

LAW & HEALTH CARE

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Focus on . . .

DRUGS & HEALTH LAW

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It is impossible to think about health care today without acknowledging the role of prescription drugs. We now rely on drugs for treatment of the large majority of our medical conditions. Drugs have improved both the quality and quantity of our lives. But, just as with health care, policy makers are challenged with the task of ensuring the quality, safety, access and affordability of drugs. To that end, legislators and government agencies are creating new laws and regulations and taking enforcement actions that generate new legal issues and work for health and food and drug lawyers. Many faculty and students at the University of Maryland School of Law are involved in research, course work and other initiatives that touch on drug laws and policies. In this issue of the L&HCP Newsletter, we highlight these various activities.

Access and Affordability

The ability of drugs to combat both acute and chronic illnesses has increased their value among the general population, yet the high cost of drugs has made them unaffordable to many. The percent of the nonelderly population without insurance rose from 17.3% in 2002 to 17.7% in 2003 (or 44.7 million uninsured), an increase of 1.4 million over 2002. Additionally, more than a third (36%) of Medicare beneficiaries had no prescription drug coverage in the fall of 2001. A 2003 Kaiser Health Insurance Survey found that 37% of the uninsured said they did not fill a prescription because of cost, compared to 13% of the insured. In order to make drug prices more affordable and thereby more accessible, policy makers have attempted to respond with some new and, in many cases, highly controversial initiatives. Among

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FROM THE DIRECTOR

In this issue of the L&HCP Newsletter, we examine the complex relationship between drugs and health law. During the past year, legal and policy issues related to prescription drugs have consistently made headlines in the news and the L&HCP has sponsored several forums to discuss these "hot" topics, including panels on drug importation and compulsory licensing. The Program also includes a number of students and faculty members who have pharmacy backgrounds. We introduce you to them and how they have combined their interest in pharmacy and law. Finally, a number of Program faculty members are teaching courses or clinics and/or conducting research on drug related issues. We highlight their teaching and scholarship.

Diane Hoffmann, JD, MS
Director

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Newsletter**

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of the Law & Health Care Program
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these is the recent passage by Congress of a Medicare drug benefit.

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) giving seniors access to outpatient prescription drugs. The MMA gives seniors the choice to access this new benefit via either a stand alone Prescription Drug Plan (PDP) or a more comprehensive plan under the Medicare Advantage (MA) program. Under the PDP, beneficiaries will pay an average monthly premium of \$35, a \$250 deductible, 25% co-pay on the first \$2250 spent on prescriptions and catastrophic coverage after out-of-pocket spending reaches \$3600. Although additional assistance is available for low-income seniors, the bill was highly controversial as it still leaves many seniors with significant out-of-pocket costs and may increase costs for some seniors if their former employers reduce or drop their retiree prescription drug benefits in response to the new benefit.

These changes to the Medicare law provided new teaching material and opportunities for policy discussions in several L&HCP courses such as the Seminar on Medicare and Medicaid Fundamentals. Also, students in externships with organizations dealing with federal health care policy had an opportunity to learn more about the new law. Linda Souter, a 2d year student in the Program, writes in this issue about her externship at BIO working with the Director for Medicare Reimbursement and attending meetings about the implementation of Medicare Part D. (See story, p. 15.)

Other highly debated approaches to reducing the costs of drugs and increasing accessibility have included drug importation from other countries and compulsory licensing of patented drugs. The passage of the MMA focused considerable attention on the issue of drug importation. In addition to providing for the prescription drug benefit, the MMA included provisions aimed at providing lower cost drugs to consumers. Under Section 384, the Secretary of the Department of Health

and Human Services (DHHS) is directed to promulgate regulations that would allow for the importation of prescription drugs in certain cases. Congress conditioned the implementation of the MMA's importation program on an initial certification by the Secretary that drug importation will pose no additional risk to public health and safety and result in a significant reduction in the cost of drugs to the American consumer. As mandated by Congress under the MMA, a DHHS Task Force on Drug Importation conducted a study to determine whether importing drugs could be done at a reasonable price without compromising safety. The Task Force's 135-page report, issued in December, 2004, included findings that importation is neither safe nor cost-effective. Secretary Tommy Thompson has refused to certify importation, and it is expected that his successor, Mike Leavitt, will take a similar stand.

Advocates for importation argue that the practice introduces much needed price competition into the marketplace and makes drugs more affordable for U.S. seniors, while the FDA warns that drug importation is unsafe and illegal because imported drugs may not meet rigorous U.S. safety standards. Several bills were introduced in Congress this session that would legalize importation. Bills S. 184, S. 334 and H.R. 700 seek to amend the Food, Drug & Cosmetic Act with respect to the importation of prescription drugs. On April 7th, Senator Mike Enzi, Chairman of the Senate Health, Education, Labor and Pensions Committee, announced that the Senate is beyond debating whether to pass a drug importation bill and has moved on to deciding the mechanics of the bill.

Professor Tom Perez, who teaches the Law & Health Care Program's Access to Health Care Clinic and who is President of the Montgomery County Council, has been an active advocate of drug importation. Last fall, the L&HCP co-hosted a forum on this topic at which Prof. Perez spoke about an initiative in Montgomery County to establish a prescription drug mail order program for its retirees. (For

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more on this issue, see article on the L&HCP's Drug Importation Forum, p. 6.)

Compulsory Licensing is also being proposed as a mechanism by which to provide necessary drugs at lower cost to individuals with certain diseases. For example, in January 2004, Essential Inventions, a nonprofit corporation, petitioned DHHS for compulsory licenses to "manufacture and sell inexpensive generic versions of latanoprost (Xalatan) and ritonavir (Norvir)."¹ The drugs are used to treat glaucoma and HIV, respectively, and were developed with federal funding. Under the Bayh-Dole Act, the government has the right to "'march in' on the patent rights and license them to another producer."² The NIH turned down the request for both drugs.

Also, as a result of the anthrax scare in fall, 2001, DHHS Secretary Tommy Thompson sought to stockpile sufficient amounts of ciprofloxacin (Cipro) to treat ten million people. This amount was significantly greater than the available supply and Bayer, the manufacturer of Cipro, did not have the capacity to quickly produce such large quantities of the drug. As a result, on October 16, 2001, Senator Schumer asked Secretary Thompson to issue compulsory licenses to generic manufacturers allowing them to produce the drug.³ Thompson declined to issue compulsory licenses claiming that the supply of Cipro the government was able to purchase from Bayer was adequate to increase the nation's emergency reserve of antibiotics. To learn more about the issue, on March 7, 2005, the Student Health Law Organization (SHLO) and the Maryland Intellectual Property Student Association co-sponsored a forum on compulsory licensing. (For more information about the forum, see article, p. 8.)

Threats of bioterrorism have raised a separate set of drug access issues. After September 11, 2001, and the anthrax scare, the possibility of a bioterrorist attack increased the urgency for new medicines to prevent and treat infectious diseases. Pharmaceutical and biotechnology companies began working with the government to develop and stockpile

vaccines to prevent outbreaks of such diseases as anthrax, smallpox, plague and others. On July 21, 2004, President Bush signed into law Project Bioshield which provides new tools to improve medical countermeasures against chemical, biological, radiological or nuclear (CBRN) attack including the expeditious development and licensing of vaccines. These products must move through the manufacturing process, pre-clinical testing, clinical trials, and the licensing and approval process prior to distribution.

On June 9, 2004, the L&HCP, in collaboration with the School of Law's Center for Health and Homeland Security, held a



conference on "Eliminating Legal, Regulatory, and Economic Barriers to Biodefense Vaccine Development." (See story, p. 16, Spring 2004 L&HCP Newsletter). The upcoming issue of the *Journal of Health Care Law & Policy* will be devoted to this topic with contributors including Michael Greenberger, Law School Professor and Director, Center for Health and Homeland Security, University of Maryland School of Law; Wendy Parmet, Professor of Law, Northeastern University School of Law; Gail Javitt, Policy Analyst, Genetics and Public Policy Center, Phoebe R. Berman Bioethics Institute, Johns Hopkins University; Cynthia Ho, Associate Professor, Loyola University of Chicago School of Law; and Elin Gursky, Principal Deputy for Biodefense, National Strategies Support Directorate at Analytic Services, Inc. (ANSER). To order a copy of this issue, contact the *Journal* at 410-706-2115 or jhclp@law.umaryland.edu.

