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Rx Ipsa Loquitur

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President's Message

Gail Bormel, RPh, JD

The New Year provides an opportunity to reflect on the accomplishments of the past year and look ahead to our goals for the coming year.

In November, we had a very successful Fall Meeting, which we held in conjunction with the National Association of Boards of Pharmacy's (NABP) Fall Educational Conference. The meeting at the Renaissance Vinoy in St. Petersburg, Florida, resulted in record attendance - ASPL attracted over 90 participants. The most valuable aspect of this joint meeting was the opportunity for ASPL members and NABP attendees to learn about and discuss topics of mutual interest. Some of the most popular educational sessions included: Responding to a Board of Pharmacy Investigations; Regulating Wholesalers, and Drug Product Integrity. ASPL thanks its sponsors Caremark, GlaxoSmithKline, Abbott, Akerman Senterfitt, Cardinal Health, Medco, Pharmacists Mutual Insurance Company, Quarles & Brady, Walgreens, and Stradley Ronon. Due to the success this joint meeting, ASPL Board of Directors is working hard to pursue additional opportunities for joint meetings. We will keep you up-to-date regarding these efforts in future issues of this newsletter.

In 2004, ASPL also implemented a new program aimed at increasing ASPL's exposure and membership base - the Student Sponsorship Program. Through this program, ASPL members can sponsor memberships for pharmacy or law students. To date, we have received 30 sponsorships from 20 of our members. In addition, we have received requests from several students at various universities for sponsorships. If you are interested in sponsoring these or other students, please contact Pam Tolson at ASPL Headquarters.

Another milestone last year was the establishment of the Joseph L. Fink III Founders Award. This award, named after ASPL's founder and first president, was established to recognize sustained and outstanding service and

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ASPL Legal Research Award

For those of you preparing an abstract for the ASPL Podium Presentation at the APhA Annual Meeting in Orlando, please consider developing a full research paper so that it may be considered for the ASPL Legal Research Award. A full paper is not required to submit an abstract for presentation, but if one is developed, it will be considered. Also note, participation at the ASPL Podium Presentation is not required to be considered for the Award.

The ASPL Legal Research Award is designed to encourage scholarly legal writing on topics relevant to practicing pharmacists or attorneys. The Award is sponsored by Abbott Laboratories and consists of a $1,000 honorarium and partial travel expenses to the 2005 ASPL Developments in Pharmacy Law Seminar to be held in November of 2005, where the Award is presented. All completed papers must be submitted by March 18, 2005 to the ASPL Corporate Office. To submit your paper, please contact ASPL, 1224 Centre West, Suite 400B, Springfield, IL 62704; phone 217-391-0219. For more information, contact Frank Palumbo, Chair, ASPL Scholarship Committee at fpalumbo@rx.umaryland.edu.

Featured Case

FTC v. Perrigo Co., No. 0210197 (D.C. Aug. 12, 2004)

Submitted by Roger Morris, RPh, JD, Quarles & Brady, Streich Lang, LLP, and Jesse Vivian, RPh, JD, Professor of Pharmacy Practice, Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences

On August 12, 2004, the only two generic drug manufacturers of over-the-counter store-brand children's liquid ibuprofen, Alpharma Inc. and Perrigo Co., settled with the Federal Trade Commission (FTC) on charges that they unlawfully agreed to limit competition and drove up the price of the drug. Alpharma agreed to pay $2.5 million and Perrigo agreed to pay $3.75 million in disgorged profits.

According to the FTC complaint, in 1996, Perrigo and Alpharma each filed abbreviated new drug applications (ANDA) with the US Food and Drug Administration (FDA) for approval to sell a generic version of liquid Children's Motrin (ibuprofen). Both parties expected to receive final approval for their products in June 1998, and, in expectation of those approvals, both companies tried to secure customer commitments. Customers used the competition between Perrigo and Alpharma to obtain substantially lower prices for store-brand over-the-counter children's liquid ibuprofen.

An April 1998, a change in the FDA's regulations gave Alpharma a significant competitive advantage. The FDA determined that Alpharma was eligible for 180 days of market exclusivity, which meant that the FDA would not approve Perrigo's product until 180 days after Alpharma began marketing its product.

The FTC alleged that Perrigo then approached Alpharma and sought to negotiate an agreement that would allow Perrigo to sell its product during the exclusivity period. Both parties, however, calculated that an agreement eliminating competition between them would allow Perrigo to raise prices. The companies projected the size of the higher profits by avoiding competition and then bargained over how to share those profits.

In June 1998, Perrigo and Alpharma signed an agreement allocating to Perrigo the sale of OTC children's liquid ibuprofen for seven years. In exchange for agreeing not to compete, Alpharma received an up-front payment and a royalty on Perrigo's sales of children's liquid ibuprofen.

Perrigo launched its children's liquid ibuprofen product in January 1999. Within six moths of launching its product, Perrigo raised prices to those customers who had obtained lower prices when Perrigo and Alpharma were competing for customers.

The FTC alleged that the agreement between Perrigo and Alpharma unlawfully drove up prices for wholesale customers – including supermarkets, drug chains and mass merchandisers – and violated Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. §45(a).

