

# Legal Trends in Bioethics

*Sigrid Fry-Revere, Alison Mathey, Nathaniel B. Revere,  
Deborah Chen, and Devon Zebrovius*

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

The opinions expressed in the introductory sections are those of Sigrid Fry-Revere, and may or may not be shared by her contributing authors.

## GENERAL INTRODUCTION

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 has its own constitutional protections, some of which clearly mirror those in the U.S. Constitution, while others do not.

Legislatures and courts play different roles in our constitutional republic. Legislatures are by nature democratic and can react relatively quickly to changes in the political climate. Courts, on the other hand, are inherently antidemocratic. As a matter of fact, their main constitutional function is to protect the rights

established by the federal and state constitutions from violation by legislative and executive action. Courts are also inherently conservative in their reaction to events because they are bound by precedents and procedural processes that are designed to assure that major philosophical changes happen gradually.

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

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

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**Sigrid Fry-Revere, JD, PhD**, is President of the Center for Ethical Solutions in Waterford, Virginia.

**Alison Mathey** is a Second-Year Law Student at Catholic University, Columbus School of Law, in Washington, D.C.

**Nathaniel B. Revere** is a Junior at the College of William and Mary in Williamsburg, Virginia.

**Deborah Chen** is a Junior at the College of William and Mary.

**Devon Zebrovius** is a Second-Year Law Student at Catholic University, Columbus School of Law. ©2008 by *The Journal of Clinical Ethics*. All rights reserved.

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; those subjects with the most activity or the most significant activity are listed first. The order of subject headings can vary, depending on what subjects have the most legal activity in any given quarter.

## INTRODUCTION

There is nothing in this "Legal Trends" that will not be significantly affected by the presidential election in November. In reading through the proposed and enacted laws and regulations described in this issue, it is worth keeping in mind that no matter how enthusiastic the new president is about his plans for the future, little can be accomplished without the cooperation of Congress, the states, the judiciary, and ultimately the people.

The period covered by this column was technically prior to the election, but relevant ballot measures results, such as the Washington Aid in Dying initiative, the Michigan Medical Marijuana Initiative, the Colorado and South Dakota anti-abortion initiatives, and others have nevertheless been included. Other significant post-election developments will be reported in the next issue.

## FOOD & DRUG ADMINISTRATION

Within the next few months the U.S. Supreme Court will decide the Food & Drug Administration (FDA) pre-emption case of *Wyeth v. Levine* (see below). Pre-emption cases are not new to the U.S. Supreme Court, and as we have reported in previous "Legal Trends," even FDA pre-emption cases aren't new to the Supreme Court (see discussion of *Riegel v. Medtronic, Inc.* and *Warner-Lambert v. Kent* in past "Legal Trends," *JCE* 19, no. 2, pp. 170-2 and 19, no. 3, p. 276). The overarching issue is how to balance federal and state authority to best protect citizens from unscrupulous drug and device manufacturers. The more immediate legal issue is who decides whether there has been pre-emption of state law by federal law and who has the authority to decide how best to achieve the desired balance of power. The Supremacy Clause of the U.S. Constitution, U.S. Const. Art. VI, c1.2, clearly states that federal law is supreme over state law, but that does not settle the question. The Constitution also clearly sets limits on what types of laws the federal government is authorized to promulgate and reserves specific areas of authority to the states.

The first questions to be answered in pre-emption cases are: "Has Congress passed a law that is relevant to the situation in question?" "Was it within Congress's authority to pass such a law?" "If yes, does that law expressly pre-empt state law?" And finally, "If not expressly, does the law passed by Congress implicitly pre-empt state law?" In February, the Supreme Court ruled that the federal Medical Device Amendments of 1976 (21 U.S.C. § 360k(a)) expressly pre-empt state law (*Riegel v. Medtronic, Inc.*, 552 U.S. \_\_\_\_ (2008), "Legal Trends," *JCE* 19, no. 2, p. 171). Since *Riegel*, it is now clear that state regulations or action that in any way contradicts federal law with respect to medical devices are legally null and void. (But see below. Legislation has been introduced in Congress to reverse the *Riegel* ruling.) Unlike the Medical Device Amendments of 1976, there is no law passed by Congress that specifically provides for the pre-emption of state law by federal law or regulation for drugs. But federal law under the Supremacy Clause, as interpreted by the Supreme Court, still pre-empts state law if an act of Congress implies pre-emption, either because a state law directly conflicts with a federal law ("conflict pre-emption"), or if in practice the federal law is so comprehensive that there is no room for state regulation ("field pre-emption"). Obviously the standard for finding implied pre-emption is far more open to interpretation than a finding of express pre-emption. Thus, unlike in *Riegel*, in *Wyeth*, the Supreme Court has more leeway to act on the broader issue of how best to balance state and federal power to protect U.S. citizens from unscrupulous manufacturers.

### Recent Judicial Cases and Regulatory Actions July-September 2008

**\*Federal.** On 3 November 2008, the Supreme Court heard oral arguments in the state law pre-emption case of *Wyeth v. Levine*. The issue in *Wyeth* is whether compliance with federal FDA regulations shields the makers of prescription and over-the-counter drugs from state tort lawsuits. Levine sued Wyeth in state court, claiming that the company should have warned against use of the IV-push method for its anti-nausea drug, Phenergan, and not just the FDA approved warning against using an IV-drip. The described risk was that arterial exposure to the drug could lead to gangrene. Levine was awarded \$6.7 million in damages from Wyeth by a **Vermont** jury after Phenergan was improperly administered through an IV-push, resulting in the drug reaching Levine's artery and causing gangrene, which resulted in the amputation of her lower right arm and hand. In *Wyeth*, the Supreme Court will decide whether the FDA's regulatory labeling standards represent a minimum to which states are permitted to add, or if the FDA has the authority to decide on the risks and benefits associated with labeling to the exclusion of any additional state regulation. *Wyeth v. Levine*, S. Ct. Docket No. 06-1249.

\*On 3 July 2008, in the U.S. District Court in **Maryland**, the Justice Department sought a court order to force Ranbaxy Laboratories Ltd. to turn over an audit proving that it distributed adulterated and misbranded products. The Justice Department is investigating whether Ranbaxy destroyed reports it was required to keep, falsified data, and failed to meet quality control specifications in manufacturing generic drugs. Ranbaxy has refused to turn over Parexel's consulting report, claiming the information is protected by attorney-client and work-product privileges. The Justice Department has also alleged that Ranbaxy blended approved and unapproved substances, sometimes using less of the active drug than was mandated by the FDA. An FDA audit in 2006 found significant violations at the company's Paonta Sahib, India, plant. The investigation investigated allegations that Ranbaxy made weak or adulterated HIV drugs that were given to thousands of AIDS patients in Africa. Prosecutors have accused the company of concealing violations of good manufacturing practice regulations from FDA. *United States v. Ranbaxy, Inc.* (U.S. Dist. Ct., Southern Div. MD Case No. 8:2008cv 01764).

\*On 18 July 2008, on a motion for reconsideration, the U.S. District Court for the Southern District of Indiana (Indianapolis Division) vacated the court's September 2007 decision in *Tucker v. SmithKline Beecham Corp.*, which had previously been dismissed on federal pre-emption grounds. The lawsuit involved a

wrongful death/failure-to-warn suit brought under Indiana state law against GlaxoSmithKline concerning the company's antidepressant drug Paxil. The court found no implied conflict pre-emption and declined to rely on FDA's "pre-emption preamble" changes. The case is now reopened for adjudication on the merits, which the court promised to address in the near future. *Tucker v. SmithKline Beecham Corp.* (U.S. Dist. Ct., Southern District IN Case No. 1:04-cv-1748-DFH-WTL).

### Recent Developments in Law and Regulation July-September 2008

**\*Federal.** On 12 August 2008, Senators Kennedy and Leahy introduced a Senate counterpart of the Medical Device Safety Act of 2008 to ensure individuals are not prevented by the Food, Drug and Cosmetic Act from suing device makers under state tort laws. The bill seeks to reverse *Riegel v. Medtronic*, which confirmed pre-emption of state tort suits for FDA-approved medical devices. The device industry warns the bill would result in more lawsuits and ultimately higher healthcare costs. S. 3398 110th Cong. 2nd Reg. Sess. (2008).

\*On 1 October 2008, Congress passed a continuing resolution for the FDA to spend nearly \$300 million in fiscal year 2009. Under the resolution, the FDA will be allowed to count supplemental funding received on 1 July as part of its fiscal year 2008. The effect is to provide the agency with about \$150 million extra, assuming the level extends for the entire fiscal year. In addition, the supplemental funds are available until 30 September 2009 and are largely unspent, providing an additional \$150 million to strengthen the agency. "FDA Nets Nearly \$300 Million More Funding for 2009," *Health Imaging*, 01 October 2008: [http://www.healthimaging.com/index2.php?option=com\\_content&task=view&id=12281&Itemid=118&pop=1&page=0](http://www.healthimaging.com/index2.php?option=com_content&task=view&id=12281&Itemid=118&pop=1&page=0), accessed 13 October 2008.

\*On 11 June 2008, the FDA Accreditation Council for Continuing Medical Education proposed the end of commercial support of continuing medical education. The ACCME proposal is intended to provoke debate on whether unbiased CME is possible when funded by individual pharmaceutical or device companies. ACCME cautioned that comments on the proposal should discuss alternatives. Additionally, ACCME outlined a restrictive new paradigm under which commercial support would be permissible only if all the ACCME's conditions are met. N. Sitthikul and A.M. Kirschenbaum, "ACCME Proposes to Ban Commercial Support for CME," *FDA Law Blog*, 03 July 2008: [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2008/07/accme-proposes.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/07/accme-proposes.html), accessed 11 October 2008.

\*In July 2008, the GAO released a report outlining the FDA's enforcement efforts in the area of off-label use. The report casts doubt on the FDA's ability to monitor off-label drug promotion. United States Government Accountability Office, "FDA's Oversight of the Promotion of Drugs for Off-Label Uses," July 2008: <http://www.gao.gov/new.items/d08835.pdf>, accessed 14 October 2008.

\*The FDA missed the deadline on the 2007 FDA Amendments Act requirement to promulgate new product approval regulations. Other missed deadlines include a report to Congress on best practices for communicating the risk-benefit balance to the public and the development of a post-marketing drug safety website. K. Rawson, "FDAAA Delays: Hurry Up and Wait," *RPM Report*, 19 September 2008: [http://therpmpreport.com/Free/36e4a78a-4950-4fd7-af88-db6f1cd895fd.aspx?utm\\_source=SmartBrief](http://therpmpreport.com/Free/36e4a78a-4950-4fd7-af88-db6f1cd895fd.aspx?utm_source=SmartBrief), accessed 13 October 2008.

