A family's quest for answers
Dateline NBC Sept. 20, 2002
After their son died as part of a medical experiment, his family struggles with the honesty and ethics of medical research in America.

What makes a parent proud? A good report card? A home run in Little League? How about seeing your child hold a door open for a senior citizen with an arm full of groceries? The teen-ager in this story gave his parents reason to be proud by doing something most of us would consider extraordinary. He volunteered for a medical experiment - one of the 80,000 clinical trials conducted each year in this country. He didn't do it out of desperation. He wasn't terminally ill. He did it to help doctors find a cure for others. But what happened left his family feeling betrayed by the very doctors they all thought they could trust. Stone Phillips reports.

"It was a good feeling that he could give. And that's where he was coming from; that he was going to be able to help others.

But, for Jesse, life had never been easy.

"Jesse battled for his life his whole life long and his father has brought him thru it every time," says Pattie Gelsinger.

They're divorced, now, but Jesse's mother, Pattie, says his father has been at Jesse's side ever since the first medical emergency at age two.

"Jesse went to sleep," says Paul Gelsinger. "And we could not wake him back up."

Jesse had lapsed into a coma and doctors at the University of Pennsylvania diagnosed a rare, but

Like he said: ‘Help the babies."
— MICKIE GELSINGER

serious, genetic problem.

An article about him in the “New England Journal of Medicine” explained that: because of a defective gene, Jesse had trouble producing one of the enzymes we need to help filter out waste.

Without it, dangerous chemicals — like ammonia — could accumulate in his blood and poison his brain, causing confusion, coma, and possibly, even death.

“So this kid had a very rare disorder that was life threatening,” says Paul.

In fact, many babies born with the same genetic problem die

within weeks. Jesse had survived. But the doctors warned — to stay healthy and keep growing, he would need a special diet and a massive regimen of drugs for the rest of his life.

“It was all based on body weight, and the bigger he got, the more pills he had to take,” says Paul. “By the time he was 15, 16, he was up to 54 pills a day.

Fifty-four a day?

“Yes, that’s a lot of pills,” says Paul. “And these were not small pills.”

“He’d say it’s a meal in itself.

So, he didn't want eat after that," says his step-mother, Mickie.

She says simple pleasures like a hamburger were off-limits for Jesse. Eating the wrong foods or skipping his pills could have disastrous consequences.

And if there was ever any doubt about that, it was erased in December 1998, mid-way thru Jesse's senior year at this high school in Tucson, Arizona.

That Christmas, his family discovered that Jesse, frustrated with the daily mountain of pills, had stopped taking some of his medication.

"He was excited to participate," says Paul. "It became a focal point — the focal point — in his life."
— PAUL GELSINGER

"I found him on his couch and he looked at me and said, 'I can't stop vomiting, and I can't hold anything down. And I'm really scared,'" says Paul.

They rushed Jesse to the hospital.

"And he started tremors," says Paul. "We had never seen this before."

"Oh, we were holding him and he had been shaking," says Mickie. "He had been shaking. And then, all of a sudden, one of his breaths, he just stopped."

"This kid wasn't breathing," says Paul.

"He stopped breathing, just

like that," says Mickie.

How scared were they?

"I thought he had died," says Paul. "For five minutes, I thought my son was dead."

But the episode that took him so close to death would lead to a major break-through. Doctors were able to revive Jesse And switch him to a new, more effective kind of medicine. Almost overnight, his entire life seemed to change.

"This kid had never had normal ammonia levels in his life," says Paul. "And now they were the same as you and I."

Paul Gelsinger

"It was joyous," says Mickie.

Paul says, "This kid popped out of it. He came out of the coma and wanted to eat. I said: 'You want to eat?'"

And he did start eating?

"Oh yes," says Mickie.

"He started eating," says Paul. "This kid put on 40 pounds in four months."

"You can see it in the pictures?

"Oh, yes," says Paul.

Mickie says, "And he was eating anything and everything. And he was enjoying it."

He was back on track, and

doing as well as ever?

"Better," says Mickie.

"Better than ever," agrees Paul.

His friends noticed the change, too. In a matter of months, jesse went from just 97-pounds to nearly 140.

"This kid was getting on a plane, going across the country for the first time by himself. He was going to hail a cab at the airport when he got to Philly to take him to the hospital. It took guts. And he

Dr. James Wilson of the University of Pennsylvania was on the front lines of medical science — a field called "gene therapy".

