



The Center for Ethical Solutions
Innovative Approaches to Health Care Policy

LEGAL TRENDS IN BIOETHICS SPRING 2011 ONLINE ISSUE, No. 4

Editors:

Phoebe Stone, Sigrid Fry-Revere

Contributors:

Phoebe Stone, Sigrid Fry-Revere

*Adam Hemmings, Amira Elhagmusa, Amy Rowland, Ashumi Merchant, Aurelia Tunru,
Casey Hayes, Claudia Kraft, Dara Jospe, Essica M. Zink, Kathryn Schwed, Lauren
Hardesty, Maybelle Y. Miranda, Megan L. Penrod, Michael Igoumenidis, Mohammad Ali
Naquvi, Sachin Gupte*

The Center for Ethical Solutions is a non-partisan, non-profit, 501(c)(3), tax-exempt charity dedicated to educating the public on issues in patient-care ethics. The Center's financial statement (990EZ IRS annual tax filing) is available at upon written request from the Center or from the Commonwealth of Virginia Office of Consumer Affairs. www.ethical-solutions.org.

TABLE OF CONTENTS

How to Use This Resource.....	3
General Introduction.....	4
Conscientious Objection.....	6
Disability.....	7
End-of-Life Decisions.....	8
FDA.....	10
Healthcare Coverage.....	10
HIV / AIDS.....	13
Informed Consent.....	15
Intellectual Property.....	15
Medical Marijuana.....	16
Mental Health.....	18
Neuroscience and the Law.....	18
Organ Donation and Procurement.....	19
Pharmaceutical Industry.....	22
Prisoners.....	23
Privacy, Genetics and DNA.....	23
Rights of Maturing Individuals and Their Parents.....	26
Stem Cells.....	30
Trust / Accountability / Conflicts of Interest.....	31
Vaccines.....	36

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.

() 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 or the Editor at legal.trends@gmail.com. The opinions expressed in the introductory sections are those of Sigrid Fry-Revere and may or may not be shared by contributing authors.

The Center for Ethical Solutions is a non-partisan, non-profit, 501(c)(3), tax-exempt charity dedicated to educating the public on issues in patient-care ethics. The Center’s financial statement (990EZ IRS annual tax filing) is available at upon written request from the Center or from the Commonwealth of Virginia Office of Consumer Affairs. www.ethical-solutions.org.

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.

CONSCIENTIOUS OBJECTION

Recent Legislative Action

***Idaho.** On 20 January 2011, H.B. 28 was introduced in the state legislature to modify the language of Idaho Code Sec. 18-611, which is known as the Freedom of Conscience for Health Care Professionals Act. The Act provides that no health care professional is required to perform services that violate his/her conscience. The amendment proposes to modify the Act such that no health care practitioner may refuse to act in

accordance with a patient's or physician's directions. H.B. 28 (2011 Leg. Sess.), available at <http://www.legislature.idaho.gov/legislation/2011/H0028Bookmark.htm> (last accessed 06 February 2011). *See also*, Idaho Code Sec. 18-611, available at <http://www.legislature.idaho.gov/idstat/Title18/T18CH6SECT18-611.htm> (last accessed 06 February 2011).

Interesting Developments in Other Countries

Europe. On 15 September 2010, the European Parliament Platform for Secularism in Politics hosted a debate in Brussels to discuss conscientious objection to abortion and physician aid in dying; the conference was held to address concerns across Europe that unregulated conscientious objection, primarily due to the religious beliefs of treating medical professionals, has been depriving patients of certain, legally permissible treatments. Debate participants agreed that a physician's wishes should be taken into account, but not if doing so put the patient's well-being at risk. In addition, debate participants addressed concerns that physicians might withhold information about treatment options in order to influence a patient's decision. "Religious conscience in medicine debate in EU Platform for Secularism," National Secular Society, 01 October 2010, available at

<http://www.secularism.org.uk/123912.html> (last accessed 17 December 2010). *See also*, Introductory Remarks, available at <http://www.secularmedicalforum.org.uk/index.php?subject=resources> (last accessed 18 December 2010).

On 07 October 2010, the Parliamentary Assembly of the Council of Europe adopted a modified version of the Women's Access to Lawful Medical Care: the Problem of Unregulated Use of Conscientious Objection, a report and resolution designed to help regulate conscientious objection by physicians in Europe. Also known as "the McCafferty Report," the proposal originally suggested that governments regulate conscientious objection within public medical facilities so that women could exercise their legal right to choose abortion. However, the text as adopted was amended to state that no physician

or hospital can be held liable for not performing an abortion or act of euthanasia as long as patients are timely informed of the practitioner's objection and referred elsewhere for treatment. Council of Europe Resolution 1763, available at <http://assembly.coe.int/ASP/APFeatures/Manager/defaultArtSiteView.asp?ID=95>

[0](#) (last accessed 18 December 2010). *See also* Women's Access to Lawful Medical Care, Doc. No. 12389 (2010), available at <http://assembly.coe.int/main.asp?Link=/documents/workingdocs/doc10/edoc12389.htm> (last accessed 18 December 2010).

DISABILITY

Recent Legislative Actions

Federal. On 05 October 2010, the President signed into law "Rosa's Law" which requires that the phrase 'mental retardation' be replaced with 'intellectual disability' and the phrase 'mentally retarded individual' be replaced with 'individuals with an intellectual disability' in all federal statutes and policies affecting health, education and labor. S. 2781 ("Rosa's Law") (111th Congress, 2009-2010) available at <http://www.govtrack.us/congress/bill.xpd?bill=s111-2781> (last accessed 17 December 2010).

On 12 October 2010, the President signed into law the Indian Veterans

Housing Opportunity Act of 2010, legislation that will protect the disability rights of Native Americans. This Act amends the Native American Housing Assistance and Self-Determination Act of 1996 by excluding from the calculation of a family's income any amounts received from the Department of Veterans' Affairs as disability compensation or related benefits as the result of the service-related disability of a family member. Public Law No: 111-269 available at <http://www.govtrack.us/congress/bill.xpd?bill=h111-3553> (last accessed on 17 December 2010).

Recent Regulatory Actions

Federal. On 28 September 2010, the Department of Veteran Affairs (V.A.) released new guidelines that will make it easier for veterans who served in Southwest Asia, including Iraq, or Afghanistan to receive V.A. health care and disability coverage. If a veteran manifests any one of nine infectious

diseases prevalent in Southwest Asia or Afghanistan, and a disability results, s/he will be eligible for medical and compensation benefits. "VA Publishes Final Regulation on "Presumptive" Illnesses for Gulf War and Iraq, Afghanistan Veterans" 28 September 2010, available at

http://www1.va.gov/opa/pressrel/pressrel_ease.cfm?id=1974 (last accessed 17

December 2010).

Interesting Developments in Other Countries

Canada. On 05 October 2010, an act to amend the Income Tax Act (hearing impairment) was introduced into Canadian Parliament as a private member's bill. The bill would make disability tax credits more readily available to those who are hearing impaired by modifying the current requirements for tax credit eligibility in several ways: (i) a person would be eligible for tax credits if s/he is unable to

understand another person; (ii) a person would not be required to wear an assisted listening device when his/her impairment is assessed for eligibility; and (iii) the eligibility assessment would occur in a 'normal' sound setting rather than in a 'quiet' setting. Bill C-577 (Canadian House of Commons, 3rd Sess, 40th Parl, 2010) available at <http://openparliament.ca/bills/2323/> (last accessed 17 December 2010).

END-OF-LIFE DECISIONS

Recent Legislative Actions

Montana. On 05 November 2010, a bill was proposed in the state Senate that would prohibit physician-assisted suicide in Montana. The bill, termed the Montana Patient Protection Act, is a response to the 2009 decision of the Montana Supreme Court's in *Baxter v. State*, in which the court held that a physician-assisted suicide does not violate public policy and that a patient's consent to the use of physician assisted suicide provided a defense to criminal charges that might otherwise be levied against the participating physician(s). LC0041 (2011 MT Reg. Sess.), available at [http://laws.leg.mt.gov/laws11/LAW0210w\\$BSIV.ActionQuery?P_BILL_DFT_N05=LC0041&Z_ACTION=Find](http://laws.leg.mt.gov/laws11/LAW0210w$BSIV.ActionQuery?P_BILL_DFT_N05=LC0041&Z_ACTION=Find) (last accessed 17 December 2010). *See also* "The Hinkle Report," available at

<http://margaretdore.com/pdf/HinkleReport.pdf> (last accessed 17 December 2010).

Vermont. On 02 November 2010, Peter Shumlin was elected governor of Vermont. Shumlin is an advocate of physician aid in dying and vowed to legalize physician-assisted suicide if elected. Vermont previously attempted to pass euthanasia legislation, but the efforts proved unsuccessful due to gubernatorial veto. Election Results 2010. available at <http://elections.nytimes.com/2010/results/vermont> (last accessed 06 February 2011). *See also* J. Lindholm, "Shumlin Ready To Work With All Parties," *Vermont Public Radio News*, 03 November 2010, available at http://www.vpr.net/news_detail/89186/ (last accessed 17 December 2010); D.

Walters, “Vermont: A Prime Candidate for First Legislative Death With Dignity Victory,” 08 December 2010, available at <http://www.deathwithdignity.org/2010/12/08/vermont-legislative-victory/> (last accessed 17 December 2010); H.B. 455 (2009 VT Leg. Sess.) (as proposed); S.B. 144 (2009 VT Leg. Sess.) (as proposed).

2/08/vermont-legislative-victory/ (last accessed 17 December 2010); H.B. 455 (2009 VT Leg. Sess.) (as proposed); S.B. 144 (2009 VT Leg. Sess.) (as proposed).

