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Opening Statement of Rep. Henry A. Waxman Chairman, Committee on Energy and Commerce Institutional Review Boards that Oversee Experimental Human Testing for Profit Subcommittee on Oversight and Investigations March 26, 2009

Thank you, Chairman Stupak, for calling today's important hearing on the role of Institutional Review Boards in protecting the health of men, women, and children who participate in experimental biomedical testing.

New drug protocols, innovative surgeries, and high tech medical devices have the potential to revolutionize the health of our citizenry and extend the lives of all Americans. But we have to make sure that any experimental techniques are examined very closely before they are actually performed on people. We have to ensure that both researchers and their subjects understand the real risks. The question for today's hearing is whether this is happening.

Last year, the Committee asked the Government Accountability Office to investigate whether IRBs were rubber stamping experimental research protocols in order to collect fees. Many IRBs are for-profit entities that have been increasing their revenues over the past several years. The Committee also asked GAO to investigate whether protocol sponsors were engaging in IRB shopping, basically going from one IRB to another until a protocol is approved.

Today we will hear the results of GAO's investigation. GAO invented a fake company, developed a fake protocol, and got it approved by a real IRB.

It is important to understand exactly what GAO was proposing to do. GAO's protocol would have been used on women undergoing invasive abdominal surgery. One of the dangers after this type of surgery is that when internal organs begin to heal, they develop scar tissue. If organs attach to each other or to other body parts, they can begin to malfunction.

According to GAO's protocol, at the end of this surgery, researchers would have poured a full liter of an experimental fluid inside a woman's abdominal cavity. The idea was that maybe this could prevent organs from attaching to each other. But GAO made up studies that did not exist, falsified the credentials of its doctors, and had absolutely no idea what the real-life implications of its proposal would be.

The company that approved this protocol, Coast IRB, will testify today about how this could have happened.

One thing we know about Coast is that they aggressively marketed their services. When GAO was considering whether to submit its fake protocol to Coast, the company actively solicited the business, even sending a coupon to GAO. Here is what it says: "Take us for a free test drive!" Then it says, "Coupon good for a one time research protocol review worth \$1300." And then it says, "Coast through your next study."

This is actually a coupon for experimental testing on human beings. The company virtually guarantees approval, and it offers the first review for free. Can you imagine going to the hospital for major invasive surgery and having your doctor ask whether he can use a device approved after cashing in a coupon?

In order to determine whether Coast was making good on its promises for quick and easy approvals, the Committee sent its own document request seeking "a list of all research protocols submitted over the past five years," including each protocol's sponsor and the final vote counts of board members either denying or granting approval.

Here is the information Coast provided to the Committee. Over the past five years, Coast's board has reviewed a total of 356 proposals for human testing, and it approved all of them. That means it approved 100% of the studies it reviewed. Of the 356 protocols approved, Coast's board almost always voted unanimously in favor of approval, usually by a vote of 7 to 0. There was only one exception, when a single board member dissented on just one occasion.

Over this same timeframe, Coast's revenues have more than doubled, increasing from \$4.4 million in 2005 to more than \$9.3 million in 2008. While this may be lucrative for Coast, it raises serious concerns about the safety of hundreds of experimental tests the company approved and the health of potentially thousands of people who may have participated in them.

We will have difficult questions for our witnesses today, and even though the answers may be unsatisfactory, this Committee will continue to push for reforms that will protect the health and safety of the American people.