AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 024
(A-22)

Introduced by: Michigan

Subject: Pharmaceutical Equity for Pediatric Populations

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Whereas, Legislation has aimed to increase the quality of evidence from clinical trials in children, 50 percent of pediatric drugs and an even greater portion of neonatal drugs are used “off-label;" and

Whereas, There are significant discrepancies between the number of drugs developed and approved for use in children compared to adults; and

Whereas, The average start-up time for pediatric drug trials is 12-16 months compared to six months for adult drug trials and the average duration of a pediatric drug trial is 15 years compared to 8-10 years in adult trials; and

Whereas, There is an average lag time of 5-10 years between a drug’s approval for adults and the addition of pediatric-specific labeling information; and

Whereas, 60 percent of pediatric drug trials stall and 40 percent of pediatric drug trials fail; and

Whereas, Historically off-label prescribing has had harmful effects on children, such as Verapamil causing hypotension and death, or Chloramphenicol causing circulatory collapse, also known as “gray baby syndrome;” and

Whereas, The Pediatric Research Equity Act and Best Pharmaceuticals Act for Children are designed to protect children; and

Whereas, The exemption of necessitating pediatric trials for “orphan drugs,” which are those indicated for the treatment of diseases that affect fewer than 200,000 individuals, creates a loophole for pharmaceutical companies that compromises the quantity and safety of available drugs that can be used in children; and

Whereas, The Institutional Review Board (IRB) is generally unlikely to approve clinical trials involving children if the drug of interest can be tested on adults; however, the physiologic differences between these groups can have a significant impact on pharmacokinetics and pharmacodynamics; and

Whereas, Extrapolating efficacy from adult to pediatric populations can streamline pediatric drug development and help to increase the number of approvals for pediatric use, implicit extrapolation of data (i.e. off-label use, without investigation) can have harmful effects on children; and

Whereas, The Institute for Advanced Clinical Trials (I-ACT) for Children is an independent 501(c)(3) public-private collaboration, funded by membership, a Food and Drug Administration (FDA) U18 grant, and donations that is dedicated to improving the efficiency and success of pediatric drug trials, leading to the development of innovative therapeutic solutions and improvement in the health outcomes of children; and

Whereas, I-ACT for Children improves pharmaceutical equity for children by connecting pediatric experts, sites, and other resources needed to conduct efficient clinical trials to clinical trial sponsors and stakeholders; and

Whereas, In 2020, I-ACT for Children was able to design an adaptive platform trial for Duchenne Muscular Dystrophy allowing multiple potential drugs to be tested in parallel, advocated for the inclusion of adolescents in adult clinical trials and planned pediatric studies targeting development of COVID-19 vaccination and treatment; and

Whereas, I-ACT for Children holds collaboration agreements with sites across the United States, Central and South America, Saudi Arabia, South Africa, Australia, Europe, Canada, and Japan allowing for expansive patient recruitment so that trials can reach enrollment goals faster, accelerating study startup; and

Whereas, Our AMA already supports policies regarding FDA surveillance of clinical trials to maintain proportional representation of women and minority groups, including consideration of pediatric and elderly populations; therefore be it

RESOLVED, That our American Medical Association amend Policy H-100.987, “Insufficient Testing of Pharmaceutical Agents in Children,” by addition to read as follows:

Insufficient Testing of Pharmaceutical Agents in Children H-100.987

1. The AMA supports the FDA's efforts to encourage the development and testing of drugs in the pediatric age groups in which they are used.
2. <u>The AMA supports collaboration between stakeholders, including but not limited to the FDA, the American Academy of Pediatrics, and nonprofit organizations such as the Institute for Advanced Clinical Trials for Children, to improve the efficiency and safety of pediatric pharmaceutical trials in pursuit of pharmaceutical equity for pediatric populations.</u> (Modify Current HOD Policy)

Fiscal Note: Not yet determined

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Sources:

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RELEVANT AMA POLICY

Insufficient Testing of Pharmaceutical Agents in Children H-100.987

The AMA supports the FDA's efforts to encourage the development and testing of drugs in the pediatric age groups in which they are used.

Citation: Sub. Res. 17, I-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmed: CSAPH Rep. 01, A-18