\*Representative John Dingell (D-Michigan) revised several of the drug-related sections of the Discussion Draft of the FDA Globalization Act. The updated draft does not significantly alter any sections of the original Discussion Draft, but it does include several new provisions of interest, many of which appear to be aimed at ensuring the purity of drugs. Several of the new additions are blank placeholders left for further updating. The updated draft calls for inspections of drug, active ingredient, device, and device part manufacturing establishments every two years. However, the FDA can permit inspections once every four years if such a time line would be appropriate when considering the class of the products, associated risks of the products, shipping volume, the history of the facility, and any other factors the FDA finds relevant. The draft discussion also adds a section calling for reports to Congress on "the risk-based process for conducting surveillance of eight current good manufacturing practices" under FDA Act § 510(h)(4). "Discussion Draft," [http://energy.commerce.house.gov/FDAGlobalAct-08/Dingel\\_60AXML.pdf](http://energy.commerce.house.gov/FDAGlobalAct-08/Dingel_60AXML.pdf), accessed 13 October 2008.

\*On 4 August 2008, the FDA announced that it will look more closely at conflicts of interest when screening potential members of the influential expert committees that advise the agency on the approval of drugs. The FDA's aim with new policies is to reduce real and perceived conflicts of interest and to ensure the objectivity of its influential advisory committees. Appointments to the FDA committees have come under attack in recent years as Congress and watchdog groups scrutinized the FDA after the withdrawal of the painkiller Vioxx in 2004. Under the guidelines, medical experts with more than a \$50,000 financial interest in companies cannot serve on advisory committees that review their products or the products of competitors. Medical experts with a financial interest of less than

\$50,000 can serve, provided the FDA considers their participation necessary and issues a waiver. The guidelines also allow the FDA in certain cases to prohibit participation on advisory committees by some medical experts. The new rules are weaker than draft guidelines the FDA released for discussion in 2007. Under those proposals, experts with conflicts of up to \$50,000 would have been permitted to attend committee meetings, but not to vote. B. Tansey, "FDA Strengthens Policy on Vetting of Advisors," *San Francisco Chronicle*, 05 August 2008: <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2008/08/05/BUMI124S2O.DTL>, accessed 13 October 2008.

\*On 17 August 2008, the FDA began consideration of regulations to govern the training required for physicians to qualify to dispense narcotics. Under current federal law, doctors need only show they are licensed to practice medicine to register with the Drug Enforcement Administration, which permits them to prescribe narcotics. FDA is concerned about potent and longer-acting narcotics like methadone, fentanyl, and certain formulations of the drug oxycodone, the active ingredient in OxyContin. FDA will most likely require that makers of such drugs develop programs to monitor how they are prescribed. B. Meier, "FDA Weighs Training to Dispense Narcotics," *New York Times*, 17 August 2008: [http://www.nytimes.com/2008/08/17/us/17methside.html?\\_r=1&oref=slogin&pagewanted=print](http://www.nytimes.com/2008/08/17/us/17methside.html?_r=1&oref=slogin&pagewanted=print), accessed 12 October 2008.

#### Interesting Developments in Other Countries July-September 2008

\***International.** On 21 July 2008, FDA announced it expects to station employees in four regions of the world to improve the safety of exports of food and drugs by the end of 2009. U.S. regulators for FDA already work full-time in China, India, Europe, and Latin America. Employees would also be stationed in the Middle East. The Bush administration and lawmakers have called for improvements in the safety of imports after tainted items from China, such as an ingredient in the blood thinner heparin, toys with lead paint, and milk products contaminated with melamine reached consumers. Members of Congress said the FDA hasn't conducted enough inspections abroad as food and drug imports by the U.S. have increased. J. Blum, "FDA Employees Should be Stationed Overseas by 2009," *Bloomberg*, 21 July 2008: <http://www.bloomberg.com/apps/news?pid=20601202&sid=adJjdI1reFKU&refer=healthcare>, accessed 13 October 2008.

#### LIFE-AND-DEATH DECISIONS

On 4 November 2008, Washington State became the second U.S. state to allow terminally ill patients to

take their own lives with state approved medications if such action meets state requirements and is approved by a physician. Oregon was the first state to pass such a law back in 1997. Between 1997 and the end of 2007, state records indicate that 292 Oregonians have availed themselves of the law. <http://www.oregon.gov/DHS/ph/pas/index>, accessed 20 November 2008.

### Recent Developments in Law and Regulation July-September 2008

**\*California.** Two state senate policy committees have approved a bill by Assemblywoman Patty Berg and Assemblyman Lloyd Levine that would require doctors to ask their terminally ill patients if they wish to be informed about end-of-life options, and to inform their patients about specific options — including hospice, palliative care, and withdrawal from treatment — if they chose to hear about options. The state Assembly approved the measure by a 42 to 34 vote on 28 May 2008. The bill now heads to a vote of the full Senate. AB 2747 2007-2008 Leg., Reg. Sess. (Cal. 2007).

**\*Washington.** On 4 November 2008, Washington voters approved the state Death with Dignity Initiative, also known as the Washington State Aid in Dying Initiative. The initiative, based on the death with dignity law in Oregon, would allow mentally competent, terminally ill adults to legally request and self-administer medication to end their lives. Wash. 2008, I-1000: <http://www.sec.state.wa.gov/elections/initiatives/text/i1000.pdf>, accessed 20 November 2008.

### Interesting Developments in Other Countries July-September 2008

**Great Britain.** On 29 October 2008, Great Britain's highest court ruled on a case involving a woman with multiple sclerosis who wanted to have the 1961 Suicide Act clarified with respect to assisted suicide. In particular she planned to go to Switzerland where aid-in-dying is legal, and she wanted to know if her husband, who wanted to accompany her, would be prosecuted for assisting a suicide upon his return to Great Britain. The court ruled it is not the court's proper role to clarify the language of the 1961 act, which states it is illegal to "aid, abet, counsel or procure the suicide of another." Instead, the Court said it was the proper role of Parliament to re-evaluate or clarify the act: <http://www.religiousintelligence.co.uk/news/?NewsID=3190>, accessed 20 November 2008.

**Italy.** On 31 July 2008, an appeal was filed in Italy's highest criminal court in a case reminiscent of the 2005 U.S. case of Terri Schiavo. A lower Italian court granted permission to the father of Eluana Englaro, who has been in an irreversible vegetative state for 16 years, to remove her feeding tube. Since the lower court ruling

on 8 September 2008, Ms Englaro's father has not been able to find a clinic willing to remove his daughter's feeding tube, due to fear of criminal prosecution. The high court has been asked to clarify Italian law on the matter. D. Ariel, "Bitter Fight Over Right-to-Die Case in Italy," *Townhall.com*, 1 August 2008: [http://townhall.com/news/world/2008/08/01/bitter\\_fight\\_over\\_right-to-die\\_case\\_in\\_italy](http://townhall.com/news/world/2008/08/01/bitter_fight_over_right-to-die_case_in_italy), accessed 12 September 2008.

### THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

This quarter saw several anti-abortion measures fail and the election of an abortion-rights-friendly president. It will be interesting to see how the types of laws that are introduced and passed next year differ from the proposals that have dominated both the courts and the state legislatures for the past eight years.

### Judicial Cases and Regulatory Actions July-September 2008

**\*Federal.** The Fourth U.S. Circuit Court of Appeals is set to review the constitutionality of a **Virginia** law prohibiting so-called "partial birth" abortion. In May, the three-judge panel declared the law unconstitutional because the Virginia law is more restrictive than the federal abortion ban. Both laws prohibit physicians from using intact dilation and extraction, but, unlike the federal law, Virginia's law would also charge a physician who performed the procedure by mistake. *Richmond Medical Center for Women v. Herring*, No. 03-1821; opinion: <http://pacer.ca4.uscourts.gov/opinion/pdf/031821A.P.pdf>, accessed 9 September 2008.

**\*On 27 August 2008, the U.S. District Court for Massachusetts ruled** constitutional a law that expands the buffer zones around abortion clinics from 18 feet to 35 feet. The law passed constitutional muster under the First Amendment, the Equal Protection Clause, and the Due Process Clause. The law claims to enhance public safety and access to medical facilities, while preserving protesters' right to express themselves on public ways and sidewalks near clinics. The law does not apply to hospitals. *McCullen v. Coakley*, No. 08-10066-JLT; opinion: [http://www.mass.gov/Cago/docs/press/2008\\_08\\_25\\_bufferzonevictory\\_attachment\\_2.pdf](http://www.mass.gov/Cago/docs/press/2008_08_25_bufferzonevictory_attachment_2.pdf), accessed 20 November 2008.

**\*On 16 July 2008, the U.S. Court of Appeals for the Seventh Circuit found** women who need time off work for infertility treatment may invoke the Pregnancy Discrimination Act as potential protection against adverse action. The ruling involved Cheryl Hall, a secretary who was laid off after taking time off for in vitro fertilization. Other courts have found that sex bias protections do not apply to fertility treatments because

both sexes experience infertility. The panel held that sex-bias protections do apply to IVF because only women undergo the treatment, which usually takes longer to complete than male infertility treatments. *Hall v. Nalco*, No. 06-3684; opinion: <http://caselaw.lp.findlaw.com/data2/circs/7th/063684p.pdf>, accessed 12 September 2008.

\***Illinois.** On 2 September 2008, the Illinois Sixteenth Judicial Circuit for Kane County refused to consider significant portions of a defamation lawsuit brought by the Pro-Life Action League against Planned Parenthood of Illinois. Planned Parenthood was accused of defaming Pro-Life Action League in written statements to a local newspaper saying the League had a “history of violence.” *Scheidler v. Trombley*, No. 07-L 513; opinion: <http://familiesagainstplannedparenthood.org/docs/2008/Label%20Decision.pdf>, accessed 20 November 2008.

\***Kansas.** On 28 July 2008, the Kansas District Court for Sedgwick County denied a motion to dismiss a criminal case against abortion provider George Tiller, MD. Tiller’s attorneys had filed the motion based on their opinion that K.S.A. 65-6703, a state law requiring an independent consulting physician to approve some abortions after 21 weeks’ gestation, was unconstitutional. However, the judge ruled that the law survived all constitutional challenges presented. Tiller faces 19 criminal charges of carrying out late-term abortions without a second opinion from an unaffiliated physician. *State of Kansas v. George R. Tiller* (18th Judicial District Ct. of Sedgwick County Case No. 07 CR 2112).

