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President's Message

William Stilling
ASPL President

"And in the end..."
McCartney & Lennon.

I expected this brief quote would trigger an immediate recollection of the tune and words only for readers from a particular generation. It is, after all, approaching fifty years ago when they were recorded. But my initial impression was wrong. I realize my children would also recognize this short phrase and place it musically in exactly the correct spot. Just as many who recognize this quote were not born at its creation, many who read this issue were not born when ASPL came into being. As I near the end of my term as ASPL president, it seems apropos to reflect on the fact that ASPL now spans at least two generations and about some of the changes that have occurred over that span.

It was forty years ago when Joe Fink invited a group of pharmacist-attorneys to meet in Chicago at the annual APhA meeting. Dr. Fink's research had revealed 134 pharmacist-attorneys and 26 pharmacists enrolled in law school at that time. This group constituted the initial mailing list for that 1974 meeting. Seventeen people attended and developed the objectives of ASPL, which can still be found on ASPL's website along with a history of ASPL by Joe Fink from which I draw this information.

Since 1975, ASPL has had a relationship with APhA and continues to cosponsor and organize continuing education programs focusing on legal issues at the annual APhA meeting. This year's meeting is in Orlando from March 28 through 31. ASPL has organized twelve hours of such programs with an additional six hours of regulatory updates provided by APhA.

Interestingly, the first objective the group developed at the 1974 APhA meeting, "[c]ommunicating accurate legal information to pharmacists," resulted from what had been perceived as the exaggeration by some of the effect of a U.S. Supreme Court decision

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FDA Warning Letters under New Compounding Pharmacy Law Emphasize Registration

By Lee Rosebush and Cory J. Fox

The US Food and Drug Administration's (FDA) recently issued its first two warning letters[1] to compounding pharmacies in Arizona and North Carolina pursuant to its expanded oversight authority under the recently enacted Drug Quality and Security Act (DQSA), and these letters may help to clarify the DQSA's impact on compounding pharmacies and outsourcing facilities nationwide.

The DQSA, which was signed into law on November 27, 2013 as part of a bi-partisan effort to bolster FDA oversight of compounding pharmacies in the wake of events involving meningitis and compounded drugs in 2012, created a voluntary registration process by which facilities wishing to engage in certain compounding activities, including compounding medications without a prescription, could register with the FDA as "outsourcing facilities." Drugs compounded by licensed pharmacists at registered outsourcing facilities are exempt from certain Food, Drug, and Cosmetic Act (FDCA) requirements under the DQSA, including the FDCA's adequate directions for use provisions, new drug requirements, and drug tracing provisions. However, in order to qualify for these exemptions, outsourcing facilities must voluntarily pay registration fees, adhere to specific labeling and reporting requirements, and undergo periodic inspections. Drugs compounded by entities that choose not to register as outsourcing facilities can also be exempt from FDCA requirements, but only if they are compounded pursuant to a prescription or, in some circumstances, in reasonable anticipation of receiving a prescription—a practice known as "anticipatory compounding."

Almost immediately after adoption of the DQSA, the FDA released three guidance documents[2] intended to clarify the newly adopted provisions. But questions still remained as to whether compounding pharmacies would choose to register as outsourcing facilities, especially given the prospective fees, inspections, and labeling obligations associated with registration. Unlike prior legislative proposals that would have required compounding pharmacies to register as outsourcing facilities based on the percentage of overall compounded sterile drug product shipped interstate, registration is voluntary under the DQSA. In an effort to encourage outsourcing facility registration, FDA Commissioner Margaret A. Hamburg sent open letters[3] to hospital purchasers and state officials on January 8, 2014, urging them to require the compounding pharmacies that supply drugs to their facilities to register as outsourcing facilities. Despite these efforts, prior

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ASPL 2014-2015 Election Results

ASPL is pleased to announce the results of the 2014-2015 elections.

Steve Gray, President-elect – Brian Guthrie, Director – Karen Peterson, Director

The new officers and directors will be installed at the ASPL board meeting on March 28, 2014 during the APhA annual meeting in Orlando. They will be joining Laura Carpenter who will become president, Bill Stilling who will become past president, James Boyd, treasurer, and Aaron Moore and Michael Yount current directors. Leaving the Board will be Donna Horn, current past president.

Thank you to all who voted.

Featured Case

Tenth Circuit Affirms Misbranding Conviction for Operator of Online Pharmacy Located on Tribal Land

United States v. Zachary C. Williams, No. 12-6097, 2013 WL 6501333 (10th Cir. Dec. 12, 2013)

By Chris Dang and Roger Morris

The Tenth Circuit Court of Appeals upheld a Food Drug and Cosmetic Act (FDCA) misbranding conviction against a non-pharmacist operator of an online pharmacy located on tribal land. The court held that the jury need not determine that the dispensed prescriptions lacked "directions for use" since the drugs themselves were dispensed by non-pharmacists. Accordingly, no label would have satisfied the FDCA's requirements. In addition, the court rejected the defendant's contention that the jury instructions were defective and that he was immune from federal prosecution due to tribal sovereign immunity.

