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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 [sfryrevere@cato.org](mailto:sfryrevere@cato.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, but 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 anti-democratic. 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 being balanced by the courts will make 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" SPRING 2008

This issue of "Legal Trends in Bioethics" extends the scope of what is covered to include not only cases, but also regulatory actions such as fines and other penalties imposed for violation of regulatory requirements. This change reflects a trend, not a recent one, but a long-term trend in the United States to rely more on regulatory discipline through the executive and legislative branches than the traditional route of judicial court action. As reflected in the *Lebron* case discussed in the "Oversight" section below, this trend poses a potential threat to the balance of power between the three branches of government. It also poses a threat to constitutional principles of due process and fairness. Regulatory bodies have the same constitutional obligation to abide by principles of due process and fairness as the judiciary, but unlike the structure of the judicial system, which is constitutionally determined, regulatory bodies are invented and reinvented as needed. It is hard to ensure fairness when regulations and the privileges and obligations they impose are constantly in flux.

The growing trend toward regulatory rather than judicial action is also reflected in the inclusion of a new section for the Department of Health and Human Service Food and Drug Administration (FDA). At the end of last year, Congress passed the largest reform of the FDA since 1997. This reform included a huge increase in the agency's budget and many new responsibilities. Also, the U.S. Supreme Court has acted on several FDA-related cases. Already reported in the last "Legal Trends in Bioethics" but repeated here is a discussion of the *Abigail Alliance* case, in which plaintiffs sought more ready access to drugs for terminally ill patients before final FDA approval. By refusing to hear the case, the U.S. Supreme Court let stand the D.C. Circuit Court's holding that the FDA had the authority to regulate access to drugs, even to the point of denying such access to terminally ill patients for whom such drugs might be the only hope of survival. Another case involving the FDA, *Riegel v. Medtronic*, however, was granted a hearing by the Supreme Court. In *Medtronic*, the issue isn't access to drugs but whether FDA marketing approval, based on its evaluation of the safety and effectiveness of a product, protects manufacturers of that product from liability if the product somehow does not meet state standards.

## FDA

The FDA is undergoing monumental changes that will affect the field of bioethics both directly and indirectly. The FDA currently has a budget of more than \$2 billion and regulates the sale of more than \$1 trillion of products annually, including food, drugs, cosmetics, and medical devices. Justin Blum, " 'Inadequacies' at U.S. FDA Risk Lives, Report Says," *Bloomberg.com*, <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=ampdOikmgaiA>, accessed 1 February 2008. And there is no end in sight for growth in both the FDA's budget and its responsibilities. The public mistrusts the medical establishment, the pharmaceutical industry, and new medical technologies, and demands that government agencies like the FDA help it negotiate ever more difficult medical decisions about increasingly useful but hazardous treatments. Understandably, Congress has bowed to public pressure, and this quarter's "Legal Trends in Bioethics" includes a new "FDA" section and a more detailed description of Food and Drug Administration Amendments (FDAA) of 2007 than reported last quarter. Regulations passed to implement the FDAA and other revisions to drug and medical device regulation and related judicial cases will be reported in future entries under this section.

### Recent Judicial Cases and Regulatory Actions October - December 2007

The U.S. Supreme Court heard oral arguments on 4 December 2007 in the case of *Riegel v. Medtronic*. The issue before the Court is whether medical device companies selling products approved by federal regulators can be sued under state laws by patients injured by the companies' products. Medtronic asserts that the device in question was approved by the FDA and federal law "preempts" patients from claiming violation of state laws related to safety and effectiveness. S. Ct. (US no. 06-179).

### Recent Developments in Law and Regulation October - December 2007

The President signed into law on 27 September 2007 the Food and Drug Administration Amendments Act of 2007. The act greatly expands the FDA's authority. The act includes a target number of \$450 million in user fees to be paid by drug companies; this would be an increase over \$100 million from previous years. The new user fees will contribute approximately 25 percent of the FDA's current \$1.6 billion budget. The act allows the FDA to issue fines of up to \$10 million if drug makers fail to complete FDA-requested studies. It strengthens conflict of interest rules for FDA drug safety panels by requiring a reduction of the number of scientists with ties to drug companies by 25 percent over the next five years. It also includes new authority for the FDA to require pharmaceutical companies to track adverse events, regulate pharmaceutical marketing, and expand the pediatric exclusivity provisions of the Best Pharmaceuticals for Children Act for another five years. Also, the FDA Amendments Act instructs the Secretary of the U.S. Department of Health and Human Services (DHHS) to create mandatory registration and reporting requirements for clinical trials to be posted on a national publicly available database, probably on the National Library of Medicine's website [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Public Law No: 110-85. Related bills include H.R. 2900 and S. 1082, 110th Leg., Reg. Sess. (2007).

The FDA issued proposed guidelines on 15 November 2007 to increase transparency regarding conflicts of interest for members of its advisory panels. The proposed rules require experts on advisory panels to disclose any financial ties to an industry if an issue involving that industry is before the panel, and to detail the reasons that they still should be allowed to serve on the committee. FDA Press Release, "FDA Announces Steps to Improve Advisory Committee Processes," 15 November 2007, <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01744.html>.

The FDA is preparing new draft guidelines that would allow pharmaceutical and medical device companies to send physicians studies on "off-label uses," that is, non-FDA approved uses, of medications. Physi-

cians 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 FDA's draft guidelines, companies can send physicians unabridged reprints of studies on off-label uses of medications published in peer-reviewed medical journals, as long as they are not significantly influenced by the companies or individuals with financial ties to them. A. Wilde Matthews, "FDA and Drug Marketing," *Wall Street Journal*, 1 December 2007, <http://online.wsj.com/article/SB119646973314510201.html>, accessed 11 February 2008. Full text of the draft: <http://oversight.shouse.gov/documents/20071130103225.pdf>.

The FDA gave a Seattle company, Targeted Genetics, permission to resume its human tests of an experimental, gene-based arthritis treatment on 26 November 2007. The FDA ordered a hold on the tests after the death of a study participant was determined to be unrelated to the treatment. An inquest into the cause of the patient's death was conducted by Targeted Genetics' own scientists, the National Institutes of Health, and doctors at the University of Chicago. R. Weiss, "Gene Study Therapy is Allowed to Resume," *Washington Post*, 26 November 2007, <http://www.Washingtonpost.com/wp-dyn/content/article/2007/11/25/AR2007112501229.html>, accessed 28 January 2008.

### OVERSIGHT: PATIENT TRUST

Some topics previously included in this section are now under the heading "FDA," so please review that section for issues involving government oversight and patient trust directly related to the FDA. Regulatory actions with relevance to bioethics issues by government entities other than the FDA at the federal and state levels are reported here. Also reported here are civil actions that often parallel regulatory actions. 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. Therefore, for example, Medtronic, Inc. has entries in both the "FDA" and "Oversight" sections.

### Recent Judicial Cases and Regulatory Actions October - December 2007

**National.** The pharmaceutical company Merck, Inc. will settle 27,000 lawsuits by paying \$4.85 billion for damages suffered by users of its painkiller Vioxx. Finalization of the agreement requires that 85 percent of all plaintiffs agree to settle. A. Berenson, "Merck Agrees to Settle Vioxx Suits for \$4.85 Billion," *New York Times Online*, 9 November 2007, [http://www.nytimes.com/2007/11/09/business/09merck.html?\\_r=1&scp=3&sq=Vioxx+settlement&st=nyt&oref=slogin](http://www.nytimes.com/2007/11/09/business/09merck.html?_r=1&scp=3&sq=Vioxx+settlement&st=nyt&oref=slogin), accessed 28 January 2008.

