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Legal Trends in Bioethics

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Readers who learn of cases, laws, or regulations that they would like reported in this column are encouraged to e-mail Sigrid Fry-Revere at *Sigrid@ethical-solutions.org.*

GENERAL INTRODUCTION

The laws governing bioethics issues are confusing and sometimes contradictory because of several types of tensions inherent in our legal system. Legislatures and courts work in different time frames and with different priorities. The guarantees of separation of church and state and individual rights in the U.S. Constitution make bioethics issues involving personal, moral, or religious convictions particularly contentious.

Each state also has its own constitutional protections, some of which clearly mirror those in the federal Constitution, while others do not.

Legislatures and courts play different roles in our constitutional republic. Legislatures are by nature democratic and can react relatively quickly to changes in the political climate. Courts, on the other hand, are inherently antidemocratic. As a matter of fact, their main constitutional function is to protect the rights established by the federal and state constitutions from violation by legislative and executive action. Courts are also inherently conservative in their reaction to events because they are bound by precedents and procedural processes that are designed to assure that major philosophical changes happen gradually.

Legislatures and courts, in the area of bioethics, also act under the existence of two contrary presumptions. Legislatures tend to act with a presumption in favor of prevailing moral beliefs. The courts, on the other hand, have the structural and theoretical obligation to protect individuals from majoritarian decisions that unnecessarily violate their constitutionally protected freedoms. They also have an obligation to uphold the separation of church and state. So, in bioethics cases, courts often have to deal with preventing governments, either through legislation or through other state action, from imposing moral or religious preferences on individuals who might not agree. Thus courts tend to show greater deference to individual choice than legislatures do, and tend to become more cautious when confronted with divisive issues.

An understanding of these inherent tensions between legislative and judicial action and the various individual interests that are balanced by the courts makes it easier to understand legal trends in bioethics.

It is also important when considering trends to watch how far bills that are introduced advance even if they do not pass. For example, a bill that is introduced and quickly moves through several committees and is voted on by one chamber but not the other before the legislative session ends has a better chance of passing if reintroduced at the next session than a bill that was introduced but was never even voted on in committee. If a bill is listed as having died or failed, that means it was voted down either in committee or by one of the legislative chambers. The success of such a bill is not likely even if it is reintroduced in the following legislative session unless there is an election that sufficiently changes the composition of the legislature or some other intervening event rejuvenates the bill's chances. If the session ends without a bill being voted on by both chambers, it has failed; but it has a better chance if it is reintroduced in a later session than if it is voted down. A bill that is reintroduced also probably has a better chance than a bill that is never even voted on in committee. The reason that some bills are listed as having died due to the end of the session, while other bills are still listed as active, is that some states have one-year legislative session cycles and other states have two-year cycles.

Please note that cases, laws, and regulations listed in earlier "Legal Trends" columns will not be repeated unless there has been a change in status since the last reporting period. Updates on previously reported cases, laws, and regulations are marked with an asterisk (*). Subject headings are not listed alphabetically. Sections are listed in descending order with those subjects with the most activity or the most significant activity listed first. It is important to note that the order of subject headings can vary from one issue of "Legal Trends" to the next depending on what subjects have the most legal activity in any given quarter.

INTRODUCTION TO "LEGAL TRENDS IN BIOETHICS" FALL 2008

This "Legal Trends" highlights an array of emerging bioethics issues, but most notable is the manipulation of informed consent to further a political agenda. It is one thing to require informed consent based on a reasonable standard of disclosure, with allowances for the specific needs of individual patients for additional information; it is quite another matter to try to legislate the smallest details of what is disclosed and when. The spring 2007 issue of "Legal Trends" included a report of legislation introduced in South Carolina that required a woman to view an ultrasound of her fetus before consenting to an abortion. As enacted in May 2008, the bill was revised so that a woman would be offered the opportunity to view her ultrasound before consenting to an abortion, but not required to do so. Also in the spring 2007 issue, we discussed South Dakota and Ohio legislative efforts that would force physicians to use specific language in describing the abortion process to patients. Similar attempts to legislate the specific details of what is communicated during the informed consent process have been reported in every issue of "Legal Trends" since. None of these efforts was successful until the Oklahoma legislature overrode the governor's veto of the Freedom of Conscience Act. The new Oklahoma law comes very close to achieving the original intent of the South Carolina ultrasound law (see "The Rights of Maturing Individuals and their Parents"). For the first time, similar tactics involving informed consent are being employed by advocates of choice at the end of life at the state legislative level (see "Life-and-Death Decisions").

Since the principles of informed consent are crucial to all medical decision making, it is with mixed feelings that, beginning with this "Legal Trends" there no longer is a specific section devoted to informed consent. Over the last decade, the general standards for informed consent have become ingrained in the law, and the actual principles are rarely in dispute any more. There is no doubt that the process of informed consent is regularly abused and observed more as a legal precaution than as a genuine attempt to help patients and their surrogates make informed healthcare decisions; nonetheless, the principles are so ubiquitous among the issues covered in "Legal Trends" that an already long column would become unwieldy if every entry that dealt with informed consent, from abortion to genetic testing and medical marijuana, were given separate treatment in a section devoted to informed consent. If ever there is a ground-breaking legal

development that directly affects the underlying principles of informed consent *per se*, be assured that a section devoted to informed consent will reappear.

Many entries in this "Legal Trends" are a good illustration of the inherent tension built into the U.S. constitutional system of government. One of James Madison's primary goals in writing the U.S. Constitution was to maintain a balance of power between the three branches of government and the state and federal governments to prevent the accumulation of too much power in any one governmental entity. Several possible shifts in power appear to be underway that have implications for laws of importance in the field of bioethics. A discussion of federal control over state activities continues with the FDA's preemption of state regulations and Congress's preemption of state marijuana laws (See "FDA" and "Unconventional Treatments"). We report on efforst by the FDA to extend its regulatory authority abroad. While Madison tried to prevent federal agencies from preempting state authority, there is no constitutional mechanism to prevent the FDA from setting up regulatory offices on foreign soil, not because Madison felt such expansion of power was acceptable, but because he never considered the possibility, other than perhaps in a military or diplomatic context.

Finally, "Legal Trends" revisits some issues repeatedly discussed here. Healthcare professionals continue to be threatened with prosecution and prison for helping their patients either with unwanted pregnancies (see "The Rights of Maturing Individuals and their Parents") or intractable pain (see "Unconventional Treatment") and the shortage of suitable organs for an increasing population of transplantation patients presents new bioethical dilemmas (see "Organ and Tissue Procurement").

FDA

The U.S. Supreme Court decided two federal preemption cases last term and is set to consider a third, *Wyeth v. Levine*, S. Ct. Docket No. 06-1249, this fall. The Court split its decisions on FDA preemption of state law last term; in *Riegel v. Medtronic, Inc.*, 552 U.S. ___ (2008), the Court ruled that federal regulations preempted state law, but in *Warner-Lambert*, the Court upheld state regulations (see "Legal Trends," *JCE* summer 2008, pp. 170-171). Given the Court's decision in *Riegel v. Medtronic* and the similarity in the facts between the *Riegel* and *Wyeth* cases, it is puzzling the Court granted *certiorari* in both cases unless at least some of the Justices intend to draw distinctions between the two cases. *Riegel* involved a medical device approved under the Medical Device Amendments of 1976, which specifically include preemption language barring states from imposing their own requirements on FDA pre-market approved devices. The *Wyeth* case involves a drug, not a device, and no such explicit preemption language exists in the laws governing drug approvals. The push and pull dynamics that sustain the balance of power among the states, the federal government, and the various branches of the federal government may prompt the Supreme Court to push back and tell the FDA, "Not so fast. Congress did not expressly grant the FDA preemptive authority for drugs under certain circumstances, as it did for devices. Unless and until Congress expressly grants the executive branch such authority, it does not exist."

New FDA regulatory efforts in China and India are listed under the heading of "Interesting Developments in Other Countries." These actions mark an expansion of FDA's oversight, moving beyond its inspection authority over products coming into the U.S. once they reach the U.S., to regulating products even before they leave foreign soil.

Recent Judicial Cases and Regulatory Actions April - June 2008

Federal. On 8 April 2008, the U.S. Court of Appeals for the Third Circuit, in *Colacicco v. Apotex, Inc. et al.* (decided together with *McNellis v. Pfizer Inc.*), found that the federal Food, Drug, and Cosmetic Act preempted the filing of claims under state law. The issue was whether actions taken by the FDA pursuant to the act and the FDA's implementation of regulations preempted plaintiffs' ability to sue under state failure-to-warn laws. Plaintiffs alleged the defendant companies violated state common law by selling products with

labeling that failed to warn consumers of the increased risk of suicide and depression. Both cases were dismissed. *Colacicco v. Apotex, Inc. et al.*, 521 F.3d 253 (3rd Cir., 2008).

Public Citizen, a consumer advocacy group, filed suit in U.S. District Court in Washington, arguing the FDA violated the law by not ruling on a two-year-old petition to ban prescription painkillers Darvon and Darvocet within the required six months. At issue is propoxyphene, a narcotic sold by numerous generic manufacturers, as well as under the brand names Darvon and Darvocet. Public Citizen cited the accidental deaths of more than 2,000 while using the drug. AP, "FDA sued for failure to act on risky painkiller," 19 June 2008, *http://www.msnbc.msn.com/id/25269705/* accessed 8 August 2008.

The FDA issued warnings to 23 companies selling supplements and products that fraudulently claim to prevent, treat, or cure cancers. Most of the products are not FDA approved and can be purchased on the internet. Officials warn that the products may cause harmful interactions with common cancer treatments. U.S. DHHS, "United FDA Warns Individuals and Firms to Stop Selling Fake Cancer 'Cures'," *FDA News*, 17 June 2008, *http://www.fda.gov/bbs/topics/NEWS/2008/NEW01852.html*, accessed 21 August 2008.

Recent Developments in Law and Regulation April - June 2008

Federal. On 17 April 2008, the Safeguarding America's Pharmaceuticals Act was introduced in the House. If enacted, the bill would substantially expand federal drug pedigree requirements. The legislation allows for the destruction of counterfeit drugs at ports-of-entry and revises federal drug pedigree standards and preempts state requirements. H.R. 5839, 110th Cong. 2nd Reg. Sess. (2008).

On 2 April 2008, Lawmakers urged the FDA to require that all TV ads for prescription medicines display the FDA's contact information to help consumers report serious side-effects. Reps. Rosa DeLauro, D-Conn., and Jan Schakowsky, D-Ill., cited a *Consumer Reports* poll that found that only one-third of respondents who had experienced an adverse reaction after taking a prescription drug knew they could inform the agency about such events. B. Dubose, "Lawmakers recommend inclusion of FDA hot line in TV drug ads," *Los Angeles Times*, 3 April 2008, *http://articles.latimes.com/2008/apr/03/nation/na-drugs3*, accessed 8 August 2008.

On 9 June 2008, Congress initiated an inquiry into the management and priorities of the FDA's Office of Criminal Investigations. The office doubled its budget from fiscal year 2000 to fiscal year 2009. This has allowed for a 50 percent increase in the number of investigators during the years 2000 to 2006. However, there has been a 20 percent drop in arrests and convictions during the same period. A. Mundy, "Congress Presses FDA on Investigations," 11 June 2008, *http://online.wsj.com/article/SB121314729048063047.html?mod=dist_smartbrief*, accessed 8 August 2008.

On 17 April 2008, U.S. House of Representatives Committee on Energy and Commerce released a Discussion Draft of the FDA Globalization Act. The bill allows the FDA to recall contaminated foods and unsafe medications and medical devices. It establishes a group of inspectors to monitor companies manufacturing food, medications, medical devices, and cosmetics abroad. Currently the FDA can only recommend recalls, not mandate them. Kaiser Family Foundation, "Draft Legislation Aimed at Overhauling FDA Would Require More Inspections, Change User Fees," *Kaiser Daily Health Policy Reports*, 18 April 2008, *http://www.kaisernetwork.org/DAILY_REPORTS/rep_hpolicy_recent_ rep.cfm?dr_cat=3&show=yes&dr_DateTime=04-18-08#51620*, accessed 8 August 2008.

On 31 March 2008, the FDA unveiled a five-year $30 million program intended to increase drug safety. Under the "Prescription Drug User Fee Act (PDUFA) IV Drug Safety Five-Year Plan," the FDA would employ more safety reviewers and risk-management and medication-error experts to improve drug security. FDA, 7 April 2008, vol. 5, no. 68, *http://fdanews.com/ newsletter/ article?issueId=11468 &articleId=105577*.

On 16 June 2008, the FDA announced a new requirement for manufacturers of "conventional" antipsychotic drugs to add label information about the increased risk of death associated with off-label use for behavioral problems in elderly people with dementia. Similar labeling requirements were announced in 2005 for newer "atypical" antipsychotic drugs. Atypical and conventional antipsychotics work similarly, as

both are dopamine receptor antagonists, but atypical antipsychotics have a lower incidence of neurological side-effects. The recently-passed Food and Drug Administration Amendments Act of 2007 gives the FDA the authority to mandate drug warnings; previously, it could only request warnings. DHHS, "FDA Requests Boxed Warnings on Older Class of Antipsychotic Drugs," *FDA News*, 16 June 2008, *http://www.fda.gov/bbs/topics/NEWS/2008/NEW01851.html*, accessed 28 July 2008.

On 28 May 2008, the FDA announced a plan to strengthen drug labels to give patients and healthcare professionals more precise information about how drugs affect women during pregnancy and breast-feeding. The proposed rule is subject to a 90-day public-comment period. U.S. Department of Health and Human Services, "FDA Proposes New Rule to Provide Updated Information on the Use of Prescription Drugs and Biological Products during Pregnancy and Breast-feeding," *FDA News*, 28 May 2008, *http://www.fda.gov/bbs/topics/NEWS/2008/NEW01841.html*, accessed 8 August 2008.

On 13 February 2008, the FDA issued new draft guidelines that allow pharmaceutical and medical device companies to send physicians studies on "off-label," or non-FDA-approved uses. Under current guidelines, physicians can prescribe medications for off-label uses, but drug companies are prohibited from marketing the drugs for unapproved purposes. Under the draft guidelines, drug companies can send physicians unabridged reprints of studies on off-label uses published in peer-reviewed medical journals, as long as those studies are not significantly supported by the drug company. FDA, "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices," (February 2008, *http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0053-gdl.pdf*.

On 22 May 2008, the FDA introduced an initiative called the "Sentinel Initiative," a system that would use information on Medicare claims to assess the risks of drugs already on the market. The system will allow the FDA to monitor almost immediately how drugs affect health. This would be a formidable departure from the current system, under which regulators may not learn about the adverse effects of a drug until years after the fact. G. Harris, "F.D.A. to Expand Scrutiny of Risks From Drugs After They're Approved for Sale," *New York Times*, 23 May 2008, *http://www.nytimes.com/2008/05/23/washington/23fda.html*, accessed 8 August 2008.

The States. Of the 50 U.S. states, 36 states have implemented laws to enable or study programs that redistribute unused prescription medications to uninsured or low-income individuals. Some states allow the drugs to be donated in sealed containers by individuals (**Arizona, Colorado, Florida, Georgia, Hawaii, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Utah, Wyoming**), while others only allow institutions to make donations (**Arkansas, California, Connecticut, Indiana, Kentucky, Maine, Minnesota, Mississippi, Montana, Nevada, New Jersey, New York, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Wisconsin**). The drugs typically are examined by pharmacists for consumer safety and then are distributed. R. Cauchi and K. Hanson, "State Prescription Drug Return, Reuse and Recycling Laws," *National Council of State Legislatures Website*, 29 July 2008, *http://www.ncsl.org/programs/health/Rx-Reuse.htm*, accessed 21 August 2008.