For years, scientists have believed that harnessing the power of genes is the golden ring of medicine. That's because defective genes may be the cause of all kinds of illnesses. If doctors can find a way to replace faulty genes with healthy ones, it could bring cures for everything from heart disease to cancer and add years to our lives.

And no one has been more hopeful than Dr. James Wilson.

"There's no doubt in my mind that gene therapy will have a tremendous impact," Dr. Wilson said when he spoke to NBC News in an interview in 1993.

Back then, Dr. Wilson's team was making headlines by giving a woman copies of a gene her body was missing. In effect, re-writing

was going of get sick, you know. I was very proud of him."
— PAUL GELSINGER

part of her genetic code — an achievement so remarkable, a fellow scientist called it: “The Kitty Hawk of gene therapy.”

Dr. Wilson went on to be elected President of the American Society of Gene Therapy — the leader in his field. Dr. Wilson’s break-through was based on a fascinating concept. He wondered: Could you take a common cold virus called an adenovirus and modify it by inserting a human gene, then use the virus to deliver a cure rather than a cold?

If the idea worked, Dr. Wilson and his team thought they could save the babies who were dying from the same genetic problem Jesse had and eventually cure dozens of other illnesses, as well.

They needed volunteers and they weren’t easy to find. But his family says Jesse jumped at the opportunity.

“He was excited to participate,” says Paul. “It became a focal point, the focal point, in his life.”

But no parent would want their child to volunteer for a medical experiment without understanding the risks. That’s why the Gelsingers had traveled to Philadelphia to meet face-to-face

with the doctors before Jesse signed up.

Dr. Wilson, the scientist in charge, didn't deal directly with patients, so the Gelsingers talked with other doctors on his team.

What did they say about the possible risks involved with receiving the adenovirus?

"There was no great risk there," says Paul. "That they hadn't seen any really bad side effects. That there was just flu-like symptoms is all Jesse would experience with this. The way they described it, this thing looked so safe. Jesse was going to get the flu."

And Paul Gelsinger says the doctors were already talking about the encouraging results they were seeing.

"It was indicated to me that a patient prior to Jesse had shown a 50 percent increase in her ability to excrete ammonia following gene therapy," he says.

Fifty percent?

"A fifty percent increase," says Paul.

WHAT WERE THE RISKS?

The doctors made it clear those remarkable results would not last. A cure was still years away.

And they warned that there were some risks:

- a one-day surgery to administer the virus.

- a stay in the hospital to monitor those flu-like symptoms.

- and, later, a biopsy to confirm the gene had been delivered.

But for Jesse, the teenager who never seemed to give up in those playful wrestling matches, another trip to the hospital seemed like a small sacrifice to help in what could be an enormous medical break-through.

And there's one other reason the Gelsingers felt confident when Jesse signed up: Dr. Wilson's plan had been approved by the federal government which has rules to protect patients and ensure safety in medical experiments.

"My last words were 'I love you son,'" says Paul. "And he gave it right back to me,''I love you,

What's more, this one was being conducted at the University of Pennsylvania's prestigious "Institute for Human Gene Therapy.

"They're experts," says Mickie. "These are the experts."

And surely they were telling the Gelsingers everything they needed to know?

"I thought so," says Paul and Mickie.

too, Dad.'"
— PAUL GELSINGER

Paul Gelisinger says he thought the riskiest part of the experiment sounded like the biopsy surgery at the end.

That's when he planned to take time off from his job as a Tucson handyman to be with Jesse.

So, early one September morning, a proud father drove his 18-year-old son to the airport.

"This kid was getting on a plane, going across the country for the first time by himself," says Paul. "He was going to hail a cab at the airport when he got to Philly to take him to the hospital. It took guts. And he was going of get sick, you know. I was very proud of him."

The experiment started on a Monday morning at a hospital at the University of Pennsylvania.

COMPLICATIONS

Jesse had surgery to insert the genetically-engineered virus. By Monday night, he was on the phone, telling his family back in Arizona that things seemed to be going as planned.

"It was a brief phone call," says Paul. "Very brief, five minutes, max."

So when the Gelsingers went

to bed that night how did they feel things were going?

"Under control," says Mickie.

"My last words were 'I love you son,'" says Paul. "And he gave it right back to me, 'I love you, too, Dad.'"

