

**Law****Legal Trends in Bioethics***Sigrid Fry-Revere*

I have reconsidered the format of this column since I first wrote it 17 years ago. I have tried to make it more useful by organizing the information with busy readers in mind who may only be looking for information relevant in their jurisdictions. I have given each section a heading that reflects the potential practical ramifications of the material it contains. I have divided entries up by jurisdiction, and underlined the status of the case, regulation, or law. Furthermore, each entry is a very brief synopsis to allow readers to glance through sections quickly and then follow up on their own if a particular development is of interest.

No entry should be relied upon without reading the full text of the law, regulation, or case in question or without checking if any more

recent developments have superseded the ones reported here. Also, please remember to be cautious about what entries might or might not be binding in your jurisdiction. Usually, jurisdiction is determined by the location of the medical institution, but that is not always the case. The law of the patient's state of residency, if different than the law where the healthcare institution is located, may also be relevant as may other jurisdictional factors.

This column is called "Legal Trends in Bioethics," so I will begin each section with a brief statement of developing changes. I have avoided legal references and citations in these introductory paragraphs to make them easier to read. Readers who would like references for any part of these paragraphs are welcome to e-mail me if an internet search for such references proves fruitless. Usually these introductory paragraphs will be only two or three sentences long, but, in this, my first "Legal Trends" in almost 15 years, I take the liberty of describing what has happened in a much broader space of time than will be the case in future columns.

The individual synopses given in this first "Legal Trends" are for developments from July through December 2006. Future columns will provide updates in three-month increments.

**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 [sfryrevere@cato.org](mailto:sfryrevere@cato.org).**

**Sigrid Fry-Revere, PhD, JD**, is Director of Bioethics Studies at the Cato Institute, Washington, D.C., [sfryrevere@cato.org](mailto:sfryrevere@cato.org). © 2007 by *The Journal of Clinical Ethics*. All rights reserved.

### **A ONE-TIME INTRODUCTION TO UNDERSTANDING LEGAL TRENDS IN BIOETHICS**

The 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 U.S. constitutional guarantees of separation of church and state and individual rights make bioethics issues involving personal, moral, or religious convictions particularly contentious.

Each state also has its own constitutional protections, some of which clearly mirror those in the federal Constitution and others that don't.

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 anti-democratic. As a matter of fact, their main constitutional function is to protect the rights established by our various constitutions from violation by legislative action. Courts are also inherently conservative in their reaction to events because they are bound by precedents and procedural processes that are designed to assure that major philosophical changes happen gradually.

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

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

### **LIFE AND DEATH DECISIONS CONTRARY TO PATIENTS' WISHES**

In the last three decades the pendulum has swung from focusing on the right to refuse or withdraw treatment to the right to demand treatment, and now may be stabilizing in recognition of the inherently private nature of such decisions. In the 1970s, 1980s, and early 1990s, most end-of-life treatment disputes involved patients<sup>1</sup> or patients' families seeking support in their efforts to stop treatment. This was reflected in court cases and in the flood of state advance directive legislation and even in a public movement to legalize forms of aid in dying. In subsequent years, this trend reversed, mostly due to the growing political influence of the right-to-life movement. Advance directive laws were amended to make them more restrictive and, while in Oregon the Death with Dignity Act was approved twice by public referendum, similar propositions in other states such as California and Washington failed repeatedly. Suddenly there were more cases in which patients or their surrogates were demanding treatment rather than refusing it.

In just the past few years, however, there has been some resistance to these developments. Several 2005 polls regarding the highly publicized Terri Schiavo case found that Americans were fairly evenly divided on whether Terri's feeding tube should be removed or not, had a slight bias in favor of having her husband rather than her parents make the decision, and consistently felt strongly that the federal government should not be involved.<sup>2</sup> In one poll when people were asked, "If a patient has been in what doctors call a 'persistent vegetative' or coma-like state with no higher brain activity for a significant amount of time, who do you think should make the decision whether the patient should be kept alive or not: The person's par-

ent or other family members, the person's spouse, or the government?" There were only 2 percent of respondents who answered, "The Government."<sup>3</sup>

These results indicate that many Americans believe such decisions should be left to family members, not courts or legislatures. The Schiavo case is too recent for there to be any evidence of a possible new trend in court decisions, but, immediately after these polls were taken, the federal government dropped all discussion of possible "Schiavo" legislation.

It is also worth noting that, while the courts have hesitated to award damages for prolonging life against patients' wishes, they have awarded damages when medical professionals shortened a patient's life against the patient's wishes. In other words, the courts have refused to recognize treatment as "futile" simply because the patient has a bad prognosis. Or, put yet another way, courts have found that patients and families have a right to prolong life even in cases when medical professionals see such efforts as resulting in unnecessary suffering or a waste of resources.

I predict that in the years to come there will be a growing emphasis on keeping end-of-life decisions more private and within the family (however defined).

#### Recent Cases, July 2006 - December 2006

**Louisiana.** In *Terry and Flowers v. Red River Center*, the daughters of a deceased patient sued the nursing home where their mother had lived because staff called 911 in violation of what the daughters believed to be a valid do-not-resuscitate order (DNR order). The patient died at the hospital, but her daughters claimed that failure to follow the patient's wishes caused her undue pain and suffering. This court upheld the lower court's finding that all three advance directives issued in the previous six years were invalid: one because the form used required two physicians' signatures and there was only one; the second because it had been executed at another institution and wasn't in the defendant's records; and the third because it was signed by

one of the daughters and not the patient herself, and there wasn't any evidence that the patient wanted the daughter to make such decisions for her. 942 So.2d 1238; 2006 La. App. LEXIS 2597 (15 November 2006).

**New York.** In *In re Matter of Claudia E.E.*, the New York Supreme Court Appellate Division, Third Department ruled that the Mental Hygiene Legal Service (MHLS) did not have the right to revoke its consent to a guardian's request to withdraw a patient's life-sustaining medical treatment simply with a letter. The guardian/sister of a mentally retarded person with Down syndrome and Alzheimer's disease decided to take her sister off the ventilator and feeding tube and transfer her to hospice care. When the patient didn't die, but instead was breathing on her own and feeding herself, MHLS sent a letter revoking its consent. The revocation was not valid because the proper procedure would have been to commence a special proceeding challenging the guardian's decision. 822 N.Y.S.2d 810; 2006 N.Y. App. Div. LEXIS 12512 (19 October 2006).

But in *In re Guardianship of Chantel Nicole R.*, the Supreme Court of New York, Appellate Division, First Department ruled that MHLS had the authority to commence a special proceeding to object to a mother of a mentally retarded child making medical decisions for her daughter concerning life-sustaining treatment. 821 N.Y.S.2d 194; 2006 N.Y. App. Div. LEXIS 10922 (21 September 2006).

#### Recent Laws and Regulations, July - December 2006

**Federal.** The Advance Directives Improvement and Education Act of 2005 (S. 347/H.R. 2058) is being considered by various congressional committees. At this point, it isn't clear whether or not the act will come to a vote this legislative session. The act, among other things, would require Medicare providers to honor advance directives executed in another state unless the provider can "reasonably demonstrate" that the directive does not express the patient's wishes or directs a form of medical treatment

prohibited by the laws of the state in which the patient is being treated. The Advance Directives Improvement and Education Act of 2005, S. 347/H.R. 2058, 109th Cong. (2005).

**California.** The California legislature passed and the governor signed on 28 September 2006 a law, effective immediately, to ease the signature requirements for advance directives and durable powers of attorney filed electronically. 2005 Bill Text CA A.B. 2805 (28 September 2006). A.B. 2805, 2005-2006 Assem., Reg. Sess. (Ca. 2006).

