

# **Legal Update 2009: The Top 10 Legal Developments in Bioethics**

**Panel Session (101): Thursday, Oct. 15, 2:45 – 3:45 p.m.**

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## **Moderator:**

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## **Speakers (in order):**

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Given the time constraints of the session, some legal developments impacting bioethics cannot be covered in this session. They are outlined and discussed in this handout.

This session is sponsored by the Law & Bioethics Affinity Group. The Group's meeting is session 301, on Saturday at 7:00 a.m.

## **I. Access to Investigational Drugs outside Clinical Trials (LS)**

In recent years, seriously ill individuals have urged, through litigation and other advocacy, for a less restrictive regulatory regime that would allow greater access to investigational drugs outside clinical trials. Some individuals have also brought claims against pharmaceutical companies, arguing that promises made to provide access to an investigational drug were not honored. In the past year, two developments in this area are of particular note.

### **A. New FDA Rules.**

The FDA released two new rules, effective Oct. 13, 2009, that relate to policies that affect patients' access to investigational drugs outside clinical trials.<sup>1</sup> Both rules were originally proposed in 2006, and allow only moderate expansion of existing access routes to the drugs.<sup>2</sup> The rule titled "Expanded Access to Investigational Drugs for Treatment Use," specifies when manufacturers may submit applications for expanded use for individual patients on a case-by-case basis, intermediate-size patient populations, and larger populations under a treatment protocol or treatment IND. It also specifies the duties of patients' physicians in administering the drugs, such as reporting adverse experiences to the sponsor and obtaining informed consent. Patients will only be allowed access to a drug under the rules if they have a serious or immediately life-threatening disease or condition, no comparable or satisfactory alternative treatment options, and cannot gain access to the drug by participating in a clinical trial.

The other rule, titled "Charging for Investigational Drugs under an Investigational New Drug Application," allows manufacturers (after receiving specific approval from the FDA) to charge patients receiving a drug under expanded access for the direct costs of manufacturing or obtaining the drug on a per unit basis and the costs of monitoring the expanded-access use.

According to the FDA, about 53,159 patients per year have had access to investigational drugs under the prior rules; an additional 3,095 patients will gain access under the new rules. Abigail Alliance, the non-profit group which brought (and lost) a lawsuit claiming a constitutional right on the part of terminally ill

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<sup>1</sup> The final rules are available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm172492.htm>.

<sup>2</sup> See Kate Traynor, *FDA Finalizes Rules on Accessing Experimental Drugs*, AJHP News, American Society of Health-System Pharmacists, Sept. 15, 2009, available at <http://www.ashp.org/import/news/HealthSystemPharmacyNews/newsarticle.aspx?id=3165>; Bureau of National Affairs, *FDA Issues Final Rules to Help Patients Gain Access to Investigational New Drugs*, Pharmaceutical Law & Industry Report, August 14, 2009, available at <http://healthcenter.bna.com/pic2/hc.nsf/id/BNAP-7UVLB6?OpenDocument>; Ashley Ochs, *A Study in Futility: Abigail Alliance for Better Access to Developmental Drugs Will Not Expand Access to Experimental Drugs for the Terminally Ill*, 39 Seton Hall L. Rev. 559 (2009).

individuals to access to post-Phase I drugs,<sup>3</sup> has criticized the new rules as just putting into regulation the FDA's existing policies "that have not worked for decades."<sup>4</sup> Specifically, the Alliance and others have argued that in order to increase access to investigational drugs, the government must, among other things, allow manufacturers (1) to profit from the sale of the drug or at least charge patients for more than merely per unit manufacturing costs, and (2) to obtain waivers of liability from patients.

## **B. Promissory Estoppel Claim in Federal Court.**

In 2008, Jacob Gunvalson, a 16-year-old boy with Duchenne muscular dystrophy, and his parents brought suit against the pharmaceutical company PTC Therapeutics, Inc., to provide Gunvalson with an experimental drug then the subject of Phase 2 clinical trials for which he was ineligible.<sup>5</sup> The plaintiffs' claim was a "common law" contract claim based on promissory estoppel, which requires: 1) a clear and definite promise, 2) made with the expectation that the promisee will rely on it, and 3) reasonable reliance upon the promise, 4) which results in definite and substantial detriment. In August 2008, a federal judge determined that these arguments had a reasonable likelihood of success and granted preliminary relief in the form of an order requiring PTC to give Gunvalson access to the drug.

Plaintiffs claimed that PTC employees had promised them that Gunvalson's failure to participate in an initial Phase 2a trial would not preclude his access to later trials. In reliance on this promise, they did not pursue participation in the initial trial, which worked to their detriment, as it later turned out that failure to participate in the initial trial did preclude Gunvalson's access to a much lengthier extension of the trial that only included earlier participants. The plaintiffs also claimed (and the district court agreed) that Gunvalson met the requirements for compassionate use under FDA regulations.

In granting plaintiffs' request, the court noted that the uniquely close relationship between Jacob Gunvalson's mother and employees of PTC made it reasonably likely that the "totality of the circumstances of PTC's speech and conduct" communicated the promise that plaintiffs alleged. This unique relationship also meant, according to the court, that the injunction it granted would not "open[] the floodgates" to litigation to receive investigational drugs outside of clinical trials: "an injunction here will not have implications beyond this case."

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<sup>3</sup> *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695 (2007) (en banc), cert denied, 128 S. Ct. 1069 (2008).

