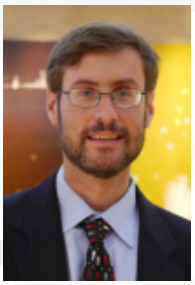
AIMBE's FDA Scholars Program

Advancing innovation and discovery from the lab to the marketplace.

Spotlight on the 2015-2016 AIMBE Scholars



Dr. Douglas Dumont

Science-for-health policy. Health policy-for-science. Regulatory science. And regulatory policy.

As a graduate student in biomedical engineering, I would occasionally come across one or more of those phrases in a news article. I would usually skim over the rest of the article, because for the most part, science and policy to me were two entirely separate worlds. Sure, I knew that in some abstract sense, research and science somehow filtered upward to inform health and regulatory policy, and that health and regulatory policy somehow filtered back downward to guide research, but it never felt "real" to me.

What was "real" to me as a graduate student was the research that was directly in front of me on the bench, the conferences that I attended to both share my work and learn from others, and the occasional free food offered at graduate student programming events. Health and regulatory policy were very much abstract ideas, black boxes that existed in some virtual place outside the very real world of graduate school.

Most graduate students in my field tend to go onto very successful careers as either professors in academia or engineers in industry, and I probably would have followed them if I had not come across a flyer advertising a STEM policy workshop in Washington, DC hosted by Vanderbilt University. I applied to the workshop on a whim and was fortunate enough to be selected. While the workshop was only the briefest of introductions to the world of science and health policy, it lifted the veil enough to catch my interest, both with helping me better understand the connection between science and policy and seeing policy as a potential career path. A few weeks later, a colleague forwarded me the announcement for the AIMBE Scholars program; I read it with great interest and I applied because I was curious in learning more about what goes on behind the Federal policy

curtain and seeing if science-policy was a potential career path for me to use my scientific training to make a greater impact on healthcare.

I cannot imagine a better introduction to the intersection between science and health policy than the AIMBE Scholars program at the Food and Drug Administration. At the AIMBE Public Policy Institute, I learned about health policy-making at the Executive and Legislative Branch levels, the FDA's budgetary process, the role that coalitions and trade associations play in policy-making, and how both FDA and Industry approach regulatory science and policy to improve healthcare. And every day in my role as an AIMBE Scholar, I find myself gaining a new appreciation of how science and regulatory policy intersect to help ensure that patients have access to safe and effective medical devices.

My AIMBE Scholar placement is in the Office of Surveillance and Biometrics (OSB) within the Center of Devices and Radiological Health. My specific AIMBE Scholars project helps OSB and CDRH work with stakeholders to begin establishing a multi-stakeholder national system that uses real-world evidence to better understand device performance and safety.

Every day, large amounts of healthcare data—i.e "Big Data"—are generated during routine clinical practice. The overall goal of the system is to improve patient healthcare by leveraging data to support patient-centric decision-making, including providing real-world evidence to patients and providers to help inform treatment decisions; using real-world evidence to understand how new devices or new uses of existing devices perform; and lowering the cost of evidence generation to guide future device innovation and improve patient access to safe and effective devices.

Most of my work in this area focuses on CDRH's 2016-2017 Strategic Priority to increase CDRH's access to real-world evidence and the use of real-world evidence in pre-market and post-market decision-making. I worked with a number of colleagues both in OSB and in other CDRH offices on Cross-Center workgroups to support and implement the Priority. I also worked with external colleagues to help convene and support a multi-stakeholder board tasked with developing recommendations for the national system.

I feel very grateful and fortunate to have been selected as an AIMBE Scholar. I have found the program to not only be personally rewarding but the support I have received from AIMBE, the FDA, and colleagues in industry and academia has been invaluable in encouraging me to explore this career path. My experience has convinced me that regulatory policy is the right career path for me and I am excited at beginning a career that allows me to leverage my scientific training to create better policy that can positively impact patient care.