**Georgia.** A bill was prefiled on 13 December 2006 to revise Georgia's advance directive laws. House Bill 24 will be introduced in the 2007 legislature. Among other things, this bill will combine Georgia's living will and durable power of attorney provisions into one form. H.B. 24, 149th Gen. Assem., Reg. Sess. (Ga. 2007). 2007 GA H.B. 24.

**New Hampshire.** The governor signed a bill (H.B. 656), effective 1 January 2007, that revises New Hampshire's advance directive laws. Among other things, the state's living will, proxy decision making, and DNR statutes have been combined into one form. H.B. 656, 159th Gen. Assem., Reg. Sess. (N.H. 2006).

Also, in New Hampshire as of 1 January 2007, new laws go into effect that set out specific requirements that must be satisfied before an agent may withhold or withdraw life-sustaining treatment. RSA 137-J:10 (2006).

**New Jersey.** A bill was introduced on 4 December 2006 in the New Jersey Senate to require surrogate decision makers to make healthcare decisions in accordance with a patient's religious beliefs. A similar New Jersey Assembly bill was introduced 9 November 2006. 2006 Bill Text NJ S.B. 2380; 2006 Bill Text NJ A.B. 3514. S.B. 2380, 211th Leg., Reg. Sess. (N.J. 2006); A.B. 3514, 211th Assem., Reg. Sess. (N.J. 2006).

**Pennsylvania.** Pennsylvania's Title 18 and 20 (Crimes and Offenses and Decedents, Estates, and Fiduciaries) were amended to protect caretakers and individuals or facilities who lawfully comply with a "health care representative's" directions as long as the care-dependent person has been documented by the attending physi-

cian to have an end-stage medical condition or to be permanently unconscious. S.B. 628 signed into law on 29 November 2006. 2005 Bill Text PA S.B. 628. S.B. 628, 2005-2006 Leg., Reg. Sess. (Pa. 2006).

**Texas.** The Texas Department of Aging and Disability Services has promulgated rules that went into effect 1 December 2006 requiring that all home and community support services maintain written policies regarding the implementation of advance directives and give notice to patients or their surrogates if the patient is incapacitated regarding any procedures the agency is unwilling or unable to provide or that the agency withheld in accordance with an advance directive. 40 TAC §97.283 (2006).

Also, on 13 November 2006 a bill was prefiled that would, among other things, provide for transferable physicians' orders, and prohibit healthcare providers or insurance companies from requiring advance directives as a condition for receiving healthcare services. 2007 Bill Text TX S.B. 28.

### Interesting Developments in Other English Common Law Countries

**Canada.** The Manitoba College of Physicians and Surgeons, which oversees Manitoba's doctors, published a report in October 2006 proposing policies that give physicians the authority to stop or withhold medical treatment under certain circumstances even if the patient or family disagrees. The College of Physicians is still considering whether or not to implement the report's recommendations. [http://www.cpsm.mb.ca/about/news/2006/10/16/38189\\_0610160758-046?pageNumber=1](http://www.cpsm.mb.ca/about/news/2006/10/16/38189_0610160758-046?pageNumber=1).

### THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

#### Pre-Birth (Abortion, Fetuses, Embryos, and Stem Cells)

There isn't an ethical or political topic more prone to semantic manipulation than abortion and the related issues of fetal rights and stem-

cell research. People immediately make assumptions based on an author's word choices. I do it myself, but I want very much to be objective in my representation of the law relevant to these issues. So, in an attempt to give as objective a representation as possible, I will do two things: First, in my synopses, I will try to use the same vocabulary and tone reflected in the particular case, law, or regulation at issue. And, second, I'm going to disclose my personal beliefs so the reader can filter out any biased wording that might slip in.

I am morally pro-life, but politically pro-choice. My moral conviction is that human identity begins with our genes. That means, for me, a new individual begins at conception. This being said, I'm also a firm believer in the constitutional goals and philosophical origins of our political system. Historically, in recognition of the pluralist nature of our society, our system was set up to protect individuals with minority moral perspectives from having the exercise of their beliefs restricted by those who believe otherwise. The more divisive an issue, the harder our courts must work to protect minority points of view. I feel very strongly that abortion is morally wrong except under very limited circumstances and that all human life should be accorded a certain degree of respect. However, I also realize that these views are not shared by all, and that, while they have a strong religious history, they are not supported by our own legal history or by the principles of the U.S. Constitution.

Even if U.S. jurisprudence recognized each new human individual as a person under the law at all stages of development (which it doesn't), there simply are no historical or legal precedents in English or American law that justify treating the pre-born with equal status to other persons. Children, at every stage of development, have always had fewer rights than adults, particularly fewer rights vis-à-vis their parents. In every culture, children's rights, and the corresponding legally supported freedom to go against their parents' wishes, increase as the child matures. Infants have fewer rights than children who can walk and talk; children who

are mobile have fewer rights than those who have reached puberty; children who have merely reached puberty have fewer rights than those who exhibit maturity. U.S. law, in the past, has adhered to the logic of this sliding scale of maturity even when considering the rights of children earlier in their development. Newborns have more rights than viable fetuses; viable fetuses have more rights than not-yet-viable fetuses, and all fetuses have more rights than embryos, blastocysts, or human life at the point of conception. Never in the history of English or U.S. law has a child at any stage of development been treated as *prima facie* having the same legal standing as a parent. Thus, the legal issue is *not* whether fetuses should be treated as equal persons under the law (that is, as with discrimination against racial minorities and women, we now need to abolish discrimination against the pre-born). The real issue is: What level of rights should be accorded the pre-born, using a traditional sliding scale of rights that is based on relative maturity?

To understand the legal debate over abortion and related issues, it is important to realize that there actually are two debates: One is the moral, religious, and philosophical debate about personhood. The other is a debate over how far those who hold either extreme of a wide range of moral perspectives should be allowed to compromise the integrity of our legal system (constitutional and common law) in order to have their own particular moral perspective become law.

The trend over the last 15 to 20 years has been a slow erosion of abortion-related rights. Some of the laws passed carry moral weight but have little effect on eroding our legal system, for example, the battle over parental notification laws. However, the partial-birth abortion debate now being waged in the U.S. Supreme Court could have a significant effect on our legal system because it could potentially change the historical relative rights of women vis-à-vis their fetuses.

The November 2006 elections gave some indication that more Americans than in the past wish the government to step back and be less

involved in pre-birth decisions. As with end-of-life decisions, more Americans seem to be indicating that these morally divisive issues should be decided privately and not by the government. This being said, most legislatures are rather evenly divided between pro-choice and pro-life advocates.

I predict that the U.S. Supreme Court will declare partial-birth abortion bans that do not include an exception for cases in which the mother's life is in danger unconstitutional, but will imply that the states are free to regulate abortion and related rights beyond what was previously allowed.

#### Recent Cases, July 2006 - December 2006

**Federal. Pending cases.** Decisions expected from the U.S. Supreme Court in the spring of 2007 include *Gonzales v. Carhart*, 05-380, and *Gonzales v. Planned Parenthood*, 05-1382. These cases challenge the constitutionality of the Partial-Birth Abortion Ban Act of 2003. In 2000, the U.S. Supreme Court held a Nebraska law banning partial-birth abortions unconstitutional because it didn't include an exception to the ban for when a woman's health is in danger. Since then, Congress passed its ban on partial-birth abortions that also doesn't include an exception for when a mother's health is in jeopardy, so the issue is once again before the Court. One major difference is that the Court's composition has changed since 2000. In 2000 Justice Sandra Day O'Connor cast the decisive fifth vote. Today, Justice Samuel Alito, who has written in the past that the Constitution does not protect the right to an abortion, sits on the Court in her place. If the Partial-Birth Abortion Ban Act of 2003 is found constitutional, it will ban the procedure in all states, whether or not individual states passed or defeated such laws on the state level.

