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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 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" SUMMER 2008

The most significant development this quarter reflects the changing approach the U.S. is taking towards accountability in the manufacturing of drugs and other medical goods. A shift in the balance of power between the federal government and the states is evident in Congress's ever-growing allocation of responsibility to the U.S. Food and Drug Administration (FDA). But it is not so clear the states and the Supreme Court are ready to put more responsibility in the hands of the federal government. The deference the Court showed Congress in *Riegel, et ux. v. Medtronic, Inc.*, reported below, was clearly not as evident in *Warner-Lambert v. Kent*, also reported below. These cases may indicate that the Court is going to draw some lines. The Court is closely divided on the issue of federal preemption of state action, and it will be important to watch how the Court decides. In *Riegel*, preemption was directly written into the Medical Device Amendments of 1976 (21 U.S.C. § 360k(a)) and dealt with the state trying to impose a stricter liability standard than imposed by federal law. *Warner-Lambert* was more of a general preemption case, in which the issue was the state's right to look into enforcement of a federal law rather than holding companies to a stricter standard than what is expected at the federal level.

Other topics in which trends are changing involve healthcare coverage and organ procurement. In most states, ambitious attempts to provide healthcare for more citizens are being thwarted by fiscal realists. And despite some remaining optimism, a sense of desperation is starting to creep into the types of measures that states (and other countries) are willing to consider, given the ever-growing organ shortage and the questionable measures some physicians have resorted to, to provide organs for their transplant patients.

FDA

Behind the scenes of this quarter's updates on the FDA is a struggle over who will control regulatory actions against pharmaceutical and medical device companies. The decision in *Warner-Lambert v. Kent*, reported below, shows that the U.S. Supreme Court is conflicted. From a constitutional perspective, this is a

states' rights issue and the Court has split its two decisions. *Riegel* decided in favor of federal preemption and *Warner-Lambert* decided against. It will be important to watch how the Court rules later this year in *Wyeth v. Levine*, another preemption case currently before the Court.

At issue in these preemptions cases is the very important constitutional issue of states' rights, but also the degree to which pharmaceutical and device manufacturers can rely on federal action or non-action as a defense against litigation. Simply put, *Riegel* made it clear that states cannot impose more-stringent liability rules on manufacturers than the federal government does (at least not if a federal statute expressly prohibits them from doing so), but *Warner-Lambert* dealt with a duplication of enforcement efforts.

If only the FDA can decide when FDA rules are violated, the burden of protecting consumers and litigating violations rests solely with the federal government. In short, state tort laws and private litigation at the state level with respect to FDA-regulated products becomes moot. Individuals could no longer ask state courts to look into the facts surrounding an FDA-regulated product's approval or regulation to see if there was wrongdoing on the part of manufacturers. It would become the sole responsibility of the federal government to do FDA-related fact-finding. Manufacturers would be relieved of the considerable burden of having to worry, not only about how the FDA enforces its regulations, but also about how each individual state decides to help the FDA enforce its regulations.

This type of federal preemption of state drug and medical device laws would clearly be advantageous for manufacturers, but whether it would be good for society as a whole is less certain. It is expensive for companies to guard against possible litigation at so many different fronts. It could be argued that the funds expended on defending state lawsuits would be better spent on testing and developing new products and that state fact-finding demands on the FDA pose an unnecessary burden on the already overburdened agency. But, on the other hand, it can be argued that it is prudent to have more rather than fewer industry watchdogs and that it is better for individuals to have several avenues for righting possible wrongs.

Can the FDA do it all? Everyone agrees that the agency is overburdened, so wouldn't it be an even greater burden to expect the FDA to investigate and litigate every potential case of manufacturers' misconduct on its own, rather than taking the time to provide state courts with the documentation they need to do the investigations themselves? Understandably the FDA prefers not to have state courts determining whether a manufacturer managed to defraud the FDA, but what about the individuals who are hurt when the FDA doesn't meet its responsibilities? While somewhat messy in execution, duplication of enforcement efforts at the state level creates more incentives for manufacturers to assure compliance and more avenues for individuals to secure redress when regulations are broken. A vital part of the states' rights issue has nothing to do with the rights of states *per se*, but with the right of the people to have someone watching the watchdog.

Recent Judicial Cases and Regulatory Actions January - March 2008

Federal. On 20 February 2008, the Supreme Court upheld a Second Circuit decision that a state tort law that required that a device be safer than what was approved by the FDA would interfere with the FDA's regulatory scheme, and that more-stringent liability state requirements were preempted by the specific language of the federal Medical Device Amendments of 1976 (21 U.S.C. § 360k(a)). The case involved an angioplasty procedure in which a catheter balloon reportedly burst, causing complications for the patient. *Charles R. Riegel, et ux v. Medtronic, Inc.*, 552 U.S. ____ (2008), decision available at <http://www.scotusblog.com/wp/wp-content/uploads/2008/02/06-179.pdf>.

On 3 March 2008, in the case of *Warner-Lambert v. Kent*, the United States Supreme Court upheld, in a four-to-four decision (Chief Justice Roberts recused himself from the case due to stock ownership), an October 2006 ruling by the U.S. Court of Appeals for the Second Circuit that declined to preempt a 1995 Michigan law that protects drug companies from products liability claims, absent cases involving "fraud-on-the-FDA." Warner-Lambert sought a decision affirming that the federal Food, Drug and Cosmetic Act preempts the Michigan law, following the precedent set in the 2001 decision of *Buckman Co. v. Plaintiffs' Legal*

Comm. 531 U.S. 341 (2001). Among other things, plaintiffs argued that the lower court's ruling would "interfere with the FDA's ability to perform its critical functions, which is precisely what [the Supreme Court] sought to avoid in *Buckman*." The issue was not whether fraud-on-the-FDA is a sufficient criteria for liability, but whether a state court could make a determination that fraud took place, even if the federal government had never made such a determination itself. *Warner-Lambert v. Kent*, 552 U.S. ____ (2008), decision available at <http://www.supremecourtus.gov/opinions/07pdf/06-1498.pdf>.

The *Warner-Lambert* decision sets the scene for another U.S. Supreme Court drug industry preemption case expected to be heard later this year, *Wyeth v. Levine*, which concerns preemption of state tort claims that impose a liability based on FDA-approved labeling. *Wyeth v. Levine*, U.S. Supreme Ct. Docket No. 06-1249 (certiorari granted 5 February 2008).

District of Columbia. On 4 March 2008, the United States District Court for the District of Columbia dismissed a suit brought by numerous nonprofit organizations seeking to vacate the FDA's supplemental New Drug Application (sNDA) pertaining to Duramed's Plan B, an emergency contraceptive tablet. The new application maintains Plan B's prescription status for women younger than 18, but allows the drug to be made available to women 18 years or older over the counter (OTC), that is, without a prescription. Plaintiffs in the case, including the Family Research Council, Safe Drugs For Women, the Association of American Physicians and Surgeons, and Concerned Women for America, argued, among other things, that the sNDA was in violation of the Food, Drug and Cosmetic Act because of its age-based restrictions. Plaintiffs also argued that by allowing simultaneous marketing under both prescription and OTC regulation, the FDA effectively created a "third class" of drugs not permitted under the Food, Drug and Cosmetic Act. The case was dismissed because the court determined that plaintiffs had not exhausted available administrative remedies and lacked legal standing because they had no "sufficient personal stake in the outcome." K. Karst, "District Court Dismisses PLAN B Case Against FDA Based on Lack of Standing and Failure to Exhaust Administrative Remedies," *FDA Law Blog: Hyman, Phelps & McNamara, P.C.*, 10 March 2008, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/03/district-court.html, accessed 7 May 2008.

Wisconsin. On 29 February 2008, the United States District Court for the Eastern District of Wisconsin dismissed a suit seeking judgment against three manufacturers of prescription polyethylene glycol 3350 (PEG-3350), a laxative. The suit was brought by Schering-Plough Healthcare Products, Inc., makers of Miralax, another PEG product that had recently switched from prescription to OTC, and sought judgment against the defendants for violating the Food, Drug and Cosmetics Act, which prohibits marketing of the same drug as prescription and OTC simultaneously. Further, Schering claimed that the manufacturers' labeling containing the statements "prescription only" and "Rx only" was "literally false," which Schering asserted established liability under the Lanham Act. Defendants argued successfully that the FDA had not definitively ruled on how the Food, Drug and Cosmetic Act should be interpreted under such circumstances, and that in this case statements pertaining to one particular product does not apply to all products of that type in general. J. Ellison, "Wisconsin Court Adds to Precedent Holding that the FDC Act Cannot Be Privately Enforced," *FDA Law Blog: Hyman, Phelps & McNamara, P.C.*, 9 March 2008, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/03/wisconsin-court.html, accessed 7 May 2008.

Recent Developments in Law and Regulation January - March 2008

*The FDA issued new draft guidelines that allow pharmaceutical and medical device companies to send physicians studies on "off-label uses," that is, non-FDA approved uses, of medications. Physicians can prescribe medications and medical devices for off-label uses, but the FDA currently prohibits the marketing of drugs and medical devices for unapproved purposes. Under the draft FDA guidelines, companies can send physicians unabridged reprints of studies on off-label uses of medications that have been published in peer-reviewed medical journals as long as the studies are not significantly influenced by a company's financial support of the studies in question. The guidelines were open for comment until 21 April 2008. Stanford

University Medical Center, "Guidance for Industry: 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," Draft Guidance FDA-2008-D-0053, <http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0053-gdl.pdf>.

