C-Path to Lead Multi-Stakeholder Engagement on FDA's Proposed Novel Framework to Enhance the Pediatric Medical Device Ecosystem

TUCSON, Ariz., March 17, 2020 — The Critical Path Institute (C-Path) today announced it has been awarded a grant to conduct stakeholder engagement to garner insights, feedback and refinement of the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health's (CDRH) proposed framework to enhance the pediatric medical device ecosystem and to develop a strategic plan for implementation. Funded by a cooperative agreement through the FDA, C-Path will work in collaboration with CDRH and other stakeholders to organize a workshop to brainstorm on the framework and strategic plan for building a viable ecosystem.

"We are thrilled to be part of this effort and honored to have been selected to work with CDRH to optimize the ecosystem," said C-Path President and CEO Joseph Scheeren, Pharm.D. "This initiative has our full support and fits in well with our ongoing efforts in the pediatric and neonatal space."

Currently, there are challenges to advancing promising new pediatric devices from ideation to clinical studies, to regulatory approval, to use for pediatric patients, including:

- The small numbers of children with any one condition, and their dispersion across the world, making it difficult to conduct clinical trials;
- The need to consider children's growth and variably influenced disease mechanisms;
- The lengthy development timeline and associated high costs;
- Lack of funding for small inventors and companies;
- Difficulty in identifying expert resources across the development-to-commercialization continuum.

Modernized regulatory programs and processes developed by CDRH during the past few years have supported a growing number of novel technologies available to improve patient care. In the pediatric area, CDRH has led a public meeting where challenges to innovation were verified and aspects of a supportive ecosystem were discussed. Additionally, CDRH has finalized guidance documents clarifying regulatory issues relevant to pediatric populations and provided millions of dollars to fund pediatric device consortia across the U.S. However, over the past decade, fewer than 10% of high-risk and high-benefit medical devices have been designed, evaluated and labelled for children below the age of 18.

"Today's health care system has yet to engender a solution to the complex public health issue of medical device development for children and small populations," said CDRH Chief Medical Officer and Director for Pediatrics and Special Populations Vasum Peiris, M.D., M.P.H. "Novel regulatory options and public-private sector collaboration informed by patient and caregiver perspectives are necessary components to create a sustainable national environment for safe technology innovation that serves the unique needs of children. We welcome input from all stakeholders as we clarify and build on the framework CDRH has proposed to transform traditional thinking around engaging, sustaining and innovating in the pediatric medical device ecosystem."

Stakeholder groups including the Advanced Medical Technology Association (AdvaMed), the American Academy of Pediatrics (AAP), the Milken Institute, and clinicians, researchers, innovators, payors and patient groups will review and refine the high-level proposed framework developed by CDRH. The framework lays out a vision for an ecosystem that would facilitate the design, development and commercialization of medical devices for children. Through stakeholder input and feedback the framework will be iterated and refined, and goals for the yet to-be-formed multi-stakeholder workgroup –

whose objective would be to optimize and complete the design of the ecosystem – will be established.

“There is an opportunity for the FDA, patient advocacy groups, academia and industry to collaborate and optimize design — with the guidance and support of C-Path — of this much needed ecosystem,” said AdvaMed Vice President for Technology and Regulatory Affairs Tara Federici. “Stakeholders will review and evaluate the proposed framework to ensure it could be effective in de-risking and accelerating pediatric medical device development while maintaining existing safety and effectiveness requirements.”

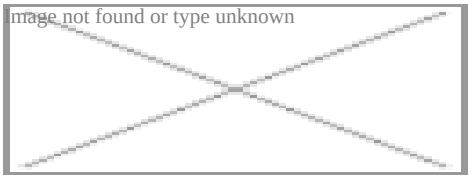
“Children are not small adults — their biology is different. Even so, every day across the nation, the care of children requires the use of many medical devices that were not specifically designed for them,” said Kurt Newman, M.D., President and CEO of Children’s National Hospital and immediate past Chair of the Board of Trustees of Children’s Hospital Association. “Children should be a priority when it comes to healthcare innovation because entire lifetimes are at stake. We commend and support the FDA’s leadership in this effort to create a system that supports innovation for children.”