**California.** In *People Advocate v. Independent Citizen's Oversight Committee*, the California Superior Court upheld the validity of Proposition 71, but plaintiffs plan to appeal. 2006 WL 1417983 (Cal. Superior Ct. 2006) (upholding the constitutionality of Proposition 71).

**Kansas. Potential action.** State Attorney General Phill Kline has twice tried to file charges against physician George Tiller for allegedly performing 15 illegal late-term abortions in 2003. Each time the criminal charges were thrown out by Sedgwick County, Kansas, District Judge Paul Clark on jurisdictional grounds, that is, Kline doesn't have authority to file such charges. Kline promises to continue to investigate.

#### Recent Laws and Regulations, July - December 2006

**Federal.** On 24 August 2006, the U.S. Food and Drug Administration (FDA) approved Plan B<sup>®</sup>, an emergency contraceptive, for over-the-counter sale to women ages 18 or older. Plan B<sup>®</sup> is still available by prescription only to women under 18. Application No. 21045/S011 (24 August 2006). Press Release, U.S. Food and Drug Administration, "FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older. Prescription Remains Required for Those 17 and Under," 24 August 2006, <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01436.html>, accessed 26 January 2007.

**California.** In 2004, California voters approved Proposition 71 and the raising of \$3 billion through state bonds to fund stem-cell research, including embryonic stem-cell research. California Health & Safety Code §125290.10. That bond issue hasn't taken place because there is a lawsuit challenging the constitutionality of the proposition and the proposed system for administering the funds. In *People's Advocate v. Independent Citizen's Oversight Committee*, the California Superior Court upheld the validity of Proposition 71, but plaintiffs plan to appeal. 2006 WL 1417983 (Cal. Superior Ct. 2006) (upholding the constitutionality of Proposition 71).

**Hawaii.** On 26 April 2006, the governor signed into law a bill that codifies the protections of *Roe v. Wade*. H.B. 1242, 23rd Leg., Reg. Sess. (Haw. 2006) (to be codified at Haw. Rev. Stat. § 453-16).

**Illinois.** Two bills were introduced in the Illinois legislature in December 2006: One would allocate \$25 million annually for the next

five years to stem-cell research, including embryonic stem-cell research (H.B. 1039); the second would ban human cloning and the sale of human embryos (H.B. 1038). H.B. 1039, 94th Gen. Assem., Reg. Sess. (Ill. 2006); H.B. 1038, 94th Gen. Assem., Reg. Sess. (Ill. 2006).

**Michigan.** The Michigan Civil Rights Commission issued a declaratory ruling in August 2006 that prescription contraceptives must be covered by employers who provide prescription drug coverage in their health plans. Not to do so is a violation of the Elliott-Larsen Civil Rights Act, which prohibits sex-based discrimination. The ruling allows an exception for nonprofit “religious employers.” Michigan Civil Rights Commission, Declaratory Ruling on Contraceptive Equity, 21 August 2006 at <http://www.chetlyzarko.com/Declaratory%20Ruling%207-26-06.pdf>, accessed 25 January 2007.

Also in Michigan, bills were introduced last August as a unit called the “Coercive Abortion Protection Act,” that, among other things, would make it criminal to coerce a person into having an abortion. The act also includes a requirement for “coercion and intimidation screening.” H.B. 5879, 93rd Leg., Reg. Sess. (Mich. 2006); H.B. 5880, 93rd Leg., Reg. Sess. (Mich. 2006); H.B. 5881, 93rd Leg., Reg. Sess. (Mich. 2006); H.B. 5882, 93rd Leg., Reg. Sess. (Mich. 2006); H.B. 5883, 93rd Leg., Reg. Sess. (Mich. 2006). 2005 Bill Text MI H.B. 5879 (26 July 2006).

**Missouri.** In the November 2006 election, Missouri voters passed an amendment to the state constitution, the Missouri Stem Cell Research and Cures Initiative, that guarantees that any stem-cell research allowed under federal law is also allowed in Missouri. Mo. Const. of 1945, art. III, § 38(d) (2007).

**New Jersey.** On 20 December 2006, the governor signed a bill that approves a state bond issue to borrow \$270 million for expansion of human embryonic stem-cell research. (S 1471). N.J. P.L. 2006, c. 102. N.J.S.A. 34: 1B-21.31-36.

**South Dakota.** The state legislature enacted a law that makes it a class five felony for any person to “knowingly administer to, prescribe for, or procure for, or sell to any pregnant woman any medicine, drug, or other substance with the specific intent of causing or abetting the ter-

mination of the life of an unborn human being.” The law contained a narrow exception in instances in which an abortion is necessary to preserve a woman’s life. H.B. 1215, 81st Leg. Assem., Reg. Sess. (S.D. 2006). The U.S. Court of Appeals for the Eighth Circuit stayed enforcement of the act (see entry above), but while it was being litigated, a voter referendum on the November 2006 ballot rejected the new law.

### After Birth (Premature Infants, Newborns, and Children)

Legislative considerations of children’s rights have fluctuated over the years based on political issues that really had little to do with the actual welfare or maturity of children. This is still true today. The courts have worked to mediate the effects of such political pressures, but not always successfully. Examples are the ongoing debates over religious exceptions to child abuse laws, over parental notification when minors seek abortions, and over the proper treatment of premature or handicapped infants.

I have seen some shift in legal arguments in favor of holding that a child’s best interest cannot be judged independently of its family unit, that is, that there should be more of a presumption in favor of parental decision making unless it is absolutely clear that the parent does not have the child’s best interest in mind. I think this development parallels developments in other areas of bioethics, in which it is clear that a growing number of Americans feel that, in a pluralistic society, there needs to be sphere reserved for private family decision making with as little government interference as possible.

I predict that this trend will grow, but very slowly, and, while a few isolated court cases will reflect this shift toward family decision making, it will take much longer for other branches of government to accept more of a hands-off approach.

### Recent Cases, July 2006 - December 2006

I have not reported any child abuse cases here because those that I found that were de-

cided or filed in the last six months didn't involve any out-of-the-ordinary medical issues. Usually, if medical treatment was involved at all, it was that the parents were accused of neglect for not providing adequate medical care. While these cases are often horrific, they don't involve any new ethical issues.

**Federal.** In *Planned Parenthood Minn. v. Rounds*, the Eighth Circuit Court of Appeals (Minnesota, Nebraska, North Dakota, South Dakota, Eastern and Western Districts of Arkansas, Northern and Southern Districts of Iowa, Eastern and Western District of Missouri) enjoined the implementation of amendments to an **Ohio** state abortion law requiring that special informed consent provisions be met unless the abortion is necessary due to medical emergency. The special provisions in question require abortion providers to notify patients that "the abortion will terminate the life of a whole, separate, unique, living human being" and to certify that the pregnant woman has read and that the physician believes her to understand the information imparted. Plaintiffs sought the injunction, claiming the law compelled providers to articulate the state's abortion ideology and philosophy in violation of the First and Fourteenth Amendments. The injunction prevents enforcement of the law while it is adjudicated. The court simultaneously enjoined a similar **South Dakota** law. 467 F.3d 716; 2006 U.S. App. LEXIS 26914 (30 October 2006).

