Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation (CERSI)
B12 Pediatric Device Survey

Phone (or video call)

Introduction: *Hello, my name is _____. I am with an independent research group based at Yale University calling on behalf of the U.S. Food and Drug Administration (or FDA). We are affiliated with the* ***Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation, and are today*** *conducting a study on pediatric medical device development. You have been identified as a thought leader in this field and we hope to learn from your insights and experiences. Your responses will be incorporated with those from others we are interviewing and presented, in aggregate form, in a report to the FDA. We greatly appreciate your time in discussing these matters; this survey should take no more than 30 minutes.*

May we record your responses? Your answers will be recorded for research purposes, but never attributed to you as an individual.

If asked about relationship with the FDA: *We are undertaking this research with funding and support from the FDA's Center for Devices and Radiological Health because of its regulatory relevance. [If applicable: We were provided with the names of some leaders in the field to reach out to, including yours.] The FDA will not be involved in the analysis of any of the primary data collected in the course of this study.*

A. State of the Pediatric Marketplace

Introduction: *We will begin with several general questions about the current state of the process for developing and bringing to market pediatric medical devices. We will then turn to more specific concerns, opportunities, and policy alternatives that are relevant for pediatric devices.*

1. **Let's begin with the most recent pediatric device project that you worked on that you considered bringing to the FDA for review or actually submitted for review.**

    a. **Would you mind providing a quick overview of that experience, sharing what worked well in any of the stages of that process?**

    b. ***That's great to hear what went well.*** **In retrospect, what do you wish had gone better or differently in that process?**

    c. **Now thinking back to other pediatric device projects in which you have been involved, have you noticed any important changes since the earliest of these projects and this most recent project that you just described.**

    d.

B. Transition

Introduction: *We're now going to move onto discussing the barriers to pediatric device development. In addition to these questions that we are asking over the phone, we have designed a quick web survey, that will allow you to rank and quantify the importance of some of the factors that influence pediatric device development and review. If you have not already completed that survey, we will provide you with a survey link via email.*

For the questions that follow we are interested in your general thoughts and experiences about these factors that influence pediatric device development.

C. Barriers to Development

1. **In your experience, what have been the 2 most consequential barriers to developing products for the pediatric population?**

    a) **Barrier #1**: What have been the most effective ways of dealing with this barrier?

    b) **Barrier #2**: What have been the most effective ways of dealing with this barrier?

2. **What, if anything, has been traditionally viewed as a barrier within the industry, but you think is becoming less of an impediment over time?**

D. The Role of the FDA

Introduction: *As you may know, the FDA is shifting to a Total Product Lifecycle approach to device regulation that emphasizes collection of information about efficacy and safety throughout the premarket and post-market process. We would now like you to consider several policies or practices that the FDA might pursue to foster this goal.*

1. **Under what circumstances is it worthwhile to the device developer to have FDA approval or clearance for pediatric use of a medical device?** *(as opposed to receiving approval for an adult device and allowing off-label use to occur)*

2. **Have there been particular changes in FDA practices or policies for the process of pediatric medical device approval that stand out to you as important successes or failures that deserve to be better understood in the industry**?

3. **How would you assess current understanding among key stakeholders and the FDA about the state of off-label use of medical devices in children?**

4. **What do you see as the advantages and disadvantages of a registry that would track off-label device use in children?**

5. **How could the FDA be a better partner to the medical device industry in facilitating the approval and clearance of devices for children?**

6. **How can the FDA position itself to help set priorities for newly developed pediatric medical devices?**

7. **What benefits might emerge from having the FDA develop a coordinated initiative with NIH and CMS regarding the initial funding of research and the eventual coverage of FDA-approved devices for pediatric use? What challenges might such an initiative face?**

8. **What benefits might emerge from creating a national initiative enhancing the capacity of centers where pediatric devices are implanted to prepare for and respond to future pandemics? What challenges might such an initiative face?**

9. **Are there any other aspects of off-label use of pediatric devices or the FDA's practices related to the development and review of pediatric devices that we have not yet addressed here but are important to consider?**

E. Conclusion

Introduction: *That concludes our questions.*

Thank you for taking the time to speak with me today; we greatly appreciate your insight.

All your responses will be reported without attribution to you as an individual, but we would like to offer the option of being acknowledged as a contributor to our final report. Would you be interested in being acknowledge in this way?