Bioethics in brief

September 2008

SUNY UPSTATE MEDICAL UNIVERSITY • CENTER FOR BIOETHICS AND HUMANITIES SYRACUSE, NEW YORK

ETHICS AND LAW

Dying Patients, the FDA, and the Right to Unproven Drugs

Ms. W has colon cancer and is not expected to live beyond six more months. Treatments used thus far have been ineffective and her disease continues to progress. She has heard about an investigational new drug (IND), but human trials to test the drug's safety (Phase I) have only just begun. In the ordinary course, before the drug becomes available it must also be studied for efficacy (Phase II) and then pass muster for safety, efficacy and its overall benefits and risks in expanded clinical trials (Phase III). Ms. W does not have the luxury of time. She wants to take her chances with the new drug now, but under Food and Drug Administration (FDA) rules drugs that have not been proven safe and effective cannot be sold. So her doctor cannot prescribe it, and she cannot obtain it. FDA rules do establish certain procedures intended to expedite access to experimental drugs for patients with life-threatening illnesses, generally referred to as the "compassionate use" exceptions. The determination is made on a case-by-case basis, and the process has allowed some patients to participate in clinical trials for which they otherwise did not qualify. But many patients, like Ms. W, cannot wait for approval, or are unwilling to risk being in the placebo arm of the study.

TAKING THE FDA TO COURT

The Abigail Alliance for Better Access to Developmental Drugs (Abigail Alliance) is a nonprofit organization committed to removing regulatory obstacles to access to experimental drugs for cancer patients and others with life-threatening illnesses. Founded in 2001, it is named after Abigail Burroughs, who died of head and neck cancer at the age of 21. After trying unsuccessfully for several years to move the FDA to allow easier, earlier access to experimental drugs, Abigail Alliance joined with the Washington Legal Foundation to challenge the FDA regulations in court. The specific rule change would have permitted the marketing of experimental drugs to terminally ill patients following completion of Phase I trials if there were also strong evidence of the drug's efficacy. But the essential basis of the lawsuit was grounded in a far more expansive claim — that there is a constitutional right to life-saving treatment, and that the current FDA regulations violate this fundamental right. The FDA defended its regulations and policies as essential to its mandate to protect the public

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The Costs of Health Insurance

BY THE NUMBERS:

90 million US residents, comprising **1 in 3** people under 65 and including **25 million children**, were uninsured for *at least one month* in 2006-2007.

47 million US residents were uninsured for *all* of 2006.

BAD FOR YOUR HEALTH

It has long been evident that the uninsured and underinsured face poorer health outcomes than patients with private insurance. Uninsured patients are more likely to be diagnosed with cancer in its later stages and are 1.6 times more likely to die within five years than patients with private insurance.

Why do uninsured patients suffer worse outcomes? One cause of these disparities, interestingly, is the lack of health insurance itself. In New York, researchers found that uninsured patients were 18 percent more likely, and Medicaid patients 22 percent more likely, to suffer a burst appendix than those with private insurance. The "most important predictor of perforation" was time to operation. Delays were attributed to "the patient's decision to seek timely medical attention" and "access to both primary and hospital care without cost concerns," both of which are

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CENTER FOR BIOETHICS AND HUMANITIES

Bioethics in Brief is a newsletter of the Center for Bioethics and Humanities.

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Have a question about an ethical issue? We are always happy to talk in confidence about ethical concerns. You may reach us at the Center for Bioethics and Humanities at 315-464-5404. Ethics consultations are available by calling the hospital operator (315-464-5540) and asking for the ethics consultant on call, or by contacting any of the ethics consultants at the Center (Catherine V. Caldicott MD; Robert Daly MD; James Dwyer PhD; Kathy Faber-Langendoen MD; Robert S. Olick JD, PhD; and Joel Potash MD).

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The Center for Bioethics and Humanities at SUNY Upstate Medical University, established through the generous support of the Medical Alumni Association, is committed to promoting clinical health care and health policy which is patient-centered, compassionate, and just. We accomplish this through educational initiatives in bioethics and the medical humanities, clinical ethics consultation, and multidisciplinary research and scholarly writing.