The device manufacturer Medtronic, Inc. reached a settlement of \$114.1 million related to its Marquis line of implanted cardiac defibrillators. Plaintiffs in the suits against Medtronic allege that the company knew for years that there was a potential for defects in the battery used in the defibrillator, but sold them anyway and didn't advise patients that safer devices were available. Medtronic argued that it fulfilled every obligation in terms of reporting the problem. K. Shwiff, "Medtronic to Pay \$114 Million in Settling Heart-Device Suits," *Wall Street Journal Online*, 21 December 2007, <http://online.wsj.com/article/SB119827448805945807.html>, accessed 4 February 2008.

**California.** The California Department of Managed Health Care fined Health Net \$1 million for lying to state investigators about paying employees bonuses based on the number of individual health insurance policies they canceled. California law prohibits insurers from compensating claims reviewers based on their claims decisions. "California Fines Health Net \$1M for Lying about Linking Employee Bonuses to Policy Cancellations," *Kaiser Daily Health Policy Report*, 16 November 2007, [http://www.kaiser-network.org/Daily\\_reports/rep\\_index.cfm?DR\\_ID=48921](http://www.kaiser-network.org/Daily_reports/rep_index.cfm?DR_ID=48921), accessed 4 February 2008.

**Illinois.** The state circuit court of Cook County declared unconstitutional a 2005 state law that caps noneconomic damages in malpractice lawsuits at \$500,000 in cases against physicians and \$1 million in cases against hospitals. The court ruled that the law violates the separation of legislative and judiciary power.

The case is likely to advance to the Illinois Supreme Court. That court has stuck down state caps on damages in negligence lawsuits twice in the past 30 years. *Lebron v. Gottlieb Memorial Hosp.* (Ill. Cir. Ct. Cook County No. 06-L-12109, 13 November 2007).

### **Recent Developments in Law and Regulation October - December 2007**

**Federal.** The President signed into law on 26 December 2007 an omnibus budget package that includes a provision that requires the National Institutes of Health (NIH) to make the results of all NIH-funded studies available to the public free of charge. Under the provision, researchers who receive grants from NIH have to submit final copies of studies accepted for publication in a scientific journal. The results of these studies will be posted in a database available to the public free of charge within one year after publication. Implementation of the program could take up to six months. Public Law No: 110-161.

\*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 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).

**Colorado.** The state department of health launched a new web-based Hospital Report Card that details information about hospital performance across the state. Information included in the site includes: the number of patients who died at Denver hospitals after heart-bypass surgery, hip replacement, or other procedures; the number of patients who got bedsores; and the number of surgeries a hospital performed. The Report Card also includes measures of mortality after 11 procedures, three measures of patient safety and data on the volume of 10 procedures at each hospital. K. Human, "State hospital report cards now available," *Denver Post Online*, 28 November 2007, [http://www.denverpost.com/news/ci\\_7581546](http://www.denverpost.com/news/ci_7581546), accessed 1 February 2008.

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

### **THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS**

#### **PRE-BIRTH (SEX, FERTILITY, CONTRACEPTION, ABORTION, FETUSES, EMBRYOS, AND STEM CELLS)**

The abortion issue continues to strain the social and legal fabric that holds the United States together. Interestingly, most of the entries in this section this quarter do not deal with determining the rights of fetuses, but instead with the scope of influence that the pro- and anti-abortion camps can exert. Notably, all of the court cases reported involve constitutional issues such as the First Amendment right to protest, the right of Congress to impose restrictions on abortions — a right that traditionally has been reserved to the states — and the public's right to petition to force a state's attorney general to empanel a grand jury. In the laws section below, there are a few bills dealing directly with the rights of fetuses, but they are outnumbered by bills focused on secondary political maneuvering instead of the heart of the issue.

### Recent Judicial Cases and Regulatory Actions October - December 2007

**Federal.** A three-judge panel of the Fourth U.S. Circuit Court of Appeals heard oral arguments on 1 November 2007 in the attorney general's appeal of the Court's previous ruling that a Virginia law permitting "partial-birth" abortions is unconstitutional in light of the U.S. Supreme Court decision in *Gonzales v. Carhart*, which upheld a federal ban on partial birth abortions. *Richmond Medical Ctr. v. Herring* (4th Cir. No. 03-1821).

U.S. District Court for Western Pennsylvania heard arguments on 19 December 2007 in a lawsuit challenging a Pittsburgh ordinance that creates a buffer zone between protesters and healthcare facilities, including abortion clinics. *Brown v. Pittsburgh* (Western PA District Court No. 06-CV-00393, 26 March 2006).

The U.S. District Court for the Eastern District of Pennsylvania ordered a Reading, Pennsylvania, man to stop posting material on the internet deemed threatening to doctors who provide abortion services. The anti-abortion activist had published the address and photographs of a doctor who worked at women's health clinics and made threatening remarks. *Gonzales v. Dunkle* (Eastern PA District Court No. 07-CV-03577, 8 November 2007).

**Colorado.** Anti-abortion advocates threatened to file suit against the city of Denver on First Amendment grounds because the city refuses to issue the groups permits to demonstrate during the Democratic National Convention scheduled to take place in Denver in August 2008. "Antiabortion Advocates Threaten to Sue Denver for Not Issuing Demonstration Permits for Democratic Convention," *National Partnership for Women and Families Daily Women's Health Policy Report*, 5 November 2007, [http://npwf.convio.net/site/News2?abbr=daily2\\_&page=NewsArticle&id=7599&news\\_iv\\_ctrl=-1&s\\_oo=D4TvnMQZLC3oTo5K9bAQTA](http://npwf.convio.net/site/News2?abbr=daily2_&page=NewsArticle&id=7599&news_iv_ctrl=-1&s_oo=D4TvnMQZLC3oTo5K9bAQTA), accessed 26 January 2008.

**Kansas.** Life is for Everyone, a coalition of the anti-abortion groups led by Operation Rescue, submitted a citizens petition to convene a grand jury to investigate whether Planned Parenthood of Kansas and Mid-Missouri's Overland Park, Kansas, clinic Comprehensive Health is complying with state abortion laws. The petition alleges that Comprehensive Health performs illegal late-term abortions, provides false information to state officials, fails to report suspected child abuse, participates in illegal trafficking of fetal tissue, fails to comply with parental notice requirements, and fails to enforce a 24-hour waiting period. National Partnership for Women and Families, "Kansas Judge Selects Grand Jury for Investigation of Planned Parenthood Clinic," 12 December 2007, accessed 1 February 2008.

\*A grand jury convened on 30 October 2007 to investigate whether Dr. George Tiller broke a state law concerning late-term abortions. Abortion opponents have garnered enough signatures of registered voters to form a grand jury pursuant to a 1970 state law that allows the public to petition for the calling of a grand jury. Six other states also have laws allowing citizens to petition for a grand jury hearing against the state attorney general's better judgment. Kaiser Family Foundation, "Kansas Abortion Opponents Petition for Grand Jury Investigation of Abortion Provider Tiller," *Kaiser Daily Health Policy Report*, 13 September 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=2&DR\\_ID=47348](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=47348), accessed 3 November 2007.

### Recent Developments in Law and Regulation October - December 2007

\***Hawaii.** Two bills were held over from the 2007 legislative session that would allow all forms of stem-cell research. H.B. 364, H.B. 1261, 24th Leg., Reg. Sess. (Haw. 2007).

