



The Center for Ethical Solutions  
Innovative Approaches to Health Care Policy

# LEGAL TRENDS IN BIOETHICS WINTER 2010 ONLINE ISSUE, NO. 2

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## TABLE OF CONTENTS

How to Use This Resource.....	3
General Introduction.....	4
End-of-Life Decisions.....	5
Rights of Maturing Individuals and their Parents.....	7
Stem Cell Research.....	9
Organ Procurement.....	10
HIV/ AIDS.....	12
Medical Marijuana.....	13
Trust / Accountability / Conflicts of Interest.....	14
FDA.....	16
Vaccines.....	16
Healthcare Coverage.....	17
Clinical Trials.....	20
Privacy.....	21
Prisoners.....	21
Unconventional Treatment (Xenotransplantation).....	22
Disabilities.....	22
Bioethics General.....	23

## 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.

The URLs provided in this report are not active links. Please retype the URL into your browser, making sure to remove any blank spaces within the address.

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) or Alison Mathey at [alison.mathey@gmail.com](mailto: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.

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## 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. As of December 2009, **Montana** became the first state whose state supreme court determined that patients may request, and physicians may legally provide, aid-in-dying, based on state public policy and not constitutional rights. This historic ruling may spur attempts in other states to uphold physician aid in dying on similar grounds. Oregon became the first state in the United States to legalize physician aid in dying in 1994 (the law did not go into effect until 1998 because of various court challenges). In 2008, **Washington** became the second state to legalize physician aid in dying. California, Hawaii and Vermont are currently considering similar legislation. Also, still pending is a suit filed in Connecticut on 07 October 2009 that asks the court to exclude physician aid in dying from the state's current law prohibiting assisting a suicide. Finally, Canada seems to be following Europe's lead in allowing active euthanasia rather than aid-in-dying, as seems to be the developing trend in the United States. The change in Canadian law proposed by Canada's college of physicians echoes the Netherlands, Belgium and Luxemburg in allowing medical professionals to

actually inject a patient with lethal medication. Under both types of laws, informed consent is a prerequisite, but voluntariness of the action is all but guaranteed in aid-in-dying because the patient must him/herself take and ingest the medication, while in jurisdictions allowing active euthanasia, the physician injects the patient with lethal medication, which creates more of a possibility that the decision to die was not voluntary. Contrariwise, it is arguably a very difficult burden to force patients to decide to end their lives while they still possess enough strength, coordination, and ability to ingest the lethal medication on their own.

### Recent Judicial Cases

**Connecticut.** On 07 October, the case of *Blick v. Connecticut* was filed in the Connecticut Superior Court. At issue is whether or not Connecticut's criminal statute governing "assisting a suicide" reaches the conduct of a physician in providing aid in dying to a terminally-ill, mentally competent adult. The case was brought by two physicians who frequently treat terminally ill patients. The physicians want the court to hold that "assisting a suicide" as defined in the Connecticut criminal code does not include situations where a physician provides aid in dying as part of treatment for a terminally ill patient who finds the

dying process unbearable. *Blick v. Connecticut*, Docket No. HHD-CV-09-5033392-S (Conn. Super. Ct. 2009) available at <http://www.compassionandchoices.org/documents/BlickVCTMemoSupportOfMotionToDismiss.11192009.pdf> (last accessed 06 January 2009).

**\*Montana.** On 31 December 2009, the Montana Supreme Court ruled in favor of plaintiffs in *Baxter v. Montana*. The court held that Montana's public policy does not criminalize, and even affirmatively supports, aid in dying. The court did not reach the question of whether the Montana constitution specifically protects aid in dying. The court concluded that there is evidence that the state legislature intended to defer to adult mentally-competent patients regarding end-of-life treatment decisions, specifically whether they involve the discontinuation of life sustaining therapies or the taking of medications that may hasten death. *Baxter v. Montana*, DA 09-0051 (Mont. Sup. Ct. 2009), available at <http://fnweb1.isd.doa.state.mt.us/idmws/docContent.dll?Library=CISDOCSVR01%5Edoaisd510&ID=003824347> (last accessed 06 January 2009).

### **Interesting Developments in Other Countries**

**Canada.** On 16 July 2009, the Quebec College of Physicians proposed a revision to Canada's Criminal Code permitting active euthanasia under controlled circumstances. The revision would allow for drug-induced euthanasia in the case of terminally ill patients with

severe pain, by request of the patient and the doctor's approval. Michael J. Marshall, ed., "Quebec Docs Endorse Controlled Euthanasia," 16 July 2009, available at <http://www.upi.com/TopNews/2009/07/16/Quebec-docs-endorse-controlled-euthanasia/UPI-76561247748937/> (last accessed 23 December 2009).

**\*Great Britain.** On 30 July 2009, Debbie Purdy, a primary progressive multiple sclerosis patient won her case in the House of Lords. 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. Purdy argued that not knowing whether her husband will be prosecuted if he accompanied her would be a violation of her human rights. The court ordered the director of public prosecutions (DPP) to issue a policy that deals with such a circumstance. The court noted that the government has an obligation to clarify what will happen if Purdy's husband accompanies Purdy to Switzerland to avail herself of aid-in-dying. The policy, to be published later this year, will determine what factors will affect prosecution in Britain when a citizen avails him- or herself of assisted suicide abroad. Afua Hirsch, "Debbie Purdy Wins 'Significant Legal Victory' On Assisted Suicide," *The Guardian*, 30 July 2009, available at <http://www.guardian.co.uk/society/2009/jul/30/debbie-purdy-assisted-suicide-legal-victory/> (last accessed 23 December 2009).

# RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

## Recent Judicial Cases

**\*Federal.** In September 2009, Attorney General Marty Jackley filed an appeal to *Planned Parenthood v. Rounds*, a Federal Court decision from the Southern Division of South Dakota that upheld the constitutionality of a **South Dakota** law requiring doctors to inform patients that abortion kills a human being. The law states that doctors should not have to tell pregnant women that abortion increases the risk of suicide and suicidal thoughts or that they enjoy a legally protected relationship with their unborn children. The lower court decision upheld a provision of the law which said abortions “terminate the life of a whole, separate, unique, living, human being.” *Planned Parenthood v. Rounds*, Civ. No. 05-4077-KES (U.S. Dist. Ct. SD Southern Div. 2009), available at <http://www.telladf.org/UserDocs/RoundsDecision.pdf> (last accessed 23 December 2009).

**Alaska.** On 08 October 2009, Planned Parenthood of Alaska and an Anchorage high school teacher filed suit against the state to block a voter initiative that would make it illegal for minors to have abortions without notifying a parent. The suit, filed in Anchorage Superior Court, is an effort to stop the voter initiative from being put to a public vote. In 1997, the Alaska Parental Consent Act was enacted by the state legislature. The Act require that girls receive parental permission, or approval from a judge, before receiving an abortion. The law never went into effect because it was challenged in court. In 2007, the Alaska

Supreme Court struck down that legislatively enacted law on constitutional grounds. The ballot initiative, which was certified by the state legislature, still needs 33,000 signatures before it can appear on the ballot in August 2010. The suit filed in October 2009 is a preemptive attempt to keep the initiative off the ballot. *Planned Parenthood of Alaska v. Campbell*, No. 3AN-09-9236 CI (3rd Jud. Dist., Anchorage Sup. Ct. 2009).

**Illinois.** On 19 November 2009, a Cook County Circuit Court sustained a temporary restraining order, sought by the American Civil Liberties Union, against enforcing the Illinois state Parental Notice of Abortion Act only a few hours after the Illinois Medical Disciplinary Board had voted to enforce the law. The law, requiring a minor to give a parent notification forty-eight hours before undergoing an abortion, has been upheld by various court actions since its original passage in 1995. *Hope Clinic v Adams*, No. 09 CH 38661 (IL. Cook County Cir. Ct. 2009).

**\*North Dakota.** On 12 August 2009, the North Dakota East Central District Court ruled in favor of Red River Women's Clinic in Fargo, the state's only abortion clinic, in a suit brought by the New York-based Center for Reproductive Rights (CRR) challenging a state law requiring that women be offered a chance to view images of the fetus at least twenty-four hours before having an abortion and that an “auscultation of the fetal heart tone ... of a quality consistent with standard medical practice in the

community” be made available to the mother. The clinic already provides ultrasounds to all of its patients prior to abortion. The CRR suit challenged the “auscultation” requirement, arguing that it was unconstitutionally vague and would place an undue financial burden on the clinic, which would need to spend more than \$28,000 to purchase the equipment necessary to comply with the law. The court held that compliance with the “auscultation” portion of the law was unnecessary. The law was supposed to take effect 01 August 2009, but the prosecutors agreed not to enforce it until the court issued a ruling. *MKB Management Corp. v. Stenehjem*, 09-09-C-02830 (ND East. Cen. Dist. Ct. 2009).

**Oklahoma.** On 20 October 2009, a superior court judge in Maricopa County, Oklahoma ruled that the Sheriff’s Office cannot demand prepayment for transportation to abortion clinics. The ruling was an extension of a 2005 injunction against the requirement of obtaining a court order before inmates could obtain an abortion. To circumvent the injunction, the sheriff told another inmate that she would have to prepay transportation costs in the amount of \$300 to \$600. To waive the fee, she would have to obtain a court order. The inmate was able to come up with the funds, but the ACLU of Arizona, which filed the initial suit, claimed the sheriff’s requiring prepayment violated a woman’s right to a timely abortion. The ACLU did not dispute the inmate’s responsibility to pay transportation costs. The judge ruled in favor of the ACLU. *Doe v. Arpaio*, No. CV2004-009286 (Sup. Ct. AZ. County of Maricopa), available at [http://www.aclu.org/files/images/asset\\_upload\\_file](http://www.aclu.org/files/images/asset_upload_file)

[439\\_40091.pdf](#) (last accessed 21 December 2009).

### Recent Laws and Regulations

**\*Federal.** On 04 August 2009, the Senate Appropriations Committee approved its fiscal year 2010 spending bill (H.R. 3293) for health, education and labor programs. The bill does not include funding for abstinence-only sex education, instead providing \$104.5 million for a comprehensive “Teen Pregnancy Prevention” program. The recently passed House version of the bill takes a similar approach. H.R. 3293 111th Cong. 1st Reg. Sess. (2009).

**New Jersey.** On 6 October, 2009, the governor announced his application for federal permission to cover free family planning for residents who do not have health insurance but do not qualify for Medicaid. If approved, the proposal would cover counseling and screenings for residents making less than \$21,000 a year, resulting in counseling and screening coverage for residents making up to twice the income allowed for general health coverage under the state’s Medicaid program. The state would cover ten percent of the cost, leaving the federal government to subsidize the remaining ninety percent. This proposal would not cover abortions. State of New Jersey, Office of the Governor, “Governor Corzine Announces Increased Access to Family Planning Services,” 06 October 2009, Press release: <http://www.state.nj.us/governor/news/news/2009/20091006b.html> (last accessed 21 December 2009).

**\*Oklahoma.** On 18 August 2009, an Oklahoma County District Judge struck down State Bill 1878 that required

doctors to perform ultrasounds and provide women with detailed information about the image before performing abortions. The suit was filed by a clinic in Tulsa, run by Nova Health System and represented by the Center for Reproductive Rights. The Center alleged that State Bill 1878 violated the state constitution's single-subject rule and infringed on women's privacy rights, violated their dignity and endangered their health. The law required any woman seeking an abortion to have an ultrasound and listen to a description of the image in detail, including organs and extremities, even if she objected. The law was passed in 2008 but never went into effect because of legal action. S.B. 1878 (52nd OK Leg. Reg. Sess. 2009), available at <http://www.sos.state.ok.us/documents/Legislation/51st/2008/2R/SB/1878-Veto&Override.pdf> (last accessed 11 November 2009).

