Energy & Commerce Committee
Oversight & Investigations Subcommittee
"Institutional Review Boards that Oversee Experimental Human Testing for Profit"
Chairman Bart Stupak
Opening Statement
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Experimental medical testing on human beings has a troubling history. From the atrocities perpetrated by the Nazis in World War II to the infamous Tuskegee Study in the 1970s when subjects were denied treatment for syphilis, we have learned that we need strong controls in place to protect the health and safety of people who participate in medical experiments.

Under current federal law, medical testing of human subjects that is federally funded or relates to federally regulated drugs or medical devices cannot proceed without the approval of an "institutional review board" — a panel of doctors, scientists, and non-scientists charged with ensuring the health and safety of the people participating in the study.

Our Committee began investigating IRBs in 2007 when we learned that Copernicus IRB allowed the study of the antibiotic Ketek to continue without examining reports of fraud it had received.

As part of our continued investigation, we asked the Government Accountability Office to conduct undercover testing of the IRB review process. We wanted to know whether IRBs are rubber stamping research studies, whether clinical researchers are "IRB shopping" or choosing IRBs based on how quickly and inexpensively they approve studies, and whether governmental oversight of IRBs is adequate.

Today we will hear the results of GAO's investigation, and they are not reassuring. GAO will explain how Coast IRB, a for-profit company, approved a fictitious study, led by a fictitious doctor, and submitted by a fictitious company. It called for a full liter of a fictitious product — the same amount as in this bottle — to be poured into a woman's abdominal cavity after surgery, supposedly to help with healing. GAO's fake protocol was based on an actual high-risk study for a product that FDA ultimately withdrew from the market because of deaths and infections among patients.

Besides Coast IRB, GAO also sent its fictitious study to two other IRBs, and they both rejected it out of hand. Here are some of the things those two IRBs said after reviewing the fake GAO study:

- "The experimental design was the most complicated thing I've seen. Doing a surgery, a major operation on a patient, then a mystery guy walks in and dumps the solution in the body. … Where is the safety for the patient?"

- "It appeared that people were just going to go out and start injecting."

- "We realized it was a terrible risk for the patient."

- "It is the worst thing I have ever seen."

But Coast IRB approved this protocol unanimously, 7 to 0. The doctor with primary responsibility for reviewing the study told the other Board members that the protocol "looks fine" and that the substance to be injected into the abdominal cavity was "probably very safe." Nobody at Coast IRB ever reviewed any of the data cited in the proposal to support those claims. If they had, they would have discovered that it didn't exist.

The doctor who reviewed the study did raise a question about whether the study's claim was accurate that the substance had been approved previously by the FDA. But nobody ever followed up with the FDA to answer this question. And in an e-mail to the rest of the Board members, the doctor stated that it would not have made any difference, that he would have voted to approve the study anyway, and that the lack of FDA approval "won't affect my recommendation." The Board chair told us she relied on this recommendation and voted to approve the study without even reading the full protocol.

Why was this review so shoddy? The evidence suggests that Coast was more concerned with its financial bottom-line than protecting the lives of patients.

- According to Coast's CEO, who will testify today, Coast had a practice of voting on research protocols within 48 hours of the Board receiving them.

- One of the testimonials that Coast sent to prospective customers reads: "Thank you very much. You guys are the quickest IRB I have ever worked with and I have done this 7 years!"

- Coast even sent a coupon offering to give a free IRB review so researchers could "coast through your next study."

After this Committee wrote to Coast IRB requesting documents associated with their approval of this fictitious study, Coast officials took pride in that they were able to discover that the study was bogus, but this was 5 months after they approved it! Coast's CEO Mr. Dueber told our staff that within seconds they were able to determine that this was not an actual medical device and within 4 or 5 hours they determined that this was a scam. Had any of his staff done this research BEFORE they approved our bogus protocol 5 months ago, Coast IRB would not be here testifying today.

GAO's investigation also exposed other problems with the IRB system. GAO was able to create a fictitious IRB that it registered with the U.S. Department of Health and Human Services (HHS) with no questions asked. The president of this fake IRB was this dog, Trooper, who sadly is now deceased. [Trooper didn't know anything about protecting human subjects in testing, but for a three-legged dog, he sure could catch a Frisbee!] GAO created a fake website for Trooper's IRB called Maryland Hause. They received real inquiries from real researchers, and actually had one research protocol submitted for review. When asked why it selected GAO's fake IRB to review its study, a research coordinator stated that it was because of the low price and quick turn around time.

GAO's findings raise serious questions not only about the specific IRB involved in this investigation, but with the entire system for approving experimental testing on human beings. As a society, we have a moral obligation to ensure that human testing is done in the most responsible and ethical manner. I look forward to the testimony today and hope we can discuss ways for both government and industry to fulfill this obligation.