Human Guinea Pigs

By: Lisa Collier Cool
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Since "health care" has become a multibillion-dollar business, over-eager, greedy, and sometimes even unscrupulous researchers are experimenting on thousands of Americans, many of whom do not know what their own bodies are being used for. "Animals have more rights than people do," says one expert.

When a researcher showed up at Viola Hughes's door about ten years ago wanting to recruit her ten-month old daughter, Erick, for a medical study, the Baltimore mom—like millions of Americans who take part in clinical trials each year – assumed tat the experiment would be safe and well supervised. After all, it was being conducted by the renowned Kennedy Krieger Institute, an affiliate of Johns Hopkins University. The project sounded harmless enough: All Hughes had to do was fill out occasional questionnaires, let researchers collect dust from her home, and permit them to test her baby's blood periodically. Enticed by the prospect of receiving several $5 to $15 payments—plus food coupons, T-shirts, and other trinkets—for participating in the study, she signed a consent form stating that "lead poisoning in children is a problem in Baltimore." The form went on to say that "your house is going to receive special repairs . . . to reduce exposure to lead in paint and dust."

What Hughes—and more than a hundred other low-income, predominantly African-American families from Baltimore who were also recruited—didn't know was that the kids would be used as guinea pigs in a study so shocking that the Maryland Court of Appeals later compared it to both Nazi experiments at Buchenwald and the notorious 40-year-long Tuskegee study in which poor black men were allowed to die of untreated syphilis. In August 2001 the court accused KKI of deliberately encouraging inner-city landlords to rent lead-contaminated buildings to families with children under age four—the group most vulnerable to lead poisoning, since little kids often put paint chips or house dust in their mouths. Yet the consent form never mentioned the terrible risks of this toxin: stunted growth, nervous-system damage, impaired hearing, mental retardation, even death.

Nor did it reveal the true purpose of the research, the court charged, which was to determine the cheapest method of lead removal: KKI arranged for each building to receive some form of cleanup, either minimal maintenance costing $1,650 or less, a better repair job for $3,500, or more extensive rehabilitation for $6,000 to $7,000. A fourth group of buildings, including Hughes's, received no improvements at all—despite the promise of "special repairs" on her consent form—because they had previously undergone "complete" abatement. Doctors then gauged how well each method worked by measuring how much lead built up in previously healthy kids' blood over a two-year period—a plan that horrified the judges, who contended that the researchers essentially used the children as "canaries in the mines."

A dust sample collected on the first day of the study, March 9, 1993, revealed dangerous "hot spots" of lead residue in Hughe's supposedly decontaminated home. Rather than warn the young mother right away, KKI sat on the findings for more than nine months—with tragic results, says Hughes's lawyer Kenneth Strong, a specialist in lead paint litigation. "At the start

of the study, Erick's lead level was nine, which is normal. Six months later, it was 32, which is extremely high. Arguably, the reason for the delay was [that] if families left these buildings, there would be not study." Despite studies showing that levels above 24 raise the risk of mental retardation, the researchers didn't sound much of an alarm, Strong contends. "Instead of saying, "Your child is lead-poisoned and you should move immediately,' they simply sent a letter with the blood-test result and suggested that Ericka be seen by a pediatrician."

Although Viola Hughes did move in 1994 (after she finally learned the truth), when her daughter started kindergarten a few years later, Strong says, she struggled in school. "Ericka was evaluated at the University of Maryland and found to have considerable problems, including attention deficits, impulsivity, and difficulty learning." Due to these impairments, which, Strong days, her doctors linked to lead exposure, Ericka has had to repeat second grade. Sometimes Ericka comes home from school crying and asking if she's stupid." In the midst of this heartbreaking situation, Ericka's mother was dealt yet another blow: In July 2000 her lawsuit against the research center was dismissed. "Kennedy Krieger filed a motion argument that it didn't have a legal duty to protect children in the study from harm," Strong explains. A lower court agreed, only to have its decision reversed a year later, when the Maryland Court of Appeals ruled that Hughes's case could go forward.

Possibly prompted by the court's blistering condemnation of the experiment, the government launched an investigation on August 24, 2001—nearly a decade after the disastrous study began. On the same date, KKI issued a press release promising cooperation with the prove, then added that kids in the study were "provided with a much improved environment compared to lead levels found within surrounding housing and the risk of lead poisoning was reduced for each and every child." (The Hopkins affiliate was less forthcoming with *Penthouse*, repeatedly promising comment but never providing any.)