**Massachusetts.** The state senate passed a bill on 23 October 2007 that would expand abortion clinic buffer zones from 18 feet to 35 feet. The current law, passed in 2000, requires protesters to stay at least six feet away from the clinic's employees and patients and establishes an 18-foot zone within which individuals may not interact with clinic visitors or staff for the purpose of counseling or protesting. S.B. 1353, Gen. Assem., Reg. Sess. (Mass. 2007).

\***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. SB 776, 94th Leg., Reg. Sess. (Mich. 2007).

**New Jersey.** A ballot initiative failed that would have allowed New Jersey to borrow \$450 million for stem cell research grants in the next decade. K. Heyboer, "Dissecting the Stem Cell Vote," *Jersey Blogs*, 8 November 2007, [http://blog.nj.com/jerseyblogs/2007/11/disectingthe\\_stem\\_cell\\_vote.html](http://blog.nj.com/jerseyblogs/2007/11/disectingthe_stem_cell_vote.html), accessed 4 February 2008.

\***Ohio.** There has been no action on a bill introduced on 19 July 2007 that would prohibit women from undergoing an abortion without the written consent of the father. Should the identity of the father be unknown, women would be required to submit a list of possible fathers to the physician, who would be required to conduct paternity tests and then seek paternal permission to abort. First-time violators would be charged with abortion fraud, a first-degree misdemeanor. Repeat offenders would be charged with a fifth-degree felony. H.B. 287, 127th Gen. Assem., Reg. Sess. (Oh. 2007).

\*There has been no action on a bill introduced on 10 July 2007 that would prohibit all abortions in the state, as well as any distribution of mifepristone (the "morning-after pill"). The bill would also increase the penalties for unlawful abortions and abortion trafficking. H.B. 284, 127th Gen. Assem., Reg. Sess. (Oh. 2007).

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 procedure can take place and are currently in the state senate's Health, Human Affairs & Aging Committee. H.B. 314, S.B. 230, 127th Gen. Assem., Reg. Sess. (Oh. 2007).

**Pennsylvania.** A bill passed the state house on 17 July 2007 that provides for umbilical cord blood banking, and is currently in the state Senate Appropriations Committee. The bill requires healthcare practitioners to give pregnant patients information regarding umbilical cord donation. H.B. 874, 191st Gen. Assem., Reg. Sess. (Pa. 2007).

**South Dakota.** A group of pro-life citizens recently filed a petition to collect signatures for a South Dakota ballot initiative that would ban abortions with limited exceptions, including cases of rape or incest, to save a woman's life, or in cases of a "substantial and irreversible health risk" of impairment to "a major bodily organ or system." Supporters must collect 16,776 signatures of registered voters by 1 April 2008 for the measure to appear on South Dakota's November 2008 ballot. "Petition Filed for Ballot Initiative in S.D. That Would Ban Most Abortions," *Daily Women's Health Policy Report*, 18 December 2007, [http://npwf.convio.net/site/News2?abbr=daily2\\_&page=NewsArticle&id=9391](http://npwf.convio.net/site/News2?abbr=daily2_&page=NewsArticle&id=9391), accessed 1 February 2008.

**Wisconsin.** A bill is moving its way through various committees in the state legislature. Originally introduced in the state senate on 19 June 2007, the bill would require 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. The bill is currently in the state senate committee on Health, Human Services, Insurance, and Job Creation. S.B. 218, 1007 Reg. Sess. (Wis. 2007).

### Interesting Developments in Other Countries

**International.** A study conducted by the Guttmacher Institute and the World Health Organization found that abortion rates are similar in countries where the procedure is legal and where it is not legal. Additionally, the study found that the number of abortions worldwide is declining due to increased access to contraception. Kaiser Family Foundation, "Abortion rates similar in countries that legalize, prohibit abortion, study says," *Kaiser Daily Health Policy Report*, 12 October 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=2&DR\\_ID=48142](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=48142), accessed 26 January 2008.

**Brazil.** The governor of Rio de Janeiro, Brazil on 24 October 2007 urged the government to legalize abortion. The governor said legal abortions could help reduce violence in the city. In Brazil, abortion is

banned except in cases of rape or to save the life of the pregnant woman. Kaiser Family Foundation, "Legalizing Abortion in Rio de Janeiro, Brazil, Could Help Reduce Violence, Governor Says," *Kaiser Daily Health Policy Report*, 26 October 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=2&DR\\_ID=48455](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=48455), accessed 26 January 2008.

The Brazilian government plans to increase the number of free birth control pills it provides at state-run clinics from 20 million to 50 million in 2008. A. Downie, "Brazil doles out 'morning after' pills: The country's most populous state now offers the contraceptive pills at metro stops in a battle to limit illegal abortions," *Christian Science Monitor*; <http://www.csmonitor.com/2007/1120/p07s02-woam.html>.

**Britain.** The British Parliament's Select Committee on Science and Technology reported on 31 October 2007 that there is "no scientific basis" for lowering the 24-week gestational limit on legal abortion in the country. The report also recommends the elimination of a requirement that women seeking abortions obtain the signature of two doctors prior to undergoing the procedure. Although the committee's report is not binding, it is expected to influence Britain's abortion debate in the coming months. Kaiser Family Foundation, "U.K. Parliamentary Committee Releases Recommendations on Gestational Limit on Abortion, Other Related Regulations," *Kaiser Daily Health Policy Report*, 1 November 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=2&DR\\_ID=48581](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=48581), accessed 26 January 2008.

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 combined 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. Bill being considered by the House of Lords: HL 2007/08 6. The entire text of the bill can be found at <http://www.publications.parliament.uk/pa/ld200708/ldbills/006/08006.i-iv.html>.

The Human Genetics Commission released recommendations for regulation of the sale of personal genetics tests on 4 December 2007. Read more about this in the "Right to Access and Control Medical Information" section.

**India.** The Indian Council of Medical Research and the Department of Biotechnology issued guidelines on 8 November 2007 governing stem cell research and cloning procedures throughout the republic. The regulations, which come after five years of deliberation, provide a nationwide ban on human cloning, and apply strict requirements on similar research. Research using embryonic stem cells, as well as research using fetal/placenta cells, is allowed, but consent must be obtained from the donor. Additionally, the Drug Controller-General of India will be charged with registering the specific blood banks. Violators of the new regulations would face stiff penalties including heavy fines and possible incarceration. Sanjay, "Stem Cell Research: Human Cloning Prohibited," *Merinews*, 8 November 2007, <http://www.merineews.com/catFull.jsp?articleID=127572>, accessed 26 January 2008.

**Slovakia.** The Slovakian Constitutional Court denied a petition in December 2007 to outlaw abortion. Although the Court ruled against a request by the Christian Democratic Party's request to make abortion illegal, it did reduce the limit on the procedure from the twenty-fourth week of pregnancy to the twelfth week. L. Lesňa, "Court upholds abortions in first 12 weeks," *Slovak Spectator*, 10 December 2007, [http://www.spectator.sk/articles/view/30150/court\\_upholds\\_abortions\\_in\\_first\\_12\\_weeks.html](http://www.spectator.sk/articles/view/30150/court_upholds_abortions_in_first_12_weeks.html), accessed 1 February 2008.

The United Nations General Assembly's Human Rights Committee voted against an amendment to a draft resolution to place a moratorium on the death penalty that would have urged member states to "take all necessary measures to protect the lives of unborn children." The U.S. voted in favor of the anti-abortion amendment, along with Iran, Egypt, Syria, Zimbabwe, and several other countries. C. Parsons, "UN Panel votes for death penalty moratorium," *Reuters*, 15 November 2007, <http://africa.reuters.com/wire/news/usnN15331328.html>, accessed 4 February 2008.