California. A number of local government bodies in California are mounting opposition to the FDA's decades-old policy barring men who have sex with men from donating blood. Read more about this under the HIV section below.

TRUST / ACCOUNTABILITY

Some topics previously included in this section are now under a new heading, "FDA," so please also review that section for issues involving government oversight and patient trust directly related to FDA regulatory actions. Regulatory actions with relevance to bioethics issues by government entities other than the FDA at both the federal and state level are reported here. Also reported here are civil actions that often parallel regulatory actions taken by government. Civil suits are filed because, while regulatory actions can result in fines and regulatory relief, they do not result in damages or reparations. For plaintiffs to receive damage awards, they must seek relief in a civil suit.

In addition to continuing battles over wrongdoing both in the private and public sectors, there are two positive events that do not, strictly speaking, fit under any heading in an article on legal trends included here, because it is easy to forget how important the sharing of information is to accountability, particularly in medicine. On 25 March 2008 a not-for-profit group, iHealth Alliance, announced its plans to implement a 2006 FDA guideline regarding notifying physicians about changes to labels, warnings, and recalls by e-mail instead of regular post. The group says that the site and e-mail system are a necessary step because previously physicians' offices had a hard time distinguishing mailings about significant updates from "junk mail" from pharmaceutical companies. The service will be offered at no cost to doctors, but pharmaceutical companies will be required to pay to receive updates about their products distributed via the e-mail service. iHealth also has plans for a website to allow doctors to comment on the label updates, and iHealth Alliance will collect and forward those comments to the FDA. Kaiser Family Foundation, "Not-for-Profit Group To Launch Web Site To Notify Physicians of Medication Label Changes, Warnings, Recalls," *Kaiser Daily Health Policy Report*, 25 March 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=51130, accessed 8 May 2008.

And second, on 3 March 2008 a group of doctors and lawyers working with a local hospital launched a pilot mediation project with the goal of keeping malpractice disputes out of court. The group started planning the program at the advice of the Pennsylvania State Supreme Court, who in 2005 recommended considering alternatives to court battles when doctors threatened to leave the state in response to rising costs of malpractice insurance. The developers of the program noticed that many lawsuits were being filed simply so that patients or their families could find out exactly what had gone wrong, so they set up the program in two parts. First, people with grievances are brought together with hospital doctors and nurses, who listen to the complaints and attempt to explain what happened clearly as possible. If they are not happy after the first part, they move to mediation, where a trained mediator works with both sides to try and get them to agree on a solution. S. Burling, "Doctor-lawyer project tackles malpractice," *Philadelphia Inquirer*, 3 March 2008, http://www.philly.com/philly/business/breaking/20080303_Doctor-lawyer_project_tackles_malpractice.html, accessed 19 June 2008.

Recent Judicial Cases and Regulatory Actions January - March 2008

Federal. A spokesman for the U.S. attorney's office in Newark announced on 21 March 2008 that the ongoing investigation into kickback payments in the form of consulting fees from manufacturers of orthopedic devices to doctors was shifting focus, and would now be looking into the conduct of individual surgeons.

The reason for the shift is that the government reached settlements last year with the five manufacturers under investigation. The terms of each individual settlement vary, but all companies agreed to stricter scrutiny of their compensation of surgeons for consulting services in exchange for the government dropping its criminal cases related to the alleged kickbacks. The companies were ordered to employ special monitors who are paid as much as \$985 per hour plus a monthly retainer to oversee all payments made to doctors. It is sadly ironic that the U.S. attorney supervising the investigation appointed his former boss to the most lucrative of those positions. B. Feder, "New Focus of Inquiry Into Bribes: Doctors," *New York Times*, 22 March 2008, <http://www.nytimes.com/2008/03/22/business/22device.html>, accessed 18 June 2008.

Alaska. On 26 March 2008, the State of Alaska settled with drugmaker Eli Lilly for \$15 million in a lawsuit seeking damages for expenses incurred by the state when it paid for the treatment of Medicaid patients who developed diabetes while taking the schizophrenia drug Zyprexa. Alaska originally sought damages in the hundreds of millions but settled for less. Eli Lilly admitted to no wrongdoing in the settlement. A. Berenson, "Alaska Suit Against Lilly is Settled," *New York Times*, 27 March 2008, http://www.nytimes.com/2008/03/27/business/27zyprexa.html?_r=1&scp=2&sq=eli+lilly&st=nyt&oref=slogin, accessed 4 May 2008.

Currently 16 other states have disclosed similar claims against Lilly, but none of them are likely to reach trial before the Supreme Court rules on preemption in the *Wythe* case, which could potentially rule out such state claims altogether. These states are **Arkansas, California, Connecticut, Florida, Illinois, Louisiana, Mississippi, Montana, New Mexico, Ohio, Oregon, Pennsylvania, South Carolina, Texas, Utah, Vermont, and West Virginia**, <http://www.psychsearch.net/lawsuits.html>, accessed 20 June 2008.

Mississippi. The Mississippi Supreme Court announced on 3 March 2008 that it will consider a request from a panel of the fifth U.S. Circuit Court of Appeals to clarify when the clock starts running towards the statute of limitations in certain malpractice cases. Specifically they are asking for clarification on cases "where the alleged negligence is either the administration of a drug by a physician or the physician's failure to disclose about the risks of a drug, and experts disagree as to whether the drug caused the plaintiff's injuries." The request stems from a 2006 holding that gave plaintiffs two years to file suit after diagnosed with a condition. Associated Press, "Miss. Supreme Court to consider clarifying medical malpractice limits," *Picayune Item*, 4 March 2008, http://www.picayuneitem.com/local/local_story_064125214.html, accessed 19 June 2008.

Pennsylvania. On 14 March 2008 the Court of Common Pleas of Philadelphia County ruled in *Clark v. Pfizer, Inc.* that drug manufacturers who fraudulently promote off-label uses of their drugs may be liable for the costs to purchasers of generic versions of their drugs. The court found that, "Under Pennsylvania law, a defendant may be liable for misrepresentation to foreseeable plaintiffs even without any direct relations between the parties." The ruling on manufacturer Pfizer's motion for summary judgment means that the class action lawsuit on behalf of people who purchased the drug Neurontin or its generic equivalent, Gabapentin, will be allowed to advance to trial. *Clark v. Pfizer Inc.*, Pa. C. No. 040601819. Opinion available at http://www.fdalawblog.net/fda_law_blog_hyman_phelps/files/clark_v_pfizer_opinion_2008.pdf, accessed 5 May 2008.

Virginia. The Virginia Supreme Court ruled on 29 February 2008 that physicians working for charitable foundations are not immune from malpractice liability under the state's charitable immunity laws. Three malpractice suits against doctors working for the University of Virginia Health Services Foundation were consolidated for this case. Each of the doctors claimed they should not be liable since they were working for a not-for-profit foundation. The court held that charitable immunity protects only groups organized and operated for charitable purposes. Although the Health Services Foundation was organized for charitable purposes, the court found that it was in fact operating much like a business, regularly ending up with a profit that it paid to its physicians as bonuses, and therefore the physicians were not immune from tort liability. *University of Virginia Health Services Foundation v. Morris*, ___ Va. ___ (Va. S. Ct. 2008), No. 070214, 29 February 2008. Opinion available at <http://www.courts.state.va.us/opinions/opnscvwp/1070214.pdf>.

Recent Developments in Law and Regulation January - March 2008

***Federal.** There has been no action on a bill introduced in the Senate on 6 September 2007 that would require drug, medical devices, 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).

***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 Other Countries January - March 2008

Britain. The pharmaceutical company Reckitt Benckiser is accused of cheating the National Health Service. Internal memos were leaked by a whistle blower within the company that 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 pounds (around 78 million U.S. dollars), but a generic version of the drug has never been developed, even though Gaviscon has been out of patent for 10 years. Reckitt's accusers say that the leaked memos reveal that this is due to deliberate manipulation of the patent process by Reckitt, via a method known as evergreening, wherein a company will repeatedly file for revised patents on their existing products that extend their 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.

THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

Not specific to this quarter of "Legal Trends in Bioethics," but nevertheless worth mentioning, is the fact that victories for either side in the abortion debate seem in general to be small and fleeting. Over time the battlegrounds shift slightly, but the issues themselves are never resolved. For example, 30 years ago protest buffer zones were frequently in the news, and in this quarter's reports there is just such a case again in the news (see *Brown v. Pittsburgh* below). Also seemingly continuously in the news are cases over parental notification (see entries for Arizona and California below) and funding battles (see Vitter Amendment below). Arguments over the appropriateness of in-vitro fertilization have developed into arguments over more recent medical advancements such as stem-cell research, and more recent informed consent debates have moved from simple verbal or written information to battles over mandating ultrasounds. While undoubtedly everyone would like to see these issues resolved, one of the beauties of our legal system is that it provides avenues for the most deep-seated disagreements to be argued and debated peacefully. "Peacefully" here doesn't necessarily mean tactfully or without bitterness, acrimony, and occasionally even violence. Yet, the fact that these issues have not resulted in systematic government censorship or mass riots is proof that the system is working.

