



**THE CENTER FOR
ETHICAL SOLUTIONS**
INNOVATIVE APPROACHES TO HEALTHCARE POLICY

LEGAL TRENDS IN BIOETHICS FALL 2009 ONLINE ISSUE, No. 1

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HOW TO USE THIS RESOURCE

“Legal Trends in Bioethics” is devoted to following bioethics-related developments in judicial cases, legislation, and other regulatory actions as they happen. This column covers topics ranging from informed consent and conscientious objection to end-of-life decisions and HIV / AIDS. Legal Trends follows laws and regulations from their introduction to their promulgation and lawsuits from their inception to their rulings. The column follows all these legal developments both at the federal and state level, and relevant developments in foreign countries or the private sector.

The most effective way to take advantage of this column is to either check the jurisdictions that apply to each state or to check under specific topic headings of interest. Topics listed first are either those with the most activity or those with the most dramatic developments. Within a topic heading, federal cases, laws, and regulations are always listed first, followed by developments in individual states, listed alphabetically.

The following is a key to some of the punctuation used throughout Legal Trends.

(*) An asterisk means the entry is a follow-up entry on a development that was previously covered in Legal Trends.

() The underlined part of every entry is the action taken, e.g., that the law was introduced, approved by a committee, passed, or signed into law; or that a court action was initiated, an intermediate motion granted, or a ruling made.

(bold) The name of the state or federal jurisdiction where the action took place is highlighted in bold.

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 or Alison Mathey at alison.mathey@gmail.com. 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 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 disagree. Thus courts tend to show greater deference to individual choice than legislatures do, and tend to become more cautious when confronted with divisive issues.

An understanding of these inherent tensions between legislative and judicial action and the various individual interests that are balanced by the courts makes it easier to understand legal trends in bioethics. It is also important when considering trends to watch how far bills that are introduced advance. 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; however, the bill 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.

END-OF-LIFE DECISIONS

The most significant developments in this column of Legal Trends are not the highly anticipated healthcare reforms, but developments with respect to end-of-life choices. Oregon became the first state in the United States to legalize physician-assisted suicide in 1997. Since then, there have been ballot initiatives and legislation introduced in several states every year, but not until 2008 has there been any movement in the direction of emulating what Oregon did more than a decade ago. Last November, **Washington** became the second state, after Oregon, to legalize physician assisted aid in dying, and it looks like **Montana** and **Vermont** might follow suit. Also earlier this year, **Luxembourg** followed the example of the **Netherlands** and **Belgium** to become the third country in the world to legalize euthanasia.

Recent Judicial Cases

***Montana.** On 02 September 2009, the state supreme court heard oral arguments in *Baxter v. Montana*. On 5 December, 2008, the Montana First Judicial District Court had ruled that physician-assisted suicide is legal in Montana. The lower court interpreted the Montana constitution to guarantee both a right to privacy and a right to dignity and therefore a right to die with

dignity. Just days after the ruling, the state attorney general's office appealed the decision, but the District Court ruling stands until the case is decided in the state supreme court. *Baxter v. Montana*, DA 09-0051 (Mont. 1st Judicial Dist. Ct. 2008).

Recent Laws and Regulations

Vermont. On 17 April 2009, Senators Lyons, Snelling, Ashe, Ayer, Bartlett, Flanagan, MacDonald, McCormack, Miler, Racine, Shumlin and White introduced a bill to legalize assisted-suicide in Vermont. The Vermont "Patient Choice and Control at the End of Life Act," S. 144, is modeled after Oregon's law. If passed, the act will grant doctors the power to prescribe lethal drug overdoses to patients with terminal illnesses who wish to end their lives, making assisted suicide a legal medical treatment in the state of Vermont. S. 144, 2009-2010 Leg., Reg. Sess. (Vt. 2009) available <http://www.leg.state.vt.us/docs/2010/bills/Intro/S-144.pdf>, accessed 28 September 2009.

***Washington.** On 05 March 2009, a Washington State law went into effect allowing terminally ill patients to take their own lives with state approved medications if such action meets state requirements and is approved by a physician. The law which passed in November 2008 made Washington State the second state after Oregon to legalize physician assisted suicide. I-1000, 2009 Wash. Leg. Reg. Sess. (Wash. 2008), available

<http://www.secstate.wa.gov/elections/initiatives/text/i1000.pdf>, accessed 28 September 2009.

Interesting Developments in Other Countries

Canada. On 13 May 2009, Canadian parliament member Lalonde introduced Bill C-384 to amend Canada's Criminal Code to allow doctors to help patients in severe physical or mental pain or who are terminally ill to die with dignity. This bill marks Lalonde's third attempt to legalize euthanasia and assisted suicide in Canada—her two previously failed bills were C-406 (2005) and C-562 (2008). Bill C-384, § 222(7), (2009).

***Great Britain.** On 02 June 2009, the House of Lords began to consider Debbie Purdy's case. On 29 October 2008, the Appellate Committee of the House of Lords gave a legal opinion on Purdy, a woman with multiple sclerosis who wanted to have the British 1961 Suicide Act clarified with respect to assisted suicide. Purdy planned to go to Switzerland where aid-in-dying is legal, and 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 Appellate Committee expressed their unwillingness to provide legal clarification and stated Parliament as a whole would need to discuss and vote on any changes or clarification of the 1961 act which states it is illegal to “aid, abet, counsel or procure the suicide of another.” James Sturcke, “Multiple Sclerosis Patient Takes Assisted Suicide Case to House of Lords,” *Guardian UK*, <http://www.guardian.co.uk/society/2009/jun/02/assisted-suicide-debbie-purdy-lords>, accessed 28 September 2009.

***Italy.** Eluana Englaro, a young disabled woman in a state of diminished consciousness since being in a car accident in 1992, died on 09 February 2009. On 06

February 2009, Prime Minister Berlusconi issued a decree that would have forced the continuation of Englaro's treatment, but the President of the Republic refused to sign the decree. On 17 November 2008, the Court of Cassation, Italy's highest court of appeals, upheld a previous court's ruling that Englaro may be allowed to die by the removal of her food and hydration tube. The nuns who run the hospice where Englaro lived for fourteen years initially refused to carry out the court order to remove her food and hydration tube. “Supreme Court Authorizes Euthanasia for Italian ‘Terry Schiavo,’” 14 November, 2008:

<http://www.catholicnewsagency.com/new.php?p=n=14343>, accessed 28 September 2009; Alessio Vinci, “Comatose Woman in Euthanasia Debate Dies,” *CNN*, 10 February 2009,

<http://www.cnn.com/2009/HEALTH/02/09/italy.euthanasia/index.html> accessed 28 September 2009.

Luxembourg. On 19 March 2009, the Luxembourg parliament approved a law legalizing euthanasia. This makes Luxembourg the third country to legalize both euthanasia and physician assisted suicide, after the Netherlands and Belgium. Under this new law, which took effect on 01 April 2009, doctors now have legal immunity from civil lawsuits if they directly kill or assist the suicide of a patient with a terminal illness who has requested to die. Joel Gaona, “Luxembourg Legalizes Euthanasia after Putting Limits on Grand Duke's Power,” *Catholic News Agency*, 20 March 2009, <http://www.catholicnewsagency.com/new.php?p=n=15419>, accessed 28 September 2009.

THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

Recent Judicial Cases

***Federal.** On 24 June 2009, the Fourth Circuit of the United States Court of Appeals upheld Virginia's ban on partial-birth abortion in a 6-5 decision. Because of the controversial nature of the issue and the extremely close vote, there is speculation that this decision will be appealed and ultimately reviewed by the U.S. Supreme Court. This decision reversed a 2008 ruling where a three-judge panel declared the law unconstitutional because Virginia's law was more restrictive than the federal partial-birth abortion ban enacted in 2003, which was upheld by the U.S. Supreme Court in *Gonzales v. Carhart* in 2007. Both the state and federal laws prohibit physicians from using intact dilation and extraction, but, unlike the federal law, Virginia's law also charges physicians who performed the procedure by mistake. Violations of the state law are a felony punishable by up to ten years in prison. After the federal ban on partial-birth abortions was upheld in *Carhart*, thirty-one states have enacted "partial-birth abortion" bans. *Richmond Medical Center for Women v. Herring*, No. 03-1821 (4th Cir. Ct. App., 2009) opinion: <http://pacer.ca4.uscourts.gov/opinion.pdf/031821A.P.pdf>, accessed 13 July 2009.

On 14 July 2009, the Seventh Circuit of the United States Court of Appeals denied a request to lift a permanent Illinois injunction that requires teen girls to notify their parents before having abortions. The appeals court described the measure as "a permissible attempt to help a young woman make an informed choice about whether to have an abortion." The law includes a judicial by-pass provision under which a minor may petition a judge not to

have her parents notified. *Zbaraz v. Madigan* No. 08-1620, (7th. Cir., 2009), opinion at <http://www.ca7.uscourts.gov/tmp/P70NKHX E.pdf>, accessed 28 September 2009.

Florida. On 03 August 2009, the ACLU of Florida filed a friend-of-the-court brief opposing the state's decision to force a pregnant woman to remain hospitalized against her will. In March 2009, the Circuit Court of Leon County ordered Samantha Burton, a mother of two suffering from pregnancy complications, to be indefinitely confined to the Tallahassee Memorial Hospital and forced to undergo any and all medical treatments deemed necessary to save her fetus. After three days of state-compelled hospitalization, Burton suffered fetal demise and was released from the hospital. The ACLU argued that women do not give up their right to determine the course of their own medical care when they become pregnant. The brief filed by ACLU also said that Florida's decision will invite state requests for court intervention in nearly all aspects of pregnant women's behavior and medical judgments. "ACLU Asks Florida Court to Protect the Rights of Pregnant Women to Refuse Medical Care," 03 August 2009, <http://www.aclu.org/reproductiverights/pregnancy/40571prs20090803.html>, accessed 20 August 2009; see also *Burton v. Florida*, No.09-1958 (Florida 1st Dist. App. Ct., 2009)

***Kansas.** On 28 July 2009, Scott Roeder plead not guilty after being bound over to trial on charges of first degree murder of the death of Wichita abortion provider, Dr. George Tiller, who ran a women's clinic. Roeder's trial has been postponed until 25 January 2010 to determine whether or not he is competent to stand trial. Abortion provider Tiller was shot to death on 31 May 2009. On 27 March 2009, the Sedgwick District Court acquitted Tiller of all charges that he had performed illegal abortions. *State of Kansas v. Roeder*, No. 09 CR 1462 (18th Judicial District Ct of Sedgwick County, 2009).

North Dakota. On 12 August 2009, the North Dakota East Central District Court denied the motion for a temporary injunction of House Bill 1371, but clarified that MKB Management Corporation doing business as Red River Clinic could continue their standard practices in providing abortions without risk of prosecution. Represented by the New York-based Center for Reproductive Rights (CRR), the clinic proposed the injunction on the claim of vagueness. The statute states that "the auscultation of the fetal heart tone must be of a quality consistent with standard medical practice in the community." The CRR argued that the requirement was unconstitutionally vague, putting the clinic at risk of criminal prosecution if it did not

purchase \$28,000 in equipment capable of detecting fetal heartbeat at the earliest stages of gestation. *MKB Management Corp. v. Stenehjem*, 09-09-C-02830 (2009), available <http://www.alliancealert.org/2009/20090813.pdf>, accessed August 24, 2009.

Ohio. On 01 July 2009, in answering two certified questions from the U.S. Court of Appeals for the 6th Circuit, the Ohio State Supreme Court declared that a state law regulating the use of the abortifacient mifepristone requires compliance with its 2000 Food and Drug Administration (FDA) approval letter and final printed labeling. Administering mifepristone beyond the 49-day gestational period or varying from the specific FDA-approved dosage would not be in accordance with the drug approval letter, thereby violating state law. The ruling addressed the interpretation of the statute, but a lawsuit addressing the constitutionality of the law remains pending in the federal courts. *Cordray v. Planned Parenthood Cincinnati Region*, Slip Opinion No. 2009-Ohio-2972, (Oh. Sup. Ct., 2009), opinion <http://www.supremecourt.ohio.gov/rod/docs/pdf/0/2009/2009-Ohio-2972.pdf>, accessed 20 August 2009.

Recent Laws and Regulations

Federal. On 24 June 2009, the U.S. Food and Drug Administration approved the first generic version of the emergency contraceptive Plan B (levonorgestrel) tablets, 0.75 mg. In 2006, Plan B was approved for nonprescription use for women ages eighteen and older and prescription-only use in women ages seventeen and under. These requirements remain

unchanged. The only development is that the drug is now also available in its cheaper

generic form. Levonorgestrel is a contraceptive, not an abortifacient. It can prevent pregnancy after unprotected intercourse or a known or suspected contraceptive failure as long as it is taken within 72 hours of intercourse. It is not effective in terminating an existing

pregnancy. U.S. Food and Drug Administration, "FDA Approves Generic Prescription-Only Version of Plan B Emergency Contraceptive for Women Ages 17 and Under," *FDA News Release*, 24 June 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm168870.htm>, accessed 28 September 2009.

On 30 July 2009, the Senate Appropriations Committee approved its fiscal year 2010 spending bill (HR 3293) for the Department of Labor, Health and Human Services, and Education. The bill does not include funding for abstinence-only sex education; instead it provides \$104.5 million for a comprehensive "Teen Pregnancy Prevention" program. H.R. 3293, 111th Cong. 1st Reg. Sess. (2009).

Arizona. On 13 July 2009, the governor signed a measure imposing new mandates and restrictions on abortions. One of the bill's provisions is a requirement that those who visit an abortion provider wait twenty-four hours before getting an abortion. Another provision toughens the existing law requiring parental consent before a minor can receive an abortion. Finally the law also allows pharmacists and other health care professionals to refuse to provide emergency contraception on moral or religious grounds. H.B. 2564, Ariz. Leg. Sess. (2009), available http://www.azleg.gov/FormatDocument.asp?inDoc=/legtext/49leg/1r/summary/h.hb2564_07-03-09_astransmittedtogovernor.doc.htm, accessed 28 September 2009.

Georgia. On 05 May 2009, a law was passed by the state house that allows the adoption of embryos. Proponents championed the bill to provide an alternative

to the destruction of surplus embryos harvested by couples trying to conceive a child. The bill's authors specifically skirted the issue of whether an embryo is a person, and the bill did not give embryos, including the estimated 20,000 now frozen in Georgia fertility clinics, any rights. H.B. 388, 107th Leg. Sess. (2009), available http://www.legis.state.ga.us/legis/2009_10/pdf/hb388.pdf, accessed 20 August 2009.