The United Nations University Institute for Advanced Studies issued on 10 November 2007 a report calling for a legally binding international ban on human reproductive cloning that would allow for therapeu-

tic research such as stem-cell techniques. The report also advises countries that intend to allow human cloning research to prepare by explicitly granting human clones the same individual rights as all citizens, to prevent "potential abuse, prejudice and discrimination." C. Kuppaswamy et al., "Is Human Reproductive Cloning Inevitable: Future Options for UN Governance," *UNU-IAS Publications*, 10 November 2007. The full report can be found at [http://www.ias.unu.edu/resource\\_centre/Cloning\\_9.20B.pdf](http://www.ias.unu.edu/resource_centre/Cloning_9.20B.pdf).

**The Vatican.** At the twenty-fifth International Congress of Catholic Pharmacists on 29 October 2007, Pope Benedict XVI spoke in favor of a right to conscientiously object to dispensing drugs such as emergency contraception, which can prevent pregnancy if taken up to 72 hours after sexual intercourse. Kaiser Family Foundation, "Pope Benedict Says Pharmacists Have Right To Conscientiously Object To Fill Emergency Contraception," *Kaiser Daily Health Policy Report*, 31 October 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=2&DR\\_ID=48544](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=48544), accessed 26 January 2008.

**Vietnam.** A series of studies released on 29 October 2007 by the United Nations Population Fund reports there is a cultural preference for male children in Vietnam. The reports found that there are approximately 110 boys for every 100 girls. The preference for male children is established in other countries in the region including India and China. This is "further tipping the balance between the sexes in Asia." For decades, Vietnam has had a two-child-per-family policy. In 2003, the country banned fetal sex selection, but many physicians continue to defy the law and tell couples the sex of their fetus. The dearth of women in the region has increased social unrest and sex trafficking of women. Kaiser Family Foundation, "Cultural Preference for Male Children in Vietnam Increasing Gender Imbalance in Asia, UNFPA Reports Say," *Kaiser Daily Health Policy Report*, 2 November 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=2&DR\\_ID=48612](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=48612), accessed 26 January 2008.

#### **AFTER BIRTH (PREMATURE INFANTS, NEWBORNS, AND CHILDREN)**

There are no cases, bills, laws, or regulations to report for this section for this issue of "Legal Trends in Bioethics." But there is one thought-provoking news item that is worth noting: the Kaiser Family Foundation reports that 2006 saw the highest number of recorded births in the United States since 1961, nearly 4.3 million. The Kaiser Foundation article states that experts attribute the steep rise in U.S. births to a decrease in contraceptive use, a decrease in abortion access, poverty, religious beliefs, cultural demographic changes, and lower levels of education. Kaiser Family Foundation, "Women's Health Policy: U.S. Experiences Highest Number of Recorded Births in 2006 Since 1961," *Kaiser Daily Health Policy Report*, 17 January 2008, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=49893](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=49893), accessed 26 January 2008.

#### **HEALTHCARE COVERAGE**

There is a growing debate in Congress and across the U.S. on legislation that would provide paid medical leave to all workers. Democratic presidential candidates Senators Hillary Rodham Clinton and Barack Obama have voiced their support for the idea. The Bureau of Labor Statistics reports that 43 percent of U.S. workers, or about 50 million people, do not receive paid medical leave benefits. Kaiser Family Foundation, "Paid Medical Leave Legislation Gains Momentum," *Kaiser Daily Health Policy Report*, 12 November 2007.

The American College of Physicians (ACP) said that the U.S. government should provide universal health coverage, but indicated that both single- and plural-payer systems should be considered. The group based its recommendations on an analysis of healthcare systems in the U.S. and 12 other industrialized nations. It found that although a single-payer healthcare system has lower administrative costs than a pluralistic system, the latter provides consumers with more choices and has more support in the U.S. Kaiser Family Foundation, "American College of Physicians Endorses Two Approaches to Achieve Universal Coverage," *Kaiser Daily Health Policy Report*, 4 December 2007.

### **Recent Judicial Cases and Regulatory Actions October - December 2007**

**Federal.** The Medicare Rights Center filed suit in the U.S. District Court for the Southern District of New York on 26 November 2007, charging 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. "Off-label prescriptions" are typically not used unless conventional therapies are ineffective. J. Young, "Advocates Sue over Medicare Drug Coverage Exclusions," *The Hill*, 28 November 2007, <http://thehill.com/business—lobby/advocates-sue-over-medicare-drug-coverage-exclusions-2007-11-28.html>, accessed 28 January 2008.

**California.** The Second District Court of Appeals for the State of California ruled 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. *Ticconi v. Blue Shield of California* (Ca. 2d Ct. App. No. B190427, 4 December 2007).

**Nebraska.** A lawsuit was filed in the Lancaster County District Court on behalf of Sandra Cartwright, alleging that state employees living in predominately Black 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 October - December 2007**

**Federal.** The President vetoed a State Children's Health Insurance Program (SCHIP) expansion bill on 3 October 2007. On 18 October 2007, the House, tried, but failed to override the presidential veto. The bill would have provided an additional \$35 billion in funding to the program over the next five years, bringing total spending to \$60 billion annually. State Children's Health Insurance Program Reauthorization Act, H.R. 976, 110th Cong., 1st Reg. Sess. (2007).

\*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).

**Alaska.** There has been no action on a universal healthcare proposal introduced 10 September 2007 at a special late summer hearing of the Senate Health, Education, and Social Services Committee. The bill, called the Mandatory Universal Health Care Act, would require all state residents to obtain health coverage, with the state subsidizing plans for low-income residents. It would create a healthcare board that determines which medical services are covered under the subsidized program and would certify private coverage plans that meet state requirements. The board would also oversee the Alaska Health Fund, funded by both the state and the federal government, 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.** A bill was introduced in the state Assembly on 11 September 2007 that is proposing a new 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. The plan has the support of the California Medical Association

and is expected to be supported by Governor Arnold Schwarzenegger. AB 1X, 2007-2008 Leg. 2d Ext. Sess. (Cal. 2007).

\*The governor vetoed a bill on 12 October 2007 that intended to extend healthcare coverage to all state residents. The legislation would have required employers to contribute as much as 7.5 percent of their payroll to cover the cost of health insurance for employees or pay into a state pool that would provide coverage. In contrast to a proposal from Governor Arnold Schwarzenegger earlier this year, the bill did not include an individual mandate. A.B. 8, 2007-2008 Leg., Reg. Sess. (Cal. 2007).

**Colorado.** The Colorado Blue Ribbon Commission for Health Care Reform approved a set of recommendations that includes requiring state residents to obtain health insurance or pay a tax penalty. The panel also recommends expanding eligibility for state health programs. The panel's recommendations will be presented to state lawmakers on 31 January 2008. The package would cost approximately \$1.1 billion and would expand coverage to 696,000 of the state's 792,000 uninsured residents. Kaiser Family Foundation, "Colorado Commission Recommends Health Care Plan Similar to Massachusetts," *Kaiser Daily Health Policy Report*, 21 November 2007.

**Louisiana.** The Coalition of Leaders for Louisiana Health Care proposed a plan that would cover uninsured adults whose incomes fall below 200 percent of the federal poverty line. The proposal hopes to divert money from the charity hospital system to a free-market model in which patients could present insurance cards to the doctor of their choice. K. Moran, "Health Care Execs float plan for the uninsured," *The Times Picayune*, 5 December 2007.

