

FDA Safety and Innovation Act signed by Obama

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Singapore: The US food and drug administration (US FDA) Safety and Innovation Act has been signed by President Barack Obama. It includes the most groundbreaking measures for rare disease patients and their families since the Orphan Drug Act of 1983.

As the long-standing and recognized policy leader and advocate for the rare disease community, the national organization for rare disorders (NORD) was instrumental in developing and shaping this legislation that includes provisions essential to patient access to safe and effective health care, issues critical to the rare disease community.

Dr Peter L Saltonstall, president and CEO, NORD, said that, "This legislation represents true progress for people with rare diseases, who often face many struggles accessing treatments for their disorders. Our heritage, understanding, leadership and commitment to the community uniquely position us to best understand the complexities and needs of people and organizations in the rare disease space. Today's approval adds to NORD's 30-year history of driving landmark legislation, which would not have been possible without the sustained efforts of our members and policy partners."

Established in 1983 by patient advocates who successfully enacted the Orphan Drug Act, NORD has been an integral part of the development of the FDA Safety and Innovation Act since 2010. The Act will provide more than \$6 billion in industry user fees to the FDA over the next five years to fund a share of the agency's review of drugs and medical devices.

Specific to the rare disease patient community, the Act provides accelerated patient access to new medical treatments; will lead to the development of humanitarian use devices, or medical devices for small patient populations; will lead to accelerated development of "breakthrough therapies"; will lead to enhanced consultation with rare disease medical experts.

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The act is a rare pediatric disease priority review voucher incentive program and addresses concerns related to conflict-of-interest regulations for advisory committee members.

Dr Saltonstall.further said that, "We are grateful for the hard work and input our member organizations and policy partners have contributed over the past two years-raising awareness among Congress, the FDA and the National Institutes of Health. NORD looks forward to continued collaborations and to support the issues that deeply affect the rare disease community."