BREAST CANCER ACTION

Thursday, March 4, 2020

The Honorable Xavier Becerra, Secretary of Health and Human Services-Designate
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Norris Cochran, Acting Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Breast Cancer Action Opposes Dr. Janet Woodcock to Head the FDA

Dear HHS Secretary-Designate Becerra and Acting HHS Secretary Cochran:

Breast Cancer Action (BCAction) is strongly opposed to the potential nomination of Dr. Janet Woodcock for the position of Commissioner of the U.S. Food and Drug Administration (FDA). Our opposition stems from concerns about her history of having strong industry ties and the resulting conflicts of interest.

BCAction is a national education and activist organization with over 60,000 members working to achieve health justice for all people at risk of and living with breast cancer. We cannot be bought, influenced, or discouraged from our mission, and through our long-standing independence, we have worked to ensure that people have access to evidence-based information about breast cancer, free of industry influence.

The FDA plays an essential role in protecting consumers and patients from harm. Over the last few decades, the FDA has lowered the bar on the approval of breast cancer drugs, therapies, and devices. The number of drugs that have been approved by the FDA has increased while the amount of time the FDA has taken to review drugs has decreased. A new leader for the agency is being considered and that person must be committed to restoring the scientific integrity of the agency that ensures breast cancer drugs and treatments are more effective, less toxic, and less expensive than existing therapies.

Timely access to drugs and treatments are important, but not at the expense of strong safety standards or by bypassing full scientific assessments of the drugs under review. Streamlining the approval process to get drugs to the market faster is good news for pharmaceutical companies that prioritize profit above all else, but terrible news for breast cancer patients. When drugs and treatments are approved to favor industry and not science, the burden falls on people living with breast cancer and their insurance companies to bear the cost of these still-experimental drugs.

In recent years, the majority of treatments intended for late-stage cancer were approved based on short-term data using biomarkers and surrogate endpoints such as tumor shrinkage, rather than data showing longer improved quality of life or long-term survival. Additionally, when the FDA approves a drug based on narrow criteria, companies are required to continue studying that drug after approval; however, many studies were not completed or did not show meaningful clinical benefits. A leader like Dr. Woodcock, who has heavily criticized regulations established to protect patients and consumers, could further lower the already diminished standards used to assess safety and efficacy of future breast cancer drugs, treatments, and devices.

Dr. Janet Woodcock is well-known for relaxing the criteria needed for certain drugs to reach the market, and is criticized by opioid and pain management groups for pushing the approval of drugs despite inadequate

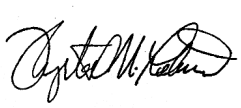
evidence of safety. We oppose Dr. Woodcock because her track record suggests that if she were to lead the FDA, she would favor industry interests over public health, undermine scientific evidence regarding the safety and efficacy of breast cancer drugs, and put patients at risk. She has a history of strong industry ties. This comes with accompanying conflicts of interest that interfere with her ability to prioritize patients and consumers. She has been heavily criticized for her lack of oversight and regulation of opioids as the head of the agency's Center for Drug Evaluation and Research (CDER). Under her leadership the agency allowed pharmaceutical companies to evade transparency and get away with false claims that drugs were more effective and less addictive than they really were. In a recent letter to the Biden administration from Physicians for Social Responsibility and co-signed by 28 groups, it is stated that as the head of CDER Dr. Woodcock was responsible for "one of the worst regulatory agency failures in U.S. history."[1] She even pushed for approvals of drugs despite inadequate evidence of safety.

The FDA has granted more new drug approvals for breast cancer than for any other type of solid tumor[2], and the breast cancer community is far too familiar with the consequences of streamlining safety protocols. BCAction has been critical of any FDA leader who has allowed patients to be exposed to expensive, toxic treatments that do not improve survival rates while pharmaceutical companies rake in profits. In order to be the strong and effective agency that patients can depend on, the FDA must act with integrity and without conflicts of interest, which is why Breast Cancer Action urges you to oppose Dr. Janet Woodcock's potential nomination.

We encourage you to select a new FDA Commissioner based on the following criteria: they are devoted to restoring the scientific integrity of the agency, they prioritize public health over industry interest, and they are committed to ensuring a balance between approval speed and drug safety and efficacy. As acting commissioner, Janet Woodcock is positioned to be potentially nominated for a permanent role as the agency's leader. We understand that Dr. Joshua Sharfstein is another potential candidate being considered for the position. Of the two potential nominees, Dr. Joshua Sharfstein has thus far exhibited more of the qualities that best fit our criteria.

Breast Cancer Action will continue to be on the forefront of applying critical analysis to current and emerging breast cancer treatments, of providing evidence-based information free from industry influence, and of holding any leader of the agency accountable for ensuring the safety for patients and consumers.

Sincerely,



Dr. Krystal Redman, DrPH
Executive Director, Breast Cancer Action

[1] https://www.theguardian.com/us-news/2021/jan/28/fda-janet-woodcock-opioids-biden
[2] https://www.nature.com/articles/d41573-019-00201-w