Interesting Developments in the Private Sector, April - June 2008

The Joint Commission on Accreditation of Healthcare Organizations issued safety recommendations to hospitals to prevent drug errors or adverse reactions in children. The recommendations ask hospitals to do the following: (1) weigh pediatric patients in kilograms on admission, because weighing children in pounds raises the risk of improper dosage; (2) clearly indicate adult medications that have been repackaged to suit pediatric patients; (3) store medications for adults away from pediatric care units. Kaiser Family Foundation, "Joint Commission Issues Alert Calling on Hospitals To Do More To Prevent Medication Errors in Children," *Kaiser Daily Health Report*, 11 April 2008, *http://www.kaisernetwork.org/Daily_Reports/rep_index.cfm?DR_ID=51477*, accessed 8 August 2008.

Interesting Developments in Other Countries, April - June 2008

China. On 17 June 2008, the U.S. Health and Human Services Secretary Michael Leavitt announced that the FDA has received diplomatic approval to set up three inspections offices in the Peoples' Republic of China to help ensure the safety of food, drugs, and medical devices imported into the U.S. The offices are expected to be open by the end of the year. Office of Health and Human Services, "United States and China Outline Progress on Agreement on Food and Feed Safety," 18 June 2008, *http://www.hhs.gov/news/press/2008pres/06/20080618a. html*, accessed 21 August 2008.

India. The FDA hopes to establish operations in India to better regulate the growing volume of food, medicines, medical devices, and animal feed exported to the U.S. FDA Deputy Commissioner Murray Lumpkin said that the FDA would first like to set up operations in China and then in Mumbai by the end of the year. He also stated that the FDA has interest in expanding the placement of staff in Amman, Jordan, to serve as a Middle East base, as well as in Central or South America and Europe. L. Richwine and S. Heavey, "U.S. FDA Seeks India Post for Food, Drug Checks," *Reuters*, 21 June 2008, *http://www.reuters.com/article/latestCrisis/idUSN20430434*, accessed 8 August 2008.

THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

In *Gonzales v. Carhart*, 550 U.S. ___, 127 S. Ct. 1610 (2007), the U.S. Supreme Court allowed Congress to put restrictions on first-trimester abortions in a way it had never done before (see "Legal Trends," *JCE* summer 2007, pp. 163, 164-166), but at least one circuit court is interpreting the Court's *Carhart* ruling as narrowly as possible (see the Fourth Circuit's decision below). Michigan's Governor Jennifer Granholm (D) and Arizona's Governor Janet Napolitano (D) also took contrarian positions when they vetoed bills that would ban "partial-birth abortions," even though the bill included an exception to save the life of the mother.

On the other side of the political aisle, the Oklahoma legislature overrode Governor Brad Henry's (D) veto of the "Freedom of Conscience Act," which would have required a woman to undergo an ultrasound prior to having an abortion.

A dozen or more laws have been introduced in the past year to require women to view ultrasounds before consenting to an abortion. A federal bill with the same type of requirements was introduced, but seems to be stalled in committee. Most of the state bills have failed or are stalled, and up until August 2008, the few that passed (**Georgia, Louisiana, South Carolina, South Dakota**) only require that a woman be offered the opportunity to take or view an ultrasound. Oklahoma's law is the first to *require* that an ultrasound be done and shared with the patient. While the new law allows the woman to "avert her eyes," it also *requires* the healthcare professional conducting the ultrasound to describe the images, including the dimensions of the embryo or fetus, cardiac activity the presence of external members, and internal organs.

Judicial Cases and Regulatory Actions April - June 2008

***Federal**. On 20 May 2008, the Fourth U.S. Circuit Court of Appeals in *Richmond Medical Ctr. v. Herring* reconsidered the constitutionality of a Virginia statute that outlaws what is termed "partial birth infanticide," Va. Code Ann. § 18.2- 71.1 and found the statute unconstitutional under *Gonzales v. Carhart*, 550 U.S. ___, 127 S. Ct. 1610 (2007). The U.S. Supreme Court in *Carhart* placed significance on the fact that the federal law imposed criminal liability only on physicians who had the intention of performing the disfavored intact dilation and evacuation (D&E), also called a "partial birth abortion." A simple or standard D&E that accidentally lead to an intact D&E would not result in criminal liability. The Fourth Circuit held that the Virginia statute, unlike the federal statute upheld in *Carhart*, would place undue burden a woman's right to abortion by discouraging all D&E procedures for fear they may accidentally result in the illegal intact D&E, instead of only prohibiting those D&Es intended by the physician from the outset to result in an

intact D&E. *Richmond Medical Ctr. v. Herring,* ___F.2d___ (4th Cir. 2008), Case No. 03-1821. Opinion, *http://pacer.ca4.uscourts.gov/opinion.pdf/031821A.P.pdf.*

***Kansas.** On 4 April 2008, the Kansas Supreme Court extended by three months the grand jury investigation of George Tiller, MD, for supposedly performing illegal late-term abortions. The grand jury was originally scheduled to expire 8 April 2008. The court held that no further extension would be allowed. The Kansas Supreme Court also ruled that the citizen-called grand jury was constitutional, and its subpoenas for medical records of Tiller's patients seeking late-term abortion were relevant and not harassing as long as the privacy of patients was protected. On 20 May 2008, 35 records were provided. Tiller, citing privacy concerns, had refused to honor the subpoenas issued by the grand jury on 25 January 2008. *George R. Tiller, MD, et al. v. Hon. Michael Corrigan, et al.* (Kas. Sup. Ct. Case No. 99,951). Tiller is also charged with 19 misdemeanors for failing to receive second opinions on abortions from doctors with whom he was not financially affiliated. On 11 June 2008, Tiller's criminal trial was rescheduled for 28 July 2008. *State of Kansas v. George R. Tiller* (18th Judicial District court of Sedgwick County Case No. 07 CR 2112).

Kentucky. On 18 August 2008, the jury trial of Hamid Hussain Sheikh, MD, was scheduled to begin. Sheikh was indicted in November 2007 on charges of defrauding Medicaid by illegally billing for abortions disguised as routine fetal ultrasounds and charging both Medicaid and his patients for treatment. Sheikh has denied all allegations. *Commonwealth of Kentucky v. Hamid Hussain Sheikh* (Franklin Cir. Ct. No. 07-CR-00236).

On 5 June 2008 the Kentucky Board of Medical Licensure suspended Sheikh's license to practice medicine. A hearing before the Board of Medical Licensure is scheduled for November 2008. Sheikh does not intend to renew his license and retired in June. V. Honeycutt Spears, "Gynecologist's Medical License Suspended," *Lexington Herald-Leader*, 26 June 2008, *http://www.kentucky.com/148/story/444141.html*, accessed 22 July 2008.

Recent Developments in Law and Regulation April - June 2008

Federal. There has been no action on a bill introduced 20 September 2007 and referred to the Committee on Health, Education, Labor, and Pensions that would require all abortion providers to perform ultrasounds before performing abortions, explain the results, and provide medical descriptions of the images. The bill would allow for exceptions in cases of medical emergency and would permit women to look away from the images. S. 2075, 110th Leg., 1st Reg. Sess. (2007).

There has been no action on a concurrent resolution introduced 27 September 2007 and referred to the House Committee on Foreign Affairs that would declare that Congress strongly condemned human rights violations in the People's Republic of China, including its strict birth limitations and the resultant coerced abortions and sterilizations. H. Con. Res. 220, 110th Leg., 1st Reg. Sess. (2007).

*There has been no action on a bill that would prevent the Indian Health Service from paying for abortion except in the case of rape, incest against a minor, or to save the life of the mother. The bill passed the Senate on 26 February 2008, and an identical bill was referred to the House Ways and Means Committee on 28 February 2008. S. 1200, 110th Leg., 1st Reg. Sess. (2007).

***Arizona**. On 4 April 2008, the governor vetoed a bill that would have prohibited minors from obtaining abortions unless they had parental consent, could prove to a judge with "clear and convincing evidence" that they were "sufficiently mature and capable of giving informed consent" without a guardian's consultation, or if the judge determined an abortion was in the mother's best interest without a guardian's consent. The governor stated the bill was unnecessary and that current law already set forth the "clear and convincing" standard of proof for a judicial bypass. H.B. 2263, 48th Leg., 2nd Reg. Sess. (Ariz. 2007).

*****On 4 April 2008, the governor vetoed a bill that would have banned partial birth abortion, allowing doctors who performed the procedure to be prosecuted on both a state and federal level. The bill included an exemption to save the life of the mother if no other medical procedure would save the mother's life. The governor stated that instead of "introducing more criminal penalties into the relationship between a woman

and her physician," efforts should be directed to the root issues of unwanted pregnancy, focusing on family planning and the prevention of sexual violence. H.B. 2769, 48th Leg., 2nd Reg. Sess. (Ariz. 2007).

Alaska. On 11 April 2008, a bill died in the state senate that would have required parental consent prior to a minor's obtaining an abortion. H.B. 364, 25th Leg., Reg. Sess. (Alas. 2008).

California. On 18 June 2008, the California Institute for Regenerative Medicine (CIRM) and Canada announced a three-year collaborative agreement that will explore approaches to evaluate, fund, and monitor stem cell research projects. Canada will contribute $100 million Canadian dollars to the Cancer Stem Cell Consortium (CSCC), which has partnered with CIRM. CIRM, "Minister Clement, Governor Schwarzenegger Join Forces to Fight Cancer Through Stem Cell Research," *State of California*, 18 June 2008, *http://www.cirm.ca.gov/press/pdf/2008/06-18-08_b.pdf*, accessed 23 July 2008. On the same day, CIRM also announced a partnership with the Australian state of Victoria. CIRM and Victoria will jointly seek and evaluate grant applications and make recommendations for funding research. CIRM, CSCC, and Victoria will initially collaborate on the CIRM Disease Team grants, which will fund multi-disciplinary teams of scientists seeking therapies for specific diseases. CIRM, "Victoria and California Announce International Collaboration to Advance Stem Cell Research toward Cures," 18 June 2008, *http://www.cirm.ca.gov/press/pdf/2008/06-18-08.pdf*, accessed 23 July 2008.

*****An initiative has been placed on the California ballot for November 2008 that would require parental notification and a 48-hour waiting period before a minor can obtain an abortion, with exemptions for medical emergencies and parental waivers. Proposition 4 represents the third time in four years California voters have considered a requirement for parental notification and a waiting period. "Waiting Period and Parental Notification Before Termination of Minor's Pregnancy," Initiative 07-0053, California Secretary of State website, *http://www.sos.ca.gov/elections/electionsj.htm.*

***Florida**. A bill has died that would have required all women to undergo ultrasound testing prior to obtaining an abortion. S.B. 2400, 2008 Reg. Sess. (Fla. 2008).

***Kansas**. On 21 April 2008, the governor vetoed an anti-abortion bill stating that it was in violation of both the Kansas and the U.S. Constitutions. The measure encouraged litigation against providers of late-term abortions. It would have allowed patients, their spouses, or family members to sue abortion providers if they believed the provider was in violation of restrictions against late-term abortions. It also allowed for the same parties to go to court to stop a late-term abortion if they believed it would be illegal. S.B. 389, 82nd Leg., Reg. Sess. (Kan. 2008).

***Michigan**. On 13 June 2008, the governor vetoed a bill that would ban "partial-birth abortions" with an exception to save the life of the mother but none to protect her health. The governor refused to support any late-term abortion ban that did not provide an exception to protect both the life and health of the mother. S.B. 776, 94th Leg., Reg. Sess. (Mich. 2007).

Minnesota. On 23 May 2008, a bill was pocket vetoed that would have allowed scientists to conduct limited research on embryonic stem cells. The governor stated the bill was both unethical and immoral and that adult-derived stem cells were superior to embryonic stem cells. He indicated he would be willing to support research using "induced" pluripotent stem cells derived from adult cells, since such a technique would not use human eggs or embryos. The bill would have allowed research on embryos donated with written consent after infertility treatment and prohibited the sale or cloning of embryonic tissue. The bill would also have allowed the University of Minnesota to use state funds for stem cell research. S.F. 0100, 85th Leg. Sess. (Minn. 2008).

***Missouri.** There has been no action on a bill that would modify the informed consent requirement for an abortion by adding new requirements to be fulfilled at least 24 hours prior to obtaining the abortion. Specifically, the bill requires that the woman be presented with printed materials and videos detailing the risks of an abortion and the physiological characteristics of an unborn child, and the opportunity to view an active ultrasound of the unborn child and hear the heartbeat of the unborn child. The bill also creates the crime of knowingly coercing a woman to seek or obtain an abortion. S.B. 1058, 94th Gen. Assem., 2nd Reg. Sess. (Mo. 2008).

***New Jersey**. The construction of a new stem cell research facility has been put on hold indefinitely. Officials are re-evaluating the project. The governor remains open to other plans for the continued funding of stem cell research, but did not have a time line for restarting construction. J. Margolin and T. Sherman, "State Pulls Back on Stem Cell Funding," *Star-Ledger*, 22 June 2008, *http://www.nj.com/newark/index.ssf/2008/06/state_ pulls_back_ on_stem_cell.html*, accessed 23 July 2008.

***Ohio**. On 20 June 2008, a law went into effect that requires abortion providers to give patients an opportunity to view an ultrasound image of the embryo or fetus and to offer to provide a physical copy of the image, both at no extra charge, as long as the ultrasound is performed before the abortion. The bill was signed into law on 21 March 2008. H.B. 314, 127th Gen. Assem., Reg. Sess. (Oh. 2007).

Oklahoma. On 17 April 2008, the state legislature overrode the governor's veto of the Freedom of Conscience Act. The omnibus bill includes a requirement that all women undergo an ultrasound prior to an abortion. Doctors must provide medical descriptions of ultrasound images as well as explain what ultrasounds depict while displaying the images, although women may avert their eyes. The bill also protects doctors and workers with moral objections to performing abortions, allows healthcare providers to refuse to perform abortions or refuse to admit patients seeking abortions, and requires abortion providers to post a notice informing women it is illegal for anyone to force them to have an abortion. S.B. 1878, 51st Leg. Sess. (Okla. 2008).

***Pennsylvania**. On 3 April 2008, the governor signed into law a bill that provides for an umbilical cord blood bank and requires healthcare practitioners to give pregnant patients information regarding umbilical cord donation. H.B. 874, 191st Gen. Assem., Reg. Sess. (Pa. 2007).

South Carolina. On 14 May 2008, the governor signed into law a bill that would require a woman to be informed that she has a right to view an ultrasound image of her fetus. The law also requires signed documentation of the doctor's offer and the woman's decision whether or not to view the ultrasound. No ultrasound may be performed sooner than 60 minutes prior to the commencement of the abortion procedure. H.B. 3355, 117th Gen. Assem. 2nd Reg. Sess. (S.C. 2008).