Quality and Safety

Prior to putting a drug on the market, manufacturers must establish that the drug is safe and effective. This requires extensive, costly and time consuming testing and clinical trials. The process of bringing a drug to market takes an average of 8.5 years and costs, on average, about \$500 million.⁴

Controversies arise in some cases as to whether certain substances should be classified as drugs or regulated by the FDA. A decision by policy makers that a substance will not be regulated as a drug clearly saves the manufacturer a great deal of time and money, but it may raise concerns about the safety of the substance and access to the substance by minors or uninformed consumers. This has been the case with both dietary supplements and tobacco. In 1994, in response to vociferous lobbying by the vitamin industry, Congress passed the Dietary Supplement Health and Education Act, which classified herbal products as food supplements rather than drugs. This result was a compromise "reached after a battle in Congress between federal health authorities who wanted tougher safety and efficacy standards, and herbal companies, who complained that they could not afford the sort of clinical testing required by the FDA for synthetic drugs."⁵ In a recent class in her multidisciplinary course, *Critical Issues in Health Care*, Professor Diane Hoffmann, along with adjunct Professor Frank Palumbo, had students testify for or against proposed legislation to regulate dietary supplements as drugs. According to Hoffmann, students in the class have strong feelings about the issue and to what extent these products should be regulated.

Whether tobacco products should be regulated as drugs or drug delivery devices has also been a topic of ongoing debate. Professor Kathleen Dacheille, Director of the Law School's Center on Tobacco Regulation, Litigation and Advocacy, has argued that from a public health perspective, there is no question that tobacco products should be considered a drug. However, political lobbying by the tobacco industry has prevented

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this from happening for years. Recently, however, a bill introduced in Congress that would give FDA authority to regulate tobacco products gained considerable support from both sides of the political aisle. Prof. Dachille writes about the bill in this issue of the newsletter. (See article, p. 7.)

Once a drug is approved for marketing, manufacturers are required to report any adverse events related to taking the drug to the FDA. If there are sufficient reports of serious adverse events that can be linked to an approved drug, FDA can remove the drug from the market or pressure manufacturers to do so.

Over the last few months several drugs for the treatment of pain have been removed from the market. Just recently, on April 7th, 2005, the FDA asked Pfizer to voluntarily remove Bextra, a Cox-2 inhibitor similar to Vioxx, from the market because of the risk of cardiovascular side effects, stroke, heart attack and serious skin reactions. Following the recall of Vioxx in September, 2004, Pfizer began an aggressive marketing campaign for Bextra, which was widely prescribed for arthritis and other acute pain. In December of last year, the FDA required Bextra to come with a black box warning, a way to tell doctors and patients that the drug has risks and should be prescribed only when there is no other alternative.

Following a joint meeting of the FDA's Arthritis and Drug Safety and Risk Management Advisory Committees in February, the FDA concluded that the overall risk versus benefit profile for Bextra was unfavorable. The FDA is also asking manufacturers of all marketed prescription Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), including Celebrex, to revise the labeling for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular events and the well described, potentially life-threatening



gastrointestinal bleeding associated with their use. Manufacturers of over the counter NSAIDs such as Motrin (ibuprofen) and Aleve (naproxen) are also being asked to revise their labeling to provide more specific information about the potential cardiovascular and gastrointestinal risks of their individual products and remind patients to take these products in accordance with the

limited dose and duration of treatment on the package instructions.

Addiction and Abuse

The reduction in the number and variety of pain medications exacerbates an already existing problem in our health care system – the under treatment of pain.

Professor Hoffmann has worked extensively on this problem, publishing several articles on legal, financial and cultural obstacles to pain management. The problem is in part a result of physician fear of legal scrutiny and sanction associated with the prescribing of opioids. These drugs are classified as controlled substances under federal law because of their potential for diversion, abuse and addiction. The prescribing of opioids is thus regulated by both the federal Drug Enforcement Agency (DEA) and the FDA.

Perhaps the most well-publicized case of drug diversion in recent years is that of OxyContin, a medication legitimately used to treat moderate to severe pain. OxyContin is a Schedule II controlled release form of the narcotic oxycodone manufactured in tablet form. OxyContin became a “drug of choice” for diverters and abusers of controlled substances because of the larger amounts of the active ingredient in relation to other previous oxycodone products and the ability of abusers to easily compromise the controlled release formulation. Simply crushing the tablet negates the timed effect of the drug and enables users to swallow, inhale or inject the drug for a morphine-like high. Common means of OxyContin diversion are

fraudulent prescriptions, doctor shopping, over-prescribing and pharmacy theft.

The DEA and state drug enforcement personnel have recently targeted a number of physicians for arrest and prosecution who prescribe OxyContin in large quantities arguing that they are prescribing the drugs to known abusers. *Professor Hoffmann is currently working on an article that examines these arrests. She argues that in several of these cases drug enforcement personnel and prosecutors are overreaching and that their actions are having a chilling effect on the prescribing of opioids for patients with chronic pain who desperately need these drugs. (See article, p. 12.)*

In cases involving the prescribing of opioids, prosecutors' claims are often based on allegations that the drugs are not being prescribed for a “legitimate medical purpose,” as required by the federal Controlled Substances Act. Questions regarding whether a drug is being prescribed for a “legitimate medical purpose” have also been at the heart of the debate regarding Oregon's Death with Dignity Act (DDA). In 1994, Oregon enacted the DDA, becoming the only state to legalize physician-assisted suicide. Under the DDA, adult Oregon residents suffering from an incurable disease likely to result in death are eligible to receive prescribed medication that would end life. A physician may prescribe, but not administer, the medication to the patient. In all cases, the drugs prescribed are listed as controlled substances under the Controlled Substances Act.

In November, 2001, U.S. Attorney General John Ashcroft issued a statement, known as the Ashcroft directive, aimed at Oregon physicians which said that assisting with suicide is not a legitimate medical purpose and that any physicians assisting with suicide under the DDA would be in violation of the CSA and could face criminal prosecution and termination of their ability to prescribe controlled substances.

In response to the directive, the State of Oregon, along with an Oregon physician, pharmacist and several terminally ill patients, filed a lawsuit against the

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PHARMACISTS IN LAW SCHOOL

When pharmacist Jeanne Brennan told her friends and family that she was going to law school, they thought she was crazy. Why would she give up pharmacy, a lucrative career with a lot of schooling of its own, to go back to school? And why law school? Well, it turns out that Jeanne's path is not terribly uncommon. She is one of several current Maryland law students with pharmacy backgrounds.

Jeanne graduated from the University of Utah with her pharmacy degree in 1990. She worked for over ten years as a pediatric pharmacist at Primary Children's Medical Center in Salt Lake City, where she was a member of a multidisciplinary ICU team. Although she was doing very well for herself and her family, Jeanne started to get bored. Pharmacy is very technical, she said, and she had reached a certain level of expertise and thought, "Now what?" She decided to go to law school because the law degree would open up opportunities for her both within the pharmacy field and without. She came to the University of Maryland School of Law as an evening student, working during the day as a pharmacist at CVS. During law school, she has worked contractually for the DC law firm of Goulston and Storrs on pharmacy related matters. She is keeping her options open following graduation this spring. She is interested in OIG work, lobbying, and issues related to e-health.

Like Jeanne, Ann Taylor has been a pharmacist at CVS by day and a law student by night. She received her PharmD from the University of Maryland School of Pharmacy in 1997. She did her post-graduate residency at Washington Hospital Center and then became a consulting pharmacist for Mariner Health Medical Services and Neighborcare Long Term Care Pharmacies. It was during this experience working with nursing home patients that Ann realized the interconnection between pharmacy and the law. She noticed how heavily regulated the nursing homes were, and how scared the nursing home employees seemed to be of the regulators.



(Left to right) Jeanne Brennan, Ann Taylor, Melanie Torain, Lori Brandes

She says that she came to understand that "there were laws in place that did not connect with clinical practice." In other words, clinical medicine was moving forward, and the law was not keeping up. This is why she decided to go to law school: "It is important for people in long term care to be involved with making the laws that regulate them."

During law school, Ann had several experiences in which she felt her pharmacy background was an asset. She did a health law practicum at the U.S. Department of Health and Human Services, Office of the General Counsel in the Public Health Division and clerked in the Maryland Attorney General's Office in the Antitrust Division. In both experiences, she felt her science background and clinical knowledge proved useful in the tasks she was asked to complete. She also participated in the Civil Rights: Access to Health Care for Vulnerable Populations Clinic in which she worked for the Coalition to End Childhood Lead Poisoning. As part of her clinic experience, she provided legal assistance to clients involved in claims in landlord-tenant court who were facing eviction and had viable legal defenses related to lead paint. She found that because of her pharmacy background she was able to explain to parents, in a way that made sense, the meaning of the medical terminology

surrounding their child's lead paint poisoning. Following graduation this spring, Ann is considering a career in legislation or health care compliance.

