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## Legal Trends in Bioethics

*Sigrid Fry-Revere, Sheeba Koshy, and John Leppard, IV*

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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 theoretic

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#### Acronyms Used in this Column

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CME	continuing medical education
DHHS	U.S. Department of Health and Human Services
FDA	U.S. Food and Drug Administration
FPL	federal poverty level
HPV	human papillomavirus
OIG	U.S. Office of Inspector General
PhRMA	Pharmaceutical Research and Manufacturers of America
PRC	People's Republic of China
SCHIP	State Children's Health Insurance Program

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cal 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 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 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" WINTER 2007

Legislative developments have slowed down a little since the last "Legal Trends in Bioethics" column. Many states are either at the middle or end of their legislative sessions and Congress is all but deadlocked because it generally lacks the two-thirds majority needed to override a presidential veto. Nonetheless there are some developments both in the courts and legislatures worth noting.

In the area of reproductive rights, the tension between legislative action and court action I mention in my general introduction is illustrated nicely in this quarter. Earlier this year, state legislative dockets were filled with laws intended to restrict abortion rights and some of them passed, but many seem to be languishing. Also, while the Supreme Court decision in *Gonzales v. Carhart* (discussed in "Legal Trends in Bioethics" in the summer 2007 issue of *JCE*) was a blow to abortion rights advocates, several court decisions since then have quietly gone the other way. There isn't one court case reported this quarter that can be seen as a right to life victory. *Gonzales v. Carhart*, 550 U.S. \_\_\_\_ (2007) (No. 05-380).

In other areas, progress seems more one-sided. Advocates of expanded health coverage seem to be gaining ground slowly but surely both in the legislatures and the courts. The 2006 Uniform Anatomical Gift Act seems to be meeting with slow acceptance. And legislation to mandate vaccination for human papillomavirus (HPV) has all but died.

The one area where there was significant movement this quarter was in issues having to do with accountability. The new federal Food and Drug Administration Amendments Act greatly increases the authority of the U.S. Food and Drug Administration (FDA) to oversee and regulate the drug and device development processes. The law also creates a mandatory registry for clinical trials and stricter conflict of interest rules for

the FDA advisory boards that oversee drug approval and review. Also, the U.S. Supreme Court agreed to hear a case, *Charles R. Riegel, et ux v. Medtronic, Inc.*, in which the primary issue is whether compliance with FDA requirements protects a company from liability. (U.S. No. 04-0412). And several states have passed legislation imposing new or improved reporting requirements on hospitals for patient infection rates.

### OVERSIGHT: PATIENT TRUST

Probably the most important development this quarter is the passage of the Food and Drug Administration Amendments Act of 2007. This act greatly expands the FDA's authority. It includes a target number of \$450 million in user fees to be paid by drug companies; this is an increase of over \$100 million from previous years. The act allows the FDA to issue fines 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 scientists with ties to drug companies by 25 percent over the next five years. And it 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). The entire bill can be found at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_bills&docid=f:h2900eh.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h2900eh.txt.pdf).

### Recent Laws and Regulations, July - September 2007

**\*Federal.** On 27 September 2007, the President signed into law H.R. 3580, the Food and Drug Administration Amendments Act of 2007. The act includes, in addition to the measures mentioned above, 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. Public Law No: 110-85. Related bills include H.R. 2900 and S. 1082, 110th Leg., Reg. Sess. (2007).

A bill introduced on 6 September 2007 would require drug, medical devices, and biologics manufacturers with at least \$100 million in annual revenue to, every quarter, disclose 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).

**California.** On 1 July 2005 a law went into effect that requires pharmaceutical companies and medical device manufacturers to implement a compliance program that conforms with the *PhRMA Code on Interactions with Healthcare Professionals* and guidance on pharma marketing from the U.S. Office of the Inspector General (OIG); the law also caps expenditures by the industry to healthcare providers. There are exemptions to the spending limits that the manufacturers establish in order to comply with this law, including an exemption for commercial support of continuing medical education (CME), as long as those grants are in compliance with *PhRMA Code* and the OIG guidance. S.B. 1765, 2003-2004 Leg., Reg. Sess. (Cal. 2004), Cal. Ch. 927 (2004) affecting Cal. Code. Regis. tit. 8 § 119400 (2004).

**\*Delaware.** On 12 July 2007, the governor signed into law H.B. 47, which amends the Hospital Infections Disclosure Act, and mandates the reporting and disclosure of hospital infection rates. Title 16, Ch. 10a (Del. 2007).

**Minnesota.** In 1993, the state passed a law limiting gifts from pharmaceutical companies to physicians to an annual value not to exceed \$50. (Minn. Stat. § 151.461 (2007)). Since the law has been in place, the

number of visits by pharmaceutical company sales representatives reported by primary care physicians in the state decreased at about twice the rate reported by physicians nationwide. "Minnesota Law Limiting Pharmaceutical Company Gifts to Physicians Could Lead to Similar Laws in Other States," *Kaiser daily Health Policy Report*, 12 October 2007, [http://www.kaiser-network.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=48157](http://www.kaiser-network.org/daily_reports/rep_index.cfm?hint=3&DR_ID=48157), accessed 6 November 2007.

**New Jersey.** The state attorney general announced on 18 September 2007 the formation of a task force that will consider whether the state should require pharmaceutical companies and medical device makers to disclose gifts they give to physicians. The goal will be to examine the effects of drug and device makers' gifts and fees to physicians on the doctor-patient relationship, as well as how much gift-giving informs physicians about new treatments. The task force will also examine ways to prevent and identify abuses, including requiring public disclosure of gifts, limiting payments physicians can accept, or requiring doctors to inform patients about such payments. In an interview, the attorney general said she plans to look closely at Minnesota's legislation for guidance. K. Stark, "N.J. Weighs Requiring Reporting Doctors' Gifts," *Philadelphia Inquirer*, 19 September 2007, [http://www.philly.com/philly/business/homepage/20070919\\_N\\_J\\_\\_weighs\\_requiring\\_reporting\\_doctors\\_gifts.html](http://www.philly.com/philly/business/homepage/20070919_N_J__weighs_requiring_reporting_doctors_gifts.html), accessed 6 November 2007. (A bill was introduced on 14 May 2007 that would require doctors to tell patients about money and gifts over \$25 that they have accepted from pharmaceutical firms in the last year. S. 2660, 2007 Gen. Assem., Reg. Sess. (N.J. 2007).)

**\*Oregon.** On 27 July 2007, the governor signed a law that would require the reporting and disclosure of hospital infection rates. Or. Ch. 838 (2007).

**\*Pennsylvania.** On 20 July 2007, the governor signed into law S.B. 968, amending the Medical Care Availability and Reduction of Error Act. The law will require more stringent reporting requirements for the rates of patients' infection to state authorities. Public Act. 52

**Vermont.** On 12 June 2002, a bill was signed by then-governor Howard Dean that requires drug companies to report gifts made to physicians valued at \$25 or more. This includes meals, trips, or consulting fees, but not free drug samples. H. 31, 2001-2002 Leg., Reg. Sess. (Vt. 2002); Vt. Act No. 127 affecting 33 Vt. Stat. Ann. tit. 19 § 5 (2002).

**\*Washington.** The governor signed a law, effective 22 July 2007, that would require the reporting and disclosure of hospital infection rates. Wa. Ch. 261 (2007).

**West Virginia.** On 21 March 2004 the governor signed into law H.B. 4084, which requires pharmaceutical companies to report prescription drug advertising costs. H.B. 4084, 76th Leg., 1st Reg. Sess. (W. Va. 2004), Ch. 193 affecting W. Va. Code § 5A-3C-1 (2004) through W. Va. Code § 5A-3C-17 (2004).

## THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

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

The state legislatures and courts are at odds this quarter. Several states passed what could be understood as pro-life measures. For example, Louisiana's governor signed a law requiring that women be informed that a fetus feels pain during an abortion procedure, and Missouri, Louisiana, and Pennsylvania funded alternatives to abortion programs, while North Carolina reenacted its restriction on public funding for abortions. On the other hand, several court decisions can be seen as pro-choice victories. The U.S. Supreme Court refused to hear a case challenging a New York law requiring insurance companies to cover the cost of contraceptives. A U.S. District Court decided it would hear a case in which abortion clinics claim that a new Missouri law will regulate them out of existence. The Arizona Supreme Court found it unconstitutional for a sheriff to have a policy to only provide inmates with transportation for medically necessary abortions; the Georgia Supreme Court held that abortion clinics have a right to sue the state for reimbursement for medically necessary abortions; and the New Jersey Supreme Court held that a law may require that a woman seeking an abortion be informed of the "medical facts," but it may not require that the woman be told that the fetus is an "existing human being."

### Recent Cases, July - September 2007

**Federal.** The U.S. Supreme Court refused to hear an appeal on 30 September 2007 brought by Catholic Charities of New York contesting a decision by the Court of Appeals for the State of New York upholding the legality of a New York law requiring insurance companies to include contraceptive coverage in drug benefit packages. *Catholic Charities v. Dinallo* (N.Y. Case no. 06-1550, 30 September 2007).

The U.S. District Court for the Western District of Missouri heard arguments on 10 September 2007 concerning the constitutionality of a state law reclassifying abortion clinics as "ambulatory surgical centers." Opponents to the new law argue that reclassification would subject abortion clinics to many new, and costly, regulations that could force them to close their doors. *Kaiser Daily Women's Health Policy Report*, 10 September 2007, [http://www.kaisernetwork.org/dailyreports/rep\\_index.cfm?DR\\_ID=47377](http://www.kaisernetwork.org/dailyreports/rep_index.cfm?DR_ID=47377), accessed 3 November 2007. See related legislation under Missouri below.

\***Arizona.** On 25 September 2007, the state supreme court upheld without comment an appellate court decision that found it unconstitutional for a state county sheriff to have a policy only requiring deputies to transport inmates to medical facilities for abortions if medically necessary. *Doe v. Arpaio* (Ariz. CV-07-0104-PR, 26 September 2007).

**Georgia.** On 24 September 2007 the state supreme court ruled that abortion clinics can sue the state for not paying for some patients who needed abortions for medical reasons. The suit was brought, initially, by a group of clinics and a physician against the state Department of Community Health for not reimbursing them under the Medicaid program when poor women with health problems underwent the procedure. *Feminist Women's Center v. Burgess* (Ga. 2003-CV-78487, 24 September 2007).

\***Kansas.** On 30 October 2007, a grand jury will convene to investigate whether George Tiller, MD, broke state law concerning late-term abortions. The state attorney general announced on 27 June 2007 that he has reviewed all the charges against Dr. Tiller's clinic filed by Phil Kline during Kline's tenure as state attorney, and charged Tiller with 19 misdemeanors for allegedly failing to get an independent second opinion on some 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 grand juries. *Kaiser Daily Women's Health Policy*, 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.

**New Jersey.** On 12 September 2007, the state supreme court unanimously held that while abortion providers are required to discuss medical facts with a patient, they are not required to inform women that the fetus is an "existing human being." *Acuma v. Turkish, M.D.* (N.J. Docket No. 59, 525, 12 September 2007).

A state superior court ruled on 24 September 2007 that a referendum that asks voters to approve the governor's plan (N.J. Pub. Law Ch. 117 (2007)) to borrow \$450 million over 10 years to fund stem cell research will remain on the 6 November 2007 ballot, despite assertions that the ballot question is deceptive because it does not explain that the funding being authorized will allow human cloning. *McKenzie v. Corzine* (N.J. Super. Ct. App. Div. A-703-07T3, 24 September 2007).

\***Texas.** On 24 August 2007, the state supreme court denied a petition for review of a state court of appeals decision in *Roman v. Roman*. At issue was the proper disposition of three frozen embryos never implanted because of the couple's divorce. The wife wanted to keep the frozen embryos and won, at the lower court level. The husband appealed that ruling and won with the judge ruling that the embryos should be discarded in accordance with a contract signed by both parties concerning what to do with the embryos in the event of a divorce. This is a case of first impression in Texas; the appellate court ruling that now stands can be understood as supporting the proposition that embryos are not persons with a right to life. *Roman v. Roman*. (Tex. Sup. Ct. Appeal No. 06-0554).

### Recent Laws and Regulations, July - September 2007

**California.** On 11 October 2007 the governor signed into law a bill that funds the development of a pilot project that seeks to diversify the umbilical cord blood supply collected in public blood banks. S.B. 962,

2007-2008 Leg., Reg. Sess. (Cal. 2007); Ch. 516. This bill is similar to A.B. 40, A.B. 482, 2007-2008 Leg., Reg. Sess. (Cal. 2007). Also on 11 October 2007, the governor signed into law a related bill that requires pregnant women be informed of the option of umbilical cord blood banking. A.B. 34, 2007-2008 Leg., Reg. Sess. (Cal. 2007); Ch. 517.

\***Hawaii.** Two bills to allow all forms of stem-cell research have been deferred until the 2008 legislative session. H.B. 364, H.B. 1261, 24th Leg., Reg. Sess. (Haw. 2007).

\***Louisiana.** On 9 July 2007 the governor signed into law a bill that requires women seeking an abortion to be informed at least 24 hours in advance about the pain their unborn child will feel while aborted. The law also requires the abortionist to offer the woman an opportunity to see her baby on an ultrasound. The law went into effect on 15 August 2007. H.B. 25, 2007 Leg. Reg. Sess. (La. 2007); La. Rev. Stat. Ann. § 40:1299.35.6 (2007).

On 12 July 2007 the governor signed into law a measure that will allocate \$1 million to alternatives-to-abortion services. What such services might be is not specified. H.B. 1, 2007 Leg. Reg. Sess. (La. 2007).

The governor signed into law two bills on 12 July 2007 that would ban "partial-birth" abortion in the state and create criminal penalties for physicians who perform the procedure. H.B. 614, S.B. 161, 2007 Leg. Reg. Sess. (La. 2007).

**Michigan.** A bill was introduced on 17 September 2007 proposing a ban on the procedure known as "partial-birth abortion." 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).

\***Missouri.** On 2 July 2007 the governor signed into law the Missouri Health Improvement Act of 2007, which includes various abortion-related provisions. In cases of medical emergency (defined as when the pregnant woman's life or a "major bodily function" is at risk), the law allows an exception to the entirety of Missouri's abortion law, including provisions concerning parental involvement, abortion counseling, and post-viability abortion. The measure also includes provisions related to clinic licensing, and funds an alternatives-to-abortion program and sex education. The law went into effect in August. S.B. 577, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2007); Mo. Rev. Stat. § 188.028-335 (2007).

The governor signed into law on 6 July 2007 that, while not an outright ban on abortion, might have a similar effect. The bill reclassifies any facility that performs five or more abortions each month as an "ambulatory surgical center," thus requiring it to comply with many costly new regulations. Opponents of the bill claim that the cost of upgrading facilities to abide by the code would be so high that abortion clinics would be forced to shut down. A temporary injunction preventing the law from going into effect is in place while the issue is being litigated (see above). However, one controversial aspect of the law is already in place. Anyone who works at an abortion clinic, or for an organization that refers patients to such clinics, is prohibited from teaching sex education in state public schools. S.B. 370, H.B. 1055, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2007); LR Number 2503L.04T; Mo. RSMo. ch. 197 § 200 (Supp. 2007).

