Hello! I’m Don Bell, the new President of ASPL. I recently took over from Melissa Madigan, our Immediate Past-President. I would be remiss if I didn’t begin my first ASPL column by congratulating Melissa on a job well done. ASPL is as strong and vibrant as ever, and Melissa deserves a great deal of the credit for that. Thank you, Melissa!

In my first column I thought it would be a good idea to discuss six goals to help make ASPL an even better and stronger society:

First, let’s convene the best pharmacy law conference. This year’s conference will be November 9-12, 2006, at the Sanibel Harbour Resort and Spa in Ft. Myers, Florida. The ASPL Education Committee is hard at work developing CE courses and recruiting speakers. Mark your calendars, and stay tuned for more information!

Second, let’s grow the ASPL membership. Do you know a

Continued on page 7

The American Society for Pharmacy Law (ASPL) once again held a successful Annual Meeting in conjunction with the American Pharmacists Association 2006 Annual Meeting in San Francisco, California, March 17-21, 2006. The highlight of the meeting was the presentation of the 2006 Joseph L. Fink, III, Founders Award to Joseph Valentino, former Senior Vice President and General Counsel of the United States Pharmacopeial Convention.

In addition to the presentation of this award, ASPL held its annual business meeting and swore in its new officers and board members. Don Bell was sworn in as president, Kim Keller-Reid was sworn in as president-elect, Bill Fassett as treasurer, and Gary Peters and Laura Carpenter as members of the ASPL Board of Directors. Leaving the Board after several years of dedicated service was Tom George.

Continuing Education Session Reviews
ASPL co-sponsored several pharmacy law-focused continuing education sessions at APhA’s meeting, all of which were well-attended and well-received.

ASPL Contributed Papers Podium Session
ASPL kicked off its APhA sessions Saturday with an exceptional Contributed Papers session. Eight authors presented research papers related to legal issues affecting pharmacy and sparked avid discussion among the attendees. The presentations included:

— Joseph L. Fink, III, BSPharm, JD, Professor of Pharmacy at the University of Kentucky presented “The Evolution Of The Legal Framework For Generic Interchange: Pharmacy And Public Policy.” This presentation explained the political and legal evolution of how states adopted generic substitution laws, and gave insight into current legislative initiatives related to the practice of pharmacy.

— William Fassett, PhD, Professor and former Dean at the Washington State University College of Pharmacy presented “Chain Store Policies And Legal Issues Concerning Legend Drug Transfers Between Pharmacies,” in which
Featured Case

Compliance 101: Developing a Compliance Plan for the Pharmacy Setting
Submitted by: Jennifer N. Willcox, JD

Background on Compliance Plans
Compliance plans have long been a feature of the health care world for many providers. Compliance programs had their beginnings in the federal Sentencing Guidelines, which provide shorter sentences for organizations with effective compliance programs. The Office of the Inspector General (OIG) of the Department of Health and Human Services has issued guidance promoting the adoption of compliance programs for all organizations that receive Medicare, Medicaid and other federal funds. Compliance programs primarily have been a matter of good business sense and risk management, however, and up until now many pharmacies have not invested the resources to develop comprehensive compliance programs.

All of that is soon to change, in light of the new Medicare prescription drug benefit (“Part D”) and the Deficit Reduction Act of 2005 (“DRA”). The increased federal payments to pharmacies under Part D are likely to make pharmacies higher priority targets for compliance enforcement, and recent guidance from CMS on Part D plans’ obligations to prevent fraud, waste and abuse could cause those plans to demand representations about pharmacy compliance plans in their network participation agreements. See CMS’ draft release of the Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse. And under the DRA, for the first time compliance plans are effectively mandated for all entities that receive $5 million or more in Medicaid payments per year.