### Interesting Developments in Other Countries

**Mexico.** On 17 November 2009, Veracruz became Mexico's seventeenth state to pass legislation declaring that life begins at conception. Veracruz lawmakers adopted a proposal that would require the Mexican congress to consider amending the constitution to outlaw abortion. A majority of Mexico's thirty-two states have now enacted anti-abortion measures in response to Mexico City's legislature permitting abortions in the first twelve weeks of pregnancy. Mexican states currently set their own laws on abortion, but, if passed, the constitutional measure proposed by Veracruz lawmakers would ban abortions nationally. Mark Stevenson, "Mexico Anti-Abortion Fight Moves to Federal Level," <http://www.wtop.com/?nid=389&sid=1816989> (last accessed 24 December 2009).

## STEM CELL RESEARCH

### Recent Judicial Cases

**Federal.** On 27 October 2009, a chief judge in the United States District Court for the District of Columbia dismissed a lawsuit filed by Nightlight Christian Adoptions challenging the National Institute of Health's ease on stem cell research restrictions. The lawsuit claimed that removing the restrictions on stem cell research would lower the number of embryos available for adoption. The judge ruled the claim lacked standing without proof that donors were choosing to donate embryos to research instead of adoption. *Shereley*

*v. Sebelius*, Civ. No. 1:09-cv-1575 RCL, (2009).

### Recent Laws and Regulations

**\*Federal.** On 02 December 2009, the National Institutes of Health (NIH) announced the approval of the first thirteen lines of human embryonic stem cell (hESC) for use in NIH-funded research under the NIH Guidelines for Human Stem Cell Research adopted in July 2009. In July 2009, the Obama administration began approving new lines of human embryonic stem cells that are eligible for federally funded experiments, opening the way for

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millions of taxpayer dollars to be used to conduct research banned by President George W. Bush. An additional seventy-six stem cell lines await vetting, and researchers have indicated that they plan to submit at least 254 more for approval. The NIH has already authorized thirty-one grants worth about \$21 million for research on human embryonic stem cells, money that was contingent on new lines passing government muster. The grants are for a variety of research, including work aimed at developing cells that could be used to treat diseases of the heart and nervous system. Department of Health and Human Services, National Institutes of Health, "First Human Embryonic Stem Cell

Lines Approved for Use Under New NIH Guidelines," Press Release: 02 December 2009, <http://www.nih.gov/news/health/dec2009/od-02.htm> (last accessed 10 January 2010).

**Missouri.** On 03 December 2009, Rep. Cynthia Davis filed a House Joint Resolution, which, if passed, would ban the use of public dollars for stem cell research. The proposed constitutional amendment would need to be approved by the state legislature before being put to a public vote on 02 November 2010. H.J.R. 49, Missouri Taxpayer Protection Initiative, 95th Gen. Assem. 2nd Reg. Sess. (2009).

## ORGAN PROCUREMENT

### Recent Judicial Cases

**Federal.** On 26 October 2009, the Institute for Justice filed a complaint in the United States District Court for the Central District of California in Los Angeles challenging the National Organ Transplantation Act (NOTA) of 1984's ban on financial compensation for bone marrow donors. They argue that the Act's prohibition violates the Fourteenth Amendment and equal protection under the law. Under NOTA, monetary compensation for organs (including bone marrow) is illegal and punishable by \$50,000 and up to five years in prison. The complaint states that bone marrow is unlike the non-renewable solid organs and should be treated as inexhaustible cells, like blood, sperm, and egg, for which compensation is allowed. *Flynn v. Holder*, Complaint: U.S. Dist. Ct. Central Dist. CA Los Angeles (2009).

**California.** On 14 October, 2009, oral arguments were heard in *Ephram Nehme v. Wellpoint, Inc. and Blue Cross of California D/B/A Anthem Blue Cross*. Nehme is suing Anthem Blue Cross for denying coverage of his out-of-network liver transplant. Nehme needed a liver transplant to stay alive. Because of his rare blood type, his UCLA physician instructed him to obtain a liver transplant outside of California, and advised him to go to Indiana for a transplant, because the wait time was much shorter in Indiana than in California. Blue Cross refused to authorize the transplant on the ground that it was not medically necessary and restricted payment for treatment Nehme received at contracted facilities within California. Nehme paid \$205,000 out-of-pocket to have his liver transplant in Indiana. *Nehme v. Wellpoint, Inc.* No. DC396316, CA Sup.

Ct. Los Angeles Cen. Dist. (2009), complaint available at [http://www.consumerwatchdog.org/resources/law\\_suit.pdf](http://www.consumerwatchdog.org/resources/law_suit.pdf) (last accessed 21 December 2009).

### **Recent Laws and Regulations**

**Federal.** On 21 September 2009, the Center for Disease Control (CDC) began planning the creation of a transplantation sentinel network (TSN) to detect and prevent the transmission of HIV, Hepatitis C virus and other diseases via organ and tissue transplants. The TSN would be responsible for standardizing allograft identifiers, tracking organ and tissue receipt, reporting on potential transmissions, and using this information to prevent future infections. Interacting with the work of the Organ Procurement and Transplantation Network and Food and Drug Administration, TSN would unify the efforts of identifying and reporting public health cases and adverse events to track such transmissions. Tanja Popovic, "Request for Information Regarding Development and Operation of a Transplantation Sentinel Network," *Federal Register*, (21 September 2009) available at <http://edocket.access.gpo.gov/2009/pdf/E9-22658.pdf> (last accessed 23 December 2009).

**Federal.** On 13 October 2009, the House of Representatives placed H.R. 3200 on the Union Calendar, a calendar of the Committee of the Whole House on the state of the Union, to which bills are referred for raising revenue, general appropriation bills, and bills of a public character directly or indirectly appropriating money. H.R. 3200 includes a provision that would require Medicare to continue paying for anti-rejection drugs beyond the current policy

of only paying for them for thirty-six months. Currently, federal law limits Medicare reimbursement for the immunosuppressant drugs that transplant recipients must take throughout the rest of their lives. Bills have been introduced in every session of Congress since 2000 to lift the thirty-six-month limit and to extend coverage of immunosuppressant drugs indefinitely. These bills have never made it to a vote. The most recent report from the United States Renal Data System found that Medicare spends an average of \$17,000 a year on care for kidney transplant recipients, most of it for anti-rejection drugs. That compares with \$71,000 a year for dialysis patients. H.R. 3200, 111th Cong. 1st Reg. Sess. (2009).