**North Carolina.** On 31 July 2007, the governor signed into law the state's budget bill, which reenacts the current restrictions that prohibit public funding for abortion unless the pregnancy is the result of incest or rape, or the woman's life is at risk. S.L. 2007-328. H.B. 1473, Gen. Assem. 2007-2008 Sess. (N.C. 2007).

**Ohio.** A bill was 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).

On 10 July 2007, a bill was introduced 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 bills were introduced on 18 September 2007 that would require abortion providers to provide a patient with an opportunity to view an ultrasound of the fetus, at no extra cost, before the procedure can take place. H.B. 314, S.B. 230, 127th Gen. Assem., Reg. Sess. (Oh. 2007).

**Pennsylvania.** A bill passed the state house that provides for umbilical cord blood banking, and is currently in the senate's Public Health and Welfare 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).

On 17 July 2007 the governor signed into law a measure that will allocate \$4,655,000 to fund alternatives-to-abortion programs and prohibit nonprofit organizations receiving alternatives-to-abortion funds from performing abortion services or counseling. Similarly, another \$4,655,000 will be used for grants for women's medical services, including non-invasive contraception supplies. Act No. 42. H.B. 1295, 191st Gen. Assem., Reg. Sess. (Pa. 2007).

**Wisconsin.** On 19 June 2007 a bill was introduced that would require a physician who is about to perform an abortion to take certain steps if the woman seeking the abortion seems to have been coerced into making that decision and seems to be in danger of being harmed should she decline. The woman must be informed of services for victims or individuals at risk of domestic abuse and be provided with private access to a telephone if she states that she wishes to call for assistance. S.B. 218, 1007 Reg. Sess. (Wis. 2007).

### Interesting Developments in Other Countries

**\*People's Republic of China.** The PRC's policies for enforcing its one-child policy are raising eyebrows. Recently in the southwest of the People's Republic, enforcement raids resulted in women being forced to have abortions as late as nine months into their pregnancies. Also the fines for violating the law can be as high as \$9,000, and when a family cannot afford to pay the "social child-raising fee," government officials destroy homes and seize belongings as punishment, even as soon as three days after the fine was assessed. Unrest resulted in attacks on family planning officials and the torching of government buildings. Riot police were sent into four different towns in Guangxi Province to quell the violence. Officials report that their one-child-per-family policy will not change, but that some enforcement measures will be reconsidered. "Clashes in Southwest China Over One-Child Policy Prompts Officials to Ease Penalties," *Kaiser Daily Women's Health Policy Report*, 23 May 2007, [http://www.kaisernetwork.org/daily\\_report.cfm?DR\\_ID=45092&dr\\_cat=2](http://www.kaisernetwork.org/daily_report.cfm?DR_ID=45092&dr_cat=2), accessed 14 August 2007.

**India.** The Indian central government is planning to create a national registry of all pregnancies and abortions in the country in an effort to curb sex-selective abortions. It also intends to set a new criterion whereby abortions will only be permitted when there is a valid and acceptable reason, however just what qualifies as "valid and acceptable" has not yet been clarified by the government. India's Women and Child Development Minister, Renuka Chowdhury, has said that the reason for monitoring abortions is to break up organized illegal-abortion rackets that the government says are contributing to the country's skewed girl-to-boy ratio (927 girls : 1,000 boys). C. Chauhan, "Government to Monitor Pregnancies, Abortions," *Hindustan Times*, 13 July 2007.

**\*Mozambique.** The government is considering lifting or at least loosening its ban on abortions because more than 40 percent of serious pregnancy complications treated at the central hospital in Maputa are a result of illegal abortions, and abortions account for 11 percent of maternal deaths in the country. "Mozambican Government Reviewing Abortion Ban, Justice Minister Says," *Kaiser Daily Women's Health Policy Report*, 11 June 2007, [http://www.kaisernetwork.org/daily\\_report.cfm?DR\\_ID=45474&dr\\_cat=2](http://www.kaisernetwork.org/daily_report.cfm?DR_ID=45474&dr_cat=2), accessed 14 August 2007.

**\*Poland.** The European Court of Human Rights announced on 25 September 2007 that it would not review its earlier judgment in the case of *Tysiack v. Poland*, despite the Polish government's request that it do so. In March 2007, the court ordered the government to award damages to a Polish woman who was denied an abortion despite warnings from her physicians that continuing her pregnancy would pose a serious risk to

her ability to see. Although the woman finally did receive permission for the procedure, by that time, it was too late and she is now seriously visually impaired. *Tysiac v. Poland*, 4 Eur. Ct. H.R. 5410/03 (2007).

**\*Portugal.** A law legalizing abortions in the first 10 weeks of pregnancy went into effect on 15 July 2007. "Portugal Law that Loosens Abortion Restrictions Comes Into Effect," *Kaiser Daily Women's Health Policy Report*, 17 July 2007, [http://www.kaisernetwork.org/daily\\_report.cfm?DR\\_ID=46263&dr\\_cat=2](http://www.kaisernetwork.org/daily_report.cfm?DR_ID=46263&dr_cat=2), accessed 13 August 2007.

**Africa.** Representatives from 10 African countries called for legalization of safe abortions at a conference of women leaders in Nairobi, Kenya, on 26 June 2007. "Leaders of 10 African Countries Call for Legalization of Safe Abortion to Help Reduce Maternal Mortality Rate," *Kaiser Daily Women's Health Policy Report*, 28 June 2007, [http://www.kaiser-network.org/daily\\_report.cfm?DR\\_ID=45892&dr\\_cat=2](http://www.kaiser-network.org/daily_report.cfm?DR_ID=45892&dr_cat=2), accessed 14 August 2007.

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

The three court cases reported here this quarter deal with quite intriguing scenarios. In two cases the courts made it clear that parental consent laws cannot be used to serve any other political or personal end other than the intended end of notifying parents, presumably to give parents a chance to discuss the decision with their child and to be aware and prepared for the physician and emotional aftermath. The Third Circuit Court of Appeals made it clear that parental consent laws are not there to protect a parent's religious beliefs, and the Mississippi Supreme Court made it clear that such laws could not be used as a shield to protect a mother from potential criminal liability, either. A Missouri Court of Appeals also narrowly interpreted the intent of the state's child endangerment laws not to include what a mother does to her fetus while it is still *in utero*.

### **Recent Cases, July - September 2007**

**Federal.** The Third U.S. Circuit Court of Appeals in Philadelphia ruled unanimously on 21 September 2007 that a city health clinic did not violate the rights of a 16-year-old girl or those of her parents by giving her emergency contraception (commonly known as the "morning after" pill) without notifying her parents. The parents argued that they opposed abortion and objected to the actions of the clinic on religious grounds. The court held that only the daughter's religious beliefs were relevant, and, since she did not voice such views during her visit to the clinic, no rights were violated. The court wrote: "the 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).

**\*Illinois.** Status unchanged. The Illinois Supreme Court issued rules necessary to implement the state Parental Notice of Abortion Act, Ill. S. Ct. M.R. 21173, in January. But the act still remains unenforceable. The state's attorney general has filed a motion to have those rules put in place, but the matter is still pending.

**Mississippi.** On 5 July 2007 the state supreme court declined to hear a case in which a mother was sentenced to jail for attempting to hide her husband's statutory rape by consenting to her 13-year-old daughter's abortion. The lower court had ruled that the state's parental consent laws were not a defense in criminal cases. *Kaiser Daily Women's Health Policy Report*, 2 July 2007, [http://www.Kaiser-network.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=45947](http://www.Kaiser-network.org/daily_reports/rep_index.cfm?DR_ID=45947), accessed 3 November 2007.

