

# National Academy of Sciences, Engineering, and Medicine (NASEM)

**Authors:** Alyson Warr and Marie Wu

**Date of Meeting:** Tuesday, April 24th, 2018

**Meeting with:** Anne-Marie Mazza, Director of Committee on Science, Technology and Law

## Overview:

The National Academy of Sciences was first established in 1863 by an act of Congress at the request of Abraham Lincoln. In later years, the National Research Council, the National Academy of Engineering, and the National Academy of Medicine were established, which together make up NASEM, the National Academies of Science, Engineering, and Mathematics. The National Academy of Sciences is a nonprofit organization that is one of the few truly independent academies in the world.

## Missions of NASEM:

1. To recognize scientific achievement through election into the academy. Individuals are selected by their peers for their work, achievements, and contributions to their field.
2. To promote a healthy research community. NAS serves a role in helping to convene scientists, such as for an international summit on gene editing. They also advise on policy for science.
3. To conduct meta-analyses of issues brought to their attention and sponsored by the government or federal agencies.

## Study Process:

The goal of each study performed by NAS is to obtain objective and scientifically balanced answers to difficult questions of national importance. The studies consolidate existing research from varied fields to generate a bigger picture look on a given topic. Studies can be sponsored in multiple ways: federal agencies are the primary sponsors, with a few from state agencies, foundations, private sponsors, as well as from the National Academies endowment. External sponsors have no control over how the study is conducted or what the results of the study will be once the statement of task and budget have been finalized. In this way, NAS maintains their independence and objectivity.

Once a study is commissioned, a study committee is drawn up of experts in relevant areas, not limited to members of the Academy. Individuals who serve on committees do pro bono work. Study committees gather information from multiple sources in public

meetings, but deliberate in private meetings to avoid influence. The committees are selected to have an appropriate range of expertise, a balance of perspectives, as well as no conflict of interest. Study committees spend on average 2 years gathering information. All materials are maintained in a public access file, although analyses and drafts remain confidential throughout deliberation. Once a study is completed, it undergoes a rigorous, independent external review by experts who remain blind to the committee. The review process ensures that the report addresses the study charge but does not go beyond it; that findings are supported by science; that exposition and organization are effective, impartial, and objective. Committees must respond to but do not need to accept or agree with all comments. Multiple layers of reviews are undergone with committee members as well as with Academy officials. The final report is transmitted first to the original sponsor of the study before being released to the public. When releasing to the public, NAS must keep in mind how to get the audience to understand the significance of the information while correcting misinformation.

An important note is that while NAS conducts studies and reports, these are meta-analyses and NAS does not perform in-house original research.

#### **Funding of NAS:**

Each study performed by NAS is funded separately. Most funding does come from the government for studies they request, although NAS also occasionally receives funding from private entities and corporations. Funders have no say in the study outcomes and may not alter the study process. This enables it to maintain independence and not compromise the integrity of the institution.

NAS will turn down funding for projects if the funding has conditions that threaten this integrity. For example, the Department of Justice asked for a report on forensic science methods, but had conditions for which the study was to be conducted. NAS refused this project until a Congressman sponsored it. The study was completed and released, despite the fact that the findings were not positive for either of the funding sources.

#### **Fellowship Information:**

NAS operates the Christine Mirzayan Science and Technology Policy Graduate Fellowship Program. The fellowship takes place over 12 weeks, with a \$9000 stipend and is open to foreign born students. The fellowship is aimed at helping graduate students get a feel for science policy as a career path. Fellows are assigned to a specific committee and work with them. Day-to-day work involves literature searches, background reading, and figuring out who the experts are and what questions to ask.