**Missouri.** Case pending. In *Planned Parenthood of Kansas and Mid-Missouri, Inc., et al. v. Jeremiah W. (Jay) Nixon, et al.*, the Missouri Supreme Court heard arguments challenging the Missouri parental consent law that gives parents and prosecutors the right to sue adults who help minors get an abortion without complying with state parental consent laws, which require either direct parental consent or court approval. The challenge is based on whether the "aid and assist" language in the law includes speech and therefore is a violation of state-protected right to free speech. *Planned Parenthood of Kansas and Mid-Missouri, Inc., et al. v. Jeremiah W. (Jay) Nixon, et al.*, No. SC87321 (Mo. filed 13 November 2006).

**Ohio.** In *Cincinnati Women's Services Inc. v. Taft*, the court held that a provision of Ohio law that required a woman seeking an abortion to have an in-person meeting with a physician at least 24 hours prior to receiving an abortion for informed consent purposes was constitutional, but that a provision that limited minors seeking a judicial bypass to parental-consent requirements to one petition for such bypass per pregnancy was unconstitutional. No. 05-4174 (6th Cir. 13 November 2006) *Cincinnati Women's Services v. Taft*, 468 F. 3d 361; 2006 U.S. App. LEXIS 28049 (6th Cir. 2006).

### Recent Laws and Regulations, July - December 2006

**Federal.** Two congressional bills failed in December 2006. The first (H.R. 6099) would have required that a woman seeking an abortion be told that "there is substantial evidence that the process of being killed in an abortion will cause the unborn child pain" and that she has the option of anesthetizing the fetus before the abortion. Another bill that hasn't left committee is H.R. 522, which would have extended the Fourteenth Amendment to guarantee "right to life" for "each born and pre-born human person." Given the new Democratic majority in Congress, it is not likely that either of these bills will be up for a vote in the near future.

**Illinois.** The Illinois Supreme Court announced 18 September 2006 that it will issue rules necessary to implement the state Parental Notice of Abortion Act. Ill. S. Ct. M.R. 21173. Until the court issues rules, the act remains unenforceable because the court needs to specify the procedures by which minors can seek judicial waivers under special circumstances. The Illinois Supreme Court holds its annual Rules Committee meeting every January.

**Oklahoma and Utah.** On 16 March 2006, Utah's governor and on 20 May 2006 Oklahoma's governor signed bills that add a parental consent requirement to their states' existing parental notification laws applicable in cases in which minors seek abortion. H.B. 85, 56th Leg., 2006 Reg. Sess. (Utah 2006) (to be codified in

Utah Code Ann. § 76-7-304) (Enacted 1974) (Last Amendment 2006); H.B. 1686, 50th Leg., 2006 Reg. Sess. (Okla. 2006).

### Interesting Developments in Other English Common Law Countries

**England.** The Nuffield Council on Bioethics, in a report published in November 2006, recommended that premature babies born before 22 weeks not be resuscitated regardless of the parents' wishes. Babies born between 22 and 23 weeks of age should only be treated if the parents insist and the doctor agrees.

### ORGAN AND TISSUE PROCUREMENT

Medical innovations in transplantation have been spectacular; unfortunately, we are stuck in a vicious cycle in which demand far outstrips supply. The organ and tissue industry, plagued by the inequities of altruistic donation on one hand and profits in the billions on the other, is fraught with abuses that range from a black market to the negligent cutting of corners in a rush to profit.

I predict a proliferation of court cases and regulation in an attempt to stem the tide of abuses, and a move to a system of presumed consent to organ donation, in an attempt to increase the supply of organs and human tissue. For various reasons, these measures will solve little in the long run. Even lifting the prohibition on the sale of organs and tissue will not solve the problem for long. Perhaps stem-cell therapies or some other "medical miracle" will eventually solve the organ shortage.

### Recent Cases, July 2006 - December 2006

**Federal. Ongoing case.** The Eighth U.S. Circuit Court of Appeals (Minnesota, Nebraska, North Dakota, South Dakota, Eastern and Western Districts of Arkansas, Northern and Southern Districts of Iowa, Eastern and Western District of Missouri) in *Wash. U. v. Catalona* is reviewing the lower court's ruling that Washing-

ton University in St. Louis owned the tissue samples that William J. Catalona, MD, had collected for prostate cancer research while at the university. The U.S. District Court for the Eastern District of Missouri held that the informed consent documents signed by Catalona's patients, which specifically gave the doctor the patients' tissue samples and included the patients' right to withdraw from the study and request that their tissue samples be destroyed, were "inconsequential" in its decision to grant full property rights to the university. Appeal No. 06-2286 (8th Cir. 15 May 2006).

**Connecticut.** In *Miller v. Hartford Hospital, et al.*, the Superior Court of Connecticut for the Middlesex Judicial District held that under Connecticut law human tissue is not a product for the purposes of product liability law. 2006 Conn. Super. LEXIS 2835 (19 September 2006).

**Massachusetts. Ongoing case.** In *Gonzales et al. v. Katz et al.*, a probable case of first impression, an organ bank is being sued because the recipient of an organ contracted a rare form of cancer, allegedly from the organ supplied by the bank. Both the recipient and the donor died of the same rare form of cancer. In this part of the case, the court refused to dismiss the case on grounds that the good faith immunity provision of the Massachusetts Promotion of Anatomical Science Act did not apply in this case, because the act does not apply to the clinical process by which the medical suitability of organs is determined, but rather to those authorizing and receiving anatomical gifts. 21 Mass. L. Rep. 351; 2006 Mass. Super. LEXIS 358 (Mass. Super. Ct. 19 July 2006).

**New Jersey. Action being initiated.** A law firm in New Jersey is organizing a first-of-its-kind class action suit against Biomedical Tissue Services of Ft. Lee, New Jersey, for selling contaminated tissue samples. <http://www.monheit.com/biomedical-tissue>; [http://www.oshmanlaw.com/pharmaceutical\\_litigation/tainted\\_tissue.html](http://www.oshmanlaw.com/pharmaceutical_litigation/tainted_tissue.html), accessed 24 January 2007.

**New York and New Jersey.** The King's County District Attorney arrested and indicted a funeral home director and several others in February 2006 for illegally selling stolen body

parts. Media Release, Office of the District Attorney, Kings County (23 February 2006). Since then, several others, from as many as seven funeral homes in New York and New Jersey, have been added to the original indictment. [http://www.usatoday.com/news/nation/2006-10-18-stolenbodyparts\\_x.htm](http://www.usatoday.com/news/nation/2006-10-18-stolenbodyparts_x.htm); <http://transcripts.cnn.com/TRANSCRIPTS/0610/18/cnr.06.html>, accessed 28 January 2007.

### Recent Laws and Regulations, July - December 2006

**Colorado.** The first-person consent rule (also present in the new Uniform Anatomical Gift Act) went into effect in Colorado on 6 August 2006. The law prohibits any disposition of an individual's remains after death that is contrary to the deceased's written wishes. Col. Rev. Stat. 15-19-102 (2006).

**Michigan.** On 31 December 2006, Michigan's governor vetoed a bill (H.B. 6292) that would have provided a tax incentive (up to \$200 in tax credits) for people who donate money to umbilical cord blood stem-cell banks. The governor stated the money would be better spent on stem-cell research.