On 3 October 2008, the Kansas District Court for Sedgwick County ruled that the 17 November hearing of abortion provider George Tiller, MD, would not be delayed as prosecutors were ordered to answer more than 500 charges of misconduct levied by Tiller’s attorneys on 15 September. On 28 September, the court denied a motion made by Tiller’s attorneys to dismiss all charges based on the opinion that K.S.A. 65-6703, a state law requiring an independent consulting physician to approve some abortions after 21 weeks’ gestation, was unconstitutional. However, the judge ruled that the law survived all constitutional challenges presented. Tiller faces 19 criminal charges of carrying out late-term abortions without a second opinion from an unaffiliated physician. *State of Kansas v. George R. Tiller* (18th Judicial District Ct of Sedgwick County Case No. 07 CR 2112).

\***Pennsylvania.** On 19 August 2008, the Pennsylvania Supreme Court unanimously ruled that Governor Ed Rendell misused his line-item veto authority in 2005 to remove abortion counseling language from a budget bill. The court stated that “language-only” vetoes are not permitted without also canceling the au-

thorized money. The language would have subjected any federal family planning funding to the same restrictions as state family planning funds. *Jubelirer et al. v. Rendell*, No. 102 MAP 2006: <http://www.courts.state.pa.us/OpPosting/Supreme/out/J-16-2008mo.pdf>, accessed 8 September 2008.

\***South Dakota.** On 29 September 2008, South Dakota filed a civil lawsuit against Republican State Representative Roger Hunt, who sponsored Proposition 1215/Vote Yes for Life, a law to ban abortion. Hunt reported to the state that Promising Future Inc. received a \$750,000 anonymous contribution, but that since Promising Future Inc. is a corporation, not a ballot question committee, he did not have to reveal the source of the money. The money is purported to be from a single South Dakota resident. The state seeks judgments deciding if Hunt should reveal the source. *South Dakota v. Promising Future, Inc.* No. 24670: <http://www.state.sd.us/attorney/office/publications/pdf/pfjudgement.pdf>, accessed 6 October 2008.

#### Recent Developments in Law and Regulation July-September 2008

\***Federal.** There has been no action (and probably never will be any action) on a draft regulation defining abortion, still under review by the U.S. Department of Health and Human Services (DHHS), and not released for public comment. Regulations under consideration define abortion as “any of the various procedures — including the prescription and administration of any drug or performance of any procedure or any action — that results in the termination of the life of a human being in utero between conception and natural birth, whether before or after implantation.” The draft states that to receive funding under any program administered by DHHS, researchers, clinics, medical schools, and hospitals would have to sign “written certifications” that they will not discriminate against people who object to abortion. This definition could include many forms of hormonal contraception and intrauterine devices. K. Pollitt, “Several ‘Disturbing Elements’ to Potential HHS Rule that Could Limit Birth Control Access,” *Medical News Today*, 5 August 2008: <http://www.medicalnewstoday.com/articles/117427.php>, accessed 9 September 2008.

\***California.** On 4 November 2008 Californians voted down a ballot initiative requiring parental notification and a 48-hour waiting period before a minor can obtain an abortion. Proposition 4 represents the third time in four years that California voters have considered a requirement for parental notification and a waiting period. California Initiative 07-0053 available at <http://www.voterguide.sos.ca.gov/argu-rebut/argu-rebut4.htm>, accessed 20 November 2008.

\*The California Institute for Regenerative Medicine has banned compensating women for donating their eggs to research. The institute claims bans are necessary to avoid creating markets for human eggs that encourage women to risk their health for speculative science. "Efforts to Revise Rules Prohibiting Paying Women for Donated Eggs," *Medical News Today*, 1 August 2008: <http://www.medicalnewstoday.com/articles/117138.php>, accessed 12 September 2008.

\*On 27 September 2008, the governor vetoed a bill claimed to have the aim of making stem-cell therapies and diagnostics funded by California's multi-billion-dollar stem-cell research agency more affordable and more accessible to California residents. The bill also would have made it easier for the California Institute for Regenerative Medicine to fund research beyond politically charged embryonic stem cells. The governor objected that the bill would have eliminated the priority for funding human embryonic stem-cell research and would have placed restrictions on CIRM's oversight committee to adopt intellectual property policies that balance patients' needs and medical research. SB 15, 2008 Gen. Assem., 2nd Reg. Sess. (C.A. 2008).

\***Colorado.** On 4 November 2008, Colorado citizens voted down a proposed right-to-life amendment to the state constitution. Amendment 48 would have amended the Colorado constitution to define "person" to "include any human being from the moment of fertilization" for purposes of the state's constitutional provisions "relating to inalienable rights, equality of justice, and due process of law." Amendment 48 would have established that the human person exists at the moment of conception, classifying abortion and some forms of contraception (including natural family planning) as homicide: [http://www.state.co.us/gov\\_dir/leg\\_dir/lcsstaff/bluebook/2008EnglishVersionforInternet.pdf](http://www.state.co.us/gov_dir/leg_dir/lcsstaff/bluebook/2008EnglishVersionforInternet.pdf), accessed 20 November 2008.

\***Michigan.** On 4 November 2008, Michigan voters approved the state Stem Cell Initiative, also known as CureMichigan. The amendment allows the donation of embryos produced in fertility clinics that would otherwise be discarded. It also allows government funding stem-cell research. Human cloning would continue to be illegal. "Stem Cell Initiative," Proposal 2: [http://www.michigan.gov/documents/sos/Approved\\_Bal\\_Word\\_Stem\\_Cell821\\_246350\\_7.pdf](http://www.michigan.gov/documents/sos/Approved_Bal_Word_Stem_Cell821_246350_7.pdf), accessed 20 November 2008.

\***South Dakota.** On 4 November 2008, South Dakota voters voted down a ballot initiative to ban abortion. Measure 11, or the Abortion Ban Initiative, would have amended the South Dakota constitution so that all instances of abortion in the state, with the exception of rape, incest, or to protect the health of the woman, would become illegal. Doctors performing these abortions could be charged with a class four

felony: [http://www.sdsos.gov/elections/voteregistration/electvoterpdfs/2008/2008regulate\\_performance\\_ofabortions.pdf](http://www.sdsos.gov/elections/voteregistration/electvoterpdfs/2008/2008regulate_performance_ofabortions.pdf), accessed 20 November 2008.

### Interesting Developments in Other Countries July-September 2008

\***Australia.** On 17 September 2008, the Australian government issued its first license allowing scientists to create cloned human embryos to try and obtain embryonic stem cells. Sydney IVF, an in vitro fertilization clinic, was granted the license and has access to 7,200 human eggs for its research. If Sydney IVF is successful, it would be a world first. A ban on therapeutic cloning or somatic cell nuclear transfer was lifted by the Australian national parliament to allow the licensing. M. Perry, "Australia Issues First License to Clone Human Embryos," 17 September 2008: [http://news.yahoo.com/s/nm/20080917/hl\\_nm/australia\\_stemcell\\_dc&printer=1;ylt=AhpVIDo\\_CSYzfZnyLVMEcnbMR.3QA](http://news.yahoo.com/s/nm/20080917/hl_nm/australia_stemcell_dc&printer=1;ylt=AhpVIDo_CSYzfZnyLVMEcnbMR.3QA), accessed 6 October 2008.

\***India.** On 13 August 2008, India's highest court asked Google, Microsoft, and Yahoo to respond to charges that they illegally advertise gender selection products. India bans tests that allow people to know the gender of unborn children. India seeks to block these advertisements. Most Indians prefer sons because they can earn more money in the workplace, while girls are seen as a financial burden because of dowry demands. India loses 7,000 girls every day through abortion. "Internet Giants in Indian Gender Dispute," *Straight Times*, 13 August 2008: [http://www.straitstimes.com/print/Breaking%2BNews/World/Story/STIStory\\_267730.html](http://www.straitstimes.com/print/Breaking%2BNews/World/Story/STIStory_267730.html), accessed 12 September 2008.

\***Japan.** Kyoto University announced that it has obtained a patent on the basics for a method of creating induced pluripotent stem (iPS) cells, which can change into various other types of cells. Professor Shinya Yamanaka successfully created the iPS cells by injecting a genetic cocktail into mouse skin cells. The patent's wording does not specify whether cells used in the creation process are those of animals or humans. Kyoto University claims the patent extends to humans. Kyoto University plans to provide technology to universities in Japan and non-profit research organizations free of charge. Another pharmaceutical company, Bayer Yakuin, also succeeded in producing iPS cells and has also applied for a patent for the production of human iPS cells. "Kyoto University Obtains Patent on iPS Stem Cells," *Mainichi Daily News*, 13 September 2008: <http://mdn.mainichi.jp/mdnnews/news/20080913p2a00m0na001000c.html>, accessed 20 September 2008.

\***Mexico.** On 28 August 2008, Mexico's Supreme Court voted 8 to 3 to uphold an April 2007 Mexico

City law allowing abortion under any condition to any woman in the first trimester of pregnancy. This historic law includes a provision to exempt physicians who are morally opposed to abortion. Mexico City is among the few places in Latin America where women can legally terminate pregnancies apart from cases involving rape and incest. Both opponents and supporters of the decision said the ruling will put pressure on other Mexican states to liberalize abortion policies. The ruling was a defeat for conservative Roman Catholics in Mexico and the conservative National Action Party of President Felipe Calderon. City officials say more than 12,600 women have had abortions since the law was approved. K. Ellingwood, "Mexican Supreme Court upholds legalized abortion law," *Los Angeles Times*, 28 August 2008: <http://www.latimes.com/news/nation/world/world/la-fg-mexabortion29-2008aug29,0,946461.story>, accessed 8 September 2008.

## RESEARCH ETHICS

### Judicial Cases and Regulatory Actions July-September 2008

**\*Federal.** On 21 August 2008, the United States District Court in Newark, New Jersey, ruled that a 16-year-old patient, terminally ill with a rare form of muscular dystrophy, should be allowed to use an experimental drug treatment despite objections from the drug's developer. PTC Therapeutics, the drug developer, contends that the plaintiff does not meet the criteria to be a part of the drug's clinical trial, but, under the ruling, he would be able to start taking the drug by joining the ongoing clinical trial despite his lack of qualifications for the trial. PTC Therapeutics has filed an appeal. *Gunvalson et al. v. PTC Therapeutics, Inc.* (U.S. Dist. Ct. of New Jersey No. 2:2008cv03559, 21 August 2008).

### Recent Developments in Law and Regulation July-September 2008

**\*Federal.** The Center for Biologics and Evaluation Research has found that a statistical demonstration of a serious infection rate of less than 1 per person-year is adequate to provide substantial evidence of efficacy in clinical trials of investigational human immune globulin intravenous products. IGIV products are used as replacement therapy for primary humoral immunodeficiency and are prepared from large pools of plasma collected from individual healthy donors. Center for Biologics Evaluation and Research, "CBER Guidance Addresses Trial Design for IGIV Products," *FDA News Drug Daily Bulletin*, 28 July 2008: <http://www.fda.gov/newsroom/newsletter/article?articleId=108904&issueId=11804>, accessed 20 September 2008.