“Pediatricians often find themselves without the medical or surgical devices they need to care for their patients because medical devices for children can lag five to ten years behind those for adults,” said American Academy of Pediatrics CEO and Executive Vice President Mark Del Monte, J.D. “That time frame is most of an entire childhood. We must do more to get children the devices they need sooner, and innovation is essential to enhance safe and effective options. We applaud those who have come together with that goal in mind and look forward to working with the FDA, C-Path, and other stakeholders to advance device development for children.”

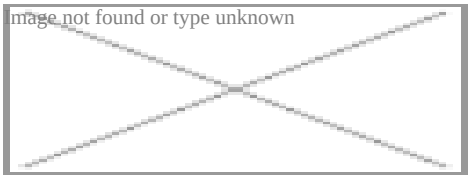
“It is essential to shift the balance of device innovation toward fulfilling the vast unmet needs of children,” said Christopher Lee, former Director of the Milken Institute Center for Financial Markets and co-chair of the FasterCures BRIDGE Initiative, a recently launched program that develops novel models for driving biomedical innovation. “This proposed framework seeks to take this challenge head on by realigning incentives across the system, and we look forward to contributing to that process.”

The project’s initial deliverable, to bring together interested stakeholders to share insights and further refine and develop the proposed framework at the workshop, will occur in the latter part of this year. Specific dates, location, and registration information for the meeting will be released soon. Meeting proceedings and a strategic development plan to enhance the pediatric medical device ecosystem will be developed within six months of the workshop.

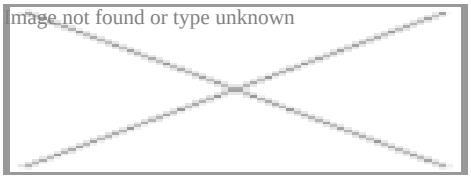
This grant is funded by a cooperative agreement through the FDA [Critical Path to Public Private Partnerships Grant Number U18 FD005320]; the grant is administered by the Center for Drug Evaluation and Research (CDER); this project is funded by the Center for Devices and Radiological Health (CDRH). Views expressed in written materials or publications do not necessarily reflect the official policies of the U.S. Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.



About Critical Path Institute
Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 as a public and private partnership. C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established numerous global consortia that currently include more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path US is headquartered in Tucson, Arizona and C-Path, Ltd. EU is headquartered in Dublin, Ireland, with additional staff in multiple other locations. For more information, visit c-path.org and c-path.eu.



About AdvaMed
AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. For more information, visit advamed.org.



About the American Academy of Pediatrics
The American Academy of Pediatrics (AAP) is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents and young adults. For more information, visit aap.org and follow us on Twitter @AmerAcadPeds

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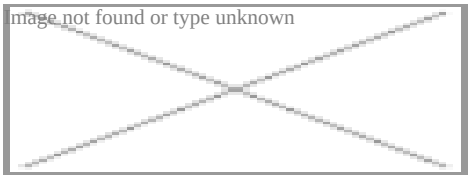
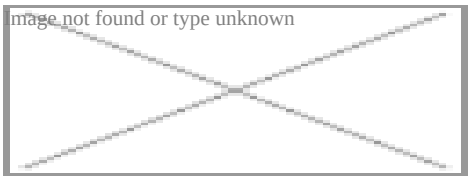


About Milken Institute
The Milken Institute is a nonprofit, nonpartisan think tank that helps people build meaningful lives, in which they can experience health and well-being, pursue effective education and gainful employment, and access the resources required to create ever-expanding opportunities for themselves and their broader communities. FasterCures is a center of the Milken Institute, with a mission to put patients in the center of the healthcare system, and break down the unnecessary barriers to

innovation. For more information, visit milkeninstitute.org.



About FDA

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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