The next day, a phone call from one of the Penn doctors, saying: There was an unexpected complication involving Jesse's all-important blood ammonia level.

"He told me that Jesse's ammonia level was elevating," says Paul. "That he was going in and out of coherency."

"He told me that Jesse's ammonia had doubled. That they were very, very seriously concerned he was going into a coma. And I said, 'Oh, man, I'm on an airplane, I'll be there as

It was something the doctors thought they could control. But Jesse wasn't responding as well as they'd hoped.

And within hours, things were getting much worse.

"He told me that Jesse's ammonia had doubled," says Paul. "That they were very, very seriously concerned he was going into a coma. And I said, 'Oh, man, I'm on an airplane, I'll be there as soon as I can.'"

Paul Gelsinger would arrive the next morning and hear a warning about his son he could hardly believe.

Three months after graduating from high school, Jesse Gelsinger

soon as I can.'"
— PAUL GELSINGER

had volunteered for a medical experiment that could lead to a revolutionary breakthrough in gene therapy.

He knew it wouldn't cure him, but it might help save other children who suffered from the same genetic illness he'd been fighting his entire life.

"It's about as pure as it gets," says Paul. "This kid was doing the right thing."

But something was going terribly wrong. Instead of the flu-like symptoms, he'd been warned about, Jesse had suddenly lapsed into coma. Doctors said it was totally unexpected in an experiment that had been going well.

Now, this father was flying across the country to be at his son's side.

"I was awake all night on that airline," he says.

SERIOUS QUESTIONS

But there was something Paul Gelsinger says he didn't know and wasn't told. Years earlier, a scientist just a few miles away from the Gelsinger's home in Tucson had raised serious questions about whether the experiment was safe.

"Such huge amounts of virus are being given. I mean fantasticall y more than would ever be produced in our body from an infection, triggering all sorts of inflammat ory responses, etc., have a potential toxicity."

— DR. ROBERT ERICKSON

Gene researcher, University of Arizona

“That’s right, yes,” says Erickson. “I came in very concerned.”

On the other hand, Erickson says Dr. Wilson’s team assured the government reviewers: the experiment would be closely monitored for safety, the doses for people would be much lower than the monkeys got, and volunteers would be fully informed of the risks.

So despite his reservations, Dr. Erickson ultimately joined others on the government panel in approving the experiment — confident, above all, that it was being supervised by a scientist with an impeccable reputation — Dr. James Wilson.

Careful?

“Careful,” says Erickson.

Methodical?

“Methodical,” says Erickson. “Really good basic science.”

He’s one of the stars in this field?

“Yes,” says Erickson. “On the physician side of things, I would say Jim is the best.”

The trouble is, Paul Gelsinger says, Dr. Wilson's team had never told him that anyone had ever raised questions about safety.

"No, I had no idea that that had occurred," says Paul.

He says he didn't know when Jesse had signed up, and he still didn't know as he rushed to be with his son.

By the time Paul Gelsinger's red-eye flight to Philadelphia arrived Wednesday morning, the doctors said the poisonous ammonia in Jesse's blood had soared even higher. He was sicker now than he had ever been.

"He was in a coma," says Paul. "He was hyperventilating. I called Mickie, I was crying. I told her this kid was in big trouble."

IMMUNE SYSTEM IN TROUBLE

It had been just 48-hours since Jesse Gelsinger had been given the experimental virus, and, now, it seemed as if his entire body was reacting to the invasion. Jesse's immune system was in over-drive — the kind of reaction Dr. Erickson had feared, only much worse.

One by one, key organs were failing, and, then, from one of the

doctors — a warning Paul Gelsinger could hardly believe: His boy, who had spent so many years successfully battling his illness, might not survive the experiment.

"I said, 'Whoa, Whoa. What are you telling me?'" says Paul. "He's saying 10 percent chance of survival. I said, 'What? Don't you have an artificial lung or something you can use to help this kid, you know, to save him.' And he said, 'You know, there's a unit. We'll need to get a specialist here.' And I said, well, let's do it."

As doctors struggled to keep Jesse alive, a hurricane was bearing down on the east coast. Mickie Gelsinger was racing across the country, her plane landing just minutes before the hurricane closed the airport. She was praying this was just another crisis they would pull through.

"In my heart, it was just another trip, another big scare. Another 'damn it, we did it again, you did it again, now let's go home,'" she says.

