Bioethics Bowl Cases

Bioethics Bowl
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Note: These cases have been culled from various news sources. Information about sources will be provided upon request.

Case #1

The question of how aggressive to be in treating late-stage Alzheimer's patients is one of the most wrenching and contentious issues in medicine. Family members and doctors struggle with decisions about whether to authorize medical treatments for patients whose bodies live on though their minds are gone.

New research has found that Alzheimer's patients at the end of their lives often receive everything that medicine has to offer. A recent study of nursing home patients, by Dr. Susan Mitchell of Harvard and the Hebrew Rehabilitation Home for the Aged, found that those with end-stage Alzheimer's received more aggressive medical treatment—including feeding tubes, intravenous fluids and antibiotics and hospitalizations—than cancer patients at the end of their lives.

But Alzheimer's patients rarely receive the palliative care intended to relieve suffering but not to prolong life that is normal in cancer cases; they make up only 7 percent of people who receive hospice care. The comparison with cancer patients is imperfect because cancer patients often die more quickly, and, unlike Alzheimer's patients, they can speak for themselves about their care.

Some experts and family members argue that intensive treatment in cases of late-stage Alzheimer's patients is inappropriate, even cruel, and that its costs are excessively high. For family members, costs of treatment are rarely an issue, because they are mostly borne by taxpayers; most medical and nursing home care is paid for by Medicare and Medicaid. So, some end-stage Alzheimer's patients get dialysis when their kidneys fail. Infections are treated with intravenous antibiotics. Patients are rushed to hospitals and intensive care units when they fall ill. Putting in a feeding tube can cost about $2,000, said Dr. Douglas Nelson, a geriatrician in Hickory, NC, whose practice mostly consists of nursing home patients. Inserting a tube requires a consultation with a speech therapist to verify that food is entering the lungs and an X-ray by a radiologist that requires swallowing barium. The procedure itself is done in a hospital, with an anesthesiologist, and a gastroenterologist or a general surgeon. A feeding tube can prolong life in a nursing home, which quickly dwarfs the cost of inserting a tube. In North Carolina, Dr. Nelson said, it costs $150 a day on average, not counting medication, to care for a patient in a nursing home. "The economics are horrific," said Dr. Steven DeKosky, director of the Alzheimer's Disease Research Center at the University of Pittsburgh. Dr. Diane E. Meier, a professor of geriatrics and ethics at Mount Sinai School of Medicine in Manhattan, agreed. "We are spending a huge amount of money keeping people with irreversible brain failure alive," she said. "If the technology exists, we feel we must use it. Our colleagues in Europe consider what we do bizarre to the point of disbelief."

But others contend that to withhold treatment is to hasten death, in effect, playing God. "There are people in my field who have legitimate concerns that we might be too eager to pull the plug," said Dr. Christine Cassel, an expert in geriatrics, ethics and end-of-life care, and president and chief executive of the American Board of Internal Medicine. "Just because someone has Alzheimer's disease doesn't mean their life has no value."

With tube feeding and medical treatment for each crisis, end-stage Alzheimer's patients can live on, sometimes for years. Many no longer recognize family members, speak only a word or two, cannot walk or eat, and are prone to pneumonia and repeated urinary tract infections.

"We have this sense that you can only be dying for a decent interval, a few months or so," said Dr. Joanne Lynn, director of the Washington Home Center for Palliative Care Studies. "You can't be dying for years." But that is what many demented patients do, Dr. Lynn said, adding, "They just sort of hang on for remarkable lengths of time."

Family members and doctors must decide what steps to take. But many find themselves at a loss. "People desperately need some guidance," Dr. DeKosky said. "Everyone, including the docs, is saying: 'Tell us what's O.K. Tell us what's appropriate.' "

Case #2

"Breast cancer runs in my family," one woman says. She is followed in quick succession by other young and middle-aged women, who say in turn: "My mother." "My grandmother." "My dad's sisters."

So opens a television commercial that began running in New York and elsewhere in the Northeast this past fall. It urges women to consider being tested for certain genetic mutations that can sharply increase the risk of developing breast or ovarian cancer. The 60-second television commercial runs in New York, Hartford, Boston and Providence, R.I., during shows like "The Oprah Winfrey Show," "Dr. Phil" and "The Today Show." There were also radio advertisements and a cover wrapper on copies of the October 2007 issue of *People* magazine that is delivered to doctors' offices and some beauty salons in the region. The commercial tells women to contact their physicians or to call a toll-free number, which connects them with Myriad. But the only mention of the company is in a brief line of text at the end, identifying the ad as "a service from Myriad Genetics." The campaign's slogan is "Be ready against cancer."