<sup>4</sup> The Bureau of National Affairs, *FDA Issues Final Rules to Help Patients Gain Access to Investigational New Drugs*, Pharmaceutical Law & Industry Report, August 14, 2009, available at <http://healthcenter.bna.com/pic2/hc.nsf/id/BNAP-7UVLB6?OpenDocument>.

<sup>5</sup> *Gunvalson v. PTC Therapeutics*, 2008 WL 4003377 (D.N.J.), order vacated by *Gunvalson v. PTC Therapeutics Inc.*, 303 Fed. Appx. 128 (3rd Cir. (N.J.) Dec 16, 2008) (not selected for publication in the Federal Reporter, NO. 08-3575).

In December 2008, the Third Circuit Court of Appeals vacated the lower court's order, finding that there was not a clear and definite promise from PTC to the plaintiffs and that the plaintiffs could not show reliance on a promise. With respect to the reliance issue, the appeals court determined that the Gunvalsons did not forgo the initial trial in reliance on any promise; because Gunvalson wasn't even eligible for the trial, "they had no decision to make." The irony is that the main reason for Gunvalson's ineligibility was that his medical records indicated, mistakenly, that he had Becker muscular dystrophy rather than Duchenne muscular dystrophy.

The take-home message from the case is that it is possible, with the right facts, to make a compelling common law case for manufacturers to supply access to investigational drugs when the requirements for compassionate use are also present. A different appellate court might have agreed with lower court's ruling. For other cases involving claims of enforceable promises to supply investigational drugs, see *Dahl v. HEM Pharmaceuticals Corporation*, 7 F.3d 1399 (9<sup>th</sup> Cir. 1993) (participants' completion of double-blind test of drug was sufficient consideration for binding contract between participants and manufacturer to provide drugs free of charge for one year; open label study was ongoing, thus FDA had not decided against any use of drug because of safety concerns); *Abney v. Amgen*, 443 F.3d 540 (6<sup>th</sup> Cir. 2006) (even if informed consent form promised participants continued access to drug following study, it was not signed by manufacturer and therefore not binding upon it; the university conducting the study might arguably have been bound, but was not a party to the lawsuit).

## **II. Advance Care Planning (LS)**

### **A. National Health Care Reform.**

The charge of "death panels" in health care reform first made by former Alaska Governor Sarah Palin and echoed by some conservative commentators and politicians this fall refers to Section 1233 of this summer's House of Representatives "tri-committee" bill, HR 3200 (House Committees on Ways and Means, Energy and Commerce, and Education and Labor). This provision essentially provides for Medicare coverage for "Advance Care Planning Consultations" every five years or more frequently if there is a significant change in the health condition of the individual or upon admission to a skilled nursing facility, a long-term care facility, or a hospice program. The consultations are not mandatory. Nor are they scripted, although the provision states that the consultation "shall include the following": (items below are summarized, rather than quoted in entirety from the bill)

- An explanation of advance care planning, "including key questions and considerations, important steps, and suggested people to talk to;"

- An explanation of advance directives, including living wills and durable powers of attorney;
- An explanation of the role and responsibilities of a health care proxy;
- The provision of a list of national and state-specific resources for advance care planning assistance, including a national toll-free hotline;
- An explanation of end-of-life services, including palliative care and hospice;
- An explanation of “orders regarding life-sustaining treatment” if the state has a qualified program that allows such orders to be respected across all care settings.

In addition, the consultation may include the formulation of an order regarding life-sustaining treatment or a similar order communicating an individual’s preferences regarding treatment, which may range from full treatment to limitations of some or all interventions.

After the controversy over this provision, Charles Grassley, the ranking Republican of the Senate Finance Committee, announced that the Senate bill would not include any similar provision.

**B. State Legislation Relating to Advance Care Consultations and Efforts to Increase the Use of Advance Directives.**

This fall, **California** passed a law that requires providers to give certain information to patients following a diagnosis of terminal illness if the patient indicates a desire to receive such information.<sup>6</sup> Thus, like the U.S. House tri-committee bill on health care reform, conversations about terminal care are not mandatory for patients. They are, however, mandatory for providers upon the patient’s request. The legislature’s statement of findings regarding the law indicates that it was motivated at least in part by the legislature’s recognition that when providers object to certain practices, they are less likely to believe that they must present the option of those practices to their patients.

The types of information that should be provided, “if the patient indicates a desire to receive the information and counseling,” includes information about hospice care, prognosis with and without the continuation of disease-targeted treatment, the patient’s right to refuse life-sustaining treatment, the patient’s right to continue to pursue disease-targeted treatment with or without concurrent

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<sup>6</sup> The California statute, Assembly Bill 2747, is codified at Cal. Health & Safety Code §442.5 and is available at [http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab\\_2701-2750/ab\\_2747\\_bill\\_20080903\\_enrolled.pdf](http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_2701-2750/ab_2747_bill_20080903_enrolled.pdf).

palliative care, the patient's right to comprehensive pain and symptom management at the end of life, and the patient's right to provide individual health care instruction and to appoint a health care proxy.

**Vermont** passed a similar law (Patient Bill of Rights for Palliative Care and Pain Management), although different in important respects. The Vermont law does not provide as specific a list of information to be provided to patients, and in some respects does not only apply to terminally ill patients.<sup>7</sup>

Neither statute includes an explicit private right of action for aggrieved patients, leaving open the question whether one might be implied.

