DR. WITTEN: -- you're going to have to wrap this up.

DR. BRODY: Thank you very much.

DR. WITTEN: Our next speaker represents U.S. Stem Cell Inc.

DR. COMELLA: Thank you. I'm Kristin Comella. I'm the chief science officer of U.S. Stem Cell. We are a publicly traded company, so I must remind you of the forward-looking statements. We have a comprehensive mix of products. We've been a company since 1999, and our focus has always been to bring stem cell therapies to patients.

I think this quote is particularly important today. All truth passes through three stages. First, it's ridiculed. Second, it's violently opposed. And third, is it accepted as being self-evident?

The re-implantation of autologous HCT/Ps is recognized in the regulations and during the same surgical procedure, this is considered the practice of medicine. And there are a variety of

different things that are recognized under this, including fat grafts, skin graft, bone marrow transplants, platelet rich plasma, tendon and ligament grafts, vascular grafts, hair grafts, and bone grafts. All of these procedures are considered surgical and they did not go through double-blind, placebo-controlled trials.

I want to focus on the comparison between bone marrow and fat tissue, and, in particular, something called stromal vascular fraction that a lot of people have been discussing today. The reason that bone marrow is accepted under a 510K is because there was preexisting technology to the 1976 amendments covering medical devices. Fat tissue does not have that same luxury because there was no preexisting technology. But why would fat and bone marrow be viewed separately? When you're taking cells from bone marrow, why is this different than taking cells from fat? And in particular, fat is a less invasive method of collecting and also isolating the cells with lower risks associated with it.

In addition, there are higher numbers of cells and stem cells and lower numbers of white blood cells which are inflammation creating in the fat tissue versus the bone marrow. So scientifically speaking, it makes zero sense that we'd regulate these two tissues in a different manner. Why would the FDA regulate our own body tissue and consider this a drug?

Who is responsible for paying for these trials if the FDA doesn't do it? Pharmaceutical companies typically cover the expenses associated with doing a double-blind, placebo-controlled trial. Because there is no drug to sell at the end of this because it's cells from your own body, no pharmaceutical company is going to cover these trials, so who is going to cover these trials if they're going to be mandated by the FDA?

In addition, why would the FDA regulate cells from bone marrow and fat tissue different? These are some images from our clinic where we treat patients. These are our medical practitioners who care very much about their

patients, and their safety and outcomes, and who have become, in some sense, disgusted with the medical system and some of the products that are currently available that are not making patients better. We need new options for patients.

The process is very simple. It can be done in under 60 minutes. A small sample of fat tissue is taken in a minimally manipulated process where the patient remains awake. There is no general anesthesia. The cells are obtained and can be administered back to that same patient.

We've trained over 600 practitioners throughout the world and in the U.S. who are doing these procedures safely. We have over 6,000 cases documented and when you consider some of our colleagues, there are tens of thousands of cases documented. If this was really a safety concern, there would be more than a handful of adverse events which are being reported. And that's all we have right now, just a handful out of ten thousands of patients. And there is no drug on the planet that has that kind of record.

Regenerative medicine is here to stay and it's continuously growing. We, as a field, have an obligation to bring these therapies forward. Patients have a right to make an informed consent decision about how they're going to use these treatments on themselves. They have a right to alternative therapies. We need more funding for these patient trials and the government should not regulate all bodies. I'm Kristin Comella and I will always stand up for patient rights. Thank you. (Applause)

DR. WITTEN: Thank you. There were three speakers who were not here at the time. Have they shown up? No.

Okay, in that case, I will call for questions -- or open into questions from the panel to the speakers. Any questions?

DR. ANATOL: I do.

DR. WITTEN: Okay.

DR. ANATOL: Okay, I have a question for the first speaker from Alliqua Biomedical. On your summary slide, you have a bullet that says