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**HEADLINE: OF MICE AND MEN; CONTROVERSY SURROUNDING TESTING OF NEW  
DRUGS ON HUMAN SUBJECTS AND THE PROFIT CORRUPT DOCTORS CAN MAKE**

**ANCHORS: STEVE KROFT  
BODY: OF MICE AND MEN**

STEVE KROFT, co-host:

If you think that the testing of new drugs is confined to lab studies on mice and guinea pigs, you only know half the story. The only way to really know if a drug is safe and effective is to test it on humans. What you may not know is that the rules protecting the real guinea pigs are, in many ways, stricter than the rules protecting these human volunteers. Those were the conclusions of a number of hard-hitting government reports which found serious problems in how people are recruited into these studies and who carries out the studies.

(Footage of researchers; photo of Dr. Robert Fiddes; footage of Susan Lester with Kroft)

KROFT: (Voiceover) Increasingly, the ones doing these studies are no longer PhD researchers at large universities. They're family doctors looking for extra cash, doctors like Robert Fiddes, who had a small practice in Southern California. Susan Lester was one of his study coordinators.

How many trials did he have going when you were there?

Ms. SUSAN LESTER: I would say 30 to 40 trials.

KROFT: And how much was he getting paid by the drug companies for each one of these trials?

Ms. LESTER: I would say an average study would be anywhere from \$50,000 to maybe \$250,000, depending on the study itself.

KROFT: That's a lot of money.

Ms. LESTER: A lot of money. Very lucrative--very lucrative business.

(Footage of list of drug companies and dollar amounts with close-up of dollar amounts; Tom Parham with Kroft)

KROFT: (Voiceover) So lucrative Dr. Fiddes eventually gave up treating patients altogether, because drug companies were paying him more money to experiment on patients than HMOs were paying him to heal them. Tom Parham was one of those patients. His family doctor, who was one of Fiddes' partners, told him that there might be some problems with his prostate and suggested he go see Dr. Fiddes to enroll in a study he had going on experimental prostate medicine.

So when he told you this, you trusted him?

Mr. TOM PARHAM: Oh, yes, I trusted him. He was my doctor. And I figured that, you know, it'd maybe be beneficial to me later on in life. I mean, what--what--what are you going to do?

(Footage of Parham with Kroft)

KROFT: (Voiceover) What the doctor neglected to tell him was that Parham's history of heart problems put him at great risk if he took the medication.

Ms. LESTER: Pulling his records, I noticed the patient had bradycardia.

KROFT: Which means?

Ms. LESTER: Low heart rate. So I told the doctor that the patient did not qualify. But he said, 'It's OK, we can put him on.'

(Footage of Parham)

KROFT: (Voiceover) A few days later, Parham felt sluggish and went back to the doctor's office.

Mr. PARHAM: And I called up the nurse and I told her, you know, how I felt and she immediately took me off of it. And just a few days later, my pulse dropped down to the 20s.

KROFT: You went to the hospital?

Mr. PARHAM: I went to the hospital, right.

KROFT: What'd they tell you?

Mr. PARHAM: They told me that I needed a pacemaker immediately.

Ms. LESTER: He ends up in the hospital and now we have what we call a serious adverse event that has to be reported.

(Footage of Lester with Kroft)

KROFT: (Voiceover) Now Dr. Fiddes was at risk of being discovered by the government.

Ms. LESTER: Hospital records show that this patient had a history of bradycardia, but he said, 'Don't worry, I will take care of it.'

(Footage of document with lines highlighted; Parham)

KROFT: (Voiceover) Dr. Fiddes took care of it by removing any reference to Tom Parham's long history of bradycardia from his medical records. Parham had no idea this was going on behind the scenes, and he certainly didn't know that

Dr. Fiddes and his partners were getting money for turning him into a guinea pig.

Mr. PARHAM: I didn't realize at that time, by waltzing me down the hall to this research center, he got \$ 1,610 for bringing in a patient.

KROFT: So he was getting paid for recruiting?

Mr. PARHAM: He was getting paid big-time, right.

(Footage of Parham; Lester with Kroft)

KROFT: (Voiceover) But finding patients like Tom Parham, and keeping them, grew increasingly difficult, especially as more and more studies rolled in.

So, Susan Lester says, they started to lower their standards on who qualified for a clinical trial.

Did you have people in high blood pressure studies that didn't have high blood pressure?

Ms. LESTER: Yes.

KROFT: Did you have people in arthritis studies that didn't have arthritis?