### **Interesting Developments in Other Countries**

**International.** On 18 October, 2009, the United Nations and the Council of Europe published a joint study, titled, "Trafficking in organs, tissue, and cells and trafficking in human beings for the purpose of the removal of organs." The study advocates development of an international treaty to prevent trafficking in organs, tissues and cells (OTC). The study highlights a need for and internationally agreed definition of "trafficking in OTC," as distinct from trafficking in human beings for the purpose of organ removal. The study calls for legislation prohibiting financial gain from transplantation. Given that the proliferation of trafficking exists due to the inaccessibility of organs, the study endorses organizational and promotional measures to increase organ availability. Joint Council of Europe/ United Nations Study, "Trafficking in organs, tissues and cells and trafficking in human

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beings for the purpose of the removal of organs,” available at [http://www.coe.int/t/dghl/monitoring/trafficking/Docs/News/Organ\\_Trafficking\\_study.pdf](http://www.coe.int/t/dghl/monitoring/trafficking/Docs/News/Organ_Trafficking_study.pdf) (last accessed 21 December 2009).

**Singapore.** On 08 January 2010, Singapore announced it is considering a process to pay organ donors as much as 50,000 Singapore dollars (almost \$36,000) for their organs. Millions of

people suffer from kidney disease, but in 2007 there were only 64,606 kidney-transplant operations in the entire world. In the U.S. alone, 83,000 people wait on the official kidney-transplant list. In March 2009 Singapore legalized a government plan for paying organ donors.. Alex Tabarrok, “The Meat Market,” *The Wall Street Journal*, 08 January 2010.

## HIV / AIDS

### Recent Judicial Cases

**Federal.** On 25 August 2009, *Doe v. Clinton*, a case set for trial in the United States District Court for the District of Columbia was settled by the State Department. The State Department settled with a United States army veteran who claimed he was discriminated against based on his HIV status. The veteran claims he was denied a security job with U.S. State Department contractor Triple Canopy, Inc. in 2005 as a result of being HIV positive, violating the Rehabilitation Act for the Americans with Disabilities Act. *Doe v. Clinton*, CV-01678, U.S. Dist. Ct. District of Columbia (2009).

### Recent Laws and Regulations

**Federal.** On 20 October, 2009, the House of Representatives reauthorized the Ryan White Care Act by a vote of 408-9. The bill ensures four more years of funding, apportioning \$2.55 billion for the 2010 fiscal year, which will rise to \$2.95 billion by 2013. The bill first passed in 1990 shortly after the death of

Ryan White, an Indiana teenager who contracted HIV from a blood transfusion. H.R. 2918 (111th Cong. 1st Reg. Sess. (2009).

**Federal.** Effective 2 January 2010, the Centers for Disease Control and Prevention (CDC) amended its regulations to remove “Human Immunodeficiency Virus (HIV) infection” from the definition of communicable disease of public health significance, along with its references to “HIV” in medical examination of aliens for immigration. Prior to this amendment, aliens with HIV infection were banned from entering the United States under the Immigration and Nationality Act (INA) of 1952 which restricts immigration into the United States in part based on whether the immigrant has a communicable disease of public health significance. In 1993 the CDC defined AIDS as such a disease. The revision just passed removed AIDS from the list of diseases “of public health significance” under the Act. Department of Health and Human Services, Centers for Disease Control and Prevention, “Medical Examination of Aliens—

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Removal of Human Immunodeficiency Virus (HIV) Infection from Definition of Communicable Disease of Public Health Significance,” 42 CFR Part 34.

**District of Columbia.** On September 30, 2009, a bill was introduced that would amend laws that provide inmates and committed youth offenders with voluntary HIV testing to make such testing mandatory. The bill also includes a provision that, if an individual is found to be HIV positive, the state will provide, offer, or arrange for him/her to receive appropriate counseling, healthcare, and support services. Council of the District of Columbia, B18-0075, (2009), available at <http://www.dccouncil.washington.dc.us/images/00001/20090109133304.pdf> (last accessed 22 December 2009).

### **Interesting Developments in Other Countries**

**South Africa.** On 01 December 2001, President Jacob Zuma announced that he would revise the South African government’s previous policies that were delaying the treatment of AIDS in pregnant women. The new policy on pregnant women is aimed at ensuring babies are born healthy, and is in line with the new treatment guidelines issued by the World Health Organization.

Treating infected babies earlier is expected to help South Africa, one of only four countries in which child mortality has worsened since 1990. More people in South Africa are HIV positive than in any other nation. Celia Dugger, *The New York Times*, December 1, 2009, “Breaking with Past, South Africa Issues Broad AIDS Policy,” available at <http://www.nytimes.com/2009/12/02/world/africa/02safrica.html> (last accessed 24 December 2009).

**Uganda.** On 10 December 2009, a revision was introduced to a bill before the Uganda Parliament that will drop the death penalty and life imprisonment for gays in a refined version of an anti-gay bill about to be presented to the Ugandan Parliament for a vote. The draft of the bill, which is under consideration by parliamentary committee, will drop the two punishments to attract the support of religious leaders who are opposed to these penalties. In addition to reformulating punishments for gay people, the bill will also promote counseling to help “attract errant people to acceptable sexual orientation. Bloomberg, “Uganda will drop death penalty, life imprisonment for gays in refined anti-gay bill,” [http://www.nydailynews.com/news/world/2009/12/10/2009-1210\\_uganda\\_to\\_drop\\_death\\_penalty\\_life\\_imprisonment\\_for\\_gays\\_in\\_refined\\_antigay\\_bill.html](http://www.nydailynews.com/news/world/2009/12/10/2009-1210_uganda_to_drop_death_penalty_life_imprisonment_for_gays_in_refined_antigay_bill.html) (last accessed 24 December 2009).