Judicial Cases and Regulatory Actions January - March 2008

***Federal.** U.S. District Court for Western Pennsylvania upheld on 22 February 2008 a Pittsburgh ordinance that creates a buffer zone between protesters and healthcare facilities, including abortion clinics. *Brown v. Pittsburgh* (Western PA District Court No. 2:06-CV-00393-NBF, 22 February 2008). Opinion available at http://www.womenslawproject.org/Briefs/Bufferzon_opinion.pdf.

***Kansas.** On 25 January 2008 a grand jury convened to investigate whether George Tiller, MD, broke a state law concerning late-term abortions ordered that Dr. Tiller provide the medical records of patients who sought late-term abortions between 1 July 2003 and 18 January 2008. Dr. Tiller refused to turn over the records, in part because he wanted to protect his patients' privacy. On 5 February 2008 the state supreme court ordered a stay on the issuing of any more grand jury subpoenas for Dr. Tiller's records and scheduled oral arguments for 8 April 2008. *George R. Tiller, MD, et al. v. Hon. Michael Corrigan, et al.* (Kas. Sup. Ct. No. 99,951).

Recent Developments in Law and Regulation January - March 2008

Federal. The Vitter Amendment, a part of the Indian Health Care Improvement Act reauthorization bill, was approved by the Senate on 26 February 2008. The amendment prevents the Indian Health Service from paying for abortion except in the case of rape, incest against a minor, or to save the life of a mother. C. Horton, "Bills limiting abortion move through state, federal processes," *Alaska Journal of Commerce*, 16 March 2008, http://www.alaskajournal.com/stories/031608/hom_20080316003.shtml, accessed 19 June 2008.

Arizona. Two bills passed the legislature in the week of 28 March 2008. The first, HB 2263, changes the parental notification laws, making it more difficult for minors to obtain a judicial bypass. The second, HB 2769, is a state ban on partial birth abortion, allowing doctors who perform the procedure to be prosecuted on both a state and federal level. Feminist Wire, "Arizona Legislature Passes Anti-Choice Bills," *Feminist Wire*, 28 March 2008, <http://www.msmagazine.com/news/uswirestory.asp?ID=10907>, accessed 19 June 2008.

California. For the third time in three years, anti-abortion advocates are trying to get enough signatures to place an initiative on the November 2008 ballot that would require parental notification and a 48-hour waiting period before a woman may obtain an abortion. Under the current initiative if a doctor performs an abortion on a dependant minor without parental approval, the doctor would be subject to a fine. M. Tafoya, "Parental Notification Effort in California," *Reproductive Health Reality Check*, 21 April 2008, <http://www.rhrealitycheck.org/blog/2008/04/21/parental-notification-amendment-may-face-california-voters>, accessed 20 June 2008.

Florida. A state senate bill that would require all women to undergo ultrasound testing prior to obtaining an abortion failed. The bill was presented as an extension of the theory of informed consent under which doctors are required to fully inform patients prior to allowing them to make a medically related decision. S.B. 2400, 2008 Reg. Sess. (Fla. 2008).

***Hawaii.** There has been no action on two bills that were held over from the 2007 legislative session that would allow all forms of stem-cell research. If no new action is taken, the bills will die at the end of the 2008 session. H.B. 364, H.B. 1261, 24th Leg., Reg. Sess. (Haw. 2007).

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 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.** The state senate passed a bill that would ban "partial-birth" abortions. The legislation includes an exception in the event that the procedure is necessary to save the life of the mother. Violation is a

felony and subjects anyone found guilty to up to two years imprisonment and a fine not to exceed \$50,000. The bill is currently under consideration in the state house. SB 776, 94th Leg., Reg. Sess. (Mich. 2007).

Missouri. A bill is stalled in the state senate that would modify the informed consent requirement for an abortion by adding new requirements to be fulfilled at least 24 hours prior to obtaining an abortion. Specifically, the bill would require that the woman be presented with printed materials and videos detailing the risks of an abortion, the physiological characteristics of an unborn child, provide an opportunity to view an active ultrasound of the unborn child, and offer to let the woman hear the heartbeat of her fetus. 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).

Nebraska. On 25 March 2008, the governor signed into law a bill that represents a compromise on the controversial issue of stem-cell research. The law prohibits the use of state money or facilities for creating or destroying embryos for stem-cell research using the therapeutic cloning technique. However, it also allows for the continuance of research using federally sanctioned stem-cell lines. The law also mandates the creation of an advisory committee that would award matching grants of up to \$500,000 for research on non-embryonic stem-cell research. L.B. 606, 100th Leg. Sess. (Ne. 2008).

***Ohio.** Two similar bills are moving their way through various committees in the state legislature. Originally introduced in the state house on 18 September 2007 and the state senate on 4 October 2007, they would require abortion providers to provide a patient with an opportunity, at no extra cost, to view an ultrasound of the fetus before the abortion can take place. Both bills are currently in the state senate's Health, Human Affairs and Aging Committee. H.B. 314, S.B. 230, 127th Gen. Assem., Reg. Sess. (Oh. 2007).

Pennsylvania. A bill that provides for an umbilical cord blood bank and requires healthcare practitioners to give pregnant patients information regarding umbilical cord donation passed the state senate on 31 March 2008. The bill passed the state house on 17 July 2007 and now goes to the governor for approval. 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.** On 17 March 2008, the governor signed into law a bill that would require abortion facilities to offer sonograms to pregnant women and document the offer and the woman's decision whether or not to view the ultrasound. The woman must attest with her signature to having made an informed decision. S.B. 88, 82nd Leg. Sess. (S.D. 2008).

Tennessee. A bill has been held over to the summer session that would require informed consent and a 24-hour waiting period prior to obtaining an abortion. SB 3512, 105th Gen. Assem., Reg. Sess. (Tenn. 2008).

***Wisconsin.** A bill died which would have required physicians who perform abortions to take certain steps if a woman seeking an abortion seems to have been coerced into having the abortion or seems to be in danger of being harmed if she declines to have the abortion. S.B. 218, 1007 Reg. Sess. (Wis. 2007).

Interesting Developments in Other Countries

***United Kingdom.** The Human Fertilisation and Embryology Bill was introduced in the House of Lords on 17 January 2008. The bill would amend the Human Fertilisation and Embryology Act of 1990 by changing the legal definition of parenthood in cases involving assisted reproduction and provides for regulation of procedures that combine several human embryos. It has progressed through the first sitting of the report stage, with a second scheduled for 21 January 2008. Amendment proposals seeking changes to current abortion law are expected to be introduced. The bill in its most recent incarnation would allow researchers to create inter-species hybrids by injecting human DNA into a hollowed-out animal egg cell. The resulting embryo would be 99.9 percent human and 0.1 percent animal. Supporters argue that this process will allow

scientists to make a large number of human embryos to allow for adequate research into the cures for many diseases. House of Lords: HL 2007/08 6. The entire text of the bill is at <http://www.publications.parliament.uk/pa/ld200708/ldbills/006/08006.i-iv.html>.

HEALTHCARE COVERAGE

The entries in this quarter reflect the sobering realization that it is one thing to wish the government could provide more healthcare coverage for its citizens, and quite another to find a way to pay for it.

Recent Judicial Cases and Regulatory Actions January - March 2008

Federal. On 24 March 2008, the U.S. Supreme Court declined to consider a challenge of a recent ruling by the Equal Employment Opportunity Commission, as brought by AARP (formerly the American Association of Retired Citizens). The AARP has argued that the ruling, which allows employers to reduce benefits for Medicare-eligible retirees, amounts to age discrimination, as employers are now able to create two different sets of retirees, and offer substantially different benefits to each group. Kaiser Family Foundation, "U.S. Supreme Court Allows Employers To Continue Reducing Health Care Benefits for Medicare-eligible Retirees," *Kaiser Daily Health Policy Report*, 25 March 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=51121, accessed 16 May 2008.

*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 argues that the 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, NY12525-#412881-v13-JL_SDNY_complaint_11_26_07.Doc*. A copy of the complaint is available at http://www.medicarerights.org/off_label_complaint_Nov_2007.pdf.

*California. There have been no further developments in the appeal of a Second District Court of Appeals for the State of California ruling on 4 December 2007 that canceling individual health insurance policies for omissions or mistakes on applications after claims are submitted is prohibited under state law. The court also held that insurers cannot cancel a member's policy if they do not attach a copy of the application to the policy. The case is on appeal to the state supreme court. *Ticconi v. Blue Shield of California* (Ca. S. Ct. No. S162434). Opinion available at <http://www.courtinfo.ca.gov/opinions/documents/B190427B.pdf>.

Illinois. A suit was filed in the Seventh Circuit Court of Sangamon County, Illinois, on 4 December 2007 by the Illinois Coalition for Jobs, Growth and Prosperity. Plaintiffs challenge the constitutionality of the governor's emergency ordered expansion of the state's FamilyCare program. The first court hearing is scheduled for 11 March 2008. *Gidwitz, et al. v. Maram*, No. 2007 MR _____. Complaint available at http://www.jobcoalition.org/1054848_1.pdf.