Ms. LESTER: Yes. Yes, we did.

KROFT: In one arthritis study, Dr. Fiddes was required to have a radiologist read the X-rays of potential research subjects in order to verify that they had a specific knee problem that was being studied. But Dr. Fiddes couldn't find enough patients who qualified, so he asked the company that was sponsoring the drug trials if he could read the X-rays. They said yes.

So Dr. Fiddes started reading the X-rays?

Ms. LESTER: Correct.

KROFT: And what happened?

Ms. LESTER: Then all of a sudden, miraculously, all the patients qualified for the study.

KROFT: So he falsified the data?

Ms. LESTER: Oh, yes. And it got worse and worse.

(Photo of Fiddes; footage of bottle of Zithromax; bacteria; blood sample being taken)

KROFT: (Voiceover) As the money rolled in, Dr. Fiddes got even more creative. When he couldn't find patients with ear infections for an antibiotic study, he just ordered up bacteria from an outside lab and faked the specimens. And when he needed certain blood and urine samples, he turned to his own staff.

Ms. LESTER: We started taking each other's blood. We had a colleague there who worked-- who always showed protein in the urine. We'd have her actually urinate into a container for 24 hours, and she would get \$ 25 per container. Yeah, so she filled up quite a few.

KROFT: So you just warehoused all of these urine samples and blood samples, and if you needed one, you just went in and got it...

Ms. LESTER: Correct.

KROFT: ...out of the fridge?

Ms. LESTER: Correct.

(Footage of issues of The Journal of Clinical Pharmacology, Clinical Therapeutics and Pharmacotherapy; Dr. Marcia Angell)

KROFT: (Voiceover) Based on a hodgepodge of real and fake data, Dr. Fiddes wrote papers that appeared in several reputable journals. Dr. Marcia Angell, former editor of the New England Journal of Medicine, says cases like Dr. Fiddes are disturbing but unfortunately not isolated.

Here are reports published by Fiddes in the--in the Journal of Pediatric Infectious Diseases, Journal of Human Hypertension...

Dr. MARCIA ANGELL: Mm-hmm.

KROFT: ...The Journal of Clinical Pharmacology...

Dr. ANGELL: Mm-hmm.

KROFT: And some of it...

Dr. ANGELL: Let me say...

KROFT: I mean, this is questionable research.

Dr. ANGELL: If the fraud is internally consistent and plausible, you--you don't find it, because you're not standing over that researcher. You're not standing at the bedside with him. You're not standing at the bench with him.

(Footage of Lester; document with photo of Fiddes and excerpt highlighted: "...Conspiracy..."; Dr. Greg Koski with Kroft)

KROFT: (Voiceover) Susan Lester eventually blew the whistle, and after federal regulators raided the office, Dr. Fiddes was convicted of conspiracy to commit fraud. He was sentenced to 15 months in prison and lost his medical license. And government regulators who oversaw this case admit that Dr. Fiddes may never have been caught if Susan Lester hadn't put her career on the line and come forward. Dr. Greg Koski, who runs the government's Office of Human Research Protection, says it's unfortunate but the system depends on whistle-blowers.

Dr. GREG KOSKI: I think it's fair to say the research environment has evolved faster than the system for protection of human subjects.

(Footage of offices of Department of Health and Human Services; person entering office with sign on door: OHRP, Office for Human Research Protections)

KROFT: (Voiceover) Dr. Koski's agency was upgraded recently, and he now reports directly to the secretary of Health and Human Services. The change was made last year, he said, to make sure that cases like the one involving Dr.

Fiddes don't happen again. But his office has only 30 employees to watch the entire industry.

Since you took over in September, how many on-site inspections have you done of--of human research projects?

Dr. KOSKI: I--I'm not sure. But I think, in fact, it may be two actual full-site inspections.

KROFT: Out of how many research projects going on?

Dr. KOSKI: Oh, I couldn't even begin to estimate the number. But it's a very large number.

KROFT: Tens of thousands?

Dr. KOSKI: That's--I--I--again, I don't know the number. But I would guess that it's on the order of--of thousands.

(Footage of Koski; documents from Department of Health and Human Services Office of Inspector General with close-up on one titled Recruiting Human Subjects, Sample Guidelines for Practice; footage of Tina Perritt; Tampa General Hospital; photo of Perritt in hospital)

KROFT: (Voiceover) And that involves about one million human research subjects. But several recent government studies have found that not all of these so-called volunteers know what they're volunteering for, or even that they're volunteering. Tina Perritt certainly didn't. When she went to Tampa

General Hospital with complications in her first pregnancy, she never expected to become a study subject in a clinical trial. Doctors gave her Demerol to dull the pain and had her sign a form agreeing to take a new drug they said might help save her unborn child.