In light of these changes, many pharmacies and pharmacy chains are reviewing their structure and operations to determine how best to implement a compliance plan. In its simplest form, a compliance program is a legal “check-up” of a pharmacy. It identifies legal requirements that affect the pharmacy’s operations and establishes tools to enable it to stay in compliance with those requirements. A compliance program can be thought of as an organizational tool to help a pharmacy carry out and document its commitment to meeting legal and ethical requirements. Many pharmacies have policies in place to monitor compliance with licensure requirements, or to ensure inventory controls of controlled substances are adequate. Such programs can be expanded to include other compliance-related concerns.

Compliance Plan Elements
Although the OIG has not yet issued compliance program guidance for pharmacies, as it has for other sectors of the health care market, compliance programs generally have the same basic elements that can be tailored to fit the unique needs of a particular organization. As outlined by the OIG and numerous commentators, those elements include:

- The development and distribution of a written code of conduct, as well as written policies and procedures that articulate the organization’s commitment to compliance and address specific risk areas;
- The designation of a compliance officer and, when appropriate, a compliance committee charged with responsibility for developing, operating and monitoring the compliance program, with the authority to report directly to the board of directors;
- The development and implementation of regular and effective training programs for affected employees (note that the DRA requires those pharmacies with $5 million or more in Medicaid business to specifically address the federal False Claims Act and procedures for “whistle-blowing” in such a training program);
- The creation and maintenance of an effective line of communication between all employees and the compliance officer, including a process (such as a hotline or other reporting system) to receive complaints or questions, and the adoption of procedures to protect the anonymity of complainants and protect whistle-blowers from retaliation;

Continued on page 3
• The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas and assist in the reduction of identified problems;
• The development of policies and procedures addressing the pre-hire screening of employees and contractors to ensure they have not been excluded from participation in federal health care programs, and the enforcement of appropriate disciplinary action against employees or contractors who have violated company policies and procedures and/or applicable federal health care program requirements; and
• The development of policies and procedures for the investigation of identified instances of noncompliance or misconduct. These should include directions regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action and preventive measures and processes to report the offense to relevant authorities in appropriate circumstances.

Risk Areas for Pharmacy Compliance Plans
Pharmacies should be alert to problems that have been identified through government audits and investigations of other pharmacies, and include those risk areas in their compliance plan. Such risk areas include:
• Return to Stock/Prescription shorting issues: A number of large pharmacy chains have been investigated and/or sued by state and federal government agencies for charging state Medicaid programs for prescriptions that were not picked up and eventually returned to stock, and for dispensing fewer than the tablets called for by a prescription. The prevalence of these issues at a number of major pharmacy chains suggests that OIG and state Medicaid investigators will continue to police pharmacies’ policies and ongoing practices for accurate filling of prescriptions and reversing any transactions when a script is taken from the will-call bin and returned to stock.
• Marketing and Anti-Kickback issues: Pharmaceutical companies often sponsor “refill reminder” or “patient education” programs which involve the mailing of material to pharmacy customers. The materials remind customers about prescription refills, include ‘lifestyle’ information about the patient’s presumed disease status, and sometimes urge the patient to switch medications. Pharmacies are paid for sending these mailings, and it is this exchange of payment that has resulted in numerous lawsuits and government investigations. Such arrangements present issues under the HIPAA privacy regulations, as well as state and federal anti-kickback statutes, and a compliance plan should include procedures for evaluating all such marketing programs entered into by the pharmacy.
• Theft-prevention, inventory-control and drug pedigree measures: Maintaining accurate records and enforcing effective physical security measures are an important aspect of a compliance plan, given the highly regulated nature of the substances dispensed at a pharmacy. A major pharmacy chain recently paid a multi-million dollar settlement to end a federal investigation relating to inadequate security measures at the chain that allegedly allowed employees to steal prescription drugs from its inventory. Aggressive federal prosecutors, such as Jim Sheehan in Pennsylvania, also have suggested that pharmacies’ failure to police drug pedigrees can, when a prescription is paid for by a Part D plan, constitute a “false claim” warranting imposition of treble damages under the federal False Claims Act.