By the time she joined Paul at the hospital Thursday morning, Jesse was on a dialysis machine to filter his blood and an external lung to breathe for him. But no

machine could stop the chain reaction the virus had triggered.

"This immune reaction was going on that was unbelievable," says Paul. "When we finally got to see Jesse in the early afternoon, he was unrecognizable. He had swollen so much, we couldn't recognize our own son."

The bloating was that extreme?

"That bad," says Paul. "His ears had swelled shut, extruded the wax out. His eyes were swelled shut. There was no movement. Not a twitch. Nothing. It was pretty overwhelming to see him like that."

And to think that he didn't even have to do this.

"Of course not, no," says Paul.

"He was looking forward to it," says Mickie.

"He wanted to help," says Paul.

The next day, when doctors said there was no sign of brain activity, the Gelsingers prayed together at Jesse's bedside and made the decision no parent wants to face.

"It was a beautiful ceremony, just very brief, five minutes," says Paul. "And when the chaplain was

done, I indicated to the doctors to go ahead and came in, turned off the ECMO unit, clamped off the blood supply. Shut off the ventilator. About 60 seconds later, Dr. Raper came in with a stethoscope, put it on Jesse's chest. And he said: good-bye Jess, we'll figure this out. My boy, doing the right thing."

Through his pain, this father was about to begin a search for the truth. Was Jesse's death really as unexpected as the doctors said?

What Paul Gelsinger was about to discover would raise questions about honesty and integrity in medical research, about cover-ups and conflicts-of-interest and, in the end, whether Jesse was betrayed by the doctors he and his family thought they could trust.

"LIKE I SAID, I'm a slow man to anger," says Paul Gelsinger. "I want to know the truth."

Paul Gelsinger's son, Jesse, was thought to have been the first person ever killed in a gene therapy experiment. And this father wasn't the only one who wanted the truth.

"He was my 18-year-old son," says Pattie Gelsinger.

Jesse's mother, Pattie, long divorced from his father, never had a chance to say goodbye to her son. She was hospitalized when Jesse left for Philadelphia, to put himself in the hands of the doctors whose dream of a medical miracle had turned into a medical disaster.

"How would they like it to happen to one of their own?" she asks. "I don't think they'd be able to live with themselves."

To help console the grieving family, doctors at the University of Pennsylvania promised a complete investigation.

"They promised to inform me of everything they discovered," says Paul.

The doctors at Penn told him this?

"Yes," Paul says. "They were going to make me a part of their team."

There was an autopsy, new tests to make sure the virus or "vector" as it was called hadn't been contaminated. And, two months after Jesse's death, a personal visit from the scientist in charge: Dr. James Wilson.

"He indicated that the vector was everywhere in Jesse's body," says Paul. "They gave this kid 37-trillion viral particles. His body

was overwhelmed by it. It was that immune response that killed Jesse."

WHAT DID RESEARCHERS KNOW?

Dr. Wilson said, and Paul Gelsinger still believed, that Jesse's fatal reaction was totally unexpected and still unexplained.

"I thought that what Jesse had died of was this very remote possibility," says Paul.

That this was an unforeseeable, unexpected?

"Unexpected," says Mickie.

A tragedy on the frontier of medical science? "Yes," says Paul.

That weekend, a father and the man in charge of the experiment that killed his son, took a late night hike alone through the Arizona desert for a heart-to-heart talk between two men devastated by the shocking turn of events.

"On our hike out, he was expressing his concern with losing his institute," says Paul. "That, you know, 250 people depended upon his institute remaining open."

He was concerned about being shut down?

"That's what he was

concerned about," says Paul. "And I turned and I stopped, and I put my hand on his shoulder, and I looked him in the eye, and I said, 'You know Jim, it could be a whole lot worse. You could lose one of your kids.' That stopped him cold. And he stopped and nodded his head, and he said, 'You're right.'"

But before the hike ended, Paul Gelsinger says Dr. Wilson made an appeal for the important work on gene therapy to continue, he needed Paul's support.

"They had had adverse reactions in monkeys and they had not reported it to the F.D.A. In fact, the monkey had the same reaction that Jesse

He asked Paul to fly to east again to meet with his staff and to appear at a government hearing in a public show of support.

"It was vital that my being on their side was a great boost for them, that I would stick in there, and back them up," says Paul.

And he did it?