Under the proposed final orders, the companies agreed to pay a total of $6.25 million to settle charges that they earned illegal profits from the agreement. The FTC will use those funds to compensate customers harmed by the companies' conduct. The proposed orders also bar each company from repeating the alleged unlawful conduct by entering into similar agreements not to compete where one party to the agreement is a first ANDA-filer, subject to certain exceptions identified in the orders. Perrigo and Alpharma must provide notice to the FTC of any agreement falling within one of these exceptions. The settlements also contain certain record-keeping provisions to allow the FTC to monitor compliance.

The FTC conducted its investigation jointly with the States of Maryland, Florida, Colorado, and Ohio. Fifty states and territories filed a complaint challenging the same agreement and reached a settlement prohibiting the same conduct that the FTC's settlements with the companies prohibit. In addition to the settlement with the FTC, the companies will pay a total of $1.5 million in lieu of civil fines for forfeitures to those states and territories.

Errata

The Featured Case published in the November/ December 2004 issue of Rx Ipsa Loquitur, *Curry v. Collins, 2004 WL 2072296 (Ky.App.)*, failed to state that it was an unpublished opinion and therefore may not be cited or used as authority in that state. This editor apologizes for any confusion this error may have caused.

Quality Assurance Programs Expanding

Submitted by Melissa Stout, PharmD Candidate, University of Illinois College of Pharmacy, Class of 2005

Many chain drug stores, as well as independent pharmacies, are implementing Quality Assurance (QA) programs. These programs document errors that occurred in the pharmacy and take the necessary steps to prevent future errors. The purpose of a QA program is not to keep track of how many errors a pharmacist has made, but rather to identify ways to prevent errors from occurring in the future. While many pharmacies already have QA programs, some states require these programs. States that mandate QA programs include California, Connecticut, Florida, Kentucky, Maryland, North Carolina, and West Virginia.

Many of the states have broad general requirements; however, there are various specific requirements in certain states. These include:

- California: The pharmacy must document errors in the dispensing of medications and may take appropriate actions to prevent recurrences.
- Connecticut: The QA program must report all prescription errors, even those that have not yet reached the patient. Also, this state requires that patients must be provided with information on how to contact the state Department of Consumer Protection in the case of a medical error.
- Florida: The Quality Improvement Committee must meet at least once every 3 months.
- Kentucky: The pharmacist-in-charge must be responsible for the QA program.
- Maryland: The QA program must analyze data from the program and the medication delivery system at least once every six months.
- North Carolina: The pharmacy managers must report to the Board information on patient deaths that may have been caused by a dispensed prescription drug or device.
- West Virginia: The pharmacist-in-charge must be responsible for the program. Also, the program must be designed to prevent and detect drug diversion.

Incorporating all the requirements into one comprehensive QA assurance program will hopefully decrease the number of errors that occur in pharmacies. Some pharmacists may worry that these programs will serve as a record of their errors. The purpose of these programs, however, is not to place blame on the pharmacist, but to document errors and use them as a learning tool to evaluate ways to improve the pharmacy drug dispensing systems.

2004 Seminar Notebooks Available for Purchase

The 2004 Developments in Pharmacy Law Seminar notebooks are now available for purchase for $175.00. Notebooks include all handout materials from the Seminar.

For more information, contact Melissa Bealon, ASPL associate director, at 217/391-0219 or member.services@aspl.org.

ASPL Annual Meeting Schedule of Events at APhA 2005

April 1 – 5, 2005
held in conjunction with the APhA Annual Meeting and Exposition
Orange County Convention Center - Orlando, Florida

www.aphameeting.org

Please note: Be sure to sign up for the ASPL Luncheon. Attendance fee is $45. Early registration for the APhA Annual Meeting ends March 2, 2005.

Saturday, April 2, 2005

8 – 10 am
Legislative and Regulatory Update

This program will review the development over the past year of statutes and regulations that affect the practice of pharmacy. Topics to be addressed include the development of regulations for the Medicare Part D drug benefit, patient safety legislation, and other recent activities of federal and state legislatures and regulatory agencies.

Learning Objectives: After attending this session, pharmacists should be able to:

1. Describe the current activities of legislatures and regulatory agencies that impact pharmacy practice.
2. Discuss the latest issues regarding the ongoing development and implementation of the Medicare drug benefit.
3. Explain current issues regarding patient safety legislation, compounding and other pharmacy topics.

Speaker:
Kristine Lunner, Director, Federal Government Affairs
American Pharmacists Association

12:00 – 1:30 pm
ASPL Membership Luncheon and Meeting

(ticket required)
Fee: $45

1:30 – 4:30 pm
ASPL Contributed Papers Podium Session

This session will feature presentations by authors of research papers related to legal issues affecting pharmacy. Each paper will be discussed and will be followed by an opportunity for audience questions.

Learning Objectives: After attending this session, pharmacists should be able to:

1. Describe the legal issues and research objectives associated with the contributed papers.
2. Identify the research methods utilized by each author.
3. Explain the results and conclusions made by each author.

Sunday, April 3, 2005

7:30 – 9:30 am
Case Law Update

This program will focus on discussion of cases involving pharmacy or the pharmaceutical industry that have been decided over the past 12-month period. Focus will be to understand the trends in pharmacy case law development. The participants will also look at how these cases may impact the future practice of pharmacy.