Conclusion
There is no “one size fits all” compliance plan – such plans can and should be scaled and tailored to the needs and resources of a particular organization. Small community pharmacies may be able to get by with a minimal set of policies and procedures, with the head pharmacist doubling as the compliance officer as well. National chains with greater resources and widely dispersed workforces likely will be held to a higher standard. Start with a commitment by the board of directors or other governing body, develop a timetable for implementation of the compliance plan, allocate adequate resources to the task and consult with expert counsel about any concerns. An effective compliance program can identify problems early, before they become costly, and place the pharmacy in the best defensive position, should a significant error be discovered.

Jennifer N. Willcox, JD
Wiggin and Dana LLP
jwillcox@wiggin.com
Case Law Update
This program’s focus was a discussion of cases involving pharmacy and the pharmaceutical industry decided since the previous APhA Annual Meeting. Trends in pharmacy case law development and extrapolation of these cases into future practice of pharmacy was discussed. The impact of these new cases engendered lively discussion among the participants.

Legislative and Regulatory Update
The Legislative and Regulatory Update this year was presented by APhA staff members Kristina Lunner, Senior Director, Government Affairs, and Susan Winckler, Vice President, Policy and Communications and Staff Counsel, who summarized US Congressional and state legislative activities, as well as federal and state regulatory initiatives that affect pharmacy. Highlighted topics included Medicaid reimbursement, methamphetamine precursor legislation, “duty to fill” and conscience clause legislation, and patient safety legislation. These speakers also brought attendees up to date on US Food and Drug Administration programs, including pharmaceutical risk management programs, anti-counterfeiting efforts, and professional product labeling, as well as programs overseen by the Centers for Medicare and Medicaid Services, including medication therapy management services. As always, this session was well-attended and well-received by all attendees.

Patient Safety Law
Chicago pharmacist-attorney and past-ASPL president Edward Rickert, partner in Smith, Rickert & Smith, provided a large audience with an overview of patient safety legislation, including the salient features of the Patient Safety and Quality Improvement Act of 2005 (PL 109-041). He reviewed the legal risks associated with compiling, maintaining, and reporting medication errors, including the risk that error reports could be used in litigation against a pharmacy or pharmacist. Important cases illustrating these risks were Harco v. Holloway, 669 So.2d. 878 (Ala. 1995), and McClure v. Walgreens, 613 N.W.2d. (Iowa 2000). He then reviewed various peer review statutes, ways in which peer review records are protected, and ways in which peer review records may become discoverable. The specific protections of PL 109-41 were reviewed, along with recommended procedures for securing these protections. Mr. Rickert reviewed
examples of state legislation from CA, CT, FL, KY, MD, WV, NC, and PA, and ended by reviewing other potential methods that have been suggested for protecting quality assurance records including attorney-client privilege, attorney work product, and assertion of undue burden, citing limitations to all of these approaches.

By Bill Fassett, ASPL Board Member

Medicare Implementation Law: Evolving Legal Issues
This session provided an update about legal issues surrounding the implementation of the Medicare drug benefit. The program emphasized the Medication Therapy Management provisions, competition, access to pharmacy standards, and network contracting issues. Participants engaged in discussions regarding the evolving legal, regulatory and guidance issues involving the implementation of key pharmacy-specific provisions of the Medicare Modernization Act (MMA) of 2003.

Pharmacy Employment Law
This session was a review of federal and state laws applicable to the employment of pharmacist, pharmacy technicians and other pharmacy personnel. Employment contracts, employment policies and compensation arrangements and the consequences of each was discussed. Major areas of interest included: minimum wages; overtime pay; privacy requirements, unemployment compensation; and workers injury compensation. Particular attention was paid to describing circumstances whereby an employee might be terminated for refusing fill a lawful prescription.

