PDUFA Testimony
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- My name is David Fassler. I am a child and adolescent psychiatrist practicing in Burlington, Vermont. I'm also a clinical professor of psychiatry at the University of Vermont, College of Medicine.

- I am here today as a board member of Mental Health America, a national consumer advocacy organization.

- Mental Health America, formerly known as the National Mental Health Association, is the country's leading nonprofit dedicated to helping all people live mentally healthier lives. With more than 320 affiliates nationwide, we represent a growing movement of Americans who promote mental wellness for the health and well-being of the nation.

- Nearly a century old, this organization is committed to supporting the development of a healthcare system that's based on and responsive to the latest research, clinician expertise, and consumer values.

- As an organization, we support many of the FDA actions and initiatives which help align the agency with the key recommendations contained in the recent Report of the Institute of Medicine. These include:

    - strengthening the science supporting and underlying the FDA's medical product safety system at every stage of the product life cycle;
    - improving communication and information flow among all stakeholders engaged in promoting the safe and appropriate use of medical products; and,
    - enhancing internal operations and management to ensure implementation of the review, analysis, consultation, and communication systems and processes needed to strengthen the U.S. drug safety system.

- <u>However, I am here today on behalf of Mental Health America to offer a number of specific recommendations for the FDA with respect to the reauthorization of PDUFA,</u> aimed at protecting people and families with mental health needs. We hope our recommendations will help inform decisions to promote transparency and enhance drug safety.

- First, we believe that the FDA must retain ultimate authority and control over the allocation of resources within the agency. Such flexibility allows and promotes timely response to the latest research, adverse event reports, and public health trends. We also believe the FDA should have the ability to require companies to conduct research on specific aspects of safety or efficacy, even after a

medication or device has received initial approval. Scientific knowledge is constantly evolving, and the activities and priorities of the FDA should be influenced and modified by the most current information, clinical data and research available.

- Second, consumers must be "at the table" in a meaningful way at every stage of the review process. Their experience, perspective and knowledge is valuable and vital -- from pre-market testing and development through post-market surveillance.

    - The FDA's Office of Special Health Issues does an excellent job of serving as a channel through which patient issues and viewpoints can be brought to the attention of FDA medical and regulatory staff.
    - It has been an extremely valuable experience for consumers with cancer and HIV—whose treatment needs are unique—to have a voice in FDA's decision-making process.
    - We'd suggest that the FDA expand the Office of Special Health Issues to include consumers in the drug review process for other serious and life-threatening diseases – and we'd recommend that resources be specifically allocated to support these efforts.

- Third, we welcome the commitment, contained in the proposed reauthorization, to expand the review of direct to consumer advertisements for pharmaceutical products. While such ads can help inform the public about specific disorders and the availability of treatment, recent research

indicates that they often tend to overemphasize benefits while minimizing potential risks and side effects. This is an area which clearly needs more oversight from the FDA.

- And finally, we believe the FDA has an obligation to monitor the impact of their actions on public health and access to care, and to revisit specific decisions when and if warranted by subsequent data and research findings.

- We believe that, if implemented, these recommendations would represent a significant step towards improving health outcomes, especially for the thousands of individuals living with mental illness in our country. Thank you for this opportunity to present the views of Mental Health America.