Interesting Developments in Other Countries

***Canada.** On 21 April 2010, the Canadian House of Commons rejected Bill C-384, seeking to legalize physician assisted suicide. The bill was defeated 228-59. This bill was first introduced in 2005 and was repeatedly re-introduced thereafter but failed in 2006 and 2008. Bill C.384, (2010 40th Parliament 3rd Sess) <http://www2.parl.gc.ca/Sites/LOP/LEGISINFO/index.asp?Langage=E&Session=23&query=6820&List=toc-1> (last accessed 17 December 2010).

Cases of Encouraging or Assisting Suicide” available at http://www.cps.gov.uk/publications/prosecution/assisted_suicide_policy.html (last accessed 17 December 2010).

***England.** In February 2010, in light of the recent events and discussion surrounding the *Purdy* case, (see, Legal Trends, Winter 2010, issue no. 2) British Courts have clarified the parameters for prosecuting cases of encouraging and/or assisting suicide. The guidelines promulgated by the Director of Public Prosecutions delineate factors that weigh in favor or against prosecution prosecution. Among other considerations, the balance tips in favor of prosecution in situations in which the victim is under 18 years of age or has diminished mental capacity. Where the victim had reached a “voluntary, clear, settled and informed decision to commit suicide” and the assistance or encouragement was rendered out of compassion, among other factors, the balance weighs against prosecution. “Policy for Prosecutors in Respect of

Europe. On 07 October 2010, the Parliamentary Assembly of the Council of Europe adopted a modified version of the Women’s Access to Lawful Medical Care: the Problem of Unregulated Use of Conscientious Objection, a report and resolution designed to help regulate conscientious objection by physicians in Europe. Also known as “the McCafferty Report,” the proposal originally suggested that governments regulate conscientious objection within public medical facilities so that women could exercise their legal right to choose abortion. However, the text as adopted was amended to state that no physician or hospital can be held liable for not performing an abortion or act of euthanasia as long as patients are timely informed of the practitioner’s objection and referred elsewhere for treatment. Council of Europe Resolution 1763, available at <http://assembly.coe.int/ASP/APFeatures/Manager/defaultArtSiteView.asp?ID=950> (last accessed 18 December 2010). See also Women’s Access to Lawful Medical Care, Doc. No. 12389 (2010), available at <http://assembly.coe.int/main.asp?Link=/>

[documents/workingdocs/doc10/edoc12389.htm](#) (last accessed 18 December 2010).

Scotland. On 20 January 2010, Scotland's [a member's bill to Parliament](#) was introduced that would legalize physician aid-in-dying. If passed, Macdonald's End of Life Assistance Bill

would make Scotland the first country in the United Kingdom to permit physician aid-in-dying. End of Life Assistance Bill, <http://www.scottish.parliament.uk/s3/bills/38-EndLifeAssist/b38s3-introd.pdf> (last accessed 17 December 2010).

FDA

Recent Regulatory Actions

Federal. On 04 October 2010, the FDA requested more information on the pain management opioid drug Nucynta from manufacturer Johnson & Johnson (J&J). A rapid release version of the medication is approved and available on the market, but this request was directed at the new extended-release version. Specifically, the FDA wanted more information about how J&J manufactured the extended release version of the pill in a tamper resistant form that helps prevent crushing or grinding of the pills, which

is common in illegal non-medical uses of opioid drugs. "J&J gets FDA request for more info on pain drug," *BusinessWeek*, 04 October 2010, available at <http://www.businessweek.com/ap/financialnews/D9IL0H8O0.htm> (last accessed 17 December 2010). *See also* "J&J Gets Complete Response Letter for Nucynta ER NDA", available at <http://www.fdanews.com/newsletter/article?issueId=14136&articleId=131123> (last accessed 17 December 2010).

HEALTHCARE COVERAGE

Recent Judicial Cases

Federal. On 13 December 2010, the U.S. District Court for the Eastern District of Virginia found that President Obama's health care reform act was unconstitutional in that its requirement that most Americans obtain insurance exceeded the authority granted Congress under the Commerce Clause. *Virginia v. Sebelius*, Case No. 310-cv-188, decision available at

<http://documents.nytimes.com/health-care-law-ruled-unconstitutional?ref=policy> (last accessed 06 February 2011).

On 31 January 2011, the U.S. District Court for the Northern District of Florida ruled that President Obama's health care reform is unconstitutional. Judge Vinson heard oral argument in the case

on 16 December 2010. Judge Vinson determined that the Affordable Care Act's requirement that all individuals purchase some form of health insurance (the "individual mandate") exceeds federal authority. *Florida v Department of Health and Human Services*, No. 3:10-cv-91, (U.S. Dist. Ct. N. Dist. FL 2010)

*On 24 February 2010, the U.S. District Court for the Northern District of Florida granted plaintiffs in the case of *Cota et. al. v. Maxwell* an injunction against proposed budget cuts to the Adult Day Health Care program (ADHC). The proposal aimed to impose stricter qualification criteria for ADHC, a program that currently serves 37,000 Californians. ADHC allows individuals with chronic conditions to continue living at home with their families while

providing access to treatment and care for the conditions. The budget cuts would have excluded between 8,000 and 15,000 current participants from the program, many of whom would be hospitalized or institutionalized without ADHC. The court's rationale for granting the injunction was recognition of the hardships faced by the plaintiffs under the proposed cuts, including likely institutionalization. The court also cited that it was probable that the plaintiffs would prevail in their claim that the cuts violated the Americans with Disabilities Act, federal Medicaid law, and Due Process. Disability Rights California, "*Cota et. al (Brantley) v Maxwell-Jolly, Director of California Department of Health Care Services*," available at <http://www.disabilityrightsca.org/advocacy/Cota-v-Maxwell/index.htm> (last accessed 17 December 2010).

Recent Legislative Actions

***Federal.** On 29 September 2010, a bill, H.R. 6306, "The Critical Care Assessment and Improvement Act of 2010" was introduced in the House. This legislation would provide an analysis of current programs, and would introduce policies to improve the delivery of care to the critically ill. One specific goal of the legislation is to improve the delivery of care in federal disasters and emergencies. H.R. 6306 (111th Congress), <http://www.govtrack.us/congress/billtext.xpd?bill=h111-6306> (last accessed 17 December 2010)

California. On 01 October 2010, the Governor signed into law A.B. 1602, S.B. 900, A.B. 2244, S.B. 1163, A.B.

2470, S.B. 1088, A.B. 2345. These laws make California the first state to implement aspects of the Patient Protection and Affordable Care Act. The reforms enacted include: establishing the California Health Benefit Exchange, an entity designed to help individuals and small businesses find affordable insurance plans; allowing individuals to remain on their parents' plans until the age of 26; making it illegal for insurers to exclude children from a policy on the basis of a pre-existing condition; enacting protections to ensure that patients will not be illegally dropped from their insurance plans; requiring insurance to cover preventative services without requiring co-payments; and requiring more clarity

in how insurers communicate information about premiums and deductibles. 2009-2010 CA Reg. Sess.,

bill text available at <http://totalcapitol.com/> (then search by bill number).

Recent Regulatory Actions

Federal. On 29 January 2010 the Departments of Health and Human Services, Labor and the Treasury announced that as of 01 July 2010, group health plans must exercise parity with respect to benefits offered for (i) mental health and substance abuse and (ii) standard medical and surgical coverage. This means that group health plans cannot limit mental health and substance abuse benefits available to plan participants and cannot require patients to pay higher out-of-pocket costs for mental health and substance abuse treatment than patients would pay for general medical and/or surgical coverage. These requirements were made possible by the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010. FR Doc 2010-2167, available at <http://edocket.access.gpo.gov/2010/2010-2167.htm> (last accessed 06 February 2011). *See also*, “Obama Administration Issues Rules Requiring Parity in Treatment of Mental, Substance Use Disorders,” 29 January 2010, available at <http://www.hhs.gov/news/press/2010press/01/20100129a.html> (last accessed 17 December 2010); H.R. 3590 (2009 US 111th Congress 1st Sess.), available at <http://www.opencongress.org/bill/111-h3590/text> (last accessed 17 December 2010); H.R. 4872 (2010 US 111th Congress 2nd Sess.), available at <http://www.govtrack.us/congress/billtext>

[.xpd?bill=h111-4872](#) (last accessed 17 December 2010).

On 28 July 2010 the Centers for Medicaid and Medicare Services published final rules for the Electronic Health Records (EHR) incentive program, which will begin accepting registrations in January 2011. This program provides payments to professionals and hospitals as they adopt, implement, upgrade or demonstrate meaningful use of EHR technology. These rules outline the requirements that practitioners and hospitals must meet in order to be eligible for such payments under the program. The Office of the National Coordinator for Health Information Technology and the Health & Human Services Office for Civil Rights’ have been involved to assure that health information privacy is protected and secure as we increase the use of technology that makes such information easily and quickly accessible. Such protections may be found in the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009. 75 Fed. Reg. 144, available at <http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf> (last accessed 17 December 2010); “HHS Strengthens Health Information Privacy and Security through New Rules,” 08 July 2010, available at <http://www.hhs.gov/news/press/2010pre>

[s/07/20100708c.html](#) (last accessed 17 December 2010).