This isn't the only horror story at Johns Hopkins—widely considered America's most respected research center. In July 2001 the feds suspended thousands of human experiments being conducted at the university, following the death of a healthy 24-year-old. After inhaling a non-FDA-approved chemical during an asthma study, Ellen Roche's lungs were so shredded that they looked like ground glass in a CAT scan taken shortly before her death. Yet an investigation by the Office for Human Research Protections, a government agency that oversees the safety of participants in federally funded research, concluded that Johns Hopkins "failed to obtain sufficient information regarding the source, purity, quality, and method of preparation and delivery" of the chemicals. "Readily available" data liking this chemical to lung toxicity, the OHRP says, can be found by conducting a routine search of medical literature.

But where are the watchdogs before people get hurt or killed? "When it comes to protection from zealous researchers, animals have more rights than people do," says Vera Hassner Sharav, president of the Alliance for Human Research Protection, a New York City advocacy group. "All the rats, dogs, and monkeys are carefully counted, and the number of studies conducted and outcomes for each animal are reported annually to Congress. Any pain or suffering an experiment causes has to be scientifically justified, and animal labs are inspected every six months. If violations are found, researchers can face big fines or the loss of their license. None of this is true for human studies." Indeed, no government body tracts the number

of people who participate in medical research or how many studies go on each year. Nor does anyone know how many volunteers are harmed or killed.

Bioethicist Adil Shamoo, Ph.D., has been digging for answers. The University of Maryland—Baltimore professor, cofounder of Citizens for Responsible Care and Research, used the Freedom of Information Act to obtain OHRP records listing 386 adverse research incidents—including eight deaths—in studies between 1990 and 2000. He found compelling proof that these numbers are ludicrously low. After headlines about 18-year-old Jesse Gelsinger's 1999 death put gene-therapy trials under the microscope, regulators were suddenly deluged with belated reports of earlier calamities, including at lease six previously unreported deaths attributed to gene treatments, as well as cases of dangerous drops in blood pressure, clotting problems, fevers, even paralysis. During the first four months of 2000 alone, the OHRP was notified of 970 such mishaps, says Shamoo. "That's more than double the number of problems reported for all U.S. studies in the previous ten years. Obviously, many researchers ignore federal law, which requires immediate reporting of any unanticipated risks to human subjects."

Scientists have a lot of scary secrets, Shamoo adds. After reviewing reams of government documents, he estimates that about seven million Americans serve as study subjects each year. "Many just fill out a survey, but two to three million receive drugs . . . or other potentially risky treatments," the professor reports. "Based on the complication rate for FDA clinical trials of two percent to six percent, there must be tens of thousands of serious adverse events—and thousands of unexplained deaths—during research that are never reported or investigated. It's a massive failure of a system in which oversight is almost nonexistent." Although at least 60,000 studies are in progress, the OHRP has only six compliance officials to monitor them—up from just three a few years ago. And these exhausted staffers are already juggling 163 open investigations. With so much else to do, it's no wonder that the agency has only managed to inspect about 30 research facilities since 1993. The FDA has a somewhat better track record: In 2000 its auditors conducted almost 800 inspections, though this covered just two percent of the estimated 35,000 study sites in this country.

Both agencies leave almost all policing to local boards set up at hospitals and universities under federal rules from the 1970s—a system even the government admits desperately needs reform. Known as institutional review boards (IRBs), these panels of doctors, scientists, and community members are supposed to protect patients by overseeing proposed and ongoing experiments. But a recent report by the Office of the Inspector General finds dangerous deficiencies: "IRBs review too much too quickly, with too little expertise." Because the boom in research has upped the average IRB's workload nearly 50 percent over the past five years, a single board sometimes watches over as many as 2,000 studies. To avoid drowning in paperwork, panelists may spend as little as two minutes evaluated proposals before approving them—and even less time monitoring research already in progress. One harried reviewer has a chilling shortcut: He told the OIG that all he does is check for deaths. If an experiment hasn't killed anyone, that's good enough for him. He rushed on the to next review.