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impacted by a person's insurance status. A ruptured appendix can lead to a longer hospital stay and larger bill, again penalizing the uninsured. The incidence of rupture correlated to a patient's insurance status even after researchers controlled for age, sex, socioeconomic status, and type of hospital.

The American College of Physicians tracked similar evidence in its 2000 report, "No Health Insurance? It's Enough to Make You Sick." In 2002, the Institute of Medicine (IOM) estimated that 18,000 uninsured adults died each year because they do not seek medical care. The Urban Institute updated that number to 22,000 in 2006. The IOM found that approximately 25 percent of adult uninsured diabetics go two years without a doctor's visit, increasing their risk of blindness, amputations, and premature death. A recent study found the health of uninsured near-elderly people, particularly those with cardiovascular disease or diabetes, improved significantly when they acquired Medicare upon turning 65. Unable to pay out of pocket, some of the uninsured have come to rely on emergency rooms, free clinics, and other forms of "charity care."

RANKS OF THE UNINSURED

Of the 47 million uninsured US residents (2006), some could afford to purchase their own insurance and some could qualify for Medicaid if they could manage the paperwork. All of them, however, remain vulnerable to the high cost of illness and lack of access to primary care.

The numbers vary by geographic region and by race. In 2006, Texas had the largest percentage of uninsured (24.1 percent), Minnesota the smallest (8.5 percent). New York ranked toward the middle, with 13.2 percent of its population (2.5 million people) uninsured. Nationwide, one in three Hispanics and one in five African-Americans were uninsured, compared with one in nine non-Hispanic whites and one in seven Asian-Americans.

The extent of uninsurance in the United States, unique among developed countries, stems in part from a deeper pathology: uncontrolled healthcare costs. Not surprisingly, the number of uninsured Americans rises with escalating premiums. Between 2001 and 2007, insurance premiums rose 78 percent while wages rose only 19 percent. Medicaid and other need-based government programs then respond to higher costs by restricting eligibility. Employers allot larger percentages of their benefits packages to health coverage or drop it altogether as the cost of providing family health insurance to one worker rises to the cost of hiring a second.

Many of the insured feel insecure about their coverage and are vulnerable if their employers drop benefits or if their union renegotiates. In addition, people with employer-sponsored health plans aren't protected from debilitating illnesses that could cost them their

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from unsafe pharmaceutical products. One purpose of the rules is to prevent increased harm and premature death from adverse events that may occur if drugs are brought to market before they have been rigorously tested. The FDA argued against a constitutional right of access, and contended that if Abigail Alliance prevailed, this would undermine the agency's mission.

A CONSTITUTIONAL RIGHT TO LIFE-SAVING TREATMENT?

Initially the trial court agreed with the FDA. On appeal a 3-judge panel sided with Abigail Alliance. But the full court of appeals for the District of Columbia agreed with the district court and upheld the FDA's regulations (Abigail Alliance v. Eschenbach, August 7, 2007). The U.S. Supreme Court has declined to review the case.

Abigail Alliance asserted that terminally ill patients have a fundamental, affirmative constitutional right of access to investigational drugs when conventional treatment options are ineffective. As a matter of constitutional law only a "fundamental" constitutional right would trump the clearly legitimate governmental purpose underlying the FDA regulations. The Alliance contended that traditional doctrines that justify reasonable actions in self-preservation and self-defense under dire circumstances of necessity should be understood as a right of those in "mortal peril" to assume perhaps enormous risks to save their own lives. Rejecting this argument, the court noted ironically that a similar position was advanced by the drug industry in opposition to the 1938 Food, Drug and Cosmetic Act that is the foundation of the FDA's authority.

The appeals court also considered whether the U.S. Supreme Court decisions in Cruzan and Glucksberg, both of which concerned the rights of dying patients, support a right to investigational drugs for the terminally ill. In Cruzan (1990) the Court reaffirmed the constitutional right to refuse unwanted bodily interventions, including life-sustaining treatment. In Glucksberg (1997) advocates of physician-assisted dying relied heavily on Cruzan to assert a constitutional right of access to prescription drugs that would allow patients to choose the time and manner of their own deaths. The Supreme Court ruled unanimously that the constitution draws a clear distinction between

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jobs and thus their health insurance. Insurance has not served its purpose if an illness can wipe out family savings. A 2001 survey of 1,771 personal bankruptcy filers found that 76 percent of those who cited medical causes in their bankruptcies had health insurance at the onset of illness.