Myriad's test, called BRCAnalysis, detects mutations in genes called BRCA1 and BRCA2. Women with a clinically significant mutation in one of those genes have a 35 to 84 percent probability of developing breast cancer by age 70 and a 10 to 50 percent probability of developing ovarian cancer, far higher than for women in general. Women with the mutations can reduce their risk of cancer by taking certain cancer-prevention drugs or having their breasts or ovaries removed. They can also be screened more frequently for early detection. But mutations in the genes account for less than 10 percent of all cases of breast cancer. And only 1 in about 400 women has the mutation. (The risk of a mutation is about 10 times as high for women who are Ashkenazi Jews, but they can be tested for three specific mutations, for a cost of $460.)

The campaign comes at a time when government officials and some health specialists are expressing concern over the direct sales and advertising of genetic tests, some of them of dubious validity, to the public.

Myriad's test is, by all accounts, valid, and the company requires a physician to order it. But one medium through which it is being advertised, television, has raised questions about whether genetic tests will one day be marketed to consumers as vigorously as pharmaceuticals are today. Critics say that advertising such a complex screening test to the general population might create unnecessary anxiety among women and lead to overuse of the test, which costs $3,120. "It really preys on the fears of our society, and one of those fears is getting breast cancer," said Ellen T. Matloff, director of cancer genetic counseling at the Yale Cancer Center. The Connecticut attorney general, Richard Blumenthal, said his office had issued a subpoena for information from the company. "We've determined that there's enough serious and significant doubt about the accuracy of some of their claims that we feel a strong need to investigate," he said in an interview.

Myriad, which said it would cooperate with Mr. Blumenthal's request, defends the commercial and other elements of what it calls a public awareness campaign. The company says that while its test has been given to about 200,000 women since 1996, only 3 percent of the women believed to harbor the harmful mutations that can be detected by the test have been identified so far. Therefore, the company says, there is a need for much more extensive testing. "What we are doing is raising public awareness so they will have a conversation with their health care providers," said Dr. Gregory C. Critchfield, president of Myriad's genetic testing business. "Those individuals, if they are tested and identified, can avail themselves of means to reduce the risk of cancer."

Another question is whether there are enough trained genetic counselors, specialists who advise on genetic tests, to cope with a surge in demand that could follow the commercials. And another is whether doctors, who might now be asked about testing, have enough expertise to discuss the procedure. Doctors "are going to get caught between the ad and the patient," said Luba Djurdjinovic, executive director of the Ferre Institute in Binghamton, N.Y., a community genetics practice that works with doctors' offices.

Myriad ran the same commercial in a five-month test in Denver and Atlanta in late 2002 and early 2003. The company said there were 38 times as many calls to its toll-free number in those cities as in control

cities. The number of tests being performed also rose in Denver and Atlanta, by about 30 percent compared with other cities. Studies at the time by outside parties found that testing or referral to genetic counselors increased, but not always for the women most likely to benefit. And a survey by the Centers for Disease Control and Prevention found that many doctors in the pilot cities had an incorrect or incomplete understanding of the genetics involved. Dr. Critchfield said Myriad waited nearly five years to start the new campaign to give more time for health care providers to learn to handle genetic testing. “We are in a far different place today than we were then,” he said.

Case #3

This past year saw contentious debates in many state legislatures about whether or not to require girls to be vaccinated against Human Papillomavirus (HPV), which causes virtually all cases of cervical cancer and genital warts. This flurry of state activity stems from the June 2006 recommendation by the national Advisory Committee on Immunization Practices (ACIP) that routine vaccination is recommended for girls between ages 11 and 12. In 2007, at least 24 states and D.C. introduced legislation to specifically mandate the HPV vaccine for school. On February 2, 2007, Texas became the first state to enact a mandate—by executive order from the governor, Rick Perry—that all females, with some exceptions, entering the sixth grade receive the vaccine. Legislators in Texas passed a bill to override the executive order and the governor withheld his veto.