Disturbing few board members ask questions about the studies they supervise. That's because many of them lack the scientific knowledge to evaluate today's increasingly arcane research, the OIG says. Others have another motive not to delve too deeply: potential conflicts

of interest. Typically all but one or two reviewers are employees of the institution whose research they oversee. "That's like having baseball umpires who are paid by Shea Stadium," says Sheldon Krimsky, Ph.D., professor of family medicine and community health at Tufts Medical School. "Even if they are honest and well-trained, these people still have a vested interest in having the home team win. There's a lot of money in getting trials done, so the institution puts pressure to get projects approved." At large universities, research can bring in $100 million or more a year.

Clinical-trial participants, however, are often left in the dark about institutional conflicts of interest that could impact their care. Doctors at the University of Texas M.D. Anderson Cancer Center enrolled 195 seriously ill patients in a study without telling them that the hospital's president, John Mendelsohn, had a huge financial stake in the experimental drug they'd volunteered to test. The study involved Erbitux, once hailed as a miracle cure and now at the heart of a scandal over stock sales by insiders at ImClone, its manufacturer. The stock's prince tanked following news that the FDA had nixed ImClone's application for fast-track approval of the drug, saying its studies were so flawed that it was impossible to tell if the treatment was of any value.

Mendelsohn, show invented Erbitux and has served on ImClone's board of directors, made $6 million by selling 90,000 shares of the company a month before its stock meltdown last December. He's said to own many more shares, which have now lost most of their value. The year 2001 was apparently a very bad one for the doctor, who also was a board member at Enron Corporation before the Houston energy-trading company went bankrupt. Mendelsohn hasn't been accused of any impropriety in connection with either collapse, but issued a public apology in July of this year for not having disclosed his stake in Erbitux to people who participated in its clinical trial, which spanned 1997 to 2001. M.D. Anderson now has a policy of informing patients if its president or the institute itself has a financial interest in any treatment being tested.

If financial interest prompted a truly bizarre study at Loma Linda University in California, the university itself vigorously denies it. In what's believed to be a medical first, consenting adults are actually being paid to down daily doses of a water pollutant. Lured by fees of $1,000 each, some 100 volunteers have enrolled in a six-month study of the health effects of perchlorate, a rocket-fuel ingredient that's known to disrupt thyroid function. (In fact it was once used as a treatment for thyroid disorders, but is no longer FDA-approved.) The real shocker, however, is who is paying for the $1.75 million study: embattled aerospace firm Lockheed Martin, which has been hit with hundreds of lawsuits for allegedly contaminating groundwater in parts of California with this very chemical. Barry Taylor, Ph.D., vice-chancellor for research affairs at LLU, defends the research: "Our IRB had vigorous discussions and decided there were important scientific reasons to do the study. This agent was used therapeutically for over 20 years at doses of 200 to 1,200 milligrams, while people in the study are only getting 0.5 to three milligrams." Still, that's 83 times higher than the level that California deems safe for drinking water.

A number of scientists have gone a few steps further—by paying volunteers to ingest pesticides in studies financed by chemical manufacturers. Such research disgusts Herb Needleman, M.D., member of an advisory committee of the Environmental Protection Agency

and professor of pediatrics and psychiatry at the University of Pittsburgh School of Medicine. "It offends human decency," he says. "There's absolutely no justification for giving humans poisons to test its effects—that's why we have animal studies." Although Needleman and another doctor made similar arguments to the EPA in June 2000—urging a ban on human tests of pesticides—the rest of the committee decided that such studies are acceptable, "subject to limitations ranging from 'rigorous' to 'severe.'"

Lucrative research grants aren't the only way to profit from human experiments, note Needleman. "It's not unusual for researchers and universities to own stock in companies that hold the patent on a drug or device they're investigating. Plenty of people have already gotten rich this way—and even more hope to cash in on a future medical breakthrough. This pursuit of fame and fortune is a very important issue today: It's creating ethical conflicts that poison the well and pervert judgment."

Eighty-six-year-old Harry Rogers was not worried about such matters when he developed vision problems in 1995. The ex-athlete from Homosassa, Florida, who had raced against the legendary Jesse Owens as a youth and remained an avid golfer, swimmer, and tennis player, just wanted the best possible care. He'd already lost one eye when a previous cornea transplant went horrible awry, triggering such a massive hemorrhage that his eye had to be removed. After his other eye started giving him trouble, he turned to a different doctor, James Rowsey, M.D., then chair of the department of ophthalmology at the University of south Florida in Tampa. "When he said I needed a cornea transplant, I assumed he knew what he was talking about," says Rogers. Still, the patient found the surgical arrangements a bit odd. "He had me come to the hospital on a Saturday and did the procedure in a secondary operating room instead of the main OR."