What did they tell you when you got to the hospital?

Ms. TINA PERRITT: That I was in premature labor. They were going to give me some medication to stop the labor. And they needed to also give me some medication to develop the baby's lungs so that the baby could breathe on its own.

(Footage of Perritt; person performing amniocentesis procedure)

KROFT: (Voiceover) But what they didn't tell her was that this was an experimental treatment that required her to have not one, not two, but 11 amniocentesis procedures, which involves inserting a long needle through the abdomen to withdraw fluid that surrounds the fetus.

Did you think that there was anything unusual about having 11 amniocenteses?

Ms. PERRITT: Unusual at that point, no, because I wa--I was young. I had never been pregnant. And--and this was an unusual circumstance. It hurt.

KROFT: Did it hurt?

Ms. PERRITT: It was very uncomfortable. And I was told that, you know, 'Do you want your baby to die, or do you want to save your baby?'

(Footage of Perritt and Steve Hanlon; sign: USF College of Medicine; exterior of College of Medicine building; hospital sign)

KROFT: (Voiceover) She wasn't the only woman at this university hospital subjected to multiple, dangerous amnio procedures. Perritt's attorney, Steve Hanlon, found that the University of South Florida did it to nearly 400 women, and he filed a class-action suit on their behalf.

Why was she given a total of 11 amniocenteses?

Mr. STEVE HANLON (Perritt's Attorney): They wanted additional data to see how drug A is doing, compared to drug A plus B. So she is, at this point, being used solely as a data collector for research. This doesn't have anything to do with her or her baby.

KROFT: She's being used as a guinea pig?

Mr. HANLON: There's no question she's being used as a guinea pig at that point.

(Footage of consent form)

KROFT: (Voiceover) But in the eyes of the law, it seemed perfectly legal because, in her Demerol haze, Tina Perritt had signed this consent form which is riddled with technical terms.

I mean, this is one, two, three pages long. I'll read you part of it: 'For the past 15 years, drug known--drugs known as corticosteroids have been injected into mothers at risk for delivery of a pre-term baby. However, a drug called thyrotropin-rel'--let me see...

Ms. PERRITT: You're having a little trouble...

KROFT: Right.

Ms. PERRITT: ...and you haven't had any Demerol.

KROFT: You're right.

Can you take a look at this informed consent form? This is for a study that was done at the University of South Florida. You think this form's fairly typical?

Dr. ANGELL: Yes, I do.

KROFT: Anything wrong with that informed consent form?

Dr. ANGELL: Like all informed consent forms, it seems to be a document written by lawyers for other lawyers.

(Footage of University of South Florida sign; documents)

KROFT: (Voiceover) And the lawyers at the University of South Florida battled it out for 10 years before they agreed to settle with Perritt and the other 400 women. Since then, the university has been reprimanded two more times by the federal government, and they're in good company. There have been hundreds of reprimands issued at some of the best universities in the country, and the government has shut down nine major research centers.

How can this go on?

Dr. ANGELL: It's money. As Deep Throat says, follow the money. The drug companies have a lot of money, a very profitable industry and they're willing to pay for what they need: human subjects.

(Footage of researchers working in labs)

KROFT: (Voiceover) The need for human study subjects has gotten so great that the pharmaceutical industry has resisted virtually any regulation that would make their job more difficult. Even major universities, which are supposed to oversee their own research studies, often have a financial stake in the drug being tested and stand to make millions in royalties if that drug is approved.

So right now, you could have a university that stands to make millions of dollars on a--on a drug that it owns part of, and they will appoint the review board to evaluate it.

Dr. KOSKI: That is true. The--no question about it.

KROFT: They've got--they've got, you know, millions and millions and millions of dollars at stake in this.

Dr. KOSKI: Which is exactly why they're not the ones who should be engaging in the research. And so this...

KROFT: But they can.

Dr. KOSKI: At the present point they can. So this is an area where we--we clearly need to have new regulations to--to protect the process.

KROFT: Perhaps easier said than done. When Dr. Koski's predecessor began cracking down and closing some research centers, he was reassigned to another job, some say after intense lobbying by the research centers and the drug industry.