Melanie Torain is another fourth year evening student with a pharmacy background. She was a pharmacy technician at Rite Aid and then at Johns Hopkins Hospital for close to ten years. She then became a radiologic technologist at Hopkins. During her time at Hopkins she attended the University of Baltimore and received her B.S. in Health Systems Management. As part of her degree requirements, Melanie took a class in health law. She was fascinated and knew then that she would go to law school. On her way to the health law certificate, Melanie has taken many health care classes. Classes such as Health Care Law: The Provider-Patient Relationship were not so abstract because she sees those relationships at work everyday. Because she also witnesses disparities in health care on a regular basis, Melanie chose to participate in the Civil Rights: Access to Health Care for Vulnerable Populations clinic. Like Ann, she represented indigent clients in the Baltimore City District Court on issues related to lead paint. She is considering a career in medical malpractice litigation following graduation.

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DRUG IMPORTATION FORUM

Pharmacists in Law School

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Lori Brandes, a second year evening student, had always liked science, so she got her bachelors degree in biochemistry and molecular biology and then went to graduate school. She received her Ph.D. in Pharmacology in 2002 from the George Washington University. She knew that she wanted an alternative career in science, but it wasn't until she had lunch with a friend one day that she considered law. Her friend from graduate school was working for a patent law firm and told her that many patent law firms had a need for people with scientific expertise. Lori looked into it and applied for a Technical Specialist position with Sterne Kessler Goldstein Fox in D.C. Sterne Kessler has a program in which they train people with technical backgrounds about the patent process and then help them to become patent agents and/or go to law school. After a year as a technical specialist, Lori went to law school, at which time she became a Student Associate with the firm. In her first two years of law school, Lori feels her pharmacy background has been very helpful. She believes the analytical skills she gained in graduate school have helped her with issue-spotting and conveying information in a clear and concise way. Prior to graduation Lori will sit for the patent bar. Upon graduation she hopes to become an associate with Sterne Kessler.

These four students entered law school with a unique perspective on life. They all believe their pharmacy backgrounds have been advantageous to them in law school and will help them get their desired job following graduation. Maybe the notion of a pharmacist going to law school isn't so crazy after all!

Over the last few years, the issue of importation of prescription drugs from foreign countries has received considerable attention from legislators, the media and the public. Advocates for the practice argue that importation introduces much needed price competition into the marketplace and makes drugs affordable for U.S. seniors. The Food and Drug Administration (FDA), however, warns that drug importation is unsafe and illegal because the drugs may not meet U.S. standards. In defiance of the FDA, at least 14 states and numerous local governments have announced plans to, or have taken steps to, import lower cost prescription drugs from Canada. In an effort to explore the complexities of this issue, the Law & Health Care Program in conjunction with the School of Pharmacy's Center on Drugs and Public Policy hosted a Forum on Drug Importation on October 27, 2004.

The panel included law professor Tom Perez, who is also President of the Montgomery County Council and represents 180,000 residents of Montgomery County; William Hubbard, Senior Associate Commissioner for Policy, Planning and Evaluation for the FDA and the FDA's point person on drug importation; Cynthia Boyle, Assistant Professor at the School of Pharmacy, current president of the Maryland Pharmacists Association and an officer in the American Pharmacists Association; and Dr. Peter Rost, Vice President of Pfizer Pharmaceuticals, who has had 20 years of experience marketing pharmaceuticals and has been involved in drug importation in Europe for Pfizer. The panel was moderated by David Knapp, Dean of the School of Pharmacy and a founder of the School's Center on Drugs and Public Policy.

Dean Knapp set the stage for the discussion by highlighting a few statistics. He noted that the cost of prescription drugs is rising, and the number of prescriptions written in the U.S. has doubled in the last couple of years to 3.3 billion prescriptions dispensed in 2003. Total prescription drug sales in the U.S. in 2003 were \$228 billion, while the dollar amount of prescriptions imported from Canada in that year was \$1.1 billion.

Professor Perez kicked off the panel by discussing the fiscal crisis that Montgomery County is currently facing. Like every county in America, he said, Montgomery County has unfunded mandates from the federal and state governments and has had to cut vital



community services such as ladder trucks and school programs because of the budget crisis. As a Council member, he looked at the County's balance sheet to see what factor was "killing" the budget. It turned out to be the cost of prescription drugs to county employees and retirees, which had doubled in six years. In an effort to save money in this area, the County Council began to explore the option of importing drugs from Canada for its employees. With the help of a technical advisory group, the Council concluded that the Canadian system was safe and cost effective. Although the legal issues are muddled, the Council is going forward with a prescription drug mail order program for its retirees. Requests for proposals went out in February. The Council is in the process of reviewing a number of bids and will make a decision some time this spring.

Bill Hubbard outlined the FDA's long list of concerns over the importation of foreign drugs. In particular, the FDA is concerned with untruthful websites, questionable sources of drugs, counterfeit

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REGULATION OF TOBACCO PRODUCTS

drugs, controlled substances coming into the country illegally, and the Canadian market running dry. He also pointed out that, in many cases, you can beat the Canadian price for a drug by buying its generic equivalent here in the U.S. In the end, he said, cost-saving should not come at the risk of safety.

Professor Cynthia Boyle opposes the importation of drugs from Canada. Whenever money is involved, she said, there is a risk to safety. She fears that importation is an end run around U.S. safety regulations and believes that drug importation is an example of treating the symptom of a problem instead of the underlying cause. If we focus on prevention of health problems, she said, the overall cost of health care in this country will go down. She proposes providing incentives for pharmacists to look over patients' drug regimens to reduce the number of their prescriptions, providing incentives for doctors to keep patients well, and encouraging people to take better care of themselves.

The last speaker was Dr. Peter Rost. To counter the FDA's argument that drug importation is unsafe, Rost points to Europe, where reimportation has been carried out safely for 20 years. He said that we hear all about how unsafe importation is, but "we haven't seen a dead body yet." Moreover, while the FDA is attacking reimportation, the real safety concern should be that we have people in this country choosing between their prescription drugs and food. He believes that "importation is no substitute for meaningful health care reform, but in the meantime, we must play the hand we're dealt." If the government would regulate importation, it could ensure safety and help the uninsured by providing an alternative supply channel for prescription drugs.

Public health advocates have campaigned for federal legislation granting the Food and Drug Administration authority to regulate tobacco products since the Supreme Court ruled in 2000 that the agency lacked such authority in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). A close call on legislative efforts in 2004 inspired advocates



to return to Congress this year with a clear, comprehensive and bipartisan bill giving FDA that authority. The DeWine-Kennedy bill (S. 666) and the Davis-Waxman bill (H.R. 1376) were introduced March 17, 2005 with the support of the Campaign for Tobacco-Free Kids, American Cancer Society, American Heart Association, and American Lung Association.

During the 2004 Congressional session, the FDA regulation bill was merged in the Senate with an important corporate tax bill and in the House with a bill that would provide \$10 billion as a "buyout" to tobacco growers. Both the tax bill and the buyout bill were destined for passage and tobacco control and public health advocates were optimistic that, as an add-on to these bills, FDA regulation of tobacco would pass as well. Despite Herculean efforts by advocates and key legislators, the tax and buyout bills passed without the FDA provisions. In response, a free-standing bill providing FDA regulation of tobacco was introduced. That bill passed the Senate (78-15) but died in the House without a vote.

Like the 2004 version, the 2005 version of the FDA bill creates a new standard by which the federal agency is to evaluate tobacco products. Currently the FDA may approve of a drug or device if there is a reasonable assurance that a product is "safe and effective." As there is no safe and effective tobacco product, the bill provides

that the agency would evaluate whether an action regarding a tobacco product would protect the public health. In addition, the bill would grant the FDA authority to:

- Restrict tobacco advertising;
- Require disclosure of all ingredients and additives in tobacco products;
- Alter health warnings on cigarettes and smokeless tobacco and in advertisements;
- Prohibit tobacco companies from marketing "modified risk" products unless the FDA approves of the product and the marketing plan.

Although the bill allows the FDA to require product modifications, such as reduction of nicotine, Congress retains exclusive power to require the elimination of nicotine or to ban the sale of cigarettes, cigars or smokeless tobacco. In contrast to an existing federal law with a broad preemption clause, the bill grants state and local governments some authority over tobacco marketing.