Tennessee. On 18 May 2009, a resolution passed the state house stating that the state constitution does not secure a right to, or funding for, an abortion. The measure was already approved by the state senate in March 2009, but must still achieve a two-thirds majority in a General Assembly vote (both houses voting together) before the measure can be put to voters in 2014. The resolution states, "Nothing in this Constitution secures or protects a right to abortion or requires the funding of an abortion." The resolution changes the state constitution in order to void a 2000 state supreme court ruling against state imposition of restrictions on the availability of abortions. Specifically the state supreme court had struck down a state law requiring all abortions, even first trimester ones, to be performed in a hospital. The state supreme court's language suggested that the right to an abortion was a "fundamental right" in Tennessee. The proposed amendment to the state constitution would make clear that there is not state right to an abortion in Tennessee. S.J.R. 0127, 106th Gen. Assem. Reg. (2009), available <http://wapp.capitol.tn.gov/apps/billinfo/BillSummaryArchive.aspx?BillNumber=SJR0127&ga=106>, accessed 30 September 2009.

Interesting Developments in the Private Sector

Project Prevention, a non profit group dedicated to reducing substance-exposed births to zero, is offering \$300 to drug users and alcoholics if they undergo procedures for long-term birth control. Project Prevention hopes to persuade local women to undergo a tubal ligation, have an intrauterine device implanted, or receive a long-term contraceptive shot. Men must undergo a vasectomy in order to receive the \$300. Participants, program verified addicts or alcoholics, only get paid once they provide proof of the required birth control. Project Prevention also covers the cost of contraceptive procedures for individuals

who cannot afford to pay. As of 22 April 2009, Project Prevention has paid 3,000 clients to undergo these long-term contraceptive procedures. S. Innes, "For Control of Births, Addicts Get \$300," *Arizona Star*, 18 December 2008, <http://www.azstarnet.com/metro/272223>, accessed 23 January 2009; "Project Prevention Announces Payment for Birth Control to the 3000th Addicted Woman," *Reuters*, 22 April 2009, <http://www.reuters.com/article/pressRelease/idUS152726+22-Apr-2009+BW20090422>, accessed 1 July 2009.

STEM CELL RESEARCH

Unlike healthcare reform, the change in stem cell policy came swiftly and quietly after Obama took office. For eight years under the Bush administration, battles raged in Congress over the morality of stem cell research and whether the federal government should be involved in funding such research, particularly embryonic stem cell research. But President Obama changed all that with a simple stroke of the pen. Executive Order 13505, which significantly loosened the Bush administration's restrictions on stem cell research, was issued and took effect within just months of President Obama's taking office.

Recent Judicial Cases (and Quasi-Judicial Regulatory Enforcement Actions)

On 18 June 2009, the Food and Drug Administration lifted a halt on a clinical trial conducted by Aastrom Biosciences Inc., which develops adult stem cells to treat heart diseases. The FDA found that the IMPACT-DCM study did not cause the death of a patient but rather that dilated cardiomyopathy was the cause of the patient's death. In the IMPACT-DCM study,

Aastrom is testing the ability of autologous stem cells, or stem cells from the patient's own body, to treat dilated cardiomyopathy. Aastrom, "FDA Removes Clinical Hold from Aastrom Phase II IMPACT-DCM Clinical Trial," <http://www.aastrom.com/releasedetail.cfm?releaseid=390469>, accessed 30 September 2009.

Recent Laws and Regulations (and Executive Orders)

Federal. On 07 July 2009, the NIH issued Guidelines on Human Stem Cell

Research, which modified the definition of human embryonic stem cells to say that they “are cells that are derived from the inner cell

mass of the blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers.” The NIH Guidelines allow for funding research using human embryonic stem cell (hESCs) derived from embryos created using in vitro fertilization (IVF) for reproductive purposes and no longer needed for these purposes, assuming the research has scientific merit and the embryos were donated after proper consent was obtained from the donor. The NIH is also establishing a set of conditions that will maximize ethical oversight, while ensuring that the greatest numbers of ethically derived hESCs are eligible for federal funding. The NIH declined to provide exact wording for consent forms, and instead endorsed a robust informed consent process where all necessary details are explained and understood in an ongoing, trusting relationship between the clinic and the donors. Additionally, the Guidelines require that donors be informed that they retained the right to withdraw consent for the donation until the embryos are actually used to derive embryonic stem cells. All the embryonic stem cell lines that qualify for federal funding are required to meet the following criteria: First, the embryo the stem cells come from must have been created for reproductive purposes. Second, the donors must have been told that the embryo would be destroyed in the process of being used for stem cell research. On 09 March 2009, President Obama issued Executive Order 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. The Executive Order lifted restrictions on human embryonic stem cell research that

had been put in place by his predecessor, President Bush. The Executive Order states that the Secretary of Health and Human Services, through the Director of the National Institutes of Health (NIH), may support and conduct responsible, scientifically worthy human stem cell research, including hESC research. National Institute of Health, “National Institutes of Health Guidelines on Human Stem Cell Research,” *The National Institutes of Health Resource for Stem Cell Research*, <http://stemcells.nih.gov/policy/2009guidelines.htm>, accessed July 9, 2009; Office of the Press Secretary, “Memorandum for the Heads of Executive Departments and Agencies,” 30 July 2009, http://www.whitehouse.gov/the_press_office/Memorandum-from-the-President-for-the-Heads-of-Executive-Departments-and-Agencies-Regarding-Guidelines-for-Human-Stem-Cell-Research/, accessed 20 August 2009.

New York. On 11 June 2009, the Empire State Stem Cell Board voted to allow funding of research on stem cell lines derived using eggs (oocytes) donated solely for research purposes where the donor was, or will be, compensated for the expense, time, burden and discomfort associated with the donation process. New York is the first state to implement a policy that allows taxpayer-funded researchers to pay women for giving their eggs for embryonic stem cell research. The Empire State Stem Cell Board has decided to allow researchers to compensate women up to \$10,000 for the time, discomfort, and expenses associated with donating eggs for experiments. One of the goals of the research is to produce cells tailored to individual patients through a process known as somatic cell nuclear transfer. As of August 2009, no one has succeeded in producing human stem cells this way. Attempts to solicit women to

donate eggs for such research without compensation have largely failed. New York State Stem Cell Science, "Statement of the Empire State Stem Cell Board on the Compensation of Oocyte Donors,"

http://stemcell.ny.gov/docs/ESSCB_Statement_on_Compensation_of_Oocyte_Donors.pdf (last accessed 30 September 2009).

Interesting Developments in Other Countries

Hungary. On 29 July 2009, Hungarian police detained four people on suspicion of carrying out illegal, untested stem cell treatments using embryos or aborted fetuses at a Hungarian private clinic. The four people include one United States citizen, two Hungarians, and one Ukrainian. There is well-founded suspicion that the United States citizen carried out stem cell treatments for money within the framework of a Hungarian stem cell research laboratory and a Hungarian-owned private clinic since 2007. Police said the suspects harvested stem cells from embryos and aborted fetuses, and carried out the treatments without permission from Hungary's health authorities. K. Than,

"Hungary Detains 4 Over Illegal Stem Cell Treatment," 31 July 2009, <http://www.reuters.com/article/latestCrisis/idUSLT392157>, accessed 20 August 2009.