**Missouri.** On 11 September 2007 the Missouri Court of Appeals in Kansas City upheld a lower court's dismissal of a child endangerment case against a mother whose baby, like herself, had tested positive for marijuana and methamphetamine the day after her baby was born. The court held that the Missouri law that makes it a crime for a third person to harm a pregnant woman, and, consequently, her fetus does not apply to harm indirectly caused by the mother. *State of Missouri v. Janet S. Wade* (Mo. Ct. App. Case No. WD67363, 11 September 2007).

### Recent Laws and Regulations, July - September 2007

**\*Missouri.** On 2 July 2007, the governor signed into law the Missouri Health Improvement Act of 2007, which includes various abortion-related provisions. In cases of medical emergency (defined as when the pregnant woman's life or a "major bodily function" is at risk), the law allows an exception to the entirety of Missouri's abortion law, including provisions concerning parental involvement, abortion counseling, and post-viability abortion. The measure also includes provisions related to clinic licensing and funds an alternatives-to-abortion program and sex education. The law went into effect in August. S.B. 577, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2007); Mo. Rev. Stat. § 188.028-335 (2007).

### Interesting Developments in Other Countries

**\*Egypt.** In July the government announced a complete ban on female circumcision after a 12-year-old girl died during the operation. While technically a ban has existed for 10 years, an exception in the law allowed the operation to be performed by qualified doctors in exceptional circumstances. The new ban is absolute and no exceptions will be allowed. It is estimated that currently 90 percent of all Egyptian women are circumcised, whether Muslim or Christian. M. Abdelhadi, "Egypt forbids female circumcision," *BBC NEWS*, 2 July 2007, [http://news.bbc.co.uk/2/hi/middle\\_east/6251426.stm](http://news.bbc.co.uk/2/hi/middle_east/6251426.stm), accessed 2 July 2007.

**\*United Kingdom.** In Britain, a Human Tissue and Embryos Bill is being considered, which, among other things, would require birth certificates to identify whether a donor egg or sperm or both were used to conceive the child. Backers of the bill suggest that not to require such information on a birth certificate makes the government complacent in a lie. M. Henderson, "Birth certificates 'should tell donor children who their real parents are'," *TimesOnline*, 1 August 2007, <http://business.timesonline.co.uk/tol/business/law/article2176357>.

### HEALTHCARE COVERAGE

Legislative battles over healthcare coverage continue at the state level, with advocates for expanded coverage making minimal but consistent gains. Beyond issues of whether the State Children's Health Insurance Program (SCHIP) will be simply reauthorized or expanded, the federal battle over expanded healthcare coverage primarily will be decided at the polls next November.

### July - September 2007

**Federal.** Despite a virtually guaranteed veto from the President, the House passed an SCHIP expansion bill on 25 September 2007. The bill would provide an additional \$35 billion in funding to the program over the next five years, bringing total spending to \$60 billion annually. The additional funding would be paid for by a 61-cent-per-pack increase in the tobacco tax. State Children's Health Insurance Program Reauthorization Act, H.R. 976, 110th Cong., 1st Reg. Sess. (2007).

**\*A bill was introduced** 29 March 2007 in the U.S. House 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.** Lawmakers are considering a universal healthcare proposal after it was introduced 10 September 2007 at a special late-summer hearing of the Senate Health, Education, and Social Services Committee to get a "jump start on the 90-day session" next year, according to the bills sponsor. 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 would determine which medical services would be 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. The contributions (read: tax) would fund a sliding-scale voucher system. Residents would be able to use the vouchers to obtain coverage from the Alaska Health Care Clearinghouse, a "marketplace" of various certified policies. S.B. 160, 24th Leg., Spec. Sess. (Alaska 2007).

**California.** Both legislative bodies passed a bill on 10 September 2007 intended to extend healthcare coverage to all state residents. The legislation would require 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 does not include an individual mandate. The governor vowed to veto the legislation, and did on 12 October 2007. A.B. 8, 2007-2008 Leg., Reg. Sess. (Cal. 2007).

**Colorado.** The Colorado Blue Ribbon Commission for Healthcare Reform, created last year by a piece of Senate legislation (S.B. 06-208, 66th Gen. Assem., 2nd Reg. Sess. (2006)), on 23 August 2007 approved its fifth proposal for reconfiguring the state's healthcare system, with an estimated cost in excess of \$1 billion. The plan would include an individual mandate for the purchasing of health insurance and would provide subsidies on a sliding scale based on income for low-income families. Additionally, low-income workers who qualify for a government subsidy would be required to use that money to purchase employer-sponsored health insurance if it is offered and costs less than the state insurance plan. The commission is expected to release its final report and recommendations to the General Assembly by 1 January 2008. A.B. 8, B. Scanlon, "Fifth Health Care Plan Unveiled," *Rocky MountainNews.com*, 24 August 2007; [http://www.rockymountainnews.com/drmn/local/article/0,1299,DRMN\\_15\\_5681302,00.html](http://www.rockymountainnews.com/drmn/local/article/0,1299,DRMN_15_5681302,00.html), accessed 2 November 2007.

**Kansas.** An advisory council representing consumers, health providers, and health purchasers submitted preliminary recommendations to the Kansas Health Policy Authority on ways to reform Kansas' healthcare system. Chief among the recommendations was an individual and employer health insurance mandate to achieve universal coverage. The Kansas Health Policy Authority is scheduled to present formal proposals to the state Legislature in November. *Kaiser Daily Health Policy Report*, 23 August 2007, [http://www.kaiser-network.org/daily\\_reports/rep\\_index.cfm?DRID=47134](http://www.kaiser-network.org/daily_reports/rep_index.cfm?DRID=47134), accessed 2 November 2007.

**Massachusetts.** On 1 July 2007, a law took effect requiring all state residents to have health insurance. Under the law, residents with annual incomes below the federal poverty level (FPL) are eligible for no-cost care. Those with annual incomes up to three times the FPL can enroll in state-subsidized plans, while those with higher incomes can choose their own coverage from new private plans via the Massachusetts "Connector" if they are not offered coverage through their employer. Although 1 July 2007 was the deadline for uninsured residents to obtain coverage; they have until 31 December 2007 before those who remain uninsured will face a financial penalty. Residents who do not have health insurance by that time will lose their state tax exemption, worth about \$219. Those who do not obtain insurance after 31 December will face a penalty of up to half the cost of insurance premiums for each month a person is uninsured. Additionally, residents can initially purchase any coverage plan they choose, but, by January 2009, all residents must have prescription drug coverage. Mass. Gen. Laws Ann. Ch. 58, §§ 1-147 (Mass. 2006).

**\*North Carolina.** On 27 July 2007, the governor signed into law the Mental Health Equitable Coverage Act, formerly H.B. 973, which would require health insurers to provide the same level of coverage for treatment of severe depression, schizophrenia, or other mental illness as they do for physical illnesses. N.C. Sess. Laws Ch. 268 (N.C. 2007).

**\*Wisconsin.** In July the state senate approved an amendment (Senate Substitute Amendment No. 1) to the state budget (S.B. 40, 2007 Reg. Sess. (Wis. 2007)) that, if adopted, will be "one of the most sweeping health care reform proposals in the country," according to the *Milwaukee Journal Sentinel*. Known as Healthy Wisconsin, the amendment represents the State of Wisconsin's effort to provide universal coverage. It would

provide coverage to 276,000 people who have been uninsured for more than one year, financed by a 9 percent to 12 percent tax on employer payrolls and a 4 percent tax on employees' wages. The amendment was eventually stricken by the Senate Conference Committee upon review. G. Boulton, "Is Senate's Health Bill Best for All?" *Milwaukee Journal Sentinel Online*, 21 July 2007, <http://www.jsonline.com/story/index.asp?id=636124>, accessed 1 November 2007.