***South Dakota**. Measure 11, an initiative to ban abortions, has been placed on the November ballot. The measure would allow for exceptions in cases of rape or incest, to save a woman's life, or in cases of a "substantial and irreversible health risk" or impairment to "a major bodily organ or system." "An Act to Protect the Lives of Unborn Children, and the Interests and Health of Pregnant Mothers, by Prohibiting Abortions Except in Cases Where the Mother's Life or Health is at Risk, and in Cases of Rape and Incest," *http://www.sdsos.gov/electionsvoteregistration/electvoterpdfs/2008/2008regulateperformanceofabortions.pdf*, accessed 23 July 2008.

Tennessee. In May 2008 an abortion-related bill died in the Senate Judiciary Committee. The bill would have required informed consent and a 24-hour waiting period prior to obtaining an abortion. SB 3512, 105th Gen. Assem., Reg. Sess. (Tenn. 2008).

Interesting Developments in Other Countries

Australia. The New South Wales government planned to introduce legislation in July requiring teenagers under age 18 seeking cosmetic surgery to observe a three-month cooling-off period in an effort to reduce unnecessary surgeries. The NSW government has taken its cue from Queensland, which banned appearance-centered cosmetic surgery for teens under 18 earlier this year. Doctors from the NSW branch of the Australian Medical Association are calling for a ban on all teen cosmetic surgery, claiming teenagers with poor body image are attempting to raise their self-esteem by resorting to cosmetic surgery. Under current laws, teenagers under 18 may only undergo cosmetic surgery in private hospitals, and those under 16 need parental consent. The new laws would also include better regulation of plastic surgery advertisements. A. Bennett, "Teen Celeb Surgery Bann Call," *Adelaide Now*, 21 April 2008, *http://www.news.com.au/story/0,23599,23575293-29277,00.html*, accessed 22 July 2008.

Stephen Peter Morrow, an Australian teacher found guilty of getting a teenage student pregnant and then paying for her abortion, was sentenced to six years in prison. S. Ertelt, "Australia Teacher Who Got Student Pregnant, Bought Abortion Gets Six Years," *Life News*, 17 April 2008, *http://www.lifenews.com/int703.html*, accessed 21 August 2008.

Brazil. On 29 May 2008, the Brazil Supreme Court decided that scientists can conduct embryonic stem cell research. A slim majority comprised of six of the court's 11 justices upheld a 2005 law allowing embryonic stem cell research, which was challenged in that same year by former Attorney General Claudio Fontelles, who argued the law was unconstitutional because it violated the right to life. The Court's ruling was immediately criticized by conservatives in the world's largest Roman Catholic country. M. Sibaja, "Brazil's Top Court approves Stem Cell Research," *AP*, 29 May 2008, *http://ap.google.com/article/ALeqM5ilSQD5t_pO3YCyS_ IdsF2jLzEX2QD90VMFDOC*, accessed 21 August 2008.

Europe. The Council of Europe, an intergovernmental organization, passed a nonbinding resolution calling for member states to legalize abortion. Although abortion is legal throughout most of Europe, it is either severely restricted or illegal in Ireland, Andorra, Poland, Monaco, and Malta. "Council of Europe Pressures Member States to Legalize Abortion," *Feminist Wire*, 21 April 2008, *http://feminist.org/news/newsbyte/uswirestory.asp?id=10953*, accessed 21 August 2008.

Norway. On 17 April 2008, the Christian Democratic Party of Norway proposed a new abortion law that would require counseling for all women considering abortion as well as free contraception for persons under the age of 24. Although the party's constituency is only 7 percent of the population, it holds considerable influence. C. Stein, "Christian Party Proposes New Abortion Law," *Aftenposten*, 17 April 2008, *http://www.aftenposten.no/english/article2375148.ece*, accessed 21 August 2008.

Romania. On 26 June 2008, a government commission of doctors and health officials allowed 11-year-old Florina Vranceanu to have an abortion due to the exceptional circumstances of her case. The girl claimed to be raped by a 19-year-old uncle who has since disappeared, although the rape has not been proven. The girl was 21 weeks pregnant at the time of the ruling, and Romania does not allow abortions after 14 weeks unless the mother's life is at risk. The committee determined that the girl's mental health was at risk if she did not terminate the pregnancy and decided that she could have an abortion in Romania. Despite the ruling, the girl's parents still plan to travel to Britain, where the abortion limit is 24 weeks, for the procedure. BBC News, "Romanian Girl Permitted Abortion," *BBC News*, 27 June 2008, *http://news.bbc.co.uk/2/hi/europe/7477448.stm*, accessed 23 July 2008.

United Kingdom. New guidelines from the National Health Services released in June 2008 expect IVF clinics in the UK to lower rates of multiple births to the national average of 24 percent by January 2009 and 10 percent by 2010. Clinics would have to increase the numbers of single embryos transferred back into women's wombs; opponents are concerned that patients would have to spend more on fertility treatments to receive multiple IVF cycles instead of implanting multiple embryos in a single cycle. Although the National Institute of Clinical and Health Excellence recommends women receive three cycles of IVF, only 5 percent of clinics in England offer three cycles, and most only offer one. Since the average success rate per cycle of IVF is only 25 percent, women feel pressured to implant more embryos. However, this tactic also increases the risks of multiple births, which are more dangerous for the mother and babies than singleton births. The chair of the British Fertility Society believes that NHS first needs to address IVF funding issues, since women who must fund their own treatments are less willing to undergo multiple cycles to successfully become pregnant. BBC News, " 'One Egg' IVF Strategy Launched," *BBC News*, 26 June 2008, *http://news.bbc.co.uk/2/hi/health/7475392.stm*, accessed 22 July 2008.

*A bill to update the 1990 Human Fertilisation and Embryology Bill is making its way through Parliament committees. The bill would allow the creation of "saviour siblings," created when parents use IVF to selectively implant an embryo that genetically matches a child with a serious illness; allow the creation of hybrid embryos for stem cell research; and remove a requirement for doctors to consider the need for a father before offering fertility treatment, allowing lesbian couples and single mothers to receive IVF treatment. A proposed amendment attempting to lower the current abortion limit of 24 weeks was tabled. Human

Fertilisation and Embryology Bill, HL 2007-08, *http://services.parliament.uk/bills/2007-08/humanfertilisationandembryology.html*, accessed 22 July 2008.

LIFE-AND-DEATH DECISIONS

Most noteworthy is a bill introduced by Compassion & Choices, a national end-of-life care advocacy organization, called the "California End-of-Life Options Act." Compassion & Choices has repeatedly tried to get an Oregon-style aid-in-dying bill passed in California, with little success. This bill reveals a new strategy for Compassion & Choices, one that has been employed for several years by pro-life advocates — and just as worthy of criticism when used by advocates on the left as when used by advocates on the right, because of its political manipulation of the informed-consent process. If the act is passed, it will make almost no difference what it mandates, as the list of legal end-of-life options that physicians must offer to discuss with patients. The mere mandate of any list presumes that legislators can predict exactly what is appropriate to share, and when, with patients who come to their prognoses from very individual experiences and emotional states. How can it be medically indicated or morally justified to give a patient aged 40 who has pancreatic cancer the same information at the same point of prognosis as an 85-year-old patient whose cancer has returned after 10 years and two successful efforts to put her or his cancer into remission? Medicine is an art. Specific communications between physicians and patients is a very real part of that art, and should not be legislated.

Political persuasion aside, both the Oklahoma ultrasound law (described above in the "Rights of Maturing Individuals and their Parents" section) and the California end-of-life options law (described below) reduce doctors and patients to puppets in a politically scripted play that unacceptably restricts their professional and personal autonomy in medical decision making. Patients need accurate information to make fully informed decisions, but patients need that information at a time when they are emotionally ready and willing to analyze and put that information to good use.

Judicial Cases and Regulatory Actions April - June 2008

Florida. On 2 April 2008, the Okeechobee Circuit Court issued an injunction to block the removal of a stroke victim's feeding tube. The woman, Karen Weber, is able to breathe on her own but can neither swallow nor speak. Weber's husband wants her feeding tube removed and his wife transferred to hospice, while Weber's mother claims she is alert and responsive and has expressed a wish not to go to hospice. The judge appointed a three-member committee to evaluate the woman's competence, but a competency hearing has not been scheduled. *Martha Tatro v. Raymond Weber* (Okeechobee Cir. Ct. No. 2008GA064 & 2008OS063). A signed copy of the court order for the appointment of the evaluation committee is included in *In re: Karen Weber* is *http://www.telladf.org/UserDocs/WeberCourtOrder.pdf*.

***Montana**. There have been no further developments on a suit filed in the state First Judicial District Court on seeking to allow mentally competent terminally ill patients to obtain medication from their physicians to help them achieve a peaceful death. The suit references Montanans' right to privacy and dignity guaranteed by the state constitution. *Baxter et al. v. Montana*, (Mt. 1st Dist. DV 2007 787), *http://www.compassionandchoices.org/localgroups/mt/documents/BaxtervMTComplaint10-17-07.pdf*.

Recent Developments in Law and Regulation April - June 2008

***California**. The bill reintroducing the California Compassionate Choices Act has died due to lack of activity. A.B. 374, 2007-2008 Leg., Reg. Sess. (Cal. 2007). It failed during the last legislative session. On 18 September 2007, Compassion & Choices, a national end-of-life care advocacy organization, announced the launch of a new program designed to help terminally ill Californians access "hospice, pain treatment, information on aid in dying options and other excellent end-of-life care." That bill, introduced on 22 February

2008, called the "California End-of-Life Options Act," is working its way through the state legislature. It has undergone many changes as it is reviewed by various legislative committees, but, as originally introduced, the act requires physicians who make a diagnosis that a patient has a terminal illness or a prognosis of less than one year to live to provide the patient with the opportunity for information and counseling on all legal end-of-life choices, including hospice, a prognosis with and without continuation of curative treatment, refusal or withdrawal from life-sustaining treatment, voluntary stopping of eating and drinking, and palliative sedation. A.B. 2747, 2007-2008 Leg., Reg. Sess. (Cal. 2008).

***Georgia.** A bill to facilitate informed consumer health insurance choices is working its way through the state legislature. The Georgia Health Marketplace Act, which passed the senate 6 March 2008, would establish a website that provides consumers with a forum to easily access comparisons of deductibles, copayments, benefits, and premiums for a wide variety of different healthcare plans; would allow purchases with pre-tax dollars; and would enable Georgians to set up personal health savings accounts. S.B. 404, 149th Gen. Assem., Reg. Sess. (Ga. 2008).

***Illinois**. No action has been taken on a bill that would overturn a state law requiring HIV-positive students to inform their school principal of their status. H.B. 4314, 95th Gen. Assem., Reg. Sess. (Ill. 2008).

New Hampshire. A bill dealing with advance directives died in committee. The bill, originally introduced on 4 January 2007, would have required an original copy of any advanced directive, instead of a copy as allowed under current law, to be used by healthcare providers as an indication of a patient's wishes. H.B. 40, 2007-2008 Leg., Reg. Sess. (N.H. 2008).

Virginia. The governor signed a bill into law on 4 March 2008 that sets up a state registry for living wills and advanced medical directives. H.B. 815, Gen. Assem., Reg. Sess. (Va. 2008).

Interesting Developments in Other Countries

Australia. An Australian Supreme Court jury found Shirley Justins guilty of manslaughter on 19 July 2008. Justins assisted the suicide of her 19-year partner, Graeme Wylie, who overdosed on a veterinary drug, Nembutal, in 2006, three years after a diagnosis of Alzheimer's. Justins was found to have given him the drug and told him he would die if he drank it. The court found Wylie was not mentally capable enough to make an informed decision to end his life, that Justins negligently breached her duty of care, and allegedly had a financial motive for Wylie's death — he recently changed his will to leave her most of his estate. A family friend who illegally brought the drug from Mexico is charged with accessory to manslaughter; she and Justins face up to 25 years in prison. K. Arlington, "Graeme Wylie's Partner Shirley Justins Guilty of Manslaughter," *Daily Telegraph*, 20 June 2008, *http://www.news.com.au/dailytelegraph/story/0,22049,23892081-5007132,00.html*, accessed 13 August 2008.

Mexico. On 22 April 2008, the Senate legalized passive euthanasia, allowing doctors to withdraw life-sustaining medication if the patient is in palliative care and has less than six months to live. Doctors are not able to euthanize patients or assist in suicide, and consent from the patient or patient's family is required. Euthanasia Research & Guidance Organization, "World Laws on Assisted Suicide," 9 May 2008, *http://www.finalexit.org/lawsnamerica.html*, accessed 13 August 2008.

ORGAN AND TISSUE PROCUREMENT

In a system that is dependent on altruistic motivation, it is important to minimize even the appearance of impropriety, let alone actual criminal activity. Confidence in organ procurement organizations, tissue banks, and transplant professionals will plummet if events like those reported in this issue of "Legal Trends" continue to dominate the news. It is tragic that a surgeon in California, whether well-meaning or not, was so careless as to actually hasten, or give the impression he was hastening, the death of a patient in order to harvest his organs. Similarly, the conviction of a former oral surgeon for secretly harvesting and selling bone and tissue from cadavers creates widespread public suspicions of the whole organ procurement process. The

potential for public misunderstanding is also great when well-meaning policies like the New York City pilot program using "rapid-organ-recovery ambulances" are implemented. Another potential public-relations nightmare is looming as more transplant programs endorse donation after cardiac death (DCD). The practice of transplanting a heart after cardiac arrest may actually be illegal, but even if other forms of DCD are legal and medically sound, they undercut and, in many people's eyes, even contradict the definition of death as a cessation of brain function. Half a century has been spent changing cultural attitudes toward death and organ donation. Medical advances have transformed heart disease from a killer to a chronic condition. Citizens have been trained to initiate CPR when a person's heart stops. Automated external defibrillators, rescue devices for persons suffering cardiac arrest, are now common in most public facilities, including schools and shopping malls. In light of these very successful educational efforts, it is not going to be easy to simply turn around and say, but now it is acceptable to treat a person whose heart has stopped for just seconds or a minute or two as dead. Efforts to facilitate paired kidney donation and develop an ethically acceptable way to compensate living donors for at least the costs associated with donation may create less public mistrust and be more productive solutions in the long run.

Judicial Cases and Regulatory Actions April - June 2008

***California**. On 16 May 2008, the California medical board filed a complaint against a transplant surgeon, accusing him of unprofessional conduct while attempting to procure organs from a patient. If found guilty under the Medical Practice Act, his license could be revoked or suspended or he could be placed on probation. L. Parrilla, "Medical Board Files Complaint Against Transplant Surgeon," San Luis Obispo, 7 June 2008, *http://www.sanluisobispo.com/news/local/story/381047.html*, accessed 18 August 2008. The surgeon has also been accused of dependent adult abuse during an attempted organ donation, allegedly hastening the patient's death with excessive painkillers and sedatives in order to harvest his organs. The defendant has asked for this charge to be dismissed, but the judge has not indicated when a decision might be made. If the charge is not dropped, the surgeon will go to trial on 2 October 2008. *People of California v. Hootan Roozrokh* (San Luis Obispo Superior Court Case No. 405885).

***New York**. On 27 June 2008, the New York Supreme Court sentenced Michael Mastromarino, a former oral surgeon illegally harvesting and selling bone and tissue from cadavers for transplants, to 18 to 54 years of imprisonment after making a plea bargain. Mastromarino will also have to forfeit $4.68 million made from selling body parts. The body parts, which were not properly screened and tested, have caused diseases in many transplant recipients. Three accomplices are also charged: Joseph Nicelli, a former embalmer, has been removed from the case until he recovers from a head injury sustained last year; Lee Cruceta, who headed the "cutting crew," has pleaded guilty for an 8 to 25 years in prison; and Christopher Aldorasi, a "cutter," was given a 27-year prison sentence. C. Kearney, "Boss of Body Parts Ring Gets 18-54 Years," *Reuters*, 28 June 2008, *http://www.reuters.com/article/sphereNews/idUSN2744659520080628?sp=true&view=sphere*, accessed 30 July 2008.