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# AAAS visit

**Date:** Tuesday April 24<sup>th</sup>

**Meeting with:** Julia MacKenzie, Cathy Campbell, Mahlet Mesfin, Meredith Drosback, Kei Zozumi

We met with five staff members from the Center for Science Diplomacy: Julia got her PhD in immunology from Northwestern University as well as a MPH degree. Prior to AAAS, she worked at the State Department where she coordinated the research portfolio for PEPFAR (the President's Emergency Plan for AIDS Relief). Cathy is a visiting scholar at AAAS. She previously served as president and chief executive officer of CRDF Global, a non-profit organization that promotes international scientific and technical collaboration. Campbell is an AAAS Fellow and served as a senior policy analyst in the White House Office of Science and Technology Policy during the Clinton administration. Mahlet served as the Assistant Director for International Science and Technology (S&T) at the White House Office of Science and Technology Policy (OSTP) under the Obama administration. She holds a PhD in bioengineering from University of Pennsylvania. Meredith is the associate director of SciLine, a new enterprise within AAAS that focuses on science and journalism. She holds a PhD in astrophysics from the University of Colorado. She served in OSTP for five years before coming to AAAS. Kei is a visiting scholar at AAAS. He is the former assistant director for federal research and development at the White House OSTP. His current focus at AAAS is a new center – Center for Scientific Evidence in Public Issues. The goal of this new center is to connect science to all levels of policy makers.

First, there is a basic introduction to AAAS. The AAAS is an independent nonprofit that was founded in 1848. It currently has 400-450 employees, including about eight former OSTP fellows. There are three major functions of AAAS: 1) publishing Science magazine, 2) functioning as a membership society, and 3) advocating for science policy issues. They also offer two popular fellowships in mass media and science policy. Recently, AAAS has been working to expand their reach to connect to journalists and policymakers.

During the Q&A section, the visiting Harvard students raised around ten questions. Some of the major ones are below:

- Q: What is the average policy background among AAAS science policy fellows when they were selected? Do they all have post-doc training experience?
- A: Many fellows successfully apply for the fellowship immediately following their PhD, and post-doc experience is not necessary. "Formal" policy experience is also not a must, but applicants need to demonstrate an interest in some aspect of science policy, such as community outreach, science communication, STEM education, student body governance, and leadership experience. Especially important are experience with compromise and negotiation, as well as good leadership and communication skills. Course work in policy also helps. In order to be successful both in the fellowship application and in the field of science policy in general, it is crucial to be flexible and to

have broad interests. Cathy emphasized the importance of flexibility when working in science policy, and said “as the world changes, your job might completely change too – you must be ready for that change.” Scientists can be more helpful to policy makers if they have more flexibility.

Q: What was your job like in science policy at the Department of Defense (DoD)?

A: Kei coordinated the investment DoD has in basic research, including DC, state level and at universities. In general science policy has two-fold of meaning: “science for policy” and “policy for science.” Science for policy includes things like scientific research used to support policy making, such as climate science can inform policies. Policy for science is mostly management of research funding, through mechanisms such as the Office of Management and Budget, OSTP, the Congress and National Institute of Health, etc.

Q: Who are the big players in regulating scientific research?

A: It depends. Ultimately Congress regulates this, but some other more specific agencies are also involved, such as NIH, EPA, FDA, etc. In general, the US government does not want to overregulate science, as they believe that this would impede innovation. Most regulation is done through the scientific community itself, as private funds are flexible and self-regulated. Importantly, stakeholders have a lot of power; if they flag an issue for their representatives, that can lead to top-down policy.

Q: What are the challenges involved in communicating with different levels of policy makers (e.g. federal, state, city)?

A: Many policy questions are the same (e.g. climate change), but focus shifts a bit depend on the level of policy making. It is important to know your audience. Who is the decision maker? What are the constraints they have? Then pick the appropriate time frame. The scientific evidence supporting policy making doesn't change, and is common across multiple levels. The difference is in what needs various stakeholders might have, and thus how the scientific evidence is used.

Q: What happens to initiatives that are less of a priority when an administration changes? For example, there used to be a lot of work on US-China collaboration in climate and energy work going on at State. Do initiatives ever get revived and what happens when they are? Is work still going on these types of initiatives but it is just below the radar? Where do you see science diplomacy in five years?

A: Science and diplomacy influence each other. Politics also matters. For example, the agreement of science and technology between US and China in 1970s helped with diplomacy. Sometimes science and technology development can pave the way for new multinational agreements, such as when scientific collaboration between US and Russian scientists helped with the diplomatic relationship between the two countries. Current issues include artificial intelligence, CRISPR, Cas9, etc., and how these issues can disrupt the global economy. So it is important to foster relationships between scientists to last through tense diplomatic relationships.

Q: What's your view on trade dispute between US and China?

