then cease using the application.
4. When a pharmacist fills a prescription in a manner that would require a notation if the prescription were a paper prescription, the pharmacy must allow the pharmacist to make and retain such notations electronically. Prescriptions received electronically must be retained electronically.
5. When a pharmacist receives a paper or oral prescription that indicates it was originally transmitted electronically to the pharmacy by the practitioner, the pharmacy must allow the pharmacist to ensure the e-version was not received. If both prescriptions were received, one must be marked void.
6. When a pharmacist receives a paper or oral prescription indicating that it was originally e-transmitted to another pharmacy, he or she must contact that pharmacy to determine whether that pharmacy received and/or dispensed the prescription. The pharmacy that did not dispense the received prescription must mark the prescription void.
7. The pharmacist retains the corresponding responsibility to insure that all prescriptions dispensed were issued for a legitimate medical purpose in the due course of the prescriber’s practice.

The rule also sets forth extensive requirements for application vendors, service providers, and for the characteristics of the applications that either transmit or receive e-prescriptions.

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**Recent Law Review Articles of Interest to ASPL Members**

- Smith DG. Preemption after Wyeth v. Levine. 70 Ohio St. L. J. 1435 (2009)
- Owen D. Dangers in prescription drugs: filling a private law gap in the healthcare debate. 42 Conn. L. Rev. 733 (2010 February)
- Altilio JV. The pharmacist’s obligations to patients: dependent or independent of the physician’s obligations? 37 J. L. Med. & Ethics 358 (2009 Summer)
- Spreng JE. The Food and Drug Administration and the pharmacy profession: partners to ensure the safety and efficacy of pharmacogenomic therapy. 13 J. Health Care L. & Pol’y 77 (2010)
- Strong A. “But he told me it was safe!”: the expanding tort of negligent misrepresentation. 40 U. Mem. L. Rev. 105 (2009 Fall)
- Mau JR. Stormans and the pharmacists: where have all the conscientious Rx gone? 114 Penn St. L. Rev. 293 (2009 Summer)
May a Pharmacist be Liable for his or her Choice of Generic Product?


By Roger Morris, BS Pharm, JD

In February, the U.S. District Court for the Southern District of New York rejected a plaintiff’s claim that a pharmacy can be held liable for dispensing the “less safe” of two competing products, even when the pharmacy filled the prescription as directed and both products are approved by the Food and Drug Administration (“FDA”).

The plaintiff, Jeffrey Winters, originally sued Alza Corp., Sandoz, Inc. and DVS Pharmacy, Inc. in New York state court, alleging that a design flaw in a generic fentanyl patch manufactured by Alza and marketed by Sandoz caused his wife’s fatal overdose. Alza and Sandoz removed the case to federal court.

When Winters sought remand, the defendants argued that DVS Pharmacy was fraudulently joined to defeat diversity jurisdiction. To rule on the motion for remand, the court had to determine whether it was legally possible for Winters to assert a claim against DVS Pharmacy in state court.

In February 2007, Laurie Winters was given a prescription for Duragesic, a brand-name, pain-relieving transdermal patch. On the prescription form, Winter’s physician indicated that the prescription could be filled with a generic version of the Duragesic patch. A DVS pharmacist filled the prescription with the generic Alza/Sandoz fentanyl patch.

The plaintiff alleged that the Alza/Sandoz patch delivered an unsafe level of fentanyl, causing his wife’s death. The plaintiff attributed the problem to a design flaw in the Alza/Sandoz patch. Specifically, the plaintiff asserted that the Alza/Sandoz patch employed an inferior “reservoir” design, meaning that fentanyl gel was stored in a reservoir between two layers of the patch, which allowed gel to leak out. The plaintiff contended that other generic fentanyl patches employed “matrix” or “multilaminate” designs which cannot leak. Additionally, the plaintiff argued that, at the time the prescription was dispensed, there had been at least one highly-publicized recall of leaking Alza patches, such that the pharmacy should have known the patch was defective because of its susceptibility to leaks and inferior to other fentanyl patches.

According to the court, the plaintiff’s case hinged on whether he could state a claim that DVS Pharmacy was negligent in filling the prescription as directed and dispensing the FDA-approved Alza/Sandoz patch to Laurie Winters. The court began its discussion by observing that “a pharmacist generally cannot be held liable for negligence under New York law in the absence of an allegation that he either failed to fill a prescription precisely as directed or was aware that the customer had a condition rendering prescription of the drug contraindicated.” The court noted that the plaintiff maintained that New York law also imposed a duty to fill a prescription with the safer of two competing products – even when both are approved by the FDA. But, the court said, the plaintiff had failed to cite a single case in any jurisdiction in which a court had used this theory to find a pharmacy liable for negligence.

Additionally, the court noted that the plaintiff’s theory was inconsistent with the longstanding “Generic Drug Laws” in New York that preclude lawsuits against physicians who authorize generic substitution for brand-name drugs. The court asserted that it would make little sense for a pharmacist to be held liable for dispensing a generic fentanyl patch when the physician who wrote the prescription could not be held liable. Finally, the court observed that the plaintiff’s theory lacked any convincing public policy rationale. Demanding that pharmacies ensure the complete safety of any drug they dispense – even when the deficiency is the result of an intrinsic design flaw – would place pharmacies on par with drug manufacturers in terms of tort liability. That is wrong as a matter of law, the court declared, and “would impose a duty on pharmacists that is grossly disproportional to their limited degree of expertise – which entails competently dispensing drugs as directed, with appropriate instructions for customers, while monitoring for potential contraindications.”

Noting that in this case the pharmacist had filled the prescription as directed, with an FDA-approved product, in accordance with the manufacturer’s prescribing information, the court stated that it could find no valid reason for finding the pharmacy negligent for “inadequately second-guessing the FDA.” As such, the court concluded that it was impossible for the plaintiff to state a claim for negligence against DVS Pharmacy in state court and, consequently, denied the motion for remand and dismissed DVS Pharmacy from the suit.

Roger Morris is Chairman of Quarles & Brady’s Health Law Group

President’s Message...

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committees, we are also starting a Technology and Website Ad-hoc Committee to work with our Executive Director on revamping our website.

The Board encourages all members to be active and if possible help us help you! Many of our members may be involved with other national pharmacy organizations - please feel free to contact us to discuss the possibility of having more exposure with them. Also, membership is key for our Society. We value our members, and hope everyone sees the many benefits of ASPL. We also ask that you share information about us with others that may be interested in becoming a member. And please don’t forget, feel free to contact us at any time with your ideas of how we can continue to grow and improve.

Lastly, don’t forget to mark your calendar for this year’s fall meeting in La Quinta, California. Like last year, the fall meeting will be in cooperation with NASPA. I personally always look forward to the fall meeting – not only for the timely and informative educational programs, but also for the opportunity to catch up with colleagues.

On behalf of myself, and all the members of the Board of Directors, we look forward to ASPL having another successful year!
Mark Your Calendar:

November 18-21, 2010

Developments in Pharmacy Law Seminar XXI
In Conjunction with National Alliance of State Pharmacy Associations
LaQuinta Resort & Club - Palm Springs, California

Sponsored by American Society for Pharmacy Law
Watch for information at www.aspl.org.