**New Jersey.** A bill was introduced in October 2006 that would require the New Jersey Motor Vehicle Commission to share organ donor information with federally designated organ procurement organizations. Currently the bill is in committee and is expected to be voted on later in this legislative session. 2006 Bill Text NJ A.B. 3137 (19 October 2006).

Also in New Jersey, a bill was withdrawn from further consideration that would have amended the New Jersey Anatomical Gift Act to require that those involved in organ procurement not ask for an anatomical gift if they have reason to believe that the gift would be contrary to the decedent's wishes or religious beliefs. The amendment further would have barred the anatomical gift if a person who is listed in the state list of potential surrogates indicates that such a gift would be contrary to the decedent's wishes or religious beliefs. 2006 Bill Text NJ S.B. 2378 (4 December 2006).

**New York.** On 16 August 2006, the governor signed into law three bills to amend driver licensing laws. One requires that "organ donor" be prominently printed on the front of organ donors' licenses. The other requires that each donor so designated be registered in the New York State Organ and Tissue Donor Registry. 2005 Bill Text NY A.B. 11883, A.B. 2995, 228th Leg. Sess., Reg. Sess. (N.Y. 2006); A.B. 11883, 229th Leg. Sess., Reg. Sess. (N.Y. 2006).

Also in New York, on 16 August 2006, the governor signed into law an act requiring the transplant council to complete a study on the issues surrounding the implications of presumed consent for organ and tissue donation. 2005 Bill Text NY A.B. 11842, A.B. 11842, 229th Leg. Sess., Reg. Sess. (N.Y. 2006).

On 16 August 2006, the New York governor signed into law a bill that allows reduction in federal adjusted gross income of up to \$10,000 to anyone who donates one or more of his or her organs to another human being. 2005 Bill Text NY A.B. 3072. (16 August 2006). A.B. 3072, 229th Leg., Reg. Sess. (N.Y. 2006).

**Pennsylvania.** The governor signed on 2 July 2006 a law that requires Pennsylvania businesses to provide up to five days paid leave for organ and bone marrow donors. The law further clarifies that this leave is in addition to any other personal or sick leave allowed the employee by the employer, and that, if such leave is provided, the employer qualifies for the state donor tax credit. 2005 Bill Text PA H.B. 153 (Act No. 2006-65, 2 July 2006). H.B. 153, 189th Gen. Assem., Reg. Sess. (Pa. 2006).

**Rhode Island.** The governor signed on 10 July 2006 a law requiring the state medical examiner and his designees to share all information necessary to facilitate organ and tissue donation with federally designated organ procurement organizations and other nonprofit federally registered eye and tissue banks. 2005 Bill Text RI S.B. 2616 (10 July 2006). S.B. 2616, 2005-2006 Leg. Sess., Reg. Sess. (R.I. 2006).

**South Carolina.** A bill has been prefiled for the 2007 legislative session that would require all patients to indicate, at the time of admission to a hospital, whether or not they are an

organ or tissue donor, or both, and, if not, whether the patient or the patient's family would be willing to discuss organ or tissue donation, or both, should the patient become a potential donor during his or her stay in the hospital. 2007 Bill Text SC S.B. 131 (6 December 2006). S.B. 131, 117th Gen. Assem., Reg. Sess. (S.C. 2006).

**Other.** The National Conference of Commissioners on Uniform State Laws has revised its Uniform Anatomical Gift Act. The 2006 version was released on 13 July 2006. Most notably, the new version supports first-person consent. The document states that, in all cases, the express wish of the donor should take precedence over any wishes expressed by the family. Uniform laws are model documents that must be adopted by individual states before they have any force of law.

### INFORMED CONSENT

In the last three decades, the documentation of informed consent has developed from a valuable form of evidence to a near meaningless formality. As consent forms become more complicated and less comprehensible, courts have begun to consider violations of informed consent as actionable, in and of themselves, as opposed to being simply one element showing negligence in malpractice suits. Mere documentation of consent is no longer always enough. *Informed* consent is starting to take on a legal life of its own. Violations of informed consent are not only an indication of negligence (a claim requiring a proof of damages) but also an affront to human dignity and/or a breach of fiduciary obligation, both of which can now sometimes be claimed without evidence of actual damages, that is, the physical or emotional harm required in malpractice claims.

As medical innovations and the availability of experimental treatments multiply exponentially, physicians and researchers are under ever-greater pressure to succeed. That pressure sometimes creates a conflict of interest with the traditional role of physician as healer — the traditional view of physician as one with the pati-

ent's best interest at heart. Patients and their families also have unrealistic expectations with respect to the curative potential of experimental treatments. These factors, along with the ever-more-complicated nature of medicine, make it important that the informed consent process actually works, that it helps ensure informed decision making, and not merely serves as a meaningless legal formality.

In this area of the law, legislatures, government agencies, and the courts have all been working, albeit slowly, toward the goal of trying to make the informed consent process more comprehensible. Opposition to such advances usually comes from medical institutions and practitioners already overburdened with legally required paperwork.

I predict that new advances in documentation technologies will eventually be used to satisfy everyone. For example, the informed consent process could include the electronic recording of a patient's verbal responses to questions designed to verify comprehension.

### Recent Cases, July 2006 - December 2006

**Federal. Ongoing litigation.** In *Ryan v. Staten Island Univ. Hospital, et al.*, the U.S. District Court for the Eastern District of New York agreed to hear a claim for malpractice, fraud, and violation of New York State consumer protection and public health laws. The plaintiff claims, among other things, that she and her husband were lured from their home in Florida for treatment of his pancreatic cancer by numerous misrepresentations, including a claim that the treatment proposed had a 95 percent success rate. 2006 U.S. Dist. Lexis 88313 (intermediary finding regarding discovery issue, 5 December 2006).

**Florida.** In *Pope v. Winter Park Healthcare Group, Ltd.*, the Florida District Court of Appeals held that the hospital was responsible for assuring that the patient received the information necessary for informed consent, even if the procedure in question was performed by a physician not employed at the hospital. The court found that the duty of informed consent rests

with the hospital, even in the case of independent contractors. 939 So. 2d 185; 2006 Fla. App. Lexis 16605 (Fla. Dis. Ct. App., 5th Dist., 6 October 2006).

**Louisiana.** In *Brown v. Louisiana, State of*, the Louisiana Court of Appeals reversed and remanded a trial court's summary judgment. The court found that a failure to inform a patient of more conservative medical approaches to a hysterectomy could be a violation of informed consent, justifying damages for negligence. The issue needs to go to a jury and cannot be decided by summary judgment. No. 06-709 (La. Ct. App. 2 November 2006).

**Michigan.** In *Compton v. Pass*, the Michigan Court of Appeals ruled that failure to inform plaintiff of the option to undergo a sentinel node procedure instead of an axillary dissection wasn't the proximate cause of her permanent axillary cording and lymphedema. The court granted summary judgment for defendant. No. 260362 (Mich. Ct. App. 22 August 2006).

**Mississippi.** In *Cleveland v. Mann*, the Mississippi Supreme Court ruled that an informed consent form that included a provision compelling arbitration in the case of disputes was not unconscionable. The patient had signed and initialed the document, there was bold type indicating that a right to a trial would be waived, and there was time between the signing and the surgery for the patient to reconsider. These facts were enough to override the patient's lack of education or inability to read and understand the agreement. Miss. Supreme Ct. No. 2005-CA-00924-SCT; 2006 Miss. LEXIS 467 (31 August 2006).