A: There is a fine balance between corporation and competition. Sometimes national benefit may be endangered if critical information is shared. In the cost-benefit calculation, the benefit of cooperation is hard to quantify and often overlooked. As often happens in politics, decisions are made sometimes without the necessary information. Many actions are done in retrospect. For example, a report last year estimated the amount of monetary losses of US to China, and that brought up more detailed examination of Chinese company's trade practice.

Q: How often are Congress members educated about S&T issues? The congressional hearings with Mark Zuckerberg showed that many members of Congress have very little understanding of internet technology.

A: First of all, congressional hearings are not the main arena for legislation – they're theater. The intended audience is not tech-elites, but rather the people back in their home states who are watching the hearings. That being said, it is challenging sometimes to get the right information to Congressional staff, because they are time limited and responsible for huge amounts of information. They need to know where to find reliable information quickly. For AAAS and scientists who want to influence policy, it is important to establish a close relationship with the staffers. This way they are more likely to think of you when they have a policy issue on hand that needs your advice.

Q: Some portion of the public are losing their faith in science, how can SciLine help solve this problem?

A: As AAAS, we need to know that are the questions that we can solve. The aim for SciLine is to solve the problem that journalists are writing stories about science without a scientific background. SciLine connects journalists to scientific experts in order to solve this problem. Some other problems that AAAS can solve include decision makers are making decisions without scientific information. The solution is to make sure scientists are at the table.

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## PhRMA: Pharmaceutical Research and Manufacturers of America

**Authors:** Mary May and Alyson Warr

**Date of Meeting:** Tuesday, April 24th, 2018

**Meeting with:** Richard Moscicki, MD, Chief Medical Officer and Executive Vice President

**Overview:**

PhRMA is a non-profit trade organization that represents large pharmaceutical and biotechnology companies in Washington. PhRMA was established in 1958 and is committed to promoting public policy that encourages innovation in biotechnology and progress in addressing patients healthcare needs in the United States and around the world. PhRMA advocates for pharmaceutical companies by explaining the need for investment in drug research development as well as explaining the increased complexity of drug development research.

PhRMA represents 38 pharmaceutical companies, major players in an industry that collectively invests \$75 billion annually in R&D in the U.S. The group employs approximately 200 people that focus on issues concerning the pharmaceutical industry and the group advocates on the international, federal and local level. Because of the intimate relationship between health insurance and pharmaceutical companies, much of what PhRMA does is to negotiate how drugs are paid for by both consumers and health insurance as well as how federal money is used to subsidize costs.

**Mission of PhRMA:**

1. Modernize the drug discovery and development process – PhRMA encourages the adoption of modern tools for drug evaluation, such as alternative endpoints in clinical trials and leveraging modern statistics to . The organization also advocates for an efficient FDA drug approval process.
2. Promote value-driven health care – PhRMA’s members are interested in making drug payment and pricing more transparent and “predictable” as well as addressing patient desires and values directly.
3. Engage and empower consumers – Improving the general information available to patients about treatment options and costs as well removing problems in insurance benefit design that may result in discrimination are also of interest to PhRMA.
4. Address market distortions – PhRMA argues that price controls that keep drug prices artificially low hinder innovation by reducing money spent on private sector research.

**About Richard Moscicki:**

Dr. Moscicki attended Northwestern University Medical School and completed a fellowship in clinical immunology and immunopathology at Massachusetts General Hospital. He served on staff at Massachusetts General Hospital and Harvard Medical School. He then worked at Genzyme Corporation as Chief Medical Officer for nearly two decades, and at then at Sanofi-Genzyme as Senior Vice President and Head of Clinical

Development. During this time, he was responsible for overseeing worldwide global regulatory affairs and managing clinical research programs. In 2013 he moved to the Food and Drug Administration's Center for Drug Evaluation and Research (CDER) in 2013. CDER regulates over-the-counter and prescription drugs, ensuring that these products are safe and effective in order to improve public health. In 2017, Dr. Moscicki joined PhRMA as the Chief Medical Officer and Executive Vice President. In this role, he will promote both scientific and regulatory advocacy work. His experience in both the pharmaceutical industry as well as his involvement in the federal regulatory landscape make him uniquely suited to PhRMA's work.