Rogers, who played tennis the day before his surgery, woke up with badly blurred vision. "Dr. Rowsey kept telling me how beautiful the transplant looked, and I'd say, 'But, Doctor, I can't see.' He just walked off. It's been downhill ever since," Rogers reports. "The world looks like a blotter with ink all over it, just random shapes going in all kinds of crazy ways. I've become blind: Even finding my way to the bathroom is quite an adventure, and sometimes I walk into a wall. I have to guard against breaking a hip, because then it's over." Until 2000, Rogers thought he'd gotten standard surgery.

If it weren't for Rowsey's born-again-Christian beliefs, however, these experiments might never have been exposed. A year before Rogers's operation, the surgeon told colleagues that a marvelous idea for a cornea-transplant tool had come to him through prayer. Called the "Tampa trephine," the device was a cookie-cutter-like instrument used to harvest corneas from deceased donors for transplantation. Unlike standard trephines, which remove a circular tissue sample, the new tool created petal-shaped tabs intended to reduce the number of stitches needed during surgery and speed up healing. The enterprising eye doctor then secured $750,000 in federal grants to test the trephine on cats, but decided to try it out on humans as well—without telling them that he was using an unapproved invention from which he hoped to profit.

Doctors in his department who later sued—charging that Rowsey forced them to pray at faculty meetings, deluged them with religious tracts, and discriminated against employees who

didn't share his evangelical faith—began taking a hard look at what the eye surgeon was up to. One colleague made a disturbing discovery. "I saw one of Dr. Rowsey's patients at Tampa General Hospital, a little Mexican boy maybe two or three years old," says this doctor. "One of his eyes had been give a conventional transplant and the other had been done with the Tampa trephine. I felt this was a clinical trial to compare the two methods, because there just wasn't any other reason why anyone would operate this way." The doctor alerted the hospital—and ultimately got the American Academy of Ophthalmology to investigate.

Rowsey had told the hospital's institutional review board that his operation was simply an improvement of accepted techniques. Therefore, he claimed, there was no need for such burdensome details as IRB oversight, informed-consent documents, reporting of complications, or a research protocol. he also predicted that the patented trephine would bring in up to $112 million in licensing fees over the next five years. This 1995 pitch was apparently quite persuasive, since the IRB at the university—which had a 50 percent interest in these rights—agreed that the surgeon was merely providing "standard therapy" not requiring its approval. In September 2000, however, the Office for Human Research Protections concluded that Rowsey—who had resigned from USF the previous year after the school barred him from research—had indeed experimented on at least 60 patients between 1995 and 1998, exposing them to "unknown risks and uncertain efficacy" without their knowledge. The university was ordered to inform these individuals that they had been unwitting research subjects. Four people, including Rogers and a 14-year-old girl who was left with severely impaired vision in one eye after a transplant by Rowsey—are now suing.

USF has totally revamped its review process, says spokesman Michael Head. "We've worked very hard on this issue, and the Office of Human Research Protection now considers us a model patient-safety program." (Roswey did not respond to request for comment.)

More gruesome still were the innovations of another surgeon, David Taylor Schwartz. Like Rowsey, this practitioner looked good on paper. The former Reston, Virginia, Urologist had degrees from Harvard and Columbia, had trained at top New York City hospitals, and had received a National Institutes of Health research fellowship. All this made him sound like the perfect physician to treat a penis disorder—or so Stanley F. Williams thought. In 1995 the then-46-year-old airplane mechanic from West Virginia consulted Schwartz about impotence triggered by Peyronie's disease, a painful condition that strikes about one percent of men, most of them middle-aged. For as yet unknown reasons, the penis develops lumpy scars that cause it to become crooked, making sex difficult or impossible. Schwartz suggested a solution: surgery to remove scars and implantation of a penile prosthesis.

The six-and-a-half hour operation turned into a man's worst nightmare, asserts Williams's lawyer, Benjamin Glass III of Fairfax, Virginia. During the surgery the urologist decided to do some creative cutting: an experimental penis-lengthening procedure to which Williams had not consented. This involved slicing along the shaft of the penis, then repairing the wounds with Gore-Tex patches. That wasn't all the doctor did, Glass says: "He then [implanted] a prosthesis that was too big, which cut off the blood supply to the end of the penis. Almost from the get-go, Stanley got an infection and the implant popped out." Schwartz did a second operation to reinsert the prosthesis, but the results were even gorier. Not only did the

device poke through again, the lawyer reports, but this time "the tip of the penis turned dark, dusky blue, and eventually necrotic. The tissue started to die. Stanley went to a urologist in West Virginia who took one look and said, 'Oh my God!'"