Learning Objectives: After attending this session, pharmacists should be able to:

1. Discuss cases involving pharmacy or the pharmaceutical industry that have been decided in the past year.
2. Understand trends in pharmacy case law development.
3. Explain how these cases may impact the future practice of pharmacy.

Speakers:
Jesse Vivian, RPh, JD, Professor of Pharmacy Practice
Wayne State University Eugene Applebaum College of Pharmacy and Health Sciences

Roger Morris, RPh, JD
Quarles & Brady, Streich Lang, LLP

1 – 3 pm
Medication Therapy Management Law

The new Medicare prescription drug benefit will require prescription drug plans to provide medication therapy management services to select Medicare beneficiaries. The goal of the program is to improve the outcomes from medication use in Medicare beneficiaries. This session will focus on the requirements of the program, and how pharmacists may be able to take advantage of this new program. The session will also review the implications for state practice acts.

Learning Objectives: After attending this session, pharmacists should be able to:

1. Describe the legal requirements of Medicare's new Medication Therapy Management program.
2. Discuss the potential for pharmacist malpractice and "duty to warn" liability as a result of medication therapy management programs
3. Discuss potential revisions that may need to be made to state pharmacy practice acts in order to allow pharmacists to participate in medication therapy management programs.

Speaker:
To be announced.

Monday, April 4, 2005

10:30 am – 12:30 pm
Legal Requirements of Establishing or Buying a Pharmacy

This session will review the legal requirements for opening and operating a community pharmacy. Attendees will learn everything from how to obtain a business to how to work with the state board of pharmacy and enroll as a Medicaid provider and how to participate in other programs.

Learning Objectives: After attending this session, pharmacists should be able to:

1. Understand the legal prerequisites for opening a pharmacy
2. Work with government agencies to satisfy regulatory requirements.
3. Locate resources for obtaining more information about running their own pharmacy.

Speaker:
To be announced.

1 - 3 pm
Is it Legitimate? Assessing Controlled Substance Prescriptions

Learn how to fulfill your legal, professional, and ethical obligations when managing a questionable controlled substance prescription. This session will review legal precedents, and explore strategies for identifying prescriptions that require further investigation.

Learning Objectives: After attending this session, pharmacists should be able to:

1. Explain the pharmacist professional and ethical responsibilities to adequately manage pain.
2. List federal requirements for controlled substance prescriptions.
3. Identify "red flags" that a prescription has been falsified or altered including methods used by the DEA when looking at prescriptions.
4. Explain the legal decisions guiding pharmacist responsibilities with controlled substances.
5. Identify liability risks associated with not filling a prescription.

Speakers:
Vickie Seeger, RPh
Drug Enforcement Administration, Office of Diversion Control

Bill Fassett, RPh, PhD, Dean
Washington State University College of Pharmacy

Tuesday, April 5, 2005

8 – 10 am
Needlestick Safety and Prevention Law

More pharmacists are administering flu shots and other injections for patients. This session will help pharmacists understand and comply with the Occupational Safety and Health Administration's needlestick safety and prevention requirements. Related legal requirements and safety procedures will also be reviewed.

Learning Objectives: After attending this session, pharmacists should be able to:

1. Describe the OSHA requirements for needlestick safety and prevention.
2. Describe related statutes and regulations.
3. Explain the potential for liability associated with needlesticks.

Speakers:
To be announced.

ASPL Developments in Pharmacy Law Seminar XV Wrap-up

November 11-14, 2004, ASPL proudly presented its Developments in Pharmacy Law Seminar XV with special sessions co-hosted with the National Association of Boards of Pharmacy (NABP) at the Renaissance Vinoy Resort and Golf Club in St. Petersburg, Florida. Meeting attendees, who were eligible to receive up to 13 hours of pharmacy and legal continuing education credit, reported the educational sessions, once again, met or exceed ASPL's tradition of excellence, and were very beneficial to their practices.

Beautiful St. Petersburg served as host to this year's Seminar, where attendees were able to visit that city's many cultural and entertainment attractions. Two joint meal functions co-hosted by ASPL and NABP gave members of both groups the unique opportunity to interact and discuss issues of mutual interest.

Mark your calendar for next year's Developments in Pharmacy Law Seminar XVI, which will be held November 10–13, 2005, at the Omni Tucson National Golf Resort and Spa in Tucson, Arizona.

ASPL Annual Meeting at APhA 2005

April 1 – 5, 2005
(held in conjunction with the APhA Annual Meeting and Exposition)
Orange County Convention Center - Orlando, Florida

www.aphameeting.org

Thanks to our Conference Sponsors

Thank you to all the sponsors of the ASPL Developments in Pharmacy Law Seminar XV. Your generous support allowed ASPL to successfully present an informative, productive, and entertaining event for all in attendance.

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ASPL Attorney Referral Service

Where can you find an attorney who can represent you in a board of pharmacy matter or a pharmacy malpractice lawsuit? *The American Society for Pharmacy Law.* The highly anticipated ASPL Attorney Referral Service (ARS) is now available. The ARS is not only a great way for attorneys to promote their services, it is a great way to connect with a lawyer who is an expert in the pharmacy law arena.

