THE ALLIANCE FOR DRUG SAFETY AND ACCESS

What is the Alliance for Drug Safety and Access?

The Alliance for Drug Safety and Access (ADSA) is a coalition of patient and provider groups working together to ensure access to safe and effective new therapies, matched with increased authority and resources for the Food and Drug Administration (FDA) to protect patient safety post-approval.

Why is ADSA needed?

No one stands to benefit or lose more than patients when it comes to legislation that will affect the speed of drug approvals and the safety of approved products for the next five years and beyond. Yet, to date, the input of patients and the providers who care for them into the user fee and drug safety debate has been limited. Through ADSA, patients and providers can join together to demand both speed and safety when it comes to accessing critical drug therapies.

Who are ADSA's member organizations?

AIDS Treatment Action Coalition, American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, American Psychiatric Association, Christopher Reeve Foundation, Elizabeth Glaser Pediatric AIDS Foundation, National Multiple Sclerosis Society, National Organization for Rare Disorders (NORD), Parkinson's Action Network, Tourette Sydrome Association, and United Leukodystrophy Foundation. We invite any other interested patient or provider groups to join us.

How many patients and providers does ADSA represent?

ADSA members advocate on behalf of over 31 million patients, including those suffering from HIV/AIDS, Parkinson's disease, spinal cord injuries, paralysis, multiple sclerosis, leukodystrophies, Tourette Syndrome, and over 6,000 known rare diseases. Our members also represent over 100,000 providers of care to pediatric patients and individuals with mental illnesses.

What is ADSA's position on drug user fees and post-market safety reforms?

ADSA supports:

- Reauthorizing the Prescription Drug User Fee Act (PDUFA) as a vehicle for speeding patient access to safe and effective new drug therapies;
- Increasing user fees to sufficiently fund needed post-market safety activities;
- Providing FDA with the authority to require post-market studies;
- Providing FDA with the authority to mandate changes to drug labels to reflect new safety information
- Creating a mandatory and publicly accessible registry of clinical trials and their results;
- Requiring FDA approval of all drug advertisements before dissemination; and
- Giving FDA flexible enforcement tools to ensure compliance with these new safety protections.