On 30 September 2010, the Department of Health and Human Services announced the award amounts allocated to each state from the Exchange Planning and Establishment federal grant fund. The monies are to be used to establish a health insurance exchange as created under the federal Affordable Care Act. Nationally, the Department of Health & Human Services distributed \$49 million to states to help them plan and prepare for the establishment of health insurance exchanges. Such exchanges are meant to facilitate the purchasing of health insurance coverage for individuals and small businesses and to give smaller purchasers the same purchasing power of large employers and to make health insurance more affordable for those with low income by providing financial assistance. The exchanges are expected to be in open in 2014. “Exchange Planning Grants: Grant Awards List,” available at <http://www.healthcare.gov/news/factsheets/grantawardslist.html> (last accessed 06 February 2011). *See also* H.R.3590 (2010) available at [\[h3590/show\]\(#\) \(last accessed 17 December 2010\).](http://www.opencongress.org/bill/111-</p></div><div data-bbox=)

Arizona. On 01 October 2010, Arizona enacted budget cuts to eliminate various medical and health services for adults covered by the Arizona Health Care Cost Containment System (AHCCCS), Arizona’s Medicaid system. The budget cuts, which reflect an overall reduction of \$874 million in the AHCCCS budget since 2008, limit availability of optional medical services, which include transplants, coverage for occupational and speech therapy, insulin pumps, hearing aids, emergency dental care, and most wellness exams. *See* AHCCCS website, available at <http://www.azahcccs.gov/shared/MedicalPolicyManual/MedicalPolicyManual.aspx> (last accessed 17 December 2010) and <http://www.azahcccs.gov/reporting/legislation/proposals.aspx?ID=2011> (last accessed 17 December 2010); B. Lorren, “Arizona Cuts AHCCCS Health Care Budget,” 29 August 2010, available at http://www.associatedcontent.com/article/5739238/arizona_cuts_ahcccs_health_care_budget.html (last accessed 17 December 2010).

HIV / AIDS

Recent Regulatory Actions

***Federal.** On 13 April 2010, the U.S. Department of Health and Human Services issued a final rule relating to the organizational integrity requirements for organizations receiving federal

funding under the United States Leadership Act Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (“Leadership Act”). The Leadership Act has always required that funding

recipients have a formal policy opposing prostitution and sex trafficking, but the final rule requires that announcements and agreements relating to the receipt of funds include a clause stating the same opposition. 75 Fed. Reg. 70 Doc. No. 2010-8378, available at

<http://www.thefederalregister.com/d.p/2010-04-13-2010-8378> (last accessed 17 December 2010). *See also*, H.R. 5501 (2008), available at <http://www.govtrack.us/congress/bill.xpd?bill=h110-5501> (last accessed 17 December 2010).

Interesting Developments in Other Countries

***South Africa.** On 01 April 2010, a South African policy went into effect in an effort to extend the use of antiretroviral drugs to more HIV-positive pregnant women, HIV-positive children and those battling an HIV-tuberculosis co-infection. Pregnant, HIV-positivewomen will now be able to start HIV treatment when their CD4 count, a measure of immune strength, is 350, instead of waiting until it falls to under 200. In addition, all HIV-positive children under the age of one year will receive treatment, regardless of their CD4 count. This new policy is more in line with the international standard and should help to drastically reduce the maternal and infant mortality rates associated with HIV. *PlusNews*, 23 February 2010 “South Africa: New treatment guidelines announced,” available at <http://www.plusnews.org/report.aspx?ReportID=88207> (last accessed 17 December 2010).

International. From 18-23 July 2010, the 18th International AIDS Conference was held in Vienna, Austria and the International Labour Organization entered the implementation phase of the

Recommendation Concerning HIV and AIDS and the World of Work (“Recommendation”). This is the first human rights program to focus on HIV/AIDS within the workforce and is intended to (i) increase sensitivity toward HIV/AIDS in the workforce by encouraging employers to have transparent and non-discriminatory policies and (ii) protect the privacy of members of the workforce affected by HIV/AIDS and their families. The Recommendation was adopted by governments, employers, and worker representatives from International Labor Organization member states. International Labour Organization, 22 July 2010, “ILO launches implementation phase of new international labour standard at XVIII International AIDS Conference (AIDS 2010)” available at http://www.ilo.org/aids/Whatsnew/lang--en/WCMS_142815/index.htm (Last accessed on 17 December 2010); Recommendation, available at http://www.ilo.org/wcmsp5/groups/public/---ed_protect/---protrav/---ilo_aids/documents/normativeinstrument/wcms_142706.pdf (last accessed 17 December 2010).

INFORMED CONSENT

Interesting Developments in the Private Sector

United States. On 06 September 2010, the Annals of Internal Medicine published the results of a study highlighting the importance of informed consent discussions in managing patient expectations and potentially protecting practitioners from malpractice actions. The article, “Patients’ and Cardiologists’ Perceptions of the Benefits of Percutaneous Coronary Intervention (PCI) for Stable Coronary Disease,” found that physicians’ beliefs about the beneficial potential outcome of PCI treatment correspond well with actual results, but patients’ beliefs do not; this suggests that despite current informed consent procedures, patients may still misunderstand or over-estimate the potential benefits of a proposed treatment. Although the 2010 Joint Commission Hospital Manual already requires that the “informed consent process include[] a discussion about potential benefits, risks, and side effects of the patient’s proposed care, treatment,

and services; the likelihood of the patient achieving his or her goals ; and any potential problems that might occur during recuperation,” this study underscores the importance of assessing a patient’s understanding of potential benefits as part of the informed consent process. Such an assessment is required in a small number of states. “Patients’ and Cardiologists’ Perceptions of the Benefits of Percutaneous Coronary Intervention (PCI) for Stable Coronary Disease,” *153 Annals of Internal Medicine No. 5*, abstract available at <http://www.annals.org/content/153/5/307.abstract> (last accessed 18 December 2010); J. Stephanian, “Recent Study Highlights the Importance of Informed Consent,” *Defense of Medicine*, 09 September 2010, available at <http://www.defenseofmedicine.com/2010/09/recent-study-highlights-the-importance-of-informed-consent/> (last accessed on 18 December 2010).

INTELLECTUAL PROPERTY

Recent Judicial Cases

Federal. On 09 September 2010, the U.S. Solicitor General filed notice in the U.S. District Court for the Eastern District of Virginia that the government declined to appeal the 03 August 2010 order of Judge Hilton requiring consideration by the U.S. Patent and

Trademark Office of the patent extension application of the Medicines Company for the blood thinner Angiomax. Because a patent-holder cannot market a patented drug until after that drug receives marketing approval from the Food & Drug Administration

(FDA), the Hatch-Waxman Act permits the patent-holder to apply for a patent term extension to compensate for the delay associated with FDA approval. Such application must be made within 60 days of receipt of FDA approval for marketing. In 2001, the patent extension application of the Medicines Company was made more than 60 calendar days after receipt of FDA marketing approval, but within 60 business days of receipt. The matter has been pending or in litigation since then. 03 August 2010 Order, Case No. 1:10-cv-286, available at http://www.fdalawblog.net/files/angioma_x---opinion-8-3-2010.pdf (last accessed 18 December 2010); 09 September 2010 Notice, Case No. 1:10-cv-286, available at <http://www.themedicinescompany.com/pdf/NOTICE-9-9-10.pdf> (last accessed 18 December 2010).

*On 22 October 2010, Appellant Myriad Genetics filed an appellate brief with the United States Court of Appeals for the Federal Circuit. Myriad is appealing the decision of *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, in which the United States District Court for the Southern District of New York invalidated the company's BRCA gene patent claims holding that the natural existence of genes prevents the patentability of genes. Myriad argues that i) the court need not reach the merits of the case because the controversy is not sufficiently immediate; ii) the isolated BRCA DNA molecules are patent-eligible as compositions of matter; and iii) the methodology is patent-eligible. Appellant's Br., No. 09-CV-4515, available at http://www.aclu.org/files/assets/brca_apellantsbrief_20101022.pdf. (last accessed 17 December 2010).

Recent Regulatory Actions

Federal. On 14 September 2010, biopharmaceutical company Amorceyte, Inc. received a patent for "Compositions and Methods of Vascular Repair." This patent covers procedures used to create regenerative stem cell products that will help repair vascular damage following a heart attack. This is the first time a U.S.

Patent has been granted for such a stem cell product, its composition, and its delivery of cell therapy. The patent will run until at least the year 2028. Patent No. US 7,794,705 B2, available at <http://www.freepatentsonline.com/7794705.pdf> (last accessed 18 December 2010).

MEDICAL MARIJUANA

Recent Legislative Actions

***Arizona.** On 15 December 2010, the governor signed into law Proposition 203, the Arizona Medical Marijuana

Act. Proposition 203 was approved by voters in November 2010 and the Arizona Department of Health Services

is currently drafting rules for public comment. The Arizona Medical Marijuana Act protects patients with debilitating medical conditions, as well as their physicians and providers, from state prosecution if the patients engage in the medical use of marijuana. The Arizona Medical Marijuana Act also allows registered patients to obtain a limited amount of marijuana from nonprofit medical marijuana dispensaries to be regulated by the Arizona Department of Health Services. If these dispensaries are unavailable within a 25-mile radius, the act would also permit qualified patients to cultivate their own marijuana for medical purposes. Proposition 203, available at <http://www.azsos.gov/election/2010/info/PubPamphlet/english/Prop203.htm> (last accessed 17 December 2010); Medical Marijuana Draft Rules, available at <http://www.azdhs.gov/prop203/documents/Medical-Marijuana-Draft-Rules.pdf> (last accessed 17 December 2010).