While both the national tri-committee bill on health care reform and the California and Vermont legislation focus on conversations between providers and patients, initiatives in some other states continue to try to improve the rate at which individuals execute living wills—in particular, by tying them to insurance.

In its 2009 session, the **Louisiana** legislature adopted House Concurrent Resolution 102 (which does not have the force of law) urging the Department of Health and Hospitals to study the use of living wills of this population and also to examine whether or not filling out living wills should be made a “voluntary requirement” (meaning?) for Medicaid applicants or persons being admitted to inpatient facilities.<sup>8</sup>

In **Vermont**, Senate Bill 131 of the 2009-10 legislative session proposed to require all health insurance forms and forms for state health programs (e.g., Medicaid) to contain an advance directive for applicants to complete, if they wish. They could opt out.<sup>9</sup>

### **III. North Carolina Supreme Court Limits Medical Board Disciplinary Authority (NS)**

State medical licensing boards generally have very broad authority to discipline physicians who engage in unprofessional or unethical conduct (as defined by the state's medical practice act). But sometimes, as evidenced by a recent decision by the North Carolina Supreme Court, state courts will limit medical disciplinary authority on policy grounds that are unrelated to the principles of medical ethics.

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<sup>7</sup> See Vt. H.B. 435 (2009), *enacted as* Vt. Laws No. 25, *codified at* Vt. Stat. tit. 18 §1871, *available at* <http://www.leg.state.vt.us/docs/2010/Acts/ACT025.pdf>.

<sup>8</sup> Available at <http://www.legis.state.la.us/billdata/streamdocument.asp?did=661333>.

<sup>9</sup> See <http://www.leg.state.vt.us/docs/2010/bills/Intro/S-131.pdf>.

### **A. N.C. Medical Board Position Statement on Capital Punishment.**

North Carolina's medical practice act authorizes professional discipline for "unprofessional conduct," including "departure[s] from . . . the ethics of the medical profession."<sup>10</sup> In 2007, the North Carolina Medical Board adopted a position statement indicating its willingness to take disciplinary action against physicians who participate in capital punishment (a practice the American Medical Association has long opposed on ethical grounds).<sup>11</sup>

The Board explicitly recognized, however, that North Carolina's lethal injection statutes require some physician participation – they provide that the prison physician or surgeon "shall be present" at every execution by lethal injection, and require that he later "certify the fact of the execution" to a court – and tailored its policy accordingly. The Medical Board's 2007 position statement provided that, although it would not discipline physicians for "merely being 'present' during an execution in conformity with" state law, physicians who "engage[] in any verbal or physical activity . . . that facilitates the execution," beyond the requirements of state law may be subject to disciplinary action.

### **B. N.C. Supreme Court's Limitation of the Board's Disciplinary Authority.**

The North Carolina Department of Corrections immediately brought suit to enjoin enforcement of this policy,<sup>12</sup> and in May of 2009, the Supreme Court of North Carolina handed down its final decision.<sup>13</sup>

The court held that the Medical Board, in promulgating its position statement, "improperly exceeded the authority bestowed upon it to regulate the practice of medicine," despite the fact that its policy specifically exempted from discipline those doctors who are merely present at an execution in compliance with the statutory requirements for lethal injection.

According to the court, the legislature's use of the word "present" in the lethal injection statute clearly and unambiguously indicates that the state "specifically envisioned" that the physician would "supply[] some sort of professional assistance" for which he was uniquely qualified during the execution process. The court found it "illogical" to think that the legislature would have intended that the physician be present "only as an uninvolved onlooker . . . or, as stated during oral arguments, 'a potted plant,'" merely occupying space. Accordingly, the court prohibited the Medical Board from enforcing its position statement by disciplining physicians who merely attend executions.

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<sup>10</sup> N.C. Gen. Stat. §§ 15-190 & 15-192.

<sup>11</sup> North Carolina Medical Board, Position Statement, Capital Punishment (adopted Jan. 2007); American Medical Association, Opinion 2.06, Capital Punishment (issued July 1980, updated June 1994, June 1996, December 1999, and June 2000).

<sup>12</sup> *N.C. Dep't of Corrections v. N.C. Med. Bd.*, Civ. No. 07-CVS-3574 (N.C. Super. Ct. Sept. 21, 2007).

<sup>13</sup> *N.C. Dep't of Corr. v. N.C. Med. Bd.*, 363 N.C. 189 (N.C. 2009).

While clearly limited to the context of physician participation in capital punishment, the North Carolina Supreme Court’s decision demonstrates at least one state court’s willingness to limit a medical board’s disciplinary authority on policy grounds unrelated to the practice of medicine, even without direction by the state legislature.

One implication of this decision is that it may encourage medical boards to shift their advocacy efforts beyond state legislatures, and engage in active public debate of these issues at a national level. If the medical profession wants to maintain its authority to discipline doctors for ethical violations in the context of capital punishment, national security, or other situations implicating national policy, it will have to work harder to defend its position to those decision makers who don’t share the profession’s goals.<sup>14</sup>

#### **IV. Courts Impose Limitations on State Laws Expanding Abortion Disclosure and Consent Requirements (NS)**

In the past few years, over a dozen state legislatures have passed laws that impose specific procedural requirements upon medical providers who treat women seeking abortions. Some laws require that the doctor perform an ultrasound or fetal heart auscultation before performing the abortion. Others standardize the disclosure language the physician must use – for example, requiring disclosure that the abortion will “terminate the life of a whole, separate, unique, living human being.”