**Work at PhRMA:**

PhRMA does not conduct any biomedical research: work at PhRMA focus on advocating for policies that benefit innovation for their member companies. Both PhD scientists and individuals who studied policy from a business perspective work at PhRMA. This work includes meeting with member companies to discuss concerns, lobbying the government for laws concerning drug prices and intellectual property rights, and advocating for fair insurance policies. The goal of this work is to create a market that incentivizes the development of novel pharmaceuticals.

**PhRMA Foundation:**

The PhRMA Foundation offers a variety of fellowships for pre and post-doctoral scientists, as well as grants for new faculty. These grants are typically awarded for work done in pharmacology/toxicology. More information can be found on the PhRMA Foundation website: <http://www.phrmafoundation.org/>

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## National Academy of Sciences Media Relations Team

**Authors:** Marie Wu and Dana Boebinger

**Date of Meeting:** Wednesday, April 25th, 2018

**Meeting with:** NAS Media Relations Team; Jennifer Walsh, Director of Media Relations; Sara Frueh, Communications Writer, Riya Anandwala, Media Officer

The National Academy of Sciences Media Relations office is responsible for communicating the content of NAS reports to the public, both during its writing and after publication. . They are the public-facing arm of the NAS, and form the main contact point between the NAS and the press. The office has four main jobs: communicating the reports, creating media materials and the annual report about the Academy, maintaining

and organizing public access records for the institution, as well as maintaining the social media channel.

- 1) **Communicating reports:** The office writes all of the press releases and pitches them to the press. This part of the job requires thinking like a journalist and considering what content within each report would be interesting and relevant to the general public. What do audiences need to know and how will this information help a general audiences? The offices does not just summarize the report but has to parse out the most critical information: for instance, a report may be highly technical due to the nature of what was requested in the original study charge, but an individual recommendation buried as a detail in the report may be what is significant to the general populace. Not all reports are turned into press releases; of the ~200 reports that get made per year, only ~12 make it to the news and get pushed to reporters, since many reports are highly technical and concern policy details that the average person doesn't care about.
- 2) **Creating materials and the annual report about the Academy:** The office creates original informational materials for the Academy, and compiles a report for Congress every year detailing the activities of the Academy. The office also sometimes creates materials to help prepare members for hearings and trials with Congress, as well as media interviews.
- 3) **Maintaining and organizing public access records for the institution:** Under the Federal Advisory Committee Act (FACA), all materials provided by outside groups are maintained and provided as public access by the Academy. The Media Relations Team manages the records and handles requests for records.
- 4) **Maintaining the social media channel for the Academy:** The office helps navigate the main social media channels for the Academy and helps manage its reputation on social media. Reports are broken down for social media and explained either via short amounts of text (such as for Twitter) or using visuals aids (graphics, videos, interviews with scientists, etc). Today's world no longer depends on traditional news outlets alone, and so NAS can go out and push social media for itself. Social media provides more leeway, and has a dual challenge of how to target not just reporters or interested science enthusiasts but the general population, as well as how to inform and educate complex issues to a wider population.

A lot of the work of the NAS Media Relations Team involves building a brand of impartiality. NAS must build trust so that people will continue to consider NAS a gold

standard for scientific impartiality, and so that reporters will continue to turn to NAS for advice and to connect with scientific experts. Reports are fact-based and do not take sides; they do not comment on policy or political platforms, only facts. NAS is not an advocacy organization. Its job is to get the conversation started about the topic at hand, but then it is up to other groups to pick up the issue and advocate for the implementation of specific policy changes. This inherently limits the messaging around a specific report and stymies personal creativity, as all of the materials produced by the Media Relations Team must be limited to “this is what the evidence says”.

One difficulty faced by the NAS Media Relations Team is in identifying the target audience, which entirely depends on the content of the report. Different target audiences will require different pitches, and different messaging. For instance, the Media Relations Team gave the example of a report detailing concussions in student athletes from grade 2 through the end of high school. This report is likely of interest to health and medical reporters, sports reporters, science reporters, as well as schools and parents. The report should be pitched to everyone, but the pitch to each will differ. Another difficulty the Media Relations Team faces is how to combat bias associated with certain words. The team has to find the right balance between jargon and misconceptions about loaded colloquial words. For example, the word “drones” has negative connotations, and can be replaced by the more neutral term “unmanned aircraft.” Although this may seem like a daunting task, it is rare for them not to find a solution that people can understand and isn’t misleading, even if this results in writing with heavy use of parentheticals. Scientists are involved at all stages of the process to help get the technical details of the report and the tone of the media releases right. However, the Media Relations Team pointed out that they are the ones who decide what aspect(s) of a report will be interesting to the public, rather than the scientists who authored the report. A constant struggle is whether to add commentary to facts. NAS sees it as a service to just give the facts clearly, and tries to not editorialize.

