I would like to start by thanking the committee for the opportunity to share my story- my personal experience with counterfeit medicine. My name is Rick Roberts and my story can be told through a series of questions I faced a year and a half ago followed by my attempts to find the answers to those questions.

I am currently a professor at the University of San Francisco and spend my summers working with at-risk high school students at the Eagle Rock School in Colorado. I serve on the Board of the Andrew Ziegler Foundation – an organization committed to access to state-of-the-art HIV care. I have been interviewed regarding my experience with counterfeit medicine by SF Frontiers Magazine, the Boston Globe, ABC Nightly News, Canadian Television (CTV), and Time Magazine (not yet in print).

My story begins about 20 years ago. I graduated from a small town high school in the Sierra Nevada Mountains of California. That summer I turned 18 and moved away to start my college career. I was a college freshman, gay, living in San Francisco, and it was 1981. HIV was isolated and determined by many to be the cause of AIDS a few years later. In 1986 I graduated from the University of San Francisco. In 1988, while in graduate school at San Francisco State University, I became ill and was diagnosed with AIDS Related Complex. I was most likely infected before anyone knew about HIV.

I started AZT, the only retroviral approved at the time by the FDA. This was the beginning of my experience with HIV medications and today I take a combination of 25 to 50 pills a day. I have become quite familiar with pharmacies, formularies, and side effects.

It has been quite a journey and along the way I was diagnosed with AIDS. There have been many critical junctures on the journey in terms of my health. One of them was my fight against AIDS Wasting Syndrome. This particular fight caused me to ask myself the first question of this story.

Would I make it through yet another health crisis? It had been a 12-year battle at that point and I knew the reality of the situation. I was already using the most accessible drugs to combat wasting. They were not working, but there was some hope. I was notified that my insurance company had approved 12 months of

Serostim (Human Growth Hormone). I had used Serostim before, with good results, when I participated in an experimental study. I started the daily injections and they stabilized my condition. It looked like I would make it.

Toward the end of my year on Serostim I noticed some subtle changes in the packaging of the drug and the actual quantity of the drug itself. This was in November and December of 2000. **Where the changes I had noticed significant?** I was not alarmed, but when I started having burning at the injection site I made a note to ask the pharmacist about it the next time I went to pick up my medications.

I asked the pharmacist during my next visit at the end of January 2001 and he simply stated that I might want to go home and check what I had because it could be fake. Fake? He said that he had heard that some people had received counterfeit Serostim. **Did I actually have counterfeit drug?** After meticulously and systematically inspecting and comparing the empty vials, boxes, and full doses of Serostim that remained, I concluded that there were differences between them. In fact, they seem to fall into one of three groups: those that were identical to the prescription Serostim I had just picked up, those that were only subtly different, and those that upon consideration had some very obvious differences.

If I had received counterfeit drug from the pharmacy, who else knew about it? I went on-line and went to the website of Serono, the manufacturer of Serostim. They indeed did know that Serostim had been counterfeited. Serono identified one particular lot number and stated that they had issued a recall of that lot. They also stated that, along with providing some contact information, they were cooperating with the FDA's criminal investigation. So, I went to the FDA website and found a warning statement.

The FDA announced that they were conducting a criminal investigation into counterfeit Serostim found in seven states. It also identified the same lot number as Serono. Naomi Aoki of the Boston Globe had also written a brief article describing what I had just found on the Serono and FDA sites. **If the pharmacy, Serono, and the FDA knew about this counterfeit, why didn't anyone tell me?**

The "Serostim" that had the obvious differences matched the lot number reported to be counterfeit. I had a couple of empty boxes- it turns out I had injected a few weeks worth of the counterfeit. I called both Serono and the FDA. After a week of trying I was never able to get in touch with the contact person at the FDA. Serono did return my call.

The person from Serono told me they would make good on anything I suspected was counterfeit and if I returned everything suspicious to the pharmacy, they would replace it with "real" Serostim. He insisted that there was only one lot of counterfeit, but I was convinced that there were two. No one said why patients had not been notified. **How could they guarantee that what they gave me would be "real" when they didn't believe there was another lot of counterfeit?** I didn't return what I had. In fact, because I seemed to be stable in terms of my weight, I stopped taking growth hormone all together. I couldn't believe that this was happening and became suspicious of all my medicine.

Then came the most critical question, after realizing I had everyday injected, for at least a month, something other than growth hormone. **If it wasn't Serostim, what had I injected and what were the consequences?** No one seemed to either know the answer or to want to answer the question.

Eventually, Serono did identify a second counterfeit. But it would be three months of fear, sleepless nights, Doctor visits and anxiety attacks before I would learn that one of the drugs I injected would have no negative long-term effects. It would be another few months before I found the same was true of the second counterfeit lot. Other than my initial ARC diagnoses in 1988, this was one of the most difficult periods of my life.

While I had been through difficult crises before, I always knew what I was up against. In this case, I was never warned (even though it was a known danger), I was told I was mistaken about a second counterfeit, and I didn't feel I could trust Serono and the pharmacy to replace the counterfeit with real drug. The most devastating period for me was the six-month wait.

How did this happen?

Who was responsible?

When the FDA finishes the investigation they started a year and a half ago I hope to have the answers to these and other remaining questions. The questions that I may never understand the answers to are:

Why were the approximately 6,000 US citizens using Serostim not warned?

Why didn't Serono use pictures and identify specific differences on their website to help us better identify counterfeit Serostim?

Why was I forced to wait so long before any one could help me know that I was going to be okay after injecting these counterfeit drugs?

Thank you for listening to my story.