## **MEDICAL MARIJUANA**

### **Recent Judicial Cases**

\***California.** On 11 June 2009, the U.S. District Court for the Central District of

California sentenced Charles Lynch, the owner of a medical marijuana dispensary in Morro Bay California, to prison for one year and one day for illegally

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dispensing marijuana. Lynch was convicted on five federal counts in connection with the running of his dispensary and the selling of medical marijuana to customers under twenty-one. Federal law prohibits the cultivation, sale, and use of marijuana for medicinal purposes, but thirteen states allow it. Lynch will serve jail time despite the Obama administration's promise not to prosecute the owners of marijuana dispensaries if they comply with state law because Lynch's prosecution began during the Bush administration. *United States v. Lynch*, 2:07-cr-00689-GW (U.S. Dist. Ct. Central Dist. CA) available at <http://www.friends-of-ccl.com/documents/2009-10-09GovernmentNudgesJudgeWu.pdf> (last accessed 13 November 2009).

### Recent Laws and Regulations

**Federal.** On 19 October, 2009, the Department of Justice issued a memorandum to federal prosecutors advising attorneys not to seek prosecution against "individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the use of medical marijuana." The memorandum maintains that the Department has not changed its commitment to prosecuting the unlawful marketing and selling of marijuana and other illegal drugs. "Office of the Deputy Attorney General," "Memorandum for Authorizing the Medical Use of Marijuana, available at <http://www.justice.gov/opa/documents/medical-marijuana.pdf> (last accessed 21 December 2009).

## TRUST / ACCOUNTABILITY / CONFLICTS OF INTEREST

### Recent Judicial Cases

**\*Illinois.** On 23 September 2009, the state supreme court heard oral arguments in the case of a hospital arguing for tax exempt status based on what it claims should be an unconditional extension of charity, regardless of the quantity of charitable care provided. The court will decide what, if any, quality of care restrictions the state may impose in its determination of tax exempt status for nonprofit hospitals. *Provena Covenant Medical Center v. The Department of Revenue of the State of Illinois* (IL Docket No. 107328 2009) available at [http://163.191.183.117/court/SupremeCourt/Video/2009/092309\\_107328.wmv](http://163.191.183.117/court/SupremeCourt/Video/2009/092309_107328.wmv) (last accessed 21 October 2009).

**\*Minnesota.** On 20 October 2009, a district court judge dismissed more than 600 state court lawsuits against Medtronic involving its 2007 recall on the Medtronic Sprint Fidelis defibrillator leads. The court followed precedent set forth in the United States Supreme Court case, *Riegel v. Medtronic*, in which the Court ruled that the FDA's pre-market approval shows federal requirements for the device were met. *In re Medtronic Sprint Fidelis*, CV-09-19604 (Minn. 4th Jud. Dist. County of Hennepin, 2009).

**Pennsylvania.** On 20 November 2009, a Philadelphia jury ordered pharmaceutical giant Pfizer to pay \$6.3 million in compensatory damages to an Illinois

breast cancer survivor after finding that menopause drugs Premarin, Provera and Prempro caused the disease. The panel also found that punitive damages are warranted because of willful and wanton conduct by Pfizer, Wyeth and Pharmacia & Upjohn in failing to warn patient about risks associated with the drugs. The award is the largest so far of about three dozen Prempro cases tried in Philadelphia, out of about 1,500 pending lawsuits. *Kendall v. Wyeth et al*, Philadelphia County Court of Common Pleas, No. 0406000965 (2009).

### **Recent Laws and Regulations**

**Federal.** On 25 September, 2009, the Government Accountability Office (GAO) issued a report recommending improved efficiency and a larger scope for the Federal Drug Administration's actions against medical product investigators involved in research fraud. Upon in-depth review of eighteen convictions from 1992 to 2008, the GAO found more than half took over four years from conviction to debarment. Debarment from drugs and biologics does not extend to medical devices, thus an investigator debarred from work in drugs and biologics research might still legally work in medical devices research. The GAO recommended increasing pervasiveness of debarment to cover all investigational medical products. Recent revisions by the FDA in the disqualification process aim to expedite the process, and the GAO encouraged monitored compliance with the established time frames. United States Government Accountability Office, "Oversight of Clinical Investigators: Action Needed to Improved Timeliness and Enhance

Scope of FDA's Debarment and Disqualification Processes for Medical Product Investigators," available at <http://gao.gov/products/GAO-09-807> (last accessed 21 December 2009).

**California.** On 24 September 2009, the state Department of Public Health issued eleven hospitals administrative penalties of \$25,000 per violation regarding noncompliance with requirements of licensure leading to, or potentially leading to, serious injury or death. The offenses varied from not following surgical policy and procedure, resulting in a second surgery to remove foreign objects, failure to monitor patient status and medical needs, using inappropriately trained staff providing nursing care, not following fall prevention, and not communicating laboratory test results to hospital personnel and providers. The penalties follow on authority of section 1280.1 of the Health and Safety Code. Hospitals are required to implement a plan of correction to prevent future incidents. Al Lundeen, "CDPH Issues Administrative Penalties to 11 Hospitals," available at <http://www.cdph.ca.gov/Pages/CDPHISSUESADMINISTRATIVEPENALTIES11HOSPITALS.aspx> (last accessed 21 October 2009).

**New Jersey.** On 03 December 2009, the state Attorney General asserted in a press conference that doctors should be required to turn down free offers from pharmaceutical companies including golf outings, most meals, and other trinkets. The Attorney General also stated that doctors need to disclose consulting and speaking fees and urged the Board of Medical Examiners and the Board of Pharmacy, the state boards that license physicians and pharmacists, to

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adopt these rules to strengthen public confidence in New Jersey's medical professionals. City of New Jersey New Jersey, Press Releases: "NJ wants doctors to turn down freebies from drug,

medial companies," [http://www.ci.newark.nj.us/press/news\\_about\\_newark/2009\\_12\\_04\\_01.php](http://www.ci.newark.nj.us/press/news_about_newark/2009_12_04_01.php) (last accessed 24 December 2009).