During our meeting, the members of the Media Relations Team mentioned multiple times that it is currently an interesting and challenging time to be in science communication. Due to the presence of “clickbait” and “fake news,” people often question what is true. The NAS must compete with these outrageous claims using only the facts presented in the NAS report. This is where the painstakingly built up brand and reputation of impartiality and scientific fairness of NAS comes in. Journalists trust that what is given to them is objective and thoroughly vetted. NAS is therefore able to serve as a valuable resource for journalists, not just on reports but on other scientific topics as well.

They have also been learning more about what does and doesn't work in communication. For example, they told us that even if you repeat a myth only to debunk it immediately, what sticks in people's minds is the myth and not the debunking, and they may now associate this myth with your organization. Communications specialists are also learning a lot more about how humans interact with media, and this has caused changes in thinking about visual components and the media consumption habits of the audience. Along these lines, the NAS Media Relations Team is also developing new projects to reach out to the public. For instance, a new video effort called "The Science Behind It" is being developed, which will involve short videos on pressing questions people want to ask of scientists.

The most important advice that the Media Relations Team wished to give to scientists is that we should read the news (especially major news such as New York Times, Washington Post, and the Wall Street Journal) and stay informed. The news from the major media outlets still sets the tone for everyone else on content, and trickles down to other organizations. This can help scientists keep a finger on the pulse of the country and better understand what issues are relevant to people's lives and what positions they take, which will ultimately inform communication.

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## **Bipartisan Policy Center (BPC),**

**Date:** Wednesday April 25<sup>th</sup>

**Meeting with:** Jason Grumet, founder and president of the BPC

### **Background on the organization and current state of politics, per Jason Grumet:**

The Bipartisan Policy Center is a 10-year-old organization founded with the recognition that both parties have good ideas, productive policy comes from a constructive collision of ideas, and that consensus has a lasting impact. Grumet found that think tanks were becoming too partisan and wanted a way to "get in the game" to impact policy. He talked about the fact that think tanks such as Brookings do not lobby; however, he feels that lobbying is not bad and is one of the best ways to help shape decisions in D.C.

Grumet also reflected on the current state of politics, saying that things are not as bad as they seem and that there is a lot of bipartisan work under the surface, which he looks to facilitate by bringing lawmakers from opposites sides of the aisle together. Interestingly, Grumet felt that in the past when congressional committees worked in private, they were most collaborative. But, now that most debates and negotiations happen in public, tensions become inflamed and it hurts the ability of lawmakers to make progress.

Additionally, Grumet spoke about the relationship between science and politics. He said that the science community often has trouble knowing the "right rooms" to influence policy. But,

Grumet reported that over the past few years, several dozen important pieces of legislation related to science policy have been enacted into law, including the 21<sup>st</sup> Century Cures Act. Moreover, he talked about the rise of the idea of evidence-based policy making, a concept that the BPC strives to include in its work. He said that there is a growing concern about the lack of evidence in policy making and wondered out loud about ways to fix this problem. Could it be to strengthen the Congressional Research Service or the Congressional Budget Office? Finally, he also lamented the lack of legislators with advanced degrees and the decrease of expert staff on committees and suggested that various private foundations are working on ways to boost the number of congressional staffers with advanced degrees on the Hill.

Question and answer session:

Q: What BPC is doing regarding climate change?

A: People who believe in climate change sometimes know nothing more than people who don't believe in climate change. Republicans who deny climate change criticized democrats of denying the economic consequences of climate policy. Some congress members just want to protect their people from the economic consequences. It does not help solving the climate problem if we just blame each other for the past. A better solution is to focus on broader solutions that have multiple stakeholders' interests, such as clean energy and innovation.

Q: How to address the partisan divide?

A: People are more complicated than parties, so it is critical to find common grounds in order to make progress. Some proposals that have received welcome from both sides of the aisle include improvement of childcare in the military. In addition, we need to increase the participation of voting, especially during the primaries in off-years. Many people are not well-informed of the date that primaries happened. Maybe we should have a national primary day?