For more information, visit our website at: www.aspl.org

ASPL 2004 Fall Meeting

Developments in Pharmacy Law Seminar XV

Session Reviews

Legislative and Regulatory Update

This joint session, co-hosted by ASPL and the National Association of Boards of Pharmacy, featured speaker Susan Winckler, Vice President, Policy and Communications, American Pharmacists Association, who summarized US Congressional and state legislative activities, as well as federal and state regulatory initiatives that impact pharmacy. Highlighted topics included malpractice reform, Internet drug distribution, expanding the importation of prescription drugs, patient safety legislation, and payment for pharmacy care services under Medicare. Ms. Winckler also brought attendees up to date on US Food and Drug Administration programs, including pharmaceutical risk management programs, Rx-to-OTC switches, anti-counterfeiting efforts, dietary supplements, and consumer medicine information, as well as programs overseen by the Centers for Medicare and Medicaid Services, including the new national provider identifier and medication therapy management services. As always, this session was well-attended and well-received by all attendees.

Melissa Madigan, PharmD, JD - Smith, Rickert & Smith
ASPL President-elect

Drug Importation

This session featured two speakers who have been on the front lines of the battle over importation of prescription drugs. The first presentation was by Bill McConagha, an FDA attorney who specializes in drug importation issues. Mr. McConagha provided an overview of the laws which make it illegal to import or reimport prescription drugs from Canada and other foreign countries. He also described how counterfeit drugs enter the US through internet pharmacies that promise cheap foreign drugs. Mr. McConagha also provided details on the FDA's recent inspections of foreign mail-order drugs. The next speaker was Mary Ellen Fleck, Associate General Counsel for the National Association of Chain Drug Stores. Ms. Fleck explained how various states, counties and cities are implementing drug importation programs, and the effect those programs have on local consumers and local pharmacies. She also described the efforts of state boards of pharmacy to shut down "storefronts" that facilitate drug importation. Finally, Ms. Fleck described a variety of bills pending in Congress that would legalize drug importation.

Don Bell, JD - National Association of Chain Drug Stores
ASPL Board of Directors

Regulating Wholesalers

Anita Ducca, Director, Regulatory Affairs for the Healthcare Distribution Management Association (HDMA), provided the perspectives of HDMA regarding the regulation of wholesalers. After reviewing the distribution supply chain, Ms. Ducca discussed several of HDMA's efforts to ensure the integrity of the supply chain. In addition to efforts such as providing suggestions on NABP's Model Rules on Regulating Wholesalers and incorporating Best Business Practices into Membership Bylaws, HDMA has recommended technological solutions such as "track and trace" technology to combat counterfeiting. HDMA also has recommended stronger, uniform licensing by the states and recommends increasing penalties for those knowingly trafficking in counterfeit drugs. HDMA's suggestions on NABP's Model Rules include clarifying pedigree requirements, authentication requirements, strengthening state responsibilities, and simplifying the designated representative.

Louis Ling, General Counsel of the Nevada State Board of Pharmacy addressed the Regulation of Wholesalers in his talk "Real World Drug Distribution-How to Prevent Bad Things From Happening to Good Drugs." Mr. Ling contrasted the regular drug distribution system with that of the irregular drug distribution system. Specifically, Mr. Ling identified the "secondary source wholesalers" as a source of introducing counterfeit drugs and drugs from other illegal sources. Mr. Ling identified the following as key licensing features of NABP's model rules that will

help to deter counterfeit drugs: 1) wholesaler must have a designated representative; 2) surety bond of at least $100,000; 3) criminal background checks for employees, officers, and owners; and 4) agent for service of process if out-of-state licensee. Mr. Ling discussed how new technology (eg. RFID) would stop counterfeiting by preventing the illegal sale of counterfeit drugs and drugs from other illegal sources. Mr. Ling also identified some non regulatory solutions to help prevent illegal activity, including destroying pharmacy stock bottles after use, monitoring counterfeit activity through FDA-CDER website, refusal by major wholesalers to buy drugs from secondary sources, and publication of current authorized distributor lists on the Internet.

Gail Bormel, RPh, JD - US Food and Drug Administration
ASPL President

Drug Product Integrity

The session on Drug Product Integrity focused on challenges to the safety of the U.S. drug supply at both the state and federal level, and recommended actions to deal with these challenges. Gregg Jones, R.Ph., from Florida's Bureau of Statewide Pharmaceutical Services, described Florida's response to abuses by secondary wholesalers in their state, including a series of grand jury indictments in 2002 and the passage of SB 2312 - the Prescription Drug Protection Act - in 2003. He further described the nature of the PDPA, including tightened procedures for tracking and tracing prescription drugs and maintenance of their pedigrees, and increased penalties, by which the use of false pedigrees and other violations are now felonies.

Joining Mr. Jones was Dr. Ilisa Bernstein, from the US Food and Drug Administration. Dr. Bernstein provided an overview of drug counterfeiting in the U.S., and updated the attendees on the FDA counterfeit drug initiative. The progress of designing and implementing track and trace technologies (e.g., radio frequency identification and barcodes), and of developing improved authentication technologies, which may be overt, covert, or forensic, is moving forward. She pointed out that the following next steps are underway: standard setting, additional research — particularly to demonstrate that RFID does not adversely affect product stability, gaining experience in commercial use, setting of e-pedigree standards, and consideration of privacy issues.