Recent Developments in Law and Regulation April - June 2008

On 20 June 2008, the board of the Organ Procurement and Transplantation Network (OPTN), run by the United Network for Organ Sharing (UNOS), approved elements of a pilot national system to facilitate kidney pair donation, which involves "two or more living donor transplants where the initially intended donor/recipient pairs are medically incompatible." The plan prioritizes giving patients the most possible opportunities to get transplants. UNOS News Bureau, "OPTN/UNOS Board Approves Measures to Broaden Access for Living Donation, Pediatric Transplantation, Highly Sensitized Kidney Transplant Candidates," *OPTN*, 20 June 2008, *http://www.optn.org/news/newsDetail.asp?id=1098*, accessed 13 August 2008.

***District of Columbia**. On 15 April 2008, the Uniform Anatomical Gift Revision Act of 2008 became effective. Among other things, the bill, signed 25 February 2008, protects a donor's decision from interference after death and re-establishes D.C.'s donor registry. D.C. Council, B17-58 (2007).

***Georgia**. On 12 May 2008, a bill was signed into law that would allow organ procurement agencies to harvest organs without further permission from family members if the donor's intent were otherwise indicated, such as on a driver's license, state issued identification card, or living will. Overrides of the deceased's wishes by family members would only occur if the potential donor were under the age of 18. The bill became effective 1 July 2008. S.B. 405, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

Kansas. On 14 May 2008, the governor signed into law a bill designating organ procurement groups as one of the places to which a corpse may be sent after someone's death. State law had previously limited those locations to a hospital, a cemetery, a coroner's lab, a funeral home, a crematory, or the University of Kansas Medical Center. Before being sent, the body would have to be released by someone appointed by the deceased or his or her family. H.B. 2700, 82nd Leg., Reg. Sess. (Kan. 2008).

*****There has been no action on a bill that would offer living organ donors up to $10,000 in tax credit, applicable to travel and lodging expenses, as well as any lost wages from time off for surgery. The measure would apply to living donors only, and would cover liver, pancreas, kidney, intestine, lung, or bone marrow donations. H.B. 2362, 82nd Leg., Reg. Sess. (Kan. 2008).

***Maine**. On 8 August 2008, a bill passed that would adopt the 2006 Uniform Anatomical Gift Act without changes, since the bill was carried over to the 2008 session. 123rd Leg. Sess. L.D. 1505, 123rd Leg., Reg. Sess. (Me. 2007).

New York. New York City officials are planning a pilot program using "rapid-organ-recovery ambulances" after receiving a three-year $1.5 million grant from the federal Health Resources and Services Administration. Ambulances would set out after EMTs give up on resuscitation, to attempt to preserve a victim's organs until his/her organ donor status or family had been located, so the family could have time to consider organ donation. Organs would not be taken without consent; the measure seeks to address complaints from families of would-be organ donors not eligible for donation because they did not die in a hospital. R. Stein, "N.Y. Planning Special Ambulance To Recover Organs," *Washington Post*, 24 May 2008, *http://www.washingtonpost.com/wp-dyn/content/article/2008/05/23/AR2008052303006.html*, accessed 14 August 2008.

Interesting Developments in the Private Sector

On 16 June 2008, the AMA called for legislators to modify current law and allow pilot studies on financial incentives for cadaveric organ donations. The National Organ Transplantation Act prohibits financial incentives, stating that altruism is the only ethical motivation for organ donation. An AMA Board member stated that motivational incentives should be studied to decrease the number of patients waiting for organ transplants. M. Turner, "Financial Incentives Could Improve Organ Donation and Reduce Donor-Recipient Gap," *AMA*, 16 June 2008, *http://www.ama-assn.org/ama/pub/category/18674.html*, accessed 13 August 2008.

Interesting Developments in Other Countries

European Union. On 22 April 2008, members of the European Parliament voted to create a voluntary EU-wide donor card and a 24-hour transplant hotline as well as to increase public awareness about the importance of organ donation. Members of the European Parliament (MEPs) believe that expanding and speeding up the organ donation system will help decrease the demand for illegal organs. BBC News, "MEPs Back Europe Organ Donor Card," *BBC News*, 22 April 2008, *http://news.bbc.co.uk/2/hi/europe/7358789.stm*, accessed 13 August 2008.

Philippines. The Philippine Department of Health banned kidney transplants for foreigners, with an exception for those related by blood to Filipino citizens. "Foreigner" was defined as someone without a

Filipino citizenship. While organ sales are illegal, the black market is thriving due to so-called transplant tourism. While hospitals are only permitted to perform 10 percent of transplant procedures on foreigners, many facilities exceed this limit. C. Conde, "Philippines Bans Kidney Transplants for Foreigners," *New York Times*, 30 April 2008, *http://www.nytimes.com/2008/04/30/world/asia/30phils.html*, accessed 13 August 2008.

UNCONVENTIONAL TREATMENT

Although the heading "unconventional treatment" was introduced in the spring 2007 "Legal Trends," what was meant by "unconventional treatment" was first discussed in the summer 2008 column. The phrase "unconventional" is meant to apply to treatments that are outside mainstream medicine, not as a derogatory or judgmental term describing the merit of those specific treatments. This is to some extent an unsatisfactory compromise, because the term "unconventional" clearly has negative connotations, albeit in the context used here those connotations are unintentional. We have struggled to find a more appropriate heading for the types of treatments included in this section. Some entries involve innovative treatments, such as those tested in clinical trials. Others discuss treatments as old as or older than medicine itself, such as midwifery. Some discuss treatments of questionable legality, such as medical marijuana, but most of the treatment options discussed are perfectly legal — just not part of mainstream medicine. As diverse as they are, these treatments have several points of commonality — society is struggling with how to regulate them and is debating whether such treatments should be permitted alongside mainstream medical treatments. At this point the only nomenclature that fits seems to be "unconventional," but alternative suggestions are welcome.

The medical marijuana issue may come to a head soon. The victims in the power struggle between states and the U.S. Drug Enforcement Administration (DEA) are adding up, and most are far from what one might call "pot-heads." For example, below we discuss a case against a former software developer who first used medical marijuana for his own migraines. Since he had to drive hours to get to a dispensary, and being a businessman always on the lookout for new business opportunities, Charles Lynch opened a medical marijuana dispensary closer to home and operated it with scrupulous care. He kept meticulous records, double-checked medical marijuana prescriptions by calling the doctors who wrote them to assure their validity, and complied with all state and local laws in establishing his dispensary. Lynch even claims to have had phone conversations in which DEA officials told him the enforcement of medical marijuana laws was a local matter. Friends of Charles C. Lynch, "About Charles C. Lynch," *Friends of Charles C. Lynch Fund,* at *http://www=.friendsofccl.com,* accessed 23 August 2008. Despite all his precautions, Lynch's dispensary was closed and his marijuana burned. He was arrested, tried, and convicted (5 August 2008) for violation of federal drug laws and faces a minimum sentence of five years in prison and as many as 85 years.

At the federal level, in the U.S. it is legal to take the active ingredient in marijuana in pill form but not to smoke marijuana. The FDA approved two cannabinoids for use as medical therapies: dronabinol (Marinol) and nabilone (Cesamet). These synthetic THC medications are not smoked but administered orally in pill form. The FDA issued an advisory against smoking marijuana for medical purposes, based on a finding that smoking marijuana for medical purposes has a high potential for abuse and evidence that smoked marijuana is actually harmful. (FDA Press Release, 20 April 2006, *http://www.fda.gov/bb/topics/news/2006/new01362.html,* accessed 19 September 2007.) Some noteworthy private organizations that have repeatedly considered and refused to endorse medical marijuana include the National Multiple Sclerosis Society, the American Cancer Society, and the American Academy of Ophthalmology. Medical marijuana laws at the state level allow prescriptions for leaf marijuana for smoking, which many advocates say is more effective than ingesting THC in other forms. In addition to the 13 states **(Alaska, Colorado, Hawaii, Maine, Maryland, Montana, Nevada, New Mexico, Oregon, Rhode Island, Washington, Vermont)** where legislatures or the citizenry (through ballot initiatives) have approved medical marijuana, nine prominent organizations have endorsed the use of medical marijuana (the American College of Physicians, the Leukemia and Lymphoma Society, the American Academy of Family Physicians, the American Public Health Association, the

American Psychiatric Association, the American Nurses Association, AIDS Action, the American Academy of HIV Medicine, and the Lymphoma Foundation of America).

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Federal. The trial of a state licensed medical marijuana dispensary in Morro Bay, California, was set for 22 July 2008 in the U.S. District Court of Los Angeles. The dispensing of medical marijuana to patients with a doctor's prescription has been legal under California law since 1996. Charles Lynch opened his dispensary in April 2006 and operated with the blessings of the mayor, who was present at the ribbon cutting ceremony. On 17 July 2007, federal agents arrested Lynch for selling marijuana in violation of federal law. Friends of Charles C. Lynch, "About Charles C. Lynch," *Friends of Charles C. Lynch Fund, http://www.friends ofccl.com,* accessed 23 August 2008. Currently, all sale and use of marijuana, even medical marijuana, which is legal in 13 states, is a violation of federal law. The U.S. Supreme Court's ruled in *Gonzales v. Raich*, 545 U.S. 1 (20005), that Congress has the authority to ban the use and sale of cannabis even if approved for medical purposes at the state level.

On 17 April 2008, a bill recognizing the medical value of marijuana was introduced in the House; it would reclassify marijuana under the Controlled Substances Act (CSA) from a Schedule I drug to a Schedule II drug, allowing it to be medically prescribed. The bill would prevent federal interference in local or state-run medical marijuana programs and protect qualified patients and caregivers and physicians from the CSA and Food, Drug, and Cosmetic Act. H.R. 5842, 110th Cong. 2nd Reg. Sess. (2008).

On 12 May 2008, the U.S. District Court for Eastern Missouri denied the Drug Enforcement Administration (DEA) its attempt to use an injunction to suspend the DEA registration of Seth Paskon, MD, before trial, stating the government did not provide sufficient evidence showing why an injunction should be issued before trial. The judge also noted that the DEA could have used administrative procedures of the Controlled Substances Act (CSA) to suspend Paskon's registration and failed to explain why it chose not to. The government alleges that Paskon issued prescriptions for narcotics beyond medical necessity, leading to overdoses and death for many patients. The judge also denied the government's motion for a partial summary judgment, stating that while expert opinion was provided, there was no evidence from patients or undercover agents with proof of the alleged CSA violations. The government's civil case against Paskon alleging Medicaid and Medicare fraud went to trial in July. *United States v. Seth Paskon* ____ F. Sup9. ____ (U.S. Dist. Ct., Eastern District of Mo. Case No. 4:2007cv01161). Opinion, *http://www.fdalawblog.net/fda_law_blog_hyman_phelps/files/paskon_opinion.pdf.*

California. On 18 April 2008, Jeffre Sanderson and his wife Alice Wiegand were given prison sentences for growing marijuana. Although Sanderson and Wiegand alleged the marijuana was for medicinal and spiritual purposes, federal law does not recognize California's medical marijuana laws. Sanderson received a 24-month sentence and Wiegand received a six-month sentence; Wiegand was allowed to remain free until 1 December to make arrangements for a caretaker for the couple's children. The couple is considering an appeal. D. Walsh, "Federal Judge Sentences Plumas Pot Growers," *Sacramento Bee*, 19 April 2008, *http://www.sacbee.com/101/story/874091.html*, accessed 30 July 2008.

***Colorado.** There have been no developments on a case in which a couple, whose medical marijuana plants were destroyed after being seized by local police, filed a motion seeking $202,800 in compensation pursuant to a Colorado law that requires that plants seized in connection with the claimed use of medical marijuana shall not be destroyed while in the possession of state or local law enforcement. The sum is the highest ever sought for the destruction of a drug, the result of a requested estimate of the plants' value from the U.S. Drug Enforcement Administration (DEA). The request put the agency in an awkward position, since it has long been criticized for inflating the value of seized marijuana to aid the prosecution of drug cases. The suit was filed 17 January 2008. L. Hernandez, "Couple Wants Police to Pay for Damaged Marijuana Plants," *ABC7 News*, 17 January 2008, *http://www.thedenverchannel.com/news/15076323/detail.html*, accessed 21 June 2008.

***Missouri**. On 24 June 2008, the Missouri Supreme Court upheld a 2007 law legalizing midwifery without the presence of a physician. Doctors' groups had complained that physicians practicing medicine with unlicensed midwives could be at risk for professional discipline, but the court said the law exempted certified midwives from prohibitions on practicing medicine. *Missouri St. Med. Health Assoc. v. State of Missouri and Missouri Midwives Assoc.* (Mo. Sup. Ct. Case No. SC88783).

Vermont. In April a Vermont Supreme Court disciplinary counsel recommended that Martha Davis, a lawyer on trial for growing and smoking marijuana, have her law license suspended for two months. Her case proceeds to the Vermont Professional Responsibility Board, which could choose to accept or reject the recommendation. Davis said she smoked the marijuana to relieve pain from migraine headaches and chronic arm and leg pain from an inflammatory disease. Davis was charged with felony marijuana possession after game wardens found 2.5 pounds of marijuana at her home. The county prosecutor amended the charges to misdemeanors and allowed her to enter the Court Diversion Program, so records of the charges will be deleted after she completes community service. S. Smallheer, "Panel: Judge Should Lose License for 60 Days," *Times-Argus*, 19 April 2008, *http://www.mpp.org/states/vermont/news/panel-judge-should-lose-licen.html*, accessed 30 July 2008.

Recent Developments in Law and Regulation April - June 2008

Michigan. On 12 April 2008, lawmakers voted to include on the November ballot a measure to legalize medical marijuana for treatment of "debilitating medical conditions." Secretary of State T. Land, "Statewide Ballot Proposal Status," *Michigan Department of State website*, 9 July 2008, *http://www.michigan.gov/documents/sos/Statewide_ Bal_Prop_Status_180489_7.pdf*, accessed 30 July 2008.

Interesting Developments in the Private Sector

On 16 June 2008, the American Medical Association (AMA) released its first guidelines regarding medical tourism. The nine-point guidelines address informed consent, financial incentives, and follow-up treatment. AMA, "New AMA Guidelines on Medical Tourism," 16 June 2008, *http://www.ama-assn.org/ama1/pub/upload/mm/31/medicaltourism.pdf*, accessed 30 July 2008.

Interesting Developments in Other Countries

Canada. On 14 April 2008, Health Canada announced it would soon be seeking bids on a seven-year contract to cultivate and distribute medical marijuana, with options for two one-year extensions. The government will accept bids until 15 September 2008. Health Canada plans to eventually cease allowing patients to grow their own medical marijuana, potentially giving the contract-winning firm a monopoly on medical marijuana. Opponents of such a monopoly are concerned that the government would only supply one strain of marijuana, noting that different symptoms are better treated by different strains of marijuana. Currently, fewer than 20 percent of medical marijuana users buy the drug from the government. Canadian Press, "Health Canada Looking for Marijuana Grower," *CBCnews.ca*, 15 April 2008, *http://www.cbc.ca/health/story/2008/04/15/healthcanada-marijuana. html*, accessed 31 July 2008.