*Nebraska. There are no new developments in a lawsuit filed in the Lancaster County District Court on behalf of Sandra Cartwright, alleging that state employees living in predominately African-American areas are offered inferior health insurance coverage. J. Funk, "Lawsuit: State discriminated against blacks with insurance choice," *Lincoln Journal-Star*, 5 November 2007, <http://www.journalstar.com/articles/2007/11/05/news/nebraska/doc472e5be94739f900866308.txt>, accessed 4 February 2008.

Recent Developments in Law and Regulation January - March 2008

Federal. The Indian Health Care Improvement Act reauthorization passed the Senate on 26 February 2008, by an 83 to 10 vote. The bill provides \$35 billion to the Indian Health Service to allow for 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).

The Healthy Americans Act, first introduced in the Senate in January 2008, was referred to the Committee on Finance on 24 April 2008. The bill would create incentives for private health insurers to provide coverage directly to individuals, while employer contributions would be shifted to wages, and eventually a health insurance contribution to the federal government. S. 334, 110th Cong., 2nd Reg. Sess. (2008).

*There has been no action on a bill that would provide universal health insurance to all U.S. residents. The AmeriCare Health Care Act would create AmeriCare, a program that would use Medicare to provide health insurance to U.S. citizens who don't receive coverage through their employers and whose annual income falls below 300 percent of the federal poverty level. On 9 July 2007, the bill was referred to the Subcommittee on Health, Employment, Labor, and Pensions, where it is still pending. H.R. 1841, 110th Leg., 1st Reg. Sess. (2007).

Alabama. The governor's proposed 2009 fiscal budget has drawn criticism from state health officials. According to the Alabama Department of Public Health, the governor's \$1.95 billion budget would not cover several important programs, including Alabama's AIDS Drug Assistance Program, the Alabama Home and Community-Based Waiver Program, the state's Breast and Cervical Cancer Early Detection Program, and Alabama's SCHIP program, known as All Kids, which officials claim would need to freeze enrollment unless additional funds were provided. State health officials also have warned that these funding cuts will result in reductions of federal matching funds made available for Alabama's healthcare programs. Kaiser Family Foundation, "Highlights Recent Budget Developments," *Kaiser Daily Health Policy Report*, 21 March 2008, http://www.kaiser-network.org/daily_reports/rep_index.cfm?hint=3&DR_ID=51095, accessed 16 May 2008.

***Alaska.** A universal healthcare proposal was sent to the finance committee. The bill, originally introduced on 10 September 2007, 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. S.B. 160, 24th Leg., Spec. Sess. (Alaska 2007).

***California.** There has been no action on a bill originally introduced in the state Assembly on 11 September 2007 that proposes a plan that would increase tobacco taxes to increase state revenues and, as a separate measure, mandate health insurance. Families for whom insurance costs amounted to more than 6.5 percent of annual family income would receive subsidies to pay for insurance. AB 1X, 2007-2008 Leg. 2d Ext. Sess. (Cal. 2007).

Illinois. On 26 February 2008, the Joint Committee on Administrative Rules rejected the governor's emergency ordered expansion of the state's FamilyCare program for the second time. The order would have expanded eligibility for the FamilyCare program from families with up to \$38,202 in annual income to families with as much as \$82,600 annual income. A similar order was overturned in November 2007 over questions of where the money would come from to finance the expansion and because the program was expanded without legislative approval. A suit has also been filed by the Illinois Coalition for Jobs, Growth and Prosperity challenging the constitutionality of both orders, and the first hearings were scheduled for 11 March 2008. Kaiser Family Foundation, "Illinois Legislative Committee Rejects Gov. Blagojevich's FamilyCare Expansion," *Kaiser Daily Health Policy Report*, 28 February 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50671, accessed 15 May 2008.

Iowa. Iowa's Health Care Reform bill passed the Senate Human Resources Committee on 6 March 2008 and was sent to the full senate for consideration. Introduced on 6 March 2008, the bill would mandate health coverage for nearly all Iowa children by 2011, and expand HAWK-I, the state's State Children's Health Insurance Program (SCHIP), to provide coverage for children from low-income families. Additionally, the bill includes regulations to mandate "quality measure" reporting by the state's hospitals and physicians, and would provide incentives for the adoption of electronic health records. H.F. 2539, 82nd Gen. Assem., 2nd Sess. (Iowa 2008).

***Maryland.** The state house approved a \$31.2 billion 2009 fiscal budget by a 105 to 34 vote on 20 March 2008. Included in the house version of the budget are appropriations of \$15.1 million to provide expanded access for oral health services, and an additional \$10 million to provide subsidies to small businesses for healthcare procurement. Kaiser Family Foundation, "Highlights Recent Budget Developments," *Kaiser Daily Health Policy Report*, 21 March 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=51095, accessed 16 May 2008.

Minnesota. On 27 March 2008, the state senate approved a proposed healthcare system overhaul that would, among other things, provide for expanded coverage for 47,000 additional residents. The bill mandates the public accounting of fees charged by healthcare providers and demands the development of tools to allow consumers to easily compare the benefits and costs of competing plans. Under the proposals, the state would also begin monitoring childhood obesity and facilitate treatment of residents who have chronic conditions. Additionally, the plan would allow small businesses to obtain private health insurance with pre-tax dollars. Governor Tim Pawlenty has expressed concerns over the costs of the legislation, which the proposals plan to offset through projected long-term savings, and some Minnesota Democrats have voiced concerns over the far-reaching implications of the omnibus package. S.F. 3099, 85th Gen. Assem., Reg. Sess. (Minn. 2008).

Oregon. The Oregon Health Plan, which, due to budgetary restrictions has had closed enrollment since 2004, was reopened in February to fill 3,000 newly available slots. Faced with an overwhelming applicant pool, state officials began drawing names through a statewide lottery to fill the new openings. More than 90,000 of Oregon's estimated 600,000 uninsured residents had applied to the lottery within a month of the announcement of the opening. The current standard plan, which currently covers about 18,000 Oregonians, provides the insured access to general services, medications, and even limited dental and vision benefits, with premiums no higher than \$20 a month. Kaiser Family Foundation, "Lottery To Fill Open Spots in Oregon Health Plan Draws 'Overwhelming Response'," *Kaiser Daily Health Policy Report*, 10 March 2008, http://www.kaiser-network.org/daily_reportsrep_index.cfm?hint=3&DR_ID=50864, accessed 16 May 2008.

Tennessee. On 10 March 2008, the governor proposed new legislation to streamline the process of qualification for state home-based care coverage. The plan hopes to reduce overall healthcare spending, while simultaneously providing an expanded array of choices in providing elderly care throughout the state. Kaiser Family Foundation, "Tennessee Gov. Bredesen Proposes Home-Based Care Plan," *Kaiser Daily Health Policy Report*, 11 March 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50894, accessed 15 May 2008.

VACCINES

Vaccines are marvels of medicine that save millions of lives every year, yet government policies have resulted in reducing rather than increasing the effectiveness of vaccine programs. The U.S. Supreme Court in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) upheld a state statute compelling smallpox vaccinations. Smallpox, the Court held, is highly contagious and extremely deadly and thus justified mandatory vaccination with no exception except for an individual's unique medical susceptibility. (A modern day example would be that vaccination not be required for someone who is immunosuppressed.) No other exemption made sense in the Court's mind because the more exemptions there are, the less effective an immunization program becomes.

Today in the U.S. the effectiveness of vaccination programs is undermined by the overzealous mandating of vaccines and a laissez-faire attitude toward the granting of exemptions. Most of the 41 vaccines for children that have been recommended by the U.S. Centers for Disease Control and Prevention — and consequently are required by the states — don't come anywhere near meeting the criteria set forth in *Jacobson* for justifying a mandate. When people learn that some vaccines are not as necessary as government officials suggest, understandably, even if erroneously, they question the necessity of other vaccines. Similarly, when legislators make exceptions to their mandates for less-critical vaccines, they open the door for people to demand exemptions from taking other vaccines.

Currently all of the U.S. states allow medical exceptions, but most of the states also allow religious and philosophical exemptions for all types of vaccines. To complicate matters, there are nearly 5,000 families who are currently suing the government for vaccine-related autism and other developmental disabilities allegedly caused by vaccines. Under such circumstances, government efforts to revitalize trust in vaccines face serious obstacles.

Recent Judicial Cases and Regulatory Actions January - March 2008

Federal. A U.S. federal judge ruled that the U.S. Department of Defense must consider exonerating two military pilots whose careers ended after they refused to take compulsory anthrax vaccine shots. The plaintiffs were two out of hundreds in the same situation. The military's mandatory inoculation program, which started in March 1998, continued for more than six years. Federal courts have since found the program illegal and in direct violation of an individual's right to informed consent. E. Grossman, "Judge advances anthrax vaccine refusal case," *Global Security Newswire*, 24 March 2008, <http://www.govexec.com/dailyfed/0308/032408gsn1.htm>, accessed 18 June 2008.

Recent Developments in Law and Regulation January - March 2008

***California.** There has been no action on a bill that would require all girls entering the sixth grade to receive the human papillomavirus (HPV) vaccine. The bill includes an opt-out provision. A.B. 16, 2007-2008 Leg., Reg. Sess. (Cal. 2007).

***Michigan.** There has been no action on a bill that would require the Michigan Department of Health to "encourage" every school (both public and private) to provide information regarding the risks associated with HPV and the availability, effectiveness, and potential risks of immunization to students and parents. The legislation makes no reference to the age or grade level at which this information should be provided. H.B. 5171, 94th Leg., Reg. Sess. (Mich. 2007).