Bill Fassett, PhD, RPh - Washington State University College of Pharmacy
ASPL Treasurer

Nationalizing Pharmacy Practice Standards

John Gilbert, Esq., from Hyman, Phelps & McNamara, PC, moderated a panel discussion. Panelists were Joseph Valentino, Esq., from the USP, and Gary Cacciatore, Esq., from Cardinal Health. The panelists recognized that pharmacy practice standards are currently governed primarily by state law, but they discussed the possibility that this may change as the federal government becomes more involved in the practice of pharmacy beyond its involvement with controlled dangerous substances which has been intense for many years. The panelists discussed the issue of compounding versus manufacturing as an example. Over the past several years, the FDA and the Congress have become more active in this area through FDAMA, with the subsequent Western States case, and the FDA's Compliance Policy Guide. The panelists also discussed compounding of controlled substance prescriptions and whether DEA would recognize this as compounding or manufacturing. Another important issue raised was reverse distributors and the fact that this type of activity was not contemplated when Congress passed the Controlled Substances Act. The panelists did not suggest that the federal government would control all of the standards of pharmacy practice. But this panel session addressed some areas where federal involvement in the practice of pharmacy has increased.

Frank Palumbo, RPh, JD - University of Maryland College of Pharmacy
ASPL Board of Directors

Responding to Board of Pharmacy Investigations

On Saturday afternoon, Michael Moné and Ed Rickert, each pharmacist-attorneys, presented a lively discussion about Responding to Board of Pharmacy Investigations. Unofficially labeled 'how to outfox state pharmacy boards' by attending state board executives, the speakers reviewed general advice for responding to Board inspections and investigations. The distinction between inspections and investigations was emphasized, with inspections described as routine and often with an educational emphasis, while investigations are often stimulated by a complaint and intended to yield specific information. The speakers also reviewed the various methods for gathering information, including warrantless searches, searches authorized via administrative inspection warrants, criminal search warrants, a subpoena duces

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tecum, and interviews. With a strong emphasis on preparation, Moné and Rickert urged pharmacists (and their counsel) to establish a "game plan:" a compliance program with a document retention and destruction policy. All pharmacy staff should be familiar with certain elements of the compliance program, including knowing who should be alerted when an inspection or investigation is initiated, including counsel and liability insurance carriers.

Case Law Update

Does a state board of pharmacy's refusal to approve the sale of a pharmacy to a third party constitute the "taking" or "inverse condemnation" of the pharmacy? Is the creation of a closed pharmacy network by an insurance company a violation of anti-trust laws? Is the policy of placing a "use before" date, instead of the manufacturer's expiration date, on a prescription vial an act of fraudulent misrepresentation and a breach of implied and express warranties?

The answers to these and other pharmacy law issues were provided by Jesse Vivian, BS Pharm, JD, Professor of Pharmacy Practice at Wayne State University, College of Pharmacy and Health Sciences, and Roger Morris, RPh, JD, Partner, Quarles & Brady, Streich Lang, LLP, who provided an excellent review of a variety of cases during this year's "Case Law Update." This session has become a tradition for ASPL, providing attendees with a concise summary of significant pharmacy law cases. During this session, Mr. Vivian and Mr. Morris discussed recent litigation involving anti-trust issues, the Americans with Disabilities Act, administrative and civil procedure, contracts, criminal law, employment law, ERISA violations, Medicaid, pharmacy malpractice, and product liability.

Melissa Madigan, PharmD, JD – Smith, Rickert & Smith
ASPL President-elect

Regulating PBMs

The ASPL Developments in Pharmacy Law XV Conference concluded with a well-attended program entitled "Regulating PBMs." The PBM industry has been in the news a lot recently and there have been calls by some groups for increased regulation of the PBM industry. One of the groups that has advocated that position has been the National Community Pharmacists Association (NCPA). This session was intended to provide for a debate on the issues by bringing in a representative from NCPA and the PBM industry to present their views and answer questions from the audience. John Rector, Senior Vice President of Government Affairs and General Counsel for NCPA was scheduled to speak but unfortunately had to cancel at the last minute. Speaking from the perspective of the PBM industry was Peter F. Harty, Vice President Government Affairs and Policy for Medco. Peter did a great job of defining the issues and even did his best to explain the positions that have been put forth by critics of the industry.

Peter's discussion included an analysis of current regulatory oversight of the PBM industry including both direct regulation and indirect regulation. He also discussed recent legislation in states that attempt to further regulate the industry. This included a discussion of the 2003 Maine legislation which was enacted in June, 2003. Among other things, the Maine legislation included disclosure requirements, financial pass-through of rebates, and designated PBMs as fiduciaries of the health plans they contract with. The Pharmaceutical Care Management Association (PCMA), the trade association for the PBM industry, filed suit against Maine in September 2003. A preliminary injunction delaying implementation and enforcement of the law was granted to PCMA in March 2004 and was affirmed by a new judge in June 2004. Both sides filed motions for summary judgment in October 2004 and are awaiting a decision from the court.