## FDA

### Recent Laws and Regulations

**Federal.** In 30 September 2009, following authority granted in 2007, the FDA issued draft guidance to the pharmaceutical industry regarding the format and content of proposed risk evaluation and mitigation strategy (REMS) and the content of assessments and proposed modifications to approved REMS. REMS, either mandated by the FDA or submitted by the pharmaceutical company, entail additional disclosures and limitations on the use of a specific drug in order to ensure that the benefit of the drug outweighs the risks. In particular, the proposed REMS will require specific elements to ensure safe use. The Food and Drug Administration, "Guidance for Industry: Format and content of Proposed Risk Evaluation and Mitigation Strategies (REMS), Proposed REMS Modifications," (2009), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInform>

[ation/Guidances/UCM184128.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInform/Guidances/UCM184128.pdf) (last accessed 23 December 2009).

**Federal.** On 19 November 2009, the FDA's weeklong concerted effort in the International Internet Week of Action (IIWA) ended. IIWA was intended to curb illegal actions involving medical products. The FDA's Office of Criminal Investigations (OCI) targeted 136 websites engaged in the illegal sale of unapproved or misbranded drugs to United States consumers. Around two dozen letters were issued to website operators. The OCI also informed internet service providers and domain name registrars of the infractions. The Food and Drug Administration, "FDA Issues 22 Warning Letters to Web site Operators: Part of International Internet Week of Action," *FDA News Release*, 19 November 2009, available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm191330.htm> (last accessed 24 December 2009).

## VACCINES

### Recent Laws and Regulations

**\*Federal.** On 01 December 2009, the Advisory Committee on Immunization Practices recommended that pregnant women, children, and health-care workers be among the first in line to

receive a vaccine for protection against H1N1 swine flu. The panel said that aside from pregnant women, shots should be given first to those in close contact with infants under six months old, health and emergency medical services workers, children and young

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adults from six months old through age twenty-four, and people over under sixty-five years old with underlying medical conditions. The panel made a point of including young adults from ages nineteen to twenty-four in the list of those to receive vaccine first because the rapid spread of the disease in schools, summer camps and military units suggests outbreaks are likely to erupt on college campuses. Currently, the H1N1 swine flu has caused 5,011 hospitalizations and 302 deaths as of July 24, according to the Centers for Disease Control and Prevention. Center for Disease Control, “General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP),” <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm> (last accessed 24 December 2009).

**Federal.** On 11 December 2009, the Institute of Medicine (IOM) asserted that the United States needs to establish a permanent group that advises the government on vaccine safety and spend more money to address safety concerns about vaccines. The institute, a member of the National Academies of Sciences advising United States policymakers, called for a stronger, more focused national vaccine strategy that sets the nation’s vaccine research agenda. The committee reviewed a draft of the U.S. Department of Health and Human Services’ National Vaccine Plan, which sets the national agenda for protecting Americans from vaccine-preventable illness. The IOM said the revised plan also should include a strategy to speed

the development of high-priority vaccines, and expand funding for safety research and monitoring, including the development of a national communications strategy to bolster public confidence in vaccines. Institute of Medicine, “Priorities for the National Vaccine Plan, Report Brief December 2009,” available at [http://www.iom.edu/~media/Files/Report%0Files/2009/Priorities-for-the-National-Vaccine-Plan/PrioritiesNational\\_Vaccine\\_Plan\\_2009\\_Report\\_Brief.aspx](http://www.iom.edu/~media/Files/Report%0Files/2009/Priorities-for-the-National-Vaccine-Plan/PrioritiesNational_Vaccine_Plan_2009_Report_Brief.aspx) (last accessed 24 December 2009).

**Federal.** On 14 December 2009, the Centers for Disease Control and Prevention removed the requirement that immigrant women be vaccinated against the sexually transmitted virus that can cause cervical cancer. In August 2008, authorities began requiring the vaccine for girls and women ages eleven to twenty-six who were applying for green cards. The vaccine was not required for citizens, and the virus is not spread through casual contact. At a cost of about \$400 for a series of three inoculations, applicants for green cards had to pay for the vaccine themselves, and this requirement placed an additional undue burden on girls and women who sought residency in this country. Centers for Disease Control and Prevention, Department of Health and Human Services, “New Vaccination Criteria for U.S. Immigration Frequently Asked Questions,” available at [http://www.cdc.gov/ncidod/dq/laws\\_regs/fed\\_reg/vaccine/revised-vaccination-immigration-faq.htm](http://www.cdc.gov/ncidod/dq/laws_regs/fed_reg/vaccine/revised-vaccination-immigration-faq.htm) - added (last accessed 24 December 2009).

## HEALTHCARE COVERAGE

### Recent Judicial Cases

**Federal.** On 21 October, 2009, twenty people in the Los Angeles area were charged in seven cases of Medicare fraud. The investigation was led by the Medicare Fraud Strike Force. The Strike Force targeted durable medical equipment (DME) providers in the Los Angeles area and discovered fraudulent billing totaling over \$26 million. Fraudulent activity included suppliers paying kickback fees for referrals, billing for equipment that was unneeded or never supplied, and claims on behalf of deceased persons. Since its March 2007 inception, the Medicare Fraud Strike Force has indicted 331 individuals suspected of Medicare fraud totaling \$720 million. United States Department of Justice, “Los Angeles Medicare Fraud Strike Force Charges 20 in Healthcare Fraud Cases Involving Durable Medical Equipment,” Press release: <http://www.justice.gov/opa/pr/2009/October/09-crm-1131.html> (last accessed 21 December 2009).