Arkansas. On 04 January 2010, Arkansas Attorney General rejected the 17 December 2009 proposal of a criminal defense attorney to amend the Arkansas state constitution. The proposed amendment would have legalized the use of medical marijuana. Despite this rejection, in the wake of reports of over-crowded prisons and skyrocketing costs of maintaining prisoners, Arkansas state senator Rancy Laverty has indicated his intent to introduce legislation legalizing the use of medical marijuana in 2011. KUAR, “Medical Marijuana Proposal Filed” 17 December 2009, available at <http://www.publicbroadcasting.net/kuar/news.newsmain/article/0/0/1590311/Ark>

[ansas.Headlines/Medical.marijuana.proposal.filed](http://www.arktimes.com/arkansas/marijuana-for-medicine/Content?oid=947613) (last accessed 17 December 2010); Attorney General Opinion No. 2009-208, 04 January 2010, available at: <http://ag.arkansas.gov/opinions/docs/2009-208.pdf> (last accessed: 17 December 2010); D. Smith, “Marijuana for Medicine: Many are ready including a prominent legislator,” *Arkansas Times*, available at <http://www.arktimes.com/arkansas/marijuana-for-medicine/Content?oid=947613> (last accessed 17 December 2010).

Ohio. On 07 April 2010, a bill was introduced in the state legislature. H.B. 478 would offer protection to caregivers, individuals who associate with medical marijuana users and providers. The bill also establishes a presumption of medical usage for medical marijuana cardholders who are in possession of certain amounts of the substance. The bill also offers immunity for non-cardholders who have had a recent diagnosis and recommendation to use medical marijuana for treatment of chronic pain and diseases. The bill has been assigned to the Health Committee for their report. H.B. 478 (2010 OH Reg. Sess.), available at http://www.legislature.state.oh.us/bills.cfm?ID=128_HB_478 (last accessed 17 December 2010); status report, available at <http://www.lsc.state.oh.us/status128/housebills.htm> (last accessed 17 December 2010).

***South Dakota.** On 02 November 2010, South Dakota voters defeated ballot Measure 13, the South Dakota Medical Marijuana Act, voting against the legalization of marijuana for medical use

in South Dakota. If adopted, the measure would have been one of the most restrictive medical marijuana laws in the country, allowing cannabis treatment for certain diagnoses but limiting the personal possession exemption for medical users with registration and identification to an ounce or six plants. Election results, available at <http://www.electionresults.sd.gov/applications/st25cers3/resultsSW.aspx?type=bq&AspxAutoDetectCookieSupport=1> (last accessed 17 December 2010). *See also* Measure 13, available at

<http://legis.state.sd.us/> (last accessed 17 December 2010); Initiative petition, available at <http://www.sdsos.gov/electionsvoteregistration/electvoterpdfs/2010/SDSafeAccessAct.pdf> (last accessed 17 December 2010); NORML, “Medical Marijuana Legalization Measure Qualifies For South Dakota Ballot”, 25 March 2010, available at http://www.norml.org/index.cfm?Group_ID=8141 (last accessed 17 December 2010).

MENTAL HEALTH

Recent Regulatory Actions

Federal. On 14 July 2010, the House Committee on Veterans’ Affairs conducted a series of inquiries into the rising suicide rate among American soldiers. Hon. Harry E. Mitchell, Chairman of the Subcommittee opened the hearing noting that last year “30,000 people took their lives by suicide in the United States,” and “twenty percent of these deaths were veterans. Each day, an estimated 18 veterans commit suicide [and] [b]y the time this hearing concludes between one and two veterans

will have killed themselves by suicide.” Concerns about suicide among servicemen and -women were peaked by the multiple suicides at Fort Hood in 2010. *Examining the Progress of Suicide Prevention Outreach Efforts at the U.S. Department of Veterans Affairs: Before the Subcommittee on Oversight and Investigation of the H. Committee on Veterans’ Affairs, (111th Congress 2010)* <http://veterans.house.gov/hearings/hearing.aspx?NewsID=604> (last accessed 17 December 2010).

NEUROSCIENCE

Recent Judicial Cases

Federal. On 31 May 2010, the United States District Court for the Western District of Tennessee Eastern Division held a Daubert hearing in *U.S. v. Semrau*

to determine whether or not functional magnetic resonance imaging (fMRI) could be used in court as a new form of lie detection. Lorne Semrau, a

psychologist, is accused of defrauding Medicare and Medicaid however he claims that he had no intention to do so and wants to submit to results of an fMRI-based lie detection test as evidence of his mental state. The court recommended that the evidence not be admitted because fMRI-based lie detection fails to satisfy standards for admissibility due to an absence of real-life error rates, a lack of industry standards as well as a lack of consensus in the scientific community about the reliability of the test. *U.S.v. Semrau*, No. 07-10074 M1/P (U.S. Dist. Ct. W. D. Tenn. 2010)
<http://blogs.law.stanford.edu/lawandbiosciences/files/2010/06/fMRI-Report-and-Recommendation1.pdf> (last accessed 17 December 2010).

New York. On 14 May 2010, the New York Supreme Court excluded testimony by an expert regarding the results of a key witness' fMRI test. The judge found that the proposed evidence (the expert's testimony and the fMRI test) went to the credibility of the witness. Because determinations of credibility are within the ability of the average juror, the judge found expert testimony on the matter unnecessary. Moreover, the judge found that the results of the fMRI test were inadmissible because fMRI testing to determine truthfulness fails to meet the standards for admissibility in that scientific validity of the fMRI test has not been proven. *Wilson v. Corestaff Services*, No. 32996/07 (Sup. Ct. NY 2010)
<http://www.nylj.com/nylawyer/adgifs/decisions/051810miller.pdf> (last accessed 17 December 2010).

ORGAN PROCUREMENT

Recent Legislative Actions

California. On 02 September 2010, the governor signed into law S.B. 1395. The bill adds the Altruistic Living Donor Registry Act to California Health and Safety Code, making California the first state to create a registry for living kidney donors, effective 01 July 2011. The Act authorizes the creation of the Altruistic Living Donor Registrar as a not-for-profit entity, permitting individuals to identify themselves as a living kidney donor, in order to “encourage charitable contributions.” The information obtained by the Registrar is then available to federally designated organizations to identify and “expedite

the match between organ donors and recipients.” Additionally, the act amends the California Vehicle Code to require that the Department of Motor Vehicles modify driver's license applications to contain “check boxes for an applicant to mark either (A) yes, add my name to the donor registry or (B) I do not wish to register at this time” and requires that the applicants be asked verbally the same question. The amended language requires that the applicant answer affirmatively either “yes” or “no,” instead of simply electing the option to be an organ donor. The legislation is intended to increase the

number of people registered as organ donors in California. S.B. 1395 (CA Reg. Sess. 2010), available at http://leginfo.ca.gov/pub/09-10/bill/sen/sb_1351-1400/sb_1365_bill_20100927_chaptered.pdf (last accessed 17 December 2010).

New York. On 05 May 2010, the New York Senate referred to the transportation committee a bill, S.B. 7725 (same as H.B. 9865). The bill would change the law so that individuals registering for a driver's license in New York would automatically be enrolled as a member of the New York State Organ and Tissue registry unless they "opt-out." The bill proposes an additional amendment to section 4031 of the Public Health Law such that those persons 18 years of age or older who do not opt-out are considered to have "given written authorization for organ or tissue donation" which cannot be rescinded by health care proxy, family, agent or guardian "except upon a showing that the donor revoked the authorization." Under the current system, those wishing

to be organ donors must opt-in. The amendment to the traffic law would make New York State the only state to adopt the "presumed consent" model for organ donation, however it is used in over twenty countries. S.B. 7725 (2nd NY Leg. Sess. 2010), available at <http://open.nysenate.gov/legislation/api/1.0/html/bill/S7725> (last accessed 17 December 2010). *See also*, NY Public Health Law § 4301, available at http://law.onecle.com/new-york/public-health/PBH04301_4301.html (last accessed 17 December 2010).

South Carolina. On 02 June 2009, the governor signed into law H.B. 345, amending laws for leaves of absence of organ donors. The bill mandates that state employees wishing to donate organs be permitted an aggregate of 30 regularly scheduled workdays' worth of leave from employment without penalty in each calendar year. H.B. 345 (118th SC Leg. Sess. 2009-2010), available at http://www.scstatehouse.gov/sess118_2009-2010/bills/345.htm (last accessed 17 December 2010).

Recent Regulatory Actions

New York. In November 2010, the Fire Department of New York City launched a \$1.5 million pilot program to keep fewer organs from going to waste by dispatching a new "Organ Preservation Vehicle" alongside emergency medical services vehicles. The team on the vehicle consists of trained EMT responders, family support specialists and a physician. Should resuscitative efforts fail and death be determined, the team will approach the deceased's family to explore the possibility of organ

donation. M. Hogan, "In New York, a Test of Organ Donation Includes Those Who Die at Home," *Nephrology Times*, October 2010, available at http://journals.lww.com/nephrologytimes/Fulltext/2010/10000/In_New_York,_a_Test_of_Organ_Donation_Includes.2.aspx (last accessed 17 December 2010). *See also*, Susan Edelman, "'Gift of Life' Ambulance for Organs," *The New York Post*, 24 October 2010, available at http://www.nypost.com/p/news/local/gift_of_life_ambulance_for_organs_DBXjL

Interesting Developments in Other Countries

Europe. On 07 July 2010, the European Parliament and the Council adopted the Directive On Standards Of Quality And Safety Of Human Organs Intended For Transplantation. The goals of the Directive are to help increase the number of organ donors across the EU, enhance the efficiency and accessibility of transplantation systems, and ensure the quality and safety of the procedures. It provides for the appointment of Competent Authorities in all Member States, for authorization of procurement and transplantation centers and activities, for traceability systems to track organs used for transplant, as well as for the reporting of serious adverse events and reactions. Moreover, the Directive sets requirements for the safe transportation of organs and for the collection and recording of certain data regarding every donor and organ. Member States must establish legal and regulatory framework to comply with the requirements of the Directive by 27 August 2012. Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:207:0014:0029:EN:PDF> (last accessed 17 December 2010).