***Wisconsin.** A bill that would have required schools to provide parents with information about the HPV vaccine has died. The bill directed the Department of Public Instruction, in conjunction with the Department of Health and Family Services, to distribute information that includes the recommendations made by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. An identical bill that was being considered by the state assembly has also died. S.B. 252, A.B. 492, 2007 Reg. Sess. (Wis. 2007).

ORGAN AND TISSUE PROCUREMENT

Since the last issue of "Legal Trends in Bioethics," one more state, Michigan, has passed the Uniform Revised Anatomical Gift Act of 2006. That brings the number of states in which the act has passed up to 21 states (**Arizona, Arkansas, California, Colorado, Idaho, Indiana, Iowa, Kansas, Michigan, Minnesota, Montana, Nevada, New Mexico, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, and Virginia**).

This quarter's entries on organ procurement indicate a mix of optimism and desperation when it comes to solving the organ shortage. New Jersey is implementing a high school organ donation education campaign and Wisconsin established a donor registry. Kansas is considering implementing tax credits for donors, and Israel is considering special benefits for donors. Britain is mandating donation with an opt-out only program; in Ireland organs were taken surreptitiously; in California a surgeon is accused of having rushed a patient's death to retrieve his organs.

Recent Judicial Cases and Regulatory Actions January - March 2008

California. On 19 March 2008 the Superior Court of San Luis Obispo ordered a transplant surgeon to trial on one count of felony dependent adult abuse, but dismissed two other felony charges against the surgeon relating to the improper administration of drugs to a dying patient. The defendant is accused of hastening the death of a man to harvest his organs. California law prohibits transplant surgeons from directing the treatment of potential donors until they have been declared dead. This action is the first of its kind in the U.S. *The People of California v. Hootan Roozrokh*, Case No. 405885.

Recent Developments in Law and Regulation January - March 2008

***Alaska.** There has been no action on a bill introduced 13 May 2007 to amend the state's anatomical gift act. S.B. 181, 25th Leg., Reg. Sess. (Alaska 2007).

***District of Columbia.** There has been no action on a bill introduced 9 January 2007 that would amend the state's anatomical gift act since it received a public hearing on 8 June 2007. D.C. Council, B17-58 (2007).

Georgia. A bill passed the state house Health and Human Services Committee on 26 March 2008 that allows organ procurement agencies to harvest organs without further permission from family members if the donor's intent is 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. S.B. 405, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

Kansas. A bill was discussed 30 January 2008 by the state house Taxation Committee 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. Arkansas and Oklahoma already have similar measures, and Missouri is currently also considering a proposal. H.B. 2362, 82nd Leg., Reg. Sess. (Kan. 2008).

***Michigan.** A bill to amend the state's anatomical gift act was signed into law on 13 March 2008. The bill sets new criteria for individuals wishing to designate anatomical gifts and, among other things, makes the selling of body parts a felony. H.B. 4940, 94th Leg., Reg. Sess. (Mich. 2007).

***Missouri.** A bill introduced on 1 February 2007 to adopt the 2006 Uniform Anatomical Gift Act without changes died. S.B. 496, H.B. 723, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2007). But a bill was passed and sent to the governor that established a first-person donor consent registry for organs and tissues. S.B. 1139, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2008).

***New Jersey.** A bill introduced on 9 January 2007 to amend the state's anatomical gift act died. A.B. 3909, 2007 Gen. Assem., Reg. Sess. (N.J. 2007).

A bill passed the state senate on 17 March 2008 that could make New Jersey the first state that would require anyone getting or renewing their driver's license to choose whether to register as an organ donor. The New Jersey Hero Act would also make mandatory teaching the importance of organ donation in high school health classes. S.B. 755, 211th Reg. Leg. Sess. (N.J. 2008).

***New York.** There has been no action on a bill introduced on 25 April 2007 to enact the Uniform Anatomical Gift Act. S.B. 5154, 230th Gen. Reg. Sess. (N.Y. 2007).

***Texas.** There has been no action on a bill introduced on 21 March 2007 to amend the state's anatomical gift act. The bill is currently under consideration in the state house. S.B. 1597, 80th Leg., Reg. Sess. (Tex. 2007).

***Washington.** A bill to amend the state's anatomical gift act was signed into law by the governor on 25 March 2008. H.B. 1637, 60th Leg., 2007 Reg. Sess. (Wash. 2007).

Wisconsin. Governor Doyle signed a bill on 19 March 2008 establishing a donor registration system that allows people to sign up at any time, not just when they renew their license. It also lowers the age of consent to 15, and grants healthcare agents elevated powers to grant consent (similar to the power of attorney) in cases when the donors' intentions are unclear. The law goes into effect within 90 days of the signing. Associated Press, "Bill expected to increase number of Wisconsin organ donors," *Journal Times*, 9 March 2008, http://www.journaltimes.com/articles/2008/03/09/local_news/doc47d463e3853d9664857945.txt, accessed 17 June 2008.

Interesting Developments in Other Countries

Israel. On 24 March 2008, the Israeli parliament passed a bill to combat the shortage of willing donors in Israel (only 4 percent of the population holds a donor card and there is a 60 percent refusal rate among relatives of the deceased). This legislation will allow doctors to remove organs from people who are brain dead, and encourages organ donation through a series of benefits for those who are alive and well. A living person who donates an organ receives the status of a chronic patient as well as having all participation fees for the medical procedure paid for. The state will also compensate them NIS 18,000 (or about \$5,100). <http://www.guysen.com/articles.php?sid=6955>; *Ynet*, 25 March 2008, <http://www.ynetnews.com/articles/0,7340,L-3523461,00.html>, accessed 17 June 2008.

United Kingdom. Under a new system spearheaded by the Organ Donation Task Force, all British citizens will become organ donors unless they specifically object. This "opt out" system is supposedly backed by Prime Minister Gordon Brown. N. Dorman, "All Brits to be put on donor list," *People*, 30 March 2008, http://www.people.co.uk/news/tm_headline=all-brits-to-be-put-on-donor-list&method=full&objectid=20367111&siteid=93463-name_page.html, accessed 17 June 2008.

Ireland. On 25 February 2008 a U.K. Freedom of Information Act inquiry revealed that a government inquiry in Ireland found "no malice or foul play" in a scandal in which the organs of deceased patients were harvested at several Irish hospitals without the consent of relatives. In some cases the organs were taken and the bodies were filled with sand so that relatives would not notice a difference in weight. While no wrongdoing was found, the inquiry report suggested that more than 2,000 families suffered needless grief and anguish due to doctors' failure to communicate openly and honestly with families at the time of their loved one's death. L. McDonald, "Children's Bodies Filled with Sand in Organ Scandal," *Redorbit News*, 26 February 2008, <http://www.redorbit.com/news/display/?id=1270877>, accessed 21 June 2008.

UNCONVENTIONAL TREATMENT

The authors do not mean to pass judgment on the merits of a form of treatment by calling it "unconventional." The term "unconventional" is meant to apply to treatments outside the mainstream; that is, those treatments that are not accepted or favored by the establishment. No assumption should be made that "acceptance by the mainstream" means a certain form of treatment (or non-treatment) is better. Nor does nonacceptance by the establishment, in and of itself, warrant banning a practice that some believe is beneficial.

In considering the cases and laws under discussion in this section, also look under the healthcare coverage and FDA sections for discussions of "off-label" uses for FDA-approved drugs.

One nongovernmental action worth noting is that the American College of Physicians (ACP) on 14 February 2008 issued a position paper endorsing the reclassification of marijuana and further study of its

medicinal uses. The ACP "urges review of marijuana's status as a Schedule I controlled substance and its reclassification into a more appropriate schedule, given the scientific evidence regarding marijuana's safety and efficacy in some clinical conditions." The ACP also criticized the notion that marijuana is a "gateway" drug, stating, "marijuana has not been proven to be the cause or even the most serious predictor of serious drug abuse," although the paper notes that "gateway drug" concerns pertain only to nonmedical uses of the controversial plant. The position paper can be found in its entirety at http://www.acponline.org/acp_news/medmarinews.htm.

Recent Judicial Cases and Regulatory Actions January - March 2008

California. The state supreme court ruled on 24 January 2008 that employers can fire employees who test positive for marijuana even if they are using it in compliance with the state's Compassionate Use Act, which permits the medical use of marijuana if approved by a doctor. Gary Ross was fired by communications firm RagingWire after a routine drug test showed he had used marijuana. He sued, claiming that RagingWire had violated his rights under the state's Fair Employment and Housing Act by discriminating against him because of his disability by not making the reasonable accommodation of allowing him to use medical marijuana at home. RagingWire maintained that they could not be obligated to accommodate him, since it was illegal under federal law. The court agreed with RagingWire in a five to two decision, holding that "no state law could completely legalize marijuana for medical purposes because the drug remains illegal under federal law, even for medical users." *Ross v. RagingWire Telecommunications*, CA S. Ct. No. S138130, 24 January 2008. Opinion available at <http://www.courtinfo.ca.gov/opinions/archive/S138130.PDF>.