United Kingdom. On 24 June 2008, Health Secretary Alan Johnson announced plans to ensure all patients in the U.K. are made aware of relevant research and clinical trials and may participate in clinical trials if they meet the criteria. Johnson announced plans to establish five to 10 Academic Health Science Centres, bringing together university research departments and teaching hospitals by partnering the education, research, and clinical functions of the institutions. Department of Health, "More Involvement and Choice for Patients," *News Distribution Service*, 24 June 2008, *http://nds.coi.gov.uk/Content/Detail.asp?ReleaseID=371664&NewsAreaID=2*, accessed 24 July 2008.

HEALTHCARE COVERAGE

In the current economic downturn, states are facing rising healthcare costs as well as increasing financial pressure on general budgetary expenses, raising new bioethics issues. One ethical question being debated in almost every state legislature is whether increasing cigarette taxes is an acceptable form of funding existing or expanded coverage for healthcare costs. According to the Campaign for Tobacco-Free Kids, since 2002, 43 states and the District of Columbia have enacted 76 tobacco tax increases, raising the average state tax from 61 cents to $1.13. The R. J. Reynolds Tobacco Company estimates that the federal excise tax of $.39 per pack could raise $7.3 billion a year, in addition to state tobacco taxes generating annual revenues of approximately $14.5 billion. In April, the New York Legislature approved a $1.25 increase in the $1.50 per pack tax, making cigarettes sold in the state the most expensive in the nation. Massachusetts is looking to follow New York with an increase of $1 per pack, bringing the total tax to $2.51. In 2008, 22 state legislatures were considering or had enacted bills to raise tobacco taxes. K. Sack, "States Look to Tobacco Tax for Budget Holes," *New York Times*, 21 April 2008, *http://www.nytimes.com/2008/04/21/us/21tobacco.html?_r=1&ref=us&oref=slogin*, accessed 21 April 2008.

Recent Judicial Cases and Regulatory Actions, April - June 2008

Federal. On 30 June 2008, U.S. District Court for the District of Columbia denied the American Association for Homecare's motion for an injunction against national competitive bidding, scheduled to start 1 July 2008. The injunction was denied because "the court concluded that the plaintiffs are unable to demonstrate an irreparable injury." Mobility Management, "AAHomecare NCB Injunction Motion Denied," Mobility Management, 30 June 2008, *http://www.mobilitymgmt.com/articles/64899*, accessed 24 July 2008. Currently, there are three other cases filed against the Centers for Medicare and Medicaid Services (CMS), the current administrator of the national competitive bidding program. The companies filing suit are King and Spalding, Washington, D.C.; Amarillo, a Texas-based Brown and Fortunato company; and VGM Group's Last Chance for Patient Choice, based in Iowa. Penton Media, "AAHomecare Lawsuit to Stop Competitive Bidding Makes Four," *HomeCare*, 2008, *http:// homecare mag.com/news/aahomcare-lawsuit-stop-competitve-0806/*, accessed 24 July 2008.

***Federal**. There have been no new developments in a suit filed by the Medicare Rights Center in the U.S. District Court for the Southern District of New York on 26 November 2007. The plaintiff, a cancer patient, argues that the Department of Health and Human Services (DHHS) should not deny coverage for "off-label" use of prescriptions. The plaintiff was using a fertility drug as a cancer treatment and Medicare refused to pay for the treatment because the drug was not approved as a cancer treatment. Such "off-label" use is common in the medical profession and is based on clinicians' experience, published guidelines, and research findings in medical journals. *Layzer v. Leavitt*, at *NY12525-#412881-v13-JL_SDNY_complaint_11_26_07.Doc*. Complaint, *http://www.medicarerights.org/off_label_complaint_Nov2007.pdf*.

California. On 05 May 2008, a coalition of healthcare providers filed suit against the state of California to prevent a 10 percent cut in Medi-Cal payments scheduled for 1 July 2008. The plaintiffs claim that such cuts are in violation of state and federal law 42 C.F.R. §447.204.*http://www.cmanet.org/publicdoc.cfm/2/1/press section2/425\http://dockets.justia.com/docket/court-cacdce/case_no-2:2008cv03363/case_id-416402*.

*On 11 June 2008, the California Supreme Court declined to review an appeals court ruling that cancelling an individual's health insurance policy for an omission or mistake on an application after a claim is submitted is prohibited under state law. The court also held that an insurer cannot cancel a member's policy if the insurer does not attach a copy of the application to the policy when it is issued. *Ticconi v. Blue Shield of California* (Ca. S. Ct. No. S162434). Opinion, *http://appellatecases.courtinfo.ca.gov/search/case/mainCaseScreen.cfm?dist=0&doc_id=530594&doc_no=S162434*.

***Illinois**. On 15 April, the Cook County Circuit Court issued a temporary injunction against Governor Rod Blagojevich's efforts to expand the state's FamilyCare program. The court found the expansion an

unauthorized and an unlawful use of tax dollars. The part of the expansion proposal dealing with breast and cervical cancer screenings for the uninsured, however, was deemed to be within the law. The injunction is part of a lawsuit challenging the constitutionality of the governor's ordered expansion of the FamilyCare program. Plaintiffs claim the expansion is unconstitutional, since it would cost $43 million in its first year without receiving legislative approval. *Richard Caro, et al. v. Rod Blago-jevich, et al.* (Cook County Circuit Ct. Case No. 07 CH 34353), *http://newsblogs.chicagotribune.com/clout_st/files/healthruling.pdf*. A previous lawsuit, *Gidwitz, et al. v. Maram*, has been dismissed and combined with the current lawsuit. *Gidwitz, et al. v. Maram*, No. 2007 MR ____.

Recent Developments in Law and Regulation, April - June 2008

Federal. On 15 July, Congress overrode the President's veto of H.R. 6331, a bill that would prevent a scheduled 10 percent decrease in Medicare reimbursements to physicians. Public Law No. 110-275.

On 2 April 2008, a bill was introduced that would expand title 38 of the U.S. Code to expand healthcare services available to female veterans, including counseling for sexual assault. The Women Veterans Health Care Improvement Act of 2008 is currently under review by the Committee on Veteran's Affairs. S. 2799, 110th Cong., 2nd Reg. Sess. (2008).

*****There has been no action on the Indian Health Care Improvement Act. The Senate version passed on 26 February 2008; an identical bill was referred to House Ways and Means Committee on 28 February 2008. The bill provides $35 billion to the Indian Health Service to allow expanded healthcare for almost two million participating American Indians. The bill also seeks to promote increased participation of American Indians in healthcare professions, the expansion and modernization of reservation healthcare services, including additional funding for cancer and diabetes screening and mental health programs, and easier and more complete tribal access to Medicare and Medicaid. S. 1200, 110th Cong., 2nd Reg. Sess. (2008).

*****There has been no movement on the Healthy Americans Act, first introduced in the Senate in January 2008. The bill would create incentives for private health insurers to provide coverage directly to individuals, while employers' contributions would be shifted to wages, and eventually a health insurance contribution to the federal government. S. 334, 110th Cong., 2nd Reg. Sess. (2008).

On 2 April 2008, the U.S. Securities and Exchange Commission, in a reversal of its previous position, has declared that companies must allow shareholders to vote on a proposal for universal health insurance coverage. The SEC has told companies such as Boeing, General Motors, and Wendy's International that they may not omit a healthcare proposal from their proxy materials. R. Pear, "S.E.C. Backs Health Care Balloting," *New York Times*, 27 May *http://www.nytimes.com/2008/05/27/business/27health.html*, accessed 28 July 2008.

Alabama. There has been no action on a bill proposed by the state house that would increase the state cigarette tax from $.26 to $.75 per pack. Funds collected through the proposed cigarette tax would go to the State General Fund, which can also used to cover state healthcare programs. HB 361, 2008 Leg., Reg. Sess. (Ala. 2008).

***Alaska**. There has been no action on a universal healthcare proposal. The bill, called the Mandatory Universal Health Care Act, would require all state residents to obtain health coverage, with the state subsidizing plans for low-income residents. It would create a healthcare board that determines which medical services are covered under the subsidized program and would certify private coverage plans that meet state requirements. The board would also oversee the state and federal government jointly funded Alaska Health Fund, as well as contributions from employers and employees. A sliding-scale voucher system would be funded by the tax revenues collected to pay for the program. Residents would be able to use the vouchers to obtain coverage from the Alaska Health Care Clearinghouse, a "marketplace" for various certified policies. The bill was originally introduced in the Senate on 10 September 2007 and was sent to the finance committee 14 March 2008. S.B. 160, 24th Leg., Spec. Sess. (Alaska 2007).

California. A bill passed the state house but failed in the state senate that would have imposed a $1.50 per pack increase to fund universal health reform. A.B. 1a, A.B. x7, 2007-2008 Leg., Reg. Sess. (Cal. 2007).

Connecticut. On 27 May 2008, the governor signed into law a bill that eliminates the requirement that patients receiving treatment in residential facilities stay in the hospital three days before insurance will cover their costs and extends the benefits to adults. The bill takes effect on 1 January 2009. S.B. 167, 2008 Gen. Assem., Reg. Sess. (Conn. 2008).

District of Columbia. On 1 April 2008, a bill was introduced to create universal healthcare for D.C. residents. The bill, called the Healthy DC Act, among other provisions, would create competition between insurance companies for individual customers (as opposed to their workplaces), and subsidize insurance premiums for the 25,000 uninsured residents who are ineligible for Medicaid. The bill would also raise the cigarette tax from $.05 to $.10 for each cigarette to increase revenue for the Healthy DC fund. D.C. Council, B17-700 (2008).

Florida. Two similar bills that would have increase the cigarette tax to help pay for state healthcare programs died in committee. The state house bill would have increased the cigarette tax by $.661 per pack, and funds would go to the General Revenue Fund that can be used for healthcare programs. The state senate bill would have increased the tax by $1.00 per pack and would increase enrollment in the Florida KidCare program. H.B. 299, S.B. 2790, 2008 Reg. Sess. (Fla. 2008).

Georgia. Two bills, introduced in February 2008, to increase the cigarette tax to cover general state expenses, including state healthcare programs, died in committee. Both would have increased the cigarette tax from $.37 per pack to $1.37 per pack. H.B. 1197, H.B. 1264, 149th Gen. Assem. Reg. Sess. (Ga. 2008).

On 7 May 2008, the governor signed into law two bills intended to make health insurance plans more affordable. Under the first bill, HB 977, insurers are exempt from a 2.5 percent tax that previously covered premiums for high-deductible plans that included health savings accounts. H.B. 977 also provides a $250 tax credit to small businesses that spend at least that much to enroll their workers in health savings accounts. The second bill, S.B. 383, would only classify health reimbursement accounts — accounts set up to allow for the use of pre-tax dollars for health-related expenses — as insurance if they are packaged with individual insurance policies. H.B. 977, S.B. 383, 149th Gen. Assem. Reg. Sess. (Ga. 2008).

Hawaii. On 2 May 2008, the legislature overrode the governor's veto of a bill that enrolls the state in the state I-SaveRX program, allowing residents to purchase lower-cost drugs from overseas. Hawaii is the sixth state to enroll in the program, and it is expected to see savings of up to 55 percent. H.B. 7, 24th Leg., Reg. Sess. (Haw. 2008).

Illinois. The state legislature is considering two bills introduced to increase the cigarette tax by $.90 per pack; revenue from the tax increase proceeds of the additional taxes be paid into the Tax Compliance and Enforcement Fund, the Healthcare Provider Relief Fund, and the Pension Stabilization Fund. One, H.B. 556, was introduced on 10 January 2008 and the other, S.B 2545, was introduced on 15 February 2008. Both bills are currently under consideration in the Rules Committee. H.B. 556, S.B. 2545, 95th Gen. Assem. Reg. Sess. (Ill. 2008).

***Iowa**. On 13 May 2008, the governor signed into law a bill increasing the income eligibility threshold for hawk=i, the state's version of the state Children's Health Insurance Program (SCHIP), from 200 percent of the federal poverty level to 300 percent. The bill lays out plans to reach universal coverage for children by 2011 and all adults by 2013. The bill also allows children between 18 and 25 to remain on their parents' health insurance plans unless they marry or move out of state. The bill does not mandate coverage for children and encourages the use of electronic health records. The bill became effective immediately upon signing. H.F. 2539, 82nd Gen. Assem., 2nd Sess. (Iowa 2008).

Kansas. On 18 May 2008, the governor signed into law a bill implementing several new healthcare initiatives. The bill expands eligibility for enrollment in the state Children's Health Insurance Program (SCHIP) and sets aside $2.5 million for "safety net clinics" and $460,000 to expand Medicare coverage for pregnant women. The bill became effective 1 July 2008. S.B. 81, 82nd Leg., Reg. Sess. (Kan. 2008).

The state legislature is considering a bill to increase the cigarette tax in order to help pay for state healthcare programs. The bill, originally introduced on 1 February 2008, would increase the cigarette tax by $.50 per pack and earmark a four cent increases in later years for health reform. The bill is under consideration in the Taxation Committee. H.B. 2737, S.B. 542 82nd Leg., Reg. Sess. (Kan. 2008).

Kentucky. A bill died in committee on that would have increased the cigarette tax by $.40 up to $0.70 per pack, to help pay for state healthcare expenditures. H.B. 443, 2008 Reg. Sess. (Ky. 2008).

Maine. On 16 April 2008, the governor signed into law a bill that would increase excise taxes on beer and wine and create a new tax on soda to fund Dirigo Health, which oversees the state's subsidized health insurance program. The beverage taxes replaced a proposed $.50 per pack increase in the cigarette tax previously supported by the governor (123rd Legislative Session, L.D. 790, L.D. 1608, 123rd Leg., Reg. Sess. (Me. 2007)). L.D. 2247, 123rd Leg., Reg. Sess. (Me. 2007). A People's Veto for the new beverage taxes has been placed on the November ballot. N. Augur,"Fed Up with Taxes Files More Than 90,000 Signatures for People's Veto," *Fed Up with Taxes*, 15 July 2008, *http://www.fedupwithtaxes.org/index.php/Press-Releases/Fed-Up-With-Taxes-Files-More-Than-90000-Signatures*, accessed 18 August 2008.

Massachusetts. On 1 July 2008, Governor Deval Patrick signed into law a bill raising the tax on Massachusetts cigarettes by $1 per pack, bringing the total to $2.51. The revenue generated from this tax is supposed to help offset the cost of Massachusetts' new health insurance law. Chapter 64C section 7A.

On 15 July 2008, the Massachusetts House Joint Committee on Health Care Financing revised portions of a bill that would prevent pharmaceutical companies from providing gifts and meals to physicians. It also removed provisions that would require drug and medical device manufacturers to disclose consulting and speaking payments to physicians. The provision, which would have made each violation punishable by a $5,000 fine, was also removed. S.B. 2526, 185th Gen. Court., Reg. Sess. (Mass. 2008).

***Minnesota**. On 13 May 2008, the governor vetoed a bill that would have established a statewide health improvement program. The governor stated that the bill increased healthcare access at the cost of quality improvement and "meaningful cost containment." H.F. 3390, 85th Gen. Assem., Reg. Sess. (Minn. 2008).