Egypt. On 27 February 2010, Egypt's Parliament passed regulations governing organ transplants performed in the country. The law is an attempt to halt commercial sales of organs by Egyptians under conditions that may be oppressive and unsanitary. According to the new

law, *in vivo* transplants are limited to transplants between family members and organs may be recovered from deceased donors only after authorization from a three-person panel convened by the Higher Committee for Organ Transplants. Furthermore, transplants between Egyptians and foreigners are now prohibited except in the case of spouses. "Egypt adopts organ transplant bill," *Maktoob*, 27 February 2010, available at http://en.news.maktoob.com/20090000440462/Egypt_adopts_organ_transplant_bill/Article.htm (last accessed 17 December 2010); "Egypt: controversial organ transplant bill welcomed by WHO," *IRIN News*, 07 February 2010, available at <http://www.irinnews.org/report.aspx?ReportId=87988> (last accessed 17 December 2010); "Egypt: controversy surrounds new organ donor law," *Bikya Masr Blog*, 04 February 2010, available at <http://bikyamasr.com/wordpress/?p=8279> (last accessed 17 December 2010).

England. On 26 July 2010, the Nuffield Council on Bioethics held a deliberative workshop with recruited members of the public about the ethical considerations of offering incentives to increase donation of organs, eggs and sperm. Currently in the UK, paying for most types of organs and tissue is illegal. The workshop addressed (i) cash incentives and (ii) the payment of funeral expenses as potential incentives to increase donation and also addressed (iii) the ethical implications of

offering financial incentives that might persuade people to donate parts of their body that they would not otherwise and (iv) the legal implications of property ownership of one's body. The counsel's findings will be published in an autumn 2011 report with recommendations for policy makers. Nuffield Council on Bioethics, "Give and Take? Human Bodies in Medicine and Research" (2010) available at <http://www.nuffieldbioethics.org/sites/default/files/Human%20bodies%20in%20medicine%20and%20research%20consultation%20paper.pdf> (last accessed 17 December 2010).

Israel. In January 2010, an Israeli law went into effect that increases priority for those awaiting organ transplant if they themselves are registered organ donors. Additionally, relatives of registered, deceased, or *in vivo* donors also receive increased priority should they need a transplant. The law was based in part on recommendations by a special committee of the Israel National Transplant Council (INTC) created to address Israel's low number of organ donors. "New Law for Organ Donation in Israel: Increased Priority for those who are Prepared to Donate," *Medical News Today*, 21 December 2009, available at

<http://www.medicalnewstoday.com/articles/174514.php> (last accessed 17 December 2010).

Pakistan. On 17 March 2010, Pakistan President Asif Ali Zardari signed into law the Bill on Transplantation, which had been introduced in the Parliament almost 15 years ago, but had remained dormant. Earlier this year, both the Senate and the National Assembly of Pakistan had approved the bill, which is now a federal law. It regulates the removal, storage and transplantation of human organs and tissues and also prohibits commercial transplantation and outlaws the organ trade. Act No VI of 2010 – an act to provide for removal, storage and transplantation of human organs and tissues for therapeutic purposes, also known as the Transplantation of Human Organs and Tissues Act, 2010, available at http://www.na.gov.pk/acts/act_2010/transplantation_human_organs_act2010_170310.pdf (last accessed 17 December 2010). *See also*, S.A.H. Rizvi et al "Pakistan Abolishes Kidney Market and Ushers in a New Era of Ethical Transplantation," available at <http://home.sums.ac.ir/~habibzaf/ojs/index.php/IJOTM/article/viewFile/48/92> (last accessed 17 December 2010).

PHARMACEUTICAL INDUSTRY

Interesting Developments in Other Countries

Switzerland. On 05 October 2010, Novartis announced that it would discontinue research into two drugs, resulting in third quarter penalties to the

company of \$590 million for discontinuing the research. One of the dropped drugs, Zalbin, was intended to treat hepatitis C, and the other,

Mycograb, was an antifungal agent intended for the treatment of yeast infections. Novartis explained the decision to drop the drugs and face the costs by citing a desire to increase productivity, a belief that the market for hepatitis C medication and antifungal treatment is already well supplied and indicating an expected off-set from the anticipated sale of U.S. rights for the bladder treatment, Enablex. Novartis

reports that going forward it will focus research on drugs that will address currently unmet medical needs. “Novartis Drops Two Drugs, Expects \$590M Charge,” 5 October 2010, available at <http://finance.yahoo.com/news/Novartis-drops-2-drugs-apf-1225574326.html?x=0&.v=10> (last accessed 17 December 2010).

PRISONERS

Recent Judicial Cases

Federal. On 28 September 2010, the United States District Court for the Northern District of California delayed Albert Greenwood Brown’s execution days before he was to receive a lethal injection. California law approves execution by lethal injection of a three-drug combination; prior regulation, which allowed for injection of a single drug, was rejected because the pain caused by the single drug was excessive and violative of the Eighth Amendment prohibition on cruel and unusual punishment. However, the state sought to execute Brown before the court would

have sufficient time to determine whether the new three-drug protocol satisfies constitutional requirements. The original September execution date was apparently established in part because the state’s supply of one of the lethal drugs, sodium thiopental, had an expiration date of October 1, 2010. Brown’s execution would have been California’s first execution in four years. *Morales-Brown v. Cate*, No. 10-99019 (US Dist. Ct. N. Dist. CA 2010) <http://www.ca9.uscourts.gov/datastore/opinions/2010/09/28/1099019ao.pdf> (last accessed 17 December 2010).

PRIVACY, GENETICS AND DNA

Recent Judicial Cases

Federal. On 14 September 2010, the Ninth Circuit ruled that DNA testing is a reasonable condition for pre-trial release of a defendant charged with a felony. The decision was rendered in *U.S. v. Pool*, in which the court determined that

requiring the defendant, Pool, to give a DNA sample for the sole purpose of confirming identity is appropriate and not violative of any Constitutional rights. *U.S. v. Pool*, No. 09-10303 (9th Cir. 2010)

<http://www.ca9.uscourts.gov/datastore/opinions/2010/09/14/09-10303.pdf> (last

accessed 17 December 2010).

Recent Legislative Actions

Federal. On 18 May 2010, the House passed the Katie Sepich Enhanced DNA Collection Act of 2010, which increases the amount of federal funds payable to states that implement DNA collection processes under the Edward Byrne Memorial Justice Assistance Grant program. The Act increases payments under the Grant by 5% to states that implement a “minimum DNA collection,” i.e. collecting DNA samples from persons arrested for, charged with, or indicted for murder, manslaughter, sexual assault, kidnapping and

abduction. States that implement “enhanced” collection, which adds sexual offenses involving a minor, burglary and aggravated assault to the list of crimes for which DNA samples are collected, are eligible for a 10% increase in payments made under the Grant. H.R. 4614 (2010 111th Congress), available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:HR04614:@@D&summ2=m&> (last accessed 17 December 2010).

Recent Regulatory Actions

Federal. On 13 September 2010, the Department of Health and Human Services proposed modifications to the Standards for Privacy of Individually Identifiable Health Information, the Security Standards for the Protection of Electronic Protected Health Information, and provisions under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The modifications are intended to incorporate recent statutory amendments under the Health Information Technology for Economic and Clinical Health (HITECH) Act and strengthen the privacy and protection of health information and to improve the effectiveness of HIPAA. 75 Fed. Reg. 134 at 40868-40924, available at <http://hipaasecurityassessment.com/wp-content/uploads/2010/07/Modifications-to-the-HIPAA-Privacy-Security-and->

[Enforcement-Rules-under-HITECH.pdf](#) (last accessed 18 December 2010).

On 05-06 October 2010, the Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) held its final meeting. Under the Federal Advisory Committee Act, SACGHS’ charter was renewed for another 6 months to provide sufficient time to complete certain administrative tasks, but after 10 years in operation, the Federal government recognized that SACGHS had fulfilled its mandate. In that time, SACGHS has issued comprehensive reports and provided advice and recommendations to the Secretary of Health & Human Services in the integration of genetics into clinical practice and public health. “Note to the Public: SACGHS will hold its final meeting October 5-6, 2010,” available at

http://oba.od.nih.gov/SACGHS/sacghs_home.html (last accessed 17 December

2010).

Interesting Developments in Other Countries

Canada. On 14 April 2010, a bill was introduced in the House of Commons to prohibit discrimination on the basis of genetic characteristics. Specifically, the bill seeks to add “genetic characteristics” to the prohibited grounds for discrimination already enumerated in the Canadian Human Rights Act. Currently, the list includes the following as prohibited grounds of discrimination: race, national or ethnic origin, colour [sic], religion, age, sex, sexual orientation, marital status, family status, disability and conviction for which a pardon has been granted. Bill C-508 (2010 40th Parliament 3rd Sess) available at http://www2.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Parl=40&Ses=3&Mode=1&Pub=Bill&Doc=C-508_1&File=24 (last accessed 17 December 2010). *See also*, <http://openparliament.ca/bills/2214/> (last accessed 17 December 2010).

On 08 September 2010, the Supreme Court of Canada decided *Canadian Blood Service (CAS) v. Freeman*, affirming the CAS policy that no man who has had sex with another man after the year 1977 can donate blood. The reasoning behind the CAS policy is that men engaging in such activity have a higher chance of carrying “certain blood-borne pathogens.” The case was brought to court after a man donated blood twice, withholding the information that he had sexual relations with other

men after the year 1977. In a 188 page decision, the court determined that the CAS policy is valid because, while it draws a distinction between gay and heterosexual donors, the distinction is not discriminatory in the context of blood donation. *Canadian Blood Service v. Freeman*, No. 02-CV-20980 (Sup. Ct. Canada 2010) [http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/SafetyAndTesting/\\$file/CanadianBloodServicesVFreeman2010-part1.pdf](http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/SafetyAndTesting/$file/CanadianBloodServicesVFreeman2010-part1.pdf) and [http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/SafetyAndTesting/\\$file/CanadianBloodServicesVFreeman2010-part2.pdf](http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/SafetyAndTesting/$file/CanadianBloodServicesVFreeman2010-part2.pdf) (last accessed 18 December 2010).