**Wisconsin.** The governor announced the details of BadgerCare Plus, a new health insurance plan for children effective 1 February 2008. Under the plan, families whose children are not eligible for existing state programs would be able to buy health insurance for a child for \$120 to \$822.36 a year, depending on the families' income. G. Boulton, "State Moves on Health Insurance for Children," *Milwaukee Journal-Sentinel*, 7 November 2007, <http://www.jsonline.com/story/index.aspx?id=683937>, accessed 28 January 2008.

## VACCINES

The only news on the issue of vaccines is still that most of the bills introduced to mandate vaccination for human papillomavirus (HPV) have failed or stalled. Since Merck's HPV vaccine was first approved in June 2006, more than two dozen states considered mandating HPV vaccinations for school attendance. As of the end of 2007, only Virginia and the District of Columbia require HPV vaccination for school enrollment, but there are still a few states considering mandating the vaccine and those are listed below.

### Recent Developments in Law and Regulation October - December 2007

\***California.** There has been no action on a bill that would require all girls entering the sixth grade to receive the 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 public hearing was held on 17 October 2007 in the state senate for a bill that would require schools to provide parents with information about the HPV vaccine. The bill directs 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 is currently being considered by the state assembly. S.B. 252, A.B. 492, 2007 Reg. Sess. (Wis. 2007).

### Interesting Developments in Other Countries

At the third annual Clinton Global Initiative conference in New York City, Merck announced that it will donate at least three million doses of its HPV vaccine Gardasil to women in developing countries. Half a million women are diagnosed with cervical cancer annually, and about 80 percent of the cases and deaths are among women in developing countries because of limited screening and treatment. Kaiser Family Foundation, "Merck to Donate Three Million Doses of HPV Vaccine Gardasil to Developing Countries," *Kaiser Daily Health Policy Report*, 28 September 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=2&DR\\_ID=47829](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=47829), accessed 26 January 2008.

### ORGAN AND TISSUE PROCUREMENT

Since the last issue of "Legal Trends," 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).

#### Recent Judicial Cases and Regulatory Actions October - December 2007

**Federal.** The Charlie W. Norwood Living Organ Donation Act was signed into law by the President on 21 December 2007. The act amends the National Organ Transplant Act to clarify that the act's provisions prohibiting the transfer of human organ for use in human transplantation for valuable consideration does not apply to human organ paired donation and similar practices. It ensures that criminal penalties do not apply to human organ paired donation. Public Law No: 110-144.

#### Recent Developments in Law and Regulation October - December 2007

\***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).

\***Maine.** There has been no action on a bill introduced on 17 March 2007 that would adopt the 2006 Uniform Anatomical Gift Act without changes since the bill was carried over to the 2008 session. 123rd Leg. Sess. L.D. 1505, 123rd Leg., Reg. Sess. (Me. 2007).

\***Michigan.** A bill to amend the state's anatomical gift act passed the state house on 4 December 2007 and is currently in the Senate Committee on Health Policy. H.B. 4940, 94th Leg., Reg. Sess. (Mich. 2007).

\***Missouri.** There has been no action on a bill introduced on 1 February 2007 to adopt the 2006 Uniform Anatomical Gift Act without changes. The bill is currently in the Missouri House Health Care Policy Committee. S.B. 496, H.B. 723, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2007).

\***New Jersey.** There has been no action on a bill introduced on 9 January 2007 to amend the state's anatomical gift act. A.B. 3909, 2007 Gen. Assem., Reg. Sess. (N.J. 2007).

\***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.** There has been no action on a bill introduced on 24 January 2007 to amend the state

anatomical gift act. The bill is currently under consideration in the state senate. H.B. 1637, 60th Leg., 2007 Reg. Sess. (Wash. 2007).

## INFORMED CONSENT

### Recent Judicial Cases and Regulatory Actions October - December 2007

**\*Federal.** The U.S. Supreme Court heard arguments on 4 December 2007 in the case of *Charles R. Riegel, et ux v. Medtronic, Inc.* The case involves an angioplasty procedure in which a catheter balloon reportedly burst, causing complications for the patient. Medtronic claims it should not be susceptible to suit under state law because the device had complied with federal regulations to receive FDA approval. A decision in the case is expected shortly. *Charles R. Riegel, et ux v. Medtronic, Inc.* S. Ct. (U.S. No. 04-0412).

## UNCONVENTIONAL TREATMENT

Please note that 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 non-acceptance by the establishment, in and of itself, warrant banning a practice that some believe is beneficial.

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

### Recent Judicial Cases and Regulatory Actions October - December 2007

**\*Federal.** The U.S. Supreme Court denied certiorari on 14 January 2008 in *Abigail Alliance v. Von Eschenbach*. By refusing to hear the case, the U.S. Supreme Court allows the lower court decision to stand. The U.S. Circuit Court of Appeals for the District of Columbia had decided that terminally ill patients do not have a constitutional right to access medications that have not been approved by the FDA. The Abigail Alliance and the Washington Legal Foundation argued that terminally ill patients who did not qualify for participation in clinical trials or otherwise qualify to obtain experimental drugs through existing FDA access programs should have a right to purchase the drugs directly from pharmaceutical companies and take them under the supervision of their own physicians. The U.S. District of Columbia Court of Appeals did not recognize this "other right to life" argument, and the Alliance has decided to appeal to the U.S. Supreme Court. S. Ct. (U.S. no. 07-444).

**\*The Federal District Court for the Central District of California** on 20 November 2007 granted defendants' motion to dismiss for failure to state a claim in the case of *Americans for Safe Access v. Department of Health and Human Services and Food and Drug Administration*. The suit was filed by the Americans for Safe Access against the DHHS and the FDA for allegedly violating the federal Administrative Procedure Act by publicly releasing "false and misleading statements" about the benefits of the use of medical marijuana. Plaintiffs called for the DHHS and the FDA to retract and correct statements it made that there are no sound scientific studies supporting the medical use of marijuana. *Americans for Safe Access v. Department of Health and Human Services and Food and Drug Administration*, No. 007-01049 (C.D. Ca., filed 21 February 2007).

**\*Colorado.** The Second District Court for the state of Colorado overturned a state health department policy that restricted providers of medical marijuana to five patients. The decision was in response to a lawsuit against the Colorado Department of Health and Environment claiming its five-patient per marijuana

provider rule was arbitrary and unfair. *Lagoy v. Colorado* (Colorado 2d District Court No. 07-CV-6089, 15 November 2007).

**\*Missouri.** The state supreme court will hear 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 October - December 2007**

**\*Delaware.** A bill to allow freestanding birth centers to hire certified professional midwives is not moving through the state legislature and may be permanently stalled. Under current law, 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 is 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, 144 Gen. Assem., Reg. Sess. (Del. 2007).

## **LIFE-AND-DEATH DECISIONS**

### **Recent Judicial Cases and Regulatory Actions October - December 2007**

**Montana.** A suit was filed in the state 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 the patients 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), <http://www.compassionandchoices.org/localgroups/mt/documents/BaxtervMTComplaint10-17-07.pdf>.

### **Recent Developments in Law and Regulation October - December 2007**

**\*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 to "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 is moving its way through various committees that would require an original copy of any advanced directive, instead of a copy as allowed under current law, to be used by careproviders as an indication of a patient's wishes. The bill, introduced on 4 January 2007, was referred to the House Judiciary Committee and is expected to be considered before 21 February 2008. 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.wi.us/2007/data/SB-151.pdf](http://www.legis.state.wi.us/2007/data/SB-151.pdf).