According to the Centers for Disease Control and Prevention (CDC), HPV infects approximately 20 million people in the United States with 6.2 million new cases each year. There is no treatment for HPV, only treatment for related health problems. There are more than 30 strains of HPV that affect at least half of sexually active people in their lifetime. Most strains of HPV do not produce any symptoms and disappear on their own.

Cervical cancer is the second leading cancer killer of women worldwide. In the United States, nearly 10,000 women are diagnosed with cervical cancer each year and 3,700 women die. This number is much smaller than in other countries largely because of the Papanicolaou (Pap) test, a screening tool for cervical cancer. The American Cancer Society reports that, with early detection, cervical cancer is usually treatable.

Currently, the only HPV vaccine approved by the federal Food and Drug Administration (FDA) is Merck's Gardasil, which protects against HPV strains 6, 11, 16 and 18. Almost 70 percent of cervical cancer cases and 90 percent of genital warts cases are linked to these four strains of HPV. The Advisory Committee on Immunization Practices (ACIP) recommends administering the vaccine to girls between 11 and 12 years of age, before they become sexually active. GlaxoSmithKline also has developed a vaccine (Cervarix) to target HPV strains 16 and 18 and is awaiting FDA approval.

Even after recommendations by the ACIP, school vaccination requirements are decided mostly by state legislatures. Some state legislatures have granted regulatory bodies such as the Health Department the power to require vaccines, but they still need the legislature to provide funding.

The debate in states has centered, in part, around school vaccine requirements, which are determined by individual states. Some people who support availability of the vaccine do not support a school mandate, citing concerns about the drug's cost, safety, and parents' rights to refuse. Still others may have moral objections related to a vaccine mandate for a sexually transmitted disease. Financing is another concern: if states make the vaccine mandatory, they must also address funding issues, including for Medicaid and SCHIP coverage and youth who are uninsured, and whether to require coverage by insurance plans. This has caused some to push for further discussion and debate about whether or not to require the vaccine.

Case #4

A recent article in the journal *Fertility and Sterility* offers a fascinating glimpse into how far some parents will go to ensure that their children share their characteristics and culture—by intentionally choosing "malfunctioning" genes that produce disabilities like deafness or dwarfism.

The article reviews the use of preimplantation genetic diagnosis, or P.G.D., a process in which embryos are created in a test tube and their DNA is analyzed before being transferred to a woman's uterus. In this manner, embryos destined to have, for example, cystic fibrosis or Huntington's disease can be excluded, and only healthy embryos implanted.

Yet Susannah A. Baruch and colleagues at the Genetics and Public Policy Center at Johns Hopkins University recently surveyed 190 American P.G.D. clinics, and found that 3 percent reported having intentionally used P.G.D. "to select an embryo for the presence of a disability." In other words, some parents had the painful and expensive fertility procedure for the express purpose of having children with a "defective" gene. It turns out that some mothers and fathers don't view certain genetic conditions as disabilities but as a way to enter into a rich, shared culture.

In 2002, *The Washington Post Magazine* profiled Candace A. McCullough and Sharon M. Duchesneau, a lesbian and deaf couple from Maryland who both attended Gallaudet University and set out to have a deaf child by intentionally soliciting a deaf sperm donor. "A hearing baby would be a blessing," Ms. Duchesneau was quoted as saying. "A deaf baby would be a special blessing." Born five years ago on Thanksgiving Day, the couple's son, Gauvin, was mostly deaf, and his parents chose to withhold any hearing aids.

It's tempting to see this practice as an alarming trend; for example, the online magazine *Slate* called it "the deliberate crippling of children."

But others defend the practice, arguing that controlling a child's genetic makeup, even to preserve what some would consider a disease, is simply the latest tactic of parents in an increasingly globalized society where identity seems besieged and in need of aggressive preservation. Traditionally, cultures were perpetuated through assortative mating, with intermarriage among the like-minded and the like-appearing. Modern technology has been adopted for this purpose; for example, a quick Web search reveals specialized dating services for almost any religious or ethnic subgroup. Viewed in this context, the use of P.G.D. to select for deafness may be merely another ritual to ensure that one's children carry on a cultural bloodline.

Moreover, parents today increasingly use medical procedures to alter healthy bodies. In 2003, for example, the FDA granted approval to Eli Lilly to market human growth hormone for "idiopathic short stature," or below-average height in children—to make them taller, purely for social reasons. Theoretically, almost a half million American boys qualify for treatment. Why, some argue, should choosing short stature be different?