FDA regulation of tobacco is considered an essential element in a comprehensive public health plan to reduce tobacco-related illness and death. Effective federal regulation should result in diminished youth access to tobacco, decreases in adult smoking prevalence and a better-educated consumer. Such regulation would complement and extend the effectiveness of smoke-free workplace laws, youth sales enforcement programs, cessation services, and other regulatory, economic and social strategies to improve public health by reducing tobacco use. For more information about the 2005 bills or to track the legislation, visit www.tobaccofreekids.org/reports/fda.

*Professor Kathleen Dachtler
Director, Center for Tobacco
Regulation, Litigation & Advocacy*

COMPULSORY LICENSING PANEL

In recent years, many policy experts have advocated for alternative drug access policies given the continued threat of bioterrorism and the rampant HIV/AIDS crisis around the world. On March 7, 2005, the Maryland Intellectual Property Student Association (MIPSA) and the Student Health Law Organization (SHLO) co-sponsored a forum on "Compulsory Licensing and Access to Medicines" to examine whether compulsory licensing of pharmaceuticals could increase access to life-saving drugs during times of national emergencies and for HIV/AIDS patients and patients suffering from other diseases. Compulsory licensing is the legal mechanism which allows the government to compel a patented-drug-maker to license the right to produce and market its patented drug to a generic drug manufacturer in

exchange for a royalty. The generic drug manufacturer can often produce the drug at a much cheaper price than the patented-drug making company, and the drug is financially accessible to a broader range of people than it would otherwise be. The panelists weighed the costs and benefits of compulsory licensing.

The forum featured Robert A. Freeman, Ph.D. (Senior Scholar, Department of Health Policy, Thomas Jefferson School of Medicine), Michelle S. Marks, Ph.D., J.D. (Special Counsel, Shaw Pittman, LLP; UM '96) and Peter J. Weina, M.D., Ph.D. (Chief of Pharmacology, Walter Reed Army Institute of Research). The panel session was moderated by Professor Francis B. Palumbo, Ph.D., J.D. (Director, Center on Drugs and Public Policy, University of Maryland School of Pharmacy). The audience engaged the

panelists in a lively discussion about the need to increase access to life-saving medicines and the prospects of compulsory licensing in achieving such a goal. Dr. Marks and Dr. Freeman suggested that compulsory licensing would infringe on intellectual property rights and could stifle discoveries of innovative, life-saving drugs. Dr. Weina, an expert on tropical medicine and infectious diseases, concluded that compulsory licensing or other suggested policy alternatives cannot realize their desired outcomes until proper distribution infrastructures are established in crisis-stricken areas.

*Rachael Melby (SHLO)
Ravi Upadhyay (MIPSA)
University of Maryland
School of Law, '05*

FOOD AND DRUG LAW CAREER PANEL

On February 9, 2005, the Student Health Law Organization (SHLO) highlighted the variety of career opportunities existing in the area of food and drug law by hosting a panel of speakers who practice in this highly specialized field. The panel consisted of three University of Maryland School of Law alumni who work on issues related to food and drug law but in different practice settings. The panel members answered questions from students and gave them some personal insights about their work in the field and their career paths. They also provided some advice for any in the audience who might be aspiring food and drug law attorneys.

Deborah Shelton, a 7th year associate at Arent Fox in Washington D.C., discussed the practice of food and drug law from the vantage point of an attorney in a private firm. Although she did not have a scientific background and had not initially planned to practice food and drug law, she found her love for the field as a summer associate at the firm and joined

the practice group after graduation. Her work has included everything from labeling issues to patent rights. One of the topics about which she spoke at length was the cost and availability of biopharmaceuticals. (*See her article, p. 9.*)

Jayson Slotnik, the Director for Medicare Reimbursement and Economic Policy at the Biotechnology Industry Organization (BIO), spoke about his experiences as a policy analyst and attorney for a trade association. Always interested in health care issues, Mr. Slotnik received his MPH and was an epidemiologist for several years prior to attending law school. He initially joined a major health law firm in Washington, D.C. after law school, but he was hoping to find a job which would better enable him to combine his public health and legal backgrounds. Describing his current position as the "perfect" job for him, Mr. Slotnik told students about the fast paced and unpredictable life of a policy analyst in food and drug law. Second year law student Linda Souter is

externing with him at BIO this semester. (*See her account of her experience, p. 15.*)

Dr. Peter Rheinstein, publisher of the journal *Discovery Medicine* and former Director of FDA's Office of Drug Standards, told students about the government side of food and drug law. He gave a unique "insiders" perspective on how the FDA works and deals with legal issues. Dr. Rheinstein enrolled in law school in the evening program while he was a full-time practicing physician. He found the FDA to be an ideal place to work given his medical and legal backgrounds. Having spent over 20 years at the FDA, Dr. Rheinstein spoke to students about the cutting-edge and substantive work with which he was involved and being at the forefront of setting regulatory standards. He currently provides consulting services for pharmaceutical companies on regulatory matters.

*Mona Shah
University of Maryland
School of Law, '06*

WILL BIOPHARMACEUTICALS SOON FACE COMPETITION FROM GENERICS?

More than \$10 billion worth of branded biologicals are anticipated to go off patent in the U.S. within the next two to three years. Unlike chemically synthesized drug products, none of these products currently face the prospect of competition from generics. Yet, many of these biopharmaceuticals can, for a single patient, cost upwards of \$1,000 per month, and in some cases, tens of thousands of dollars a year. Unlike conventional chemically synthesized pharmaceuticals, however, there is, at present, no abbreviated approval pathway for would-be generic versions of biopharmaceuticals. That absence has begun to garner increasing attention, spurred on by the convergence of two critical factors: the increasing promise of biopharmaceuticals as breakthrough medical therapies and the need to render those therapies accessible to patients without financially overburdening the U.S. healthcare system.

Thus far, Congress has played only a very small role in the debate. It has instead decided to allow the U.S. Food and Drug Administration (FDA) to take the lead. To date, FDA has maintained its primary focus on the scientific issues that it has identified as being central to a determination as to whether an abbreviated approval pathway should be created for a generic version of a brand name biopharmaceutical.

Legal Overview. With few exceptions, including human growth hormone and insulin, biologics are approved under the Public Health Service Act (PHSA). Drugs, by contrast, are approved under the federal Food, Drug and Cosmetic Act (FDCA). Full new drug applications (NDAs) under the FDCA, and biologics license applications (BLAs) under the PHSA, require complete reports of pre-clinical and clinical data to support approval. A crucial difference arises, however, in the context of biologics approved under the PHSA. Unlike the FDCA, the PHSA includes no abbreviated approval pathway for a generic version of a previously approved biologic. Therefore, the consensus is that the creation of an abbreviated approval pathway for a

generic biopharmaceutical will require legislation. Indeed, FDA itself has acknowledged the need for statutory authority in order to do so. Moving toward legislative and regulatory change requires resolution of a set of difficult scientific and technical questions.

Scientific Issues Raised by the Prospect of Generic Biologics. The scientific arguments surrounding the debate can be classified as deriving from two main premises: (1) that unlike chemically synthesized drugs, biologically derived products raise special concerns due to their molecular size, complexity, and heterogeneity; and (2) that there is an inextricable link between a biologic's manufacturing process and its clinical attributes.

On the first point, some argue that the chemical composition and structure of a chemically synthesized drug can be determined precisely by physical and chemical assays, and thus any differences between a reference listed drug and a proposed generic version can be readily identified. In contrast, the complexities of many biologics make it difficult, if not impossible, to fully characterize, and thus any differences between a biological and a proposed generic version, and the potential clinical effect of any such differences, are difficult, if not impossible, to identify and assess.

On the second point – often framed as the “product is the process, and the process is the product” – some argue that unlike the clear and linear manufacturing process of a chemically synthesized drug, biopharmaceuticals have an inherent metabolic and synthetic variability that renders them vulnerable to minute differences between manufacturing processes, which, in turn, may cause significant differences in the clinical properties of the products. Thus, the argument continues, it is simply not possible for different manufacturers to produce an identical biological product; therefore, FDA should require a full complement of pre-clinical and clinical data as part of each and every marketing application for a biological product.