## Interesting Developments in Other Countries July-September 2008

**\*India.** In 2008, 49 children died during clinical trials at the Delhi-based All India Institute of Medical Sciences. Since January 2006, more than half of the 4,142 children AIIMS enrolled from its pediatric department were below the age of one. Five medicines tested were foreign made. All the trials were conducted after clearance by the Indian Council of Medical Research ethical committee, and strict protocols were followed while conducting the tests. India has become a top Asian destination for clinical trials. DPA, "49 Children Died During Clinical Trials at Top Medical Institute," *Earthtimes*, 18 August 2008: <http://www.earthtimes.org/articles/show/226500,49-children-died-during-clinical-trials-at-top-medical-institute.html>, accessed 20 September 2008.

## HIV/AIDS

### Judicial Cases and Regulatory Actions July-September 2008

**\*Texas.** On 14 May 2008, an HIV-positive man was convicted and sentenced to 35 years in prison for harassing a public official with a deadly weapon. The defendant had spit into the open eye and mouth of a police officer. The defendant will not be eligible for parole until he has served half of his sentence due to the deadly weapon finding. The U.S. Centers for Disease Control and Prevention (CDC) stated that contracting HIV from saliva is extremely rare. According to reports in the *New York Times*, the police officer has not contracted HIV. G. Kovach, "Prison for Man With H.I.V. Who Spit on a Police Officer," *New York Times*, 16 May 2008: <http://www.nytimes.com/2008/05/16/us/16spit.html>, accessed 28 September 2008.

### Recent Developments in Law and Regulation July-September 2008

**\*Federal.** On 30 July 2008, the President signed into law a bill that would reauthorize the President's Emergency Plan for AIDS Relief. The \$50 billion plan allocates \$48 billion for PEPFAR and \$2 billion for American Indian issues; \$5 billion and \$4 billion respectively are provided for malaria and tuberculosis programs; 10 percent of the funds will go to programs for orphans and vulnerable children. The bill requires that more than half of the funds go to HIV treatment and care and overturns a previous law requiring that one-third of HIV prevention funds be spent on abstinence and fidelity programs, instead requiring a report to Congress if countries spend less than half the funds on such programs. The bill also lifts current restric-

tions making it extremely difficult for HIV-positive people to get U.S. visas, a move the Russian government is considering replicating. The previous \$15 billion plan expires at the end of September. The 30 July 2008 PEPFAR ban against foreigners with HIV traveling or immigrating to the United States has been lifted. H.R. 5501, 110th Cong. 2nd Reg. Sess. (2008).

\*On 22 August 2008, the CDC announced it will no longer fund an advanced HIV/AIDS monitoring system in Georgia, Illinois, Maryland, Missouri, Ohio, Oklahoma, Pennsylvania, Puerto Rico, and Tennessee. The HIV/AIDS monitoring system uses a new test to distinguish recent HIV infections from old ones. The change in CDC funding will reduce the number of states using the advanced system from 34 to 24, although total funding for the advanced testing method will remain the same. Federal funding for HIV surveillance had decreased in states struggling to meet CDC standards for HIV monitoring. Julie Scofield, executive director of the National Alliance of State and Territorial AIDS Directors, estimated that the money lost by the jurisdictions was about \$3 million. CDC, "HIV/AIDS Surveillance Report," 22 August 2008: <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/index.htm>, accessed 6 October 2008.

\***California.** On 30 July 2008, the mayor of San Francisco signed into law the 2008-2009 city budget, including \$10 million for HIV/AIDS services. The mayor had rejected a proposal from the director of the city Department of Public Health to cut HIV/AIDS services by \$3 million. Services include legal aid, support groups, acupuncture, and herbal therapy. The director said the city did not provide these services to those who suffer from any other chronic disease, and, if the services are a priority, they should be available to all. The mayor said he could not justify a cut of such magnitude. HIV/AIDS advocates praised the decision, but called for more funding to support the city's growing HIV/AIDS population. G. Newsom, "Mayor's Proposed Budget 2008-2009," City and County of San Francisco, California, 5 August 2008: [http://www.sfgov.org/site/uploadedfiles/mayor/policy0809\\_BUDGETBOOK\\_06-1-08\\_5pm.pdf](http://www.sfgov.org/site/uploadedfiles/mayor/policy0809_BUDGETBOOK_06-1-08_5pm.pdf), accessed 28 September 2008.

\*On 30 September 2008, the governor signed two bills creating a state office to police patients' privacy and to allow the state to issue fines as high as \$250,000 for multiple violations. Financial penalties seek to deter repeated violations of patients' confidentiality. These measures also raise maximum penalties for serious medical mistakes to \$125,000 when their occurrence indicates that other patients may also be in danger. AB 211, SB 541, Gen. Assem., 2nd Reg. Sess. (C.A. 2008).

\***North Carolina.** In November 2008, prisons in North Carolina will begin an HIV screening process for all inmates. Public health officials have formally asked

prison officials to be in line with provisions recommended by the CDC. The testing will become part of the annual physical inmates receive. M. Locke, "More N.C. Prisoners to be Tested for HIV," 25 September 2008: <http://www.newsobserver.com/news/story/1231474.html>, accessed 6 October 2008.

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

#### Interesting Developments in Other Countries July-September 2008

\***China.** Beijing's Health Bureau distributed approximately 400,000 no-cost condoms and 250,000 HIV/AIDS prevention pamphlets to 119 contract hotels during the Olympic Games. The condoms were placed in 90,000 rooms in 424 hotels that were rated three stars or higher. Health authorities trained Olympic volunteers to promote HIV/AIDS prevention during the Olympics and worked with the UN Joint Program on AIDS (UNAIDS) and the international Olympic Committee to distribute information. "Beijing's Health Department Distributes No-Cost Condoms, HIV/AIDS Pamphlets to Olympic Hotels," *Kaiser Daily HIV/AIDS Report*, 18 August 2008: [http://www.kaiser-network.org/daily\\_reports/print\\_report.cfm?DR\\_ID=53999&dr\\_cat=1](http://www.kaiser-network.org/daily_reports/print_report.cfm?DR_ID=53999&dr_cat=1), accessed 20 September 2008.

\***India.** On 11 September 2008, the high court in Mumbai formed a committee to create guidelines aimed at preventing the spread of HIV in prisons in response to the increasing spread of viruses among inmates. These guidelines would address prevention and treatment for prisoners living with HIV/AIDS, and sexual contact between prison inmates. The court also discussed the idea of counseling centers and making anti-retroviral therapy available in the prisons. "Indian High Court Forms Committee to Address HIV/AIDS in Prisons," *Kaiser Daily HIV/AIDS Report*, 15 September 2008: [http://www.kaiser-network.org/daily\\_reports/print\\_report.cfm?DR\\_ID=54443&dr\\_cat=1](http://www.kaiser-network.org/daily_reports/print_report.cfm?DR_ID=54443&dr_cat=1), accessed 20 September 2008.

\*On 29 September 2008, Indian Health Minister Anbamani Ramadoss stated in an interview that the Indian National AIDS Control Programme, which is in Phase III (2007-2012), has been adversely affected by difficulties in reaching out to India's gay population. Ramadoss estimated that there are 2.46 million men who have sex with men (MSM) in India, and that 86 percent of HIV transmission is via sexual contact, including MSM and transgender sexual contact. Ramadoss stated that under Section 377 of the Indian Penal Code, which bans "unnatural sex," physicians who treat MSM and health workers who advise MSM about transmission of HIV could be subject to arrest. "Wake up to Global Reality on Gays: Ramadoss (Interview)," 29 September 2008: [http://www.thaindian.com/newsportal/india/wake-up-to-global-reality-on-gays-ramadoss-interview\\_100101284.html](http://www.thaindian.com/newsportal/india/wake-up-to-global-reality-on-gays-ramadoss-interview_100101284.html), accessed 6 October 2008.

\*Ireland. The Irish Minister for Health Promotion and Food Safety launched an HIV and AIDS Education and Prevention Plan 2008-2012. The plan prioritizes encouraging HIV testing for at-risk groups and educating the public, and includes providing condoms to at-risk groups in targeted health settings for no cost. "HIV and AIDS Education and Prevention Plan 2008-2012," [http://www.dohc.ie/publications/pdf/hivand\\_aids\\_education.pdf?direct=1](http://www.dohc.ie/publications/pdf/hivand_aids_education.pdf?direct=1), accessed 4 October 2008.

\*Liberia. On 02 September 2008, Liberia's House of Representatives passed the Anti-HIV/AIDS Act, which would make it unlawful to disclose a person's HIV/AIDS status without the individual's prior consent. The act states that people with access to medical records cannot release the results of any individual's HIV test. Violation results in a fine of 1,000 Liberian dollars, or about US\$16, and the suspension of a person's professional license or operating permit for at least one year. The act states that people living with HIV have the right to pursue civil action for the disclosure of confidential information. It further states that if the offense is committed by a hospital or clinic, it shall be fined an amount not less than 10,000 Liberian dollars. The act also states that any individual who transmits HIV to another person through negligence or carelessness can be tried for that offense. Finally, the act states that willfully transmitting HIV or continuing to have unprotected sex while aware of one's HIV-positive status is a crime. "Liberia's House of Representatives Passes HIV/AIDS Confidentiality Act," *Kaiser Daily HIV/AIDS Report*, 8 September 2008: [http://www.kaisernetwork.org/daily\\_reports/print\\_report.cfm?DR\\_ID=54323&dr\\_cat=1](http://www.kaisernetwork.org/daily_reports/print_report.cfm?DR_ID=54323&dr_cat=1), accessed 20 September 2008.

\*Zimbabwe. Zimbabwe Lawyers for Human Rights have launched a charter to protect and promote the rights of people living with HIV/AIDS. The charter is a result of concentrated efforts by many national part-

ners committed to ensuring dignity, justice, and equality for all. Zimbabwe has one of the lowest life expectancy rates (35 for men and 37 for women), and 45 percent of its people are malnourished. "ZLHR Launches HIV/AIDS Rights Charter," *Zimbabwe Standard*, 30 August 2008: <http://www.thezimbabwestandard.com/local/18831-zlhr-launches-hivaidrights-charter.html>, accessed 5 October 2008.

## MENTAL HEALTH

### Recent Developments in Law and Regulation July-September 2008

\*Federal. On 23 September 2008, the House approved mental health parity legislation as a stand-alone measure, while the Senate attached its mental health parity bill to the legislation. Republicans are concerned that support for a free-standing measure would reopen the bipartisan Senate tax-extender package. Senators allege that the tax-extender package cannot be changed or the agreement reached on the legislation would fall apart. House Democratic leaders are not acting on the Senate package and instead split it up for consideration and did not include mental health parity. HR 6983, HR 6049, S 3335, 110th Leg., Reg. Sess. (2008).

