AIMBE's FDA Scholars Program

Advancing innovation and discovery from the lab to the marketplace.

Spotlight on the 2017-2018 AIMBE Scholars

Dr. Mary Clare McCorry

Prior to my experience as an AIMBE Scholar, I spent most of my professional career as a researcher in academia. Through the years I gained what I thought to be a diverse experience. My research was highly interdisciplinary and translational. I worked and collaborated across scientific fields as well as scientific industry sectors, interacting closely with industry, medical clinicians, veterinarians, engineers, and biologists. Despite the translational qualities of my research, my experience was limited to early phase research and development. After finishing my PhD, I wanted to be a part of bring highly innovative technologies to market. However, as a graduating PhD student I realized I was essentially playing a game that I did not know the rules to. Having spent most of my career working to develop the technology, I had a very limited knowledge of how to bring that product to market and how knowledge of that process can inform early technology development. Through the AIMBE Scholarship program, my goal was to learn not just the rules of the game, so to speak, but how these rules are made, enforced, and evolve over time.

My AIMBE project was with the program for Pediatrics and Special Populations in Office of the Center Director (OCD) at Center for Devices and Radiological Heath (CDRH) where I worked to organize and lead the development of projects associated with the Pediatric Medical Device Development Public Meeting that was hosted by FDA in August of 2018. In August of 2017, Congress passed the Food and Drug Administration Reauthorization Act (FDARA). One of the Congressional requests was for FDA to gather key stakeholders in the pediatric medical device field for a public meeting to discuss solutions to barriers for pediatric medical device development. Developing and approving devices for pediatric use can be challenging since most pediatric populations are relatively small, especially compared to the adult population. These small pediatric populations present unique challenges in obtaining sufficient clinical evidence to support a marketing application. Furthermore, companies often perceive pediatric device development as prohibitively expensive or companies are dis-incentivized by a low return on investment (ROI). This results in a disproportionate development of devices for adults compared to pediatrics.

In preparation for the public meeting, I coordinated content and agenda development working groups both internal and external to FDA. The internal working group included pediatric leadership within CDRH as well as other Centers across the Agency. To better understand industry needs and concerns, extensive collaboration was required with industry representatives, both small and large, as well industry trade organizations, such as AdvaMed which has a dedicated pediatric working group. The CDRH's Pediatric Team also worked with the American Academy of Pediatrics (AAP), which lobbies on behalf of pediatricians, to gain insight on the physician perspectives and the legislative history of pediatric medical devices. Furthermore, we engaged internally with FDA's economics team as well as externally with investors and academic experts, to gain insight on the pediatric medical device market and associated concerns about low return on investment for pediatric devices. Through the process of developing the content and agenda for this meeting, I was able to engage with leaders across the ecosystem to address three key areas: optimizing evidence generation, creating regulatory value and simplicity, and developing a supportive marketplace.

In the medical device field, innovators, physicians, regulators, investors, and companies are aware of the relative dearth of pediatric medical devices compared to adults; however, there is a lack of quantifiable evidence to support this claim. In my time as a scholar, I investigated trends in medical devices indicated for use in pediatrics. I examined the three medical device evaluation pathways for innovative devices: Premarket Approvals (PMAs), Humanitarian Device Exemptions (HDEs), and De Novos. Data trends in pediatric approvals over the last decade are linked to historical legislation and regulatory actions. While pediatric device approvals have been increasing, the increase has been proportional to the overall rise in innovative device approvals. Over the last decade, only a quarter of device approvals are indicated for use in pediatrics. The retrospective data analysis that I conducted was presented at the Pediatric Medical Device Development Public Meeting. This presentation helped set the stage for future talks at the meeting which sought to clarify some of the challenges to getting medical devices developed and approved for pediatrics as well as potential incentives and methods to overcome these challenges.

Through my experience as an AIMBE scholar, I gained invaluable insight into not just the regulatory process but a greater understanding of the broader medical product ecosystem. I learned how regulatory process and decision-making influences the market from early stage discovery and ideation to post-market monitoring. Furthermore, as an AIMBE scholar working in OCD, I was able to interact and engage with leadership at the highest levels of the Agency. I am incredibly grateful for the opportunity to be an AIMBE scholar and my time at the FDA will be highly informative as I progress through my career. I look forward to applying the skills and experience I gained through this program in my future position where I will be working to scale-up and translate innovative technologies and shaping regulatory policy and standards that keep pace with these highly innovative medical products.