Advocates of such legislation promote it as furthering the traditional goals of informed consent. However, many pro-choice commentators argue that the new abortion disclosure laws, most of which were initially proposed by pro-life advocates, are the first steps on a slippery slope towards national prohibition of abortion.

In 2009, however, three courts have overturned or limited such laws on various procedural and substantive grounds:

##### **A. South Dakota**

In 2005, legislators in South Dakota passed a law significantly expanding abortion disclosure requirements.<sup>15</sup> The law required that physicians make a “biological disclosure” (that “the abortion will terminate the life of a whole, separate, unique, living human being”), a “relationship disclosure” (that “the pregnant woman has an existing relationship with that unborn human being”), and a “medical risk disclosure” (describing the known medical risks and “statistically significant risk

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<sup>14</sup> See generally Nadia N. Sawicki, *Doctors, Discipline, and the Death Penalty: Professional Implications of Safe Harbor Policies*, 27 *Yale Law & Policy Review* 107 (2008).

<sup>15</sup> S.D. Codified Laws § 34-23A-10.1(1).

factors” of the abortion procedure, including “increased risk of suicide ideation and suicide”) before providing abortions.

The U.S. District Court for the District of South Dakota initially enjoined enforcement of this law, finding that the required disclosures violated physicians’ First Amendment rights.<sup>16</sup> An en banc panel of the 8<sup>th</sup> Circuit then reversed this decision, remanding the case back to the District Court for further deliberations. In August of 2009, the District Court reconsidered the case in light of the 8<sup>th</sup> Circuit’s decision. Although it upheld the biological disclosure, it held that the relationship and medical risk disclosures were unconstitutional and could not be enforced.

## **B. Oklahoma**

Adopted in 2008, Oklahoma’s Freedom of Conscience Act prohibits a medical provider from performing an abortion unless he has first performed an ultrasound on the woman seeking the abortion, “display[ed] the ultrasound images so that the pregnant woman may view them,” and provided a verbal description of what the ultrasound is depicting.<sup>17</sup> The Act clarifies that, while a patient is permitted to “avert[] her eyes” or “refuse[] to look” at the ultrasound images, a medical provider will be liable for damages if he does not comply with the Act’s requirements.

In August of 2009, an Oklahoma District Court judge overturned these provisions and others on the grounds that the Freedom of Conscience Act violated a requirement under the Oklahoma Constitution that laws only address “single subjects.”<sup>18</sup> While this technical ruling did not speak to the substantive merits of the ultrasound requirement, a substantive challenge is likely to follow, as Republican legislators have promised to split the Act into multiple single-subject bills and pass them in the next legislative session.

## **C. North Dakota**

North Dakota’s 2009 Abortion Control Act imposes criminal penalties on any physician who performs an abortion without first having offered an ultrasound and heart tone auscultation to the woman seeking the abortion.<sup>19</sup>

When a medical clinic challenged the auscultation requirement as imposing an unconstitutional burden (given that the auscultation equipment used in early pregnancy can cost almost \$30,000 and that auscultation is of limited diagnostic value in this context), a North Dakota District Court upheld the requirement, but

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<sup>16</sup> *Planned Parenthood v. Rounds*, No. 05-4077-KES (Dist. S.D., Aug. 20, 2009).

<sup>17</sup> 63 Okla. Stat. § 1-738.3b (2008).

<sup>18</sup> *NovaHealth v. Henry*, No. CJ-2018-9119 (Okla. Dist. Ct., 8/18/09) (bench ruling, no written decision).

<sup>19</sup> N.D. Cent. Code 14-02.1-01 *et seq.*

only by narrowly interpreting it to require only that clinics provide information about auscultation, rather than provide the service itself.<sup>20</sup>

#### **D. Implications.**

Although South Dakota was the only state to overturn an abortion disclosure statute on substantive grounds, the fact that courts are limiting the scope of the new disclosure requirements for any reason suggests that some legislatures have gone too far. That said, advocates of abortion disclosure requirements are still promoting their message as furthering the traditional goals of informed consent, and it will likely be a few more years before courts and legislatures reach equilibrium on this issue.<sup>21</sup>

### **V. Legal Developments in Genetic Testing (NS)**

#### **A. GINA.**

In 2008, Congress passed the Genetic Information Nondiscrimination Act (GINA), which prohibits employers and health insurance providers from discriminating against employees/participants on the basis of genetic information. GINA does not apply to providers of life, long-term-care, or disability insurance.<sup>22</sup>

Federal agencies (including EEOC, IRS, DHHS, and Labor) are required to adopt implementing regulations before GINA's nondiscrimination provisions go into effect on November 21, 2009. Accordingly, many of these agencies have already either adopted or proposed amendments to HIPAA, the ADA, the Civil Rights Act to bring them into line with the GINA requirements. For example, HIPAA will be amended to provide for monetary damages upon the use or disclosure of genetic information in violation of the HIPAA Privacy Rule, and the ADA will be amended to prohibit employers from asking for family medical history of employees who have been offered a job.

While GINA has been hailed by many as a breakthrough anti-discrimination law, some argue that it simply doesn't go far enough. For example, GINA does not prohibit health plans from discriminating against patients by increasing premiums once a patient "manifests" a disease such that it could be diagnosed by a medical professional. Although GINA provides that "manifestation" of a disease cannot

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<sup>20</sup> *MKB Management Corp. v. Stenehjem*, No. 09-09-C-02839 (N.D. Dist. Ct, Aug. 11, 2009).