\*Massachusetts. On 21 August 2008, the governor signed into law a bill that will help the state identify and treat children with mental illness. The bill has been dubbed "Yolanda's Bill," named after Yolanda Tufts, who struggled with anxiety and bipolar disorder before committing suicide. The law strengthens Massachusetts's commitment to children living with mental illness, and helps train teachers, guidance counselors, and nurses to better identify mental health needs in students. Under the law, the Department of Early Education and Care provides behavioral health consultation services in early education and care programs to reach children with mental illness earlier, and encourages behavioral health screening for children during doctors' visits. The law ensures greater cooperation between agencies by creating a children's behavioral health research and evaluation council and service teams to collaborate on cases for children who may need multiple state services. S. 2804, 185th General Court, Reg. Sess. (Mass. 2008).

## ORGAN AND TISSUE PROCUREMENT

### Recent Developments in Law and Regulation July-September 2008

\*Federal. On 25 September 2008, the House passed the Organ Transplant Authorization Act of 2008. This act amends the Public Health Service Act to increase the maximum amount of funds provided for the estab-

ishment and operation of the Organ Procurement and Transplantation Network for any fiscal year. H.R. 6469 110th Cong. 2nd Reg. Sess. (2008).

**\*Missouri.** On 10 July 2008, the governor signed into law a bill that established a first-person consent organ and tissue donor registry. Individuals may withdraw consent to be listed in the registry. Minors old enough to apply for driver's permits may choose to donate organs with parental consent. The law went into effect on 28 August 2008. S.B. 1139, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2008).

**\*New Jersey.** On 22 July 2008, a bill passed that would start a program for high school students in the 2008-2009 school year providing accurate information and dispelling myths about organ donation and the recovery process. The bill would also require all residents to acknowledge the option to become a donor before receiving or renewing a driver's license or identification card. S.B. 755, 211th Reg. Leg. Sess. (N.J. 2008).

**\*North Carolina.** On 2 August 2008, the governor signed into law a bill clarifying unclear language in the Revised Uniform Anatomical Gift Act, passed last year. The bill is clear that the organ donor status on a driver's license is a legally binding directive. The bill also lowers the age of consent for donating blood from 17 to 16. S.L. 2008-153. The act is effective immediately. S.B. 1651, Gen. Assem. 2007-2008 Sess. (N.C. 2007).

#### Interesting Developments in Other Countries July-September 2008

**\*Canada.** On 12 August 2008, federal, provincial, and territorial ministries of health announced a combined investment of \$35 million in the next five years to create an integrated national system, which would significantly improve organ donation and transplantation in Canada. Under the new funding arrangement, the Canadian Council for Donation and Transplantation will merge with the Canadian Blood Services. This merge will expand its mandate and operations beyond blood services and into organ and tissue donation and transplantation. Provinces and territories, except Québec, will provide half the total funding, and jurisdictions will collaborate with Canadian Blood Services in the creation of three priority national registries to more quickly match patients and donors across Canada. Canadian Blood Services, "Organ Donation and Transportation Streamlined in New National System-Patient Donor Registries and \$35 Million in Funding Will Save Lives," *CNW Telbec*, 12 August 2008: <http://www.cnw.ca/fr/releases/archive/August2008/12/c3380.html>, accessed 14 October 2008.

**\*Egypt.** On 23 July 2008, it was discovered that a man who had gone to the hospital to have kidney stones

removed had instead had a kidney stolen by the doctor. For two months, the 43-year-old taxi-driver of meager means thought the kidney stones that gave him trouble had been removed until he received an anonymous phone call. The caller told him that his right kidney had been stolen during the operation. X-rays confirmed the claims by the mysterious caller. The man paid the equivalent of US\$227 for the operation. "Egyptian Doctor Accused of Stealing Patient's Kidney," *Earth Times*, 23 July 2008: <http://www.earthtimes.org/articles/show/220939,egyptian-doctor-accused-of-stealing-patients-kidney.html>, accessed 14 October 2008.

**\*Jordan.** In the past three years, as many as 35 Jordanians have died due to infection or otherwise botched kidney retrieval operations after illegally selling their kidneys, mostly in Egypt and Pakistan. The victims were a group of 120 citizens lured by brokers into selling their kidneys for about 3,000 dinars (US\$4,300) each. The victims belonged to poor families from Palestinian refugee camps of Baqaa and Hussein. The victims endured unsafe operations for the removal of their kidneys and, after returning home, were forced to consult local kidney specialists after suffering complications. The victims' confessions helped authorities to arrest brokers who were involved. "Thirty-five Jordanians Die After Selling Kidneys," *Earth Times*, 03 August 2008: <http://www.earthtimes.org/articles/show/223173,thirty-five-jordanians-die-after-selling-kidneys.html>, accessed 14 October 2008.

#### TRUST / ACCOUNTABILITY

##### Judicial Cases and Regulatory Actions July-September 2008

**\*Federal.** On 14 August 2008, the United States District Court for the Northern District of Illinois ruled that health insurer Amerigroup Corp. must pay \$225 million to settle federal and state claims of fraud in a government health insurance program. The agreement settles allegations that Amerigroup's health plans excluded pregnant women and unhealthy patients in the Illinois Medicaid plan. *United States v. Amerigroup Illinois Inc.* (U.S. Dist. Ct., Northern Dist. Ill. Case No. 1:2005cv01416).

**\*On 27 August 2008, the Ninth U.S. Circuit Court of Appeals in San Francisco, California, reinstated Santa Clara County's lawsuit** against pharmaceutical companies for allegedly overcharging county hospitals for prescription drugs for Medi-Cal patients, in violation of a federal law requiring discounts. The ruling is the first in the nation to find that counties have the right to sue manufacturers under the Veterans Health Care Act of 1992 (Pub. L. No. 102-585). The law requires companies supplying medicines to the Medicaid program (Medi-Cal in California) to sell them to

public hospitals at a specified percentage of their average nationwide price. The government's pricing contracts with manufacturers are intended to benefit counties, which can sue when the contracts are violated. A breach-of-contract suit, although not expressly authorized by the 1992 law, is one way to ensure that drug companies comply with their obligations under the program and provide the discounts. *County of Santa Clara v. Astra USA, Inc.* (9th Cir. San Francisco Case No. 06-16471); opinion: [http://www.ca9.uscourts.gov/ca9/newopinions.nsf/E7C88CA469AACCA882574B2004B658D/\\$file/0616471.pdf?openelement](http://www.ca9.uscourts.gov/ca9/newopinions.nsf/E7C88CA469AACCA882574B2004B658D/$file/0616471.pdf?openelement), accessed 20 November 2008.

\*On 27 August 2008, the United States District Court for the Southern District of Ohio sentenced Steven Warshak, founder of Berkeley Premium Nutraceuticals, to 25 years in prison followed by five years of supervised release, with a fine of \$93,000 for crimes including mail fraud, conspiracy to commit fraud, and money laundering. Warshak and other defendants must forfeit money and assets in excess of \$500 million in profits from the sale of Enzyte, a dietary supplement, which was claimed to promote "natural male enhancement." The United States District Court jury convicted Warshak on 22 February 2008 of five counts of conspiracy to commit money laundering and various types of fraud as well as conspiracy to obstruct proceedings before the U.S. Federal Trade Commission, 12 counts of mail fraud, three counts of bank fraud, and 73 counts of money laundering for a total of 93 counts. *United States v. Warshak*, 562 F.Supp.2d 986 (U.S. Dist. Ct., Southern Dist. Oh. Case No 1:2006cv 00357).

\*On 9 September 2008, the Third U.S. Circuit Court of Appeals ruled that a securities lawsuit can go forward against Merck & Co. stemming from the removal of Vioxx from the market. The suit seeks class action status. The panel reversed a ruling by a federal judge in Newark, New Jersey, who had dismissed the lawsuit brought on behalf of investors in April 2007. Merck announced it will fund a \$4.85 billion settlement expected to resolve roughly 50,000 lawsuits associated with the painkiller Vioxx. Approximately 97 percent of the eligible claimants have enrolled in the settlement program. Payments will be decided through a complicated formula that factors in how serious a claimant's injury is, how much Vioxx was taken, and how many other risk factors the claimant has. *In re Merck & Co. Securities, Derivative and "ERISA" Litigation*, Case No. 07-2431, 07-2432; opinion: [http://www.blbglaw.com/news/media\\_mentions/00081/\\_res/id=sa\\_File1/2008.09.08-MerckThirdCircuit Decision.pdf](http://www.blbglaw.com/news/media_mentions/00081/_res/id=sa_File1/2008.09.08-MerckThirdCircuit Decision.pdf), accessed 20 November 2008.

**California.** On 28 July 2008, a California Court of Appeals in San Francisco upheld a dismissal for Pfizer Inc. for price-fixing claims by drugstores that accused

the company of conspiring to keep cheaper medicines from Canada out of the U.S. market. The court upheld the dismissal of a 2004 lawsuit against Pfizer and 18 other pharmaceutical makers alleging inflated drug prices, which led drugstores to pay more than they should have. *Clayworth v. Pfizer, Inc.* (CA App. Ct., 1st Dist. Ct. of Appeals for San Francisco Case No. A116758); opinion: <http://www.courtinfo.ca.gov/opinions/documents/A116798.PDF>, accessed 20 November 2008.

\***Florida.** WellCare of Florida has agreed to pay \$35.2 million as part of a Medicaid fraud investigation. The payment includes \$24.5 million in estimated Medicaid repayments related to behavioral health claims from 2002 to 2006. The remaining \$10.7 million will be put in escrow while federal investigators continue the probe. The payment is not a settlement, thus allowing the U.S. government and state of Florida to pursue further claims in their continuing investigation. "Wellcare to Pay \$35.2 M in Deal," *St. Petersburg Times*, 19 August 2008: <http://www.tampabay.com/news/business/article775862.ece>, accessed 12 October 2008.

#### Recent Developments in Law and Regulation July-September 2008

\***Federal.** On 26 July 2008, a bill was introduced in the Senate that would require physicians to disclose their financial ties to imaging services when making self-referrals under Medicare. The bill is intended to reduce physicians' incentives for referring patients to imaging providers in which the doctor has a financial stake by requiring them to disclose such ties. The bill would also require physicians to provide beneficiaries with a written list of alternative providers when referring imaging services, such as MRIs, CT scans, and PET scans, in addition to requiring physicians to specify which providers are in proximity to the beneficiary's home. S.3343, 110th Cong. 2nd Reg. Sess. (2008).