Montana. On 18 June 2008, an initiative, No.155, the Healthy Montana Kids Plan Act, received enough signatures to be included on the November 2008 ballot. The act would establish a children's health insurance coverage plan by raising the minimum income level that qualifies for Medicaid. Currently, 16 percent of the children in Montana are uninsured. Text of the initiative is available on Ballotpedia at *http://www.ballotpedia.org/wiki/index.php?title=The_Healthy_Montana_Kids_Plan_Act_%282008%29*, accessed 21 July 2008.

Nebraska. On 21 February 2008, a bill to increase cigarette taxes that would have used a portion of the revenue for behavioral health funding was withdrawn. The bill, originally introduced on 23 January 2008, would have increased the cigarette tax by $.10 to $.74 per pack. L.B. 1149, 100th Leg. Sess. (Ne. 2008).

New Jersey. On 8 July 2008, New Jersey Governor Jon Corzine signed into law S1557, a bill which, as well as nearly doubling the previous annual income threshold for FamilyCare coverage (from $27,645 to $42,400), would mandate healthcare coverage for all New Jersey residents under the age of 19. This is the first part of a three-step plan to achieve universal healthcare within the state. S. 1557, 2008 Gen. Assem., Reg. Sess. (NJ. 2008).

New York. On 19 April 2008, the governor signed into law a bill that would increase the state cigarette tax by $1.25, from $1.50 per pack, making it the highest in the nation at $2.75 per pack. The state budget office projected the tax would raise $265 million annually. Much of the revenue would be used for health programs including those to help smokers quit and to keep youths from starting. Ch. 57, S.B. 6807, 230th Gen. Reg. Sess. (N.Y. 2007).

Senator Jeffrey Klein (D-NY) released a report that alleges that some of the HMOs in New York State are restricting patients' access to "single-source drugs," brand-name medications that do not have low-cost generic versions. The report involved a survey of 15 HMOs that have drug plans in New York. It suggests that HMOs block brandname drugs to make larger profits. W. Sherman, "HMOs Block Key Brand-Name

Medicines to Make Big Bucks, Report Says," *New York Daily News*, 18 May 2008, *http://www.nydailynews.com/news/2008/05/18/2008-05-18_hmos_block_key_brandname_medicines_to_ma.html*, accessed 20 August 2008.

North Carolina. Recently, three bills were introduced that would increase the state cigarette tax to help fund state healthcare programs. H.B. 1026, introduced 26 March 2008, would fund a cancer hospital at the University of North Carolina at Chapel Hill. H.B. 1565, introduced 17 April 2008, would raise the cigarette tax by $.02 per cigarette to $.0375, and H.B. 2034, introduced 9 May 2008, would levy an excise tax on tobacco products other than cigarettes at 20 percent of the product's price. Both the latter bills would create revenue for the state general fund, which in turn could be used for healthcare programs. H.B. 1026, H.B. 1565, H.B. 2034, Gen. Assem. 2007-2008 Sess. (N.C. 2008).

Rhode Island. On 13 March 2008, a bill was introduced that would increase the cigarette tax to fund a tobacco control program. S.B. 2860, 2008 Gen. Assem., Reg. Sess. (R.I. 2008).

South Carolina. On 27 May 2008, the governor vetoed a bill that would raise the cigarette tax by $.50 per pack in order to help pay for healthcare programs. On the same day, an attempt to override the veto in the state legislature failed. H.B. 3567, 117th Gen. Assem., 2nd Reg. Sess. (S.C. 2008).

Utah. On 5 March 2008, a bill was voted down in the state house that would have raised the cigarette tax by $.50 per pack of 20 to $1.195, appropriating $3.1 million, or the total amount of the revenue, whichever was less, for the Cigarette Tax Restricted Account, and any extra funds for the Department of Health for cancer screening and the Gold Medal Schools Program. H.B. 355, 2008 Gen. Sess. (Utah, 2008).On 17 March 2008, the governor signed into law a bill that would levy a tax on moist snuff, of $.75 per ounce, that would generate revenue for the general fund, which, in turn, would help cover state healthcare programs. H.B. 356, 2008 Gen. Sess. (Utah, 2008).

Washington. On 1 April 2008, the governor signed into law a bill that empowers the state insurance commissioner to monitor individual health plan premium rate changes, reject "unreasonable" proposals, and order the return of excess profits to the state. S.B. 5261, 60th Leg., 2008 Reg. Sess. (Wash. 2008). The full text of Chapter 303 as signed by the governor can be found at *http://apps.leg.wa.gov/documents/billdocs/2007-08/Pdf/Bills/Session%20Law%202008/5261-S.SL.pdf.*

West Virginia. A bill died in committee that would have increased the cigarette tax to $1.35 per pack to help pay for state healthcare reforms. H.B. 3123, 80th Leg., Reg. Sess. (W. Va. 2008).

Wyoming On 4 March 2008, a bill was voted down in the state house that would have lowered the discount on cigarette stamps sold to wholesalers from 6 percent to 1.2 percent. The general funds raised would have in part been available to cover the cost of state healthcare programs. H.B. 41, 59th Leg., Reg. Sess. (Wyom. 2008).

VACCINES

A recurring theme in "Legal Trends" is: Who should bear the burden of healthcare costs, both preventative and curative? One of the costs of preventative medicine in the form of vaccines is the cost in quality of life, and sometimes in life itself, caused by the physical adverse reactions that vaccinations can cause in some patients. It is well-established health policy and legal doctrine that when a population is protected from a deadly, highly contagious and otherwise untreatable disease, the cost of an occasional adverse reaction is a small price to pay for protecting the entire community from a tragedy of epic proportions (See the U.S. Supreme Court Decision in *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905) involving a smallpox epidemic). However, who should bear the cost of the care of those who suffer adverse reactions? In the U.S., the federal government pays claims for injury caused by vaccines recommended by the Centers for Disease Control and Prevention (CDC) that are mandated at the state level. While this seems like a fair scheme in general, many vaccines are mandated today that fall far below the original requirements set out by *Jacobson,*. and arguably should be voluntary, particularly those vaccines intended to protect an individual rather than the community at large (for example, the HepB and HPV are vaccines that arguably fall into this

category). Even if someone disagrees that any of the vaccines on the CDC's recommended list that states now mandate should be voluntary, there are other questions worth asking: Is the cost-benefit analysis done by policy makers when they mandate a vaccine accurate? How many lives are expected to be saved by mandating the vaccine versus the number of adverse events, including those causing death, that can be expected? Could an unintended consequence of relieving vaccine manufacturers of liability for adverse reactions, as is the case when a vaccine is mandated by law, be that the incentive to produce the safest vaccine possible is diminished?

Judicial Cases and Regulatory Actions April - June 2008

Federal. A decision by the U.S. Court of Federal Claims in November 2008, conceding that childhood vaccines contributed to a nine-year-old girl's autistic symptoms, recently became public on an autism advocacy website. The court statement indicates that five vaccines received on a well-baby checkup in 2000 aggravated a rare underlying mitochondrial disorder that manifested with features of autism spectrum disorder. A Portuguese study suggests the disorder, caused by a point mutation in a gene for the 16S ribosomal RNA, is more common in autistic children, with incidence rates of about 7 percent compared to 0.02 percent in the general population. The concession did not specify whether thimerosal, a mercury-based preservative now only used in certain flu shots, or something else in the vaccine was at fault. Public health officials state this decision is an exceptional case rather than a landmark ruling linking vaccines and autism. The Poling family will be paid from a federal vaccine-injury fund (on 1 October 1988, the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) created the National Vaccine Inury Compensation Program), although the exact amount has not been determined. Two other cases alleging that vaccination caused children's autism went to trial in May 2008. *Poling, et al. v. Secretary of Health and Human Services* (U.S. Fed. Ct. of Claims, Case No. 02-1466 V).

Recent Developments in Law and Regulation, April - June 2008

Federal. On 25 June, the Advisory Committee on Immunization Practices (ACIP) voted to add the rotavirus vaccine Rotarix to the list of recommended infant inoculations. Rotarix, created by GlaxoSmith Kline Plc, is in competition with another vaccine, RotaTeq, created by Merck and Co., approved by the FDA two years ago. The FDA approved Rotarix on 3 April0. The CDC did not express a preference for either vaccine. ACIP, "ACIP Provisional Recommendations for the Prevention of Rotavirus Gastroenteritis among Infants and Children," 1 July 2008, *http://www.cdc.gov/vaccines/recs/provisional/downloads/roto-7-1-08-508.pdf*, accessed 30 July 2008.

The FDA is still considering whether or not to approve Merck's human papillomavirus vaccine (HPV), Gardasil, for women 27 to 45, stating there are "issues" preventing approval. Merck discussed the FDA's questions with the agency and was expected to respond to the FDA in July. Merck will also seek approval to use Gardasil for males by the end of 2008. L. Krauskopf, "Merck's Gardasil Not Cleared for Older Women," *Reuters*, 25 June 2008, *http://www.reuters.com/article/rbssPharmaceuticals%20-%20Diversified/idUSN254263042008 0625?sp=true*, accessed 30 July 2008.

Missouri. On 3 April 2008, the Health Care Foundation of Greater Kansas City announced that it would provide the HPV vaccine Gardasil to uninsured and underinsured girls and women free of charge at 139 participating clinics and health centers. Gardasil's usual commercial cost of about $360 limits access for girls and women with inadequate insurance who do not qualify for Missouri's free Vaccines for Children program. Missouri Foundation for Health, "Free HPV Vaccine Available at 139 Missouri Sites," 3 April 2008, *http://www.mffh.org/press_release1408.htm*, accessed 24 July 2008.

West Virginia. On 4 June 2008, a bill went into effect that would allow pharmacists to vaccinate those 18 or older. The bill, signed into law 31 March 2008, initially allows pharmacists to administer vaccines for influenza and pneumonia, but once the state Boards of Pharmacy, Medicine, and Osteopathy propose rulings

for legislation, vaccinations for hepatitis A and B, tetanus, and shingles may be administered. Pharmacists must first complete a board-approved immunization administration course and maintain American Red Cross or American Heart Association certification for basic medical training. H. B. 3056, 78th Leg., Reg. Sess. (W. Va. 2008).

Interesting Developments in Other Countries

***Canada**. Quebec has joined other Canadian provinces in establishing an HPV vaccination plan for schoolgirls. Girls in fourth and ninth grades will receive Gardasil for free if their parents request it. Health Canada has approved Gardasil for girls aged nine and up, and most vaccinations will take place in schools. C. Nordqvist, "Quebec to Offer Schoolgirls Free HPV Vaccine," *Medical News Today*, 14 April 2008, *http://www.medicalnewstoday.com/articles/103936.php*, accessed 24 July 2008.

THE RIGHT TO ACCESS AND CONTROL MEDICAL INFORMATION (INCLUDING MEDICAL TESTING, PRIVACY, AND DISCRIMINATION BASED ON TEST RESULTS)

Recent Developments in Law and Regulation April - June 2008

Federal. On 21 May 2008, the President signed into law the Genetic Information Nondiscrimination Act (GINA), which protects Americans from genetic discrimination when seeking health insurance or employment. H. R. 493, 110th Cong. 2nd Reg. Sess. (2008).

On 24 April 2008, the President signed into law a bill amending the Public Health Service Act to set up guidelines standardizing newborn screening tests. It would establish grants to set up programs that screen newborns, educate healthcare professionals and families about newborn screening, and set up a system to assess and coordinate treatment of congenital, genetic, or metabolic disorders. S. 1858, 110th Cong. 2nd Reg. Sess. (2008).

Federal. On 15 April 2008, the New Democrat Coalition announced a proposal to pattern a federal healthcare information technology (IT) program after one in New York City as the city transitions to electronic health records. The long-term goal is 75 percent participation in a fully interoperable health information exchange by 2018. New Democrat Coalition, "New Dems Offer Roadmap Forward on Health IT," 15 April 2008, *http://www.house.gov/apps/list/press/ca10_ tauscher/healthIT.html*, accessed 13 August 2008.

On 27 June 2008, the U.S. Drug Enforcement Administration (DEA) published proposed regulations that would permit authorized medical providers to use electronic prescriptions for restricted drugs, including the sleep medications Lunesta and Ambien. Pharmacies would be able to receive, dispense, and archive the e-prescriptions. DEA, "DEA Issues Proposed Regulations to Allow Electronic Prescriptions for Controlled Substances," 27 June 2008, *http://www.usdoj.gov/dea/pubs/pressrel/pr062708.html*, accessed 13 August 2008.

New York. On 28 March 2008, the governor announced $105 million in grants were awarded to 19 community-based health information technology projects. The grants would help develop a unified statewide electronic medical record system, and are part of a plan to overhaul New York's healthcare system. "New York Awards $105 Million In Health Information Technology Grants," 28 March 2008, *http://www.state.ny.us/governor/press/press_0328081.html*, accessed 13 August 2008.

Interesting Developments in the Private Sector

On 19 May 2008, Google opened public access to Google Health, which allows users to store health records online. Users can import records from hospitals and pharmacies partnered with Google Health, search for doctors and hospitals, and enter data on health conditions, medications, allergies, and lab test results. Users decide which medical organizations can view or send updates to their profile. In response to concerns on users' privacy, Google's vice president of search products and user experience said there would

be extra security on the servers holding the records. J. Vascellaro, "Google Helps Organize Medical Records," *Wall Street Journal*, 20 May 2008, *http://online.wsj.com/article/SB121123806355705263.*html, accessed 12 August 2008.

MEDICAL TOURISM

Interesting Developments in the Private Sector

On 16 June 2008, the American Medical Association (AMA) released its first guidelines regarding medical tourism. The nine-point guidelines address informed consent, financial incentives, and follow-up treatment. AMA, "New AMA Guidelines on Medical Tourism," 16 June 2008, *http://www.ama-assn.org/ama1/pub/upload/mm/31/medicaltourism.pdf*, accessed 30 July 2008.

Interesting Developments in Other Countries

Philippines. The Philippine Department of Health banned kidney transplant for foreigners, with an exception for those related by blood to Filipino citizens. *Foreigner* is defined those who are not Filipino citizens. While organ sales are illegal, the black market is thriving due to so-called transplant tourism. While hospitals are only permitted to perform 10 percent of transplant procedures on foreigners, many facilities exceed this limit. C. Conde, "Philippines Bans Kidney Transplants for Foreigners," *New York Times*, 30 April 2008, *http://www.nytimes.com/2008/04/30/world/asia/30phils.html*, accessed 13 August 2008.

HIV/AIDS

Judicial Cases and Regulatory Actions April - June 2008

Texas. On 14 May 2008, an HIV-positive man was convicted of harassing a public official with a deadly weapon: he spat into the open eye and mouth of a police officer and was sentenced to 35 years in prison. The man, indicted under a habitual-offender statute resulting in a minimum of 25 years imprisonment, will not be eligible for parole until he has served half of his sentence due to the deadly weapon finding. The CDC has stated that contraction of HIV from saliva is extremely rare. The police officer has not contracted HIV. G. Kovach, "Prison for Man With H.I.V. Who Spit on a Police Officer," *New York Times*, 16 May 2008, *http://www.nytimes.com/2008/05/16/us/16spit.html*, accessed 8 August 2008.

Recent Developments in Law and Regulation April - June 2008

Minnesota. On 20 May 2008, a bill was pocket vetoed that would have created an exemption in the informed consent policy of Minnesota's 2006 Genetic Privacy Law for the collection, analysis, and indefinite storage of infant blood and DNA. The bill would have allowed parents to object to the taking, analyzing, sharing, and storing of infant blood; however, persons collecting blood samples would not be required to advise parents of this right. Prior to collecting the blood samples, it would have been required to provide parents with a document with information about how the blood would be used, and that parents could sign a written exemption to the blood testing, use, and storage. S. F. 3138, 85th Leg. Sess. (Minn. 2008).

