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”And Now for Something Completely Different” – A Faculty Sabbatical in Public Policy

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"And Now for Something Completely Different" – A Faculty Sabbatical in Public Policy

Introduction

The title phrase,[1] coined and made popular by Monty Python, uniquely describes the transition from engineering educator to public policy participant for a biomedical engineering faculty member partaking in a one-semester public policy sabbatical at an honorific and advocacy organization in Washington, DC. A major goal of the sabbatical was to work with a biomedical engineering advocacy organization to learn about public policy issues related to the field and use this knowledge to develop congressional briefings aimed at increasing federal funding for medical research. In addition, due to the proximity of numerous federal agencies and nonprofit organizations, a second goal was to attend relevant meetings, workshops, and briefings in the Washington, DC area associated with engineering and public policy.

The National Academy of Engineering (NAE) recognizes the need for engineers to have an understanding of the public policy implications of the technologies they create.[2] Even more desirable, according to the NAE,[2] is the engagement of engineers in the public policy arena to provide sound scientific data on which policy makers can base legislation or regulation and to inform the public of the role of engineering and its value to the economic vitality of the country.

Most undergraduate biomedical engineering students are exposed to public policy in their capstone design or other required course in the form of the Food and Drug Administration (FDA) Quality System Regulation (QSR)[3] related to the design and marketing of medical devices. Biomedical engineering students, either through coursework or research, may also be exposed to the federal regulations regarding the use of animals[4] or humans as research subjects,[5,6] either in research or in the testing of medical devices. Students may not, however, gain perspective on their ability to contribute to the development of these standards and regulations as a member of the engineering community.

Public Policy Sabbatical

Host Organization

The host organization for the sabbatical was the American Institute for Medical and Biological Engineering (AIMBE). AIMBE is a nonprofit organization which is made up of four pillars representing the medical and biological engineering community: the College of Fellows, the Academic Council, the Industry Council, and the Council of Societies. Individual membership in AIMBE is obtained by election to the Council of Fellows, whose ranks represent the top 2% of leaders in the medical and biological engineering fields. The Academic Council is made up of institutions that have educational programs related to the medical and biological engineering fields, usually undergraduate and/or graduate programs in biomedical engineering or bioengineering. The Industry Council and Council of Societies are made up of companies and professional/scientific organizations, respectively, having an interest in medical and biological products and research. The author is a member of the Council of Fellows and serves as representative for her institution on the Academic Council.

The primary mission of AIMBE is to provide advocacy for the role of medical and biological engineering in medical innovation and public health. Founded in 1991, AIMBE, along with the Academy for Radiological Research (ARR), was instrumental in the establishment of the National Institute for Biomedical Engineering and Bioengineering (NIBIB) at the National Institutes of Health.[7]

Current notable advocacy activities include a Scholars Program that places postdoctoral scholars into the Center for Devices and Radiological Health at the Food and Drug Administration (FDA), as well as a website to introduce prospective undergraduate and graduate students to educational opportunities and careers in the biomedical engineering field, and an Annual Event to educate its members about current policy issues. In addition to participating in workshops and events described later, I provided assistance to AIMBE to identify new educational institutions and technical societies as potential members of the Academic Council and Council of Societies, respectively.

Public Policy Institute

My foray into the public policy arena began with the AIMBE Public Policy Institute, a three-day extensive introduction to the public policy arena. The institute was designed to introduce new AIMBE Scholars and other postdoctoral fellows from the FDA to the public policy issues they were likely to face in their positions. Speakers from the administration, government agencies, nonprofit organizations, and industrial governmental affairs offices among others presented information related to current and future health policy topics. Included were a review of the lawmaking process as well as discussions of the federal budget process and the ongoing lack of regular order, the Affordable Care Act and the legal ramifications of the Supreme Court's Hobby Lobby decision, the role of nonprofits in advocacy and lobbying efforts, a discussion of regulatory science efforts at the FDA, and the role of scientists and engineering in public policy. The institute served as an introduction to the important health policy topics related to patient care, regulatory science, and funding for basic medical research.

Biomedical Engineering Policy Activities

Attendance at Congressional Briefings

My first event related to biomedical engineering policy was the Congressional briefing sponsored by the American Academy of Arts & Sciences to introduce their report entitled "Restoring the Foundation: The Vital Role of Research in Preserving the American Dream." This publication, written in response to the continual decline in federal support of basic research and concomitant decline in innovation and associated economic growth, calls for a new model of government-industry-university support of basic research and serves to provide policy makers with "prescriptions" by which the United States can regain its prominence in research and innovation.