\*On 31 July 2008, a bill was introduced in the Senate intended to provide doctors with unbiased information on prescription drugs. The bill will provide an important alternative to the way doctors currently receive their information about drugs. The Independent Drug Education and Outreach Act of 2008 would amend the Public Health Service Act to establish a program to award grants or contracts for the development and production of educational materials concerning the evidence available on the relative safety, relative effectiveness, and relative cost of prescription drugs, non-prescription drugs, and non-drug interventions for treating selected conditions. Grants or contracts would also be established for distribution to healthcare providers who prescribe such drugs, and to their patients,

and for the development and implementation of a program to appropriately train and deploy health professionals to educate physicians and other drug prescribers concerning the relative safety, relative effectiveness, and relative cost of prescription drugs, nonprescription drugs, and non-drug interventions for treating selected conditions. The House of Representatives has introduced a similar bill. H.R. 6752.IH, S.3396.IS, 110th Cong. 2nd Reg. Sess. (2008).

\*On 10 September 2008, the Senate Finance Committee approved two bills that seek to prevent neglect and abuse of elderly patients. The first bill, S.1070, would authorize \$777 million to establish state and local training and assistance programs for long-term care employees. Additionally, the bill would establish a database to identify and track cases of elder abuse. The second bill, S.1577, seeks to establish a nationwide system of background checks to screen potential long-term care employees for a history of abuse or a violent criminal record. These pieces of legislation, which would expand a seven-state pilot program established under the 2003 Medicare law, would provide as much as \$160 million in grants over three years to states that seek to participate in the program. S.1070, S.1577 110th Cong. 2nd Reg. Sess. (2008).

\*On 17 September 2008, the House passed a bill that expands the definition of disability for people claiming discrimination under the Americans with Disabilities Act. The bill states that the Supreme Court erred by “eliminating protection for many individuals whom Congress intended to protect” under the original Americans with Disabilities Act, passed in 1990. According to the bill, courts should not consider the effects of “mitigating measures” such as hearing aids, prescription drugs, and artificial limbs. A better definition would be that an impairment that is episodic or in remission is a disability if it would substantially limit a major life activity when active. S.3406 110th Cong. 2nd Reg. Sess. (2008).

On 29 July 2008, a medical malpractice reform bill was introduced and referred to the Senate Committee on Health, Education, Labor and Pensions. The Volunteer Health Care Program Act of 2008 is designed to promote access to health and dental care by encouraging volunteerism among healthcare providers. The bill would award grants to states to establish demonstration programs that would give qualified healthcare providers sovereign immunity protection for providing uncompensated services. S. 3354, 110th Cong., 2nd Reg. Sess. (2008).

\***District of Columbia.** On 27 June 2008, the District of Columbia Department of Public Health proposed regulations to implement Title I of the SafeRx Amendment Act of 2008. Under the proposed regulation, pharmaceutical retailers would need to be licensed by the

Board of Pharmacy by 1 April 2009. The board will begin to accept applications for licensure on 1 October 2008. “Department of Health Notice of Proposed Rule-making,” D.C. Law 17-013; 55 DCR 4462, *District of Columbia Department of Public Health*, 27 June 2008: [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/files/dc\\_pharmaceutical\\_detailer\\_proposed\\_rule.pdf](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/files/dc_pharmaceutical_detailer_proposed_rule.pdf), accessed 11 October 2008.

\***Kansas.** Effective 1 October 2008, Preferred Health Systems will no longer reimburse hospitals for “serious and costly errors in the provision of healthcare services that should never happen.” Also effective 1 October 2008, Kansas’s largest health insurers stated they will no longer pay for avoidable medical complications that happen in hospitals. A. Atwater, “Hospitals Won’t Get Payments for Errors,” *Wichita Eagle*, 28 July 2008: <http://www.kansas.com%2F101%2Fstory%2F475452.html&tbn=vendio&type=404&lg=en>, accessed 11 July 2008.

\***Massachusetts.** On 10 August 2008, the governor signed into law one of the nation’s strictest limits on gifts given to medical professionals by drug salespeople. A key part of An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care requires that all gifts or payments in excess of \$50 given to physicians by health industry representatives be reported to the Department of Public Health, which will post them on a website for public inspection. The law provides \$25 million to promote electronic medical record-keeping in doctors’ offices and requires the state university to graduate more primary care doctors. It gives regulators the power to hold hearings when health insurers want to raise premiums; requires the state to develop a code of conduct for the drug industry; and includes a \$5,000 fine for every violation. The law is effective 1 January 2009. S.B. 283, 185th Gen. Court., Reg. Sess. (Mass. 2008).

On 15 July 2008, the Massachusetts Joint Committee on Health Care Financing removed requirements from a bill to ban drug companies from providing gifts and meals to physicians. The panel also removed requirements that drug and medical device companies report payments they make to doctors for consulting and speaking to other physicians and that the Department of Public Health post that information on its website. The measure requires drug companies to adopt a marketing code of conduct, such as the one created by the pharmaceutical industry trade association. H.B. 4974, 185th Gen. Court., Reg. Sess. (Mass. 2008).

\***New York.** On 29 August 2008, the governor enacted a moratorium, effective until June 2009, on medical malpractice insurance rate increases, which could halt increases of up to 30 percent. New York physicians currently have the highest malpractice premiums in the U.S. “Governor Patterson Calls for Greater Ac-

cess to Primary and Preventative Care," 24 April 2008: [http://www.ny.gov/governor/press/press\\_0424081.html](http://www.ny.gov/governor/press/press_0424081.html), accessed 12 October 2008.

### Interesting Developments in the Private Sector July-September 2008

\*On 10 July 2008, PhRMA (Pharmaceutical Research & Manufacturers of America) announced the release of a new marketing code, "Code on Interactions with Healthcare Professionals," to take effect in January 2009. It is substantially more restrictive than the July 2002 version, and prohibits distribution of non-educational items (pens adorned with a company or product logo), completely prohibits entertainment and recreational activities, and prohibits company sales representatives from providing restaurant meals to healthcare professionals. PhRMA also urges companies to set publicly stated caps on payments to physicians for speaking engagements. The new marketing code came a day after the Senate passed HR 6331, the Medicare physician payment extension. In issuing the revised code, the industry hopes to respond to a recent round of criticisms and to specify its own changes, rather than be forced to adopt changes from outside parties. "Code on Interactions with Healthcare Professionals," 10 July 2008: <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>, accessed 11 October 2008.

### UNCONVENTIONAL TREATMENT

At this writing, 12 U.S. states have either decriminalized or specifically allowed the use of marijuana for medical use. In some states such as Massachusetts, all types of marijuana use have been decriminalized as long as the police find the person in possession of one ounce or less of marijuana. In such circumstances, no lawyer or court proceeding is necessary, only a fine that can be paid by mail (\$100 in Massachusetts). Other states such as Michigan have passed initiatives specifically allowing medical use of marijuana for seriously ill patients. (For a state-by-state update of medical marijuana related laws see <http://www.mpp.org/legislation>, accessed 20 November 2008.)

### Recent Judicial Cases and Regulatory Actions July-September 2008

**California.** On 6 August 2008, the U.S. District Court of the Central District of California found Charles Lynch, a marijuana dispenser, guilty of five counts of distributing drugs, punishable by at least five years in prison. Prosecutors charged Lynch with distributing marijuana, conspiring to distribute marijuana, and providing marijuana to people under 21 years of age. The

defense portrayed Lynch as a responsible businessman who was duped by the Drug Enforcement Administration when an official told him enforcement on marijuana dispensaries would be dealt with by local authorities, and that he thus was immune from federal prosecution. The DEA denies that any assurances were made. While the growing, use, and sale of prescribed marijuana is sometimes allowed in California, it is fully banned under federal law, which has precedence over state laws. S. Glover, "Morro Bay Pot Dispensary Owner Found Guilty of Federal Charges," *Los Angeles Times*, 06 September 2008: <http://articles.latimes.com/2008/aug/06/local/me-pot6>, accessed 20 September 2008. *United States v. Charles C. Lynch* (U.S. Dist. Ct., Central Dist. of Cal. at Los Angeles, Case No. CR 07-689-GW).

On 20 August 2008, the U.S. District Court of the Northern District of California, San Jose Division, refused to dismiss *County of Santa Cruz v. Mukasey*, holding that the U.S. Constitution bars deliberate subversion of state medical marijuana laws, as doing so would make the state's law unworkable and therefore violate the 10th Amendment. The American Civil Liberties Union argued that the Constitution permits states to determine for themselves what is or is not illegal, and that the federal government's actions undermined this process. Judge Fogel agreed. D. Stancliff, "Judge says Feds violated Tenth Amendment by subverting state marijuana laws," *Times-Standard*, 14 September 2008: [http://www.times-standard.com/ci\\_10461558?source=most\\_viewed](http://www.times-standard.com/ci_10461558?source=most_viewed), accessed 29 September 2008. *County of Santa Cruz v. Mukasey* (U.S. Dist. Ct., No. Dist. Cal. Case No. CV-03-01802-JF); complaint: [http://www.aclu.org/images/asset\\_upload\\_file\\_155\\_32959.pdf](http://www.aclu.org/images/asset_upload_file_155_32959.pdf), accessed 20 November 2008.

**Florida.** In September, advocates for nearly 8,500 institutionalized Medicaid recipients filed a class action lawsuit against the Florida Agency for Health Care Administration, the Florida Department of Elder Affairs, and Governor Charlie Crist. The suit alleges the recipients are illegally forced to receive care in nursing homes rather than in community care, as a result of increased political pressure by nursing homes, fearful of losing funds, to make community-based qualifications more difficult. They hope to bolster their stance with the 1999 Supreme Court ruling in *Olmstead v. L.C. and E.W.*, which equated the unjustified assignment of disabled persons to institutions with discrimination under the American with Disabilities Act. Patients must now be given community care by the states if they desire it, as appropriate, if they can be accommodated. The defendants refute the charge and say the plaintiffs have not proven that community-based care is suitable for each patient. [http://www.aarp.org/research/legal-advocacy/aarp\\_fights\\_for\\_the\\_ability\\_to\\_age\\_in\\_place.html](http://www.aarp.org/research/legal-advocacy/aarp_fights_for_the_ability_to_age_in_place.html), accessed 29 October 2008.

### Recent Developments in Law and Regulation July-September 2008

**Massachusetts.** On 4 November 2008, the people of Massachusetts passed the first statewide ballot initiative to decriminalize the possession of an ounce or less of marijuana. Question 2 replaced the threat of arrest and jail time for the possession of an ounce or less of marijuana with a \$100 fine. Mass. 2008 Ballot Question 2: [http://www.boston.com/news/politics/2008/massachusetts/question2\\_text](http://www.boston.com/news/politics/2008/massachusetts/question2_text), accessed 20 November 2008.