Italy. On 24 June 2009, the Italian government decided to exclude human embryonic stem cell research from acceptable proposals for stem cell biology funding. In response to this new policy, scientists are challenging the decision in court and an appeal was filed with Rome's administrative appeals court on 24 June 2009. A. Abbot, "Italians sue over stem cells," p. 19, *Nature*, 2 July 2009, available <http://www.politeia-centrostudi.org/doc/nature%20staminali.pdf>, accessed 20 September 2009.

ORGAN AND TISSUE PROCUREMENT

This issue of Legal Trends reflects developments not unexpected in light of the increasingly serious organ shortage. To date there are over 100,000 Americans waiting for organs, nearly 80 percent of whom need kidneys. Desperate need creates desperate people. Criminal activity in black market organ sales is likely to increase, as are cases where physicians stretch the common understanding of death in order to facilitate organ harvesting. Hopefully judicial and legislative accommodations for innovative ways to increase the organ supply, such as chain donations and giving living donors priority on the organ waiting list should they ever need an organ themselves, will also continue.

Recent Judicial Cases

Federal. On 23 July 2009, Levy Izhak Rosenbaum of Brooklyn **New York** was arrested by the FBI for buying and selling kidneys. Rosenbaum brokered the sale of black-market kidneys, buying organs

from vulnerable people from Israel for \$10,000 and selling them to desperate patients in the United States for as much as \$160,000. This is a violation of the 1984 National Organ Transplant Act (NOTA), 42

U.S.C. §273-74. If true, it would be the first documented case of organ trafficking in the United States. Under NOTA, it is illegal for anyone to knowingly buy or sell organs for transplant. The practice is also illegal (or at least not expressly legal) everywhere else in the world, except Iran. *United States of America v. Rosenbaum*, No. 09-3620 (New York Dist. Ct, 2009).

***California.** On 18 December 2008, a jury verdict in the San Luis Obispo Superior Court of California found Dr. Hootan Roozrokh not guilty of causing the death of a patient in his care by prematurely

harvesting his organs. The jury took the opportunity to highlight the need for well-defined ethical standards in the transplant procedure known as “donation after cardiac death.” The surgeon was charged first with murder, and then with dependent adult abuse, for allegedly hastened the death of a patient in a coma following a heart attack in order to harvest his organs. This case is believed to be the first of its kind in the United States. *The People of California v. Hootan Roozrokh* (San Luis Obispo Superior Court Case No. 405885).

Interesting Developments in Other Countries

China. In June 2009, the Red Cross Society of China announced that it is currently working to develop a system to manage human organ donations. The ultimate goal is to encourage the public to become organ and tissue donors after death in order to increase the organ supply. Currently, China has no official organ donation system and more than a million people who need organs. The goal is to make organ donation more efficient and transparent by matching up possible donors with recipients and then making the waiting list public. “China Plans Organ Donation System to Ease Shortage,” *Taiwan News*, 05 June 2009, http://www.etaiwannews.com/etn/news_content.php?id=968327&lang=eng_news, accessed 30 June 2009. These developments are of particular relevance given rumors that in China physicians provide organs to the highest bidder and that those people are often foreigners. There supposedly also is a thriving black market in live kidney sales in China. Dominick Tao, “Organ Trafficking Fueled by Worldwide Market,” *The New York Times*, 29 July 2009, [http://www.nytimes.com/2009/07/30/nyregion/30organs.html?_r=1&scp=7&sq=organ%](http://www.nytimes.com/2009/07/30/nyregion/30organs.html?_r=1&scp=7&sq=organ%20transplant&st=cse)

[20transplant&st=cse](http://www.nytimes.com/2009/07/30/nyregion/30organs.html?_r=1&scp=7&sq=organ%20transplant&st=cse), accessed 30 September 2009.

Malaysia. On 07 June, 2009, the Health Ministry Director-general announced that the government will clamp down on “transplant tourism” and human trafficking. He pointed out that as more vulnerable and poor people become affected by the financial crisis, reports of organ trafficking have increased. DLee Yuk Peng and NG Cheng Yee, “Organ transplant getting unscrupulous: Health DG,” *The Malaysia Star*, 8 June 2009, <http://thestar.com.my/news/story.asp?file=/2009/6/8/nation/20090608200705&sec=nation> accessed 20 June 2009.

Philippines. Legislators are pushing for the enactment of a bill that would regulate kidney donations to protect poor donors from abuse, stop organ trafficking, and help save terminally ill patients needing organs. House Bill 6210 gives the Department of Health the authority to supervise and regulate organ donation. House Bill 5930, known as the Human Organ Transplant Bill, also aims to regulate

organ donation in ways that will protect both donors and recipients. F. Marasigan, "Tighter Control on Organ Donations Pushed," *Business Mirror*, 12 July 2009, <http://businessmirror.com.ph/home/nation/13038-tighter-controls-on-organ-donations-pushed.html>, accessed 1 August 2009.

Taiwan. On 1 January 2009, the Bureau of Medical Affairs announced that it lifted Taiwan's ban on organ transplants between relatives and a new program intended to motivate people to donate their organs upon death. Under this rule, blood relations have priority in the use of a deceased person's organs for transplant, as long as the deceased person has signed a donor card or expressed the wish to make the donation before death. The deceased person's spouse can also enjoy the same

priority. However, while one organ of the deceased person can go to relatives, other organs must be donated through the Taiwan Organ Registry and Sharing Centre for general use. Under the previous Human Organ Transplant Bill enacted in 1987, a deceased person's organs could only be donated to people on the waiting list. Many Taiwanese do not want to donate their organs after death due to the traditional Chinese belief that a body must be buried whole if the soul is to ascend to heaven. "Taiwan to Relax Rules on Human Organ Donation," *The Earth Times*, 28 December 2008, <http://www.earthtimes.org/articles/show/247994,taiwan-to-relax-rules-on-human-organ-donation.html>, accessed 23 June 2009.

Interesting Developments in the Private Sector

On 15 June 2009, at the Ronald Regan ULCA Medical Center, Harry Damon and Nicole Lanstrum, initiated two rare kidney transplant chains. A "donor chain" allows for endless donor-recipient pairings. The chain starts with an altruistic donor—someone donating an organ to someone unknown to him or her. To keep the chain going, an incompatible donor originally willing to give an organ to the friend or relative who has now received an organ from a stranger, gives a kidney to another patient. These are the second and third chains at UCLA. OneLegacy, a nonprofit organ and tissue recovery organization serving the greater Los Angeles area, facilitated the chains by coordinating interstate transport of the kidneys. E. Rivero, "Two altruistic donors launch rare kidney transplant chains at UCLA," *UCLA Newsroom*, 15 June 2009, www.newsroom.ucla.edu/portal/ucla/two-altruistic-donors-launch-rare=94189.aspx, accessed 20 June 2009.

Paired and chain donations are becoming more and more common because of recent legal developments. In a 2008 opinion issued by the Justice Department, the attorney general stated that paired donations were legal under the 1984 National Organ Transplantation Act (NOTA), which was amended by the Charlie W. Norwood Living Organ Donation Act of 2008. Senator Specter requested the legal opinion because it was feared pair kidney donations and giving preference on the waiting list to kidney donors might be a violation of NOTA's prohibition against the exchange of valuable consideration for human organs. NOTA prohibits any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. Charlie Norwood Living Organ Donation Act of 2008, Pub. L. No. 110-144 (2008).