New York. In June 2008, New York City Department of Health and Mental Hygiene clinics discontinued use of a rapid oral fluid HIV test, the OraQuick Advance Rapid HIV-1/2 Antibody Test, after it delivered an unusual number of false positive results. Use of the test was previously suspended in December 2005 after a spike of false-positives, but was reinstated after three weeks with the stipulation that all positive results had to be confirmed with a finger-stick test. The more recent increase in false positives began in late 2007. The reason for the false-positive spikes has not been determined. NYC hospitals began using the tests

widely in April 2008; the tests use a gum swab and return a result after 20 minutes. CDC, "False-Positive Oral Fluid Rapid HIV Tests — New York City, 2005—2008," *Morbidity and Mortality Weekly Report*, 18 June 2008, *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm57e618a1.htm*, accessed 4 August 2008.

South Carolina. On 11 June 2008, the governor vetoed a bill that would eliminate a current requirement that school district superintendents and school nurses must be given the names of any students who test positive for HIV/AIDS at any of the state's clinics or private doctor's offices. The bill would have given the students' names only to the Department of Health and Environmental Control (DHEC). School nurses would have to contact the DHEC in the event a student came into contact with another student's blood, and the DHEC would inform the nurse of any blood-borne diseases and any necessary medical treatment. The governor stated a personal belief that the bill was moving in the wrong direction and that he felt more "highly contagious diseases," like Hepatitis B and Hepatitis C, should be added to the list. S. 970, 117th Gen. Assem., 2nd Reg. Sess. (S.C. 2008).

In May, the legislature passed a $2.4 million budget for the state's AIDS Drug Assistance Program. The money will help prevent long waiting lists; after federal funding was cut last year, 567 people were on a waiting list. Kaiser Family Foundation, "South Carolina Legislature Approves $2.4M for State ADAP," *Kaiser Daily HIV/AIDS Report*, 9 May 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint =1&DR_ID =52042*, accessed 8 August 2008.

Interesting Developments in the Private Sector

On 24 April 2008, five groups of Atlanta students produced several public service announcements designed to be viewed and shared via cell phone, called Personal Public Service Announcements, encouraging young adults to be tested for HIV. The student groups received funding, information, and donated equipment from the CDC and Verizon. Verizon aired the PPSAs from 20 June - 20 July 2008 on a VCast mobile video network channel, and the CDC created a channel on the popular video-sharing site YouTube. University of Georgia New Media Institute, "The AIDS Personal Public Service Announcement Project," 23 April 2008, *http://www.mynmi.net/aids_ppsa/*, accessed 4 August 2008.

Interesting Developments in Other Countries

***International**. On 24-26 June 2008, the International Task Team on HIV-related Travel Restrictions concluded its third meeting after drafting recommendations to remove HIV-specific restrictions on entry, stay, or residence in a country, noting that such recommendations are discriminatory. The final recommendations will be presented in December 2008 at the next meeting of the UNAIDS Programme Coordinating Board. UNAIDS, "Third meeting of the International Task Team on HIV-related Travel Restrictions," 18 July 2008, *http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2008/ 20080718_travel_ restrictions.asp*, accessed 5 August 2008.

Brazil. On 7 April 2008, Brazil opened its first government-run condom factory. The factory will produce 100 million condoms annually with rubber from trees in the Amazon. The factory will generate 2.2 million reais (about $1.3 million) annually for workers and will reduce pressure to cut down rain forest trees as well as reduce Brazil's current dependence on imported condoms, which it distributes at no cost. Brazil's government says it is the largest purchaser of condoms in the world. Reuters, Inc., "Brazil says Condoms to Stem Amazon Losses, AIDS," *Reuters*, 7 April 2008, *http://www. reuters.comarticle/environmentNews/idUSN 0721438020080407*, accessed 4 August 2008.

Egypt. On 29 May 2008, an appeals court upheld three-year prison terms given to five men with HIV/AIDS. The men were charged with "habitual practice of debauchery," which in Egyptian law includes homosexual sex acts. Before conviction, the men were forcibly submitted to HIV tests and abusive anal examinations to "prove" they had engaged in sex acts with other men, and men who tested HIV-positive were chained

to hospital beds. Human Rights Watch, "Egypt: Court Upholds HIV Sentences, Reinforces Intolerance," *Human Rights News*, 29 May 2008, *http://www.hrw.org/english/docs/2008/05/29/egypt18959.htm*, accessed 5 August 2008.

Ireland. On 16 June 2008, the Minister for Health Promotion and Food Safety announced the HIV and AIDS Education and Prevention Plan 2008-2012. The plan prioritized encouraging HIV tests for at-risk groups and educating the public. The plan includes providing condoms to at-risk groups in targeted health settings for no cost. Department of Health and Children, "Minister Wallace Launches the HIV and AIDS Education and Prevention Plan 2008 – 2012," 17 June 2008, *http://www.dohc.ie/press/releases/2008/20080617b.html*, accessed 8 August 2008.

Jamaica. In April, the National Family Planning Board announced plans to unveil the FC2, a new female condom, in an effort to provide women with more control over HIV/AIDS prevention measures. The board also planned to conduct workshops to promote use of the condoms and address negative stigma and myths about the condoms. Kaiser Family Foundation, "Jamaica to Launch New Female Condom as Part of HIV/AIDS Prevention Efforts," *Kaiser Daily HIV/AIDS Report*, 22 April 2008, *http://www.kaisernetwork.org/Daily_reports/print_category.cfm?dr_cat=1&dr_DateTime=04-22-08*, accessed 8 August 2008.

Kenya. On 10 April 2008, the Kenyan government announced a plan to fasttrack a national roll-out of male circumcision by mid-2008 to help prevent HIV. Several trials in 2006 report that circumcision decreased new HIV infections in men by more than half. National AIDS Control Council, "Government to Roll out Male Circumcision," 10 April 2008, http*://www.nacc.or.ke/2007/default2. php?active _page_id=272&id=279*, accessed 9 August 2008.

Singapore. On 22 April 2008, the parliament approved a bill making it illegal people who think they might be HIV-positive to have sex without first informing their partners of the risks. Violations could be punished with up to 10 years of imprisonment and a $50,000 fine. A 1992 law makes it illegal for people knowing they have HIV to choose not to tell their partners; punishment for a violation would be increased to the same amount. The government said it would only act if a victim filed a complaint and only after a through investigation. The bill also encourages people to get tested for HIV and avoid risky behaviors. Kaiser Family Foundation, "Singapore's Parliament Approves Measure That Addresses Spread of HIV Through Unsafe Sex," *Kaiser Daily HIV/AIDS Report*, 24 April 2008, *http://www.kaisernetwork.org/Daily_reports/rep_index.cfm?DR_ID=51720*, accessed 9 August 2008.

CONSCIENTIOUS OBJECTIONS (HEALTHCARE PROVIDERS AND RELATED PROFESSIONS)

Recent Judicial Cases and Regulatory Actions April - June 2008

***Federal**. The U.S. District Court for the District of Western Washington State is scheduled to hear arguments in October 2008 to review of a preliminary injunction handed down on 8 November 2007 to forestall the imposition of two recent regulations that would require pharmacists to sell emergency contraception and other controversial drugs, regardless of any moral or religious objections they may have. The injunction does require that inquiring customers be referred to an alternative nearby source. A lawsuit has been filed on behalf of several pharmacists seeking to overturn the law. *Stormans v. Selecky* (U.S. Dist. Ct. of Western Wa. No. C07-5374RBL 25 July 2007).

***Illinois**. There have been no developments in a case filed by a group of pharmacists who seek the nullification of a 2005 rule that mandates that all pharmacies provide emergency contraception when requested. The pharmacists' lawyers point to two state laws that they believe are violated by the ruling: one prohibits compelling healthcare decisions over moral objections, and one that protects citizens from religious interference. The state attorney general's office argues that the pharmacists lack standing, as they have not yet faced any repercussions. The Illinois Supreme Court heard arguments on 18 March 2008 but have not yet published an opinion. *Morr-Fitz v. Blagojevich* (Ill. Docket No. 104692, 18 March 2008).

***Michigan.** There have been no further developments in a case filed on 30 November 2007 by a Detroit-area pharmacist against Target Corporation, his former employer, alleging that his November 2006 firing over refusal to dispense emergency contraception violated the U.S. Civil Rights Act of 1964 by not accommodating his expressed religious beliefs. *Bundy v. Target Corporation* (U.S. Dist. Court of Eastern Michigan No. 2:2007cv 15091, 30 November 2007).

Recent Developments in Law and Regulation April - June 2008

New York. A bill is still pending that was introduced on 2 February 2007 that would amend Section 6810 of the state's education law to prohibit pharmacists from refusing to dispense or refill a prescription based on philosophical, moral, or religious reasons. The bill was referred to the Committee on Higher Education on 9 January 2008. S.B. 2344, 2007 Gen. Assem., Reg. Sess. (N.Y. 2007).

MENTAL HEALTH

Recent Developments in Law and Regulation April - June 2008

***Federal**. On 3 June 2008, the Senate unanimously passed Mental Health Improvements Act of 2007. The bill, originally introduced on 15 October 2007, would provide for improved treatment of veterans with posttraumatic stress and/or substance abuse disorders. The bill was referred to the House Veterans' Affairs Committee on 4 June 2008. S.B. 2162, 110th Leg., Reg. Sess. (2007).

*****There has been no action on a bill that seeks to reauthorize and strengthen the Mentally Ill Offender Treatment and Crime Reduction Act, which established a grant program to provide for improvements in mental healthcare provided to inmates in correctional facilities. Among other changes, the reauthorization would increase funding from $50 million to $75 million from fiscal years 2009 to 2013. The bill was tailored to easily reconcile with HR 3992, which passed the House 23 January 2008. S.B. 2304, H.R. 3992, 110th Leg., Reg. Sess. (2008).

*****There has been no recent activity on the Paul Wellstone Mental Health and Addiction Equity Act of 2008. The act passed the House on 5 March 2008 and has been read twice in the Senate and placed under General Orders Calendar No. 610. Originally introduced on 9 March 2007, the bill would require insurers to cover mental illness at the same level as they cover physical illness. The Senate passed a similar but less ambitious bill in September 2007, which is favored by officials in the Bush Administration, leading to a possible showdown in conference over the reconciliation of the different legislation. The Senate version is also favored by a majority of health insurance providers and employers, as they worry the House bill would drastically increase expenses, and feel the Senate version allows greater flexibility in determining coverage. The House version also includes prohibitions on "self-referrals" by physicians to specialty hospitals in which they share a "financial interest," and language that would prevent insurers and employers from discriminating against U.S. residents on the basis of genetic test results. H.R. 1424, S.B. 558, S.B. 358, 110th Leg., Reg. Sess. (2008).

*****There has been no action on a Down syndrome-related bill. Originally introduced in the Senate on 17 July 2007, the bill would increase provision of scientifically sound information and support services to patients receiving a positive test diagnosis for Down syndrome or other prenatally and postnatally diagnosed conditions. S. 1810 and H.R. 3112, 110th Cong. (1st Sess. 2007).

The Amyotrophic Lateral Sclerosis (ALS) Registry Act is progressing through Congress. Originally introduced in the Senate on 14 May 2007, the bill would establish a national registry to collect and store data on ALS. The bill was placed on the Senate Legislative Calendar on 4 December 2007. A similar version of the bill passed the House in October. H.R. 2295, S.B. 1382, 110th Leg., Reg. Sess. (2007).

The Medicare Mental Health Prescription Drug Access Act of 2007 is stalled in the Senate. Originally introduced on 17 October 2007, the bill was referred to the Committee on Finance where it is still under

consideration. The bill would amend Title XVIII of the Social Security Act to include barbiturates and benzodiazepines as covered part D drugs. S.B. 2190, 110th Leg., Reg. Sess. (2007).

NEW TECHNOLOGIES (NANOTECHNOLOGY, HYBRIDS, XENOTRANSPLANTATION, AND MORE)

Artificial embryonic stem cells made from adult skin cells were just as effective as real embryonic stem cells, according to scientists attending the Biotechnology Industry Organization conference 16 through 20 June 2008. The use of these artificial stem cells, created by adding genes coding for transcription factors to skin cells, would relieve ethical pressures involving embryonic cells and relieve the bottleneck created by the limited supply of embryonic cells. Although the technique currently used to create artificial stem cells has a low success rate, scientists believe the process can be rapidly improved. B. Fikes, "Artificial Embryonic Cells Fuel Research 'Explosion'," *North County Times*, 23 June 2008, *http://www.nctimes.com/articles/2008/06/23/business/doc485fda4aca79b142165416.txt*, accessed 29 July 2008.

Concerns have recently been raised about the safety of nanoparticles in consumer products like cosmetics and sunscreen. Some believe the FDA should require cosmetic manufacturers to note the presence of nanoscale materials in their products, but the FDA's 2007 Nanotechnology Task Force found no evidence to suggest that nanoscale materials were inherently more hazardous than non-nanoscale materials. R. Carvajal, "Why FDA Currently Can't Require 'Nanotech' Labeling on Cosmetics," *FDA Law Blog*, 17 April 2008, *http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/04/why-fda-current.html*, accessed 29 July 2008.

Judicial Cases and Regulatory Actions April - June 2008

Missouri. On 30 June 2008, a suit was filed to delay the state from providing $21 million in funding to the Life Science Research Board. The lawsuit questions whether limits on spending from the state life-sciences research fund blocking spending for abortion and human cloning are overridden by a 2006 amendment supporting stem cell research. Opponents are concerned that money from the fund may be used to support embryonic stem cell research. *Missouri Roundtable for Life vs. Sarah Steelman et al*., (Cole County Cir. Ct. Case No. 08AC-CC00517).

Recent Developments in Law and Regulation April - June 2008

California. On 6 June 2008, a bill was unanimously approved by the assembly that would allow biotech companies to claim tax deductions based on net operating losses over 20 years instead of the current 10. Since biotech companies take, on average, 14 years to develop their first products and several more years to reach profitability, the current 10-year carry-forward usually expires before companies begin to make profits. The bill would match the current 20-year carry-forward of the federal government. The bill would take immediate effect but have no fiscal impact until 2019. A.B. 1370, 2007-2008 Leg., Reg. Sess. (Calif. 2007).

Maryland. On 16 June 2008, the governor announced the BIO 2020 Initiative, a plan to invest $1.1 billion in biotechnology research over the next decade. The initiative includes directing at least $20 million annually to stem cell research, expanding the technology incubator network, and doubling the Biotech Investment Tax Credit once in fiscal year 2010 and again in 2013. M. O'Malley, "Announcement of the Bio 2020 Initiative" (speech transcript), 16 June 2008, *http://www.gov.state.md.us/speeches/080616.asp*, accessed 29 July 2008.

***Massachusetts**. On 16 June 2008, the governor signed into law a bill that would provide $1 billion over 10 years to strengthen the state's life sciences industry. The bill will create the Massachusetts Life Sciences Center (MLSC), which is responsible for overseeing the initiative. The $1 billion initiative provides $300 million for targeted infrastructure projects, including building a stem cell bank at the University

of Massachusetts Medical School; $200 million for public infrastructure project investments at the discretion of the MLSC; $25 million annually for ten years in tax credits for life sciences projects; and $25 million annually for ten years for the Massachusetts Life Sciences Investment Fund held by the MLSC for loans, fellowships, grants, and investments in the life sciences sector. H. 4829, 185th General Court, Reg. Sess. (Mass. 2007).