## VACCINES

Out of an original number of more than two dozen states considering mandating HPV vaccination for preteens, several have instead passed laws to study the value of HPV vaccination and a few have passed laws requiring HPV education, but only two states and the District of Columbia have actually passed laws requiring HPV vaccination.

### Recent Laws and Regulations, July - September 2007

**\*Federal.** The session ended without any action on H.R. 1153. The bill was introduced in the U.S. House of Representatives and would prohibit federal funds to be used by states who make the HPV vaccine mandatory. H.R. 1153, 110th Cong. (1st Sess. 2007). However, a similar provision passed on 18 July 2007 as part of the House Labor, Health, and Human Services, Education Appropriations Bill. The amendment prohibits federal funds from being used by states to implement requirements that a student be vaccinated for HPV as a condition of school admittance. "House passes Gingrey amendment to keep HPV vaccination a family decision," press release from the office of Representative Phil Gingrey (R-Georgia), 19 July 2007.

Gardasil, Merck's HPV vaccine, has been adopted by all 55 of the CDC's Vaccines for Children Program immunization projects. This is a program that provides vaccines at no cost to children ages nine to 18 who are covered by Medicaid, the Alaska native and American Indian Children program, and some other programs for uninsured children. *Kaiser Daily Women's Health Policy Report*, 18 July 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=46298](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=46298), accessed 18 July 2007.

**Arizona.** On 25 June 2007, the governor signed into law the Arizona state budget, which included an amendment supported by the Center for Arizona Policy (a family-advocacy group) that prohibits the State Department of Health Services from including the HPV vaccine among the immunizations necessary for school entry. H.B. 2789, 48th Leg., 1st Reg. Sess. (Ariz. 2007); Ariz. Rev. Stat. Ann. § 36-672 (2007).

**\*California.** A bill passed the state assembly and is currently in the Senate Committee on Rules. The bill 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).

A.B. 1429 was vetoed by the governor on 14 October 2007. The bill would have expanded any insurance plan that covers cervical cancer screening or surgery to additionally cover the HPV vaccine with a referral from the healthcare provider. A.B. 1429, 2007-2008 Leg., Reg. Sess. (Cal. 2007).

**\*District of Columbia.** Congress approved on 12 July 2007 a city council bill that would require girls entering the sixth grade to receive the HPV vaccine. The provision has an opt-out provision. D.C. ST. §7-1651.04. Note that City Council Members Yvette Alexander and Muriel Bowser said on 17 September 2007 that they want to repeal this law. N. Stewart, "Two Council Members Urge Repeal of Law," *Washington Post*, 14 September 2007.

**Illinois.** The governor signed into law Public Act 95-0422 concerning the HPV vaccine. The bill requires that schools provide parents with information linking HPV and cervical cancer, and that private health plans cover the cost of the vaccine. Ill. Pub. Act 94-0422.

On 24 August 2007, the governor signed into law a bill that requires health plans to cover the HPV vaccine for girls under the age of 18. S.B. 0937, 95th Gen. Assem., Reg. Sess. (Ill. 2007); 410 Ill. Comp. Stat. 225/1 (2007).

**\*Michigan.** On 5 September 2007 a bill was introduced that will require the Michigan Department of Health to "encourage" every school (both public and private) to provide information regarding the risks

associated with the 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).

**\*New Jersey.** On 6 August 2007, the governor signed into law S.B. 2286. The law mandates the distribution of information regarding HPV to parents and guardians and requires vaccination of girls in grades seven to 12. It also proposes a public awareness campaign. N.J. Pub. Law Ch. 134 (2007).

**\*Rhode Island.** On 7 July 2007, a bill became law without the governor's signature. The bill requires health insurance providers to cover the HPV vaccine. H.B. 5061 Ch. 320.

**West Virginia.** On 21 August 2007 a bill was passed that allocates \$100,000 for HPV "education." H.B. 209, 2007 Leg. 2nd Spec. Sess. (W. Va. 2007); 2007 W. Va. Acts page no. 108.

**Wisconsin.** On 16 August 2007 a bill was introduced in the state senate which directs the Department of Public Instruction, in conjunction with the Department of Health and Family Services, to collect information about the HPV, including the causes and symptoms of the virus; how it is spread; how it may be prevented; how to obtain additional information about the virus; and the availability, effectiveness, and risks of vaccinations against the virus. The information must include the recommendations regarding the vaccine and prevention of the virus made by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. The bill directs Department of Public Instruction to make the information available to school districts, private schools, and charter schools, and requires each school board, private school, and charter school, at the beginning of each school year, to provide the information to the parents and guardians of pupils enrolled in grades six to 12 in the school district or school. An identical bill was introduced in the assembly on 28 August 2007 and received its first public hearing on 26 September 2007. S.B. 252, A.B. 492, 2007 Reg. Sess. (Wis. 2007).

### Interesting Developments in Other Countries

**\*Canada.** Several Canadian provinces are considering providing Gardasil at government expense to sixth-grade girls. K. Gillespie, "Girls to get cancer vaccine," *Toronto Star*, 2 August 2007, p. A 1, A18. On 20 September 2007 the Canadian province of British Columbia approved an HPV program, including about \$258 million in the 2007-2008 budget to help pay for provincial HPV vaccination programs. The national government recommended providing 40 million Canadian dollars over three years for B.C.'s program. Perry Kendall, B.C.'s medical health officer, has said that girls in the sixth to ninth grade could begin receiving the vaccines at no cost in September 2008 because there are provincial vaccine programs in place for those grades. Kendall added that no vaccine in the province is mandatory and that parents can opt their daughters out of the program. "B.C. to Vaccinate Girls Against HPV," *Canadian Press*, 20 September 2007; <http://cnews.canoe.ca/CNEWS/Canada/2007/09/20/4513270-cp.html>, accessed 1 November 2007.

**European Union.** In July, the European Committee for Human Medicinal Products recommended GlaxoSmithKline's experimental HPV, Cervarix, for sale and marketing in the European Union. The committee reviewed data on the vaccine from clinical trials involving 30,000 women, and on 24 September 2007 the European Commission approved it for sale and marketing in the European Union. "UPDATE 1-Glaxo Prepares to Launch Cervarix After EU Okay," *Reuters*, 24 September 2007.

**\*United Kingdom.** The Department of Health's Joint Committee on Vaccination and Immunisation has advised the British government to mandate HPV vaccines for 12- and 13-year-old girls starting in 2008. I. Sample, "Girls could be offered cervical cancer jab by autumn 2008," *Guardian*, 21 June 2007.

### ORGAN AND TISSUE PROCUREMENT

It has been a year since the Uniform Anatomical Gift Act of 2006 was passed by the National Conference of State Legislatures. The conference has no legal authority, but it carries quite a bit of persuasive authority. Once it proposes a model law, it is up to the legislators in their various states to introduce the law and help it

get passed. The Uniform Anatomical Gift Act of 2006 updated the version with some significant changes. One of the most significant changes was the adoption of first-person consent, meaning that family members do not have the authority to override a deceased patient's known wishes with respect to organ donation. The act has passed in 20 states (Arizona, Arkansas, California, Colorado, Idaho, Indiana, Iowa, Kansas, Minnesota, Montana, Nevada, New Mexico, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Virginia) and the Virgin Islands, and is pending in another six states (Maine, Michigan, New Jersey, New York, Texas, Washington) and the District of Columbia. In Missouri the bill failed for lack of action but is expected to be reintroduced during the next legislative session. The states with movement on bills in this reporting period are included below.