CONSCIENTIOUS OBJECTIONS

The issue in conscientious objection cases is how to balance a patient's right to access health care against a provider's right to refuse to provide services that are legal but morally objectionable to that provider. In principle, there is little problem in respecting provider's wishes if patients have sufficient notice that certain services will not be provided and if patients have ready access to alternative providers who are willing to provide the service. The battle over conscientious objection legislation often hinges on the fact that the easier it is for a provider to refuse to provide certain services, the harder it is for patients to obtain those services. For example, a young woman trying to purchase an abortifacient drug she has a legal right to purchase may not have the transportation necessary to seek the drug in another community. The countervailing legal principle is that specific performance should be a last resort, that is, the law (the courts) frown on ordering individuals to do things for the benefit of others against their will, particularly if the objection is on moral grounds.

Recent Judicial Cases

Washington. On 09 July 2009, the Ninth Circuit for the United States Court of Appeals in Seattle overturned an injunction issued by the United States District Court for Washington allowing pharmacies to refuse to fill prescriptions for Plan B. The Ninth Circuit held pharmacies cannot legally refuse to fill lawfully prescribed FDA-approved prescriptions. Plaintiffs argued that their Christian beliefs prevented them

from dispensing the pills because they considered them abortifacients. The Ninth Circuit held that a patient's right to timely medication supersedes any right to the free exercise of religion that a pharmacist may have under the First Amendment of the U.S. Constitution. *Storman's Inc. v. Selecky*, No. 07-36039, opinion: <http://www.ca9.uscourts.gov/datastore/opinions/2009/07/08/07-36039.pdf>, accessed 20 August 2009.

Recent Laws and Regulations

Louisiana. On 7 July 2009, the governor signed a bill into law expanding Louisiana's current "conscience protection" for healthcare workers. Currently, the state's "conscience protection" laws only cover abortion, but this new law adds several other healthcare services employees can refuse, due to personal beliefs, without any fear of losing their jobs or prosecution. The law

"allows any person not to provide abortions, distribute abortifacient drugs, work on human embryonic stem-cell research or cloning, or participate in euthanasia or physician-assisted suicide." H.B. 517 Reg. Sess. (La. 2009), available <http://www.nola.com/printer/printer.ssf?/base/news-7/124703057228210.xml&coll=1&style=print>, accessed 24 September 2009.

INFORMED CONSENT

The cases listed here are also listed under other sections, but informed consent is an important enough topic to warrant repeating them here.

Recent Judicial Cases

Federal. On 14 July 2009, the Seventh Circuit of the United States Court of Appeals denied a request to lift a permanent **Illinois** injunction that requires teen girls to notify their parents before having abortions. The appeals court described the measure as “a permissible attempt to help a young woman make an informed choice about whether to have an abortion.” The law includes a judicial bypass provision under which a minor may petition a judge not to have her parents notified. *Zbaraz v. Madigan* No. 08-1620, (7th. Cir., 2009), opinion at http://www.ca7.uscourts.gov/tmp/P70NKHX_E.pdf, accessed 28 September 2009.

North Dakota. On 12 August 2009, the North Dakota East Central District Court denied the motion for a temporary injunction of House Bill 1371, but clarified that MKB Management Corporation doing business as

Red River Clinic could continue their standard practices in providing abortions without risk of prosecution. Represented by the New York-based Center for Reproductive Rights (CRR), the clinic proposed the injunction on the claim of vagueness. The statute states that “the auscultation of the fetal heart tone must be of a quality consistent with standard medical practice in the community.” The CRR argued that the requirement was unconstitutionally vague, putting the clinic at risk of criminal prosecution if it did not purchase \$28,000 in equipment capable of detecting fetal heartbeat at the earliest stages of gestation. *MKB Management Corp. v. Stenehjem*, 09-09-C-02830 (2009), available <http://www.alliancealert.org/2009/20090813.pdf>, accessed August 24, 2009.

Recent Laws and Regulations

Arizona. On 13 July 2009, the governor signed a measure imposing new mandates and restrictions on abortions. One of the bill’s provisions is a requirement that those who visit an abortion provider wait twenty-four hours before getting an abortion. Another provision toughens the existing law requiring parental consent before a minor can receive an abortion.

Finally the law also allows pharmacists and other health care professionals to refuse to provide emergency contraception on moral or religious grounds. H.B. 2564, Ariz. Leg. Sess. (2009), available http://www.azleg.gov/FormatDocument.asp?inDoc=/legtext/49leg/1r/summary/h.hb2564_07-03-09_astransmittedtogovernor.doc.htm, accessed 28 September 2009.

FORCED TREATMENT OF A COMPETENT ADULT

This case was reported in the news as a reproductive rights case, but its significance is far more than that. Here a woman was forced to receive treatment against her will in order to benefit her fetus. There have been other cases where one person is forced to undergo treatment for the sake of another, but such cases are extremely rare, and most involve fetuses.

Recent Judicial Cases

Florida. On 03 August 2009, the ACLU of Florida filed a friend-of-the-court brief opposing the state's decision to force a pregnant woman to remain hospitalized against her will. In March 2009, the Circuit Court of Leon County ordered Samantha Burton, a mother of two suffering from pregnancy complications, to be indefinitely confined to the Tallahassee Memorial Hospital and forced to undergo any and all medical treatments deemed necessary to save her fetus. After three days of state-compelled hospitalization, Burton suffered fetal demise and was released from the hospital. The ACLU argued that women do

not give up their right to determine the course of their own medical care when they become pregnant. The brief filed by ACLU also said that Florida's decision will invite state requests for court intervention in nearly all aspects of pregnant women's behavior and medical judgments. "ACLU Asks Florida Court to Protect the Rights of Pregnant Women to Refuse Medical Care," 03 August 2009, <http://www.aclu.org/reproductiverights/pregnancy/40571prs20090803.html>, accessed 20 August 2009; see also *Burton v. Florida*, No.09-1958 (Florida 1st Dist. App. Ct., 2009)

FOOD & DRUG ADMINISTRATION

In preemption cases, 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 preemption 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?" Since *Riegel v. Medtronic, Inc.*, 552 U.S. ___ (2008) it is clear that state regulations or actions that contradict federal law with respect

to medical devices are legally null and void. But, unlike the Medical Device Amendments of 1976, there is no law passed by Congress that specifically provides for the preemption of state law by federal law or regulation for drugs. Nonetheless, federal law under the Supremacy Clause, as interpreted by the Supreme Court, still preempts state law if an act of Congress implies preemption, either because a state law directly conflicts with a federal law (“conflict preemption”), or if in practice the federal law is so comprehensive that there is no room for state regulation (“field preemption”). Obviously the standard for finding implied preemption is far more open to interpretation than a finding of express preemption.

Note that this section includes both preemption cases and other FDA related cases.

Recent Judicial Cases (and Quasi-Judicial Regulatory Enforcement Actions)

***Federal.** On 4 March 2009, the **Supreme Court ruled against** Wyeth in *Wyeth v. Levine*. The issue in *Wyeth* was 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 ultimately sided with Levine deciding that the FDA’s regulatory labeling standards represent a minimum to which states are permitted to add. Justice Stevens wrote in the majority opinion, “We conclude that it is not impossible for Wyeth to comply with its state and federal law obligations.” *Wyeth v. Levine*, S. Ct. Docket No. 06-1249, opinion: <http://www.supremecourtus.gov/opinions/08pdf/06-1249.pdf>, accessed 24 September 2009.

