

Congress of the United States
Washington, DC 20515

November 8, 2010

Margaret Hamburg
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We are writing to express our serious concerns over recent actions by the Administration that pose a serious threat not only to the thousands of breast cancer patients who will no longer have access to life-saving medical interventions, but also pose a threat to the very foundation of our health care system. Building on the Democrat-backed health care reform legislation, the Administration is continuing a large-scale intrusion into Americans' lives and their personal health care decisions that have previously been left up to a patient and their health care provider.

Specifically, we are concerned about the upcoming Food and Drug Administration (FDA) decision regarding the use of Avastin for the treatment of metastatic breast cancer. As you know, the FDA is set to decide in December whether to withdraw approval for the use of Avastin to treat metastatic breast cancer. Currently, there are limited options for the patients suffering from this terminal disease that takes the lives of 40,000 women in the United States each year. As is the case with many cancers, the unfortunate reality is that researchers have yet to discover a cure. However, Avastin has proven to be a viable treatment option that helps over 17,000 patients annually manage their disease and live more productive lives.

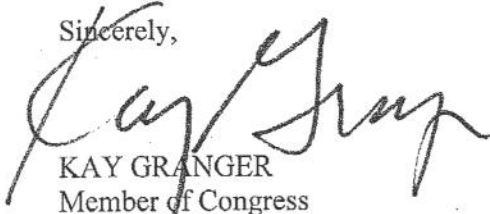
In addition to these facts, patients from all over the country have been sharing their stories in response to the very real threat of being denied further access to this treatment. Many patients have had miraculous results from Avastin and have been living disease-free for years. While there are certain risks associated with taking Avastin, most patients would agree that the biggest risk is the one associated with dying from their disease. We fail to see why this Administration would want to remove a viable treatment option that has the support of thousands of doctors and patients around the country. Limiting access to this treatment is unthinkable and we are struggling to see any justification other than cost.

The United States health care system is unrivaled anywhere else on the globe. Unlike other countries, where agencies like the National Institute for Clinical Excellence (NICE) frequently deny patients access to treatments deemed not to be cost-effective, our system has provided patients with unparalleled access to innovative, cutting edge medical technologies that have improved the lives of millions of individuals. Perhaps most important, the decision about

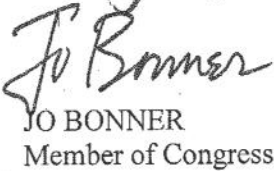
what course of treatment is best kept between the patient and their health care provider, not a group of bureaucrats whose mission is to contain costs. Nowhere has this been more prevalent than in the area of cancer, where the United States leads the world in survival rates because of a historical commitment to early diagnosis, introduction of innovative treatments, and strong government programs that provide coverage and access to these services. We are concerned that this decision is the beginning of eroding this successful system in a manner that will harm patients in order to save money in a health care system fraught with other inefficiencies that can be addressed without limiting patient choice.

The United States health care system is at a crossroads. The fundamental pillars of access, physician choice, and innovation that have led us to prominence are going to be key to the continued success of our health care system. As Members of Congress who fund the agencies that make decisions that are vital to the health of Americans, we express our strong concern that the current Administration is overreaching into the personal health care options of Americans. We hope that you will take our concerns under consideration as the FDA considers approval of Avastin for the treatment of metastatic breast cancer.

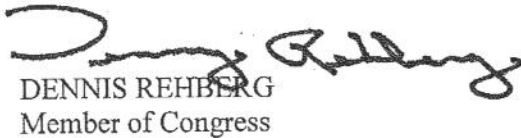
Sincerely,



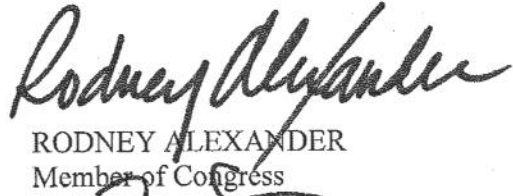
KAY GRANGER
Member of Congress



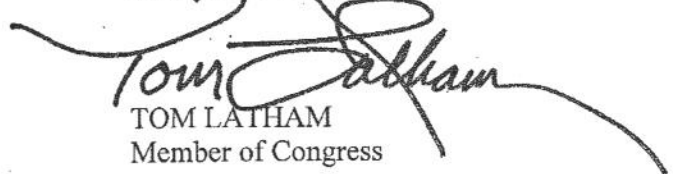
JO BONNER
Member of Congress



DENNIS REHBERG
Member of Congress



RODNEY ALEXANDER
Member of Congress



TOM LATHAM
Member of Congress

Cc: Secretary Kathleen Sebelius