Colorado. A couple whose medical marijuana plants were destroyed after being seized by local police filed a motion on 17 January 2008 in Larimer County District Court seeking 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 motion requesting an estimate of the value of the plants from the U.S. Drug Enforcement Administration (DEA) puts the agency in an awkward position because it has long been criticized for inflating the value of seized marijuana to aid the prosecution of drug cases. 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.** The state supreme court heard oral arguments on 5 March 2008 in the Missouri Midwifery Supporters' appeal of a permanent injunction barring midwives from delivering infants without the supervision of a trained nurse or doctor. *Missouri St. Med. Health Assoc. v. State of Missouri and Missouri Midwives Assoc.* (Mo. SC88783, 6 September 2007).

Recent Developments in Law and Regulation January - March 2008

***Delaware.** A bill to allow freestanding birth centers to hire certified professional midwives may be permanently stalled. Under current law, all midwives working in a freestanding birth center, whether certified professional midwives or certified nurse midwives, must have a backup agreement with a physician who has hospital admitting privileges and would be available around-the-clock for consultation and referrals. A registered nurse with adult and infant resuscitation skills also must be present for each delivery. H.B. 106, 144th Gen. Assem., Reg. Sess. (Del. 2007).

Michigan. The Board of State Canvassers approved petitions on 3 March 2008 to put the issue of legalizing marijuana for medical purposes before state lawmakers. The Michigan initiative would allow patients to grow and use small amounts of marijuana for relief from pain associated with several conditions, if recommended and approved by a doctor. If lawmakers don't approve the measure within 40 days, the proposal will be placed on the November ballot for voters to decide, which is the likely outcome, since the

legislature has not acted on medical marijuana legislation that has been introduced in recent years. Five cities (Ann Arbor, Detroit, Ferndale, Flint, and Traverse City) have recently passed symbolic initiatives in favor of legalizing medical marijuana. Associated Press, "Medical Marijuana to go before lawmakers," *MLive Michigan News*, 4 March 2008, http://www.mlive.com/news/index.ssf/2008/03/medical_marijuana_to_go_before.html, accessed 19 June 2008.

Montana. The Montana Department of Corrections proposed new rules at a hearing on 3 January 2008 that would prohibit those on probation or parole from obtaining medical marijuana, which voters legalized in 2004. The new rules would also prohibit them from drinking alcohol or gambling. In Montana, sentencing judges can already ban convicts from such activities if there is a connection between the activity and their crime, but the agency states that the new rules would lead to a lower recidivism rate. Associated Press, "Ban Sought on Medical Marijuana for Parolees," *Washington Post*, 4 January 2008, <http://www.washingtonpost.com/wp-dyn/content/article/2008/01/03/AR2008010303669.html>, accessed 19 June 2008.

Interesting Developments in Other Countries

Austria. The United Nations-affiliated International Narcotics Control Board issued a press release on 8 February 2008 saying that computerized "vending machines" in medical marijuana dispensaries violate international drug control treaties, specifically citing the Single Convention on Narcotic Drugs of 1961. The press release called on the government of the U.S. to enforce its federal laws prohibiting marijuana use, and noted that research on the medical benefits of marijuana was inconclusive. There is nothing distinct about the machines that make them in violation any more than any other method of distributing marijuana. INCB Secretariat, "Marijuana Vending Machines in Los Angeles are Contrary to International Drug Control Treaties, says INCB," *United Nations Information Service*, 8 February 2008, <http://www.unis.unvienna.org/unis/pressrels/2008/unisnar1023.html>, accessed 21 June 2008.

Canada. A federal judge ruled on 10 January 2008 that patients who use medical marijuana will no longer have to rely on the government for their supplies. The ruling invalidated a provision of the medical marijuana program that prohibited growers from supplying more than one patient. Previously, medical users were given the option of growing their own marijuana, buying it from the official government source, or buying it from another grower who was allowed to supply only one patient. A group of medical users sued, claiming that this scheme made the federal supplier the de-facto sole legal provider of marijuana, and that the one patient per grower rule was arbitrary. The judge sided with them, saying the restrictions were unconstitutional and caused "a major difficulty with access." Canadian Press, "Ruling Brings 'Great Remedy' for Medical Pot Users," *Edmonton Sun*, 10 January 2008, <http://www.edmontonsun.com/News/Canada/2008/01/10/4766737.html>, accessed 19 June 2008.

LIFE-AND-DEATH DECISIONS

Recent Judicial Cases and Regulatory Actions January - March 2008

***Montana.** There has been no further action in a suit originally filed in the Montana First Judicial District Court on 1 November 2007 seeking declaratory judgment and injunctive relief that would prohibit law enforcement officials from prosecuting physicians who assist mentally competent terminally ill patients by facilitating medication that allows patients to have a choice in ending their life. The suit makes reference to rights expressed in Montana's Constitution including rights to privacy, individual dignity, due process, equal protection under the law, and the "right to seek safety, health, and happiness in all lawful ways," and seeks to prove that charging any such physician with a crime is, therefore, unconstitutional. Plaintiffs hope the decision will clarify state law on the issue of a patient's right to choose how and when to die. *Baxter et al. v. Montana* (Mt. 1st Dist. DV 2007 787, 1 November 2007).

Recent Developments in Law and Regulation January - March 2008

***California.** The California Compassionate Choices Act will be reintroduced in early 2008. It failed due to lack of action 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." AB 374 2007-2008 Leg., Reg. Sess. (Cal. 2008).

New Hampshire. A bill that 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 died in committee. H.B. 40 2007-2008 Leg., Reg. Sess. (Nh. 2008). Full text of the bill can be found at <http://www.gencourt.state.nh.us/legislation/2008/HB0040.html>. www.legis.state.nh.us/2007/data/SB-151.pdf.

Virginia. Governor Tim Kaine 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

Canada. The Court of the Queen's Bench of Manitoba, in *Golubchuk v. The Salvation Army Grace General Hospital et al.*, granted the plaintiff's request to continue an injunction prohibiting the hospital from disconnecting Samuel Golubchuk from the ventilator that is keeping him alive until the case has been heard by the court. Golubchuk's level of consciousness and cognitive function are in dispute, but the court also pointed out, "Contrary to the assertion of the defendants, it is not settled law that, in the event of disagreement between a physician and his patient as to withdrawal of life support, the physician has the final say." So both the facts and the law will be at issue in the forthcoming trial. *Golubchuk v. The Salvation Army Grace General Hospital et al.* 2008 MBQB 49. (The authors thank Pat Murphy, Clinical Ethicist at St. Boniface General Hospital in Winnipeg, Manitoba, for sending us this document.)

In March 2008, Jocelyn Downie, the Canada Research Chair in Health, Law and Policy from Dalhousie University, stated that new legislation was being drafted to legalize euthanasia. Francine Lalonde, the Bloc Québécois member of the Canadian House of Commons who in 2005 introduced bill C-407, a bill that would have legalized euthanasia and assisted suicide in Canada, stated in an interview in *Canada Press* that she intends to introduce new legislation to "relaunch the debate on assisted suicide." A test case has been drafted to combat this new legislation. A. Schadenberg, "Canadian MP About to Propose Assisted Suicide Bill; Court Challenge Also in the Works," *LifeSite News.com*, 14 April 2008, <http://www.lifesitenews.com/ldn/2008/apr/08041404.html>, accessed 18 June 2008.

France. Chantal Sébire was found dead on 19 March 2008, two days after her request for "active euthanasia" was denied. Sébire suffered from esthesioneuroblastoma, an incurable cancer that attacked her nose and sinuses, leaving her disfigured, blind, unable to taste or smell, and in terrible pain. According to ABC News, the Dijon court ruled that "Sébire could not have a doctor help her die because it would breach medical ethics and French law, under which assisted suicide is a crime." D. Zaru, "Denial of active euthanasia in France sparks global debate," *Guilfordian*, 28 March 2008, <http://media.www.guilfordian.com/media/storage/paper281/news/2008/03/28/World/Denial.Of.Active.Euthanasia.In.France.Sparks.Global.Debate-3290412.shtml>, accessed 18 June 2008.

Netherlands. A March 2008 study published in the *British Medical Journal* found that terminal sedation may be being used by doctors as an alternative to euthanasia in some countries. The authors suggest this may be the case in the Netherlands, where the 2001 terminal sedation rate of 5.6 percent has risen to 8.2 percent in 2005. It is also unclear if these sedations were always in accordance with the patients' wishes. Of the sedated patients in this study, 9 percent had previously asked for euthanasia, suggesting that some of these sedations were to sidestep the legal issues involved in euthanasia. K. Kingsbury, "When Is Sedation Really Euthanasia?" *Time*, 21 March 2008, <http://www.time.com/time/health/article/0,8599,1724911,00.html>, accessed 18 June 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 January - March 2008

Federal. There has been no movement on a bill introduced by Senators John Kerry (D-Massachusetts) and John Ensign (R-Nevada) on 5 December 2007 that proposed appropriating Medicare funds as incentives for physicians to adopt e-prescribing technology. Medicare Electronic Medication and Safety Protection (E-MEDS) Act, S. 2408, 110th Cong., 1st Reg. Sess. (2008).

California. The California Pharmacy Board began consideration of an extension in the deadline for the implementation of an electronic drug-tracking system called for by the state legislature in 2004. The plan would extend the deadline from 1 January 2009 two additional years, for the first law of its kind in the nation to require an "electronic pedigree" that would enable pharmaceuticals to be tracked from production through sale. Pharmaceutical companies and wholesalers have expressed support for the legislation, but stress that more time is needed to refine the now costly and inefficient technology. Kaiser Family Foundation, "California Pharmacy Board To Consider Delaying Deadline for Electronic Drug Tracking System," *Kaiser Daily Health Policy Report*, 25 March 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=51129, accessed 10 May 2008.