*As of 29 June 2009 there is no action on the Justice Department’s request from the U.S. District Court in **Maryland** (for the Southern Division) for a court order to force

Ranbaxy Laboratories Ltd. to turn over an audit proving that it distributed adulterated and misbranded products. The Justice Department has accused the company of concealing violations of good manufacturing practice regulations from FDA. Prosecutors allege the company 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 FDA investigated allegations that Ranbaxy made weak or adulterated HIV drugs that were given to thousands of AIDS patients in Africa. *United States v. Ranbaxy, Inc.*, No. 8:2008cv 01764 (U.S. Dist. Ct., Southern Div. MD, 2009).

*As of 29 September 2009 the motion for reconsideration in the U.S.

District Court for the Southern District of Indiana (Indianapolis Division) decision in *Tucker v. SmithKline Beecham Corp.* has not been granted. That case was previously dismissed on federal preemption 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 preemption and declined to rely on FDA's "preemption preamble" changes. The case is now reopened for adjudication on the merits. *Tucker v. SmithKline Beecham Corp.*, No. 1:04-cv-1748-DFH-WTL (U.S. Dist. Ct., Southern District Ind., 2009).

The FDA has ordered dozens of website operators to stop making fraudulent claims regarding swine flu treatments. In the six weeks since the start of the FDA's campaign, almost three-quarters of the websites selling swine flu treatments have pulled down sites or removed illegal claims. The FDA's Office of Criminal Investigation could seek product seizures, injunctions against sales, and criminal prosecutions of those website operators failing to comply. Christopher Kelly, "FDA Warns Web Sites against Marketing Fraudulent H1N1 Flu Virus Claims," *FDA*, 15 June 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm166801.htm>, accessed 24 September 2009.

Recent Laws and Regulations

Federal. On 5 March 2009, a bill to reverse the U.S. Supreme Court ruling in *Riegel v. Medtronic, Inc.* was introduced in the House. The purpose of the Medical Device Safety Act of 2009 is to ensure individuals are not prevented by the Food, Drug and Cosmetic Act from suing device makers under state tort laws. H.R. 1346 111th Cong. 1st Reg. Sess. (2009).

In June 2009, Senator Dorgan dropped an amendment he had proposed for The Family Smoking and Tobacco Control

Act. His amendment would have allowed importation of lower priced medicines from countries like Canada and Europe into the United States. Majority Leader Reid promised Dorgan that the drug importation issue would be brought to the floor soon. President Obama has asked Congress to give the FDA five million dollar to develop policies allowing Americans to buy medicines approved in other countries. S.982, H.RES.532 (111th Cong. 1st. Reg. Sess. 2009).

Interesting Developments in the Private Sector

A growing number of drug companies are pitching their products using social media tools such as Facebook, YouTube, Twitter, Blogs and MySpace. The FDA has yet to set rules for marketing drugs via the Internet. Drug companies are not giving up on TV advertising, but their online budgets are beginning to grow. The FDA is

watching the development with interest. A survey published by Manhattan Research in

November found that more than 60 million U.S. adults are consumers of what some are calling "Health 2.0", which includes health blogs, online support groups and other health related social media applications.

Francesca Lunzer Kritz, “Drug Firm Jockey for Space Online,” *The Washington Post*, 16 June 2009. www.washingtonpost.com/wp-

[dyn/content/article/2009/06/12/AR2009061203230_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2009/06/12/AR2009061203230_pf.html), accessed 24 September 2009.

HEALTHCARE COVERAGE

The new Congress and President Obama have made healthcare reform a priority, but the details are not as easy to iron out as they had hoped. In the first eight months of 2009 over 500 healthcare reform related bills were introduced in Congress. It will probably be well into 2010 before any definitive legislation is produced. In the meantime, the States have taken the lead in developing proposals for reform. Many governors and state legislators have announced comprehensive healthcare proposals or have established commissions charged with developing recommendations for healthcare reform. Usually the goal is to increase the number of people covered, but the recession is causing some states to consider cutting rather than increasing government healthcare programs.

Recent Laws and Regulations

Federal. President Obama has outlined eight principles for health reform. This interactive side-by-side compares the leading comprehensive reform proposals across a number of key characteristics and plan components. The report will be regularly updated to reflect changes in the proposals and to incorporate major new proposals as they are announced. United States Department of Health and Human Services, “Health Reform,” available <http://www.healthreform.gov/about/index.html> accessed 24 September 2009.

On May 25, 2009, the National Healthy Families Act was introduced, sponsored by the now late Senator Edward M. Kennedy and Representative Rosa DeLauro. The Act seeks to create a safety net for those who must stay home from work to care for themselves or their family members during sickness. The bill seeks to grant greater freedom for families to take sick leave without losing their jobs or risking financial instability. If passed, the Healthy Families Act would require

employers with fifteen or more employees to allow workers to earn up to seven paid sick days per year. The bill includes a pro-rated leave payment for part-time employees. This is the third time Kennedy and DeLauro have

introduced the Act but this version has been updated to include a ‘paid safe days’ provision where workers can use paid sick days to address domestic violence, stalking, or sexual assault. S.1152, H.R. 2460 111th Cong. 1st Reg. Sess. (2009).

California. On 29 July 2009, the governor signed a budget plan. The new reductions will affect child welfare and children’s healthcare, the elderly, and AIDS treatment and prevention, going beyond the dramatic cuts that were part of the deal the governor negotiated with legislative leaders. The extra cuts the governor made—\$489 million—took nearly \$80 million that pays for workers who help abused and neglected children, \$50 million from Healthy Families, which provides healthcare to children in low-income families, \$50 million from services for developmentally delayed

children under age 3, \$16 million from domestic-violence programs; and \$6.3 million from services for the elderly. California Department of Finance “State Budget 2009-10,” *California Department of Finance*, 28 July 2009, <http://www.ebudget.ca.gov/pdf/Enacted/BudgetSummary/FullBudgetSummary.pdf>, accessed 28 September, 2009.

Colorado. In June 2009, Medicaid benefits were cut for hundreds of developmentally disabled people in Colorado. Services such as transportation and work programs are being cut by at least half for about 700 Coloradans with developmental disabilities. Others will lose a lesser percentage, but some stand to gain financial assistance. The change was set in motion by the Centers for Medicaid and Medicare Services, which required that Colorado’s reimbursement system be standardized after an audit found discrepancies in how Medicaid dollars were being spent. The state’s developmental disabilities division created a new model that bases benefits on a person’s level of disability and the system also places limitations and caps on spending. Previously, the amount had been individually negotiated between the agency providing the service and the agency coordinating the services. Colorado Medicaid Department of Health Care Policy and Financing, “Public Notice for June 2009 Release: Fee-for-Service Provider Payments,” *The Colorado secretary of State*, June, 2009,

http://www.sos.state.co.us/pubs/CCR/Notice_HCPF_Medicaid_Fees_EffJul1-2009.pdf, accessed 28 September, 2009.

Connecticut. On 24 June, 2009, the governor signed an executive order that cuts funding to several walk-in centers that assist people living with AIDS throughout the state. This cut in funding would affect more than 10,000 residents. Furthermore, several representatives from these centers stated that they would have to close without state funding. Jodi Rell, “Executive Order No. 28: Fiscal Year 2010 July Allotment,” *State of Connecticut Executive Chambers*, 24 June, 2009, http://www.ct.gov/governorrell/lib/governorrell/fy10_july_allotments_30jun09.pdf, accessed 28 September 2009.