Q: How can scientist stay engaged with policy without compromising our own legitimacy and objectivity?

A: It varies case by case. It is important to figure out what you are comfortable with, and what is acceptable in your scientific community. "Lobby" has been emotionally connected to negative meanings. It is not completely true. If one wants to have an influence on policy, one is essentially lobbying. When scientists talk to policy makers, don't think of it just in the word of lobbying, instead think of it as you have someone set up an appointment so that you can talk to the policy maker about something you truly care about.

Q: What are the lessons learned from Affordable Care Act? What can be done differently?

A: It is hard to pass a significant issue without much objection. The key to the solution is to reduce the cost curve and to create a community for care. Until we figure that out, no answer can be perfect. The current administration has spent much effort to undermine the ACA, for example losing the individual mandate. Another impact could be premium

that keeps going up no that federal subsidy has come down. In the future, there needs to be more plans to make health care reform more sustainable.

Q: A question on gun control. Do you see any movement in the next five to ten years?

A: There is some progress in some area, while concern in other area. For example, it is concerning that some entities want to prevent the Center for Disease Control and Prevention from thinking about gun controls. On the other hand, it is encouraging to see that more congress members are not afraid of National Rifle Association. RAND issued a report recently and concluded that more data is needed in determining the efficacy of different policy interventions. Universal background check, for example, may be possible for the four to five states that endorse more aggressive intervention. There is also support for mental health support, and ways to reduce gun related suicide. It is a critical time to start building evidence around efficacy of intervention. Changing design of fire arms and changing who has access to guns are harder interventions to gain political support.

Q: What does BPC think about the current immigration policy issues?

A: The president does not have the capacity to do everything in immigration policy just by himself. When it comes to the dreamers. If talented students are deported, the impact on public opinion of the administration won't be good. So this is less likely to happen.

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## Congressional Research Service (CRS)

**Authors:** Michele Zemplenyi and Jeeyun Kim

**Date:** April 25, 2018

**Meeting with:**

Pravish Shikh, Specialist in Natural Resources

Daniel Morgan, Specialist in Commercial Space Policy and Dept of Energy

John F. Sargent Jr., Specialist in Science and Technology Policy

Eliot Crafton, Specialist in Fish & Wildlife Services

### Overview

The Congressional Research Service (CRS) is a resource for congressional committees and Members of Congress with the goal of helping Congress through all steps of the legislative process. This includes analyzing draft legislation, helping with preparation for hearings, providing perspectives on different aspects of legislation, testifying at meetings, and preparing memos, briefings, or seminars on special topics. The main tenet of the CRS is to provide objective, factual information to Congress. CRS analysts are tasked with providing a set of options based on all sides of an issue along with the

pros and cons associated with each option. Rather than serving the public directly, CRS's mission is to serve Congress. As such, most CRS memos and reports requested by Congress are considered confidential and are not released to the public.

### **Organizational Structure**

CRS has about 600-650 employees working in Washington, D.C. at the Library of Congress, of which approximately 350 are employed as analysts. These employees include policy analysts, lawyers, librarians, and information professionals working across disciplines in one of CRS's five research divisions: American Law; Domestic Social Policy; Foreign Affairs, Defense, and Trade; Government and Finance; and Resources, Science and Industry. The analysts we met described the structure of the organization as relatively flat and emphasized lateral interactions with Congress. It is not uncommon for analysts to have long careers (upwards of 20-25 years) at CRS. This low turnover of employees gives CRS a longstanding institutional memory, which is a key aspect of the organization.

### **Work as an Analyst**

Traditionally, analysts have maintained a low-profile since CRS does not have a public mission. Analysts receive assignments from more than 540 clients in the Senate and others at the Capitol, including Congressional interns. All staff are expected to communicate with Congressional staff, such as through telephone interviews, seminars, or written reports. There is considerable autonomy in management, which enables analysts to conduct in-focus reports and raise issues on specific topics for Congress. The analysts described the work as "constantly stimulating" and liked the fact that they had a great deal of autonomy. That said, being an analyst at CRS is a challenging job and one must be flexible and dynamic since Congressional staffers may request CRS's last minute help in the hour right before a Congress Member is set to vote on an issue. The type of request they receive from Congress can range from very specific to broad in scope; analysts may also assist Congressional staffers with identifying a question through discussion and negotiation. Other tasks are on longer timescales, like preparing content for a Congressional hearing scheduled months in advance.