<sup>21</sup> See generally Rebecca Dresser, *From Double Standard to Double Bind: Informed Choice in Abortion Law*, 76 *George Washington Law Review* 1599 (2008); Carol Sanger, *Seeing and Believing: Mandatory Ultrasound and the Path to a Protected Choice*, 56 *U.C.L.A. Law Review* 351 (2008).

<sup>22</sup> The text of the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110-233, 122 Stat. 881) is available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_public\\_laws&docid=f:publ233.110.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ233.110.pdf)

be based principally on genetic information, some commentators worry that patients will nevertheless be reluctant to pursue genetic testing if GINA doesn't offer greater protections.<sup>23</sup>

## **B. Regulation of DTC Genetic Testing.**

Another legal issue at the forefront of genetic testing is the question of whether the federal government will take additional steps to regulate lab-developed direct-to-consumer (DTC) genetic tests.

Currently, only the laboratories themselves are being regulated – the FDA has no authority to regulate either the DTC genomics companies (including 23andMe and Navigenics), or the quality or clinical validity of the actual genetic tests. Although the issue is certainly on the FDA's radar, it has not given any indication of how it plans to proceed. In the absence of federal regulation, however, some states have taken proactive measures – in 2008 and 2009, for example, New York and California sent cease-and-desist letters to many DTC genomics companies, requiring that they be licensed as clinical laboratories before soliciting business within the state.

## **C. Patent Litigation and Genetic Testing.**

A key court case to watch in the coming months is *Association for Molecular Pathology, et al v. United States Patent and Trademark Office et al*, which was filed in May 2009 in the United States District Court for the Southern District of New York.<sup>24</sup>

A group of plaintiffs, including the ACLU and the Public Patent Foundation, filed this complaint against the U.S. PTO and other defendants, including Myriad Genetics, the holder of patents on two genetic mutations (BRCA1 and BRCA2) correlated with increased risks of breast and ovarian cancer, as well as patents on the methods for screening for the BRCA mutations.

The complaint alleges that Myriad's patents restrict innovation and harm the public because they prohibit anyone other than Myriad from examining or interpreting a woman's BRCA genes. That is, the Myriad patents prohibit physicians and laboratories from independently testing for BRCA mutations, and even from discussing the test results with their patients. Myriad charges approximately \$3000 for its BRCA tests, a price that is prohibitive for many patients. Furthermore, the complaint alleges, patents on isolated genes (such as

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<sup>23</sup> See generally Jessica L. Roberts, *Preempting Discrimination: Lessons from the Genetic Information Nondiscrimination Act*, 63 *Vanderbilt Law Review* No. 4 (2010), available at <http://ssrn.com/abstract=1342903>; Mark A. Rothstein, *GINA, the ADA, and Genetic Discrimination in Employment*, 36 *Journal of Law, Medicine and Ethics* No. 4 (2008).

<sup>24</sup> The complaint in *Association for Molecular Pathology, et al v. United States Patent and Trademark Office et al* (S.D.N.Y.) is available at [http://www.aclu.org/images/asset\\_upload\\_file939\\_39568.pdf](http://www.aclu.org/images/asset_upload_file939_39568.pdf).

the ones held by Myriad) are unconstitutional because they violate a legal prohibition on patenting products or laws of nature.

This litigation is worth following closely because it promises to answer important questions about the patentability of genetic material, which has significant implications for physicians and patients who rely on genetic testing to guide medical decision making.

## **VI. Developments in Federal Stem Cell Research Policy (MAM)**

New National Institutes of Health Guidelines on Human Stem Cell Research took effect July 7, 2009.<sup>25</sup> The Guidelines implement Executive Order 13505,<sup>26</sup> which overturned the prior administration's policy limiting Federal funding of human embryonic stem cell (hESC) research to lines created before August 9, 2001. (The Executive Order was notable for the wide discretion accorded to the agency; it authorized the NIH to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.")

The Guidelines retain the restriction of funding to hESCs derived from embryos leftover following reproductive treatment, but without any cut-off date. In this respect they mirror Clinton-era policy. They also lay out detailed informed consent requirements vis-à-vis the individuals who sought reproductive treatment, create a review process for non-conforming hESCs derived from embryos donated in the U.S. before July 7 and hESCs from embryos donated outside the U.S., and promise a registry of hESCs eligible for use in NIH funded research. The Guidelines have been criticized for, among other things, failing to require any kind of consent from gamete donors, respond to donor interest in information about the kinds of research that may be conducted, and offer sufficient guidance for research involving chimeras.<sup>27</sup>

On August 12, 2009, two scientists, Nightlight Christian Adoptions for itself and for all human embryos that are or will be potential sources of eligible hESCs, two couples hoping to adopt embryos, and the Christian Medical Association filed a lawsuit in U.S. District Court for the District of Columbia challenging the Guidelines.<sup>28</sup> The complaint charges that the guidelines violate the Dickey Amendment and the Administrative Procedure Act. Similar suits in the past have faced barriers in areas such as standing (related to the status of the parties) and

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<sup>25</sup> National Institutes of Health Guidelines on Human Stem Cell Research, <http://stemcells.nih.gov/policy/2009guidelines.htm>.