Defendant Zachary Williams was the operator of White Eagle Pharmacy, an online fulfillment pharmacy located on the Ponca Tribe Indian Reservation in Oklahoma. Mr. Williams himself was not a licensed pharmacist. Nevertheless, Williams appeared before the tribe's governing body and proposed that his company operate a tribal-owned pharmacy on tribal land. In return, the pharmacy would pay the tribe fifty cents for every prescription filled and hire tribal members as pharmacy employees. Williams also suggested that the tribe adopt a pharmacy act and issue pharmacy licenses. Williams provided a draft pharmacy act which he represented as being similar to Oklahoma's Pharmacy Act. Williams also told the governing body that a licensed pharmacist would be on duty at the pharmacy at all times.

The tribe adopted Williams' draft pharmacy act, issued a pharmacy license to him, and, on June 19, 2009, entered into a pharmacy management and administrative services agreement with him to operate White Eagle Pharmacy.

That same year, White Eagle pharmacy began contracting with companies to fill batch prescriptions. The companies operated online pharmacies where customers from different states completed online questionnaires detailing their ailments. A physician in Puerto Rico would then review the questionnaire and write prescriptions. No physical exam or in person interview was performed. Williams then filled the online prescription drug orders, primarily for Soma, Tramadol, and Fioricet, without the presence or authorization of a licensed pharmacist. Rather, Williams had employees count pills into bottles and ship the filled bottles directly to customers.

In a December 8, 2010 amended indictment, Williams was charged in federal district court with one count of conspiracy to distribute Fioricet, a controlled substance in violation of 21 U.S.C. §§ 841(h)(1), 846; one count of conspiracy to misbrand prescription drugs Fioricet, Soma, and Tramadol in violation of 21 U.S.C. §§ 331(a), 331(k); and four counts of distributing and aiding and abetting distribution of Fioricet via Fed-Ex shipment in violation of 21 U.S.C. § 841(a) and 18 U.S.C. § 2. The jury subsequently found Williams guilty on count 2, conspiracy to distribute misbranded Fioricet, Soma, and Tramadol in violation of the FDCA.

Williams' Appeal

On appeal, Williams argued that the definitions of "valid prescription" and "online pharmacy" offered in the jury instructions were confusing or improperly applied, that he was immune from prosecution due to tribal sovereign immunity, and, in particular, that his Fifth Amendment rights were violated when the misbranding charge was constructively amended.

Williams asserted that the evidence presented at trial and the jury instructions regarding the misbranding charge constructively amended the indictment to eliminate the requirement that the government show that Williams' drugs were distributed without a label "bearing adequate directions for use." To back this argument, Williams pointed to the fact that the government failed to present any evidence that adequate directions for use *were not* included on the labels affixed to White Eagle's prescription bottles. Further, Williams pointed to the jury instruction on the misbranding charge which stated:

Federal law provides that prescription drugs, such as Fioricet, Soma and Tramadol, are misbranded if they are not in the possession of a retail pharmacy regularly and lawfully engaged in the dispensing of prescription drugs, or if the drugs are not dispensed pursuant to a valid prescription.

In Williams' eyes, the FDCA required the government to literally show that the drugs he dispensed were devoid of "adequate directions for use."

The Tenth Circuit Court of Appeals rejected Williams' argument, stating that the argument reflected a misunderstanding of the FDCA. Namely, the FDCA starts with the position that prescription drugs can never satisfy the "adequate directions for use" requirement because they are unsafe for use by laypersons. Criminal liability for misbranding can only be avoided if a prescription drug is lawfully dispensed by a licensed pharmacy or lawfully dispensed by a licensed practitioner authorized to administer or prescribe such drugs. Dispensing pharmacies or practitioners must also ensure that the drug is properly labeled in accordance with 21 C.F.R. § 201.100(b).

In Williams' case, the jury did not need to determine that "directions for use" were absent from the label because it was shown that there was no pharmacist on duty at White Eagle when the drugs were dispensed. Without proper authority to dispense the drugs, there is no label that would have satisfied the requirements under the FDCA. Accordingly, both the indictment and the jury instructions properly established the elements of misbranding.

The Tenth Circuit also held that the definitions offered in the jury instructions were properly explained, rejected Williams' claims of tribal sovereign immunity as unsubstantiated, and ultimately affirmed his misbranding conviction.

Christopher T. Dang, JD is an associate in Quarles & Brady's Health Law group in Phoenix, and Roger N. Morris, BSPharm, JD, is member of the Executive Committee and chairman of the Health & Life Sciences Industry Group at Quarles & Brady in Phoenix.

Compounding Pharmacy Law

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to issuance of the first warning letter on January 14, 2014, the FDA's website indicated that less than twenty compounding pharmacies had registered as outsourcing facilities.

It now appears that the FDA may be using its enforcement authority to encourage entities to register as outsourcing facilities. More specifically, the FDA's recently published warning letters indicate that the agency will require entities compounding drugs without a prescription to register as outsourcing facilities. Both warning letters state that the entities involved have been compounding drugs without receiving valid prescriptions for individually identifiable patients, and that only registered outsourcing facilities can engage in such activities. The letters also identify several Good Manufacturing Practice (GMP) issues that the entities must correct.