Florida. On 16 June 2009, the governor signed legislation that will allow end stage renal disease patients under sixty-five to have Medigap coverage. The bill (HB 675) was dubbed the “Alonzo Mourning Access to Care Act,” after Alonzo Mourning who suffered from kidney disease. Mourning was a retired NBA basketball player who suffered from kidney disease and received a transplant in 2003. The bill becomes law on 01 October 2009. FL.Stat.Ann. §627.671-627 (2009) available at http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=Ch0627/ch0627.htm accessed 28 September 2009.

HIV/AIDS

Recent Judicial Cases

On 7 July 2009, a federal appeals court for the **Ninth Circuit** ruled in favor of Abbott Laboratories in a lawsuit accusing

the company of antitrust violations. In 2004, advocacy groups and drug benefit providers sued Abbott for hiking up the price of one of their HIV-fighting drugs, Norvir, by 400%

for the alleged purpose of stifling competition in order to increase sales of the company's other HIV-fighting drug, Kaletra. *Doe v. Abbott Laboratories*, No. 08-17699 (2009),

<http://www.ca9.uscourts.gov/datastore/opinions/2009/07/07/08-17699.pdf>, accessed 24 September 2009.

opinion:

Recent Laws and Regulations

***Federal.** On 31 December 2008, the FDA approved the TaqScreen MPX test, a new HIV test manufactured by a Roche subsidiary that screens for two less common forms of the virus in the United States, in addition to the most common forms of HIV and hepatitis. The TaqScreen MPX Test is designed to screen blood and tissue samples from donors for infectious disease, and is the first capable of detecting HIV-2 and HIV-1 Group O strains of the virus at the same time. "FDA Approves First Nucleic Acid Test to Screen for Additional Types of HIV in Donated Blood and Tissue," *United States Food and Drug Administration*, 30 December 2008, <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01936.html>, accessed 20 July 2009.

District of Columbia. On 05 August 2009, the District's HIV/AIDS Administration put pressure on healthcare providers to make HIV testing part of routine patient treatment. The District asked for \$4 million from the federal Centers for Disease Control to support a campaign aimed at encouraging people to get tested and practice safe sex. Health officials want all medical providers in the city to implement an "opt-out" policy in which patients would be tested automatically for HIV unless they choose to refuse the test. District of Columbia Mayor's Office, "Fifth DC Appleseed Report Card Shows District's Steady Improvements in Addressing HIV/AIDS," 05 August 2009, <http://www.dc.gov/mayor/news/release.asp?id=1653&mon=200908>, accessed 30 September 2009.

MENTAL HEALTH

Recent Laws and Regulations

***Federal.** On 3 October 2008, the Senate passed an economic bailout bill, which folded in the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. This Act amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act, and the Internal Revenue Code to require a group health plan that provides both medical and surgical benefits and mental health or substance use

disorder benefits to ensure that: (1) the financial requirements, such as deductibles and copayments, applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant

financial requirements applied to substantially all medical and surgical benefits covered by the plan; (2) there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits; (3) the

treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan; and (4) there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits. Public Law No: 110-343, 110th Leg., Reg. Sess. (2008).

* On 26 January 2009, a bill to provide for research on services for individuals with

post partum depression (PPD) and psychosis was introduced in the Senate by Senator Menendez. There has been no action on the bill as of September 2009. The bill has sparked debate over whether all women should be screened for the condition. The issue at the center of the debate is whether PPD screening identifies actual cases or simply contributes to the potentially dangerous medicalization of motherhood. H.R. 20, S.324 111th Cong. 1st Reg. Sess. (2009).

TRUST / ACCOUNTABILITY / CONFLICTS OF INTEREST

Recent Judicial Cases

Federal. *On 27 August 2008, the Ninth Circuit for the U.S. Court of Appeals reversed the U.S. District Court for the Northern District of **California**'s dismissal of a complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. Applying federal common law of contracts, the court held that the covered entities are intended direct beneficiaries of these agreements and thus have a right to enforce the agreements' discount provisions against the manufacturers and sue them for reimbursement of excess payment. The lawsuit was brought 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. 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., No. 06-16471, (9th Cir. San Francisco, 2008); opinion: [http://www.ca9.uscourts.gov/ca9/newopinions.nsf/E7C88CA469AACCA882574B2004B658D/\\$file/0616471.pdf](http://www.ca9.uscourts.gov/ca9/newopinions.nsf/E7C88CA469AACCA882574B2004B658D/$file/0616471.pdf), accessed 15 July 2009.

On 7 July 2009, the Ninth Circuit for the U.S. Court of Appeals ruled in favor of Abbott Laboratories in a lawsuit accusing the company of antitrust violations. In 2004, advocacy groups and drug benefit providers sued Abbott for hiking up the price of one of their HIV-fighting drugs, Norvir, by 400% for the alleged purpose of stifling competition in order to increase sales of the company's other HIV-fighting drug, Kaletra. *Doe v. Abbott Laboratories*, No. 08-17699 (2009), opinion: <http://www.ca9.uscourts.gov/datastore/opini>

ons/2009/07/07/08-17699.pdf, accessed 24 September 2009.

On 4 July 2009, consumers initiated a suit in the United States District Court for the Eastern District of Pennsylvania against Stryker Corporation. Stryker is a maker of artificial knees and hips. Glen and Angela Gore claimed that Stryker's pain pumps used for delivering medication post-surgery caused arthritis and that the company actively concealed or misrepresented information regarding the pumps' safety. Glen Gore used Stryker's pump after undergoing shoulder surgery in December 2002. However, he was unable to raise his arm above shoulder level after using the pump and now needs shoulder replacement surgery. *Gore v. Stryker Corp.*, No. 02987 (Pa. Dist. Ct., 2009).

On 29 July 2009, Susan Bulger's case was voluntarily dismissed by her family's lawyer. On 27 July 2009, Pfizer Inc., the world's biggest drug maker, went to trial in the **United States District Court of Massachusetts** in Boston to defend against claims that its epilepsy medication Neurontin increases the risk of suicide. Susan Bulger, 39, hung herself in 2004 after taking the drug. The trial is the first of approximately 1,200 such cases pending. *Bulger v. Pfizer Inc.*, No. 1:07-cv-11426, (Ma. Dist. Ct., 2009).

On 05 August 2009, in the **U.S. District Court for the District of New Jersey**, the pharmaceutical manufacturer Merck agreed to pay \$41.5 million in settlement of class-action lawsuits over its cholesterol drugs Vytorin and Zetia. The suits involved allegations arising from the Enhance clinical trial, whose results released in January 2008 raised questions about the efficacy of Zetia and Vytorin. The settlement will resolve all class-action

lawsuits that seek economic damages related to the purchase of the two drugs. Merck disclosed about 145 such lawsuits pending in federal court in New Jersey. *In re: Vytorin/Zetia Marketing Sales Practices and Products Liability Litigation*, No. 2:08-cv00285, doc. 189-4 (N.J. Dist. Ct., 2009).

California. On 09 July 2009, twenty people were arrested in a \$4.6-million Medi-Cal fraud scheme. Law enforcement officials allege these people used unlicensed individuals to provide in-home nursing care for disabled patients. About seventy-five patients, many of them children with cerebral palsy or developmental disabilities, were treated at home or at school by the unlicensed individuals who stole identities to pose as licensed nurses. This is the largest single case alleging Medi-Cal fraud in the state of California. Thom Mrozek, "42 Defendants Indicted in \$4.6 Million Medi-Cal Fraud Case," *United States Attorney's Office Central District of California 09 July 2009*, <http://www.usdoj.gov/usao/cac/pressroom/pr2009/082.html>, accessed 24 September 2009.

