



American Cancer Society  
Cancer Action Network  
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June 7, 2017

The Honorable Lamar Alexander  
Chairman  
Committee on Health, Education, Labor, and  
Pensions  
455 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Patty Murray  
Ranking Member  
Committee on Health, Education, Labor, and  
Pensions  
154 Russell Senate Office Building  
Washington, DC 20510

The Honorable Greg Walden  
Chairman  
Energy and Commerce Committee  
2185 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone  
Ranking Member  
Energy and Commerce Committee  
237 Cannon House Office Building  
Washington, DC 20515

Re: FDA User Fee Reauthorization

Dear Chairman Alexander, Senator Murray, Chairman Walden, and Representative Pallone,

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, urges the swift reauthorization of the U.S. Food and Drug Administration (FDA) User Fee Agreements (UFAs). The four separate UFAs dealing with new drugs, generic drugs, devices, and biosimilars all impact cancer patients, who depend on these products as they battle cancer. FDA's work is dependent on the thousands of employees funded by user fees, and a disruption in their work, or even the threat of being furloughed, would create an unnecessary hurdle to medical progress. We appreciate your diligence in addressing additional policy recommendations that we and other stakeholder groups have put forward outside of the initial agreement, but also ask you to ensure this legislation not be encumbered by extraneous issues that could jeopardize its passage.

The negotiated agreements represent a strong investment in innovation and we are pleased to see a number of provisions of particular importance to cancer patients. These include provisions that incorporate rare disease staff into product review teams, increase resources dedicated to biomarker development and validation, advance the science supporting the use of real-world evidence, institute efforts to better hire and retain highly qualified staff, and add resources to account for the added workload generated as part of the success of the breakthrough therapy pathway.

We are particularly pleased with the dedication of new staff with patient-focused drug development expertise and responsibilities. During the last user fee reauthorization, ACS CAN successfully advocated to enshrine the patient representative program in statute (Section 1137 of

the Food and Drug Administration Safety and Innovation Act), and we continue to advocate for a greater role for patient input into drug development and approval. To that end, we have developed a proposal in cooperation with the National Organization for Rare Disorders (NORD) to coordinate and centralize patient engagement staff at FDA into an elevated office.

Currently, much of the patient engagement staff resides in the Office of Health and Constituent Affairs (OHCA), where the patient representative program is managed. The OHCA is also the office that currently handles a significant portion of FDA's interaction with the public regarding expanded access to unapproved therapies outside of clinical trials. Our proposal aligns with a recent request for comment put forth by FDA to create an Office of Patient Affairs. The request for comment was published in the Federal Register on March 14<sup>th</sup>, and FDA's proposal to create such an office reflected the Agency's recognition of better coordination of patient-focused staff and activities. Our proposal would codify such an office and respond to important needs.

Among those needs are:

- Better visibility and coordination of expanded access requests for unapproved drugs,
- Better coordination of conflict-of-interest clearance procedures for patients seeking to be involved in the patient representative program,
- Better visibility and coordination of the myriad opportunities across FDA for patients to actively engage,
- More transparency and metrics for the use of patient representatives by FDA.

While FDA is very willing to engage patients, it is not always easy for an individual patient, or even some patient groups, to find the appropriate office and contact person to initiate interaction. By centralizing and elevating the staff and functions tied to patient engagement, we believe that it will be easier for patients to engage FDA, and the performance of existing patient interactions will be improved.

Our proposal is aligned with the recent patient focus in the 21<sup>st</sup> Century Cures Act, the patient provisions within the negotiated UFA's, and the FDA's own proposal for an Office of Patient Affairs. As the Senate HELP Committee and the House Energy and Commerce Committee move the user fee agreements forward we urge that you consider codifying an Office of Patient Affairs at FDA in the final bill.

We are appreciative of the significant efforts that have gone into negotiating the user fee agreements and we look forward to the increased focus on patients that they will bring when enacted. As discussion of this legislation continues, we look forward to continuing to offer our support and perspective. If you have any questions, please feel free to contact me or have your staff contact Keysha Brooks-Coley at [Keysha.Brooks-Coley@cancer.org](mailto:Keysha.Brooks-Coley@cancer.org) or 202-661-5720. We look forward to working with you to improve the lives of individuals with cancer.

Sincerely,

A handwritten signature in black ink that reads "Dick Woodruff". The signature is written in a cursive, flowing style.

Dick Woodruff  
Senior Vice President, Federal Advocacy  
American Cancer Society Cancer Action Network