Analysts must be flexible to deal with any topic of interest to the government and need to have some knowledge of the history of the legislative process for certain issues. Requests to CRS can come either through the formal CRS request system or directly from a Congressional staffer, the latter being much more common (approximately 85% of requests, according to Dr. Shikh) for analysts who have been at CRS for many years and have established a rapport with Congressional offices. Often, the staffer may ask that the report be confidential. Each analyst has specific issues areas and is responsible for compiling information and explaining various issues in the policy context. Research

at the CRS is primarily based on analyses of secondary sources, census or survey data, rather than original analysis. If there is a knowledge gap for a certain question, CRS refers to their sister agency, the Government Accountability Office (GAO), or the National Academies of Sciences, Engineering, Medicine (NASEM).

Every product that comes out of CRS (including interviews, confidential memos and slides) undergoes a thorough peer review process. There are several steps in the review process: the product first undergoes an optional peer review process by two members from the internal staff, a required section review by the manager, then a division review, and a final front office review. The reviewers check for balance of perspectives and ensure that the product is not based on the author's personal opinion and the writing is crafted in such a way that snippets of their work can not be taken out of context. As part of their job to provide comprehensive and reliable research and analysis, analysts are also encouraged to attend conferences, read scientific literature, meet with professors, interest groups, and other federal agencies. Each of the analysts we met had a PhD in a STEM field and saw themselves as the bridge between science and policy.

The majority of employees at the CRS tend to have a policy or legislation-focused research background and joined the CRS through fellowships and academic societies. One of the analysts, Dr. Crafton, had previously worked as a Congressional staffer and described his work on the Hill as shallower than that at CRS since he was required to field a broader portfolio of issues to his Congressman. At CRS, Dr. Crafton appreciates the chance to be a deeper expert. Another analyst, Dr. Morgan, had previously worked at the NASEM and appreciates the fact that at CRS the reports he writes are his own, whereas at NASEM Dr. Morgan's writing was attributed to the NASEM committee members. Dr. Morgan also appreciated the fast-pace and variety of the work at CRS.

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## **Biotechnology Innovation Organization (BIO)**

**Author:** Elaine Garcia, Raehoon Jeong

**Date:** April 25th, 2018

**Meetings with:**

Dan Durham, MPP

Rina Singh, PhD

David Thomas, CFA

## **Overview**

In short, Biotechnology Innovation Organization(BIO) is an advocacy group for U.S. and foreign based biotechnology firms and some academic institutions. The group aims to influence U.S. policy decisions that allow the member companies to pursue their goal to heal, fuel, or feed the world. To accomplish their aims, a significant portion of BIO's efforts is to debunk misconceptions and myths that policymakers have. As new innovation is brought to the public, it is often faced with oppositions from the existing industry or skeptics. Therefore, by presenting facts about these new technologies, BIO hopes to help shape policy so these technologies can reach their full potential and make the highest positive impact.

Some of the industries that biotechnology touches on include healthcare, energy, and agriculture. They correspond to the organization's agendas: "Heal the world, Fuel the world, and Feed the world." The panels for our meeting included people from the healthcare and industrial & environmental branch, and their presentations touched on various biotech firms' effort towards sustainable products and practices, as well as the challenges in drug and therapeutic developments.

Generally, BIO promotes policies that encourage and protect innovation from emerging small-to-medium companies to develop new products. These small companies often do not yet have products to create revenue, so BIO is there to promote a political environment that fosters investment in them. An important component are laws that protect intellectual properties, which are critical in order to ensure that firms are compensated for their innovations.

## **Industrial and Environmental**

Firms in this category aim to develop new technologies that can be applied to multiple industries. These technologies aim to lower costs, reduce pollution, enhance resource conservation, and introduce novel processes or products through engineering biomaterials. Some technologies that may not be directly linked to economic benefits still are valuable because they are sustainable. In order to ensure that these companies have a market and to promote a wide use of sustainable products, BIO informs policymakers of their positive benefits to society.