CONCLUSION

Studies indicate that the insured have better access to health care and better outcomes. The 1986 Emergency Medical Treatment and Active Labor Act guarantees access to emergency services to everyone, but since many health conditions are chronic and require routine attention, millions of people lack medically necessary care. As costs increase, that number is swelling.

—Eli Braun

Update on Pharmaceutical Influence

As noted in our January 2008 issue, industry representatives argue that free samples help poor patients cover the cost of care. Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers of America, wrote in 2006 in a New York Times letter to the editor that free samples "often serve as a safety net" for uninsured and low-income patients. Critics argue that free samples lead doctors to ignore cheaper, equally effective generic drugs.

WHO'S RIGHT?

In 2003, 82 percent of patients who received free samples had health insurance for the entire year, while fewer than a third qualified as low income, according to a new survey of 32,000 people nationwide. Because low-income and uninsured patients were less likely to receive free samples than were high-income and insured patients, the researchers concluded that free samples were more of a marketing tool than a safety net.

—Eli Braun

Source: Cutrona SL, Woolhandler S, Lasser KE, Bor DH, McCormick D, Himmelstein DU. Characteristics of recipients of free prescription drug samples: a nationally representative analysis. Am J Public Health. 2008 Feb;98(2):284-9.

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the right to be left alone and an affirmative right to medical intervention. Like Glucksberg, the Abigail Alliance case asserts a right to obtain medical interventions, not the right to be left alone. The Abigail Alliance court found that the patient's purpose in seeking access, namely to preserve life rather than to end it, does not transform a claim of access into a constitutional right. Indeed, a number of previous decisions from various courts have rejected the view that a right to health care exists under the U.S. Constitution. Rights of access are established by legislation.

DYING PATIENTS AND THE PUBLIC GOOD

In the halls of Congress, whether dying patients should have the right to demand access to unproven, experimental "treatments" raises a series of challenging ethical and policy questions. Some argue that the decision to accept the unknown risks and pursue the speculative benefits of investigational drugs belongs to dying patients in consultation with their physicians; if the courts will not establish needed exceptions, Congress should. Others contend that such exceptions to current safety and efficacy standards would compromise the FDA's ability to protect the public. One purpose of carefully regulated, rigorous drug testing is to protect against misleading marketing and false hopes. Are dying patients especially vulnerable and less able to give informed consent to accepting the largely unknown risks and benefits of experimental drugs outside of clinical trials? Few would dispute that our system for oversight of the development, testing, marketing and use of pharmaceuticals serves the common good. The Access, Compassion, Care, and Ethics for Seriously Ill Patients Act (ACCESS) would establish a right of access to investigational drugs and devices. First introduced in 2005, the bill would create new rules designed to expedite the application, review and approval process for access for patients with serious or life-threatening diseases. Patients, families, and all those who care for seriously ill patients will want to keep a watchful eye on the fate of this initiative.

—Robert S. Olick

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Legislative Watch

Listed below are newly enacted laws and selected pending legislation in New York and at the federal level that concern bioethical issues.

NEWLY ENACTED

Dateline Albany

- Amendments to the Public Health Law make legal recognition of the bright pink Medical Orders for Life-Sustaining Treatment (MOLST) form statewide. (A. 10764/S. 7683) The form has been used under a pilot project in Onondaga and Monroe counties for the past several years.
- Section 4310 of the Public Health Law changes the state organ donor registry from an intent registry to a consent registry, and titles the new registry the New York State Donate Life Consent Registry. The new law makes clear that the patient's decision to donate controls, and family permission is not required.

Inside the Beltway

- The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination on the basis of genetic information with respect to health insurance and employment.

PENDING LEGISLATION

In Albany

- New York law requires two witnesses for the execution of a valid health care proxy document. Senate bill 6695 would reduce the number of witnesses required from two to one, except for persons residing in mental health facilities.

Inside the Beltway

- In the last session the House of Representatives passed by an overwhelming vote a bill to expand protections under the Americans with Disabilities Act (ADA). If enacted the bill (H.R. 6258) would overrule several rulings of the U.S. Supreme Court that have narrowly defined "disability" that qualifies for ADA protection.

— Robert S. Olick