Next Steps. On August 16, 2004, FDA issued a Federal Register Notice summarizing

the specific scientific issues it identifies as critical to the biopharmaceuticals debate. These scientific issues have been the subject of two public hearings within the past calendar year and a public docket of submission of written comments. FDA has announced that it will set forth its findings and conclusions on these and other relevant scientific issues in a draft guidance document. The primary focus of this guidance is anticipated to be on defining how the Agency evaluates issues related to biological comparability across different regulatory schemes and in different stages of product lifecycles. FDA has described the intended purpose of this guidance as to ensure that a consistent scientific approach is applied across biological products, regardless of whether they are approved under the FDCA or PHSA. This guidance will likely issue in the form of a series of draft guidance documents, each one discussing one or more of the scientific issues raised in the biopharmaceuticals debate.

Before it issues any of the so-called “scientific framework” guidance documents described above, however, the Agency has announced that it will first issue a background document that provides a comprehensive historical overview of the regulatory and scientific steps that the Agency has taken with regard to biological products over the past 50 years. Once these documents are issued, FDA may hold one or more public hearings to receive additional input on them. Finally, based on the current state of affairs, it is probable that only after FDA has issued more definitive findings on the scientific questions that the arduous legislative process will begin.

In sum, it is likely that some sort of abbreviated approval pathway for generic biopharmaceuticals will be created at some point in the future. Given the numerous and complex scientific issues that remain to be resolved, however, and the need for legislation to create such a pathway for most biologics, it is likely to be at least another two to three years before such a process is actually put into place.

Deborah M. Shelton, '98
Arent Fox PLLC

ROME LECTURE EXPLORES MEDICAID IN ITS FORTIETH YEAR

On March 10, 2005, the Law & Health Care Program sponsored the annual Stuart Rome Lecture. This year's distinguished speaker was Sara Rosenbaum, the Harold and Jane Hirsh Professor of Health Law and Policy and Chair of the Department of Health Policy at the George Washington University Medical Center, School of Public Health and Health Services. Professor Rosenbaum's lecture was entitled "The Elimination of Racial and Ethnic Disparities in Health Care: Focusing on What Is Real and True in Medicaid's Fortieth Year."

The Rome Lecture was established by Stuart Rome's family and friends to celebrate Rome's life and work. In her introduction, Dean Karen Rothenberg cited Rome as a pioneer in the field of health law, particularly with regard to issues crossing racial and religious lines.

Rosenbaum has similarly made many significant contributions to health law and policy. Rosenbaum has focused her career, beginning as a legal services attorney for the poor, on improving access to health care for low income, minority and medically underserved populations. She has played a major role in the design of federal and state legislative and regulatory health policy in a wide range of areas, including Medicaid, private health insurance and employee health benefits, health services for medically underserved persons, maternal and child health, civil rights, and public health. In 1993 and 1994, Rosenbaum worked for the White House Domestic Policy Council, where she directed the drafting of the Health Security Act for President Clinton. Rosenbaum has been named one of America's 500 most influential health policymakers and has been recognized by the U.S. Dept. of Health and Human Services for distinguished national service on behalf of Medicaid beneficiaries.

Rosenbaum's lecture focused on the realities of ethnic and racial health disparities and the challenges of financing adequate health care for minority populations through Medicaid. The Medicaid program supports health care for the nation's poorest and most vulnerable



residents, and is the health care safety net on which they depend. Rosenbaum stressed that Medicaid's role in our health care system cannot be underestimated because it is the single largest health insurance program and the most important program for minority populations nationwide. There are significant correlations between proportions of minorities and the presence of uninsured populations in most states, and many health care problems and health care needs are statistically greater in minority populations.

Rosenbaum believes that the country is poised for a huge public conversation about Medicaid. According to Rosenbaum, the program is a victim of its own successes, and much of health care reform over the last forty years has in some way been tied to Medicaid. The program has helped to shape health policy and the nation's response to significant public health crises, including infant mortality, the tuberculosis epidemic of the 1980s, HIV, aging of the population, child developmental disabilities and the incidence of breast and cervical cancer among low income women. However, this significant and yet most misunderstood of all public programs faces unprecedented challenges to its survival. Rosenbaum described the challenge of fixing Medicaid as a "passion play" that has unfolded as Congressional budget committees call for major spending reductions in Medicaid. Constraints in state spending make the suggestion of such reductions even more significant. Currently, much of the power to effect change is held by

proponents of the federal government's desire to switch Medicaid to a defined contribution program.

The debate over Medicaid is highly political. Rosenbaum believes that the fate of Medicaid may depend on how Americans and policymakers who represent them, respond to the ongoing debate. She described the Medicaid debate as "double edged" and spoke about the importance of illustrating to state policymakers that there is pain felt on both sides of the issue. Proponents of Medicaid argue that there is nothing "optional" with respect to the program's services and the populations that Medicaid covers, presenting strong arguments for finding ways to fix the program because it is a vital part of our health care system. Alternately, other policymakers believe that making certain cuts in Medicaid funding is required as a first step to making cuts in other parts of the health care system. There is no consensus among states about the best way to reform Medicaid. Although a purely federal program would eliminate pressure from individual states, it would require decisionmakers in the federal government to make decisions while being farther removed from the populations that Medicaid most affects.

Medicaid is, as Rosenbaum concluded, easy to misunderstand and even easier to entirely overlook in larger national debates about the fate of our country's health care system. However, changes affecting the fate of Medicaid represent a potentially profound shift in U.S. health care policy that may fundamentally alter relationships between Americans, especially minority Americans, and our health care system. How these challenges are resolved not only will shape the health care system for decades to come, but also will test the commitment of political leaders to the reduction of racial, ethnic, and economic disparities in health care.

Amy F. Siegel
University of Maryland School of Law, '07
Adapted from an article in *The Raven*,
Vol. XVII No. 4 (April 14, 2005)

CONFERENCE ON RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE

On March 11, 2005, the Law & Health Care Program in conjunction with the *Journal of Health Care Law & Policy* and the Abell Foundation hosted a conference entitled “Bridging the Racial Divide in Health Care: Eliminating Racial and Ethnic Disparities in Health Status.” Conference organizer Professor Tom Perez, gathered an impressive line-up of speakers to discuss promising practices for eliminating health disparities, the role of the legislative branch in combating disparities, increasing workforce diversity as a strategy to eliminate disparities, and foundations and government funders as catalysts to eliminate disparities.

Among the keynote speakers was the Deputy Director of the National Institutes of Health, Raynard Kington, M.D., Ph.D.



Prof. Tom Perez and Dr. Raynard Kington

Dr. Kington was appointed to this position on February 9, 2003. In this capacity, he shares in the overall leadership, policy direction, and coordination of NIH biomedical research and the research training programs of NIH’s 27 Institutes and Centers. Prior to this appointment, Dr. Kington was Associate Director of NIH for

Behavioral and Social Sciences Research. Dr. Kington’s own research has focused on the role of social factors, especially socioeconomic status, as determinants of health. His current research includes studies of the health and socioeconomic status of black immigrants, differences in populations in willingness to participate in genetic research, and racial and ethnic differences in infectious disease rates. In his conference address, Dr. Kington stated that every person and every organization has a role to play in the movement to eliminate disparities in health care. Researchers, government, health care providers and community organizations alike must all make strides to address this challenge. Dr. Kington ended his talk with the following narrative: “Many years ago, I remember being told that dealing with large social problems like health disparities is like dancing with a bear: you can’t sit down when you get tired. You have to wait for the bear to get tired. As you will hear over and over again at this conference no doubt, it is high time for each of us to put on his dancing shoes and get to work.”

Congressman Elijah Cummings also spoke at the conference. Congressman Cummings, a graduate of the University of Maryland School of Law, has been a member of the U.S. House of Representatives since 1996 and is now in his sixth term in Congress. He serves on the House Government Reform Committee, is the Ranking Member of the Criminal Justice, Drug Policy and Human Resources Subcommittee and is a member of the Wellness and Human Rights Subcommittee. In addition to his



Congressman Elijah Cummings

standing committee assignments, Cummings is the co-chair of the House AIDS Working Group and is a member of the House Task Force on Health Care Reform. He is the immediate past chair of the Congressional Black Caucus. At the conference, Congressman Cummings related the story of his grandfather, who died before his time, in part due to racial prejudice by his physician. Because of this personal tragedy, Congressman Cummings has been determined to seek solutions to the health disparities problem. In his remarks, he said, “I believe that health care is a fundamental right of every human being. I ask you who share this vision to work with us. Our goal is a health care system that truly serves ALL Americans. Now is the time to transform our human right to health care into a civil right guaranteed by federal law.”