The discussion also included other litigation and enforcement activities involving PBMs including the action pending by the U.S. Attorney's Office for the Eastern District of Pennsylvania, which was discussed by Cathy Thomer from the U.S. Attorney's office at last year's ASPL conference. Peter described the industry's position on a number of the issues including disclosure and transparency, the fiduciary issue, and issues related to the PBMs pharmacy mail services.

Even without "both sides of the issue" presenting, the session achieved its goal of generating much discussion and debate due to active participation from audience members.

Gary Cacciatore, RPh, JD – Cardinal Health
ASPL Immediate Past President

Next Steps Campaign Moving Forward in 2005!

Thanks to the ASPL Members listed below, the ASPL "Next Steps Campaign" has reached approximately 25 percent of its fund raising goal and is moving into the next phase of seeking large contributions. To date, 26 members have pledged $45,000, of which $27,050 has been collected. These ASPL members challenge all members to join them in making a commitment to the Association. Your participation will insure the future of ASPL and the invaluable resource the Association provides to pharmacists, attorneys, and other organizations.

At the 2003 ASPL Annual Meeting, then-President Gary Cacciatore first introduced the Next Steps Campaign, a three-year program aimed at raising $200,000. The Campaign provides an opportunity for individuals and organizations to make contributions to four different funds or projects with the intention of expanding the programming offered by the Association.

The four categories are:

1) Operational Excellence Fund – With a goal of $100,000, the Operational Excellence Fund is supported by unrestricted gifts to be used by ASPL to maintain existing programs and services, including administration and fundraising, and to develop and implement new programs and services. To date, funds contributed have been used to develop the attorney referral service and the expert witness listing service, expand the website, and assist with cash flow when needed. In the future, Operational Excellence funds may be invested long-term to insure the financial stability of the Association.
2) Pharmacy Law Symposium – With a goal of $25,000, plans have begun for a Symposium that will bring together leaders in pharmacy and pharmacy law to present papers and address developing pharmacy jurisprudence. ASPL has already received expressions of interest from several pharmacy and law schools interested in partnering with ASPL on the development of this program. The ASPL Finance & Development Committee has targeted this program as a priority in 2005 to begin implementation.
3) Pharmacy Law Resource Center – The pharmacy and legal professions need a single, comprehensive, reliable resource they can turn to for information on relevant pharmacy law issues. We believe ASPL should be the source of that information. This web-based information center would include a searchable database of articles on pharmacy law topics, information on current legal and regulatory issues in pharmacy, legislative and regulatory research tools and links to other useful sites. ASPL may combine its efforts with a selected law school in order to insure permanent housing of the site with ease of updating. The ASPL Finance & Development Committee has this program on its priority list for 2005 and is researching Foundations for a grant to assist with the $50,000 needed for funding.
4) ASPL plans to establish a $25,000 scholarship fund specifically for instructors of pharmacy law that will allow for their attendance at ASPL educational programming to further enhance their knowledge of the legal issues impacting the practice of pharmacy.

To make a contribution, contact the ASPL office and ask for a Next Steps Campaign Kit. Join the following members in support of this exciting fund raising program that will help ASPL take the "next steps" to expand and develop its programs and services. Your gift is tax deductible and will greatly impact the Association and the discipline of pharmacy law!

Name	Category
David Brushwood	Founders Circle
Gary Cacciatore	Founders Circle
David Blumenfeld	ASPL Academy
John Cronin	Founders Circle
Mark Conradi	Founders Circle
Martha Rumore	Founders Circle
Ed Rickert	Founders Circle
Ken Baker	ASPL Academy
Peter Previte	Friends of ASPL
Joseph L Fink III	Founders Circle
Laura Carpenter	Individual
William Fassett	ASPL Academy
Jesse Vivian	Founders Circle
Ilisa Bernstein	Founders Circle
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James O'Donnell	ASPL Academy
Jay Warner	Friends of ASPL
Joseph Valentino	Friends of ASPL
Frances Gail Bormel	Friends of ASPL
Norman A. Campbell	Individual
William Feinberg	ASPL Academy
Paul Weisner	Friends of ASPL

President's Message
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contributions to the professions of pharmacy and law. Nominations and supporting documentation must have been received by the ASPL Office by February 1st. *More information on the award can be found on the ASPL web site at www.aspl.org.*

This year we look forward to successful educational sessions at the APhA meeting in Orlando, Florida, which will be held April 1-5, 2005. At the meeting, ASPL will host a luncheon on Saturday, April 2nd and a reception on the evening of Sunday, April 3rd. Tickets for the luncheon are $45 and can be purchased when registering for the APhA meeting.

The New Year will also bring improvements to our website. The upgrade will give the site a new, more professional look and feel, will provide members with more information and services, will give ASPL the ability to more easily and effectively communicate with and among its members and accept membership renewals and meeting registrations and fees via the Internet.

The ASPL Board and its Committees are also working on other projects, including an educational symposium and newsletter sponsorship. Our goals for this year guarantee that we will be very busy, and we look forward to continued success in 2005.

Mark Your Calendar!

November 10-13, 2005

ASPL Developments in Pharmacy Law Seminar XVI

Omni Tucson National Golf Resort and Spa Tucson, Arizona

Rx Ipsa Loquitur

The Rx Ipsa Loquitur is the official newsletter of ASPL. It is published on a bimonthly basis and the editorial content includes coverage of various ASPL sponsored meetings and events, current legal issues, the latest happenings in Washington, DC and synopses of the latest court rulings that affect pharmacy.