WALGREEN CO. is seeking a Healthcare Attorney for its corporate offices in Deerfield, IL. Primary responsibilities include the review and provision of advice to Company on corporate and regulatory matters, including federal, state and local laws and regulations, FDA, DEA, FTC, Medicaid and Medicare issues, pharmacy regulations, and local zoning matters, and representing Company on such matters before federal, state and local agencies. Juris doctorate degree and bar licensure required with 3-8 years of practice related to corporate and regulatory matters in retail pharmacy, health care or related field. Walgreens is an equal opportunity employer and welcomes individuals of diverse talents and backgrounds. Fax resume to: R. Delaney, Corp. & Regulatory Law Dept., (847) 315-4660, or email to bob.delaney@walgreens.com.

CVS is a leader in the retail drugstore industry and a Fortune 100 company with $37+ billion in sales and over 5,400 stores nationwide. CVS also operates PharmaCare, a pharmacy benefits management and specialty pharmacy business. Together, CVS companies employ about 140,000 employees in 37 states and Washington, D.C.

We seek Senior Legal Counsel to provide focused legal counsel and advice to PharmaCare as it relates to contractual, corporate, regulatory and other legal matters. Responsibilities will include: the preparation and negotiation of agreements; preparing bids and RFPs; acting as a liaison with corporate counsel on matters affecting business operations; providing counsel and guidance on issues involving health care regulatory matters including federal and state pharmacy practice regulations; and managing litigation matters and outside counsel and providing counsel and advice to management with regard to settlement and strategy.

Qualified candidate must be a graduate of a law school accredited by the American Bar Association, and be admitted to a state bar and currently in good standing. 5-7 years experience in commercial law and litigation experience, as well as 3-5 years Health Regulatory legal experience, are required. Must be a team player with excellent written and verbal communication skills and able to work in a fast-paced atmosphere with minimal supervision.

Please forward your resume, along with salary requirements, to LMCavedon@cvs.com.
Equal Opportunity Employer
Joe Valentino Wins Joseph L. Fink, III, Founders Award

The American Society for Pharmacy Law (ASPL) presented long-time ASPL member Joseph Valentino, RPh, JD, the Joseph L. Fink, III, Founders Award for 2006. The award was presented at the ASPL Annual Meeting, which was held in conjunction with the American Pharmacists Association Annual Meeting, on March 19, 2006, in San Francisco, California.

Dr. Valentino is the former Senior Vice President and General Counsel of the United States Pharmacopeial Convention. Joe has been instrumental in the advancement of pharmacist understanding of compendial activities and has been a role model for many pharmacist-attorneys. Dr. Valentino’s innovation and forward thinking resulted in the establishment of outreach efforts by USP and publication of USPDI and the Pharmacists Pharmacopoeia. One of Dr. Valentino’s nominators stated:

Perhaps the most compelling justification for awarding the Fink Award to Dr. Valentino is his commitment to the advancement of pharmacy law in the United States. Dr. Valentino has contributed to the expansion of the marketplace of ideas concerning the relationship of pharmacy and law. Dr. Valentino is a prolific writer and his contributions to the Pharmacopoeial Forum and other publications have stimulated considerable change in the practice of pharmacy. Dr. Valentino provided leadership and guidance to the United States Pharmacopoeia in the development of its process and publication of the Dispensing Information, a publication ahead of its time from a man whose thinking and actions have always been ahead of his peers.

The Founders Award was established in 2004 to recognize sustained and outstanding service and contributions to the professions of pharmacy and law. It is named for Joseph L. Fink, III, who founded ASPL in 1974 and served as the Society’s first president. It consists of a perpetual plaque kept in the ASPL office with the names of each of the past recipients, as well as an individual award for the recipient.

New Members

Be sure to welcome the following new members:
- Charlotte Byrd, Precision Rx, Fort Worth, TX
- Thomas Cabral, Gallagher Sharp, Cleveland, OH
- Nick Calla, Oncology Pathways, Carnegie, PA
- Jack Campbell, Chapel Hill, NC
- Martin Chan, Coral, FL
- Robert P. Esbro, Villanova, PA
- Corey Goldsand, Cardinal Health, Dublin, OH
- Michael Grinman, Brooklyn, NY
- Leah Hohenberger, Gallagher Sharp, Cleveland, OH
- Kelley Johnson, New London, WI
- John Keller, Medinah, IL
- Amy Montes, Aventura, FL
- Tracey Moore, Target Corporation, Salem, OR
- Aaron Moore, Greenbelt, MD
- Michelle Notrica, Phoenix, AZ
- Edward O’Brien, Burbank, IL
- Raymond Pepe, Harrisburg, PA
- Amanda Ropp, Winchester, VA
- Michele Wasmuth, Albuquerque, NM
- Robert Wicker, Marrero, LA

