

Law

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.

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

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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 market-

ing 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=ampdOikngaIA>, 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. 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. 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 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.house.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, 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, 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 biological 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*, 23 November 2007, 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. "Anti-abortion 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, 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 pa-

rental 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.kaiserfamily.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/dissectingthe_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=News Article&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.kaisernet.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.kaisernet.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.kaisernet.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/006/08006.1-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.mernews.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. Lesňá, "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, 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 therapeutic 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