I also attended two companion events sponsored by the Alliance for Eye and Vision Research (AEVR): a release event for the AEVR/Research!America poll on American attitudes toward vision loss and vision research and a Congressional briefing on Aging Eye Disease. The

AEVR/Research!America poll showed that across all demographics, loss of vision is a significant concern for Americans and that they support increasing federal research expenditures on vision research. The Congressional briefing on Aging Eye Health included a presentation on the mechanisms of macular degeneration and current research on treatments to slow the progression of this disorder.

Attendance at FDA Workshops

In order to better understand the process by which the FDA evaluates medical devices for safety and efficacy, I attended two workshops related to new technologies for which the FDA has not yet issued guidance documents. The purpose of the workshops was to meet with stakeholders such as industry, clinicians, and patient groups in an effort to understand the current state of the art in the industry as well as to understand the risk associated with the devices. Patient groups were invited to gauge the benefits desired by patients from the technologies and what risk may be acceptable to patients.

The first workshop topic was the use of additive manufacturing for production of medical devices. Several industry representatives, both from companies who develop the additive manufacturing equipment as well as those in the medical and aerospace industries who currently produce additively manufactured products, presented information on the capabilities of the technologies and benefits compared to traditional manufacturing. The workshop resulted in a list of questions of interest to the FDA, the answers to which will inform the agency on various aspects of additive manufacturing for the production of medical devices including cleaning and sterilization of the devices, reproducibility both within and between machines, potential leachability and toxicity of material additives, and changes in material properties during the manufacturing process.

The second workshop topic was on brain-machine interface devices and focused on devices for patients with either amputations or some degree of paralysis. Unlike the workshop on additive manufacturing that featured mostly industrial perspectives, the presentations were given by researchers in the field, therapists, and end users of any potential device. Questions of interest for this technology included what specific clinical endpoints are desired, how these devices should be tested prior to implantation into patients, and how modularity of the devices impacts both the regulatory process as well as the economic feasibility of these technologies.

National Institute for General Medical Sciences Strategic Planning Meeting

The National Institute for General Medical Sciences (NIGMS), one of the National Institutes of Health (NIH), is in the process of developing a strategic plan. NIGMS is the institute that supports basic medical research that may not yet be associated with diagnosis or treatment of a specific disorder. To assist in the strategic planning process, the institute director convened a meeting of representatives from seventeen scientific organizations that represent researchers funded by NIGMS-administered grants. I served as the representative from AIMBE at this meeting. Participants were sent a draft of the plan prior to the meeting and provided input to the director about the strategic objectives outlined in the plan.

The Society of Neuroscience Public Advocacy Forum

I also attended The Society for Neuroscience public policy forum held as part of its annual scientific meeting, Neuroscience 2014, at the Washington Convention Center. The forum, entitled "Implications for Science Funding in an Era of Global Brain Initiatives," included speakers from The Gatsby Charitable Trust and The Kavli Foundation, both private foundations supporting neuroscience research, as well as researchers from the United States and Japan who described their contributions toward the BRAIN Initiative and the Brain/MINDS project, respectively. The panelists described funding priorities and international efforts to understand the fundamental mechanisms of the brain.

STEM Policy Activities

Although my sabbatical goal included attendance at meetings and workshops related to biomedical engineering policy, the opportunity arose to participate in activities related to Science, Technology, Engineering, and Math (STEM) policy issues.

I served as the AIMBE representative for a workshop held by the National Academy of Engineering entitled "Workshop on Pathways for Engineering Talent." This workshop was organized by the NAE's Committee on Understanding the Engineering-Education Workforce Continuum. Attendees included members of the NAE, engineering educators, industry representatives, and public policy fellows. The goal of this workshop was to investigate the career paths of four-year engineering graduates and to delve into factors affecting the persistence of engineering graduates in engineering and other technical fields. Presenters included economists, sociologists, engineering recruiters, university and professional career counselors, and educational researchers. Information from this workshop, including that obtained from breakout session discussions, will be used to develop the committee's final report.

I also attended a Congressional briefing, sponsored by The Society for the Psychological Study of Social Issues, entitled "Psychological Perspectives on Women in STEM." Topics discussed included the leaky pipeline for females pursuing STEM careers as well as potential interventions that may help to increase the number of girls planning to pursue STEM careers as well as to decrease the number of girls and women who leave the pipeline at any time during their education and career.

Lessons Learned

The primary lesson learned during this sabbatical is the importance of communication in the advocacy process; specifically, the ability to engage nonscientific audiences, present data relevant to the issue, and, most importantly, provide a compelling story to which the audience can relate. Engineering educators must understand the need for students and graduates to communicate with both technical and nontechnical audiences and provide opportunities throughout the curriculum to learn and hone these skills. In communicating with nontechnical audiences, however, it is important to strike a balance between under hyping and overselling. Failure to communicate positive ramifications of one's work along with its results may lead to

the former while overstating the broad applicability and promise of the work may lead to the latter. Effective advocacy requires a balanced message.