Still, most providers of P.G.D. find such requests unacceptable. Dr. Robert J. Stillman of the Shady Grove Fertility Center in Rockville, Md., has denied requests to use the process for selecting deafness and dwarfism. "In general, one of the prime dictates of parenting is to make a better world for our children," he said in an interview. "Dwarfism and deafness are not the norm." Dr. Yury Verlinsky of the Reproductive Genetics Institute in Chicago, who also refuses these requests, said, "If we make a diagnostic tool, the purpose is to avoid disease." But both doctors said they would not oppose sending families to other doctors who might consent.

Case #5

Ritu Sodhi, a furniture importer from Los Angeles who was born in India, spent $200,000 trying to get pregnant through in-vitro fertilization, and was considering spending another $80,000 to hire a surrogate mother in the United States. "We were so desperate," she said. "It was emotionally and financially exhausting." Then, on the Internet, Sodhi found Dr. Nayna Patel's clinic in Anand, India.

The small clinic at Kaival Hospital matches infertile couples the United States, Taiwan, Britain and beyond with local women, cares for the women during pregnancy and delivery, and counsels them afterward. Anand's surrogate mothers, pioneers in the growing field of outsourced pregnancies, have given birth to roughly 40 babies.

The surrogate mothers and the parents sign a contract that promises the couple will cover all medical expenses in addition to the woman's payment, and the surrogate mother will hand over the baby after birth. The couples fly to Anand for the in-vitro fertilization and again for the birth. Most couples end up paying the clinic less than $10,000 for the entire procedure, including fertilization, the fee to the mother and medical expenses

Young women in Anand are flocking to the clinic to sign up to be surrogates. Suman Dodia, a pregnant 26-year-old, said she will buy a house with the $4,500 she receives from the British couple whose child she's carrying. It would have taken her 15 years to earn that on her maid's monthly salary of $25.

But the program raises a host of uncomfortable questions that touch on morals and modern science, exploitation and globalization, and that most natural of desires: to have a family.

Dr. Patel defends her work as meaningful for everyone involved. "There is this one woman who desperately needs a baby and cannot have her own child without the help of a surrogate. And at the other end there is this woman who badly wants to help her [own] family," Patel said. "If this female wants to help the other one ... why not allow that? ... It's not for any bad cause. They're helping one another to have a new life in this world."

Experts say commercial surrogacy—or what has been called "wombs for rent"—is growing in India. While no reliable numbers track such pregnancies nationwide, doctors work with surrogates in virtually every major city. Commercial surrogacy has been legal in India since 2002, as it is in many other countries, including the United States. But India is the leader in making it a viable industry rather than a rare fertility treatment. Experts say it could take off for the same reasons outsourcing in other industries has been successful: a wide labor pool working for relatively low rates. The industry is not regulated by the Indian government.

Critics say the couples are exploiting poor women in India—a country with an alarmingly high maternal death rate—by hiring them at a cut-rate cost to undergo the hardship, pain and risks of labor. "It raises the factor of baby farms in developing countries," said Dr. John Lantos of the Center for Practical Bioethics in Kansas City, Mo. "It comes down to questions of voluntariness and risk."

Patel's surrogates are aware of the risks because they've watched others go through them. Many of the mothers know one another, or are even related. Three sisters have all borne strangers' children, and their sister-in-law is pregnant with a second surrogate baby. Nearly half the babies have been born to foreign couples while the rest have gone to Indians.

But if commercial surrogacy keeps growing, some fear it could change from a medical necessity for infertile women to a convenience for the rich. "You can picture the wealthy couples of the West deciding that pregnancy is just not worth the trouble anymore and the whole industry will be farmed out," said Lantos. Or, Lantos said, competition among clinics could lead to compromised safety measures and "the clinic across the street offers it for 20 percent less and one in Bangladesh undercuts that and pretty soon conditions get bad."

After spending about $20,000—more than many couples because it took the surrogate mother several cycles to conceive—Sodhi and her husband are now back home with their baby, Neel. They plan to return to Anand for a second child.