## **Interesting Developments in Other Countries**

**International.** A study sponsored by the University of Utah and conducted in collaboration with medical health professionals in Oregon and the Netherlands was released in late September 2007. The study,

published in the October issue of the *Journal of Medical Ethics*, found no evidence that "vulnerable" groups were more likely to seek access to physician-assisted suicide measures. The study, conducted in Oregon and the Netherlands, compared "the elderly, women, the uninsured (inapplicable in the Netherlands, where all are insured), people with low educational status, the poor, the physically disabled or chronically ill, minors, people with psychiatric illnesses including depression, or racial or ethnic minorities," relative to background populations, and found that the only factor that showed a "heightened risk" was in people with AIDS. M. Battin, "Legal physician-assisted dying in Oregon and the Netherlands: evidence concerning the impact on patients in 'vulnerable' groups," *Journal of Medical Ethics* 33 (October 2007): 591-7.

**Canada.** The College of Physicians and Surgeons of Manitoba formally released a final statement "Withholding and Withdrawing Life-Sustaining Treatment" on 30 January 2008. The stated purpose of the document is to stipulate the ethical obligations of physicians, to emphasize open communication to achieve consensus, and to provide conflict resolution strategies when consensus cannot be reached. Of particular interest are the procedures delineated in the event that consensus cannot be reached. The "minimum goal" of life-sustaining treatment is defined as "the maintenance of or recovery to a level of cerebral function that enables the patient to: achieve awareness of self; and achieve awareness of environment; and experience his/her own existence." If the "minimum goal is not realistically achievable" and the physician concludes that life-sustaining treatment should be withheld or withdrawn, he or she must "if possible" consult with another physician. If that consulted physician disagrees, the consulting physician must either provide the treatment or transfer the patient to someone who will. But if the consulting physician agrees (or "it is not possible to consult with another physician"), treatment may be withheld or withdrawn once the "patient/proxy/representative" is advised of (1) the consulted physician's agreement or the fact that a consultation could not be obtained, and (2) the location, date, and time at which treatment will be withheld or withdrawn. If the minimum goal is achievable, there is no consensus and the physician believes the best course of action is to withhold or withdraw treatment, a consultation with a second physician becomes mandatory, and implementation, even with the consultant's agreement, becomes more complicated.

The statement also includes procedures for implementing DNAR (do not attempt resuscitation) orders and for emergency situations when communication between physician and patient/proxy/representative cannot occur. College of Physicians and Surgeons of Manitoba, "Statement: Withholding and Withdrawing Life-Sustaining Treatment," no. 1602 (30 January 2008). (The authors thank Pat Murphy, Clinical Ethicist at St. Boniface General Hospital in Winnipeg for sending us this document.)

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 the 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 that "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 for sending us this document.)

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

### **Recent Judicial Cases and Regulatory Actions October - December 2007**

**Federal.** The U.S. District Court for the District of Maine issued a preliminary injunction on 21 December 2007 against a new state law that sought to restrict medical data companies from accessing prescription information. The court relied heavily on an April 2007 ruling by the U.S. District Court for the District of New Hampshire that struck down a similar New Hampshire law, declaring that the statute violated the First

Amendment by preventing the transfer of truthful commercial information. Both cases are now on appeal at the 1st U.S. Circuit Court of Appeals in Boston. *IMS Health Corp. et al. v. Rowe*, No. cv-07-127-B-W (D. Me. 21 December 2007). *IMS Health Corp. et al. v. Ayotte*, Appeal No. 07-1945 (U.S. 1st Circuit Ct. 14 August 2007). The full text of the Maine ruling can be found at [http://www.med.uscourts.gov/Opinions/Woodcock/2008/JAW\\_01022008\\_1-07-cv127\\_IMS\\_V\\_MAINE.pdf](http://www.med.uscourts.gov/Opinions/Woodcock/2008/JAW_01022008_1-07-cv127_IMS_V_MAINE.pdf). (Also, see below how Vermont is trying to avoid this type of litigation through new legislation.)

### Recent Developments in Law and Regulation October - December 2007

**Federal.** The President signed into law a reauthorization bill for Medicaid, Medicare, and SCHIP on 29 December 2007, despite the removal of an information technology mandate that the administration had requested. DHHS had sent congressional leaders a letter that suggested that the President's approval was conditioned on the inclusion of an expansion of certified electronic health technologies. S.B. 2499, 110th Cong., 1st Reg. Sess. (2007). Health Data Management, "I.T. Mandate out of Medicare Bill," *HDM Breaking News*, 21 December 2007, [http://www.healthdatamanagement.com/news/mandate\\_legislation\\_Medicare\\_25383-1.html](http://www.healthdatamanagement.com/news/mandate_legislation_Medicare_25383-1.html), accessed 30 January 2008.

House Speaker Nancy Pelosi held a closed meeting with Oregon Governor Ted Kulongoski and others on 27 November 2007 to discuss, among other things, Oregon's place in leading the charge to establish a centralized electronic health records (EHR) database. H. Esteve, "Pelosi says health care change can start here," *Oregonian*, 28 November 2007, <http://www.oregonlive.com/oregonian/stories/index.ssf?/base/news/1196222112166530.xml&coll=7>, accessed 30 January 2008.

DHHS announced on 29 October 2007 the launching of a new pilot program that plans to enlist 1,200 physicians across the country to institute a system for electronic health records in return for increased Medicare reimbursements. Officials are also suggesting that insurance providers consider similar payment increases. Kaiser Family Foundation, "Physicians Who Adopt Electronic Health Records Will Receive Higher Medicare Payments Under Pilot Project," *Kaiser Daily Health Policy Report*, 30 October 2007, [http://www.kaisernet.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=48524](http://www.kaisernet.org/daily_reports/rep_index.cfm?hint=3&DR_ID=48524), accessed 31 January 2008. This program was launched despite the warnings of Patients Privacy Coalition (a bipartisan partnership of lawmakers, nonprofit organizations, and private corporations) about possible abuses of electronic health record databases considered in comprehensive healthcare reforms. The group asserted any database would provide an open season on individual health information for data-mining companies that could sell the information, resulting in identity theft, fraud, predatory practices, and/or discrimination. E. Pfeiffer, "Bill sought to shield medical data," *Washington Times*, 18 October 2007.

**Oregon.** The governor announced on 27 November 2007 that the state has received a \$20 million grant from the Federal Communications Commission to fund installation of broadband cable at rural health facilities throughout the state. H. Esteve, "Pelosi says health care change can start here," *Oregonian*, 28 November 2007, <http://www.oregonlive.com/oregonian/stories/index.ssf?/base/news/1196222112166530.xml&coll=7>, accessed 30 January 2008.

**Vermont.** Amendments were accepted to Act No. 80, Vermont's version of prescription restraint legislation. Among other things, the act restricts access to prescriber data for marketing use, and imposes new regulations on pharmacies in an attempt to increase patient privacy and decrease costs. The amendments were made in anticipation of a pending lawsuit, *IMS Health Corp. et al. v. Sorrell*, as similar cases struck down laws in Maine and New Hampshire in 2007 (see entry above under federal cases in this section). The suit asserts the unconstitutionality of the law, as it restricts the transfer of truthful commercial information. S.B. 115, 2007 Gen. Assem., Reg. Sess. *IMS Health Corp. v. Sorrell*, No. 2:2007cv00188 (D. Vt. 29 August 2007.)