L&HCP Ranked in Top Three in *U.S. News & World Report* Survey

The Law & Health Care Program ranked third in *U.S. News & World Report's* 2004 annual survey of law school specialty programs. Since 1995, the L&HCP has been consistently named among the top five health law programs nationwide.

SPOTLIGHT ON ... FACULTY SCHOLARSHIP

Diane Hoffmann

Professor Hoffmann and colleague, Anita Tarzian, Ph.D., recently completed an article entitled “Dying in American Nursing Homes: An Examination of Policies that Deter Adequate End-of-Life Care.” In the article, which is forthcoming in the *Journal of Law, Medicine & Ethics*, Hoffmann and Tarzian assert that dying nursing home residents often do not receive appropriate end-of-life care and



could benefit substantially from enrollment in hospice. Studies have shown that nursing home patients enrolled in hospice, when compared to those at the end-of-life who were not in hospice, are less likely to be hospitalized in their last six months of life, receive superior pain assessment and treatment, and are less likely to be physically restrained or have feeding tubes. While utilization of hospice care has increased during the last decade, there is considerable evidence that hospice care remains underutilized in the long term care setting. There are a host of reasons for this lack of utilization, but Hoffmann and Tarzian focus on several government policies including Medicare regulations that define hospice eligibility and the type of care that must be provided to nursing home residents, reimbursement of both hospice and nursing home care, and initiatives of the Office of the Inspector General to combat fraud in this area. They argue that these policies and practices are based on questionable

assumptions about “where people die, the predictability of death, and the financial incentives of nursing homes to utilize hospice.” As a result, they call for a shift in a number of paradigms that have affected policies related to caring for nursing home patients at the end-of-life.

Hoffmann is currently working on an article tentatively titled: “Arrest and Prosecution of Physicians for Prescribing Opioid Analgesics: The Indirect Costs of Prosecutorial Overreaching.” In the piece, Hoffmann questions the actions of some federal and state prosecutors who have arrested and charged scores of physicians with criminal violations related to their prescribing of opioid analgesics. In a number of these cases, the charges were subsequently dropped, or if the provider was found guilty at the trial court level, the verdict was overturned on appeal. The motivation for this increased legal action on the part of prosecutors appears to have its roots in the war on drugs and the recent spate of deaths related to the abuse of OxyContin. While the intense scrutiny is a response to a relatively new drug, prosecution of physicians related to the prescribing of narcotics has a long history in this country, and drug regulators have long attempted to balance negative effects (toxicity, addiction, and diversion) with positive effects (therapeutic benefit and pain relief). In the article, Hoffmann argues that these recent actions by prosecutors have led to a significant imbalance in the administration of drug control policy and that in a number of cases law enforcement officials are wrongly construing the definition of “legitimate medical purpose” and are overstepping the boundaries of appropriate prosecution. As a result, she argues, they are harming not only the lives of the physicians wrongly accused but also the patients of these physicians and other individuals who suffer from chronic pain. The law enforcement climate surrounding prescribing of opioid analgesics appears to be causing some physicians to stop prescribing opioids or to stop treating chronic pain patients, reducing to a very small figure the number of physicians who are willing to treat these needy patients.

Robin Wilson

Professor Robin Wilson continues her work on nanotechnology. (See article, p. 9, *L&HCP Newsletter*, Fall 2004.) Recently, she presented a paper entitled “Planning for the Unknown: Lessons from Bioterrorism” at a national conference on Nano Ethics at the



University of South Carolina, where she proposed a unique framework for regulating the new technology.

Some have argued that we should anticipate nanotechnology’s possible darker side by regulating individual applications or all nanotechnologies. Wilson highlights the difficulty of regulating a newly emerging technology in advance of actual experience and argues instead that we should regulate the entities that are developing nanotechnologies. Specifically we should plan for the possibility of a bad outcome by requiring companies to insure against such risks.

In advocating for this approach, Professor Wilson cites the fact that the United States has not adopted a precautionary principle as a basis for risk regulation. In fact, the U.S. Supreme Court has held that agencies cannot regulate on the basis of mere speculation about uncertain risks, but must act instead on a demonstrably significant risk. Any regulation of the technology, rather than the entity, also raises significant definitional problems about scope and

the difficulty classifying exactly what activities fall into nanotechnology. All of chemistry concerns atoms and molecules already on the nanoscale, the regulation of which would be unfeasible and undesirable. Equally challenging, the government has historically regulated a field only after a devastating event has already occurred. The Clean Water Act resulted from the polluting of the Cuyahoga river, Congress enacted CERCLA in the wake of toxic waste dump sites like the Love Canal, and September 11th gave rise to the Patriot Act, the Homeland Security Act, and Terrorism Insurance Act. Regulation after adverse events offers a number of advantages because the event highlights the need for regulation, crystallizes the policy choices we face, and allows us to consider real, not perceived, costs of regulating or choosing not to regulate, making the regulations we adopt more meaningful. This is the same reason why courts in the U.S. are loath to give advisory opinions, choosing instead to consider only live cases and controversies. Additional problems with anticipatory regulation are that it could result in too much regulation, unnecessarily stifling technological development, or too little regulation resulting in unchecked practices. Wilson's article will appear in a forthcoming symposium issue addressing the topic of regulating nanotechnology, to be published by the *Journal of Law, Medicine & Ethics*. She will serve as a co-editor for the issue.

Dan Gilman

Visiting Professor Daniel Gilman, J.D., Ph.D., is working on several articles touching on issues related to the regulation of drugs. His article "Thou Shalt Not Kill" as Defeasible Heuristic: Law and Economics and the Debate over Physician-Assisted Suicide" is slated for publication this spring in the *Oregon Law Review*. There, Gilman takes a critical look at Judge Richard Posner's account of physician-assisted suicide (PAS), one of the very few economically framed analyses of the topic. In his book,

Aging and Old Age, Posner offers a sort of cost benefit analysis favoring the legalization of PAS. Central to Judge Posner's account is a view of PAS as a technological innovation that brings a radical reduction in critical information costs attending end-of-life decision-making. Professor Gilman argues that Judge Posner's model—although innovative and instructive—is incomplete and, consequently, inadequate to the



normative task of justifying a change in legal regime. Of central concern, is the failure to address the larger social costs of errors—legally sanctioned (and perhaps publicly funded) non-voluntary killings. Examining the relevant behavioral literature, Gilman argues that such errors are liable to be frequent under Posner's scheme or any plausible alternative. Gilman asserts that the task of assessing the costs of PAS is probably intractable, and that the legal prohibition of PAS in nearly all the states should be "regarded as a strong default position."

As a follow-up to that article, Professor Gilman is working on a paper entitled "Poison Pills: *Oregon v. Ashcroft* and the Regulation of Dangerous Substances." Attempts to establish a constitutional right to PAS on due process and equal protection grounds were repudiated by the Supreme Court in the last decade, thus casting the debate about PAS back into the states. Recently, however, then-U.S. Attorney General John Ashcroft advocated that Oregon physicians practicing PAS

pursuant to Oregon's "Death with Dignity Act" are in violation of the federal Controlled Substances Act. In May 2004, a divided panel of the U. S. Court of Appeals for the Ninth Circuit rejected the Attorney General's position as unenforceable. Professor Gilman argues that the Attorney General's enforcement position appears eminently defensible, given the established statutory scheme and well-established principles of agency deference. He suggests that the Ninth Circuit's decision is variously problematic, although quite possibly limited in its reach. He also suggests that the case raises interesting questions regarding the fit between extant regulatory categories and the regulation of certain dangerous substances (e.g., recent legislative attempts to establish FDA regulatory authority over tobacco products as a species of over-the-counter drugs.) The Supreme Court has just announced that it will hear the case (now captioned *Gonzalez v. Oregon*) next term, and Professor Gilman will incorporate the Court's opinion in his discussion.

Professor Gilman is also working on an article addressing "Price Discrimination and Property in the Pharmaceuticals Industry." Price discrimination between U.S. and Canadian Pharmaceuticals markets is a conspicuous and contentious area of policy debate. Little examined, however, is the question of how general economic models of price discrimination, as species of monopolist price setting, may illuminate the debate about drug prices and the hotly contested "solution" of drug reimportation. Gilman argues price discrimination within and across U.S. borders is such that the cost to U.S. consumers of international price discrimination may not be as large as many have thought. Furthermore, he asserts that extant drug reimportation schemes are not likely to provide substantial long-term price relief to U.S. consumers of drug products. He does, nonetheless, suggest the need to reexamine the variety of statutory and regulatory property protections in the U.S. that form the basis of price discrimination in the pharmaceuticals market.