<sup>26</sup> Executive Order 13505, <http://www.gpoaccess.gov/presdocs/2009/DCPD200900136.pdf>.

<sup>27</sup> See generally Mary A. Majumder and Cynthia B. Cohen, *The NIH Draft Guidelines on Human Stem Cell Research*, 324 Science 1648-1649 (2009).

<sup>28</sup> Complaint for Declaratory and Injunctive Relief, *Sherley et al. v. Sebelius*, No. 1:09-cv-1575 (D.C. Dist. Ct., Aug. 12, 2009).

justiciability (appropriateness of the case for judicial resolution, especially mootness where courts anticipate policy shifts due to changes in administration). No such case has ever proceeded to a ruling on the merits.

As of October 1, NIH Director Francis Collins has constituted a Working Group for Human Embryonic Stem Cell Eligibility Review, and a number of hESC lines have been submitted for review or are listed as in process with the intent to submit.<sup>29</sup> The registry itself is still in “check back” mode, but given the flexibility permitted by the Guidelines, the composition of the working group, and the number of lines submitted or in process, it seems clear that the new administration will indeed expand the number of hESC lines available for use in federally-funded research.

## **VII. Parental Refusals of Medical Treatment (MAM)**

Those charged with creating and enforcing the law have long wrestled with what to do in cases where religious beliefs motivate parents to refuse medical treatment for their children. At least since 1944, it has been clear that the free exercise clause of the First Amendment does not protect parental conduct that exposes children to “ill-health or death.”<sup>30</sup> Nonetheless, a number of cases in 2008-2009 attracted national attention and illustrated some of the hard questions remaining, especially where parents are charged with manslaughter or a similar criminal offense.

### **A. Daniel Hauser.**

The Daniel Hauser (13-year-old with Hodgkin’s Lymphoma) case in Minnesota was perhaps the least interesting legally, since the judge clearly had the authority to order treatment. The only close question was whether to allow Daniel to remain in the custody of his parents after his mother fled the state with him to avoid additional court-ordered chemotherapy, the pair having returned voluntarily after a weeklong “manhunt.”

### **B. Ava Worthington and Madeline Kara Neumann.**

Two other high profile cases involved criminal prosecutions following child deaths. In Oregon, 15-month-old Ava Worthington died from complications of untreated pneumonia and a blood infection. Her parents were acquitted of the most serious charge, manslaughter, and Raylene Worthington was acquitted of all

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<sup>29</sup> NIH hESC Registry, [http://grants.nih.gov/stem\\_cells/registry/current.htm](http://grants.nih.gov/stem_cells/registry/current.htm).

<sup>30</sup> *Prince v. Massachusetts*, 321 U.S. 158 (1944), [http://supct.law.cornell.edu/supct/html/historics/USSC\\_CR\\_0321\\_0158\\_ZS.html](http://supct.law.cornell.edu/supct/html/historics/USSC_CR_0321_0158_ZS.html).

charges. On July 31, Carl Worthington was sentenced to 60 days in jail and 5 years probation with orders to provide medical care for his other children.<sup>31</sup>

In Wisconsin, the parents of 11-year-old Madeline Kara Neumann were convicted of reckless homicide in separate trials following her death from diabetic ketoacidosis. The Neumanns are due to be sentenced on October 6; their attorneys have said they will appeal. Both juries were deadlocked for a considerable period of time before reaching a verdict.

Interesting features of these cases include: (a) the confusion created by religious exemptions in laws related to child neglect and sometimes criminal laws, most dating back to a requirement imposed under the Nixon administration on states receiving federal funds for child protection programs (changed in 1983); (b) the growing prominence of New Age belief systems (the Nemenhah Band, for the Hausers) and Internet-based faith communities (Unleavened Bread Ministries, for the Neumanns) in these kinds of conflicts; and (c) the difficulty many jurors experience in applying criminal laws to parents they perceive as well-intentioned and caring, in some cases perhaps amounting to a kind of jury nullification (as suggested in the Worthington case based on statements made by the presiding juror).

From a policy perspective, the issue of deterrence seems important, especially in relation to sentencing decisions. If a parent's faith in spiritual practices is firm enough to cause her to reject medical treatment even as her own beloved child is visibly suffering, hovering near death and, ultimately, crossing over that threshold, is the threat of a significant prison stay going to make a difference? Perhaps more so for those who view a turn to medical treatment as merely ineffectual, versus as a testament to one's abandonment of God.

## **VIII. New Federal Laws Affecting Coverage and Delivery (MAM)**

The prospects for passage of comprehensive health care reform legislation are still uncertain, but two pieces of legislation passed in 2009 are incremental steps toward universal coverage and improved outcomes.

### **A. Children's Health Insurance Reauthorization Act of 2009.**

On February 4, 2009, President Obama signed the Children's Health Insurance Reauthorization Act of 2009 (CHIPRA). CHIPRA extends and expands the State Children's Health Insurance Program (CHIP), created under the Balanced Budget

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<sup>31</sup> Randy L. Rasmussen, *Worthingtons Acquitted on All but one Charge in Daughter's Faith-Healing Death*, *The Oregonian*, July 23, 2009, [www.oregonlive.com](http://www.oregonlive.com); Dirk Johnson, *Trials for Parents who Chose Faith over Medicine*, *New York Times*, January 21, 2009, at A23, [http://www.nytimes.com/2009/01/21/us/21faith.html?\\_r=2](http://www.nytimes.com/2009/01/21/us/21faith.html?_r=2); Shawn Peters, *When Prayer Fails: Faith Healing, Children and the Law* (New York: Oxford University Press, 2007).