Interesting Developments in Other Countries

International. On 12 June 2008, the International Society for Stem Cell Research (ISSCR) announced a draft set of stem cell research guidelines for both researchers and the public to fight back against misleading websites claiming to have new stem cell treatments for any number of diseases. The guidelines address stem cell creation, studies, and research; make specific recommendations for oversight, accountability, and informed consent; and address social justice issues such as fair access. The ISSCR hopes to release final guidelines by the end of the year. ISSCR, "International Committee Recommends Stringent Guidelines for Translating Stem Cell Therapies from the Lab Bench to the Bedside," 12 June 2008, *http://www.isscr.org/press_releases/clin_guidelines.html*, accessed 28 July 2008.

European Union. On 1 June 2008, the European Union's new law on chemical standards, the Registration, Evaluation and Authorization of Chemicals (REACH), came into effect. It included no regulations on nanotechnology, but new scientific evidence suggesting nanoparticles could cause health risks is pressuring officials to create regulations on nanomaterials. The study, published in *Nature Nanotechnology* on 20 May 2008, reveals that long, straight carbon nanotubes can cause cancerous lesions when injected into the lungs, much like asbestos. Researchers have not yet studied the effects of environmental exposure or inhalation, and one scientist suggests that these problems may be avoided by using only short, curly nanotubes or mixing nanotubes with liquids instead of powders so they cannot be accidentally inhaled. The EU's decisions about nanotechnology will likely affect nanotechnology regulation worldwide. M. Dalton, "EU to Pace Nanotechnology," *Wall Street Journal*, 29 May 2008, *http://online.wsj.com/article/SB121201044102027389.html?mod=MKTW,* accessed 29 July 2008.

South Korea. On 16 May 2008, the South Korean Parliament passed a law that banned cross-species cloning, the process of inserting human cells into animal eggs, and allowed the use of stem cells to treat "general" diseases instead of only "rare and incurable" diseases or infertility. The cross-species cloning ban is punishable by three years of imprisonment. Opponents say the ban will hinder stem cell research, since human eggs are difficult to obtain and many eggs are needed for research. Agence France-Presse, "South Korean Parliament Passes Law Banning Type of Cloning, Broadening Embryonic Stem Cell Research," *Daily Women's Health Policy Report*, 19 May 2008, *http://www.national partnership.org/site/News2?abbr=daily2_&page=NewsArticle&id=11349*, accessed 28 July 2008.

***United Kingdom**. A bill to update the 1990 Human Fertilisation and Embryology Bill is making its way through Parliament. The bill will allow:

- The creation of "saviour siblings," whereby parents use IVF to selectively implant an embryo that genetically matches another child with a serious illness;
- Allow the creation of hybrid embryos for stem cell research; and
- Remove a requirement for doctors to consider the need for a father before offering fertility treatment, which would allow lesbian couples and single mothers to receive IVF treatment.

A proposed amendment attempting to lower the current abortion limit of 24 weeks was tabled. Human Fertilisation and Embryology Bill, HL 2007-08, *http://services.parliament.uk/bills/2007-08/humanfertilisationandembryology.html*.

On 30 June 2008, the Human Fertilisation and Embryo Authority (HFEA) approved an application from the Clinical Sciences Research Institute at the University of Warwick to create human-pig hybrid embryos to study cardiomyopathy. The license lasts for 12 months and comes into effect 1 July 2008. HFEA, "HFEA

Statement on Warwick University hybrid embryo research," 30 June 2008, *http://www.hfea.gov.uk/en/1698.html*, accessed 30 July 2008.

TRUST / ACCOUNTABILITY

The federal government has not established adequate guidelines to prevent hospital-acquired infections nor has it pushed hospitals to follow standards to reduce infections, according to a Government Accountability Office (GAO) report released 18 April 2008. C. Bascetta, "Health-Care-Associated Health Risks in Hospitals," *Government Accountability Office*, April 16, 2008, *http://www.gao.gov/docsearch/abstract.php?rptno=GAO-08-673T*, accessed 21 August 2008.

Judicial Cases and Regulatory Actions April - June 2008

Federal. On 25 June, the California Northern District Court denied requests from two veterans groups for a permanent injunction to prevent the Department of Veteran Affairs (VA) from "continuing certain widespread practices and policies." Such policies included failing or refusing to provide timely medical treatment and tampering with records and claim files. The veterans groups claimed that the VA was not fulfilling its obligation to provide care for veterans with posttraumatic stress disorder (PTSD), citing extensive processing delays and backlogs. The court stated the requested injunctions would require an overhaul of the VA, which would be outside the scope of the court's jurisdiction. *Veterans for Common Sense et al. v. James B. Peake, Secretary of Veterans Affairs, U.S. Department of Veterans Affairs, et al.* (Northern CA District Ct. Case No. 3:2007cv03758). The case is on appeal in the Ninth Circuit U.S. Ct. of Appeals (Case No. 08-16728).

On 4 June 2008, the U.S. Department of Justice announced the settlement of a legal action against Walgreens. The company has agreed to pay $35 million to settle claims filed against it from 2001 to 2005. The Department of Justice alleged that Walgreens switched prescriptions for Medicaid patients who were prescribed Ranitidine, Fluoxetine, and Eldepryl to more expensive capsules, to substantially increase its reimbursement from Medicaid while providing no additional medical benefit to patients. U.S. Department of Justice, "Walgreens to Pay $35 Million to U.S., 46 States & Puerto Rico to Settle Medicaid Prescription Drug Fraud Allegations," 4 June 2008, *http://www.usdoj.gov/opa/pr/2008/June/08-civ-496.html*, accessed 21 August 2008.

Alabama. On 19 June 2008, in the case of *State of Alabama v. AstraZeneca, LP,* the Montgomery County Circuit Court upheld the fraud conviction and $40 million in compensatory damages that Alabama won against AstraZeneca Pharmaceuticals, LP, in a Medicaid drug-pricing suit, but ruled the $175 million punitive damages awarded were unlawfully excessive. The court ruled that state law limits punitive damages to three times compensatory damages and cut the amount down to $120 million. J. Lewis, "Punitive Damages Reduced," 22 June 2008, *http://www.injuryboard.com.aspx?id=242338*, accessed 23 August 2008.

California. On 9 June 2008, the state health department sent cease and desist letters to 13 companies, including 23andMe, deCODEme Genetics, and Navigenics, that offered genetic testing online. The businesses were operating without clinical laboratory licenses, and the genetic tests offered were not clinically validated for accuracy or medical utility. California law requires that all lab tests, including genetic testing, must be ordered by a license physician, but many of the labs were doing testing without a doctor's prescription. Critics believe consumers should not require a doctor's permission to investigate their own genetic information. K. Ravn, "DNA Testing Industry Wrestles with California Law," *Los Angeles Times*, 14 July 2008, *http://www.latimes.com/features/health/la-he-closer14-2008jul14,1,1444195.story*, accessed 31 July 2008.

The City of Los Angeles filed suit on 16 April 2008 alleging that Anthem Blue Cross engaged in a widespread pattern of false advertising and fraud. The complaint alleges that the insurer's coverage is largely illusory and sold to consumers based on false promises, and accuses Anthem Blue Cross of concealing a

scheme to renege on policies for those diagnosed with serious medical conditions, including cancer and congestive heart failure. The City of Los Angeles is seeking damages totaling $1 billion. L. Girion "Anthem Blue Cross sued over rescissions," *Los Angeles Times*, 17 April 2008, *http://www.latimes.com/business/la-fi-insure17apr17,0,3901131.story*, accessed 8 August 2008.

Massachusetts. Blue Cross and Blue Shield of Massachusetts and MassHealth, the state Medicaid program, announced that hospitals and doctors who operate on the wrong limb or give a dangerous dose of medication will no longer be able to bill them for costs related to fixing the error. Health policy analysts said the move represents the boldest attempt by any state to use payments to reduce preventable life-threatening errors. S. Smith, "Medical Mistakes No Longer Billable," *Boston Globe*, 19 June 2008, *http://www.boston.com/news/local/articles/2008/06/19/medical_mistakes_no_longer_billable*, accessed 8 August 2008.

Michigan. On 14 May 2008, a Michigan administrative law Judge David Lick ruled that Blue Cross Blue Shield (BCBS) of Michigan would not be justified in increasing premiums by 24 percent to 42 percent for individual health insurance plans. BCBS of Michigan is a not-for-profit company and the state's insurer of last resort. As such, is and must seek state approval for all premium rate increases. Kaiser Family Foundation, "Michigan Judge Rules Against Blue Cross Blue Shield Rate Hikes, Cites Large Surplus," 16 May 2008, *Kaiser Daily Health Policy Report*, *http://www.kaisernetwork.org/Daily_Reports/rep_index.cfm?DR_ID=52196*, accessed 8 August 2008.

Recent Developments in Law and Regulation April - June 2008

Federal. On 20 May 2008, the Senate issued a new version of the Physicians Payments Sunshine Act of 2007. The revised bill would require drug and medical device manufacturers to publicly report payments and gifts to physicians. The previous bill required all gifts valued at $25 or more to be disclosed, but that amount has been revised to $500. The legislation would require companies to begin disclosing payments on 31 March 2011. S. 2029, 110th Cong. (1st Sess. 2007). A companion bill was introduced in the House on 13 March 2008. The House bill would not only fine companies that knowingly fail to report these payments and gifts with a penalty of $10,000 to $100,000 for each infraction but would also bar the companies from taking tax deductions on advertising for that year. H.B. 5605, 110th Cong. (2nd Sess. 2008).

*There has been no action on a bill introduced in the Senate on 6 September 2007 that would require drug, medical device, and biologics manufacturers with at least $100 million in annual revenue to disclose, every quarter, gifts or payments that they make to physicians exceeding $25 in value. The legislation would require the Secretary of the U.S. Department of Health and Human Services (DHHS) to create a website and post payment information. Penalties would range up to $100,000 per violation. Companies would be required to disclose any payment or benefit made "directly, indirectly, through an agent, subsidiary or other third party," which might include payments by universities and by companies that set up conferences for influential physicians with drug or medical device manufacturer funding. Funding of continuing medical education would also need to be disclosed. No-cost drug samples and financing for clinical trials would not have to be disclosed under the bill. The legislation was read twice and referred to the Committee on Finance. S. 2029, 110th Cong. (1st Sess. 2007).

On 2 April 2008, a bill was introduced that would require the VA to make several changes to improve care for female veterans. The VA would be required to have a women's health expert on staff at each facility, and VA mental health professionals would have to be trained to treat sexually assaulted women. The bill authorizes several studies, including one that would focus on the physical, mental and reproductive health of women returning from Iraq and Afghanistan, and another which would examine women's barriers to healthcare access at VA clinics. S. 2799, 110th Cong. 2nd Reg. Sess. (2008).

On 3 April 2008, the Center for Medical Standards, a branch of the U.S. Department of Health and Human Services, released a final rule that updates requirements and standards of care for Medicare-approved dialysis facilities nationwide. The current requirements were first published in 1976. The revised requirements will reflect the clinical and scientific advances since then and focus on patients' rights, safety

and participation. Dialysis centers will have up to 180 days to comply with the new requirements. Kaiser Family Foundation, "CMS Issues Final Rule To Update Dialysis Center Standards," 4 April 2008, *Kaiser Daily Health Policy Report, http://www.kaisernetwork.org/DAILY_REPORTS/rep_index.cfm?DR_ID=51361*, accessed 8 August 2008.

On 18 June 2008, the Center for Medical Standards, a branch of the U.S. Department of Health and Human Services, announced plans for a five-star rating system to help consumers make more informed decisions when selecting a nursing home. CMS will seek comments from the nursing home industry and consumers to decide the specific criteria for the ratings. Ratings will be available on the Medicare website by the end of the year. Kaiser Family Foundation, "Bush Administration Announces Quality Rating System for Nursing Homes," 19 June 2008, Kaiser Daily Health Policy Report, *http://www.kaisernetwork.org/DAILY_REPORTS/rep_index.cfm?DR_ID=52839*, accessed 8 August 2008.

On 21 May 2008, the Disabled American Veterans (DAV) proposed a bill to ensure predictable funding for the VA at a hearing in the Senate Veterans' Affairs Committee. Under this proposal, lawmakers would approve funds for medical care in the VA's budget one year in advance. The proposal was presented as an alternative to S. 2639, introduced in February, which would make VA healthcare funds mandatory. R. Tiron, "Veterans' Groups Pushing for More Predictable VA Funding," *The Hill*, 19 May 2008, *http://thehill.com/business—lobby/veterans-groups-pushing-for-more-predictable-va-funding-2008-05-19.html*, accessed 16 August 2008.

Colorado. Colorado Springs-based Coast Independent Review board had its right to grant expedited approval revoked after allegations it violated FDA regulations to protect patients in medical research. Allegations stem from an approval on 19 March 2008 of an advertisement for a California biotechnology firm seeking test subjects. The ad's language was found to be coercive and was submitted for review. The man who appointed to review the ad approved it without any change, even though he was not authorized to do so. Coast hopes to have the suspension lifted within a month. W. Heilman, "FDA disciplines local firm," *Gazette*, 14 April 2008, *http://www.gazette.com/articles/board_35273_article.html/coast_mcdaniel.html*, accessed 18 June 2008.

***New Jersey**. There has been no action on a bill originally introduced on 14 May 2007 that would require doctors to inform patients of gifts of more than $25 accepted from pharmaceutical firms in the last year. S. 2660, 2007 Gen. Assem., Reg. Sess. (N.J. 2007).

Interesting Developments in the Private Sector

According to a report released by the Association of American Medical Colleges, medical schools should not allow pharmaceutical or medical device companies to provide food, gifts, or travel to physicians, faculty members, or students. Such "forms of industry involvement tend to establish reciprocal relationships that can inject bias, distort decision-making and create the perception among colleagues, students, trainees and the public that practitioners are being 'bought' or 'bribed' by industry." Most medical schools follow AAMC recommendations, but they may decline to adhere to them. Kaiser Family Foundation, "Association of American Medical Colleges Proposes Ban on Pharmaceutical Company Gifts to Physicians, Staff, Medical Students," 28 April 2008, *Kaiser Daily Health Policy Report, http://www.kaisernetwork.org/dailyreports repindex.cfm?DR_ID=51788*, accessed August 8 2008.

Interesting Developments in Other Countries

Britain. The pharmaceutical company Reckitt Benckiser is accused of cheating the National Health Service. Internal memos leaked by a whistle-blower within the company describe a secret plan to manipulate regulators and doctors to prevent a generic version of a highly successful indigestion drug, Gaviscon, from coming on the market and undercutting Reckitt's existing NHS contracts. The NHS estimates that generic versions of the drug would have saved them as much as £40 million (about U.S.$78 million), but a generic

version of the drug was never developed, even though Gaviscon was out of patent for 10 years. Reckitt's accusers say that the leaked memos reveal this is due to deliberate manipulation of the patent process by Reckitt, via "evergreening," a method by which a company repeatedly files for revised patents on existing products that extend the period of patent protection from competition. D. Leigh, "Company Accused of Cheating NHS," *Guardian*, 7 March 2008, *http://www.guardian.co.uk/society/2008/mar/07/health.nhs*, accessed 19 June 2008.