**California.** On 10 September 2009, the Northern District of California for the Oakland Division issued a preliminary injunction halting cuts to Medi-Cal Adult Day Health Care, as proposed in the Budget Act of 2009. These cuts would have temporarily reduced this service to a maximum of three to five days per week and were found in violation of the Americans with Disabilities Act (ADA). *Lillie Brantley, Gilda Garcia, Allie Jo Woodard v. David Maxwell-Jolly and Department of Health Care Services*, (U.S. Dist. Ct. Northern Dist. Cal. Oakland, Docket

14,25, 10 September 2009), available at [http://www.cdcan.us/legal\\_issues/CDCA-N-FederalJudgeOrder-AdultDayHealthCenters.pdf](http://www.cdcan.us/legal_issues/CDCA-N-FederalJudgeOrder-AdultDayHealthCenters.pdf) (last accessed 21 December 2009).

### Recent Laws and Regulations

**Federal.** On 28 October, 2009, the Senate Judiciary Committee held a hearing on healthcare fraud and the proposed amendments to the Health Care Fraud Enforcement and Recovery Act. It is estimated that at least \$60 million is lost to healthcare fraud every year. Representatives from the Department of Justice (DOJ) and Health and Human Services (HHS) provided testimonies on their respective efforts to combat fraud. They highlighted successes and noted that President Obama’s investment in fraud detection has resulted in excellent returns (exceeding 400 percent by some estimates) in money recovered. Department of Health and Human Services, “Effective Strategies for Preventing Health Care Fraud Before the Senate Judiciary Committee, October 28, 2009,” Testimony available at <http://judiciary.senate.gov/pdf/10-28-09-Corr-Testimony.pdf> (last accessed 23 December 2009).

**California.** On 22 September 2009, the California governor signed into law a bill that ensures taxation of the total operating revenue to provide proceeds for the Medi-Cal program and the Managed Risk Medical Insurance Board for the Healthy Families Program. In so doing, the law provides funding for health care services for children less than

nineteen years of age with certain criteria and increase premiums paid for Healthy Families Program. CA HSC § 130105, A.B. 1422 2009, available at [http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab\\_1401-1450/ab\\_1422\\_bill\\_20090922\\_chaptered.pdf](http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab_1401-1450/ab_1422_bill_20090922_chaptered.pdf) (last accessed 22 December 2009).

**New Jersey.** In July 2009, twelve New Jersey hospitals began a trial run of a Medicare project intended to improve health care and decrease spending by providing financial incentives to physicians to improve the quality and coordination of patient care as well as long term outcomes for patients. Doctors will receive gainsharing for medical and surgical episodes of care based on their participation in the program and the resulting cost savings. Centers for Medicare and Medicare Services, “Physician Hospital Collaboration Demonstration,” (2009) available at [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/PHCD\\_646\\_Fact\\_Sheet.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/PHCD_646_Fact_Sheet.pdf) (last accessed 23 December 2009).

**New Jersey.** On 22 September 2009, the mayor of Newark announced in a press conference that NewarkHealth Plus and NewarkRx will provide health care to uninsured and underinsured residents at little or no cost. These new programs are aimed at providing critically-needed prescription medications and a medical home, with all medical services in one location. Newark has partnered with organizations including the Heinz Family Philanthropies to demonstrate the savings that can be achieved by providing care before residents have no alternative than to resort to emergency room care. Newark Press release,

“September 22 – Qualifying Newarkers to Receive Low cost/No Cost Primary Care and Prescription Drugs,” 22 September 2009, available at [http://www.ci.newark.nj.us/press/press\\_releases/2009\\_09\\_22\\_01.php](http://www.ci.newark.nj.us/press/press_releases/2009_09_22_01.php) (last accessed 21 December 2009).

**North Carolina.** On 27 April, 2009, the Governor signed Senate Bill 287 into law. The bill includes financial incentives for weight management and cessation of tobacco use. Effective July 1, 2010, state employees and teachers will be automatically enrolled in the 70/30 Basic Plan, unless they can show that they do not use tobacco, thus placing them in the 80/20 Standard Plan. Beginning July 1, 2011, the same will be true unless members show a body mass index (BMI) lower than 40. The bill estimates that 70,000 Plan members currently use tobacco. Each accounts for approximately \$2,000 more in health coverage per year than non-users. The bill links obesity to an over thirty-seven percent increase in healthcare spending. The incentives aim to decrease healthcare expenditures. S.B. 287, NC Gen. Assem. Sess. (2009) available at <http://www.ncga.state.nc.us/Sessions/2009/Bills/Senate/PDF/S287v7.pdf> (last accessed 23 December 2009).

**Texas.** In February 2009, the U.S. Government Accountability Office (GAO) reported on a study of fraudulent Medicare home health agency (HHA) abuses in the state of Texas. Nationwide, Medicare home health spending rose forty-four percent to \$12.9 billion between 2002 and 2006. Texas Medicare home health spending rose 144% in the same timeframe. A key area of waste is attributed to upcoding—wherein the severity of a condition being

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managed by an HHA is overstated. Examining 670 claims of the most severe clinical ratings in the Houston area, the GAO found that only nine percent were correctly coded. The GAO offered four recommendations: investigate officials named on HHA enrollment applications for criminal history, provide physicians to certify HHA statement of services, conduct prepayment review of HHAs with high rates of improper claims, and amend regulations to expand grounds for revocation of billing privileges. Government Accountability Office, "Medicare: Improvements Needed to Address improper Payments in Home Health," February 2009, available at <http://www.gao.gov/new.items/d09185.pdf> (last accessed 21 December 2009).

**Utah.** On 11 March 2009, the Department of Health, the Insurance Department, and the Governor's Office of Economic Development launched the Utah Health Exchange, a website designed to allow employers to set up health insurance contributions for its workers, and for individuals to compare and enroll in health insurance plans. The site is an effort to move the health

system towards a consumer-based system, empowering the individual to take a more active role in his/her health, health care, and health care financing. Primary goals of the exchange include informing consumers, providing means to compare and select health insurance, and standardization in the electronic application and enrollment system. H.B. 188, UT Gen. Sess. 2009, available at <http://exchange.utah.gov> (last accessed 23 December 2009).