**Texas.** In *Gray v. Woodville Health Care Center*, the Court of Appeals of Texas, Eighth District, held that a family didn't have a case for malpractice or wrongful death. The court did not discuss informed consent or the meaning of "hospice" care, but analyzed the case purely along traditional notions of malpractice. The facts, however, clearly indicated a misunderstanding as to the meaning of "hospice" care. The family consented to having the patient transferred to hospice care, but was shocked to

find that the patient died the day after transfer; in their minds it was negligent for the patient's physician to order most treatments stopped in conjunction with the transfer. 2006 Tex. App. LEXIS 6904 (3 August 2006).

### Recent Laws and Regulations, July - December 2006

**California.** On 29 September 2006, the governor vetoed a bill passed by the California legislature that would have amended the Health and Safety Code to include special informed consent provisions for participants in biomonitoring experimentation. Of special interest were the requirements that participants be informed and consent to the intended use of any biospecimen, including any potential patentable pharmaceuticals or other products, and that participants have full access to all laboratory reports and final research results. 2005 Bill Text CA A.B. 1062 (31 August 2006). A.B. 1062, 2005-2006 Gen. Assem., Reg. Sess. (Ca. 2005).

**Rhode Island.** On 3 July 2006, a bill amending the state informed consent laws took effect without the governor's signature. The new law (P.L. No. 2006-225) allows for an exception to informed consent requirements in the case of experimental procedures being tested in emergency settings. No informed consent is required if the patient is unable to consent due to a life-threatening condition. 2005 Bill Text RI H.B. 8073; 2005 Bill Text RI S.B. 2613 (7 July 2006). H.B. 8073, 2005-2006 Leg., Reg. Sess. (R.I. 2006); S.B. 2613, 2005-2006 Leg., Reg. Sess. (R.I. 2006).

### UNCONVENTIONAL TREATMENT

As in other areas of bioethics, a significant number of people are disillusioned with the government's ability to make wise decisions regarding the appropriateness of care. Twenty years ago, Americans had more faith in both doctors and the government, when it came to protecting the population from the hazards of developing pharmaceuticals and technologies.

In recent years, some of this faith has eroded. Citizens are not only questioning and challenging the government, but also suing to take certain decisions out of government hands.

I predict that few plaintiffs will be successful in their challenges to government authority, but that challenges will increase and, with time, some will begin to bring about change.

#### Recent Cases, July 2006 - December 2006

**Federal.** Ongoing case. In *Abigail Alliance v. Eschenbach*, the U.S. Court of Appeals for the District of Columbia Circuit granted the FDA's petition to rehear the question of standing *en banc*. The court had previously held that the lower court erred in dismissing the Alliance complaint. The circuit court found that the Alliance case had standing and a due process interest in self-determination that protected the pursuit of promising new drugs. The issue in the case is whether individuals should have the right to purchase drugs before full approval by the FDA. Oral arguments are scheduled for 1 March 2007. 2006 U.S. App. LEXIS 28834 (21 November 2006) Rehearing *en banc* granted 21 November 2006 (Case # 04-5350).

**Washington.** In *State of Washington v. Tracy*, the Washington State Supreme Court held that the recognized Washington State compassionate-use defense, for those arrested for the use of marijuana who claim to possess the drug for medical reasons, does not apply if the "qualifying doctor" is not a Washington State doctor. In this case, the defendant had a medical marijuana card issued by a California doctor and an authorization for use issued by an Oregon doctor. Her convictions were upheld. 158 Wn. 2d 683; 2006 Wash. LEXIS 883 (Wash. 2006).

#### Recent Laws and Regulations, July - December 2006

**Federal.** The FDA is considering regulations to expand its current Compassionate-Use Programs that make experimental drugs available to individuals or groups under certain circumstances. The rules make drugs available during

all stages of development, including during Phase I testing, and allow manufacturers to charge the cost of making and providing the drugs, but not to make a profit. Such regulations would allow patients to use drugs before safety trials have been completed (Phase I) and before testing for efficacy has even begun (Phase II). Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75147 (14 December 2006).

#### THE RIGHT TO ACCESS AND CONTROL MEDICAL INFORMATION

One of the biggest changes in the last 30 years has been the ease with which information can be transmitted and stored, and with that comes privacy concerns.

I predict that errors in transmitting information by e-mail will lead to some interesting cases, and perhaps even regulation in the near future. Are your e-mail communications encrypted? Are you sure when you press that send button that your response is reaching the correct person, and only that person? As wonderful as new technologies are, it is important to pause and think about how best to use them.

Like e-mails, data storage on computers and computer systems isn't as secure as some people think. Experimental data or hospital records, particularly now that there is a movement to create nationwide medical information systems, might be vulnerable. Some private companies are providing their clients with "memory sticks," replete with all their medical records, ready to plug into any doctor's or hospital's computer either to be printed or downloaded. Giving patients memory sticks is cheaper than linking all U.S. medical providers electronically, and is also safer from a privacy perspective.

#### Recent Cases, July 2006 - December 2006

**California.** Pending litigation. *Taus v. Loftus, et al.* is a case in which a child abuse victim gave permission (at age 17) — and so did her father — to be interviewed, and for the taped interview to be shown for "educational pur-

poses.” A case study was published that referenced “Jane Doe,” but other identifying information was disclosed when the researcher gave presentations about the case, including videotaped interviews with the subject in which the subject’s first name was used by the researcher, and the city where the subject lived as a child was disclosed. Based on this information, in conjunction with information disclosed in the researcher’s published case study, reporters discovered more about the case and published allegedly defamatory remarks about the subject and the researcher’s claims regarding her recovery of repressed memories. 2005 Cal. App. Unpub. LEXIS 3048, 22 media L. Rep. 1545. *Taus v. Loftus, et al.*, 2006 CA S. Ct. S133805 (appeal).

#### Recent Laws and Regulations, July - December 2006

**Federal.** The FDA is collecting comments on a proposed project for the “Development of an Electronic System for Reporting Medication Errors and Adverse Drug Events in Primary Care Practice.” 71 Fed. Reg. 74537 (12 December 2006).

The FDA has also issued a request for information regarding “Improving Health and Accelerating Personalized Health Care Through Health Information Technology and Genomic Information in Population — and Community-Based Health Care Delivery Systems.” 71 Fed. Reg. 64282 (Nov. 1, 2006).

**California.** On 30 September 2006 the governor signed into law the Local Pandemic and Emergency Health Preparedness Act of 2006. This act, among other things, authorizes local public health officials to demand and receive medical information regarding patients from healthcare providers and health insurance plans without first obtaining patient authorization. 2005 Bill Text CA S.B. 1430 (31 August 2006). S.B. 1430, 2005-2006 Leg., Reg. Sess. (Ca. 2006).

**Iowa.** There is a bill pending before the Iowa state legislature to implement electronic health records systems incrementally throughout the

state. H.B. 2637, 81st Gen. Assem., 2nd Sess. (Iowa 2005).

#### MEDICAL TESTING

There are no new trends in the handling of medical testing issues. The ethical questions associated with the accuracy of tests, proper reporting of results, and the risks associated with certain types of disclosure have not changed. This is, however, an important section to include in “Legal Trends,” because, as genetic testing improves, some very difficult ethical questions, with correspondingly difficult policy questions, will arise. As testing becomes a more reliable predictor of a person’s potential for sickness or health (as well as a predictor of other things as well) there is a danger that some people will put too much stock in genetically identified propensities and act, legislate, or regulate accordingly.