Georgia. The state senate approved the Georgia Health Marketplace Act on 6 March 2008. The bill seeks to establish a web site that would provide consumers with a forum to easily access comparisons of deductibles, co-payments, benefits, and premiums for a wide variety of different plans; would allow purchases with pre-tax dollars; and would enable Georgians to set up personal health savings accounts. The bill also requires insurance providers to cover additional tests mandated by state law. S.B. 404, 149th Gen. Assem. Reg. Sess. (Ga. 2008).

Louisiana. The governor proposed a state budget for fiscal year 2009 that includes \$18.6 million in funding for health information technology projects next year. The majority of the funding, \$11.1 million, would be allocated to the Louisiana Rural Health Information Exchange to facilitate the acquisition of digital technologies for rural medical facilities. The budget proposes appropriating \$4 million for continued development of the Louisiana Health Information Exchange, and \$3.5 million as incentives to increase the use of interoperable electronic health record (EHR) software systems. Louisiana physicians who adopt and adequately implement such systems are eligible for annual Medicare bonuses of as much as \$58,000 throughout the five-year pilot program. Kaiser Family Foundation, "Louisiana Initiatives Encourage Adoption of Health Information Technology," *Kaiser Daily Health Policy Report*, 12 March 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50926, accessed 10 May 2008.

New York. On 25 February 2008, New York City Mayor Michael Bloomberg announced the launch of a new \$60 million electronic health record system. The EHR system, which draws half of its funding from state and federal governments, already has 200 physicians (with a combined total of 200,000 patients) committed to participate, and the city health commission hopes to increase those numbers to 1,000 and one million, respectively, by the end of the year. The system will store information including medical histories, lab results, and prescription information, and notify physicians to alert them about past-due prescriptions or treatments and provide information about current best practices. The city will provide licensing, low-cost tech support, and on-site training for all practices that have at least 30 percent uninsured or Medicaid patients. The health department will not be allowed access to the information of individual patients, but will be able to utilize general information on healthcare providers from the EHR system. Kaiser Family Foundation, "New York City Launches EHR System," *Kaiser Daily Health Policy Report*, 27 February 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50639, accessed 10 May 2008.

Interesting Developments in the Private Sector

On 24 March 2008, Angie's List, an online consumer ratings site, launched an expansion that will allow its registered members to provide and access feedback concerning their healthcare experiences in 55 different categories, including dental, insurance provision, and hospital care. The members will be able to assign grades of A through F to each appropriate area, and access compilations of other members' feedback for the healthcare providers in their area. Criticism of the service has come from some medical professionals who worry that the complexities of medical care may be overlooked by consumers in favor of more easily rated characteristics such as staff courtesy or office appearance. Kaiser Family Foundation, "Web Site Launches New Service To Allow Members To Rate Health Care Experiences," *Kaiser Daily Health Policy Report*, 27 March 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=51200, accessed 10 May 2008.

The iHealth Alliance, a not-for-profit subsidiary of Medem, announced plans to launch the Health Care Notification Network, a website designed to supplement current regular mail practices by notifying healthcare professionals of substantive label changes, warnings, and recalls through electronic media. The service will provide the information for free to participating physicians, but pharmaceutical companies will be charged for the service, which will not include any pharmaceutical marketing materials. Medem officials report that at least five major pharmaceutical companies have already requested contracts for the service, although no agreements have been finalized yet. Kaiser Family Foundation, "Not-for-Profit Group To Launch Web Site To Notify Physicians of Medication Label Changes, Warnings, Recalls," *Kaiser Daily Health Policy Report*, 25 March 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=51130, accessed 10 May 2008.

The Alliance for Health Reform sponsored a forum conducted over the last week of February 2008, where Patient Privacy Rights, and others, stressed their reluctance to support new healthcare IT legislation, such as S 1693 introduced by Senator Ted Kennedy (D-Massachusetts) last June. Privacy advocates have been wary of supporting any new legislation that does not include concrete language ensuring privacy safeguards. There has been no action on S 1693 since October 2007. Kaiser Family Foundation, "Forum Discusses Health IT Privacy Concerns," *Kaiser Daily Health Policy Report*, 6 March 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50806, accessed 10 May 2008.

On 28 February 2008, Google announced the inauguration of Google Health, an expansion that will allow users to store personal health records online. The new site will compete in an emerging market that already includes similar internet-based applications from Microsoft and Revolution Health Group. Privacy concerns have been the main obstacle in attracting users, as some healthcare professionals worry that the federal medical privacy rule may not cover online records. Kaiser Family Foundation, "Google To Announce Web Site To Allow Storage of Personal Health Records Online," *Kaiser Daily Health Policy Report*, 28 February 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50670, accessed 10 May 2008.

HIV/AIDS

Recent Developments in Law and Regulation January - March 2008

Federal. A bill to reauthorize and improve upon the President's Emergency Plan for AIDS Relief (PEPFAR) was approved by the House Foreign Affairs Committee on 27 February 2008. The bill would allocate \$50 billion to the program over the next five years, and seeks to replace the requirement that abstinence education programs account for at least one-third of each country's appropriation with a call for "balanced funding" for abstinence, fidelity, and condom programs relative to evidence gathered in each focus country. Additionally, the bill mandates that reports be made to Congress if abstinence and fidelity programs comprise less than 50 percent of spending on virus prevention programs. Unlike previous propos-

als for the renewal, the bill does not allow funds to be used for contraception or abortion services, and PEPFAR recipient nations must continue to oppose commercial sex work. The bill also seeks appropriation of \$9 billion to fight tuberculosis and malaria, and to provide for food supplements and loans for people living with HIV. A Senate version of the reauthorization was introduced on 7 March 2008, and referred to the Committee on Foreign Relations. H.R. 5501, 110th Cong. 2nd Reg. Sess. (2008).

*There has been no recent action on a bill introduced in the House in September that would require inmates to undergo an HIV test upon entering and leaving prison. There would be an opt-out provision, unless it is determined that the inmate was exposed to a state-defined HIV risk, such as a pregnancy or a sexual encounter, while in prison. Additionally, the measure would require the Prisons Bureau to report to Congress its procedures for testing, treating, and preventing hepatitis and other sexually transmitted diseases, and those transmitted through intravenous-drug use. The Prisons Bureau would also be required to provide legislators with statistics on the results of the HIV tests. The bill has been read twice in the Senate and was referred to the Committee on the Judiciary. H.R. 1943, 110th Cong. (1st Sess. 2007).

Alabama. The Alabama Department of Corrections is facing pressure to remove its prohibition barring HIV-positive inmates from participating in their work release program. Alabama is the only state with such a prohibition, which prison officials attribute to a 2004 settlement that established a series of healthcare requirements, including dietary needs and monitoring of antiretroviral treatments, that the corrections system is responsible for meeting. The Alabama work release programs allow participants to work during the day outside of corrections supervision, which prison officials worry would not meet their responsibilities under the settlement. Kaiser Family Foundation, "Alabama Advocates Urge Officials To Remove Work Release Restrictions for HIV-Positive Inmates," *Kaiser Daily HIV/AIDS Report*, 25 March 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=51112, accessed 6 May 2008.

California. On 26 February 2008 the Santa Clara County Board of Supervisors voted unanimously in support of a motion to oppose the decades-old FDA policy that prohibits homosexual men from donating blood. The measure also directs the board's federal lobbyists to work to retool the FDA policy, which the board maintains is excessive in light of recent advances in HIV screening of donated blood. Previously, many organizations, including the American Red Cross and the American Association of Blood Banks, have argued for the reduction of the ban to a moratorium within 12 months of homosexual activity. The board's vote comes in the wake of San Jose State University's decision to prohibit blood drives on campus, asserting that the FDA policy violates the school's antidiscrimination regulations. Kaiser Family Foundation, "California County Board of Supervisors Votes To Oppose FDA Policy Barring MSM From Donating Blood," *Kaiser Daily HIV/AIDS Report*, 28 February 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=50653, accessed 5 May 2008.

Illinois. On 4 March 2008, the state house rejected 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 Jersey. Directors of the state's pilot needle-exchange programs are reporting low enrollment numbers for new programs created late last year. Some officials blame the low numbers on the absence of state funding, and fears from some injection-drug users that the program is a police sting operation. Recent estimates suggest that more than 40 percent of the state's 48,000 HIV cases were the result of intravenous-drug use. Despite the early struggles, program officials still assert that the programs show promise. Kaiser Family Foundation, "Needle-Exchange Pilot Program in New Jersey is 'Struggling' To Enroll IDUs," *Kaiser Daily HIV/AIDS Report*, 26 February 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=50598, accessed 5 May 2008.