## Interesting Developments in Other Countries

**United Kingdom.** The U.K. Human Genetic Commission (HGC) issued in December 2007 recommendations for the regulation of personal genetics tests. The proposals include independent reviews of all tests before they reach the market, banning public advertising for tests with "major health implications," and requiring that such tests only be administered by a health professional. Though the HGC has stressed it does not want to ban any particular tests, in general they support stricter control under oversight by the Medicines and Healthcare products Regulatory Agency. "Tougher gene test regulation call," *BBC News*, 5 December 2007.

## HIV/AIDS

### Recent Developments in Law and Regulation October - December 2007

**\*Federal.** Since the end of 2007, all states and the District of Columbia are now required to report their HIV cases by name if they wish to receive funding from DHHS under the federal Ryan White Grant Program. 42 U.S.C. § 201. All states except Hawaii and Vermont have complied, making anonymous HIV testing almost a thing of the past in the U.S.

Thirty members of Congress sent a letter on 6 December 2007 to the Secretary of the Department of Homeland Security calling for the repeal of the HIV/AIDS statutory ban, instead of, as the department proposes, merely streamlining the waiver process for HIV-positive individuals seeking short-term business or tourist visas to the U.S. The congressional letter sees the department's proposal and the statutory ban as a violation of human rights. The Department of Homeland Security has proposed to shift decision-making authority from the U.S. Citizenship and Immigration Services to the respective U.S. consular offices. The congressional letter prefers a repeal of the statute that would return the decision to the Secretary of Health. B. Lee et al., "Letter to Secretary Chertoff," 6 December 2007. The full letter can be found at <http://lee.house.gov/index.cfm?ContentID=1165&ParentID=0&SectionID=4&SectionTree=4&lnk=b&ItemID=1160>.

**\*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).

**\*California.** The governor signed into law a bill on 12 October 2007 to amend sections of the Health and Safety Code relating to HIV/AIDS. Previously, physicians were required to test pregnant women for HIV unless the test was explicitly refused in writing. This bill removes that stipulation and instead merely requires that women be told that an HIV test is planned and made aware of their right to refuse. Ch. 550, A.B. 682, 2007-2008 Leg., Reg. Sess. (Cal. 2007); Cal. Code Regs. tit. 106 § 120990, 125090, 125107 (2007).

**District of Columbia.** President Bush signed into law an omnibus spending bill on 26 December 2007 that, among other things, lifts a long-standing ban on the funding of needle-exchange programs within the District of Columbia. The D.C. Department of Health now plans to allocate \$1 million to fund needle exchanges. H.R. 2764, 110th Cong., 1st Reg. Sess. (2007). Kaiser Family Foundation, "City Funding for Needle-Exchange Programs in Washington, D.C.," *Kaiser Daily HIV/AIDS Report*, 21 December 2007, [http://www.kaisernet.org/daily\\_reports/rep\\_index.cfm?hint=1&DR\\_ID=49539](http://www.kaisernet.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49539), accessed 27 January 2008.

The D.C. State Board of Education unanimously approved on 13 December 2007 new guidelines for the D.C. schools' health curriculum. The guidelines include grade-specific information about HIV/AIDS and

controversial subjects such as "sexual orientation," and "gender identity." Kaiser Family Foundation, "Washington, D.C., Board of Education Approves Health Education Standards That Include HIV/AIDS Information," *Kaiser Daily HIV/AIDS Report*, 17 December 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=1&DR\\_ID=49433](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49433), accessed 27 January 2008.

**D.C.** Mayor Adrian Fenty announced plans in November 2007 to help curb the spread of HIV/AIDS within the district. Fenty hopes to triple the number of free condoms distributed by the government by the end of 2008, for a total of three million, and to pressure district hospitals to provide more comprehensive and timely HIV testing to pregnant women. D. Nakamura, "More Testing Pledged On HIV," *Washington Post*, 27 November 2007, B01.

**New Jersey.** The state legislature passed a bill on 28 December 2007 mandating HIV testing for all pregnant women within the state. The law stipulates two tests, one at the inception of pregnancy and the second during the third trimester. There is an exemption if the mother objects, but any objection will be noted on her medical record, and, in these cases, the newborn will be tested after birth unless a religious exemption is requested. The law will go into effect on 25 June 2008. P.L. 2007, c.218, 2007 Gen. Assem., Reg. Sess., [http://www.njleg.state.nj.us/2006/Bills/PL07/218\\_.HTM](http://www.njleg.state.nj.us/2006/Bills/PL07/218_.HTM).

**New York.** The governor is considering a plan that would mandate the state's HIV-positive Medicaid beneficiaries enrollment in managed-care plans. The plan, still in its initial stages, has drawn scrutiny from Housing Works, an HIV/AIDS advocate, 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](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49159), accessed 29 January 2008.

**Oregon.** The state Department of Human Services launched a pilot project on 1 November 2007 that seeks to provide mental health support service and affordable rental housing to HIV-positive Oregonians living with mental illnesses. See "Mental Health" section below.

### Interesting Developments in Other Countries

**International.** A report released on 2 November 2007 by the Forum for Collaborative HIV Research, a public-private partnership based out of George Washington University, has increased scrutiny on the BCG vaccine, which is used to prevent tuberculosis among children in developing countries. The forum's findings, among other things, suggest that the BCG vaccine may lead to higher susceptibility to illness, and in some cases death among HIV-positive infants. These findings follow the recent changes in policy at the World Health Organization, which stepped back from its former recommendation for the vaccine when its own report, released in May 2007, showed that HIV-positive infants stood a higher chance of developing the BCG disease, a weaker strain of tuberculosis that causes bovine TB. The Forum for Collaborative HIV Research et al., "HIV-TB Co-Infection: Meeting the Challenge," 2 November 2007. The forum's full report can be accessed at <http://www.hivforum.org/uploads/TB/Final%20HIV-TB%20Report.pdf>.

**South Asia.** The World Bank, in collaboration with the United Nations and private entities, announced the launching on 11 December 2007 of "Tackling HIV and AIDS Stigma and Discrimination," an initiative that seeks to reduce HIV/AIDS stigmatization in Southern Asia by providing numerous grants to small-scale projects that show promise for replication. Grants will be distributed through a competitive award program. Kaiser Family Foundation, "World Bank, Partners Launch Competition in South Asia to Develop Approaches Aimed at Reducing HIV/AIDS-Related Stigma," *Kaiser Daily HIV/AIDS Report*, 13 December 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=1&DR\\_ID=49377](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49377), accessed 28 January 2008.

**China.** The Beijing Municipal Health Board issued in November 2007 a new regulation mandating that condoms be provided in all city hotel guest rooms by the end of 2008. The mandate comes after city authori-

ties recorded 973 new HIV/AIDS cases between January and October 2007, 54 percent higher than in 2006. Kaiser Family Foundation, "Beijing Health Bureau Orders Hotels to Provide Condoms in Guest Rooms by End of 2008," *Kaiser Daily HIV/AIDS Report*, 26 November 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=1&DR\\_ID=49016](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49016), accessed 29 January 2008.

**Indonesia.** UNESCO and L'Oreal announced on 12 December 2007 the launch of Hairdressers against AIDS, a program designed to stem the spread of HIV/AIDS in Indonesia, a country with an estimated HIV-positive population of 290,000. With the help of the Indonesian AIDS Foundation, the program will work to educate the nation's hairdressers on HIV prevention, and how to educate others in the community. Kaiser Family Foundation, "L'Oreal, UNESCO Launch Campaign That Trains Indonesian Hairdressers To Promote Discussion, Educate People About HIV/AIDS," *Kaiser Daily HIV/AIDS Report*, 17 December 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=1&DR\\_ID=49432](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49432), accessed 27 January 2008.