**Michigan.** On 4 November 2008, the people of Michigan passed a ballot initiative to allow terminally and seriously ill patients to use marijuana with a physician's approval. Michigan 2008 Ballot Proposal 1: [http://michigan.gov/documents/sos/APPROVED\\_Bal\\_Word\\_CCC1821\\_246348\\_7.pdf](http://michigan.gov/documents/sos/APPROVED_Bal_Word_CCC1821_246348_7.pdf), accessed 20 November 2008.

### Interesting Developments in Other Countries July-September 2008

**Canada.** On 9 September 2008, three urologists were denied approval by the British Columbia College of Physicians and Surgeons to use a new ultrasound device. The doctors wanted to use the machine in a private setting to attempt to destroy cancer cells in patients with prostate cancer. The College of Physicians argues that the procedure is unproven and should only be part of studies in controlled academic or hospital environments, and that the equipment has not been approved for such use by either Canada or the U.S. The doctors have asked the British Columbia Supreme Court for judicial review of the college's injunction. G. Bellett, "Doctors Go to Court Over Cancer Treatment," *Vancouver Sun*, 9 September 2008, <http://www.canada.com/vancouvernews/news/westcoastnews/story.html?id=9efff6cd-1965-4a1f-b891-2757261487c6>, accessed 19 September 2008.

### Interesting Developments in the Private Sector July-September 2008

**Georgia.** Frustrated with traditional medicine, many primary care doctors are making a switch to concierge, or boutique, medicine. Their patients are assessed an annual fee, anywhere from a few hundred to \$20,000, and the doctors provide such services as same-day appointments, shorter waiting times, and 24/7 call access. Advocates of the program feel that it has more focus on the patient's wellness, with longer visits, fewer case loads, and more in-depth examinations. Opponents argue that the practice is elitist and exclusionary because many people who cannot afford the fee are being forced to rely on emergency rooms for medical

care. The American Medical Association said the concierge services could "raise ethical concerns" if they grow large enough to impact patients' access to care. B. Hendrick, "More Doctors Charging Retainer Fees to Lower their Caseloads," *Atlanta-Journal Constitution*, 8 September 2008: [http://www.ajc.com/search/content/health/stories/2008/09/08/Doctor\\_extra\\_bigfees\\_0910.html](http://www.ajc.com/search/content/health/stories/2008/09/08/Doctor_extra_bigfees_0910.html), accessed 19 September 2008.

**Maryland.** On 18 August 2008, Bethesda-based WellNet Healthcare launched Point to Point Healthcare, a social network between patients and their doctors. The goal of the online network tool is to improve communication between doctors and patients to enable the provision of the best possible care, and to improve the assessment of corporate healthcare plans. The network will protect patients' privacy by using the same software that banks use to protect clients' online banking, although some detractors are still concerned about access. WellNet's toughest hurdle, however, will be to convince its 300,000 primary-care physicians to begin using the network. "WellNet Unveil Point to Point Healthcare," *WellNet Healthcare*, 18 August 2008: <http://www.wellnethealthcare.com/pdfs/news/p2prelaunch.pdf>, accessed 20 September 2008.

## HEALTHCARE COVERAGE

### Judicial Cases and Regulatory Actions July-September 2008

**Federal.** On 4 September 2008, the California Department of Health Care Services agreed to comply with a U.S. District Court order in favor of the Medicaid Defense Fund. On 18 August, the court had granted a temporary injunction requiring the state to eliminate a 10 percent rate cut to Medi-Cal health service providers until the suit is settled. The cut was implemented on 1 July in an attempt to fight the fiscal budget deficit. Medi-Cal, California's Medicaid program, has approximately 6.7 million recipients, and would have lost around \$1.3 billion as a result of the rate cut. MDF alleges that the Medi-Cal reduction would violate laws requiring adequate payments to ensure equal service access between Medicaid beneficiaries and the public. *Indep. Living Ctr. of S. Cal., Inc. v. Shewry*, 2008 U.S. App. LEXIS 19725: [http://www.ca9.uscourts.gov/ca9/newopinions.nsf/4EC95574AAD7692A882574C7005082E4/\\$file/0856061.pdf?openelement](http://www.ca9.uscourts.gov/ca9/newopinions.nsf/4EC95574AAD7692A882574C7005082E4/$file/0856061.pdf?openelement), accessed 30 September 2008.

**Arizona.** On 14 August 2008, Maricopa County Superior Court ruled that 22 signatures on Proposition 101 petitions that had previously been deemed invalid should be counted. These 22 signatures were a random sampling of 5 percent of the names checked by the Maricopa County Recorder's Office and were representative of more than 440 signatures originally con-

sidered invalid; these additional signatures were enough to put the initiative on the November ballot. If passed, Proposition 101, the Freedom of Choice in Health Care Act, would prevent any law from requiring Arizona citizens to enroll in healthcare or health-insurance programs. H. Fischer, "Initiative on Health Care will be on Ballot After All," *Arizona Daily Star*, 15 August 2008: <http://www.azstarnet.com/sn/printDS/252899>, accessed 8 September 2008. As of this writing, votes were still being counted and the final vote was too close to call: [http://ballotpedia.org/wiki/index.php/Live\\_2008\\_election\\_coverage](http://ballotpedia.org/wiki/index.php/Live_2008_election_coverage), accessed 20 November 2008.

**Illinois.** On 26 September 2008, Illinois' First District Appellate Court ruled that Governor Rod Blagojevich does not have the administrative power to expand state-subsidized healthcare without legislative approval. Last year, Blagojevich offered FamilyCare to families of four who earned less than \$83,000 per year, over the objections of the General Assembly and the Illinois Secretary of State. This ruling will affect those families who are currently covered by the program, although their actual numbers are as yet unclear, because Blagojevich's records are minimal, and the administration does not know how many adults were enrolled, how much money in premiums has been collected, or where that money is located. *Caro v. Blagojevich* (Ill. Docket No. 1-08-1061, 26 September 2008); opinion: <http://www.state.il.us/court/opinions/appellatecourt/2008/1stdistrict/september/1081061.pdf>, accessed 20 November 2008.

**Nebraska.** On 26 September 2008, the Third District Court heard arguments on a motion to dismiss a lawsuit regarding how Nebraska's health plan was formerly structured. A 2007 health plan program restricted state employees' health insurance packages based upon where they live; 96 percent of the state's Black employees, living in one of three ZIP Codes in Lincoln and Omaha, had a choice only between two Mutual of Omaha plans and two BlueCross BlueShield (BCBS) plans, while state workers who lived outside those ZIP Codes could also choose BCBS plans with broader coverage. A lawsuit filed last year, which alleged that inferior health coverage was offered to employees who lived in mainly African-American ZIP Codes, was dismissed in July 2008, when the Lancaster Third District Court ruled that the governor and state officials who were named in the suit had sovereign immunity. By that time, however, Nebraska had already decided to alter its health coverage program by making BCBS the only health insurance plan available for the state, and to end the ZIP Code program on 1 January 2009. Attorney for the plaintiffs, Kathleen Neary, amended the lawsuit in August 2008 to charge that state officials are not immune, because they knew, or should have known,

that the program was discriminatory. N. Jenkins, "State to Stop Disputed Insurance Practice," *Journal Star.com*, 8 August 2008, <http://www.journalstar.com/articles/2008/08/08/news/nebraska/doc489cd97e822ba940813658.txt?orss=1>, accessed 22 September 2008.

**\*New Hampshire.** No decision has yet been made in the case of *IMS Health v. Ayotte*, for which oral arguments were held on 9 January 2008. The case states that H.B. 1346, which prohibits the sale of prescription data to pharmaceutical companies, protects doctors' and patients' privacy. Opponents claim the law violates the First Amendment right to free speech by prohibiting the disclosure of truthful information. The consolidation of drug prescription information by companies such as IMS Health and its sale to drug makers can be a useful tool to track which doctors are prescribing which types of drugs; salespeople can use this information to selectively target physicians based on prescription habits. However, the information is also used by the healthcare industry to monitor medication safety, implement drug recalls, and alert physicians to new treatment options. While lower court judges in Maine and New Hampshire sided with the companies in earlier decisions this year, at least 18 other states hope that the impending appellate decision will soon allow them to enact data restriction laws of their own. A ruling is expected by the end of the year. *IMS Health v. Ayotte* (N.H. Dist. Ct. No. 06-cv-280-PB).

#### Recent Developments in Law and Regulation July-September 2008

**Federal.** On 22 September, the Department of Veterans Affairs confirmed it will substantially increase disability benefits for veterans with mild traumatic brain injury. Payments may reach \$600 per month, a large jump from the current \$117 monthly benefit. As many as 320,000 soldiers who served in Iraq or Afghanistan have traumatic brain injury; the majority are mild injury from explosions. Most soldiers recover, but some experience problems for the rest of their lives. The new payments will start in 30 days, and should help 3,500 to 5,000 veterans, with an approximate cost of \$120 million. Department of Veterans Affairs, "VA Announces Changes to the Disability Rating Schedule for Traumatic Brain Injuries and Burn Scars," 23 September 2008: <http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1582>, accessed 10 October 2008.

On 23 September 2008, the Department of Veterans Affairs announced that veterans with 90 days or more of continuously active service who have amyotrophic lateral sclerosis (ALS, also known as Lou Gehrig's disease) will receive support for themselves and their families. The change is based on findings that link military service with an increased risk of devel-

oping ALS. Department of Veterans Affairs, "VA Secretary Establishes ALS as a Presumptive Compensable Illness," 23 September 2008: <http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1583>, accessed 25 September 2008.

On 23 September 2008, the House and Senate passed two compromise mental health parity bills, H.R. 6983 and H.R. 6049. Both require insurers to cover mental illness at the same level as physical ailment. A 1996 law prohibits insurers from setting limits on mental health services, but companies have been sidestepping the law by charging higher co-payments or setting stringent restrictions on access. It is not certain yet where the funding for the bills will originate, nor whether they will be a stand-alone measure or part of a larger package. Both sides of the aisle and President Bush have shown support for the bill. H.R. 6983, 100th Cong. 2nd Reg. Sess. (2008); H.R. 6049, 110th Cong. 2nd Reg. Sess. (2008).

On 23 September 2008, the Senate passed a bill requiring physicians to provide information and support services to women whose babies are diagnosed with prenatal or postnatal conditions such as Down syndrome. Women will be given access to hotlines, support groups, websites, and a national registry of individuals who are willing to adopt children with these diagnosed conditions. The bill allots \$5 million per year through 2013 for the program. A similar measure is pending in the House. As 80 to 90 percent of women who have an abortion do so after their fetus has been diagnosed with a prenatal or postnatal condition, senators hope to alleviate the possibility that physicians will focus on the negative features of the conditions. S1810, 110th Cong. 2nd Reg. Sess. (2008); National Partnership for Women & Families, "Senate Passes Bill on Doctors Providing Information on Down Syndrome Tests," 25 September 2008: [http://www.nationalpartnership.org/site/News2?news\\_iv\\_ctrl=-1&abbr=daily2\\_&page=NewsArticle&id=13590](http://www.nationalpartnership.org/site/News2?news_iv_ctrl=-1&abbr=daily2_&page=NewsArticle&id=13590), accessed 30 September 2008.