Williams was then referred to a specialist, who gave him the grimmest possible news: Part of his penis was dead and would have to be amputated. After removing the organ, the doctor fashioned a replacement using a flap of skin from the mechanic's forearm, Glass says. "It doesn't work like the real thing.

Painful experiments in animal labs have to be scientifically justified. This is not the case for human studies.

This poor guy has to self-catheterize to urinate and has no feeling in the area." Williams sued and won a $3.97 million verdict, later reduced to $1 million—the maximum allowable under Virginia law. Schwartz, who carried no malpractice insurance, promptly declared bankruptcy but ultimately settled the case for a smaller sum, according to Glass.

It turns out that the urologist has botched at least 14 cases between 1989 and 2000, according to Virginia's Board of Medicine, which finally got around to suspending Schwartz's license in November 2000. And in August 2001 the 64-year old Schwartz was accused of treating 65 patients without a license, performing bladder scans, blood tests, and other procedures. He even submitted several claims to health-insurance companies for reimbursement. Understandably, prosecutors took a dim view of this and charged Schwartz with four felony counts of practicing without a license. As part of a plea bargain, Schwartz did not admit guilt but was sentenced to four years in prison, will all but the first four months suspended. (Schwartz, who was in jail as of this writing, could not be reached for comment.)

The fact that a knife-happy surgeon like Schwartz could experiment on patients highlights a dangerous gap in research oversight: Unlike new drugs or medical devices, which must be tested in clinical trials and approved by the FDA before being put into public use, there's no such requirement for experimental surgery. Instead, doctors who devise a new operation are free to grab a scalpel and try it out on people, says Alan Milstein, a Pennsauken, New Jersey, plaintiff lawyer specializing in research-related litigation. "That leaves patients unprotected and extremely vulnerable to a doctor's quest for fame, recognition, and in some cases, money. If the surgeon is doing the operation to test a hypothesis, technically that's research and a protocol should be submitted to an IRB, but that almost never happens. Institutions don't realize they should have the same standards for surgery as they do for drugs and medical instruments."

Nor does IRB review and an approved protocol always ensure patient protection, Jeff Teel of Tulsa, Oklahoma, thought that getting advanced-stage melanoma—the most deadly form of skin cancer—at age 28 was the worst thing that could happen to him. It wasn't. After a baseball chunk of his forearm and several cancerous lymph nodes were removed in 1998, the auto-parts sales manager says he was told his best chance of survival was a melanoma vaccine trial at the University of Oklahoma Health Science in Tulsa. "Dr. [J. Michael] McGee really sold the vaccine as a cure, and said he'd had very promising results," says Teel. "I thought it

was a godsend." For two years, Teel endured a series of injections that, he says, gave him raging fevers. "It was like the worst flue you've ever had. I'd get the chills so bad that my wife had to lie on top of me, under three or four blankets, to try to warm me up. Every 30 minutes I'd run to the bathroom to throw up. I'd dread going back for the next shot, but I had to because I wanted to live.

In April 2000 he got a troubling letter from Dr. McGee. "It said the vaccine had run out because of the overwhelming demand and funds had run out too. We felt there was something fishy about this." There was. In reality, the trial had been halted after an alarmed nurse blew the whistle on shocking safety lapses. The school called in consultants who found that the vaccine was being manufactured under such hazardous conditions that they advised all remaining lots be either destroyed or labeled "For research use only—not for use in humans." Not only had the shots varied in content from batch to batch, but they hadn't even been tested for bacterial or viral contamination that could pose a grave threat to already ill cancer patients. What's more, the lab workers who prepared the material had little training—and even less supervision—concluded the consultants, who cited "an egregious lack of control."

An OHRP probe uncovered still more violations. First, the experimental vaccine had been administered to nearly 100 people—more than double the number authorized by the school's IRB. Some subjects were allowed to self-inject, violating the protocol, which required a nurse to give the shots and to monitor volunteers for adverse reactions. Nor was there any system to report serious side effects, even though 26 participants died. (A review by outside experts later concluded that the deaths weren't linked to the vaccine.)