New Zealand. As of 06 September 2010, the Criminal Investigations Amendment Bill authorizes New Zealand police to collect DNA samples when they take an offender’s fingerprints, including youth offenders as young as 14 years old. Under the Criminal Investigations Amendment Bill, offenders who consent to DNA collection will provide a mouth swab but offenders who do not consent to DNA collection may be fined and forced to give a blood sample. Hamish McNeilly, “Law allows for wider sampling of DNA,” *The Otago Daily Times*, 7 September 2010, available at <http://www.odt.co.nz/news/dunedin/124949/law-allows-wider-sampling-dna> (last accessed 17 December 2010).

RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

Recent Judicial Cases

***Alaska.** On 13 December 2010, the Alaska Superior Court declined to enjoin a new parental notification requirement from taking legal effect but did amend certain provisions of the law. On 24 August 2010, Alaskan voters approved Ballot Measure 2, which requires notification of parents or guardians before a minor can receive an abortion and imposes potential fines, criminal charges and prison sentences of up to five years on persons who did not comply. Planned Parenthood of the Greater Northwest brought suit to enjoin the parental notice law on 19 November 2010 and plans to appeal the 13 December 2010 ruling of Judge Suddock which upheld the law, but struck some of the provisions imposing fines and prison sentences. *Planned Parenthood of the Great Northwest v. Alaska*, Case No. 3AN-10-12279. *See also*, M. Pemberton, “Judge won’t block Alaska abortion notification law,” *The Washington Post*, 14 December 2010, available at <http://www.washingtonpost.com/wp-dyn/content/article/2010/12/13/AR2010121306672.html> (last accessed 18 December 2010); Complaint, *Planned Parenthood v. State*, Case No. 3AN-10-12279, available at http://media.adn.com/smedia/2010/11/23/11/11.19.10_Complaint_for_Declaratory_and_Injunctive_Relief.source.prodaffiliate.7.pdf (last accessed 18 December

2010). *See also*, Press Release, “Lawsuit Filed Challenging Parental Notice Law,” 22 November 2010, available at <http://www.plannedparenthood.org/about-us/newsroom/local-press-releases/lawsuit-filed-challenging-parental-notice-law-35188.htm> (last accessed 18 December 2010); Parental Notification Act, available at http://www.elections.alaska.gov/petitions/09PIMA/09PIMA_severed.pdf (last accessed 18 December 2010).

***Florida.** On 12 August 2010, the Florida District Court of Appeal ruled that the rights of a pregnant woman were violated when she was forcibly hospitalized against her will, reversing the March 2009 decision of the circuit court, which had ordered the woman to submit to any medical treatment deemed necessary by the attending obstetrician, including detention in the hospital for enforcement of bed rest, administration of intra-venous medications, and anticipated surgical delivery of the fetus. The district court explained that the test to overcome a woman’s right to refuse medical intervention in her pregnancy is whether the state’s compelling state interest is sufficient to override the pregnant woman’s constitutional right to the control of her own person, including her right to refuse medical treatment. Furthermore, where the state does

establish a compelling state interest in forced treatment and the court has found the state's interest sufficient to override a pregnant patient's right to determine her course of medical treatment, the state must then show that the method for pursuing that compelling state interest is "narrowly tailored in the least intrusive manner possible to safeguard the rights of the individual." *Burton v. State*, No. 1D09-1958 (Ct. App. FL 2010) <http://opinions.ldca.org/written/opinions/2010/08-12-2010/09-1958.pdf> (last accessed 18 December 2010).

***Illinois.** On 19 November 2010, Americans United for Life filed an amicus brief supporting the Illinois Parental Notification Act of 1995. This Act prohibits anyone from performing an abortion on a minor unless he/she gives the pregnant minor's parent or legal guardian notification 48 hours before the procedure. The fate of the Act has been in limbo due to constitutional challenges brought in the case of *Hope Clinic v. Adams*. On 29 March 2010, Judge Riley of the Circuit Court of Cook County dismissed the

matter with prejudice despite acknowledging "compelling evidence that parental notification of abortions for minors will often expose minors seeking abortion to increased risks and anxieties," but stayed the effect of his order for 60 days to permit the plaintiffs time to appeal the matter to the Appellate Court of Illinois, where the case now resides. *Hope Clinic v. Adams*, No. 09 CH 38661 (Cook County Cir. Ct. IL 2010) available at <http://www.thomasmoresociety.org/docs/2010/notice/Hope-Memorandum-Opinion.pdf> (last accessed 18 December 2010); Brief of Amicus Curiae Americans United for Life, Case No. 10-1463 (App. Ct. IL 2010) (last accessed 18 December 2010). *See also*, The Parental Notice of Abortion Act of 1995, 750 ILCS 7/1 et seq., available at <http://ilga.gov/legislation/ilcs/ilcs3.asp?ActID=2103&ChapAct=750%26nbsp%3BILCS%26nbsp%3B70%2F&ChapterID=59&ChapterName=FAMILIES&ActName=Parental+Notice+of+Abortion+Act+of+1995> (last accessed 18 December 2010).

Recent Legislative Actions

***Kansas.** On 28 May 2010, a bill died in the state House Committee on Insurance. H.B. 2564 would have excluded insurance coverage for abortions except in cases of reported rape, reported incest involving a minor, or necessity to preserve the life of the mother. H.B. 2564 (76th KS Leg. Sess. 2010)

<http://www.kslegislature.org/legsrv-billtrack/searchBills.do;jsessionid=B2B04CEAA7A1D1DF75C04F33FCE0A701> (bill status) (last accessed 18 December 2010) and <http://www.kslegislature.org/bills/2010/2564.pdf> (text of bill) (last accessed 18 December 2010).

Recent Regulatory Actions

New Jersey. On 13 October 2010, the New Jersey Board of Medical Examiners temporarily suspended Dr. Steven Brigham's medical license for performing late-term abortions on patients. On 16 September 2010 a cease and desist order was served on Brigham who allegedly ferried his pregnant patients to Maryland to undergo abortions after the 14th week of pregnancy. Dr. Brigham was not authorized to perform such abortions in New Jersey, where state law imposes additional requirements on abortions performed after 14 weeks of gestation. Maryland state laws do not impose the same requirements. However, Maryland authorities have ordered Dr. Brigham to stop practicing medicine. Summary of State Board of Medical Examiners Administrative Action available at <http://www.state.nj.us/lps/ca/bme/index.html> (then click "Find Your Doctor" and search for "Steven Brigham") (last accessed 06 February 2011). *See also*, "New Jersey suspends last license of late term abortion doctor Steven Brigham," *The Trentonian*, 14 October 2010, available at <http://www.trentonian.com/articles/2010/10/14/news/doc4cb676efc2983508809436.txt?viewmode=fullstory> (last accessed 17 December 2010).

Pennsylvania. On 13 September 2010, a bill was referred to the state Banking and Insurance Committee. S.B. 1399, which aims to bring Pennsylvania into compliance with federal health care reforms, prevents qualified health plans offered through a state exchange from covering "elective abortions." Insurance

funds would only be provided where necessary to (i) avert the death of the mother, (ii) for cases involving rape reported within 72 hours of the attack, or (iii) incest reported within 72 hours of the act. The state insurance exchange will commence under the new federal health care law effective in 2014. S.B. 1399 (2009-2010 PA Reg. Sess.), available at <http://www.legis.state.pa.us/CFDOCS/Legis/PN/Public/btCheck.cfm?txtType=HTML&sessYr=2009&sessInd=0&billBody=S&billTyp=B&billnbr=1399&pn=2175> (last accessed 18 December 2010).

Texas. On 24 September 2010, the Attorney General of Texas issued an advisory opinion regarding whether a facility must have a license to perform a medical abortion (defined for the purposes of the advisory opinion as an abortion caused by the use of drugs) and whether drugs, specifically RU-486, that are administered for the purpose of inducing an abortion must be ingested by the patient in the presence of the prescribing physician. Texas law currently requires that a facility that provides medical abortions be licensed, but does not require a patient to ingest abortifacients in the presence of the prescribing physician. The Attorney General notes that whether the act of prescribing or providing particular drugs is properly considered an "abortion" under Texas law is a matter for determination by the Texas Department of State Health Services. Opinion No. GA-0803, available at <https://www.oag.state.tx.us/opinions/opinions/50abbott/op/2010/htm/ga->

[0803.htm](#) (last accessed 18 December 2010).

Texas. On 24 September 2010, the Attorney General of Texas issued an advisory opinion on whether abortion facilities may use prerecorded telephone messages or one-way conference calls to relay certain information to patients seeking abortions. Texas law requires that a patient seeking an abortion be informed of the name of the physician performing the abortion, the gestational age of the fetus and the risks associated with both the abortion procedure and carrying the fetus to term. The patient must also be made aware of medical assistance benefits, paternal liability, pregnancy prevention counseling and alternatives to abortion. This information must be provided “orally by telephone or in person” and at least 24 hours before the abortion is performed. While “orally by telephone” is ambiguous, the Attorney General states that a court would be unlikely to find use of a prerecorded message or a one-way conference call sufficient given that other statutes make specific provision for the sufficiency of prerecorded information. Opinion No. GA-0802, available at <https://www.oag.state.tx.us/opinions/opi>

[nions/50abbott/op/2010/htm/ga-0802.htm](#) (last accessed 18 December 2010).

