

Good afternoon. My name is Rick Dulin. In November of 1997, after experiencing chest pain for several weeks, I went to the hospital and learned that I had distal heart disease and blockage in all vessels. This required that I undergo a 3 vessel CABG.

I was doing fine, I thought, until I experienced angina in March 2006. I went again to the same hospital, and a cardiac cath was performed. Immediately after the procedure and while I lay on the OR recovery table with the compress on my groin, I was introduced to a cardiologist and a research coordinator. They began to explain to me that the three vessels had closed and that I required a stent. They recommended, because of the condition of my arteries, that I elect to participate in a clinical trial with a new type of stent that released a medicine to prevent clotting. Did I ask questions? No. Did I fully comprehend? No. I knew only that I wanted to live.

They had clipboards and many forms for me to sign and I signed them all from a flat position on the recovery table. I was then officially enrolled in the Spirit III Clinical Trial where the Xcience and Taxus stents are being evaluated.

Since March of this year, I have had many instances where I have needed some level of support, especially in the last few months. With all of the information regarding the safety of the devices, their impact on those of us with heart disease, and how I am to carry on with my life when I feel somewhat discomfort, this need for support is ever more obvious.

On last week, I logged onto MSNBC and read an article that stated something along the lines of "Tiny Time Bombs Ticking in the hearts of patients" and experienced a fear like none other that I have felt. I immediately called the telephone number of the Research Coordinator listed on my little card that I have carried in my wallet since March and...got her voicemail stating that she was on vacation until the next week, and was given another number to call. I called it and left a message. The next day someone called me back, listened to my concerns, and noted that they had not heard of any issues with the Stent. I asked for the persons email address and sent an email of the link to the article that had prompted me to call. I was then called two days later, right before Thanksgiving by the Research Coordinator and asked if I could come in for a followup appointment.

What I would like for the panel to realize from my experience is this very lack of serious support services available to assist patients who experience adverse emotional or physical responses. Patients report that they get this device and are left to figure out the rest by themselves. The disconnect is huge. On my last visit, there were about *300 responses* on the MSNBC Website regarding the fear raised about this stent. The vast majority of the persons who write have experienced some type of adverse event, and note the lack of support services.

Questions go unanswered, other than a website that I was able to find called Angioplasty.com, but for those who don't have internet access or are just not a part of the electronic communication generation, please examine how those patients can also have access to this information and support.

Finally, may I suggest that the panel examine how this highly complex information (for me) can be presented in a culturally accurate, linguistically diverse, and appropriate literacy level manner so that support services can be developed and provided to the entire patient population that have received one of these stents.

On yesterday, I requested to speak in the unannounced segment, but I left out of a fear that I experienced on learning so much confusing information which I know to be indicative of what others are also feeling based on the posted responses on so many different websites... I went home and got in the bed.

As a patient with this device inside my heart, I ask that the panel take under consideration how the implantation of these devices can be coordinated to also include the development and provision of compassionate care supportive services via a provision of information that will reach each patient.

This will serve as a means of educating those of us who are living with the fear of not knowing what's next. This will also assist physicians responsible for monitoring these devices. On yesterday I learned that the percentage of Stents implanted off label was approximately 60% and then I read it in an article. Today, I am still learning what it actually means.

How can these support services not be available and provided? I once read that fear is false evidence appearing real...if these stents are really doing what they are supposed to do...please help alleviate the fear that many persons, such as myself, are experiencing.