The following ad rates are effective January 1, 2005. Insertion orders for multiple issues receive a discount on the per issue rate.

Size		1x	3x	6x
Full-page	(8-1/2" x 11")	$600	$570	$540
Half-page horiz..	(7-1/2" x 4")	$325	$310	$290
Half-page vert.	(3-1/2" x 9-1/2")	$325	$310	$290
Quarter-page	(3-1/2" x 4-1/4")	$175	$165	$155
Eighth page	(3-1/2" x 2")	$100	$95	$90

Position Listings:
$150 per line ad for the first 100 words. A $50 discount is available to those firms or institutions where there is a member of ASPL.

Website Advertising:
Logo and hyperlink on opening page - $100/month
Logo and hyperlink on specific page - $50/month

Advertising Specifications:
- Advertisement printed in black & white.
- Artwork must be camera-ready.
- Advertisements must conform to specified sizes.
- Electronic artwork is accepted and high resolution .pdf file is preferred. However, the following formats are accepted .tif, .jpg, .eps, or .pdf.

An Advertising Agreement can be found on-line at www.aspl.org or contact Melissa Bealon at the at ***ASPL Business Office:***
1224 Centre West, Suite 400B
Springfield, IL 62704
217-391-0219 Phone - 217-793-0041 Fax
e-mail her at member.services@aspl.org

ASPL Student Sponsorship Program Underway

ASPL's new Student Sponsorship Program is off to a running start with already more than 20 members sponsoring 30 students. For $40, ASPL members can sponsor a student from any pharmacy or law school. Once a member chooses to be a sponsor, unless a specific student is identified, the dean of the law or pharmacy school is contacted and recruited to select the student to receive the membership. ASPL then sends a letter to the student welcoming them and providing them with a membership card. Unless the ASPL sponsor member chooses to remain anonymous, that person's contact information is also included in the letter. Each student receives a one year membership to ASPL, which includes all the benefits except voting privileges.

The Student Sponsorship Program is a great way to introduce students to the discipline of pharmacy law and increase visibility for the Society among pharmacy and law schools. More information on this program can be obtained by contacting the ASPL Office at member.services@aspl.org.

The following ASPL members have joined the Student Sponsorship Program:

John Cronin	Sponsored six students at any California pharmacy school
David Bobb	Sponsored two students at Ohio Northern University Pharmacy School
Gail Bormel	Sponsored two students at the University of Maryland Law School
Hal Wand	Sponsored two students, one at the University of Arizona College of Pharmacy and one at Georgetown University Law Center
Reinhold Mueller	Sponsored two students at the University of Southern California School of Pharmacy
Edward Rickert	Sponsored two students, one at the University of Illinois College of Pharmacy and one at the University of Iowa College of Pharmacy
Don Bell	Sponsored one student at George Washington University Law School
Gary Cacciatore	Sponsored one student at the University of Houston
Thomas Cerullo	Sponsored one student at the Massachusetts College of Pharmacy
Jane DeWitt	Sponsored one student at Drake University College of Pharmacy
William Fassett	Sponsored one student at Washington State University College of Pharmacy
Nina Foushi	Sponsored one student at the University of Illinois College of Pharmacy
James Lindon	Sponsored one student at Ohio Northern University Pharmacy School
Grant Moak	Sponsored one student at University of Oklahoma College of Law
Jerry Mucheno	Sponsored one student at Wilkes University Nesbitt School of Pharmacy
Julie Nelson	Sponsored one student at the University of Texas College of Pharmacy
Mary Power	Sponsored one student at the University of Toledo College of Pharmacy
Teresa Stanek Rea	Sponsored one student at Wayne State University Law School
Susan Winckler	Sponsored one student at University of California San Diego College of Pharmacy
Thomas Winslow	Sponsored one student at Ohio Northern University Pharmacy School

Society News

Call For New Committee Members

ASPL's 2005-2006 committees are now being formed. If you are interested in serving on a committee, please contact Melissa Madigan at mmpharmdjd@earthlink.net. Committee objectives are as follows:

- **Scholarship Committee**
  Coordinating the ASPL Writing Competitions and the ASPL Contributed Papers sessions at the American Pharmacists Association Annual Meeting; working with the Finance Committee to obtain award sponsorship; ensuring widespread publicity for these competitions; coordinating paper review and judgment processes.
- **Education Committee**
  Planning the educational programming for ASPL's Fall Meeting and spring American Pharmacists Association Annual Meeting; coordinating the implementation of these sessions with cosponsoring organizations; and investigating the feasibility of joint regional meetings with other cosponsors, such as the American College of Legal Medicine.
- **Finance Committee**
  Working with the Board of Directors to maintain the fiscal strength and integrity of the Society; overseeing fundraising (outside of the Next Steps Campaign), budgeting, auditing, and filing of all required tax/informational returns with government agencies; ensuring an annual financial audit is conducted; working with ASPL staff to develop preliminary and final budgets; identifying potential sponsors and soliciting sponsorship for ASPL's fall and spring meetings; securing funding for ASPL awards.
- **Membership Committee**
  Retaining and increasing membership of the Society; contacting nonrenewed members; developing a plan to recruit new members, including working with other committees and organizations to create and manage displays at certain designated pharmacy and legal group meetings.
- **Communications Committee**
  Publishing the ASPL newsletter every other month; assisting the editor in identifying potential news articles and developments that may be of interest to ASPL members; contributing articles for the newsletter; maintaining and updating the ASPL website, including the Attorney Referral Service and Expert Witness Listing; developing a plan to market both the Attorney Referral Service and Expert Witness Listing to members and non-members; identifying significant news and/or developments of interest to members to be sent out via push e-mail; obtaining links to the ASPL website from other pharmacy and legal sites; review website content to ensure it is up-to-date and working properly.
- **Nominating Committee**
  Selecting the slate of candidates to run for ASPL Office; overseeing election procedures; nominating the recipient of the Annual Joseph Fink Award.
- **Next Steps Campaign Coordinating Committee**
  Further developing the campaign to raise $200,000; identifying and planning programs and projects in accordance with campaign objectives.