Virginia. On 20 August 2010, the Attorney General of Virginia issued an advisory opinion concluding that the state may regulate the facilities in which first-trimester abortions are provided and the practitioners who provide such abortion services, despite ambiguities in definitions of organizations and practitioners subject to state regulation. The State Health Commission may adopt administrative rules to regulate facilities which provide first trimester abortion services under the broad authority vested in the Commission to ensure public health, safety and welfare. The State Board of Medicine may adopt administrative rules to regulate medical personnel who perform first trimester abortions as long as the regulations fall within constitutional parameters under the broad police power to protect the public’s health, safety and welfare. Opinion, available at [http://www.oag.state.va.us/OPINIONS/2010opns/10-012%20\(Smith\)%20-%20Marshall%20version.pdf](http://www.oag.state.va.us/OPINIONS/2010opns/10-012%20(Smith)%20-%20Marshall%20version.pdf) (last accessed 18 December 2010).

Interesting Developments in Other Countries

Europe. On 07 October 2010, the Parliamentary Assembly of the Council of Europe adopted a modified version of the Women’s Access to Lawful Medical Care: the Problem of Unregulated Use of Conscientious Objection, a report and resolution designed to help regulate conscientious objection by physicians in

Europe. Also known as the McCafferty Report, the proposal originally suggested that governments regulate conscientious objection within public medical facilities so that women could exercise their legal right to choose abortion. However, the text as adopted was amended to state that no physician or hospital can be held

liable for not performing an abortion or act of euthanasia as long as patients are timely informed of the practitioner's objection and referred elsewhere for treatment. Council of Europe Resolution 1763, available at <http://assembly.coe.int/ASP/APFeaturesManager/defaultArtSiteView.asp?ID=950> (last accessed 18 December 2010). See also Women's Access to Lawful Medical Care, Doc. No. 12389 (2010), available at <http://assembly.coe.int/main.asp?Link=/>

[documents/workingdocs/doc10/edoc12389.htm](http://assembly.coe.int/main.asp?Link=/documents/workingdocs/doc10/edoc12389.htm) (last accessed 18 December 2010).

Sweden. On 04 October 2010, physiologist Dr. Robert G. Edwards was awarded the Nobel Prize for his work in developing in vitro fertilization (IVF) in humans.

http://nobelprize.org/nobel_prizes/medicine/laureates/2010/edwards-lecture.html (last accessed 06 February 2011).

STEM CELLS

Recent Legislative Actions

Federal. On 28 September 2010 the Committee on Energy and Commerce reported to the U.S. House of Representatives on the amended Stem Cell Therapeutic and Research Reauthorization Act of 2010, H.R. 6081. The act reauthorizes and amends the two major federal programs, The National Cord Blood Inventory (NCBI) and the C.W. Bill Young Cell Transplantation Program (a program that matches donated cord blood and transplant recipients), that facilitate the collection and banking of cord and stem cell blood units for transplants. The Act is amended to provide that NBCI enter into 10-15 year contractual relationships with private cord blood banks, in order to maintain, at a minimum, 150,000 units of "high quality" (diverse) cord blood for transplantation on the condition that NBCI report and demonstrate

measurable progress towards the goal of self-sufficiently collecting and banking cord blood for transplants. The amendments also provide for C.W. Bill Young Cell Transplantation Program research incentives into innovative methods for expanding the number of blood unit collection sites that partner with NBCI. The reauthorization extends financial support for the program in the amount of \$23 million per year for NCBI, and \$30 million per year for C.W. Bill Young Transplantation Program for FY2011-FY2014. \$30 million and \$33 million are authorized for appropriation for FY2015 for the programs, respectively. H.B. 6081, (2010 111th Congress), available at <http://thomas.loc.gov> (search by bill number) (last accessed 17 December 2010).

Interesting Developments in the Private Sector

Georgia. On 11 October 2010, officials in Atlanta announced that embryonic stem cell treatment for paralysis had been administered for the first time. The patient, who had suffered partial paralysis as the result of a spinal cord injury, is being treated at Atlanta's Shepard Center as part of a research project sponsored by Geron Corp. of California. The study was approved by the FDA in July after extensive

laboratory experiments and evidence led the FDA to conclude that the procedure was safe enough for additional testing in human patients. Rob Stein, "First Patient treated in stem cell study", 11 October 2010, available at <http://www.washingtonpost.com/wp-dyn/content/article/2010/10/11/AR2010101102946.html> (last accessed 17 December 2010).

TRUST / ACCOUNTABILITY / CONFLICTS OF INTEREST

Recent Judicial Cases

***Federal.** On 14 July 2010, a motion was submitted in to the United States District Court for the Eastern District of Pennsylvania to have James R. Dugan, II appointed as lead counsel in both of the cases pending in regards to the diabetes drug Avandia: *Allied Services Division Welfare Fund v. Smithkline Beecham Corp. et. al*, No. 09-00730-CMR and *UFCW Local 1776 and Participating Employers Health and Welfare Fund v. Smithkline Beecham Corp. et. al*, No. 10-02475-CMR. While there are proposed settlements for personal injury claims related to the drug, Dugan proposes to represent claims that are non-personal injury in nature, seeking to collect refunds for payments made by third-party payors for Avandia on the basis of false advertisement. *In re: Avandia Marketing, Sales Practices and Products Liability* Litigation, No. 1871, 14 July 2010
<http://newsroom.law360.com/articlefiles/>

[181107-Murray%20Law%20Firm.pdf](#)
(last accessed 17 December 2010).

*On 08 September 2010, the First Circuit Court of Appeals affirmed the district court's dismissal of Jacqueline Poteet's qui tam action (an action brought by a private person on behalf of the U.S. government as permitted in certain circumstances). In 2007, Poteet alleged that 120 spine surgeons and 18 medical device distributors violated the False Claims Act, by unlawfully promoting Medtronic products to third-party doctors, knowing that the promotion would result in third-party doctors submitting false claims for reimbursement to the federal government. The district court dismissed Poteet's action with prejudice, meaning that she was not free file an amended complaint, because it determined that Poteet failed to meet the requirements of a qui tam action. Specifically, the district court

determined that Poteet failed to allege any information in her qui tam action that was not already public knowledge as a result of previous lawsuits brought against Medtronic and the doctor defendants as is required for maintaining a qui tam action. Furthermore, claims against the distributor defendants did not meet federal requirements to constitute fraud. The First Circuit affirmed the district court's reasoning and dismissed the action. *United States ex rel. Poteet v. Bahler Medical*, No. 09-1728 (1st Cir. 2010) available at <http://www.scribd.com/doc/37153774/First-Circuit-Qui-Tam-Opinion> (last accessed 17 December 2010).

*On 28 September 2010, the U.S. Supreme Court agreed to review *Astra USA, Inc. v. County of Santa Clara* after an appeal from pharmaceutical companies such as Pfizer Inc., Merck & Co. and Sanofi-Avantis SA. The Ninth Circuit held that health care providers have a private right of action under federal common law if drug makers have violated a federal program enabling public hospitals and community health clinics to buy medicines at a discount. A 2006 government report revealed that of the \$4 billion spent annually on outpatient drugs, health care providers have overpaid by as much as \$3.9 million during one month. Drug makers have appealed on the grounds that the federal law which governs the discount program does not authorize private suits. The matter is set for oral argument before the Supreme Court on January 19, 2011. *Astra USA, Inc. v. County of Santa Clara*, No. 09-1273 (U.S. Sup. Ct. 2010) [http://www.supremecourt.gov/qp/09-](http://www.supremecourt.gov/qp/09-01273qp.pdf)

[01273qp.pdf](http://www.supremecourt.gov/qp/09-01273qp.pdf) (last accessed 17 December 2010). *See also* G. Stohr, "Drugmakers Gest U.S. High Court Review of Clinic Suits," *Bloomberg*, 28 September 2010, available at <http://www.bloomberg.com/news/2010-09-28/drugmakers-win-u-s-high-court-hearing-in-bid-to-stop-suits.html> (last accessed 17 December 2010); http://www.supremecourt.gov/oral_arguments/argument_calendars/monthlyargumentcalendarjanuary2011.pdf (last accessed 17 December 2010).

On 29 September 2010, the owner of two health care companies in Houston plead guilty to Medicare fraud before Judge Miller of the U.S. District Court for the Southern District of Texas. Clifford Ubani owned and operated both Family Healthcare Services, a medical supply company, and Family Healthcare Group, a nursing service provider. Ubani conspired with other individuals, who provided him with patient referrals, to obtain payment for \$6.3 million worth of services patients never needed or received. Ubani faces up to ten years in prison. Press Release, "Owner of Two Houston Healthcare Companies Pleads Guilty to Defrauding Medicare of \$6.3 Million," 29 September 2010, available at <http://www.justice.gov/opa/pr/2010/September/10-crm-1097.html> (last accessed 17 December 2010).

*On 07 October 2010, a status conference was held regarding the Vioxx product liability litigation in the Eastern District of Louisiana. The litigation stemmed from the recall by Merck of its pain-reliever, Vioxx, after clinical trials indicated that use of Vioxx increased

risk of heart attack, sudden cardiac death, and strokes. On 30 June 2010, Merck filed a motion for judgment on the pleadings or to strike the class allegations for purchase claims, the only class-action claims remaining in the litigation. The court heard oral arguments on the motion following the monthly status conference on 07 October 2010. A decision will be forthcoming. The next status conference will be held on January 6, 2011. *In Re: Vioxx Products Liability Litigation*, No. 1657 (U.S. Dist. Ct. E. Dist. La. 2010), 07 October 2010 Minute Entry, <http://vioxx.laed.uscourts.gov/Orders/M10072010.pdf> (last accessed 17 December 2010). See also *In Re: Vioxx Products Liability Litigation*, No. 1657, 19 October 2010 Order & Reasons <http://vioxx.laed.uscourts.gov/Orders/or101910.pdf> (awarding attorney's fees and providing background information regarding the litigation) (last accessed 17 December 2010).