I also became acquainted with the various federal agencies of relevance to biomedical engineers, the medical device industry, and the healthcare industry such as the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC). Both of these organizations are working to facilitate the use of Electronic Health Records (EHR) to improve healthcare. CMS offers incentives to healthcare providers to demonstrate meaningful use of EHR technology while a main focus of ONC is on establishing standards for interoperability between EHR systems. Related to these efforts are new regulations on the use of unique device identifiers (UDI) on medical devices which, along with EHR, could be used to track safety and efficacy of devices over their lifespan.

During my sabbatical, I also witnessed successes and failures of science and public policy during the Ebola outbreak. A patient with Ebola from West Africa, seen at the emergency room of a Texas hospital, was originally misdiagnosed. Some have suggested that the workflow related to the EHR may have been a factor in the clinician missing vital information related to the travel history of this patient. Another failure of science and public policy in this outbreak was related to the recommendations by the CDC for the proper personal protective equipment (PPE) required to safely treat Ebola patients and the assumption that any US hospital could safely treat these patients. Lack of training of clinical personnel and lack of access to the appropriate PPE pointed to failures of the public health system. The lack of coordination between state and federal officials led to disparate strategies for the reintegration of healthcare workers returning from West Africa. Successes of public policy in this outbreak included the significant resources in place supported by federal funding that allowed for transportation of patients in isolation via specially equipped aircraft and treatment of Ebola patients in specialized centers. My sabbatical experience has helped shape how I view the public health system and led to a better understanding of the promise and limitations of this system.

Contributions to Public Policy via Development of Congressional Briefings on Medical and Biological Engineering

Based on information learned from the AIMBE Public Policy Institute and other events I attended throughout the duration of my sabbatical, I worked with the AIMBE staff to propose a series of congressional briefings to highlight the contributions of medical and biological engineering in developing novel diagnostic and therapeutic technologies that can provide better patient outcomes or reduce healthcare costs. I proposed briefing topics of neuroengineering, tissue engineering and regenerative medicine, injury biomechanics, engineering the fight against cancer, medical imaging, and bioinstrumentation. My task was to identify AIMBE members having NIH funding in these topic areas to present these briefings to highlight the importance of federal funding of basic and applied research. Paramount in my decision process to select these speakers was their ability to articulate the nature of their research and its potential benefit with respect to the prevention, diagnosis or treatment of disorders well known to nontechnical audiences. These briefings will be further developed by AIMBE staff and delivered to Congressional staffers throughout this year during FY16 Congressional budget discussions.

Proposed Integration of Public Policy Topics into Biomedical Engineering Curriculum

Our undergraduate biomedical engineering curriculum already contains material related to public policy issues, although not explicitly defined as such to students. For example, our junior-level laboratory course contains a module on the use of humans and animals in research which traces the origins of legislation related to these issues and the relevant regulations involving Institutional Review Boards (IRB) and Animal Care and Use Committees (IACUC). This is followed by a senior-level laboratory where students perform experiments on human subjects after completing the process to obtain IRB approval. Finally, students are introduced to the FDA Quality Systems Regulations during the first semester of our two-semester senior capstone design sequence and follow the process outlined in the regulations as they complete their designs. Missing from the discussion of these important public policy issues is the role of engineers and scientists in the setting of these policies and regulations and how students themselves can participate in the public policy process. We propose to develop a module on engineering and public policy in our sophomore-level Foundations of Biomedical Engineering course, introducing these students to the FDA and the varied role of engineers in the regulatory process. We also propose to expand the module on the use of humans and animals in research which has previously been couched as a study of ethics. We will present additional detail on the development of the various legislation (National Research Act and Animal Welfare Act) related to these topics and describe the motivations surrounding the various amendments to these Acts. The role of engineers and scientists, including any relevant advocacy organizations such as FASEB, will be highlighted in these discussions. In the senior laboratory course, we propose to develop a module on the successful advocacy efforts of AIMBE and ARR in the establishment of the NIBIB at NIH.

Finally, we will introduce an additional public policy topic currently missing in our curriculum. As described previously, many biomedical engineering students are introduced to public policy in the form of FDA regulations for the review of medical devices prior to marketing. For a medical device company to be successful, however, approval/clearance of the device is not, in general, the final step in the product development/marketing process. Coverage of the cost of the device and related procedures by private insurers or Medicare is crucial for the acceptance of a device by medical practitioners and patients. The Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services performs its own scientific and economic review for devices intended for their patient populations, and, in general, private insurers follow the CMS lead in approving a device/procedure for coverage.[8] Biomedical engineering students should understand the importance of CMS/private insurers' procedures for evaluation of reimbursement and the role insurance plays in the success of a device in the marketplace. We will introduce a discussion of reimbursement of these costs through private insurers/Medicare in the second semester of our year-long capstone design course to augment the information provided in the first semester on the FDA QSR guidelines.