SPOTLIGHT ON ... FACULTY AND ADJUNCTS

Judge John Fader

Many people know that Judge John Fader is a retired Baltimore County Circuit Court Judge and a senior judicial fellow who teaches several courses at the School of Law. What many people do not know is that Judge Fader is also a licensed pharmacist.



Judge Fader graduated from the University of Maryland School of Pharmacy in 1963. During the last year of pharmacy school, he took a class called Pharmacy and the Law. This class and the professor who taught it greatly influenced Fader, and he and three other students from his graduating class decided to go to law school. Fader practiced pharmacy while attending the School of Law at night. He graduated from the evening program in 1968 and was sworn into the Maryland Bar on November 26, 1968.

During law school, Fader assumed that after he graduated he would go to work for a pharmaceutical company or pharmaceutical association. In the first semester of his last year of law school, however, Fader took a law clerk position for a local attorney. It was through this

experience that Fader grew to realize he wanted to be a litigator. Following graduation from law school, he started his own practice in Towson, MD. From 1970 to 1977, Fader worked in private practice. Among other things, he was general counsel to St. Joseph's Hospital and represented five or six contractors.

After seven years of private practice, Fader had become what he calls "a glorified business consultant." He spent most of his time writing contracts and sitting in on business meetings. What truly interested him was "the law, litigation, analyzing cases," so in 1977 he ran for a judicial position. On November 23, 1977, he became a judge for the District Court of Baltimore County. He later ran for election to the Circuit Court for Baltimore County and was sworn in on February 10, 1982 for a fifteen year term. He ran again in 1998. He served five years of his fifteen year term and retired from the bench in 2003.

Fader continues to be active in teaching, both here at the law school and in the pharmacy school. He has taught Pharmacy and the Law at the pharmacy school every year since 1974. He has been an adjunct at the law school for seven years and teaches classes such as Family Law, Maryland County and State Administrative Law, Administrative Law, and Maryland Civil Procedure.

Fader maintains his pharmacy license and says that his pharmacy degree made him a better lawyer and judge: "The method of science and drugs has made me very meticulous and detail-oriented." Pharmacy was also what allowed him to make a living to get through law school. "I keep my pharmacy license up. I'm very proud of being a pharmacist, and one who graduated from Maryland's pharmacy school."

Dr. Frank Palumbo

Dr. Frank Palumbo is both a licensed pharmacist and a member of the Maryland Bar and has practiced both pharmacy and law. He teaches Pharmacy Law at the School of Pharmacy and has been teaching Food and Drug Law at the School of Law since 1997.

Dr. Palumbo received his B.S. in pharmacy from the Medical University of South Carolina in 1968. He was then drafted into the army and assigned to the Pentagon until 1971. From 1971 to 1974 he worked on his M.S. and Ph.D. in Health Care Administration at the University of Mississippi. He then joined the faculty at the University of Maryland School of Pharmacy. Over the course of



several years, Dr. Palumbo took law classes at the University of Baltimore because he was "always interested in legal issues as they pertained to drugs and pharmacy." In 1982, he completed his J.D.

LAW & HEALTH CARE PROGRAM

EXTERNSHIP

Biotechnology Industry Organization Externship Spring 2005

During 25 years at the School of Pharmacy, Dr. Palumbo has held a number of positions. He was initially recruited as an Assistant Professor and rose through the academic ranks to full professor in 1992. In addition, he has served as an acting department chair and a department chair of Pharmacy Practice and Administrative Science. He also served as Special Assistant to the Dean and Interim Associate Dean for Administration.

Dr. Palumbo co-founded the School of Pharmacy's Center on Drugs and Public Policy in 1988 and served as its Associate Director until 1998 when he assumed the directorship of the Drug Policy Research Center. The Center currently has 10 faculty associates and approximately 17 staff who collectively are involved in several millions of dollars of projects. The Center specializes in providing credible, unbiased and pragmatic solutions for government agencies, the pharmaceutical industry, professional organizations and private businesses on public health issues and practices involving medication use and regulatory matters.

From 1988 to 1989, Dr. Palumbo took a sabbatical from teaching to work at the law firm of Hyman, Phelps & McNamara practicing FDA law. He continues to act as an expert witness in cases involving FDA law. His research interests include counterfeiting and drug importation, specialty pharmaceuticals, drug use in the elderly, direct to consumer advertising, and the Medicare and Medicaid programs and drug use. As for teaching at the law school, Dr. Palumbo says, "It keeps me on my toes."

The first time I heard about BIO was in 1999, while I was still an undergraduate studying biology at Arizona State University (ASU). I was taking a class on biotechnology and the law through ASU's law school. The class focused on the intersection of biotechnology, law, business, and health care. My interest in biotechnology was a huge motivating factor in my decision to go to law school. Seven years later when I got an email from Cindy Tippet, Director of Health Law Externships at Maryland, about an externship opportunity at BIO, there was no doubt in my mind what to do. I leapt at the opportunity to be an extern at the place that had, in part, altered the trajectory of my career from going into medicine to studying law.

Externing at BIO through Maryland's Law & Health Care Program gave me the unique opportunity to look at legal issues through the lens of an industry organization. I was able to earn credit toward a certificate in health law, build my resume, and network with professionals in health law and policy whom I will likely work with in the future.

While externing at BIO for four months, I gained an appreciation for the unique role of trade organizations. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the U.S. and thirty-one other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

Because BIO's membership is diverse, there are departments for everything from food and agriculture to intellectual property and bioethics. I was impressed with the open process that BIO used to develop positions on issues that promote the biotechnology industry and address the needs of both small and large companies.

Since I had worked for a few years before entering law school, I enjoyed the feeling of going to work again, even if it was only Monday through Wednesday nine to four. Taking the train to Washington, D.C. was a thrill for me. I grew up in Oklahoma, Indiana, and Arizona, so D.C. always seemed like the place—way over in the east—where important people made big decisions. Now that I've moved to the Maryland/D.C. area, D.C. still has its allure, and I feel fortunate to have had the opportunity to become a part of the action.

From the beginning, I was treated like a member of BIO's staff. I had my own cubicle, computer, email, and phone. I attended several meetings on a weekly basis, and I valued the opportunity to meet with BIO member company representatives. Some of my first impressions of BIO were very telling. The pace at the office was fast because BIO is constantly reacting to federal and state legislation, member questions, breakthroughs in science and technology, and current events. I'm a fast walker, so I liked the pace at BIO immediately.

During the first few weeks my acronym vocabulary grew exponentially. I knew some of the most common acronyms in health care (e.g. FDA, CMS, and HIPAA), but what I didn't know was all of the acronyms *within* the agencies, especially CMS. Four months later, I was ready for the acronym spelling bee! The

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LAW & HEALTH CARE PROGRAM EXTERNSHIP

Cont. from p. 15

first time I went to a health care reform and reimbursement meeting I was astonished by who was at the table. The big names in biotech that I regularly saw in headlines were sitting at the table with me! Meetings were always a learning opportunity. I enjoyed fleshing out my knowledge of emerging health care issues along with professionals. For example, I learned the details about Medicare Part D implementation, the overlap between Parts B and D, competitive acquisition programs (CAP), drug compendia, and the research exemption in patent law. More importantly, I learned how new federal regulations and state legislation affect biotechnology companies in ways I could not have predicted. By being aware of companies' needs and imagining how they would have to respond to rules and state legislation, I learned how to spot issues that would be important for biotechnology companies.

While at BIO, I took advantage of the D.C. location. I had fun attending Kaiser Family Foundation media briefings on health care issues where I learned about national drug spending projections, Medicare Part D implementation, and the nation's top health care objectives for the year. One afternoon I attended a welcome lunch for Representative Dan Lipinski, Jr. (D-Ill.). To complement a memo I drafted on the Federal Advisory Committee Act, I covered meetings of the Medicare Payment Advisory Commission (MedPAC) and the Secretary's Advisory Committee on Genetics, Health, and Society (SAGGHS). I was amazed by how many meetings and events occur every day in D.C. that are related to health care law. An unseasonably cold and windy day was made a lot brighter by my very first trip



Second year law student Linda Souter (left), with BIO supervising attorneys Jayson Slotnik and India Valentine who graduated from Maryland Law in 2001 and 1998 respectively.

to the Capitol for a Massachusetts Biotech and National Venture Capital Association briefing. I was with BIO staff who had been inside the Capitol many times, so I tried to control my excitement; however, it was probably quite obvious that I was a first-timer when I was the only person with eyes glued to the ceiling in the Brumidi corridors! Nevertheless, I saw the rotunda and felt like a real D.C. extern. To my delight, I had the opportunity to return to the Hill for a second time for BIO's Fly-In, which involved member companies meeting state leaders on the Hill and discussing biotech issues in their states.