### Recent Cases, July - September 2007

**\*Federal.** (Ongoing case.) The Eighth U.S. Circuit Court of Appeals (Minnesota, Nebraska, North Dakota, South Dakota, Eastern and Western Districts of Arkansas, Northern and Southern Districts of Iowa, Eastern and Western District of Missouri) in *Wash. U. v. Catalona* is reviewing the lower court's ruling that Washington University in St. Louis owned the tissue samples that William J. Catalona, MD, had collected for prostate cancer research while at the university. The U.S. District Court for the Eastern District of Missouri held that the informed-consent documents signed by Catalona's patients, which specifically gave the doctor the patients' tissue samples and included the patients' right to withdraw from the study and request that their tissue samples be destroyed, were "inconsequential" in its decision to grant full property rights to the university. Appeal No. 06-2286 (8th Cir. 15 May 2006). The case was argued 13 December 2006. A decision should be forthcoming shortly. *Wash. U. v. Catalona* (8th Cir. Appeal No. 06-2286, 13 December 2006).

### Recent Laws and Regulations, July - September 2007

**Alaska.** A bill introduced on 13 May 2007 to amend the state's anatomical gift act is under consideration. S.B. 181, 25th Leg., Reg. Sess. (Alaska 2007).

**\*California.** On 13 October 2007, the governor signed into law the Uniform Gift Act of 2006. Ch. 629; A.B. 1689, 2007-2008 Leg., Reg. Sess. (Cal. 2007); Cal. Code Regs. Tit. 3.5 § 7150 (2007).

**\*District of Columbia.** A bill was introduced on 9 January 2007 to amend the state's anatomical gift act. The bill received a public hearing on 8 June 2007. D.C. Council, B17-58 (2007).

**\*Maine.** A bill introduced on 17 March 2007, that would adopt the 2006 Uniform Anatomical Gift Act without changes, was carried over to the 2008 session. 123rd Legislative Session. L.D. 1505, 123rd Leg., Reg. Sess. (Me. 2007).

**\*Michigan.** On 19 June 2007 a bill was introduced to amend the state's anatomical gift act. That bill is still under consideration. H.B. 4940, 94th Leg., Reg. Sess. (Mich. 2007).

**\*Missouri.** A bill passed the Senate on 19 March 2007 that would adopt the 2006 Uniform Anatomical Gift Act without changes. It is currently in the House Health Care Policy Committee as H.B. 723. SB 496, HB 723, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2007).

**\*New Jersey.** A bill was introduced on 9 January 2007 to amend the state's anatomical gift act. The bill is still under consideration. A.B. 3909, 2007 Gen. Assem., Reg. Sess. (N.J. 2007).

**\*New York.** A bill was introduced on 25 April 2007 that would enact the Uniform Anatomical Gift Act. The bill is still under consideration. S.B. 5154, 230th Gen. Reg. Sess. (N.Y. 2007).

**\*Texas.** A bill passed the Senate on 14 May 2007 to amend the state's anatomical gift act. The bill is currently under consideration in the state house. S.B. 1597, 80th Leg., Reg. Sess. (Tex. 2007).

**\*Washington.** A bill passed the state house on 12 March 2007 to amend the state's anatomical gift act and is currently in the state senate. H.B. 1637, 60th Leg., 2007 Reg. Sess. (Wash. 2007).

## INFORMED CONSENT

*Informed consent* is a legal principle that can be understood as shifting some of the risks for treatment from the provider to the patient who has "assumed the risk" after being fully informed. What constitutes being fully informed from the patient's perspective is clearly the essence of informed consent, but, from a legal perspective, what a reasonable person would want to know creates certain specific disclosure requirements. These requirements can come from standard medical practice, reasonable expectations on the part of patients, and from government standards for disclosure. When disclosure requirements are clear, the question arises whether a provider who complies with those requirements can be held liable if a patient suffers an unanticipated adverse event or one the government established standard did not require the provider to disclose. Of specific interest is that the U.S. Supreme Court has granted *certiorari* in a case in which a medical device manufacturer's defense is that it should not be held liable for the plaintiff's injuries because it complied with all of the labeling requirements of the U.S. Food and Drug Administration (FDA). The Court is also considering granting *certiorari* on a similar case involving a drug manufacturer.

### Recent Cases, July - September 2007

\***Federal.** The U.S. Supreme Court granted *certiorari* on 25 June 2007 in *Charles R. Riegel, et ux v. Medtronic, Inc.* The case involves an angioplasty procedure in which the catheter balloon reportedly burst, causing complications for the patient. Medtronic claims it should not be susceptible to suit under state law because the device was already subject to federal regulations with which it complied to receive FDA approval. *Charles R. Riegel, et ux v. Medtronic, Inc.* S. Ct. (U.S. No. 04-0412).

\***The U.S. Supreme Court** is also considering *certiorari* in the case of *Wyeth v. Levine*. In this case, Diana Levine suffered the amputation of her arm as a result of being injected with the Wyeth anti-nausea drug Phenergan. Levine argued and won at the state level (Vermont) that Wyeth was negligent in its failure to provide adequate warnings of a known danger of injecting Phenergan directly into a patient's vein. Wyeth's position is that the jury should not have been allowed to consider Levine's claim because Wyeth's label for Phenergan complied with FDA regulations for prescription drug labeling. The Court's decision as to whether or not it will hear the case is expected within the next two months. *Wyeth v. Levine*. S. Ct. (U.S. no. 06-1249).

### Recent Laws and Regulations, July - September 2007

\***California.** On 12 October 2007, the governor signed into law the California Routine HIV Screening Bill. The bill revoked the need for written informed consent for HIV testing. Patients will now only need to give verbal consent to HIV testing as part of a routine blood workup. Ch. 550. A.B. 682, 2007-2008 Leg., Reg. Sess. (Cal. 2007); Cal. Code Regs. tit. 106 § 120990, 125090, 125107 (2007).

\***Georgia.** On 1 July 2007, the governor signed into law a bill (H.B. 147) that requires every woman seeking an abortion be offered an ultrasound and the option to see her fetus before an abortion may be performed. The attending physician must either offer to perform one or provide the patient with a list of providers, facilities, and clinics that can perform the procedure. "A Woman's Right to Know Act." GA. Act. 207 (2007).

\***Massachusetts.** A bill was withdrawn that would have amended existing pre-abortion requirements for a 24-hour period between when a woman receives state-mandated information and performance of the abortion procedure. H.B. 1687, Gen. Assem., Reg. Sess. (Mass. 2007).

## UNCONVENTIONAL TREATMENT

Questions regarding the medical use of marijuana seem to be back in the news. While medical use advocates haven't gained any ground in this reporting period, a recap of some of the most recent legislation

is in order, particularly since the medical marijuana entries included here weren't included in earlier issues of "Legal Trends in Bioethics."

### Recent Cases, July - September 2007

**\*Federal.** On 7 August 2007, the U.S. Court of Appeals for the District of Columbia Circuit decided in *Abigail Alliance v. Von Eschenbach* 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 ongoing clinical trials or otherwise qualify to obtain experimental drugs through existing FDA access programs should have a right to purchase those 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. U.S. Ct. App. D.C., 7 August 2007 (Case no. 04-5350).

\*On 21 February 2007, a suit was filed by the Americans for Safe Access against the DHHS and the FDA in an Oakland, California federal district court for allegedly violating the federal Administrative Procedure Act by publicly releasing "false and misleading statements" about the benefits of the use of medical marijuana. The suit is calling for the DHHS and the FDA to retract and correct statements that there are no sound scientific studies supporting the medical use of marijuana. The government filed its response on 25 May 2007, and the case is now pending before Judge William Alsup for his decision. *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.** On 22 June 2007, a private citizen, Damien LaGoy, filed suit against the Colorado Department of Health and Environment claiming its five-patient per marijuana provider rule was arbitrary and unfair. On 3 July 2007, the Denver District Judge granted a temporary injunction preventing the state from enforcing its five-patient rule. As yet, no date has been set for a trial on the merits. D. Montero, "Pot law on hold," *Rocky Mountain News*, 4 July 2007.