On 25 September 2008, the Senate passed a bill that would add \$45 million to a previous \$400 million Medicare package to help low-income seniors with Medicare payments, and to provide higher financial incentives for drug manufacturers to produce antibiotics. Under this bill, drug manufacturers would also receive more intellectual property protections when an antibiotic receives FDA approval. S. 3560, 110th Cong., 2nd Reg. Sess. (2008).

On 25 September 2008, the President signed the American with Disabilities Act Amendment, which expands the original ADA of 1990. The changes provide coverage to those individuals with partial physical disability or impairment that may be treated by medicine or a medical device. With this amendment, Congress intends to give broad coverage and to help

anyone being discriminated against due to a disability. S. 3406, 110th Cong., 2nd Reg. Sess. (2008).

On 27 September 2008, the Senate passed two bills to improve treatment for veterans. The first bill, S 2162, works to help veterans with mental illnesses such as posttraumatic stress disorder (PTSD). The House amended the bill to include increased funding for several programs, such as \$1.9 billion for Veterans Affairs healthcare facilities and \$8 million for PTSD research. The Senate also passed S 3023, which requires the VA to lay out guidelines for the notification of their medical claims in plain language, and requires that they include information about their claims such as timing and evidence. The House has approved the amendments. Both will now go to the President for his signature. S 3023, 110th Cong., 2nd Reg. Sess. (2008), S 2162, 110th Cong., 2nd Reg. Sess. (2008).

On 15 July 2008, Congress overrode President Bush's veto of a Medicaid bill designed to prevent doctors' wages from being cut by almost 11 percent on 1 July 2008 and 5.4 percent on 1 January 2009. Fearful that cutting wages would have discouraged doctors from taking on new Medicaid patients, groups like the AARP applauded Congress. The new legislation will generate the required revenue needed to pay doctors' increased wages by limiting spending on private health insurance plans. H.R. 6331, 110th Cong. 2nd Reg. Sess. (2008).

**California.** On 16 September 2008, the state legislature approved a 2009 fiscal year budget plan. The March 2009 plan will restore most of the 10 percent payment cuts to healthcare providers in California's Medicaid program, Medi-Cal, and will also increase monthly premiums for the state's State Children's Health Insurance Program (SCHIP), Healthy Families. Altogether, the plan is based on \$7.1 billion in budget cuts, but — it is claimed — will not negatively impact the delivery of healthcare services, human services, or education. California State Budget 2008-09 Summary: <http://www.ebudget.ca.gov/pdf/Enacted/BudgetSummary/FullBudgetSummary.pdf>, accessed 20 September 2008.

**Illinois.** On 12 September 2008, the governor announced a plan to allow children to stay on their parents' health insurance plan until age 26, or age 30 for children in the military. The bill is designed as a preventative measure against serious illnesses by allowing young adults to receive annual check ups and to reduce admissions to emergency rooms. H.B. 5285, Gen. Assem., Reg. Session. (Ill. 2008).

**Louisiana.** On 14 July 2008, the governor signed into law the 2009 budget that includes a cut in the state's Medicaid program. The budget's allocation for Medicaid, \$6.76 billion, is nearly \$50 million short of what the state Department of Health and Hospitals requested. The shortfall is a result of the \$4.66 billion

allocated to refund private healthcare providers. H.B. 1, 2008 Leg. Reg. Sess. (La. 2008).

**Massachusetts.** In July, the legislature approved a program to provide financial incentives to recruit young and primary care physicians to the state, in response to an annual survey by the Massachusetts Medical Society that found an average wait time of 36 days to see a primary care physician and up to 100 days to see an internist. The act includes increasing the class size at the University of Massachusetts Medical School, providing tuition and fee waivers to students who will work in-state for four years as primary care physicians after graduation, \$1.7 million toward loan repayment of community health center physicians, and at least \$500,000 for primary care physicians who work for two years in underserved areas. A housing grant or loan program also will be instituted to help doctors buy houses in state. L. Kowalczyk, "Across Mass., wait to see doctors grows: Access to care, insurance law cited for delays," *Boston Globe*, 22 September 2008: [http://www.boston.com/news/local/massachusetts/articles/2008/09/22/across\\_mass\\_wait\\_to\\_see\\_doctors\\_grows/](http://www.boston.com/news/local/massachusetts/articles/2008/09/22/across_mass_wait_to_see_doctors_grows/), accessed 24 September 2008. Legislative program: <http://www.mass.gov/legis/08budget/senate/section2.htm>, accessed 12 October 2008.

On 28 July 2008, the governor introduced legislation that would require employers to increase their share of employees' healthcare costs. The new Employer Fair Share Contribution regulations modify the existing law, which gave employers with 11 or more full-time employees the option to offer health coverage to their workers or pay a penalty of \$295 per worker. Under the new regulations, employers would be required to have at least one-quarter of their work force enrolled in the employer's health plan in addition to paying at least 33 percent of the premium cost of the health plan for all employees working for the first 90 days. Employers that are out of compliance will have to pay the per-worker penalty. A public hearing on the legislation was held 5 September; if it is adopted, it will become effective on 1 October 2008. S.B. 2857, Gen. Assem., Reg. Sess. (Mass. 2008).

**New York.** Later this fall, the New York Department of Civil Service plans to begin a yearlong audit to examine state employees' family health policies. There have been charges that state employees are listing ex-spouses, ex-stepchildren, and grown children as dependents on their health insurance policies long after they have become ineligible. Once the audit begins, employees will be allowed a two-month grace period to remove dependents from their policies. Penalties for violating the taxpayer-funded health insurance regulations could be civil or criminal and could include a refund of premiums and a cut in benefits. The Civil Service Department is currently evaluating bids from

three auditing firms. R. Karlin, "No More Free Ride for Health Insurance," *Albany Times Union*, 3 September 2008: <http://timesunion.com/AspStories/storyprint.asp?StoryID=717255>, accessed 12 September 2008.

On 20 August 2008 the governor signed an agreement with the state legislature enacting a plan to cut more than \$1 billion in state spending, including more than \$500 million in cuts to Medicaid spending over a two-year period. Some savings will be achieved by capping the amount of Medicaid reimbursement that medical facilities receive and lowering Medicaid premiums paid to insurers, all without sacrificing the care given to patients. Cutting the Medicaid budget by this amount would reduce Medicaid spending by more than half. "Governor Paterson Announces Agreement With Legislature To Enact An Over \$1 Billion, Two-Year Savings Plan At Special Economic Session," *New York State*, 20 August 2008: [http://www.budget.state.ny.us/pubs/press/2008/press\\_release08\\_0821.html](http://www.budget.state.ny.us/pubs/press/2008/press_release08_0821.html), accessed 30 October 2008.

## VACCINES

In July 2008, Merck's Gardasil vaccine sales declined from \$1.9-\$2.1 billion, to \$1.4-1.6 billion. This drop is due in part to Merck's failure earlier this year to win U.S. approval to market the vaccine to an older group of women aged 27 to 45. Although consumers and doctors have raised questions about Gardasil's safety, the FDA and CDC said that the most serious adverse events did not appear to be linked to the vaccine; the agencies reviewed approximately 9,700 reports of health problems following Gardasil injections, including Guillain-Barre Syndrome, a rare neurological disorder. ("FDA, CDC back Merck's Gardasil Shot as Safe," *Reuters*, 22 July 2008, <http://www.reuters.com/article/healthNews/idUSN2231596120080723>, accessed 20 September 2008). The downward trend may be offset by a recent FDA approval of expanded use of Gardasil for treatment of conditions other than cervical cancer and genital warts. (See below.)

## Recent Developments in Law and Regulation July-September 2008

**\*Federal.** On 12 September 2008, the FDA approved expanding the use of Merck's Gardasil to protect against cancers of the vagina and vulva. The government estimates 3,460 new cases of vulvar cancer and 2,210 new cases of vaginal cancer occur in the U.S. each year. Merck is also studying the effectiveness of Gardasil in men with the aim of submitting data to the FDA by the end of the year. U.S. Food and Drug Administration, "FDA Approves Expanded Uses for Gardasil to Include Preventing Certain Vulvar and Vagi-

nal Cancers,” 12 September 2008: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01885.html>, accessed 4 October 2008.

### GENETIC TESTING

#### Recent Developments in Law and Regulation July-September 2008

**\*California.** On 19 August 2008, two genetic companies, Navigenics and 23and Me, received licenses allowing them to continue operations in the state. In June, the state health department had sent cease-and-desist letters to these companies and 11 others that offer genetic testing directly to consumers, stating that the companies needed to be licensed to operate as laboratories and have doctors involved in ordering genetic testing. The action was a result of concern over the accuracy and legitimacy of genetic testing sold on-line. Navigenics and 23andMe interpret raw genetic data that is tested by licensed outside labs rather than testing the DNA samples themselves, and both companies employ doctors. After investigating the companies' procedures, the health department was satisfied that both companies' interpretations have a scientific foundation. A. Pollack, "California Licenses 2 Companies to Offer Gene Services," *New York Times*, 20 August 2008: [http://www.nytimes.com/2008/08/20/business/20gene.html?\\_r=2&sq=california%20licenses%20%20companies%20gene%20services](http://www.nytimes.com/2008/08/20/business/20gene.html?_r=2&sq=california%20licenses%20%20companies%20gene%20services), accessed 12 September 2008.

### CONSCIENTIOUS OBJECTION

#### Recent Developments in Law and Regulation July-September 2008

**Federal.** On 21 August 2008, the U.S. Department of Health and Human Services (DHHS) proposed new legislation intended to protect healthcare workers who object to assisting in abortion for moral or religious reasons. The "Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law" bill is designed to protect more than 584,000 workers at government-funded medical facilities — from doctors performing abortions to personnel laying out equipment — from possible retaliation by their employers. The regulation would build on three previous federal funding statutes that prohibit DHHS funds from being distributed to agencies that discriminate against healthcare providers: the 1970s Church Amendments, the 1996 Public Health Service Act, and the 2005 Weldon Amendment. DHHS would require medical facilities to provide written certification that they were following the law, or they would risk losing

government funding. The DHHS accepted public comment on the proposed regulation until 25 September 2008. The Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 45 *CFR* Part 88: <http://www.hhs.gov/news/press/2008pres/08/20080821reg.pdf>, accessed 20 November 2008.