### **Recent Developments in the Private Sector**

**Minnesota.** On 01 December 2009, Blue Cross of Minnesota tested a healthcare virtual clinic, whereby patients can seek medical advice by logging onto their home computers. The partnership puts Minnesota at the forefront of such online technology. A Blue Cross affiliate in Hawaii already offers patients access to the system. Blue Cross in Minnesota will be the second. Jeremy Olson, "Blue Cross workers try out health care in a virtual clinic," [http://www.twincities.com/ci\\_13904533?nclick\\_check=1](http://www.twincities.com/ci_13904533?nclick_check=1) (last accessed 24 December 2009).

## **CLINICAL TRIALS**

### **Recent Laws and Regulations**

**\*Federal.** On 12 August 2009, the U.S. Food and Drug Administration finalized new regulations to provide broader access to experimental drugs for seriously ill people who have exhausted all other commercially available treatments. The new rules clarify regulations explaining how patients can

receive drugs in development outside of a clinical trial, and set standards for when drug companies or researchers can charge for the treatments. The two new rules include: 1) Describing how patients can obtain access to drugs outside of a clinical trial; and 2) Allowing companies and researchers to charge patients for the experimental treatments, potentially allowing more start-up or smaller firms

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to participate in expanded-access programs. Currently patients can obtain access to experimental products by participating in a study of the drug. Not all patients qualify for such trials, but they can seek FDA approval to obtain a drug or biologic outside such a trial through a so-called expanded-access program. The FDA must approve patient

participation in an expanded-access program. United States Department of Health and Human Services, *FDA Issues Final Rules to Help Patients Gain Access to Investigational Drugs*, FDA, available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm176526.htm> (last accessed 21 December 2009).

## PRIVACY

### Recent Laws and Regulations

**Federal.** On 30 November 2009, the US Department of Health and Human Services issued an interim final rule increasing the financial penalties for the Health Insurance Portability and Accountability Act of 1996 (HIPAA) violations. The new regulations reflect the requirements enforced by the Health Information Technology for Economic

and Clinical Health (HITECH) part of the American Recovery and Reinvestment Act (ARRA) of 2009. The new penalties incorporate HITECH's categories of violations, tiered ranges of financial penalties, and revised limitations on imposing financial penalties for established HIPAA violations. S. 350, 111th Cong. 1st Reg. Sess. (2009).

## PRISONERS

### Recent Laws and Regulations

**New York.** On 30 September 2009, the Governor signed into law a bill that will make New York the sixth state to prohibit the practice of shackling incarcerated pregnant women during labor. Incarcerated women nationwide routinely are shackled while giving birth, often by correctional staff who do not have medical training. The bill bans restraints on inmates giving birth, except when needed to keep a woman from

injuring herself, medical workers or correctional officers. It was common practice for one of the woman's wrists to be cuffed while being transported from prison to the hospital. Federal prisons and five states, California, Illinois, New Mexico, Texas and Vermont, have also banned the procedure. A. 9168, NY Reg. Sess. (2009), available at <http://assembly.state.ny.us/leg/?bn=A09168&sh=t> (last accessed 22 December 2009).

## UNCONVENTIONAL TREATMENT (XENOTRANSPLANTATION)

### Developments in Other Countries

**Australia.** On 31 December 2009, the National Health and Medical Research Council's (NHMRC) ended its five-year ban on xenotransplantation, allowing the NHMRC to review its position. The ban was implemented in 2004 due to concerns about the transmission of animal viruses to human recipients. A lift of the ban will allow cells, tissues, or organs to be transplanted into humans for research on therapeutic clinical trials

and technological advancements. In the United States, the clinical use of xenotransplantation products is regulated by the FDA under the PHS Act (42 U.S.C. 262) and Section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321). "Animal to Human Transplantation Research (Xenotransplantation)," *Research and General Notices 2009*, 16 November 2009, <http://www.nhmrc.gov.au/media/noticeboard/notice09/index.htm> (last accessed 24 December 2009).

## DISABILITIES

### Recent Judicial Cases

**New York.** On 08 September 2009, a federal district court found that the state of New York discriminated against mentally ill residents when it denied thousands of individuals with mental illness the benefit of services provided in appropriate integrated settings. The plaintiff sought an injunction to remove and prevent further placement of mentally ill adults in group homes if they qualify to live in other settings. The court withheld issuing an injunction on defendants until they have had the opportunity to propose a remedial plan consistent with the findings. *Disability Advocates, Inc. v. David A. Paterson, Richard F. Daines, and Michael F. Hogan* (03-CV-3209 08 September

2009), available at <http://www.nhmrc.gov.au/media/noticeboard/notice09/index.htm> (last accessed 21 December 2009).

### Recent Laws and Regulations

**\*Federal.** On 21 November 2009, the Genetic Information Nondiscrimination Act (GINA) of 2008 went into effect. This act protects Americans from unfair treatment due to differences in their DNA that may affect their health. The Act prohibits employers from requesting genetic testing or considering genetic background in decisions regarding hiring, firing, or promoting. It was signed on May 21, 2008. H.R. 493, 110th Cong. 2nd Sess. (2008).

# BIOETHICS GENERAL

## Recent Laws and Regulations

**Federal.** On 24 November 2009, the White House announced the formation of a new Presidential Commission for the Study of Bioethical Issues, and elected Emory University President James Wagner as its vice chairman. The commission will be chaired by University of Pennsylvania President Amy Gutmann. The commission will advise President Barack Obama on issues of bioethical importance as new technologies and research in biosciences emerges. The Commission will work with the goal of identifying and promoting policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in an ethically responsible manner. White House Office of the Press Secretary, “President Obama Establishes New Presidential Commission for the Study of Bioethical Issues, Names Commission Leadership,” <http://whitehouse.gov/the-press-office/president-obama-establishes-new-presidential-commission-study-bioethical-issues-nam> (last accessed 24 December 2009).