**\*Missouri.** The Missouri State Medical Association filed suit in June 2007 to enjoin implementation of a law that would have allowed midwives to deliver infants without the supervision of a trained nurse or doctor. The midwife provision of an insurance law was challenged on the grounds that it was passed without adequate opportunity for discussion; it was added to an insurance-related bill without notifying legislators of the change in the bill. Cole County Circuit Court placed a temporary injunction on the law in June and a permanent injunction on implementing the midwifery portion on 7 August 2007. The group Missouri Midwifery Supporters plans to appeal the case to the state supreme court. "Missouri Judge Issues Permanent Injunction Against State Law That Would Allow Midwives to Deliver Infants at Home," *Kaiser Daily Women's Health Policy Report*, 10 August 2007, [www.kaiser-network.org/daily\\_report.cfm?DR\\_ID=46799&dr\\_cat=2](http://www.kaiser-network.org/daily_report.cfm?DR_ID=46799&dr_cat=2), accessed 11 August 2007.

### Recent Laws and Regulations, July - September 2007

**\*Federal.** The FDA is still considering regulations to expand its current Compassionate-Use Programs that make experimental drugs available to individuals or groups under certain circumstances. The rules make drugs available during all stages of development, including during Phase I testing, and allow manufacturers to charge the cost of making and providing the drugs, but not to make a profit. Such regulations would allow patients to use drugs before safety trials have been completed (Phase I) and before testing for efficacy has even begun (Phase II). "Expanded Access to Investigational Drugs for Treatment Use," 71 *Fed. Reg.* 75147 (14 December 2006).

**New Mexico.** On 3 April 2007, the governor signed into law the Lynn and Erin Compassionate Use Act which permits a "practitioner" to prescribe "medical cannabis" to a "qualified patient" with "debilitating medical conditions." Ch. 210. S.B. 523, 48th Leg., Reg. Sess. (N.M. 2007).

**Oregon.** On 25 June 2007, the governor signed into law a bill (S.B. 161) that would require the Oregon State Department of Human Services (DHS) to conduct a criminal records check for persons who are responsible for a marijuana cultivation site. It also authorizes the DHS to deny an application for a registry identification card to persons prohibited by court order from obtaining a registry identification card. Similarly, it requires the DHS to revoke registry identification cards that were issued to persons prohibited by court order from participating in medical use of marijuana. Or. Ch. 573 (2007).

**Rhode Island.** On 22 June 2007, the state legislature overrode the governor's veto of the repeal of a law's expiration date. The Edward Hawkins and Thomas Slater Medical Marijuana Act, which was due to expire on 30 June 2007, is still law. The act prevented a qualifying patient who has in his or her possession a registry identification card from being subject to penalty in any manner for the medical use of marijuana, provided that the qualifying patient possesses an amount of marijuana that does not exceed 12 marijuana plants and 2.5 ounces of usable marijuana. Ch. 72, H.B. 6005, 2007 Gen. Assem., Jan. Sess. (R.I. 2007).

## LIFE-AND-DEATH DECISIONS

### Recent Laws and Regulations, July - September 2007

\***Georgia.** The governor signed an act effective 1 July 2007 that revises Georgia's advance directive laws. Among other things, the law combines Georgia's living will and durable power of attorney provisions into one form. It also provides for the creation of a website for the purpose of providing consumers information on the cost and quality of healthcare in Georgia. Ga. Act. 48 (2007).

### Interesting Developments in Other Countries

\***Canada.** After investigation, the government decided not to press charges against members of the Right to Die Society of Canada for counseling a Canadian citizen to travel to Switzerland to die in accordance with Swiss physician-assisted suicide laws. The decision not to prosecute in this case was based on a lack of evidence, not on a conclusion that such assistance was legal. J. Lalsevac, "No Charges Laid in Nova Scotia Assisted Suicide Case," *Lifesite.net*, 5 July 2007, <http://www.lifesite.net/ldn/2007/jul/07070511.html>, accessed on 5 November 2007.

\***United Kingdom.** The Mental Capacity Act of 2005 will incrementally go into effect between April and October 2007. Under this act, patients are permitted to write advance directives that specifically refuse treatment if their illness meets statutorily specified conditions or to appoint what the British call "lasting powers of attorney," that is, durable powers of attorney or healthcare proxies. Patients can refuse and request the withdrawal of life-saving/life-sustaining treatment including the withdrawal of nutrition and hydration. Under the law, if physicians or nurses refuse to comply with qualifying patients' directives, they could be prosecuted for "willfully neglecting" an incapacitated patient or for assault. A copy of the act can be found at <http://www.dca.gov.uk/menincap/legis.htm>.

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

### Recent Cases, July - September 2007

\***California.** (Ongoing litigation.) *Taus v. Loftus, et al.* is a case in which a child abuse victim gave permission (at age 17) — and so did her father — to be interviewed, and for the taped interview to be shown for "educational purposes." A case study was published that referenced "Jane Doe," but other identifying information was disclosed about the young woman when the researcher gave presentations about the case,

including videotaped interviews with the subject in which the subject's first name was used by the researcher, and the city where the subject lived as a child was disclosed. Based on this information, in conjunction with information disclosed in the researcher's published case study, reporters discovered more about the case and published allegedly defamatory remarks about the subject and the researcher's claims regarding her recovery of repressed memories. 2005 Cal. App. Unpub. LEXIS 3048, 22 media L. Rep. 1545. *Taus v. Loftus, et al.*, 2006 CA S. Ct. S133805. On appeal, the opinion was affirmed in part and reversed in part, and the matter is remanded to the court of appeals for further proceedings. 2007 Cal. LEXIS 2340 (26 February 2007) (Case # S133805).

### Recent Laws and Regulations, July - September 2007

**\*Federal.** There has been no action on a bill that was introduced in the House that, among other things, would encourage the use of electronic health records. The bill was referred to the House Ways and Means Committee Subcommittee on Health on 25 April 2007. H.R. 1952, 110th Cong. (1st Sess. 2007). C. Itkowitz, "Clinton to Reintroduce Health IT, Respite Care Proposals," *Congressional Quarterly*, 17 February 2007, "Health-Beat."

The FDA, however, is working on a proposed rule to regulate the electronic health records that are transferred directly from a medical device to a database. The justification for such regulation is that such records are part of the device itself. J. Miller, "FDA to propose rule on e-health records," *Government Health IT*, 5 June 2007, <http://govhealth.it.com/article102901-06-05-07-Web&print Layout>, accessed 6 June 2007.

There were two bills introduced in Congress on 16 January 2007 (placed on Senate calendar 30 April 2007 and referred to the HELP Committee by Senator Edward Kennedy, D-Massachusetts) that would make it illegal for an employer or health insurer to access genetic information and then make either insurance coverage or decisions regarding the hiring, firing, or promotion of an employee based on such information. The house version of the Genetic Information Nondiscrimination Act was passed and the senate version is still in the senate committee. H.B. 493, S.B. 358, 110th Cong. (1st Sess. 2007).

**\*Pennsylvania.** A bill passed the state house that amends the Newborn Child Testing Act. The bill is currently in the Senate. The bill provides a list of required newborn screening tests and allows the Department of Health, with the approval of the board, to add to the list. H.B. 883, 191st Gen. Assem., Reg. Sess. (Pa. 2007).

### HIV

All states have complied with the name-reporting requirements under the Ryan White Grant Program. Anonymous HIV testing is now a thing of the past in the United States.