Case #6

“Extremely premature infants are the nightmare of every neonatal hospital and obstetrician,” writes Art Caplan, Director of The Bioethics Center at Pennsylvania University. “Medicine does not know how to save them and when it tries, it often produces a child whose life is very short and whose suffering is beyond description.”

In late 2006, the Nuffield Council on Bioethics, an independent body charged with examining moral issues that arise from medical advances, issued guidelines to help doctors and parents make difficult decisions about the care of extremely premature infants. The Council, whose reports are very influential in Britain, concluded that premature babies born before 22 weeks gestation should not be given treatment to prolong their lives. Its view is that since only 1 percent of infants born between 22 and 23 weeks of age survive long enough to leave the hospital, starting aggressive treatment on babies born at 22 weeks or younger is wrong. “Natural instincts are to try to save all babies, even if the baby’s chances of survival are low,” said Professor Margaret Brazier who chaired the committee that produced the report. “However, we don’t think it is always right to put a baby through the stress and pain of invasive treatment if the baby is unlikely to get better and death is inevitable.”

The Council stressed that active euthanasia of newborn babies should not be allowed. Active euthanasia would allow doctors to hasten the end of a brief, pain-filled life by, for instance, using morphine, if the parents agreed. The Dutch are considering permitting active euthanasia for babies, and some doctors in the Netherlands openly admit to having killed very sick children. Baby euthanasia has also been debated in Belgium.

The “Baby Doe Law”—a federal law governing support for child abuse and neglect programs—mandates that all infants born in the United States receive medical care, regardless of the wishes of the parents, unless the baby is irreversibly comatose or the treatment would be futile. Concerns about a child's quality of life, which are often the primary factors in deciding to withhold medical treatment from premature infants, are not seen as valid reasons for withholding medical care. This law is intended to protect the rights of the disabled. For many years children born with Down syndrome or spina bifida were not given aggressive treatment if their parents did not want it or if doctors deemed it inappropriate. But in the early 1980s, the Reagan administration and the famous Surgeon General C. Everett Koop protested these practices, resulting in the passing of the law that stopped discrimination against the disabled in the neonatal nursery.

Case #7

Dr. Daniel Gunther and Dr. Douglas Diekema first revealed details of "The Ashley Case" in an article published in the *Archives of Pediatric and Adolescent Medicine* (Oct 2006).

Ashley is a brain-damaged girl whose parents feared that as she got bigger, it would be much harder to care for her; so they set out to keep her small. Through high-dose estrogen treatment over two years, her growth plates were closed and her prospective height reduced by about 13 inches, to 4'5". "Ashley's smaller and lighter size," her parents write on their blog "makes it more possible to include her in the typical family life and activities that provide her with needed comfort, closeness, security and love: meal time, car trips, touch, snuggles, etc." They stress that the treatment's goal was "to improve our daughter's quality of life and not to convenience her caregivers."

But the treatment went further: doctors removed her uterus to prevent potential discomfort from menstrual cramps or pregnancy in the event of rape; and also her breast tissue, because of a family history of cancer and fibrocystic disease. Not having breasts would also make the harness straps that hold her upright more comfortable. "Ashley has no need for developed breasts since she will not breast feed," her parents argue, "and their presence would only be a source of discomfort to her."

The parents say that the decision to proceed with "The Ashley Treatment" was not a hard one for them, but the same cannot be said for the doctors. "This was something people hadn't thought about being a possibility, much less being done," says Diekema, who chairs the bioethics committee of the American Academy of Pediatrics and was brought in to consult on this case. For the ethics committee of Seattle Children's Hospital, which reviewed the proposed treatment, "it took time to get past the initial response—'wow, this is bizarre'— and think seriously about the reasons for the parents' request," says Diekema. The ethics committee essentially did a cost-benefit analysis and concluded that the rewards outweighed the risks. Keeping Ashley smaller and more portable, the doctors argue, has medical as well as emotional benefits: more movement means better circulation, digestion and muscle condition, and fewer sores and infections. "If you're going to be against this," Gunther says, "you have to argue why the benefits are not worth pursuing."

