



Assistant Secretary for Legislation
Washington, DC 20201

JAN 06 2026

The Honorable John Thune
Majority Leader
United States Senate
Washington, DC 20510

Dear Senator Thune:

I write to inform you of the views of the Department of Health and Human Services (HHS) on H.R. 1262, a bill titled the "Mikaela Naylor Give Kids a Chance Act".

The bill aims to accelerate the development of pediatric cancer treatments along with several other goals to improve the health of Americans. The Department of Health and Human Services (HHS) is supportive of this legislative package as the provisions related to pediatric and generic drug development would result in new treatments for rare diseases, and increased availability of more cost-effective generic drugs. Additionally, the provisions related to the Organ Procurement and Transplantation Network (OPTN) would support improvements to the organ procurement and transplantation system in the United States.

Rare diseases and conditions as defined by the Orphan Drug Act generally affect less than 200,000 people in the United States. Most of these diseases and conditions currently have no approved treatments. However, with recent scientific developments and the Food and Drug Administration's (FDA) commitment to help foster the development of new and innovative medical products to treat rare diseases that were previously considered incurable, there is hope that someday FDA-approved therapies will be available to patients to treat the many rare diseases that currently have no cure.

The rare pediatric disease (RPD) priority review voucher (PRV) program aims to incentivize drug development for rare pediatric diseases by awarding priority review vouchers to sponsors of certain approved rare pediatric disease product applications. Although FDA continues to consider RPD designation requests, these designations will not be meaningful unless the program is reauthorized. HHS strongly supports reauthorization of the RPD PRV program through September 30, 2029 as proposed in Section 5.

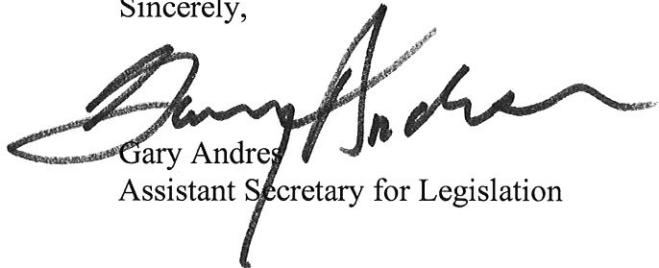
In addition to the FDA-related sections of the bill, I also note that Section 8 ensures the Health Resources and Services Administration (HRSA) has the authority to have direct oversight over the collection, distribution, and use of the fees which will enable HRSA to support multiple OPTN vendors with the goal of ensuring a fair, transparent, and effective organ procurement and transplantation system. Permanent authorizing language will help maintain the reforms Congress

envisioned when passing the Securing the U.S. Organ Procurement and Transplantation Network Act (P.L. 118-14).

We have provided technical assistance in several areas to improve clarity and ease implementation. We look forward to working with Congress to direct the cost savings toward deficit reduction on this important piece of legislation.

The Office of Management and Budget has advised that, from the standpoint of the Administration's program, there is no objection to the submission of this letter. I am sending an identical letter to the Minority Leader.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary Andres".

Gary Andres
Assistant Secretary for Legislation