Much of my BIO experience felt like being at a fantastic health law summer camp. Instead of learning how to make

lanyards and canoes, I had a mini course in administrative law and learned how to navigate the waters of Medicare Part D. There were always lots of meetings, events, and activities to take part in at BIO or in D.C., but not enough time to do them all. While at BIO, I developed a working knowledge of Medicare and Medicaid. I developed a new interest in reimbursement issues and a respect for how important they are in the health care economy. Externing at BIO provided me with valuable lessons about health care and biotechnology that I will certainly use in the future. I'm looking forward to an exciting career in health care law after I graduate in May 2006!

*Linda Souter
University of Maryland
School of Law, '06*

STUDENT AWARDS AND PUBLICATIONS

Congratulations to second-year law student Brooke Courtney and fourth-year evening student Drew Smith for their achievement in the annual Epstein, Becker & Green Health Law Writing Competition. Brooke's paper, "Is Obesity Really the Next Tobacco? Lessons from Tobacco for Obesity Litigation," and Drew's paper, "Maryland's Medical Malpractice Crisis: The Real Diagnosis," were selected as being among the top 20% of papers entered in the competition and are being considered for publication in the *Annals of Health Law*.



Brooke Courtney (2D) and Drew Smith (4E)

Cori Annapolen, a second-year law student, also deserves kudos for her first place prize in the student writing competition held at the Second World Conference on Nonsmokers' Rights. Cori's paper, "Maternal Smoking During Pregnancy: the Harmful Effects on the Exposed Fetus and the Proposed Legal Implications for the Mother's Actions," prevailed over 19 other finalists. The award included \$5,000 and publication in the *Virginia Journal of Social Policy and the Law*.

A CAKE WALK THROUGH LAW SCHOOL

Second year law student Mikaela Rossmann came to law school to pursue the certificate of concentration in health law. This semester she is externing at Washington Hospital Center, where she splits her time between the General Counsel's Office and the Bioethics Office. In addition to her busy work and class schedule, Mikaela finds time to run her own business. The following story ran in *The Daily Record* last December.



To deal with the stress of her first year at law school, Mikaela Rossmann started baking. And baking. And baking some more.

"I didn't want to eat it all so I started taking it into school and giving it away," she said. Pretty soon, orders for cakes and other desserts started pouring in, giving rise to *Torts and Tarts*.

A year later, Rossmann's novelty cakes command prices of \$35 to \$125 each. Most of her business comes by word of mouth, and the holiday season has been particularly busy for her: She's been baking practically nonstop since her last exam on December 15.

But Rossmann expects business to pick up even more in the New Year as she begins selling her signature gourmet desserts through the Hickory Ridge Grill, a Greek restaurant in Columbia. Her cakes, sold whole or by the slice, will supplement the restaurant's otherwise limited two-dessert menu.

Now a second-year student at the University of Maryland School of Law, Rossmann said she's been looking to expand *Torts and Tarts* for the past few months, and is seeking help to incorporate in the near future.

"I could figure it out but I don't have the time between law school and the baking to do it," said Rossmann, who will begin an internship with the general counsel's office at Washington Hospital Center in January.

She developed an interest in health care law and policy after undergoing treatment for aggressive fibromatosis, a type of cancer.

"Through that experience, just being in the health care system, you really realize how helpless you are," she said.

But for baking guidance, Rossmann sought advice from Warren Brown — not the famed Baltimore criminal defense attorney, but a successful government-lawyer-turned-baker in Washington. Brown left his job as a litigator with the Department of Health and Human Services in 2002 to open *Cakelove*, a bakery in Adams Morgan. His journey from law to flour has been featured in *The Washington Post* and *People* magazine, as well as on Oprah Winfrey's show.

Like Brown, Rossmann said she's been baking since childhood. "Law is my career, baking is my passion," she notes on her web site.

"I grew up in a house where there was a lot of baking," Rossmann said, standing in her Columbia kitchen with her hands covered in batter. "My mother is an amazing baker. People have been telling her for years that she should quit her job and go into baking."

Rossmann has no plans to abandon the law for baking, although eventually she would like to find some way to combine the two. "I would love to find a lawyer or a small law firm that would want to expand as a bakery, too," she said.

December 27, 2004
By ALISA BRALOVE,
Daily Record Legal Affairs Writer

STUDENT HEALTH LAW ORGANIZATION NETWORKING EVENT

On March 30, 2005, SHLO held its Health Law Networking Dinner. More than 35 attorneys from different areas of health law attended. This annual event gives students the opportunity to mingle with practicing attorneys in an informal setting and ask about all things related to careers in health law.



(Left to right) Monika Ras (2D); Virginia Evans, Chief of the Civil Division, U.S. Attorney's Office; and Rachael Melby (3D).



(Left to right) Jennifer Martin (1D), Kristen King (1D) and Benjamin Cohen, Attorney, Centers for Medicare and Medicaid Services, Office of Hearings.



(Left to right) Michelle Saffan (1D); Melissa Sviatko (1D); Jeff Pecore, Pecore & Doherty; Jaime Doherty, Pecore & Doherty; and Mindy Caplan ('01), Kramon & Graham.



Kristin Cline (2D) and Jason Weinstock, Attorney General's Office, Medicaid Fraud Unit.



(Left to right) Kelly Walsh (1D); Irv Cohen, Fulbright & Jaworski; and Meaghan Shepard (1D).



Christine Morse ('99), Ober Kaler, and Mona Shah (2D).

Focus on Drugs & Health Law

Cont. from page 4

Attorney General to prevent enforcement or application of the directive. A U.S. District Court judge issued a permanent injunction preventing implementation of the directive. Judge Robert Jones ruled that the CSA was not intended to overrule a state's decision on what constitutes "legitimate medical practice" and found that the Attorney General and the DEA went beyond their authority in trying to control physicians acting under the DDA. The Ninth Circuit ordered a continuation of the injunction. The case is now on appeal to the Supreme Court. (*Visiting Prof. Dan Gilman, is current writing an article about the case. See article on Faculty Scholarship, p. 13, for more on his perspective.*)

Many other drugs are also subject to abuse and addiction. These range from steroids to heroin and cocaine. Often individuals with a history of drug abuse or who are in drug treatment programs face discrimination in obtaining housing, employment and treatment. *In Prof. Ellen*

Weber's Drug Policy and Practice Clinic, students examine a range of public health and civil rights strategies to assist persons with histories of drug and alcohol dependence and the programs that serve them. Examples of the legal work students have performed in the past include presenting testimony and conducting advocacy to address discriminatory zoning barriers to the establishment of treatment services; representing individual clients in employment discrimination matters; conducting administrative and legislative advocacy to address the denial of drug treatment to individuals detained in the Baltimore City Detention Center; and advising organizational clients on the implementation of the Health Insurance Portability and Accountability Act (HIPAA) health privacy regulations. Also, students in Prof. Kathleen Dache's Tobacco Control Clinic have worked on initiatives to assist individuals who are addicted to tobacco products. This legislative session, the clinic students were instrumental in the passage of a bill that will require health insurers in Maryland that provide prescription benefits to cover prescription drugs used to assist in tobacco use cessation. Currently, bupropion, known as Zyban, is

commonly used to assist smokers, and there are at least two other drugs under FDA review that are designed to assist in tobacco use cessation. The clinic students drafted the original bill for Delegate Dan Morhaim, testified in support of the bill in the House Health and Government Operations Committee and the Senate Finance Committee, and drafted amendments to the bill necessary to achieve passage.

Notes

¹ Consumer Project on Technology, *Recent Health-Related Compulsory Licenses and Disputes*, <http://cptech.org/ip/health/cl/recent-examples.html> (Apr. 25, 2005).

² *Id.*

³ *See id.*

⁴ FDA, *FDA and the Drug Development Process: How the Agency Ensures that Drugs are Safe and Effective*, <http://www.fda.gov/opacom/factsheets/justthefacts/17drgdev.html> (Apr. 25, 2005).

⁵ S. Waxman, *Lawsuits Blame Women's Deaths on Unregulated Herbal Products*, THE WASH. POST, Mar. 24, 1996, at A1.

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