Act of 1997. CHIPRA adds \$33 billion in federal funding over the next four and half years to support state programs to cover an estimated 4.1 million children in Medicaid and CHIP who would otherwise have been uninsured by 2013.<sup>32</sup>

The legislation does not address a directive issued under the Bush administration limiting states' flexibility to cover children with family income over 250% of the federal poverty level, but President Obama took separate action to change that policy. CHIPRA does reverse a ban on coverage for legal immigrant children and pregnant women during their first five years in the country. CHIPRA also adds new incentives for outreach and enrollment, including an enhanced federal match for translation and interpreter services; requires states to include dental services in CHIP plans and requires mental health parity if states choose to include mental health services; establishes the Medicaid and CHIP Payment and Access Commission to review access and payment policies; and provides \$225 million over 5 years for child health quality initiatives. CHIPRA spending will be financed through a 62-cent per-pack increase in federal cigarette taxes and other tobacco tax increases.

## **B. American Recovery and Reinvestment Act of 2009.**

On February 17, President Obama signed the American Recovery and Reinvestment Act of 2009 (ARRA). Although only a small part of overall ARRA spending, the \$1.1 billion allocated for comparative effectiveness research over a two-year period marks a major expansion of funding in this area.<sup>33</sup> The money will be distributed by the U.S. Department of Health and Human Services (HHS), more specifically, by the Office of the Secretary of HHS (\$400 million), the National Institutes of Health (\$400 million), and the Agency for Healthcare Research and Quality (\$300 million).

ARRA also created a Federal Coordinating Council for Comparative Effectiveness Research.<sup>34</sup> Both the Council and the Institute of Medicine (IOM) were charged with making recommendations related to comparative effectiveness not later than June 30, 2009. The Council report, in accordance with its mandate,

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<sup>32</sup> Children's Health Insurance Reauthorization Act of 2009, Pub. L. 111-3, [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_public\\_laws&docid=f:publ003.111](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ003.111); Henry J. Kaiser Family Foundation, *Children's Health Insurance Program Reauthorization Act of 2009*, February 2009, <http://www.kff.org/medicaid/upload/7863.pdf>.

<sup>33</sup> American Recovery and Revitalization Act of 2009, Pub. L. 111-5 (text related to comparative effectiveness funding), <http://www.dhhs.gov/recovery/programs/cer/recoveryacttext.html>.

<sup>34</sup> Federal Coordinating Council for Comparative Effectiveness Research, *Report to the President and Congress* (Washington, DC: Department of Health and Human Services, 2009), <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>; Institute of Medicine, *Initial National Priorities for Comparative Effectiveness Research* (Washington, DC: Institute of Medicine, 2009), <http://www.iom.edu/CMS/3809/63608/71025.aspx>; Henry J. Kaiser Family Foundation, *Explaining Health Reform: What is Comparative Effectiveness Research?* (October 2009), <http://www.kff.org/healthreform/upload/7946.pdf>; Randall Brown, *Strategies for Reining in Medicare Spending Through Delivery System Reforms* (September 2009), <http://www.kff.org/medicare/upload/7984.pdf>.

focuses on the funds allocated to the Office of the Secretary, concluding that data infrastructure development should be the primary investment for those funds. The IOM report includes a list of 100 priority topics. Half the topics concern health care delivery systems, “*how* or *where* services are provided, rather than *which* services are provided.” Racial and ethnic disparities, patient decision-making, and dissemination methods are also prominently featured on the list. HHS is supposed to consider both sets of recommendations in directing ARRA funds.

Controversy about comparative effectiveness research has focused on a possible link to rationing, and even references to cost or use of research findings in coverage decisions have drawn fire. The text of the ARRA includes two statements on these matters: “Nothing in this section shall be construed to permit the Council to mandate coverage, reimbursement, or other policies for any public or private payer” and “[n]one of the reports submitted under this section or recommendations made by the Council shall be construed as mandates or clinical guidelines for payment, coverage, or treatment.” A small number of the IOM priority topics do reference cost or cost-effectiveness. Some state Medicaid programs already use comparative effectiveness research from the Drug Effectiveness Review Project to develop preferred drug lists. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 bars the Centers for Medicare and Medicaid Services from incorporating results from the comparative effectiveness research authorized under that Act into Medicare coverage decisions, and Medicare regulations require coverage of any treatment shown to be effective without regard to cost.

## **IX. Free Speech and Physician Prescribing Habits (EE)**

Free speech is a central facet of our understanding of rights that the government may not restrict. However not all speech is “free” speech for the purposes of regulation. “Commercial speech” is a contested example. The boundaries of commercial speech regulation has been tested several times in the health care arena. Notable examples include regulation of alcohol and tobacco advertising, and aspects of drug marketing.<sup>35</sup>

Another process that is emerging is the increasing pressure on both physicians and pharmaceutical companies to avoid the appearance of influence over doctors’ prescribing habits. University medical centers are increasing their restriction on the presence of pharmaceutical company representatives on campus and the availability of pharmaceutical company “gifts” or free meals. There is strong evidence that physicians prescribing practices are improperly influenced by pharmaceutical company detailing.<sup>36</sup>

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<sup>35</sup> R. Bayer, *Tobacco, Commercial Speech, and Libertarian Values: The End of the Line for Restrictions on Advertising*. 92 American Journal of Public Health No. 3 (2002).

