Statement of Sally Greenberg, Executive Director
National Consumers League

FDA-2017-N-2732

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

Open Public Hearing Re: Consideration of Mylan's biosimilar to Genentech Inc.'s HERCEPTIN (trastuzumab)

July 13, 2017

The National Consumers League (NCL) appreciates the opportunity to testify today in support of biosimilars. My name is Sally Greenberg, Executive Director of NCL. Since our founding in 1899, NCL has long been concerned with ensuring the safety, effectiveness, and appropriate use of both prescription and OTC drugs, and medication adherence, which we have helped to advance through our *Script Your Future* Campaign.

In addition to being a champion for safe and effective medicines, NCL is committed to ensuring that consumers have access to quality medicines that are also affordable. NCL is a strong supporter of biosimilars, and testified last October in support of the reauthorization of the Biosimilar User Fee Act (BsUFA). We recognize that the entry of biosimilars into the U.S. market presents an opportunity to broaden patient access to life-saving biologic treatments while bolstering competition, reducing costs, and realizing better health outcomes.

Biologics are a manifestation of revolutionary advancements in the development of therapies for patients with debilitating and deadly diseases such as diabetes, multiple sclerosis, rheumatoid arthritis, and various forms of cancer. Unfortunately, the price for these complex therapies is often prohibitive for the vulnerable patients who need them the most – with some costing upward of several hundred thousand dollars per year. Biosimilars provide a less expensive alternative to their reference products, offering the same potency and therapeutic benefits at a fraction of the price. Similar to the dynamic relationship of generic and brand name drugs, the presence of biosimilars will not only encourage patient choice, but also boost market competition and drive down costs.

The biosimilar being considered today would be an alternative to the biologic medicine trastuzumab, which treats HER2-positive breast cancer and gastric cancer. HER2+ breast cancer is a particularly aggressive form of breast cancer that affects 1 in 5 women with the disease. In 2017 alone, it is estimated that over 300,000 people will be diagnosed with breast cancer and over 40,000 women will die as a result of this

terrible disease. Fortunately, biologic therapies have transformed the way in which we treat breast cancer, with many patients experiencing decreased odds of recurrence, increased odds of survival, and an improved quality of life.

NCL supports FDA's science-based review of Mylan's and other new biosimilar applications so that patients can have expanded and affordable access to the safe and effective biologic medicines they need. Thank you for the opportunity to testify today.