"And I did it," says Paul. "I was on Penn's side."

In fact, during an interview, on the very day of the government hearing, he told reporters: the doctors at Penn were not to blame.

"I've never had a problem with the people at Penn," Paul said in 1999. "I've always had faith in these men. I have more faith now than I did when Jesse went."

had."
— PAUL GELSINGER

But Paul Gelsinger was about to discover something that would shake that faith forever.

Although Dr. Wilson and his team told scientists, gathered for the meeting, that Jesse's death was unexpected, they also began to acknowledge some irregularities in the way the experiment had been handled.

And Paul Gelsinger says he began hearing things that didn't match what he'd heard before. Remember, those remarkable results he says he was told about?

Well, listen carefully to how this doctor from Wilson's team described the results at a conference:

"... Had some evidence for partial correction of the deficiency. Nothing that would be statistically significant."

Not statistically significant? In other words, no proof it ever worked.

"That's a piece of information that I absorbed at the meeting, and just did not believe," says Paul. "How could that be? I was told this worked."

ADVERSE REACTIONS WERE NOT REPORTED

And that was just the

beginning. Federal investigators, pouring through Penn's records, announced at the conference that they had made a series of startling discoveries, raising questions about whether the doctors had covered up problems and broken basic test rules.

In addition to those animal deaths Dr. Erickson was concerned about years ago, records revealed others that hadn't been reported.

In fact, just a few months before Jesse had signed up for the experiment, several monkeys given viruses similar to Jesse's got sick. And two of them died.

The doses were larger, but, even so, government rules say reactions like that in animals must be reported in order to protect people.

But neither the Gelsingers nor the government was notified.

"I read that statement at the end, the little tiny paragraph, one sentence, that Jim

"They had had adverse reactions in monkeys and they had not reported it to the F.D.A.," says Paul. "In fact, the monkey had the same reaction that Jesse had."

And Paul Gelsinger heard something else just as alarming. The rules for the experiment said: Even if volunteers didn't get visibly ill, if tests showed that any

Wilson had a vested interest in this. And I said: 'Yes, well I'd have an interest in something that I was doing, too. But I had no idea the extent of that interest. That this man had patents on this adenovirus .'"

— PAUL GELSINGER

of them had a significant reaction called "grade 3," the experiment was supposed to be "halted" immediately.

Records show there were "grade 3" reactions in more than one patient. The first time, doctors stopped, called the government and got permission to continue, saying an unusual condition with the patient might have been the cause.

The second time, they stopped, called and got permission again, citing another unusual condition.

But when it happened a third time, they didn't stop, didn't call.

Then, a fourth time. They didn't stop or call then either.

"They continued anyway, in violation of the protocol," says Paul. "And I had no knowledge of that."

Nobody said anything about that in their meeting or subsequent conversation?

"No," says Paul.

In the months that followed, leading up to Jesse, there were several more volunteers who didn't get sick. But the dose kept getting larger.

And there was more. Government investigators said the

Penn doctors had even bent the rules about who could volunteer for the experiment.

For their own safety, volunteers weren't supposed to have a blood ammonia level higher than 50. But people were coming in with higher levels and without proper approval. The limit was raised to 70.

When Jesse signed up over the summer, he was within the limits, but records show that when Penn doctors tested him, just days before the experiment, his reading was 114 — more than double the original safety limit.

With medication, doctors brought the level down, but the government concluded: Jesse Gelsinger should never have been allowed in the experiment in the first place.

Sitting in the audience, a stunned father knew he would have to share the painful disclosures with his wife, Mickie and with the mother who never got to say good-bye.

"My God, my Jesse," says Pattie.

She says what the doctors did was inexcusable.

"They knowingly went ahead with the whole thing," she says.

Paul says, “I put them on all notice, that I was going to go seek legal counsel. That too many things had happened here that were not right.”

Does Paul believe the doctors at Penn misled him?

“Yes,” he says. “Absolutely.”

HIGH FINANCIAL STAKES

With so many red flags from the monkey deaths to the reactions in other volunteers, even to Jesse’s own ammonia levels, Why had Dr. Wilson’s team allowed the experiment to continue?

Now, for the first time, Paul Gelsinger was about to confront a disturbing possibility: that something he never imagined might have played a role in his son’s death.

Did he know that Dr. Wilson had a big financial stake in a company that had rights to this research?