New York. The governor is considering a plan that would mandate the enrollment of state Medicaid beneficiaries who are HIV positive in managed-care plans. The plan, still in its initial stages, has drawn scrutiny from Housing Works, an HIV/AIDS advocacy group, which worries that mandatory enrollment could prove to be a "large-scale disruption" of the current system, noting that the current HIV Special Needs Plans are only available in New York City, and cater to less than 5 percent of the state's 65,000 Medicaid

beneficiaries living with HIV/AIDS. Kaiser Family Foundation, "New York Gov. Spitzer Considers Imposing Mandatory Managed Care Enrollment Among HIV-Positive Medicaid Beneficiaries," *Kaiser Daily HIV/AIDS Report*, 3 December 2007, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49159, accessed 29 January 2008.

Interesting Developments in Other Countries

International. On 25-26 February 2008, an international task force headed by the Joint United Nations Programme for HIV/AIDS (UNAIDS) and the Norwegian government met for the first time in Geneva to discuss HIV/AIDS-related issues. The task force issued calls to ease travel restrictions, which exist in some form in as many as 74 nations worldwide. The group is expected to hold another meeting at the U.N. General Assembly in June and at the Global Forum on Migration and Development in October. Kaiser Family Foundation, "Task Force Calls for Lifting of HIV/AIDS-Related Travel Restrictions," *Kaiser Daily HIV/AIDS Report*, 10 March 2008, http://www.kaiser-network.org/daily_reports/rep_index.cfm?hint=1&DR_ID=50843, accessed 6 May 2008.

Canada. A study released on 22 February 2008 by the British Columbia Centre for Excellence in HIV/AIDS claims that 40 percent of the 1,436 AIDS-related deaths in British Columbia, Canada, from 1997 to 2005 were of patients who never received antiretroviral treatments, despite the no-cost provision of antiretroviral medications. According to the study, the most common factors among the untreated included low-income, homelessness, mental illness, and drug use. The centre proposes a provincial government plan to establish outreach teams that would provide rapid-response testing and treatment to vulnerable populations. Kaiser Family Foundation, "40 percent of AIDS-Related Deaths in British Columbia Among People Who Never Received Treatment," *Kaiser Daily HIV/AIDS Report*, 27 February 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=50627, accessed 5 May 2008.

On 25 February 2008, the British Columbia Centre for Disease Control initiated the Chee Mamuk Aboriginal HIV/STI Program in an attempt to stem the spread of HIV and other sexually transmitted diseases (STIs) among aboriginal communities in Prince George, British Columbia. The five-day program sought to link healthcare providers with HIV/AIDS and sexual health services within Prince George's aboriginal communities in hopes of creating a network of community-based solutions. According to plan managers, aboriginal people make up 5 percent of the provincial population, but as much as 15 percent of all new HIV cases in 2006. Kaiser Family Foundation, "Program Launched To Curb HIV Among Aboriginal Community," *Kaiser Daily HIV/AIDS Report*, 27 February 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=50627, accessed 5 May 2008.

China. A Ministry of Health report released on 22 February 2008 outlines a 45 percent increase of reported HIV/AIDS cases from 2006 to 2007. Though the report did not include raw data, a government statement in November 2007 estimated the number of cases at 700,000. Health Ministry officials suggest the increasing numbers do not represent a major increase in infections, but more likely an increase in screenings. The report also outlined increases by 30 percent in hepatitis C cases, and 24 percent of syphilis infections during 2007. Kaiser Family Foundation, "Reported HIV/AIDS Cases in China Increase 45 percent From 2006 to 2007," *Kaiser Daily HIV/AIDS Report*, 26 February 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=50595, accessed 5 May 2008.

Malawi. On 4 March 2008, Malawi legislators began consideration of a bill that would create a registry of an estimated 30,000 traditional healers under the Ministry of Health. The legislation seeks to prohibit local healers from making claims that they can cure HIV/AIDS by such methods as sex with albinos, or virgins. The bill also contains provisions that would prevent religious leaders from urging HIV-positive Malawians to forgo antiretroviral treatments in favor of prayer. Official estimates suggest that 14 percent of Malawi's 12 million residents live with HIV, with 100,000 new cases occurring every year. Kaiser Family Foundation, "Draft Legislation Seeks to Protect People in Malawi From Healers Claiming To Cure HIV/AIDS," *Kaiser Daily HIV/AIDS Report*, 5 March 2008, http://www.kaisernetwork.org/daily_reports/rep_

index.cfm?hint=1&DR_ID=50761, accessed 5 May 2008.

United Kingdom. On 14 March 2008, the U.K.'s Crown Prosecution Service released new guidelines governing the prosecution of "intentionally or recklessly transmitting HIV" that limits prosecution to HIV-positive people who infect a series of partners, or who infect a partner during a period of high-risk activity. The statement outlines the need to show a "sustained course of conduct during which the defendant ignores current scientific advice regarding the need for and the use of safeguards." The guidelines also include "special measures" that cover the sensitive treatment of victims, which may include the accused, to lessen the possible traumatic situations. Kaiser Family Foundation, "U.K. Crown Prosecution Service Issues Guidelines To Clarify Law on Intentional, Reckless Transmission of HIV," *Kaiser Daily HIV/AIDS Report*, 18 March 2008, http://www.kaisernet.org/daily_reports/rep_index.cfm?hint=1&DR_ID=51006, accessed 6 May 2008. The full text of the guidelines is available at <http://www.cps.gov.uk/publications/prosecution/sti.html>.

CONSCIENTIOUS OBJECTIONS (HEALTHCARE PROVIDERS AND RELATED PROFESSIONS)

The cases in this section seem to indicate a confusion of conscience with convenience. There should be no dispute as long as companies make their policies clear to potential hires and give customers notice by openly posting any possible unavailability of a product commonly supplied through similar merchants. Consider the following analogy. The owner of a restaurant should not be required by law to exempt a vegan waiter from serving steak. Nor would the restaurant owner be obliged to provide a vegan meal for a vegan customer when the owner has chosen not to have such a meal on the menu. No matter how hungry the vegan patron, the restaurant owner should not be forced by law to carry vegan meals on the menu, not even if this is the only restaurant in town. Admittedly the analogy isn't perfect, but the point is that a pharmacy employee who wants to be excused from selling certain drugs should work for a different pharmacy or be in a different line of business. A patron who wants access to a drug that is not available everywhere needs to be prepared to go to a place where that drug is available, much like the vegan can't expect every restaurant owner to have vegan meals on the menu.

Recent Judicial Cases and Regulatory Actions January - March 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. On 18 March 2008, the Illinois Supreme Court heard arguments from 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. *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 January - March 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.

MENTAL HEALTH

Recent Developments in Law and Regulation January - March 2008

Federal. On 6 March 2008, a bill was approved by the Senate Judiciary Committee 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).

*The Paul Wellstone Mental Health and Addiction Equity Act of 2008 was passed in the House by a vote of 268 to 148 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).

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 Mental Health Improvements Act of 2007 is progressing through Congress. The bill, originally introduced on 15 October 2007 in the Senate, would provide for improved treatment of veterans with post-traumatic stress and/or substance abuse disorders. An identical bill was introduced in the House and referred to the House Veterans' Affairs Committee on 1 November 2007. H.R. 4053, S.B. 2162, 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).

There is movement 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).

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

Some new technology information can be found under the "Pre-Birth" subsection of "The Rights of Maturing Individuals and Their Parents" section, where legal developments in stem cell research are discussed. Also, some relevant entries can be found in the new "FDA" section.

Aetna Inc. and Cigna Corp., two major health insurance providers, announced an expansion of coverage to include internet-based doctor's visits. Aetna's actions expand on pilot programs that have been operating in **California, Florida, and Washington** with promising, yet limited, results. S. Burling, "Insurers look at virtual visits to doctor," *Philadelphia Inquirer*, 30 March 2008, <http://www.philly.com/philly/news/homepage/17133061.html>, accessed 6 May 2008.

Recent Developments in Law and Regulation January - March 2008

***Federal.** The U.S. Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society will discuss its draft proposal for the oversight of genetic testing at its February meeting. The report identifies "significant gaps in this oversight system that could lead to harms," and asserts that the FDA has not made clear how efforts to regulate genetic testing will function. The report comes as multiple companies are planning the release of direct-to-consumer genetic test kits, which have faced criticism over their cost, necessity, reliability, and privacy implications. Secretary's Advisory Committee on Genetics, Health, and Society, *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of HHS*, draft report, 5 November 2007. It is also worth noting that in November 2007, Navigenics Inc. announced the release of Health Compass, a \$2,500 direct-to-consumer saliva-based whole-genome scan set for release in early 2008. Another company, 23andme of Mountain View, California, has announced plans for the release of a similar test later in 2008. R. Winslow, "Is There a Heart Attack in Your Future?" *Wall Street Journal*, 6 November 2007, D1.

Massachusetts. The governor's comprehensive life sciences industry bill continues its way through the state legislature. The bill, introduced in the summer of 2007, seeks to revitalize the life science industry within the commonwealth. The bill was set for public hearings on 17 December 2007, as well as 16 and 31 January 2008. H4234, 185th General Court, Reg. Sess. L. Wangsness, "Biotechnology incentives bill called unlikely to move in '07," *Boston Globe*, 20 November 2007.

MEDICAL ETHICS COMMITTEES AND INSTITUTIONAL REVIEW BOARDS

Recent Judicial Cases and Regulatory Actions January - March 2008

Colorado. Colorado Springs based Coast Independent Review board had its right to grant expedited approval revoked after allegations that Coast violated FDA regulations intended to protect patients in medical research. The 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 was appointed to review the ad approved it without any changes, 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.