
42 U.S. Code § 284m

Program for pediatric studies of drugs

(a) List of priority issues in pediatric therapeutics

(1) In general

Not later than one year after September 27, 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs, biological products, or indications that require study. The list shall be revised every three years.

(2) Consideration of available information

In developing and prioritizing the list under paragraph (1), the Secretary—

(A) shall consider —

- (i) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;
- (ii) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, and identification of biomarkers for such diseases, disorders, or conditions, may be beneficial in pediatric populations; and
- (iii) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators; and

(B) may consider the availability of qualified countermeasures (as defined in section 247d–6a of this title), security countermeasures (as defined in section 247d–6b of this title), and qualified pandemic or epidemic products (as defined in section 247d–6d of this title) to address the needs of pediatric populations, in consultation with the Assistant Secretary for Preparedness and Response, consistent with the purposes of this section.

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