Florida. On 5 May 2009 in the **U. S. District Court for the Middle District of Florida** (Tampa Division), WellCare of Florida agreed to a settlement to pay \$80 million to Florida Medicaid and Healthy Kids. WellCare was charged with defrauding Medicaid and Healthy Kids. The money serves as part of the deferred prosecution agreement which allows WellCare to avoid fraud conviction if it follows certain requirements. Additionally, WellCare agreed to take full responsibility for the conduct that led to the government probe, and to continue cooperating with the government's criminal investigation of former WellCare executives and employees. In August 2008, WellCare had agreed to pay

\$35.2 million as part of a Medicaid fraud investigation. The payment included \$24.5 million in estimated Medicaid repayments related to behavioral health claims from 2002 to 2006. The remaining \$10.7 million was put in escrow while federal investigators continued the probe. *United*

States v. WellCare Health Plans, Inc., 8:09-cr-00203-JDW-EAJ, available at http://www.wellcare.com/WCAssets/corporate/assets/00_dpa_complete.pdf, accessed 01 September 2009.

Recent Laws and Regulations

***Federal.** As of 30 June 2009, there has been no action on two bills the Senate Finance Committee approved on 10 September 2008. The bills 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). Updated June 2009.

***District of Columbia.** On 01 October 2008, regulations published by the District of Columbia Board of Pharmacy regarding pharmaceutical sales representatives went into effect. The regulations were promulgated in response to the passage of the SafeRx Amendment Act of 2008, which states that by April 1, 2009, a person must be licensed by the District of Columbia Board of Pharmacy to engage in pharmaceutical detailing. The practice of pharmaceutical detailing is defined as, “The practice by a representative of a

pharmaceutical manufacturer or labeler of communicating in person with a licensed health professional, or an employee or representative of a licensed health professional, located in the District of

Columbia, for the purpose of selling, providing information about, or in any way promoting a pharmaceutical product.” “Department of Health Notice of Proposed Rulemaking,” D.C. Law 17-013; 55 DCR 4462, *District of Columbia Department of Public Health*, 27 June 2008: http://www.fdalawblog.net/fda_blog_hyman_phelps/files/dc_pharmaceutical_detailer_proposed_rule.pdf, accessed 11 July 2009.

***Massachusetts.** On 01 January 2009, An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care went into effect. This Act is one of the nation’s strictest limits on the giving of gifts to medical professionals by pharmaceutical sales representatives. The Act 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. S.B. 283, 185th Gen. Court., Reg. Sess. (Mass. 2008).

Vermont. Effective 01 July 2009, Vermont adopted a new Pharmaceutical Marketing Disclosure Law that bans some gifts and requires the reporting of marketing expenditures. These expenditures include clinical trials, biological products, and medical devices. Office of the Attorney

General, “Disclosures of Marketing Expenditures for Prescription Drugs, Biological Products and Medical Devices,” 08 June 2009, <http://www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php> accessed 31 July 2009.

Interesting Developments in the Private Sector

*On 1 January 2009, the new Pharmaceutical Research & Manufacturers of America (PhRMA) marketing code of conduct, “Code on Interactions with Healthcare Professionals,” went into effect. The new code is substantially more restrictive than the earlier July 2002 version. It prohibits distribution of non-educational items (pens adorned with a company or product logo), entertainment and

recreational activities, and sales representatives from providing restaurant meals to healthcare professionals. The code also urges companies to set publicly stated caps on payments to physicians for speaking engagements. CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (PhRMA, 2009), available <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>, accessed 15 July 2009.

VACCINES

Recent Judicial Cases (and Quasi-Judicial Regulatory Enforcement Actions)

***Federal.** In June 2009, the FDA ordered dozens of website operators to stop making fraudulent claims regarding swine flu treatments. In the six weeks since the start of the FDA’s campaign, almost three-quarters of the websites selling swine flu treatments have pulled down sites or removed illegal claims. The FDA’s Office of Criminal Investigation could seek product

seizures, injunctions against sales and criminal prosecutions of those website operators failing to comply. United States Food and Drug Administration, “FDA Warns Websites against Marketing Fraudulent H1N1 Claims,” 15 June 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm166801.htm>, accessed 30 September 2009.

Interesting Developments in Other Countries

The World Health Organization has endorsed the use of a second cervical cancer

vaccine, Cervarix, this one made by GlaxoSmithKline (GSK). This means that United Nations agencies and partners can now officially buy millions of doses of the vaccine for poor countries worldwide. GlaxoSmithKline said the approval would

help speed access to Cervarix globally. More than eighty percent of the estimated 280,000 cervical cancer deaths a year occur in developing countries. In the West, early diagnosis and treatment has greatly reduced

the number of cases in the West. GAVI, formerly known as the Global Alliance for Vaccines and Immunization is in talks with Merck & Co and GSK to see if either might sell their vaccines to donor agencies at a reduced price compared to the price they charge in the West. .“WHO approves Cervical Cancer Vaccine Cervarix,” The Associated Press, 9 July 2009, <http://www3.signonsandiego.com/stories/2009/jul/09/eu-med-cancer-vaccine-approved-070909/>, accessed 1 August 2009.

DEFINING DISABILITY

Recent Laws and Regulations

Federal. On 01 January 2009, amendments to the Americans with Disabilities Act went into effect. The bill signed into law by the President on 25 September 2008 expands the definition of disability for people claiming discrimination under the Act. The new law 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 act, courts should not consider the effects of “mitigating measures” such as hearing aids, prescription drugs, and artificial limbs. A better definition would take into consideration 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). Updated June 2009.

PRIVACY

Federal. A new FTC regulation, the ‘Red Flags Rule,’ is set to take effect on 01 November 2009 to address the problem of medical identity theft. The rule would require physicians’ offices and hospitals, among other businesses, to create new protocols to spot the “red flags” of identity theft. These could include detecting fake or altered IDs, inconsistencies in a patient’s medical records or fraud alerts from consumer reporting agencies. Doctors are

not only required to implement procedures that allow them to detect these warning signs effectively but also to spell out what they will do when they find something suspicious. The new regulation states that businesses that regularly extend or renew credit are required to implement the new protocols. This category includes auto dealers, lawyers, utility companies and any physician’s office or hospital that accepts insurance or allows for payment plans.

Federal Trade Commission, “New ‘Red Flag’ Requirements for Financial Institutions and Creditors Will Help Fight

Identity Theft,” available <http://www.ftc.gov/bcp/edu/pubs/business/alerts/alt050.shtm>, accessed August 24, 2009.

BIOETHICS GENERAL

Federal. In June 2009, The White House notified members of the President’s Council on Bioethics that they will be replaced by a set of members appointed by President Obama. The council had been appointed by George W. Bush in 2001. According to the White House, President Obama will appoint a new bioethics commission that will “offer practical policy

options” and allow the president to react rapidly to new ethical challenges in the scientific field. “Obama Plans to Replace Bush’s Bioethics Panel,” *NYTimes.com*, 18 June 2009, http://www.nytimes.com/2009/06/18/us/politics/18ethics.html?_r=1&pagewanted=print, accessed 21 June 2009.