***Illinois.** On 18 March 2010, the Supreme Court of Illinois upheld the appellate court's decision to deny Provena Hospitals charitable exemption under Illinois Property Tax Code. Provena Hospitals owns and operates six hospitals, including the Provena Covenant Medical Center (PCMC). In 2002, Provena Hospitals applied to have all 43 parcels in the PCMC exempt from property taxes totaling approximately \$1.1 million on the grounds that the parcels were owned by a public charity institution and were not used for profit purposes. The Illinois Department of Revenue declined the application, asserting that the property was not used exclusively for charitable religious

purposes as would be required for tax-exempt status. The Supreme Court of Illinois affirmed the Department of Revenue's decision to deny the exemptions because there was insufficient evidence that charitable care was the main purpose of the property in question. *Provena Covenant Medical Center v. The Department of Revenue*, Docket No. 107328. (Ill. Sup. Ct. 2010) 18 March 2010, available at <http://www.state.il.us/court/Opinions/SupremeCourt/2010/March/107328.pdf> (last accessed 17 December 2010).

***Pennsylvania.** On 30 August 2010, the Superior Court of Pennsylvania reinstated 14 lawsuits brought by women alleging that the hormone replacement therapy drugs, Prempro, Premarin and Provera, by Pfizer's Wyeth and Pharmacia, caused them to develop breast cancer. The cases had been summarily dismissed by a lower court because the statute of limitations for bringing the action had expired; the latest ruling may lead to the reinstatement of 1,000 lawsuits which were dismissed for similar reasons. Hormone replacement therapy (HRT) uses hormones and progestins to artificially boost hormone levels and relieve symptoms associated with menopause. A 2002 study by the Women's Health Initiative found evidence linking hormone replacement therapy to an elevated risk of breast cancer, heart attack, and stroke. Drug makers argued that because plaintiffs waited more than two years to file their claims after being diagnosed with breast cancer, they were time-barred from bringing suit. Plaintiffs countered that the statute of limitations did not begin to

run until 2002 when the study data became available. The Pennsylvania Superior Court ruling establishes the release of the study linking HRT to breast cancer, and not the date of cancer diagnosis, as the appropriate point at which the statutory limitation begins to run. *Coleman v. Wyeth Pharmaceuticals, Inc.* No. 2678 EDA 2007 (Pa. Super. Ct.) 30 August 2010. See also “Ruling Reinstates 14 HRT Breast Cancer Lawsuits,” 03 September 2010, available at <http://www.aboutlawsuits.com/hrt-claims-reinstated-on-appeal-12560/> (last accessed 17 December 2010).

***Texas.** Two Texas nurses settled their unlawful discharge lawsuit against Winkler County for \$750,000. The nurses, Anne Mitchell and Vickilyn Galle, filed suit in federal court in February 2010 asserting that they had been unlawfully fired, denied their First Amendment rights and vindictively prosecuted for properly reporting allegations of improper medical treatment by Dr. Ronaldo Arafiles, Jr. at

Winkler County Memorial Hospital. Although both nurses faced criminal charges, the charges against Galle were dropped prior to trial but Mitchell was prosecuted for, and later acquitted of, the felony of misuse of official information in connection with reports made to the Texas state medical board. In June 2010, the Texas state medical board charged Dr. Arafiles with a number of violations, including failure to maintain adequate medical records, poor medical judgment, poor decision-making, overbilling, improper coding, non-therapeutic prescribing and intimidation of witnesses. Dr. Arafiles continues to work at the county hospital, pending a hearing before an administrative law judge on the medical board’s charges. His license could be restricted or revoked. K Sack, “Texas Nurses Fired for Alleging Misconduct Settle Their Suit,” *New York Times*, 10 August 2010, available at http://www.nytimes.com/2010/08/11/us/11whistle.html?_r=1 (last accessed 17 December 2010).

Recent Regulatory Actions

Federal. On 16 December 2010, the President’s Commission for the Study of Bioethical Issues delivered its report on synthetic biology to the President. Synthetic biology (“synbio”) is an emerging field that combines biology, engineering, genetics, chemistry and computer science. Synbio may lead to the creation and development of new drugs, vaccines and biofuels. Obama requested that the Commission review synbio following the announcement on 20 May 2010 by the J. Craig Venter

Institute that the use of synbio had allowed the laboratory creation of an organism not found in nature. The Commission recommended federal oversight of the field, international discourse on regulation, and involvement of the NIH and other federal bodies in evaluating proposed research protocols. Report of the Commission, “The Ethics of Synthetic Biology and Emerging Technologies,” available at <http://www.bioethics.gov/documents/syn>

[thetic-biology/PCSBI-Synthetic-Biology-Report-12.16.10.pdf](#) (last accessed 16 January 2011).

On 1 October 2010, the Centers for Medicaid and Medicare Services (CMS) awarded \$9 million in grants to help Senior Medicare Patrol (SMP) programs fight Medicare fraud. Recent changes in the health care system have made seniors and other Medicare recipients a target of fraudulent scams and these funds will be used to educate Medicare beneficiaries about Medicare fraud and raise awareness of fraud prevention, identification and reporting. The grants

will be administered by both CMS and the Administration on Aging. “Federal Government Expands Grassroots Fraud Prevention Effort,” 01 October 2010, available at <http://www.cms.gov/apps/media/press/release.asp?Counter=3843&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srcHData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date> (last accessed 17 December 2010).

Interesting Developments in Other Countries

Europe. The European Medicines Agency (EMA) banned Avandia, a diabetes drug manufactured by GlaxoSmithKline (GSK), in Europe due to concerns that its active substance, rosiglitazone, increases the risk of heart attack and strokes in patients. The EMA has also recommended the suspension of two other diabetes drugs made by GSK, Avandamet and Avaglim, which also contain rosiglitazone. The Europe-wide suspension will remain in effect unless and until data proves that the benefits of the medicines outweigh their risks. GSK says they are currently working with regulators to resolve concerns. In the United States, the Food and Drug Administration (FDA) has placed a health warning on the drug and has restricted the drug’s availability. “Diabetes drug Avandia banned in Europe, restricted in US,” Turkish Press, 23 September 2010, available at <http://www.turkishpress.com/news.asp?i>

[d=357714](#) (last accessed 17 December 2010).

Guatemala. The United States government has recently revealed that unethical research was conducted in Guatemala in the 1940s. Doctors and scientists in a government sponsored research program “infected soldiers, prisoners, prostitutes and mental patients with syphilis and other sexually transmitted diseases.” As many as 1,500 individuals may have been exposed in the studies. President Obama has offered an apology to Guatemalan President Álvaro Colom. The studies along with other unethical scandals of the era highlight the importance of informed consent requirements. The US informed consent doctrines of the 1970s revamped the research field ensuring ethical treatment for patients and participants in research surveys, domestically and abroad. S Sternberg, “Guatemala revelation recalls era of research

abuses,” *USA Today*, 04 October 2010, available at <http://www.usatoday.com/news/nation/2>

[010-10-04-STD04_ST_N.htm](#) (last accessed 17 December 2010).

VACCINES

Recent Judicial Cases

Federal. On 12 October 2010, the Supreme Court heard oral arguments in *Bruesewitz v Wyeth*, a case brought to determine the scope of a vaccine manufacturer’s liability for injuries. The National Childhood Vaccine Injury Act of 1986 gives manufacturers immunity from liability for injuries “if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warning.” Petitioners, whose daughter developed a seizure disorder after receiving a Diphtheria-Tetanus-Pertussis (DTP) vaccine, claim that the vaccine created an avoidable and unnecessary risk to patients and that such risks are

not contemplated within the immunity created by the 1996 Act; defendant contends that it bears no liability and is protected by the 1996 Act. A determination of the matter is pending as of the time of this publication.

Bruesewitz v. Wyeth, Case No. 09-152 (2010), available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/09-152.pdf (last accessed 18 December 2010); Docket Report, available at <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/09-152.htm> (last accessed 18 December 2010). *See also*, <http://www.scotusblog.com/case-files/cases/bruesewitz-v-wyeth/> (last accessed 18 December 2010).

Interesting Developments in the Private Sector

Switzerland. On 07 October 2010, the pharmaceutical company Novartis announced that it will develop influenza vaccines with Synthetic Genomics Vaccines Inc. (SGVI) incorporating synthetic genomics technology. The project is supported in part by a grant from the U.S. Biomedical Advanced Research and Development Authority and is expected to help increase vaccine production response times for both seasonal and pandemic flu outbreaks because the use of SGVI technology will allow more rapid growth of cultures

from which vaccines for various strains of flu are produced. Press Release, “Novartis announces agreement to develop influenza vaccines using revolutionary ‘synthetic genomics’ technology” 07 October 2010, available at <http://www.novartis.com/newsroom/media-releases/en/2010/1449685.shtml> (last accessed 18 December 2010). *See also* C. Nordqvist, “Synthetic Genomics Technology for Future Flu Vaccines, Novartis Announces,” *Medical News Today*, 07 October 2010, available at

<http://www.medicalnewstoday.com/articles/203918.php> (last accessed 18

December 2010).

The Center for Ethical Solutions is a non-partisan, non-profit, 501(c)(3), tax-exempt charity dedicated to educating the public on issues in patient-care ethics. The Center's financial statement (990EZ IRS annual tax filing) is available at upon written request from the Center or from the Commonwealth of Virginia Office of Consumer Affairs. www.ethical-solutions.org.