New Members

Be sure to welcome the following new members:

Jackie Artinger, Prescription Solutions
Cathy Bellehumeur, Accredo Health, Inc.
Alison Berges, Pet Med Express, Inc.
Robert Delaney, Jr., Walgreen Co.
Susan deMars, US Pharmacopeia
Danna Droz, Florida Board of Pharmacy
Anita Ducca, Healthcare Distribution Management Association
Robert Earnest, ACS State Healthcare Solutions
Chris Freed, Caremark
James Horton, II
Douglas Lipton, First Health Services Corporation
Kevin Mitchell, Rite Aid Pharmacy
David R. Overstreet, Kirkpatrick & Lockhart, LLP
Warren Richards, Palm Beach Atlantic University
Tom Sheer, Caremark
Christopher Thomas, Rite Aid Pharmacy
Brenda Warren, Accredo Health, Inc.

Submissions Wanted

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, please contact Melissa Madigan at mmpharmdjd@earthlink.net or the ASPL Business Office. All contributing authors receive by-line recognition.

American Society for Pharmacy Law
Membership Application

Please Print

Name: _____

Company: _____

Work Address: _____

City, /State Zip: _____

Membership Type:

❑ Member	$110.00
❑ Student	$40.00
❑ Retired	$40.00

Work Phone: _____ Work Fax: _____

E-Mail Address: _____

Current Position or Title: _____

Admitted to Bar in the following jurisdictions: _____

Licensed to practice Pharmacy in the following states: _____

Recruited by: _____

Areas of Practice (Check all that apply)

Pharmacy...

- ❑ Community
- ❑ Hospital
- ❑ Consultant
- ❑ Education
- ❑ Pharmaceutical Industry
- ❑ Association
- ❑ Government
- ❑ Other_____

Law...

- ❑ Law Firm - Litigation - Plaintiff
- ❑ Law Firm - Litigation - Defense
- ❑ Law Firm - Food and Drug Law
- ❑ Law Firm - Administrative/Regulatory
- ❑ Law Firm - Transactional
- ❑ Law Firm - Other
- ❑ Governmental Agency
- ❑ Education
- ❑ Corporate - Litigation
- ❑ Corporate - Regulatory
- ❑ Corporate - Other
- ❑ Board of Pharmacy
- ❑ Other _____

Send to:

American Society for Pharmacy Law
1224 Centre West, Suite 400B
Springfield, IL 62704
or fax form with credit card
information to: (217) 793-0041

Join a Committee...

ASPL has several committees to address issues of importance to the society as a whole and to you and the those involved in pharmacy law. If you would like to participate by joining an ASPL Committee, please indicate below:

- ❑ **Education --** Develop educational programming for the Fall seminar and Spring APhA meeting and other special programs.
- ❑ **Membership --** Develop plans to retain and recruit members and to expand member services.
- ❑ **Finance --** Identify sources and develop strategies for obtaining non-dues revenue for the society.
- ❑ **Newsletter --** Assist *Rx Ipsa Loquitur* editor with article ideas and submissions.
- ❑ **Scholarship --** Review and select writing competition winners and abstracts presented at APhA Annual Meeting.

Method of Payment...

Total Amount Due: $ _____

❑ Check Enclosed ❑ Charge my credit card ❑ Visa ❑ Mastercard

Card Number: _____

Exp. Date: _____

Name on Card: _____

Signature: _____

ASPL is a 501(c)(3) tax exempt, non-profit corporation - Tax ID Number: 52-1250852

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American Society for Pharmacy Law
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217-793-0041 Fax

Complete Board contact information can be found on the ASPL website
www.aspl.org

Calendar of Events

March 18, 2005	Deadline for submitting to ASPL completed papers for ASPL Legal Research Award.
April 1-5, 2005	ASPL Annual Meeting (held in conjunction with the APhA Annual Meeting and Exposition), Orange County Convention Center, Orlando, Florida *Please note: Be sure to sign up for the ASPL Luncheon. Attendance fee is $45. Early registration for the APhA Annual Meeting ends March 2, 2005.* *Register for the meeting at:* **www.aphameeting.org**
November 10-13, 2005	ASPL Developments in Pharmacy Law Seminar XVI, Omni Tucson National Golf Resort and Spa, Tucson, Arizona

www.aspl.org