<sup>36</sup> For further discussion see [http://npalliance.org/pages/the\\_unbranded\\_doctor\\_campaign/](http://npalliance.org/pages/the_unbranded_doctor_campaign/)

These two issues have combined around the use of physician information to market pharmaceuticals. The clash between free speech and inappropriate influence in health care is not new. Pharmaceutical companies have claimed that their ability to market directly to physicians as well as directly to consumers is protected as free speech. The FDA has the authority to restrict representations made about the efficacy of medications, requiring proof that the medication is safe and effective for the use being promoted.<sup>37</sup> This authority includes regulation of advertisements.<sup>38</sup>

Drug company interactions with providers have become more complex with the proliferation of technology. Repositories of information including pharmacy records can be used and cross-referenced to determine individual doctors actual prescribing habits, and those data could be sold and bought.<sup>39</sup> Marketing strategies can then be tailored to the physician. New Hampshire enacted a statute restricting the sale of prescribing information, and this was challenged as unconstitutional on the basis that such disclosure of data was “commercial speech.” “Commercial speech” is traditionally protected, but the First Circuit Court of Appeals made a distinction between commercial speech and data that was refined and sold for commercial purposes.<sup>40</sup> The data are not merely transmitted, but they are processed and interpreted to the point that the information is no longer speech, but has become a commercial product.<sup>41</sup>

The New Hampshire law reflects the growing sense that pharmaceutical company/physician interactions are not simply a form of marketing, but are an exploitation of human nature and behavioral psychology to promote commercial interests. Increasingly, physicians are distancing themselves from direct interaction with pharmaceutical companies and representatives, closing off one avenue of influence. Allowing states to regulate on the issue increases the distance between pharmaceutical companies and prescribing physicians. There are organizations that target local governments to implement reform, making state legislatures a viable forum for reform.<sup>42</sup> Allowing protection of this information facilitates an important trend toward eliminating inappropriate influences on physician prescribing habits.

## **X. Public Health and Civil Liberties (EE)**

With the upcoming flu season and the prospect of a serious outbreak of H1N1 flu, it is possible that public health authority may be utilized in a manner more

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<sup>37</sup> Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a) (2006).

<sup>38</sup> 21 U.S.C. § 352(n) (2006).

<sup>39</sup> R. Steinbrook, *For Sale: Physicians' Prescribing Data*, 354 *New England Journal of Medicine* No. 26 (June 29, 2006).

<sup>40</sup> *IMS Health Inc v Ayotte* available at <http://www.cal.uscourts.gov/pdf/opinions07-1945P-01A.pdf>

<sup>41</sup> D. Grande & D. Asch, *Commercial versus Social Goal of Tracking What Doctors Do*, 360 *New England Journal of Medicine* No. 8 (Feb. 19, 2009).

<sup>42</sup> <http://www.prescriptionproject.org/>

pervasive than most people have experienced in the US, providers or the public. Public health infrastructure hasn't been required to deal with a major, acute public health issue in the recent past. Even 9/11 and Katrina, while devastating, were limited in geography. A flu pandemic will be widespread and may tax resources to the point of true scarcity.

Most states have public health laws including some or most of the Model State Emergency Health Powers Act (MSHEPA).<sup>43</sup> The MSEHPA gives broad authority for a variety of actions when a public health emergency is called. Governors of states have the authority to declare a disaster and put the state public health law into effect. Public health laws based on the MSHEPA enact authority to quarantine, to appropriate medications, vaccines, property and supplies, and to divert state resources to deal with the public health crisis. It creates some mechanisms to improve the health care provider response: there is the ability to credential providers quickly and to create limited immunity for care providers.

These powers are necessary to deal with a widespread health concern, whether that be flu, a terrorist act, or a natural disaster. However, some elements of the MSHEPA will create significant limitations on individual liberty. Physicians can be compelled to participate in the disaster response under threat of loss of licensure or de-credentialing. True quarantine on a large scale would be a novel experience for most Americans and would be as surprising as it would be restrictive. Knowledge of the potential state powers is necessary to facilitate discussion and measured analysis, and understanding and exploration of the provisions of the MSEHPA.

The most pressing issue is transparency in planning so that meaningful discourse occurs. Transparency in the implementation process is also essential for people to be prepared for the response. Public health has been a neglected sphere of modern health care in the United States, despite the fact that public health initiatives have been an overwhelming actor in increasing longevity. Whether or not we are able to initiate a massive public health response is questionable, but the actions that would be taken must be sufficiently transparent and justice based to be ethically defensible in the event that such measures are required.

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## FURTHER RESOURCES

Legal developments impacting bioethics are covered by Thaddeus Pope in "Legal Briefing" and "Legal Update" columns in the *Journal of Clinical Ethics*. "Briefing" is an extended discussion of just one or two developments. "Update" more briefly covers several issues. The Fall 2009 (*JCE* 20(3)) Briefing was "Medical Futility and Assisted Suicide." The Winter 2009 (*JCE* 20(4)) Briefing will be "Advance Care Planning."

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<sup>43</sup> L. Gostin et al. *Model State Emergency Powers Act*, [www.publichealthlaw.net/msehpa.pdf](http://www.publichealthlaw.net/msehpa.pdf).