Do you have an interesting article, case, or pharmacy law related discussion that would be of interest to Rx Ipsa readers? Are you interested in writing an article? Do you have any ASPL member updates? Awards, position changes, presentation, and publications are all welcome. If so, contact Michael Moné at gatorxjd1210@msn.com or the ASPL Business Office. All contributing authors receive by-line recognition.

Next Month - Send in your cases for this newsletter. I have received numerous submissions, and am developing summaries of them. Don’t forget gatorxjd1210@msn.com when you see something that others might find interesting!!

Mark Your Calendars

Legal Issues for Pharmacists and Pharmacies
Co-Sponsored By American Society for Pharmacy Law & Illinois Pharmacists Association
June 14, 2006 9:00 am – 4:00 pm - Sofitel, Chicago O’Hare - Rosemont, IL

The American Society of Pharmacy Law (ASPL) and the Illinois Pharmacists Association (IPhA), both headquartered in Illinois, are partnering on a special day of educational programming on some of the key issues affecting our industry at this moment! Pharmacists, lawyers and pharmacy lawyers are invited to participate. Up to seven (7) Legal and Pharmacy Continuing Education Credits will be offered.

Look for more information soon.
pharmacist, attorney, student, or anyone who may be interested in pharmacy law? Then suggest they go to www.ASPL.org and click on the “JOIN ASPL NOW” link.

Third, let’s team up with like-minded associations and institutions for pharmacy law conferences and seminars. In the last two years ASPL has held conferences with APhA, NABP and NACDS. Now the ASPL Board is exploring the possibility of holding seminars with other groups, such as state pharmacy associations and academic institutions. Stay tuned!

Fourth, let’s expand the content and reach of this newsletter. Do you have an idea for a pharmacy law article? Have you seen a court decision or news article that may be of interest to ASPL members? If so, forward your ideas and articles to Michael Mone at gatorxjd1210@msn.com or to me at dbell@nacds.org.

Fifth, let’s increase participation in the attorney and expert witness referral services on the ASPL website. Whenever anyone asks me for the name of a good lawyer or expert, I direct them to these resources. If you are a pharmacy law attorney or pharmacy practice expert, you will want the exposure that comes with an ASPL listing. Signing up is easy and inexpensive. Just go to www.ASPL.org and click on the “Referral Service” or “Expert Witness” links.

Sixth, let’s raise funds to turn these goals into reality. Conferences, websites, newsletters, and other ASPL resources cost money. Your tax-deductible contributions to ASPL, a not-for-profit charitable organization, will help us achieve these goals. For information on how to contribute and what your contributions can achieve, I encourage you to visit the ASPL website and click on “Next Steps Campaign.”

All these goals have something in common: We can only achieve them by working together. I hope we can all embrace and strive to achieve these goals.

Finally, I have a confession to make: I rarely read the “President’s Column” in the newsletters I receive. I want to make this column more than just me writing about my ideas. Let’s make this a two-way discussion. How can we grow and improve ASPL? If you have ideas, suggestions, questions or criticism, please let me know. Contact me at dbell@nacds.org.
Calendar of Events

June 14, 2006  
Legal Issues for Pharmacists and Pharmacies  
Co-Sponsored By American Society for Pharmacy Law & Illinois Pharmacists Association  
9:00 am – 4:00 pm  
Sofitel, Chicago O’Hare - Rosemont, IL

November 9-12, 2006  
ASPL/NACDS Developments in Pharmacy Law Seminar XVII  
Sanibel Harbour Resort and Spa, Fort Meyers, Florida