While both letters were issued based on inspections conducted prior to passage of the DQSA, there has been a recent push in Washington to use enforcement mechanisms to persuade entities to register with the FDA. Interestingly, in the warning letters, the FDA acknowledged the uncertainty surrounding compounding pharmacy regulation that existed at the time of the inspections. In addition, both letters include a footnote stating that they are not intended to address anticipatory compounding. Nonetheless, the FDA makes clear in both warning letters that entities must register as outsourcing facilities in order to compound drug products without a prescription. At least one of the two compounding pharmacies receiving a warning letter, Avella of Deer Valley, Inc., has stated that it intends to register as an outsourcing facility.

Whether and to what extent these warning letters will impact outsourcing facility registration remains to be seen, but the warning letters appear to be just one part of a broader effort by the FDA to encourage outsourcing facility registration. Entities that compound drugs in bulk without a prescription should carefully consider registering as an outsourcing facility in order to avoid potential FDA enforcement actions.

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1. *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm*
2. *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm*
3. *http://www.hpm.com/pdf/blog/FDA%20compounding%20letter%20to%20hospitals.pdf*

President's Message

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in 1973, *North Dakota Board of Pharmacy v. Snyder Drug Stores, Inc.* The court held the state did not violate substantive due process by requiring that pharmacies be owned by pharmacists or a business entity with a majority of pharmacists owning it.[1] ASPL is still dedicated to ensuring the information it provides is accurate and as objective as possible.

Over the last few decades, pharmacy law has burgeoned and much has changed. Pharmacy cases were relatively rare and those who presented the case law updates each year had to scour for enough judicial decisions to fill the time allotted. Now, cases abound and many are omitted so the presentation fits within the allotted time. Today's students are shocked to learn that the majority rule in most states has been that pharmacists are protected by the learned intermediary doctrine, which has been generally held to mean pharmacists have no duty to warn about the drugs they dispense. Yet, that doctrine has been eroded and narrowed by many courts with exceptions that swallow the rule. The common law often lags behind practice, but as one court explained, judicial holdings have been limiting the scope of that rule "to account for the nature of modern pharmacy practice."[2]

Unlike the world of 1974, pharmacists now make key decisions about formularies for benefit plans, provide medication therapy management without dispensing, administer vaccines, and have expanded the scope of compounding to alleviate shortages and optimize therapeutic outcomes. With these expanded roles, the roles for attorneys have also expanded. In 1974, Medicare Part D, HIPAA, OBRA-90, mandatory patient counseling laws, and collaborative practice laws, to name a few, didn't exist. In 1974, the federal Controlled Substances Act was relatively new and few could foresee the imposition of a law enforcement role upon wholesalers, pharmacies, and pharmacists. While "pharmacy law" is still a specialized area, those of us who practice understand that it encompasses a vast range of often conflicting legal concepts and requires an array of skills.

This brings us to ASPL's aspiration to be the first and best source of pharmacy law information. The annual fall conference continues to grow and the feedback from participants demonstrates this program is the one, most relevant conference for their practice. The *Pharma-Law e-News* grows with information about new cases, regulations, and legal developments. ASPL's role at the APhA annual meeting helps educate pharmacists on the front lines to have a better understanding of the legal milieu they inhabit.

In the end, there is no end; there is only transition. So, while my short tenure as ASPL president closes, ASPL transitions to its new president Laura Carpenter, who assumes her role at the APhA meeting in March. ASPL's healthy growth over the last few years appears to be a transition to an organization serving a more diverse group of individuals who must understand pharmacy law. I look forward to being involved in these transitions and I thank ASPL members, the ASPL Board members, committee members, our Executive Director, Nathela Chatara, and her staff for all the work and support they have provided over this last year.

1. One more sign of changes since 1974 is our reliance on the Internet to do research. One site where the opinion can be found, and the site cited by Wikipedia, explains the North Dakota law as requiring ownership by an organization in which "the majority stock is owned by registered pharmacists in goof standing..." http://supreme.justia.com/cases/federal/us/414/156/case.html. The original opinion uses the correct adjective.
2. *Downing v. Hyland Pharmacy*, 194 P.3d 944 (UT 2008).

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ASPL Annual Business Meeting and Reception

Please join us for the ASPL Annual Business Meeting and Reception to be held on Saturday, March 28, from 6:00–7:00 pm in Room Columbia 35 at the Hyatt Regency Hotel in Orlando.

ASPL Pharmacy Law Track at APhA 2014 Annual Meeting & Exposition

ASPL is once again sponsoring a Pharmacy Law track at the 2014 APhA Annual Meeting & Exposition to be held March 28-31, 2014 in Orlando, Florida.

Pharmacy Law Track Sessions

- Case Law Update
- Legislative & Regulatory Update
- Hot Law Topics
- FDA Update
- A Prescription for Negligence
- Civil Liability for Generic Medications
- Ethical & Legal Responsibilities of Pharmacist-in-Charge
- Pharmacy Promotional Activities

For more information go to www.aspl.org

To register for the APhA 2014 meeting, go to www.aphameeting.org.