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### **Written Statement for May 9, 2012 Arthritis Advisory Committee Meeting**

#### **Grounds for concern**

For the past six years, I have been diagnosed with the disease commonly referred to as Rheumatoid Arthritis or RA. Within a few short months, all of my joints were painful, stiff, and weak. For the past six years, I've lived with daily fevers, eye problems, and loss of muscle and bone. I have also experienced loss of voice, infections, or irregular heart rate due to my RA. Frequently, I miss family events or cannot perform daily activities because of RA. When a weekly dose (twice the recommended dose) of Humira (adalimumab) with a full dose (25mg) of methotrexate did not alleviate symptoms, I began to research about RA. For the past three and a half years, I've worked more than full-time reading and writing about RA and interacting with RA patients.

In the process, I've built the most comprehensive website about RA and one of the largest most interactive communities around a health condition. Living with RA and interacting with thousands of patients has provided me with a unique vantage point. I've learned that RA patients often have needs and opinions which have not been represented accurately.

There are several mistaken assumptions about us who live with RA because public understanding of the disease is mostly derived from advertising. The thousands of patients who I've encountered are mostly bright, optimistic, and brave. However, the sad facts are that remission is rare and the majority of RA patients do not have sufficient treatment alternatives.

#### **Current situation of RA patients**

It is often said that this is the "best time to have RA" because there are miraculous treatments to help RA patients "get their lives back." Recently, I heard a paid advocate for an established organization say, "Biologics keep people out of wheelchairs." Unfortunately, the facts are more limited: *Certain Biologics help keep certain people out of wheelchairs.* For example, my friend Jamie was a nurse, but the disease destroyed her ankles within two years of diagnosis. The currently available treatment options did not keep her out of a wheelchair. Many people I know need wheelchairs at least sometimes, including me.

Interacting with patients every day, our community has become aware that a large percentage of RA patients experience systemic or non-articular symptoms of the disease. Hospitalizations, emergency room visits, and long-term health issues are not rare. For example, my friend Tom has been forced to

retire from the New York Police Department with liver and heart problems related to his RA. We also see that most patients have to manage some side effects or adverse events related to medications.

Good progress is being made, yet many RA patients are left behind. Most people with RA still must rely upon the use of steroids and / or non-steroidal anti-inflammatory medicines, in spite of other treatments. Matters are complicated by several problems which are not well-recognized. Here, briefly, are a few of them.

1. Trial and error: Doctors are unable to tell RA patients which treatment will work. It is often said that we have begun the age of personalized medicine, but our immune systems respond differently to the disease itself and to the treatments.
2. Pain and various types of damage often continue during treatment, especially for low level responders (such as ACR20) who need more options.
3. The recommended period to adjust treatment for patients with inadequate response was shortened by American College of Rheumatology in April of 2012 to 3 and 6 months. Patients like me who took a few years to run out of treatment options, in pursuit of relief, will do so much more quickly. For example, I spent 2.5 yrs on a first biologic that did not work well; with new guidelines, that could be 3 months.
4. Adverse events, allergic reactions, or severe side effects in many patients necessitate treatment changes. These can occur even in patients who previously responded well to treatments.
5. Clinical trials are not a last resort option that is open to many patients because they cannot qualify due to exclusive criteria.

## **Conclusion**

New options like tofacitinib are needed to help at least 4 types of patients:

1. The 34% non-responders to currently approved treatments.
2. People who quit responding to a treatment, often due to the creation of antibodies. It is likely that a majority of patients eventually make antibodies against treatments, making them ineffective. Since tofacitinib is a small molecule synthetic chemical, this is less likely to occur.
3. The 29% of patients on average who have a minimal response to current treatments (ACR20).
4. People likely to be diagnosed in the future, including my own children, one of whom shows symptoms already.

People with RA are often told that they are lucky because it's no longer "the age of steroids or aspirin." However for many RA patients, it still is: many people I know do live on handfuls of Advil or prednisone to survive as I do. People with RA are often told that they ought to accept their fate and be thankful for the care they do have in a modern age, but I believe we ought to fight for as much of life as we can get.

My friend Angie is a responder to tofacitinib, having been in a clinical trial since phase 2. I watched her get her life back. I hope that you approve this drug for people like Angie who will continue to be a teacher and rake leaves and go biking with her kids.

But, mostly I speak on behalf of people like me, Tom, Jamie, or my son. As I have shown, we are often on the outside looking in, with our faces pressed against the glass. We can see that hope of relief exists and will be within reach for some of us. We deserve every opportunity to taste a reprieve from this disease.

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## Excerpts referenced from Rheumatoid Patient Foundation 2011 survey of 1467 RA patients

### Response to treatment

- In spite of disease tx, I use steroids or NSAIDs or pain meds for relief of RA sx - 64.69%
- I live w/ a lot of pain, stiffness, weakness no matter what I do 35.72%
- I responded well to tx, but it was temporary 13.97%
- My sx are completely relieved w/ DMARDs or Biologics 8.18%
- I have never taken DMARDs or biologics 5.73%

### Fatigue

- Daily 69.73%
- Often 20.59%
- Once in while 8.79%
- Never 0.89%

### Pain

- 67% report zero days per month RA pain-free
- 28% report moderate to severe pain at least 20 days per month

### Damage

- 82% reported having some kind of damage from RA although 94% have used DMARDs or Biologics as disease treatment