### Recent Laws and Regulations, July - September 2007

**\*Federal.** By the end of 2007, all states and D.C. will be required to report their HIV cases by name, not anonymously, if they wish to receive funding from the DHHS under the federal Ryan White Grant Program. 42 U.S.C. § 201.

On 25 September 2007, the U.S. House of Representatives passed by voice vote a bill that would alter HIV testing requirements for federal prison inmates. The bill would require inmates to be required 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.** On 11 September 2007, the governor signed into law S.B. 443. The law will allow HIV-positive men to use their own sperm in fertility treatments (there is a process by which sperm can be "washed" of HIV). Ch. 207 (Calif. 2007).

On 12 October 2007, the governor signed into law a bill 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).

**\*Georgia.** The governor signed a bill that would require doctors to offer all pregnant women an HIV test effective 1 July 2007. Women can opt out of the test, but such refusal becomes part of their medical record. GA. Act. 60 (2007).

**Illinois.** On 14 August 2007, the governor provided an amendatory veto for a measure that would have required healthcare providers to test a pregnant woman for HIV, unless she declines the testing in writing. In his veto message, the governor proposed changes that would allow a woman to give her refusal verbally and mandate testing of newborns whenever the mother's HIV status is unknown.

Both houses have since accepted the amendatory veto and the bill will go into effect on 1 June 2008. H.B. 1759, 95th Gen. Assem., Reg. Sess. (Ill. 2007); 410 Ill. Comp. Stat. 335/10 (2007).

**Massachusetts.** A bill was introduced on 10 January 2007 and received a hearing in the Senate Committee on Public Health on 26 September 2007. The legislation would require any healthcare provider attending to a pregnant woman to supply her with information relating to HIV and AIDS, and to also give her the information necessary to make an informed decision about testing, including information about the availability of anonymous testing, and present her with the option of being tested. The woman would be required, in a manner to be prescribed by the Massachusetts State Commissioner of Health, to acknowledge receipt of the information. If she elects to undergo testing, the healthcare provider must arrange such a test to take place as early as possible or within four weeks. S.B. 1293, 185th Gen. Assem., Reg. Sess. (Mass. 2007).

**\*Rhode Island.** On 2 July 2007 and 6 July 2007, two identical bills initiated in the Rhode Island House and the Rhode Island Senate became law without the governor's signature. The bills permit a healthcare provider to perform an HIV test on a pregnant woman unless she explicitly refuses the test. H.B. 6095, Gen. Assem., Reg. Sess. (R.I. 207) and S. 0841, Gen. Assem., Reg. Sess. (R.I. 2007), Ch. 170; Ch. 279.

### Interesting Developments in Other Countries

**Canada.** A new law in Alberta allows emergency workers who believe they may have been exposed to HIV to request a court order from a judge requiring the person responsible for the possible exposure to submit to a blood test. *Kaiser Daily HIV/AIDS Report*, 17 September 2007, [http://www.kaiser-network.org/dailyreports/rep\\_index.cfm?DR\\_ID=47528](http://www.kaiser-network.org/dailyreports/rep_index.cfm?DR_ID=47528), accessed 4 November 2007.

**\*India.** Star Health and Allied Insurance, an Indian insurance company based in the Chennai province, in July launched that country's first insurance policy that covers people living with HIV/AIDS. Under the policy, an HIV+ individual with a CD4+ T-cell count of 500 copies per cubic millimeter of blood or more will pay an annual premium of 3,000 rupees (about \$74) for coverage. If the disease progresses to full-blown AIDS, the company will pay a one-time compensation of 50,000 rupees (about \$1,200) to the individual. Star Health and Allied Insurance has partnered with 1,800 hospitals and laboratories across the country to administer tests to measure the CD4 counts of those seeking coverage. V. Jagannathan, Chair of Star Health, told the *Times of India* that "at present, we have fixed the premium at \$74. However, we plan to revise that and lower it at the next renewal." K. Sinha, "Insurance Coverage for HIV+ Likely," *Times of India*, 12 July 2007.

**\*Libya.** On 16 July 2007, the Supreme Council commuted the death sentences of five Bulgarian nurses and a Palestinian doctor who had been convicted of intentionally infecting 426 children at Al Fateh Children's

Hospital in Benghazi, Libya with HIV-contaminated blood products, after a \$460 million compensation package for the families of the HIV-positive children was arranged through an international fund supported by several countries including Bulgaria and other Balkan nations. "Libya's Judicial Council Commutes Death Sentence for Medical Workers in HIV Infection Case," *Kaiser Daily HIV/AIDS Report*, 17 July 2007, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=1&DR\\_ID=46261](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=46261), accessed 13 August 2007.

**Peru.** All blood banks in Peru have been closed because at least four people were infected with HIV after a blood transfusion performed in a public hospital. Associated Press, "HIV Spurs Peru Blood Bank Closings," MSNBC.com, 13 September 2007, <http://www.msnbc.msn.com/id/20765564>, accessed 4 November 2007.

## CONSCIENTIOUS OBJECTIONS (HEALTHCARE PROVIDERS AND RELATED PROFESSIONS)

### Recent Cases, July - September 2007

**\*California.** The state supreme court agreed to hear a case involving two physicians who refused to provide intravenous fertility treatment to a lesbian couple. The state supreme court granted review on 14 June 2006, but is accepting briefs until October 2007. After that the court will set a date to hear the case. *North Coast Women's Care Medical Group, et al. v. Superior Court of San Diego County, Guadalupe T. Benitez (Real Party in Interest)*. Cal. Supreme Ct. Case. No. S142892.

### Recent Laws and Regulations, July - September 2007

**Washington.** On 26 July 2007, two new regulations went into effect that require pharmacists to sell emergency contraception, commonly known as the "morning after" pill, regardless of any moral or religious objections they may have. The rule does make an allowance if the pharmacist can find a coworker to fill the prescription, but only if the patient is able to get the drug in the same pharmacy visit. Several pharmacists have since sued the state, saying the rule violates their civil rights by forcing them into "choosing between their livelihoods and their deeply held religious and moral beliefs." See discussion of case above. Wash. Admin. Code § 246-869-010.095 (2007).

## MENTAL HEALTH

### Recent Laws and Regulations, July - September 2007

**Federal.** On 27 September 2007, The Joshua Omvig Veterans Suicide Prevention Act was sent to the President for his signature. The act directs the Secretary of Veterans Affairs to develop and implement a comprehensive program designed to reduce the incidence of suicide among veterans. H.R. 327, 110th Leg., 1st Reg. Sess. (2007).

**\*The Senate passed** on 18 September 2007 a bill that would require insurers to cover mental illness at the same level as they cover physical illness. The bill is now being considered by the House. H.R. 1424, S.B. 558, 110th Leg., Reg. Sess. (2007).

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

There is not much to report in this category right now, but with time, the number of entries is sure to grow.

### July - September 2007

**\*Federal.** The FDA Nanotechnology Task Force issued its report on 25 July 2007. The report essentially concluded that there was no need for the FDA to rush to regulate the advertising of nanotechnology. The FDA should consider each product using nanotechnology on a case-by-case basis, since there is nothing inherent about nanotechnology that warrants a special form of labeling or special warnings to consumers. FDA, "Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force," 25 July 2007, <http://www.fda.gov/nanotechnology/taskforce/report2007.html>, accessed 25 July 2007.

### Interesting Developments in Other Countries

**United Kingdom.** On 5 September 2007 the Human Fertilisation and Embryo Authority decided it has jurisdiction to look at protocols considering the creation of embryos that are part human and part animal. The authority is expected to make its first decisions as to the acceptability of hybrid embryos in November. R. Weiss, "Britain to Allow Creation of Hybrid Embryos," *Washington Post*, 6 September 2007, A11.