

Jay Cuetara  
Cancer Patient's Impact Statement

Hello, my name is Jay Cuetara. I live in San Francisco and work for a Fortune 50 technology company. I am currently 49 years old. I'd like to begin by thanking the organizers of this FDA Workshop for the invitation to speak at today's session. As you'll hear in my comments, this is a very important issue for me personally as well as for the thousands of others who have been and or will be affected.

In April of 2009 I was officially diagnosed with Stage IV rectal cancer which had already spread to my lungs. Fortunately, before the diagnosis I had been – and luckily continue to be – asymptomatic. For the most part I live a pretty normal life, working full-time, spending time with friends and family, vacationing and watching really bad reality TV. I am able to accomplish these things due to the wonderful care I'm receiving from the incredible medical staff of UC San Francisco's Helen Diller Cancer Center.

In April 2009, when I first met my oncologist Dr. Alan Venook, I could tell he knew exactly what he was talking about. He made it very clear that for me a "cure" was highly unlikely, but that we should be able to treat the rectal cancer as a chronic condition providing me with a good quality life for years to come. Critical to treating the cancer would be the targeted use of chemotherapy. Dr. Venook assured me that most of the rectal cancer chemo cocktails had been around for years and were very effective with minimal side effects. I soon began a 12-cycle regimen of FOLFIRI which concluded December of 2009. Fourteen months later, after a routine PET/CT scan this past February, we found that the cancer had spread to my L5 and T10 vertebrae. After two Cyber Knife

radiation treatments, I started a twelve cycle regimen of FOLFOX in June.

Now on the day of my sixth cycle of FOLFOX – just this past August 9<sup>th</sup> - after having been given all of my pre-meds, I was informed that the 5-FU injectable drug was not in stock and that I wouldn't be able to have chemo that day. My first reaction was utter surprise. I had not known that there could be issues with lack of chemo drugs. I asked to speak with the pharmacist who told me that UCSF had had supply issues with the 5-FU injectable drug specifically as well as other chemo drugs used for breast, ovarian and other cancers. She told me that the chemo drug supply issue was so serious that the UCSF Infusion Center has a pharmacist that spends the bulk of his time sourcing drugs to ensure availability. At that point I was dumfounded. The question I then asked myself was “How – in the United States of America - could critical life-saving or life-prolonging drugs be in short supply?”

I went home that afternoon and spent the rest of the day researching the issue in order to better understand the situation. I came across and read the “Drug Shortages Summit November 5, 2010 Summary Report”. I contacted the American Society of Health-Systems Pharmacists. I contacted APP Pharma, Mylan Pharmaceuticals and Teva Pharmaceuticals to find out their reasons for their inability to provide the 5-FU injectable drug. I also contacted US Senators Dianne Feinstein and Barbara Boxer along with Congresswoman Nancy Pelosi. I concluded that afternoon by calling US Senator Amy Klobuchar's office to discuss the legislation she is sponsoring to help resolve this issue.

During this research, I also learned that 160+ of the drugs currently in short supply having nothing to do with cancer treatment, that the bulk are generic drugs whose efficacy has been proven time and time again, and that in most cases the reasons for the shortages

were not known. Once again, the question: “How – in the United States of America – could this be happening?” came popping into my head.

In addition to speaking about my own personal situation, I want to ensure that I also speak for the ***THOUSANDS of non-cancer patients*** who most likely never knew or will know that the most effective drug they should have been given was not available. As I mentioned earlier, 160+ drugs on the shortage list have no connection to cancer treatment and are typically given to patients in emergency situations. Situations like:

1. Surgical patients not getting the best anesthesia drug (Propofol).
2. Premature babies not getting the best preservative-free antibiotic (Gentamicin).
3. Herpes patients at a loss for a drug that will ease their situation (Acyclovir).
4. Mental patients not getting the best drug to help them think clearly and reduce nervousness (Haloperidol).

As I stated earlier, I am not part of the health profession, but I have learned a lot over the past 30 months while dealing with my cancer. I also have close friends who are anesthesiologists, hospitalists and nurses. I asked them how this critical drug shortage affects them and their ability to treat their patients - regardless of health issue - and to a person they all said “substantially”. Whether it’s having to use a less effective drug, having to deal with dosing issues and/or medication errors, delays in treatment, or the time they and their counterparts have to spend dealing with these issues, it is greatly impacting patient safety and increasing the cost of care.

I find it incredibly ironic that the ***least expensive drugs*** are the ones we have the greatest difficulty in sourcing. I am convinced

that a detailed cost-benefit analysis would clearly show that the benefits - financial, societal and emotional - associated with ensuring the availability of these critical drugs would FAR outstrip the costs. In other words, sometimes “you have to spend a little to save a lot.”

Now, I am actually one of the fortunate cancer patients. UCSF was able to acquire the 5-FU injectable drug and my chemo treatment was delayed by just one week. I am now back on a regular schedule – at least for now. BUT the medical professionals and drug experts in this room know that there are many chemotherapy protocols where even a one week delay greatly impacts the efficacy of the treatment and could potentially change what would normally be a “cure” to “life prolonging” and “life prolonging” to “imminent death”. Many oncologists have been put in the position of rationing care, having to determine which of their patients will receive a limited chemo drug and which won’t. Again, the question I ask myself: “How – in the United States of America – could this be happening?”

Let me conclude with the following. I firmly believe that this group of pharmacists, doctors, medical professionals, pharmaceutical representatives and government officials are here today to ensure that the thousands of people like me have access to the best critical drug at the right time and every time it’s needed. Everyone in this room understands the root causes of the critical drugs shortage and everyone in this room has a vested interest in solving the problem. ***Let’s get it done. Let’s fix this problem NOW!***

Thank you all very much for your time today.