**Madagascar.** The government has already played a role in increasing access to condoms and training teachers on HIV prevention, as well as establishing over 100 testing clinics. In August, the Parliament passed a law protecting HIV-positive people from discrimination, the first of its kind in Africa. Additionally, Madagascar officials distributed 400,000 HIV test kits in 2007, and hope to provide 90 percent of the HIV-positive population with antiretroviral drugs by the end of 2012. Kaiser Family Foundation, "Madagascar's Response to HIV/AIDS One of 'Most Aggressive' in Africa," *Kaiser Daily HIV/AIDS Report*, 18 December 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=1&DR\\_ID=49459](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49459), accessed 27 January 2008.

**Uganda.** The Minister of Health announced in December plans to initiate a program that would provide free circumcision to males throughout the country in an effort to reduce the risk of HIV transmission. Kaiser Family Foundation, "Uganda Plans To Introduce No-Cost, Countrywide Male Circumcision Program to Prevent Spread of HIV," *Kaiser Daily HIV/AIDS Report*, 11 December 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_Index.cfm?hint=1&DR\\_ID=49327](http://www.kaisernetwork.org/daily_reports/rep_Index.cfm?hint=1&DR_ID=49327), accessed 28 January 2008.

## CONSCIENTIOUS OBJECTIONS (HEALTHCARE PROVIDERS AND RELATED PROFESSIONS)

### Recent Judicial Cases and Regulatory Actions October - December 2007

**Federal.** The U.S. District Court for the District of Western Washington State handed down a preliminary injunction 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. The case, *Stormans v. Selecky*, is scheduled to be heard in October 2008. *Stormans v. Selecky*, (U.S. Dist. Ct. of Western Wa. No. C07-5374RBL 25 July 2007).

**Michigan.** On 30 November 2007, a Detroit-area pharmacist filed suit 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. 2:2007cv15091, 30 November 2007).

**Pennsylvania.** The Third Circuit Court of Appeals for the state of Pennsylvania ruled on 21 September 2007 that a Philadelphia clinic did not violate the rights of 16-year-old Melissa Anspach, or the rights of her parents, by providing emergency contraception to Anspach, at her request, in January 2004. In the ruling, Judge Theodore McKee stressed, "[t]he Constitution does not impose an affirmative obligation on the defendants to ensure that children abide by their parents' wishes, values or religious beliefs." *Anspach v. Phila. Dept. of Pub. Health* (Phila. 3d Cir. Appeal No. 05-3632, 21 September 2007).

## Recent Developments in Law and Regulation October - December 2007

**Connecticut.** A law went into effect on 1 October 2007 that requires all licensed healthcare facilities to administer emergency contraception, upon request, to victims of sexual assault unless the woman tests positive for pregnancy. Public Act No. 07-24, 2007 Gen. Assem., Reg. Sess. Roman Catholic officials announced on 27 September 2007 that the state's four Catholic hospitals would abide by and not challenge law in court as some thought they might. Catholic News Service, "Catholic hospitals agree to provide emergency contraception to rape victims," *Catholic Online*, 1 October 2007.

**New Jersey.** The governor signed into law on 2 November 2007 a bill requiring the state's pharmacies to fill all lawful prescriptions without delay, "notwithstanding sincerely moral, philosophical, or religious beliefs of [the] pharmacist." The act, Public Law 2007, c.199, does have an exception for pharmacies that choose not to carry any particular drug or device, but mandates that in such cases the pharmacist must offer to locate a substitute pharmacy that is "reasonably accessible to the patient" and does stock the drug/device in question. P.L. 2007, c.199, 2007 Gen. Assem., Reg. Sess.

**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.

**Pennsylvania.** Pennsylvania's Independent Regulatory Review Commission adopted proposals on 18 October 2007 to require that hospitals provide emergency contraception to survivors of rape. Hospitals can apply for an exemption on moral grounds, but state legislators are considering a bill, H.B. 288, that would remove the possibility of such an exemption. The bill, however, was re-committed to the Rules Committee on 11 December 2007, and no action on passage is expected in the near future. H.B. 288, 2007 Gen. Assem., Reg. Sess.

## Interesting Developments in Other Countries

**Slovakia.** Slovakia's Ministry of Health has stepped back from previous statements when on 20 September 2007 it announced that it would not strike the "conscience clause" that currently allows medical workers to refuse to perform procedures, such as abortions, that conflict with their religious beliefs. The announcement comes on the heels of strong statements from Pope Benedict XVI and Slovakia's Roman Catholic leadership who seek a strengthened conscience clause. Kaiser Family Foundation, "Slovak Health Ministry Drops Effort To Abolish Clause Allowing Health Workers To Object To Performing Abortions, Other Procedures," *Kaiser Daily Health Policy Report*, 20 September 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=2&DR\\_ID=47624](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=47624), accessed 23 January 2008.

The **Vatican.** At the twenty-fifth International Congress of Catholic Pharmacists on 29 October 2007, Pope Benedict XVI spoke in favor of a right to conscientiously object to dispensing drugs such as emergency contraception, which can prevent pregnancy if taken up to 72 hours after sexual intercourse. Kaiser Family Foundation, "Pope Benedict Says Pharmacists Have Right To Conscientiously Object To Fill Emergency Contraception," *Kaiser Daily Health Policy Report*, 31 October 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=2&DR\\_ID=48544](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=48544), accessed 26 January 2008.

## MENTAL HEALTH

### Recent Judicial Cases and Regulatory Actions October - December 2007

**Virginia.** The Virginia Supreme Court's Commission on Mental Health Reform issued recommendations on 21 December 2007 following the release of Virginia's Crisis Intervention Continuum Survey 2007. The panel called for expanded out-patient treatment and more specific procedures to monitor patients and

enforce current laws. The debate over proposals to strengthen Virginia's preventative out-patient commitment law, which stem from an April incident at Virginia Tech in which a mentally ill student killed 32 students and faculty before killing himself, is expected to intensify once the state's General Assembly convenes in early 2008. C. Jenkins, "N.Y. Law Raises Issues of States' Reach in Patient Care," *Washington Post*, 30 December 2007, C01.

### **Recent Developments in Law and Regulation October - December 2007**

**\*Federal.** The President signed into law on 5 November 2007 the Joshua Omvig Veterans Suicide Prevention Act. The act directs the Secretary of Veterans Affairs to develop and implement a comprehensive program designed to reduce the incidence of suicide among veterans. Public Law No. 110-110.

**\*The Paul Wellstone Mental Health and Addiction Equity Act of 2007 is progressing through Congress.** 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 bill passed both the Committee on Ways and Means and the Committee on Education and Labor on 15 October 2007 and was ordered to be reported to the House as a whole on 16 October 2007. A similar bill, The Mental Health Parity Act of 2007, was passed in the Senate in September. H.R. 1424, S.B. 558, 110th Leg., Reg. Sess. (2007).

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

The 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 was introduced in the Senate on 17 October 2007 and referred to the Committee on Finance. 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" sub-section of the "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.

### **Recent Judicial Cases and Regulatory Actions October - December 2007**

**Federal.** The U.S. Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society released a draft report on the oversight of genetic testing on 5 November 2007. 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. The draft's public commentary period is now closed, and the Committee is set to finalize the report at their next meeting on 12-13 February 2008. 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, 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. Winslow, R., "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 is 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.