Case #8

In his recent book *Oath Betrayed: Military Medicine and the War on Terror*, Dr. Stephen Miles, professor of medicine and bioethics at the University of Minnesota, documents how many members of the military medical profession have compromised the Hippocratic Oath in the name of military duty. The book is based on 35,000 pages of government documents obtained under the Freedom of Information Act

One of former Defense Secretary Donald Rumsfeld's first instructions for military interrogations outside the Geneva Conventions was that military doctors should be involved in monitoring "special methods of interrogation." Rumsfeld ordered that a prisoner's medical information could be provided to interrogators to help guide them to the prisoner's "emotional and physical strengths and weaknesses" in the interrogation process. At an interrogation center called Camp Na'ma, where the unofficial motto was "No blood, no foul," one intelligence officer testified that "every harsh interrogation was approved by the [commander] and the Medical prior to its execution." Doctors, in other words, essentially signed off on "special interrogations"—which some regard as a euphemism for torture—in advance. And they often didn't inspect the victims afterward. At Abu Ghraib, according to the Army's surgeon general, only 15% of inmates were examined for injuries after interrogation.

At Guantánamo, Major General Geoffrey Miller, under Rumsfeld's policy, approved the creation of a Behavioral Science Consultation Team (BSCT, pronounced biscuit). Psychiatrists and psychologists on the team at Guantánamo prepared psychological profiles of the prisoners whose personal health information they had access to for use by interrogators. They also sat in on some interrogations, observed others from behind one-way mirrors, and offered feedback to interrogators. According to Miles, "The BSCT doctors suggested . . . how to break the prisoners down. . . . [One] approach aimed at a prisoner's personal vulnerabilities, his worst fears, for example."

In one of the few actual logs of a high-level interrogation, that of Mohammed al-Qhatani, doctors were present during the long process of constant sleep deprivation over 55 days, and they induced hypothermia and the use of threatening dogs, among other techniques. According to Miles, medics had to administer three bags of medical saline to Qhatani — while he was strapped to a chair — and aggressively treat him for hypothermia in the hospital. They then returned him to his interrogators. Elsewhere in Guantánamo, one prisoner had a gunshot wound that was left to fester during three days of interrogation before treatment, and two others were denied antibiotics for wounds. In Iraq, according to the Army surgeon general as reported by Miles, "an anesthesiologist repeatedly dropped a 2-lb. bag of intravenous fluid on a patient; a nurse deliberately delayed giving pain medication, and medical staff fed pork to Muslim patients." Doctors were also tasked at Abu Ghraib with "Dietary Manip (monitored by med)," in other words, using someone's food intake to weaken or manipulate them.

Of the 136 documented deaths of prisoners in detention, Miles found, medical death certificates were often not issued until months or even years after the actual deaths. One prisoner's corpse at Camp Cropper was kept for two weeks before his family or criminal investigators were notified. The body was then left at a local hospital with a certificate attributing death to "sudden brainstem compression." The hospital's own autopsy found that the man had died of a massive blow to the head. Another certificate claimed a 63-year-old prisoner had died of "cardiovascular disease and a buildup of fluid around his heart." According to Miles, no mention was made that the old man had been stripped naked, doused in cold water and kept outside in 40^0 cold for three days before cardiac arrest.

Case #9

An investigation conducted by the Associated Press in 2005 found that Government-funded researchers tested AIDS drugs on hundreds of HIV-positive foster children over two decades, often without providing them a basic protection afforded in federal law and required by some states. The research funded by the National Institutes of Health spanned the country. It was most widespread in the 1990s as foster care agencies sought treatments for their HIV-infected children that weren't yet available in the marketplace.

The practice ensured that foster children—mostly poor or minority—received care from world-class researchers at government expense, slowing their rate of death and extending their lives. But it also exposed a vulnerable population to the risks of medical research and drugs that were known to have serious side effects in adults and for which the safety for children was unknown.

The research was conducted in at least seven states—Illinois, Louisiana, Maryland, New York, North Carolina, Colorado and Texas—and involved more than four dozen different studies. The foster children ranged from infants to late teens, according to interviews and government records.

Many studies that enlisted foster children involved early Phase I and Phase II research—the riskiest—to determine side effects and safe dosages so children could begin taking adult "cocktails," the powerful drug combinations that suppress AIDS but can cause bad reactions like rashes and organ damage. Some of those drugs were approved ultimately for children, such as stavudine and zidovudine. Other medicines were not.

Several studies that enlisted foster children reported patients suffered side effects such as rashes, vomiting and sharp drops in infection-fighting blood cells as they tested antiretroviral drugs to suppress AIDS or other medicines to treat secondary infections. In one study, researchers reported a "disturbing" higher death rate among children who took higher doses of a drug. That study was unable to determine a safe and effective dosage.