#### Recent Cases, July 2006 - December 2006

**Ohio.** In *Galland v. Meridia Health Sys. Inc.*, the Ohio State Court of Appeals held that a five-year-old child who was stuck by a used needle from an unidentified patient could not comprehend HIV enough to be emotionally distressed by the thought that she might have contracted AIDS. The court also summarily dismissed the parents’ claim of emotional distress, stating that, under Ohio law, the damage suffered by bystanders must be severe and debilitating for recovery to be possible and there was no evidence that the parents’ damages were that severe. No. 23163 (Ohio Ct. App. 20 September 2006); 2006 Ohio 4867, 2006 Ohio App. LEXIS 4785.

In *Bright v. Family Med. Found. Inc.*, the Ohio State Court of Appeals upheld a finding of malpractice against a medical facility and doctor for using a lidocaine bottle contaminated with HIV. The bottle had been used to numb the plaintiff’s foot after being used on another patient with AIDS. No. 05AP-835 (Ohio Ct. App. 28 September 2006); 2006 Ohio 5037; 2006 Ohio App. LEXIS 4947.

### Recent Laws and Regulations, July - December 2006

**Federal.** The U.S. Department of Health and Human Service Centers for Disease Control and Prevention (CDC) published a document on 22 September 2006 that recommends HIV screening for all patients in all healthcare settings unless the patient declines such testing. The document is a little unclear with respect to whether it is recommending “presumed consent” or “notice with an option to opt-out.” At several points in the document it is stated that “HIV screening is recommended after the patient is notified that testing will be performed unless the patient declines.” In other parts it is stated that “general consent for medical care should be considered sufficient to encompass consent for HIV testing.” “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.” 55 (RR14):1-17 (22 September 2006).

In *Hickman v. Laboratory Corp. of America Holdings Inc.*, the Abingdon Federal District Court for the Western District of Virginia found that a medical worker who was stuck with a needle who then received a “false positive” HIV result could not recover from the lab that tested her blood. The plaintiff’s smoking and taking of fertility drugs were intervening factors that could have caused her anxiety. Her claims for emotional distress due to breach of express warranty or negligence were summarily dismissed. VLW 006-3-429 (6 October 2006) and VLW 006-3-4769 (9 November 2006); 2006 U.S. Dist. LEXIS 82119 (W.D. Va. 2006).

**Ohio.** A bill was introduced on 28 November 2006 in the Ohio state legislature to limit the liability of hospitals, among other things, for the genetic screening of newborns. 2005 Bill Text OH H.B. 692. H.B. 692, 162nd Gen. Assem., Reg. Sess. (Ohio 2006).

### DECISION-MAKING CAPACITY/COMPETENCY

Decision-making capacity and competency continue to be among the most vexing practical

questions in clinical ethics. Philosophically, determining capacity doesn’t seem all that difficult: Does the person understand the consequences of his or her decision? However, in reality, the situation is often very different. Judgment is impaired either temporarily or permanently by pain, by medication, by emotional insecurities, by the potentially coercive nature of experts or family members, and by illness itself.

One major development over the last 30 years is that most legal and medical professionals, even if not the public, now understand that the standard for determining capacity in the medical context is different than the standards applied in conservatorship or criminal proceedings. Also, while not anywhere near perfect in its application, it is now generally recognized that advance planning with respect to healthcare decisions is wise. When patients are unconscious or express wishes consistent with their advance directives, the capacity to make healthcare decisions is a non-issue; the advance directive, if valid, should be followed. Only if a patient expresses inconsistent wishes or gives other signs of possible diminished or compromised capacity does an evaluation of the ability to comprehend the consequences of a healthcare decision become important.

I predict that over the next few years scientific advances in our understanding of cognitive functions will make determinations of capacity less subjective and take some of the anguish out of situations in which a patient’s capacity to make healthcare decisions is in doubt.

### Recent Cases, July 2006 - December 2006

**California.** In *In re Gregory A.*, the California Appeals Court upheld a lower court’s decision to appoint a conservator. The plaintiff sought denial of reappointment of a conservator, claiming that the lower court applied the wrong standard when it decided that a conservator was necessary. The appointment was upheld on the grounds that the plaintiff was, in fact, presently disabled because he had a history of resisting taking his medication and “re-

quired constant prompting.” The court found that the plaintiff sufficiently lacked “insight into his mental illness” to justify a conservator. No. A113587 (Cal. Ct. App. 7 November 2006). *In re Gregory A.*, 2006 Cal. App. Unpub. LEXIS 10119 (Cal. Ct. App. 2006).

### Recent Laws and Regulations, July - December 2006

**Federal.** The U.S. Department of Health and Human Services (DHHS) Centers for Medicare and Medicaid Services (CMS) published its final rule on patients’ rights with respect to the use of restraints and seclusion on 8 December 2006. These rules became effective 8 January 2007 and apply to all participating Medicare and Medicaid hospitals, including short-term, psychiatric, rehabilitation, long-term, children’s, and alcohol/drug treatment facilities. The rule expands the category of practitioners who may conduct patient evaluations when restraint or seclusion is being used, and includes special notice requirements regarding patients’ care, records, and the right to be free of the use of inappropriate restraints or seclusion. The rule also includes stricter reporting requirements for deaths associated with the use of restraints or seclusion. 71 Fed. Reg. 71378 (8 December 2006).

**California.** The California legislature is considering revisions to the state conservatorship and guardianship laws. The Jones Omnibus Conservatorship and Guardianship Reform Act of 2006 is the newest version of Assembly Bill 1363, which was first introduced in 2005 and has undergone almost a dozen amendments. A vote is anticipated in 2007. 2005 CA A.B. 1363 (22 August 2006); A.B. 1363, 2005-2006 Gen. Assem., Reg. Sess. (Ca. 2005).

### PALLIATIVE CARE AND PAIN CONTROL

Issues of palliative care for the elderly and for newborns will become increasingly divisive. Baby boomers, who have now experienced having children and their elderly relatives strug-

gling with debilitating illnesses, will demand changes. They will demand changes for their grandchildren and for themselves.

After a flurry of concern and consequent regulations, laws, and cases involving handicapped newborns in the 1980s, there was a lull in politically airing such concerns until the recent Bush administration made the protection of infants (at all stages of development) from the potential ill-intent of parents and doctors one of its missions. The U.S. Federal Born-Alive Infant Protection Act became law in 2001, and, in 2005, DHHS Secretary Mike Leavitt promised to enforce any violations of the Born-Alive Infant Protection Act or the federal Emergency Medical Treatment and Labor Act, which, he states, requires aggressive treatment to try to save the life of every child born alive, no matter how young or under what circumstances. The American Academy of Pediatrics and many physicians don’t adhere to these standards. Instead, they believe that, at times, it is acceptable for parents in consultation with the infant’s physician to limit or cease treatment if they believe doing so would be in the child’s best interest. As yet, this inconsistency in policy and practice hasn’t led to any noteworthy cases.

Usually when asked, “What is a ‘good death’?” most people respond, “A peaceful, painless death, preferably at home.” Yet only 20 percent of people die at home, and how many of those deaths are peaceful or painless is debatable. Most people die in hospitals, and, of those, more than in the past are demanding that everything be done to save their lives. The divide between those who believe life of any kind is valuable and those who believe some forms of life aren’t worth living is great, and both sides mistrust the healthcare community to carry out their wishes.

I predict that the more divisive these issues become, the more likely it will be that governmental bodies will leave such decisions up to individuals and their families. Judges who are now squeamish about finding for plaintiffs in wrongful-life cases will do so more frequently, first at the end of life but eventually also at the beginning. The violations found will be trust-

based: a failure of a professional duty to “care,” expressed either through concepts of informed consent or professional responsibility.