Teel is furious—and frightened. "I put my life in the hands of a doctor and trusted that he'd live up to his oath. But he didn't. If I'd known what I know now, I'd have gone with the proven treatments: chemotherapy and radiation. Weird things are happening. I keep getting a rash on my scalp and forehead. If I get a cut or burn myself on the stove, it takes a really long time to heal—which wasn't true in the past. Any time I notice something odd, I worry. It's always hanging over me, because I just don't know what could happen five years from now."

Since then, the university has drastically overhauled its research. Not only did the four people most closely associated with the vaccine fiasco—including McGee—lose their jobs, but the Tulsa IRB that approved the trial was disbanded. Says Gary Raskob, Ph.D., associate vice-president for clinical research at the Oklahoma center, "We've been very busy over the past year with a number of positive changes to go with our first priority of protecting patients in clinical trials." These measures include having the school's IRB accredited by an outside agency, unannounced spot checks on trials, and a no-fault hot line for staff to report violations. (McKee did not return calls for comment.)

Teel sued McGee, the university, and the company that sponsored the trial. So did 18 other former participants, relatives, or estates of those who died in the study. Their class action, filed in January 2001, is believed to be the first to include IRB members. This approach has drawn fire from scientists, who contend that the possibility of costly lawsuits will scare people off from serving on review boards. "I've been accused of destroying research," says Alan Milstein, who handled the case. "But why is it okay to sue researchers who screw up, but not the

watchdogs who are supposed to keep this from happening? People think the IRBs are watching the doctors, the OHRP is watching the IRBs, the Department of Health and Human Services is watching the OHRP, and the FDA is watching the HHS. The truth is that nobody is watching for wayward experiments until after someone gets hurt."

The university has now settled the class-action case for an undisclosed sum, says Milstein. The lawsuit, however, is proceeding against several named doctors in state court, while a federal court has dismissed a parallel case filed in that venue.

Chris Addicott, a 32-yearl-old attorney, can definitely sympathize. Until recently, he believed his mother had simply lost a desperate gamble when she died in a 1993 experiment. After all, 48-year-old Kathryn Hamilton had such advanced breast cancer, doctors predicted that, at most, she had only a year or two left to live with conventional treatment. Facing such dire odds, she searched for an alternative—and found a trial called Protocol 681 at the famed Fred Hutchinson Cancer Research Center (known as "the Hutch") in Seattle, Washington. Addicott found the consent form and protocol puzzling. "I was confused," he says, "because there was a lot of medical jargon and I initially didn't understand the point of the experiment. I didn't get why they wanted to give her such a dangerously high dose of chemotherapy—more than the amount that had killed a woman in an earlier study. I asked one of the doctors, but he brushed off my questions."

This scenario sounds all too familiar to Abbey Meyers, president of the national Organization for Rare Disorders in New Fairfield, Connecticut. During the seven years she worked at the National Institutes of Health, she reviewed hundreds of consent forms. "So many of them were appalling. Non only were they full of scientific gobblegook the average person can't understand, but a lot of them didn't tell the truth. Documents for phase I trials [toxicity tests of a new therapy] are supposed to say that you can't expect to gain personally, because this research is just for the benefit of science and hopefully will help others in the future. Instead," she says, "I saw many forms that read, 'We hope this treatment will cure you.' I'd say we had to do something about these dreadful documents, and the others said we couldn't because it was all up to the IRBs. At times I'd pound the table and say we can and we should—or there's going to be a terrible tragedy.

After poring over the protocol some more, Chris Addicott figured out the plan. Although his mom would be getting a potentially lethal dose of chemotherapy, she'd also be given two other drugs—Cipro and one called PTX—that were supposed to act as antidotes. "We realized this was very risky," the young lawyer says, "because if the rescue drugs didn't work, she wasn't going to survive. We were extremely upset and my sister was crying." Forty-four days into the trial, the family was weeping again—at Kathryn Hamilton's gruesome death. "Within the same 24 hours, her heart, liver, and kidneys all failed. She turned green from infections and had blood in her eyes."

Two years ago, by complete chance, Addicott learned there was a lot about Protocol 681 that he never knew. While he was at law school in1999, one of his professors got a call from a *Seattle Times* reporter who was investigating patient deaths in a leukemia experiment at the Hutch and wanted comment on legal issues. The professor put the writer in touch with Addicott.