Opportunities and Challenges Related to Sabbaticals in Washington, DC

My view of public policy arena was from the perspective of a nonprofit whose primary mission was to advocate for federal funding of medical research, primarily via NIH. Thus, it was related to advocating to Congress the need to support the research programs of AIMBE members in

order to fuel medical innovation. Engineering faculty, however, can participate in public policy across its spectrum. The American Association for the Advancement of Science (AAAS) sponsors the most well-known fellowship program in Washington, placing engineers and scientists with doctoral degrees in positions across the legislative, executive, and judicial branches. Many professional engineering societies also offer programs by which members can learn about and contribute to the public policy issues related to their fields. ASME, for example, offers a year-long Federal Fellows Program placing mechanical engineers in the legislative branch as technical advisors to Congressional committees or in Congressional offices as technology experts as well as in the Office of Science and Technology Policy (OSTP) in the executive branch. ASCE has a similar program year-long program placing civil engineers into Congressional office and committees. IEEE-USA is a partner society with AAAS and provides fellowships with Congressional placements as well as placements in the State Department and USAID within the executive branch. In general, these fellowships provide both salary and moving allowances. For faculty receiving salary support from their institution during their sabbatical, the opportunity to "volunteer" with a nonprofit advocacy group may be appealing. It was in this manner that I volunteered my services to AIMBE during my sabbatical to learn about public policy issues related to medical and biological engineering.

Based on the teaching schedules of our department, I chose to take my sabbatical during the Fall 2014 semester. While favorable timing for the department, it did not mesh as well with the Congressional schedule. I arrived in DC in August during the summer recess and left in December, shortly after the end of the lame duck session of the 113th Congress. Due to the November election, members of Congress spent most of my time in Washington back in their home districts. For a one-semester sabbatical, I recommend the spring semester to coincide with the Congressional budget deliberations. For a one-year sabbatical, a calendar year (January to December), if possible, is recommended to be engaged throughout the budget process including any debate on continuing resolutions that may occur even after the beginning of the federal fiscal year on October 1.

Relocation to Washington, DC for a short term requires thoughtful consideration of housing and transportation options available in the area. The housing market in the Washington, DC metropolitan area is ideally suited for a sabbatical leave since it is easy to find apartments having leases for less than a year in duration. This convenience, however, comes at a cost since there is usually additional monthly rent, often hundreds of dollars, for the convenience of a short-term lease. Additional fees for amenities, pets, and garage parking may also add hundreds of dollars to the monthly rent. The location chosen for sabbatical housing depends on the desired rent payment as well as the length of commute. In general, lower rents are found farther from the district, but commuting costs often offset much of the savings. My sabbatical housing was located in the Penn Quarter area of the district, near the National Mall. My host organization contributed a stipend to help defray housing costs. Note that housing, food, moving, and commuting costs may be tax deductible as business expenses.[9]

Conclusion

I successfully completed the goals of my sabbatical and have gained an appreciation for the need for engineers, including engineering educators, to participate, in some fashion, in the public

policy arena. Lessons learned from this sabbatical will be integrated into the biomedical engineering curriculum to make students aware of their ability to shape the medical device regulatory process and serve as a voice for the field.

References

1. "And Now for Something Completely Different." Ian MacNaughton (Director). Columbia Pictures (USA), 1971. DVD.

2. National Academy of Engineering, "Educating the Engineer of 2020: Adapting Engineering Education to the New Century." Washington, DC: National Academies Press, 2005.

3. "Quality System Regulation." Title 21 CFR Part 820, 2014.

4. "Animal Welfare." Title 9 CFR Subchapter A, 2013.

5. "Protection of Human Subjects." Title 5 CFR Part 46, 2009.

6. "Institutional Review Boards." Title 21 CFR Part 56, 2014.

7. W. R. Hendee, S. Chien, C. D. Maynard, and D. J. Dean. "The National Institute of Biomedical Imaging and Bioengineering." Annals of Biomedical Engineering, vol. 30, pp. 2-10, 2002.

8. J. J. Smith and J. A. Henderson. "Bringing New Medical Technology to Market: Understanding CMS Coverage and Payment Determinations." Internet: https://www.cimit.org/news/regulatory/cms_coverage.pdf, [Feb. 2, 2015].

9. J. A. Miller and R. Pikowsky. "Tax Planning and Sabbatical Leaves." The Chronicle of Higher Education. [On-line]. Available: http://chronicle.com/article/Tax-PlanningSabbatical/126293/ [Feb. 1, 2015].