### Recent Cases, July 2006 - December 2006

**California.** Pending case. In *Ross v. Raging Wire Telecommunications, Inc.*, the Supreme Court of California agreed to hear a case in which the plaintiff was fired from his job when he began smoking marijuana as part of his medical treatment. The treatment was prescribed by his physician and is legal in California. It is alleged that plaintiff’s doing so while off-duty did not affect his job performance, and that firing him was a violation of the established California body of law that protects disabled workers. *Ross v. Raging Wire Telecommunications, Inc.*, No. S138130 (Cal. 2005).

### Recent Laws and Regulations, July - December 2006

**Federal.** In December 2006, H.R. 6099 failed to pass the House. The bill would have required that a woman seeking an abortion be told that “there is substantial evidence that the process of being killed in an abortion will cause the unborn child pain” and that she has the option of anesthetizing the fetus before the abortion.

### Interesting Developments in Other English Common Law Countries

**England.** The Nuffield Council on Bioethics, in a report published in November 2006, recommended that premature babies born before 22 weeks not be resuscitated regardless of the parents’ wishes. Babies born between 22 and 23 weeks of age should only be treated if the parents insist and the doctor agrees.

## DEFINITION OF DEATH

Twenty years ago, the struggle was still to help the general public, judges, government officials, and some medical professionals understand and accept the concept of “brain death,”

or, more precisely, the concept of death as determined by the complete and irreversible cessation of all the functions of the entire brain. At the time, patients on ventilators or cardiovascular support seemed to be alive because their lungs and hearts were still functioning, albeit with mechanical support. It took time to accustom people to the notion that such patients are really corpses because they have no chance of recovering any brain function.

In recent years, there has been a push to return to more classical criteria for death: irreversible cessation of circulatory and respiratory functions. This movement is driven primarily by transplant physicians who seek to harvest organs while they are most viable. A growing general mistrust in the medical profession and the need for rushed decision making in such situations is once again making people uncomfortable. Now, many feel that a patient isn’t truly dead until the brain stops functioning, even if such cessation is unquestionably going to happen given that the patient’s heart and lungs have already irreversibly stopped. People don’t understand why in one decade they are told that death comes with brain death and in the next decade that it is acceptable to harvest a person’s organs even before brain death because the lungs and heart have stopped functioning. People are asking themselves: Is such organ procurement vivisection? Does a patient with a still-functioning brain sense what is going on? Do such patients feel pain?

These questions need to be addressed and answered to the public’s satisfaction, otherwise their already diminished faith in the medical profession will diminish further.

### Recent Cases, July 2006 - December 2006

**Texas.** *Grotti v. State of Texas*, 2006 Tex. App. Lexis 10018 (17 November 2006). The court overturned a jury verdict that held that a doctor had caused a patient’s death by occluding the patient’s endotracheal tube (ET) after 60 minutes of coding the patient with little success. At the time of the occlusion, the patient’s respiration had slowed to three or four respira-

tions per minute; she had no heart sounds or pulse, but some electrical activity on the monitor. The court found that (1) the evidence contrary to the verdict demonstrates that the patient experienced irreversible cessation of her spontaneous respiratory and circulatory functions prior to 21:50 (the time of the occlusion), and (2) her respiratory efforts between 20:50 and 21:50 were insufficient to maintain life. It is pretty clear, given the facts of this case, that there wouldn't have been a trial if the defendant doctor had simply withdrawn the patient's ET tube, rather than holding her finger over it until the patient stopped moving. (The physician had occluded the ET tube for five minutes.)

#### **Recent Laws and Regulations, July - December 2006**

**New Jersey.** The New Jersey Board of Medical Examiners has published a proposed rule, 17360 NJAC 13:35-6A, entitled "Declarations of Death Upon Neurological Criteria State ID: 38 NJR 2021." The comment period ended 14 July 2006. It is unclear when the final rule will be published.

**Wisconsin.** The Wisconsin Department of Health and Family Services has enacted new rules that were effective on 1 December 2006 that require that a prescribed form be filled out by physicians, technicians, and tissue bank employees. When organs and tissue, other than cardiovascular tissue, are removed from decedents, the form requires details regarding the time and cause of death, the types of organs/tissues requested, and the tests done to determine the appropriateness of transplantation. CR 06-076 (Ref. Wisconsin 20742) (31 October 2006).

#### **OVERSIGHT: PATIENT TRUST**

There is no doubt that we are in a general crisis of trust. In the last 20 years, the public has become more cynical with respect to many social institutions, including government and the healthcare industry. David Shore, founder of the Harvard School of Public Health's Trust Initiative, has been arguing for half a decade

that the healthcare industry needs to make the engendering of trust both internally and with respect to the public a top priority.<sup>4</sup>

In the absence of functional internal mechanisms to reduce clerical and medical error, employee burn-out, and iatrogenic illness, the public will demand governmental intervention. It is my prediction that healthcare organizations will do too little too late, and there will be a drastic increase in governmental regulation of healthcare.

#### **Recent Laws and Regulations, July - December 2006**

**California.** A bill has been introduced in the California Assembly to establish an Office of Patient Advocate in the State Department of Public Health. 2007 Text CA A.B. 52 (4 December 2006); A.B. 52, 2007-2008 Gen. Assem., Reg. Sess. (Ca. 2007).

#### **HIV**

Twenty years ago, HIV was probably the most explosive bioethics topic, but today, while still very important, the issues involved are no longer novel. In addition to the law mentioned below, please look in two sections above, "Medical Testing" and "Unconventional Treatment." There are some cases involving HIV mentioned in those sections as well.

#### **Recent Laws and Regulations, July - December 2006**

**New Jersey.** On 19 December 2006, the governor signed a bill establishing a needle-exchange program in six cities. The bill also provides \$10 million for state drug-treatment programs. P.L. 2006, c.99; N.J.S.A. 26:5c-25 through 26:5c-25.

#### **CONSCIENTIOUS OBJECTIONS (HEALTHCARE PROVIDERS)**

Sometimes in the rush to protect patients' rights, people forget that the rights being protected are individuals' rights; everyone has a

constitutionally protected right to act in accordance with his or her personal moral convictions, even medical professionals. If the right that a patient is exercising requires that someone act to help, then the potential for conflict becomes obvious. In most cases, a healthcare employer can decide, as a condition of employment, whether or not employees will be obligated to perform certain procedures or provide certain information that they might find morally objectionable. The employee can then accept the conditions, renegotiate, or decide to work elsewhere. In situations in which laws have made specific performance mandatory, such as emergency treatment situations, employees and employers have fewer options. If an employer accepts, or the law requires, provisions for medical conscientious objectors, then procedures must be established to accommodate both the objecting medical professional and the patient.

The best way to approach questions of conscientious objections by healthcare professionals is to implement policies for dealing with potential problems before they arrive. Employers and clinical ethics committees need to be aware of the issues involved, educate themselves on their legally permissible options, and then, after creating policies regarding medical conscientious objectors, educate staff regarding those policies.

While several bills on this issue were introduced a year ago or more, none have been introduced or passed within the last six months.

#### NOTES

1. The term "patient," when not referring to a particular patient, is henceforth used to include the patient and any decision maker appointed either by the patient or by operation of law to act for the patient.

2. This website includes the polling results from 11 polls taken between 1 March 2005 and 27 November 2005, <http://www.pollingreport.m>.

3. *Ibid.*, Fox News/Opinion Dynamics Poll, 1-2 March 2005.

4. D. Shore, ed., *The Trust Crisis in Healthcare: Causes, Consequences, and Cures* (New York: Oxford University Press, 2007).