The result was an exposé published in the Seattle daily in 2001, accusing the research center of atrocious misconduct—accusations that the Hutch vigorously denies.

According to the newspaper, and a lawsuit filed by Hamilton's family, Hutch doctors had evidence that PTX, one of the "rescue drugs" begin given to the desperately ill woman, didn't work, and actually submitted an article to that effect six days after she died. The article was published in the medical journal *Blood* later that year. More crucially, Kathryn Hamilton had not been told that the rescue drugs would not be available intravenously; the consent form she signed said exactly the opposite in three different places. Another woman in the study had died following high-dose chemotherapy before Hamilton signed up, but that wasn't mentioned in the consent form. The Hutch continued the experiment, the newspaper reported, and two more women died from "regimen-related toxicity" (RRT)—meaning the chemo, not the cancer, killed them. And the Hutch stood to profit from the success of the "rescue drugs" being tested, something else Hamilton wasn't informed of. Addicott says, "she wouldn't have gone ahead. It would have been suicidal."

When *Penthouse* asked the Hutch for comment, the research center castigated the *Seattle Times* news stories. *Penthouse* was informed that "it is absolutely false to say that the Center's physicians knew that Ms. Hamilton could not tolerate the dose level of chemotherapy that was given," and that the first victim had not suffered from RRT, but had died of "other causes." "Approximately 30 women," the hospital wrote in a letter to *Penthouse*, "had been treated without any fatal RRT, including several at the same dose level. Accordingly, [Hamilton's] death was neither expected nor predictable." In his letter and in its formal response to the lawsuit, the Hutch further argued that the studies indicating that PTX was not effective were not definitive or conclusive as to Hamilton's case, because, among other reasons, they dealt with only PTX alone, and not in combination with other drugs. And the Hutch claims that its patents on the drugs being tested, which it had licenses out, had "no commercial value" and that no doctor with any financial interest in the drugs had "played a role in Ms. Hamilton's care." A federal judge disagreed, ruling in July that had Hamilton known the IV drug wasn't available, she "would not have signed up for the treatment which ultimately killed her." He also concluded that the Hutch had given her "false and misleading" information on how many patients had died in the experiment, and rejected a motion by the cancer hospital asking that the estate's lawsuit be dismissed. The case is set for trial later this year.

Despite the Hutch's assertion that the *Seattle Times* reports "contained a number of substantive inaccuracies" and were "demonstrably untrue and misleading," the articles won a prestigious 31st Annual Public Service Award from the Associated Press Managing Editors last year. More important, the *Seattle Times* exposé, described by the APME as "one of the most chilling and important that [we] have ever seen in some time," almost certainly resulted in the Office for Human Research Protections opening an investigation of the Hutch in July 2001—eight years after Hamilton's death. In a press conference shortly after the *Seattle Times* stories broke, the president and director of the clinical-research division of the Hutch denied any wrongdoing (except for one error, discussed below), and stated that the accusations were "blatantly false." According to the report in the *Seattle Times*, while stressing that "the doctors could not have benefited from a successful clinical trial," the president of the Hutch defended

"the marriage of for-profit business and medical research." In response to *Penthouse's* queries, a spokeswoman for the Hutch says that "the OHRP investigation has had no bearing on our oversight practices. We updated our IRB policies and procedures about four years ago, with the assistance of an expert consultant."

The one mistake the Hutch admitted to in the news conference involved the statement in the consent form that said Hamilton would get the antidote drugs by IV—the only form she could tolerate because of her history of severe vomiting during previous rounds of chemotherapy. But PTX wasn't actually available to the Hutch in this form. Instead, she got pills—and promptly threw them up. The spokeswoman then argued that this "misunderstanding" didn't matter, since the drug "did not prove to be useful whatsoever."

Such cynicism outrages the Alliance for Human Research Protection's Vera Sharav: "This woman was fighting for her life, and based her decision to enter a very-high-stakes trial on a lie. She risked everything because she believed these doctors had a magic cure—and died in excruciating agony when she was poisoned by megadoses of chemotherapy. I want to know why this experiment wasn't stopped immediately. It's very troubling that the law puts no limits on what doctors can do, as long as some IRB signs off on the protocol. But just how many humans should researchers be allowed to sacrifice because trusting patients signed a consent form? People think that because these guys are doctors, they promised to do no harm. Apparently, that doesn't apply to medical research."