After his son died, Paul Gelsinger began his own lobbying campaign, because, in addition to those irregularities in the experiment that killed Jesse, this father discovered a web of financial conflicts that raise disturbing questions about whether money played a role in his son’s

death.

"Jesse should never have died," says Paul.

Near the end of the 11-page consent form Jesse signed when he volunteered, there was a short statement:

That "the University of Pennsylvania and Dr. James Wilson," the man in charge of the experiment, had a "financial interest in a successful outcome."

Paul Gelsinger told this government committee he never imagined what that could mean.

"I read that statement at the end, the little tiny paragraph, one sentence, that Jim Wilson had a vested interest in this," says Paul. "And I said: 'Yes, well I'd have an interest in something that I was doing, too. But I had no idea the extent of that interest. That this man had patents on this adenovirus.'"

Only later, did he discover that Dr. Wilson indeed had the right to patent his gene therapy viruses. What's more, Wilson had founded his own for-profit company called "Genovo," which had the exclusive rights to market his medical breakthroughs.

If an experiment, like the one on Jesse, was a success, Dr.

Dr. Wilson and officials at the University of Pennsylvania declined Dateline's requests for interviews, but they have denied that money

affected their judgments. And, as a safeguard, they say Dr. Wilson played no role in recruiting or treating patients like Jesse.

Wilson's techniques — applied to other illnesses — could translate in to millions of dollars. In fact, records show that "Genovo" was already signing multi-million dollar contracts with major bio-tech companies.

Is it wrong for a doctor to want to profit from his research?

"His profit should be attached to his Hippocratic Oath," says Paul. "These men take an oath that they're going to take care of their patients, and that their patients are first, and that they will not harm them in any way shape or form. If profits are playing a part in it, are they going to be able to be looking at the patient totally?"

Even some of James Wilson's fellow gene researchers were surprised at the amount of money involved.

One of them was Dr. Robert Erickson, the man who, years earlier, had questioned the safety of the experiment.

"I did not know the degree of investment that the Institute of Human Gene Therapy at Penn had from private companies," says Erickson. "I was quite amazed when I learned that."

What did that say to him?

“Well, it said that institute and many of these other companies are much more tied up with commercial events and probably pressured to have positive results,” says Erickson.

Certainly at least the appearance of a conflict? “Yes,” says Erickson.

Research partnerships between universities and private industry are increasingly common these days, with companies providing badly needed funding for projects that might otherwise be delayed for years.

And at major universities, there are committees to oversee possible conflicts-of-interest to make sure money doesn’t corrupt the scientific process or put lives in danger.

At the University of Pennsylvania, the conflict committee approved Dr. Wilson’s arrangement with Genovo.

In fact, the university itself owned a piece of his company and stood to profit, too.

“I’m not sophisticated business-wise,” says Paul. “But it doesn’t, you know, I can see the major conflict there. People were blind. They were blinded by all the money, the prestige that was going

to be attained by getting this to work. And willing to take risks with innocent people, who didn't have the knowledge they need to know, to be able to participate properly in this."

Is that what he thinks happened here?

"Absolutely," he says. "This is an outrage what happened here."

Could money explain why those monkey deaths weren't reported? Why the experiment didn't stop, as the rules required when people had adverse reactions and why Jesse Gelsinger was allowed to volunteer, even though his ammonia levels were too high to be eligible?

"Jesse should never have been part of this study. He should never have been injected with the adenovirus based on

Dr. Wilson and officials at the University of Pennsylvania declined Dateline's requests for interviews, but they have denied that money affected their judgments. And, as a safeguard, they say Dr. Wilson played no role in recruiting or treating patients like Jesse.

In a statement, the university acknowledged that some information "should have been shared with the FDA sooner."

But they said that Jesse "was properly enrolled" and his

the rules in place at the time of the study."
— ALAN MILSTEIN
Attorney for the Gelsinger family

elevated ammonia "did not cause his death, "that the monkey experiment involved a different disease and "did not have significant implications for the safety" of Jesse's experiment and that those "grade 3" reactions were included in a report to the FDA months before Jesse's death, the government "expressly approving the continuation of the trial."

In the end, they say "as deeply regrettable as Jesse Gelsinger's death was ..." it was "simply not foreseeable based on informed medical judgment..."

