



CONSORTIUM FOR CITIZENS
WITH DISABILITIES

FAULTY PRESCRIPTION DRUGS AND MEDICAL DEVICES CAN DIMINISH HEALTH THAT CAN CONTRIBUTE TO DISABILITY

Medical devices and prescription drugs need to be assessed for risks and benefits throughout their life cycle.

A forum was held at the Center for American Progress entitled “Protecting America from Unsafe Drugs and Medical Devices.” Presenters addressed issues related to the U.S. Food and Drug Administration (FDA) and the tort system involved with enforcement of FDA regulations.

Summary

The mission of FDA is to protect the public health with vigorous oversight and enforcement to ensure medical interventions are as safe as possible. The consequences can be lethal if the FDA fails to fulfill this mission through enforcement. The tort system is part of the enforcement system to protect the public from unsafe prescription drugs and faulty medical devices. If the FDA is effective, it may reduce stress on the tort system. Some the issues raised at the forum as barriers to fulfilling its mission were: 1) the agency needs more authority to regulate devices (The Medical Device Safety Act), 2) agency workforce is understaffed, and 3) there is undue influence from industry.

Disability Prevention Issue

Medical devices and drugs need to be assessed for risks and benefits throughout their life cycle. The medical device industry has been shielded from this responsibility that protects consumers after approval of drugs and devices through disclosure of newly discovered risks to physicians and consumers. An effective FDA can assist with the prevention of a host of chronic health conditions, which consume 70% of acute health care costs and prevent diminished health that can contribute to disability.

Activity

A letter was written that confirmed post-forum discussions with a forum panelist who directed a public policy center on the tort system of FDA, and affirmed that the essential aspect for protection of the public from faulty drugs and devices was an effective FDA.

Principle

The Food and Drug Administration should be provided with resources and authority to make it an effective agency that protects the public from faulty drugs and medical devices.