The government provided special protections for child wards in 1983. They required researchers and their oversight boards to appoint independent advocates for any foster child enrolled in a narrow class of studies that involved greater than minimal risk and lacked the promise of direct benefit. Some foster agencies required the protection regardless of risks and benefits. Advocates must be independent of the foster care and research agencies, have some understanding of medical issues and "act in the best interests of the child" for the entirety of the research, the law states.

However, researchers and foster agencies told AP that foster children in AIDS drug trials often weren't given such advocates even though research institutions many times promised to do so to gain access to the children. Illinois officials believe none of their nearly 200 foster children in AIDS studies got independent monitors even though researchers signed a document guaranteeing "the appointment of an advocate for each individual ward participating in the respective medical research." New York City officials could find records showing 142 — less than a third — of the 465 foster children in AIDS drug trials got such monitors even though city policy required them. Likewise, research facilities including Chicago's Children's Memorial Hospital and Johns Hopkins University in Baltimore said they concluded they didn't provide advocates for foster kids.

Researchers typically secured permission to enroll foster children through city or state agencies. And they frequently exempted themselves from appointing advocates by concluding the research carried minimal risk and the child would directly benefit because the drugs had already been tried in adults. "Our position is that advocates weren't needed," said Marilyn Castaldi, spokeswoman for Columbia Presbyterian Medical Center in New York.

If they decline to appoint advocates under the federal law, researchers and their oversight boards must conclude that the experimental treatment affords the same or better risk-benefit possibilities than alternate treatments already in the marketplace. They also must abide by any additional protections required by state and local authorities.

Arthur Caplan, head of medical ethics at the University of Pennsylvania, said advocates should have been appointed for all foster children because researchers felt the pressure of a medical crisis and knew there was great uncertainty as to how children would react to AIDS medications that were often toxic for adults. “It is exactly that set of circumstances that made it absolutely mandatory to get those kids those advocates,” Caplan said. “It is inexcusable that they wouldn’t have an advocate for each one of those children. When you have the most vulnerable subjects imaginable — kids without parents — you really do have to come in with someone independent, who doesn’t have a dog in this fight,” he said.

Those who made the decisions say the research gave foster kids access to drugs they otherwise couldn’t get. They defend the decision to enlist foster children en masse, saying there was a crisis in the early 1990s and research provided the best treatment possibilities. And they say they protected the children’s interest by carefully explaining risks and benefits to state guardians, foster parents and the children themselves. “I understand the ethical dilemma surrounding the introduction of foster children into trials,” said Dr. Mark Kline, a pediatric AIDS expert at Baylor College of Medicine. He enrolled some Texas foster kids in his studies, and doesn’t recall appointing advocates for them. “To say as a group that foster children should be excluded from clinical trials would have meant excluding these children from the best available therapies at the time,” he said. “From an ethical perspective, I never thought that was a stand I could take.”

Case #10

Starchild Abraham Cherrix's case has spurred debate on whether the government should get involved in family medical decisions. It also led to a state law named after him that gives Virginia teenagers and their parents the right to refuse doctor-recommended treatments for life-threatening ailments.

Abraham Cherrix was diagnosed in 2005 with Hodgkin's disease, a lymphatic cancer. He went through an initial round of chemotherapy at a hospital in Norfolk, VA. But when the cancer resurfaced in early 2006, the 16 year old Cherrix refused the recommended second round of chemotherapy. He instead started drinking an herbal mix from a Mexican clinic. The tonic, called the Hoxsey method, was initiated by Harry Hoxsey, a former Texas cancer clinic operator who was accused by the Food and Drug Administration of peddling worthless medicine—and who died of cancer. The tonic is banned from sale in the United States, and The American Cancer Society says there is no proof that it works.

"I should have the right to tell someone what I want to do with this body," Cherrix told *USA Today*. "I studied. I did research. I came to this conclusion that the chemotherapy was not the route I wanted to take." Abraham's father, Jay Cherrix, said, "When Abraham mentioned that he didn't want to take radiation and that he wanted to try alternative treatments, I tested him and questioned him to make sure that was what he really wanted to do. I researched it myself and saw that there were other options."