You should know, the federal government rejected each of Penn's explanations long ago, saying that Jesse didn't qualify, that the monkey deaths were important, that the grade three reactions, while reported, weren't properly flagged and it was Penn's responsibility to stop the experiment.

When Paul Gelsinger heard all this, he decided to go to court.

"Jesse should never have been part of this study," says Alan Milstein. "He should never have been injected with the adenovirus based on the rules in place at the time of the study."

Milstein is the lawyer the

Gelsingers hired to sue one of the world's most honored scientists and one of America's most respected universities.

He filed suit even though officials at Penn said everyone in the study, including Jesse, had been adequately warned in lengthy meetings about the risks and had signed a form saying they understood.

Straight out of the consent form signed by Jesse, "It is even possible that this inflammation could lead to liver toxicity or failure and be life-threatening." That's pretty back-and-white, isn't it? Isn't it a pretty clear warning?

"No," says Milstein. "There was no information given to Jesse or his family about the monkey deaths. There was no information given to Jesse or his family about toxic results in prior patients. There was no information that would allow Jesse and his family to make any kind of informed decision."

Penn says every patient gave informed consent. The Gelsingers were informed and consented.

"I read that informed consent document," says Paul. "And I read those statements. And they were so down-played and made to

appear such a remote possibility that they were not a major consideration in determining whether Jesse should participate in this clinical trial or not."

But Paul Gelsinger and his lawyer never had to make that argument in court. Within weeks of filing this lawsuit against the university, Dr. Wilson, and other doctors on his team, the defendants settled without admitting any wrongdoing.

CONFIDENTIAL REPORTS

Paul Gelsinger agreed not to disclose how much they paid his family, but he refuses to stay silent about what he thinks killed his son, and he says Dr. Wilson and the university aren't the only ones to blame.

"When lives are at stake, and my son's life was at stake, money and fame should take a back seat," Paul told congress.

He told congress that other private companies in the race for cures had also been doing gene therapy experiments and had also gotten adverse reactions. But instead of sharing the information, government rules allowed them to stamp those reactions "confidential," classifying them as

trade secrets to protect their research investments.

So, while the government knew about them, other researchers like Dr. Wilson and volunteers like Jesse Gelsinger were never allowed to see them.

What did he think when he learned that it was legal to stamp these things "confidential?"

"I was outraged," says Paul. "I had a right to know. Jesse had a right to know. This is probably happening all the time in all kinds of research. And it needs to stop. We need to know."

"I read that informed consent document. And I read those statements. And they were so down-played and made to appear such a remote possibility that they

At public hearings and in private meetings with key lawmakers and in his testimony to congress, Paul Gelsinger warns, there need to be more safeguards and less secrecy to make sure patients are more important than patents.

"The concern should be not on getting to the finish line first, but on making sure no unnecessary risks are taken," Paul told congress. "No lives filled with potential and promise are lost forever. No more fathers lose their sons."

Is Gelsinger opposed now to gene therapy experiments?

"I am not opposed to gene

were not a major considerati on in determinin g whether Jesse should participate in this clinical trial or not."
— PAUL GELSINGER

therapy," says Paul. "Do it right. Get it right."

A lot of people out there waiting for cures would say that what he sees as safeguards is red tape and bureaucratic delay.

"I see it as the right way," says Paul. "They need to reign it in, get better control, know what they're dealing with."

In long hikes, alone, in the desert, Paul Gelsinger still tries to come to grips with what happened.

Although his law suit was settled, the government's investigation continues.

In February, the Food and Drug Administration said that because Dr. Wilson filed "false and misleading" reports and "repeatedly and deliberately violated regulations". It is attempting to ban him from any other experiments involving humans.

Just as he'd feared, that night in the desert, Dr. Wilson is fighting to save his professional future.

When dealing with something on the frontier of science like this, can any doctor guarantee that a tragedy like this won't happen?

"There aren't any guarantees in life, are there?" says Paul. "But

when you're doing the right thing, and you think other people are doing the right thing, you expect good things to happen. When you find out that you were the only one doing the right thing, then it's really no surprise to me that something bad happens.

"You need to go back and take care of this. Fix it. Don't let this happen to anyone else."

This week marks the third anniversary of Jesse Gelsinger's death. At the University of Pennsylvania, Dr. Wilson is still on the faculty but no longer in charge of its gene therapy program. And, in Congress, lawmakers are still debating legislation to provide more protection for medical volunteers