Had Abraham been two years older, the decision would be his alone, and no court could challenge his choice, no matter how medically unorthodox. But because he was a minor, social services authorities intervened. His parents were taken to court for medical neglect by the Accomack County Department of Social Services, and a juvenile court judge gave social services joint custody of Abraham and ordered him to report to the hospital to begin chemotherapy. Abraham's parents immediately appealed this decision, and in August 2006, Cherrix's attorneys and social services officials reached an agreement to allow the teen to forgo chemotherapy in favor of alternative therapies. Abraham has since been treated by Dr. Arnold Smith, a radiation oncologist who combines conventional treatment with a more innovative "immunotherapy"—medicines and supplements, including a form of Vitamin C, that Smith says bolster the immune system. Tests have shown Abraham's tumors have shrunk, but his lymph nodes are swollen, which could indicate active cancer cells.

Art Caplan, director of the Center for Bioethics at the University of Pennsylvania, doubts that the immunotherapy has value. But he said Cherrix's seemingly improved health shows the state was right to intervene. "While Cherrix is not getting the complete medical treatment that his original doctor wanted, the radiation means he's getting most of it. He'd probably be dead by now if they [state officials] did not react," Caplan said.

In March 2007, Virginia Gov. Timothy M. Kaine signed a bill dubbed "Abraham's Law," giving parents and children more leeway in refusing medical treatment. The law permits parents or legal caregivers to refuse medical treatment for a child if they and the child are in agreement, if the child is at least 14 years old and mature, if they've considered other options, and if they think their decision is in the child's best interest. The measure "strikes the appropriate balance between the rights of parents and a mature child to make informed medical decisions, and the responsibility of the state to protect the health and safety of children," Kaine said in a prepared statement.

Abraham said he hopes the law will keep other families from going through what his endured. "I think it's a great thing," he said. "This is like the apex achievement of all I've gone through." He said he hopes other states will follow suit. Opponents of the law say it may allow parents to make decisions that could endanger children's lives.

Case #11

One of the most intriguing processes in medicine is the placebo effect: the healing power of a sham therapy, when it's offered to patients with the suggestion that it will help. Neuroscientists have even observed where and how the placebo effect may work in the brain. In one recent study by University of Michigan researchers, participants who were told they would receive painkillers showed increased production of endorphins — the brain's natural pain reliever — even though they got no analgesic at all. It makes sense. Most people can attest that the mere expectation of relief can somehow prompt the body to respond. What most people don't know, however, is that doctors occasionally prescribe placebos to their patients in regular practice.

In a study published in the *Journal of General Internal Medicine*, a student-and-professor team at the University of Chicago surveyed 466 faculty physicians at Chicago-area medical schools. Almost half of the 231 respondents (45%) said they had prescribed placebos in regular clinical practice and, of those, just over half had prescribed them in the previous year. Among the reasons the doctors gave: to calm a patient down, to respond to demands for medication that the doctor felt was unnecessary, or simply to do something after all other clinical treatment options had failed.

Most prescribing doctors felt they were doing the right thing. Of all the physicians surveyed — whether or not they had prescribed placebos — 96% believed that dummy pills could have real therapeutic effects. But does that make it acceptable to administer them? If placebos work by manipulating a patient's expectations, then prescribing them suggests that doctors are deliberately deceiving their patients. That undermines one of the key principles of Western medical ethics: informed consent. Most patients believe they have the right to know — and in most cases to refuse — the treatments that doctors recommend.

Doctors seem aware of this quandary. Twelve percent of survey participants said they thought placebos should be banned completely from regular clinical practice. Among the doctors who prescribed them, one in five said they outright lied to patients by claiming a placebo was medication. But more commonly, the physicians came up with creative ways to explain, saying the substance might help but wouldn't hurt, or that "this may help you but I'm not sure how it works."

For its part, the American Medical Association (AMA), the largest association of U.S. doctors and medical students, tells its members that "[p]hysicians may use placebos for diagnosis or treatment only if the patient is informed of and agrees to its use."

But wouldn't disclosure drain the power from a placebo? Not necessarily, according to the AMA. Once physicians have been given general permission to use placebos, the AMA's guidelines say, they don't need identify to their patients which treatments are true medical interventions and which are not: "In this way the physician respects the patient's autonomy and fosters a trusting relationship, while the patient still may benefit from the placebo effect."