One example of a policy is the Farm Bill. It includes an initiative to promote the purchase and use of biobased products. These products can range from synthetic rubber to biobased fabrics. The BioPreferred program in the Farm Bill consist of mandatory purchasing of biobased products in federal agencies and labeling of biobased products. This program acknowledges the benefits of products derived from biological materials and intends to encourage the ordinary customer to use them more. This bill is integral to the Industrial and Environmental branch of BIO, and they are working towards having this clause included in the new version of the Farm Bill due to be discussed in 2018.

Another aspect of its activities is educating the general public. For instance, the general public's concern with GMO products is directly linked to the industry. Thus, their programs also inform the public about what they really are and correct misinformation.

## **Healthcare**

This is BIO's largest unit and focuses on regulatory hurdles and misconceptions that affect publicly funded scientific research, proactive biodefense research, and rare and pediatric diseases.

In general, time to approval for a New Drug Application (NDA) has risen 2-3 times in the last 50 years, largely in response to the thalidomide crisis and the Kefauver Harris Amendment. Although the new "proof-of-efficacy" criteria introduced by the Kefauver Harris Amendment seemed intuitive, it marked a shift in the methodology of analyzing new therapeutics for which a drug already exists on the market to treat. Therefore, not only must NDAs prove safety with a large enough therapeutic index between effective and toxic dose, but the new drug must be more effective or "outperform" the existing drug on the market. This new unofficial criteria extends the time and capital investment required to get a drug to market. The rising bar for FDA approval pushed the industry to invest most of their efforts on "blockbuster" treatments - treatments that would gain the most return of investment (ROI) for the company. Consequently, a number of rare and pediatric diseases were left behind due to the high up-front cost of research and development. BIO's efforts in this realm push for pre-clinical and clinical trial regulations which allow for faster and more efficient study designs without compromising safety and efficacy standards.

BIO keeps the conversation of new drugs and emerging biotechnologies for standard and personalized medicine fluid between regulatory agencies, industry, and patient advocacy groups while trying to maintain fair and effective legislature that benefits all parties. BIO advocates for good post market vigilance practice and makes sure its members can support their drug prices to the federal agency and consumer.

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## **The National Aeronautics and Space Administration (NASA)**

**Authors:** Darcy Frear and Michele Zemplenyi

**Date:** April 26th, 2018

**Meeting With:** Tom Cremins, Associate Administrator for Strategy and Plans

### **Overview**

NASA has a lot of ongoing projects with an aim to progress space exploration and aerospace research. In contrast to the 1950s when the Soviet Union and the United States were the sole

players in space, there are now at least 23 countries with space agencies and the US government has over 800 space-related agreements with 120 nations. As more and more countries become involved in issues related to space exploration, NASA needs to increase its diplomatic resources, communicate well with other countries, and become more interdisciplinary. Naturally, policy work is playing an increasingly important role and NASA's need for scientifically competent people in policy is growing.

### **Relationship with the US Government**

NASA used to be in its own "bubble" but now they deal with many government agencies and have over 1000 agreements with these agencies. Luckily there is strong support for a space budget. Changes in administrations in government do not greatly affect large-scale plans at NASA as the timeline for completion of a project typically extends beyond one or two terms of a president. However, this means change is difficult and there are a lot of starts and stops if any change needs to occur. Because NASA can sometimes be seen by Congress members as just another agency or budget item, it is important that NASA tailor its message about its value to US interests to its audience. For example, in a discussion with the National Security Council, NASA would highlight the value of its collaboration with Russia on the International Space Station, whereas with the Department of Education, NASA would describe its ability to inspire students to enter STEM fields. Overall both the current President and Vice President and Congress are relatively supportive of funding NASA and its current goals.

### **Current Goals**

Current space travel goals are focused on going back to the Moon and how to successfully get people to Mars by the 2030s. Going back to the Moon is not a return to the Apollo era; rather, NASA sees much value in studying the structure of the Moon as this could reveal more about the early solar system. NASA also sees the Moon as a potential base or launch site for future space exploration missions. NASA aims to explore Europa, the smallest of the moons orbiting Jupiter, for primordial life by the mid-2020s. NASA is also spearheading an exoplanet program to look beyond our galaxy to find planets situated like Earth in the "Goldilocks Zone" with just the right conditions for sentient life to develop.

### **Relationship with Private Industry**

Rather than view private companies as competitors, NASA supports private companies like SpaceX and Blue Origin. It is in NASA's interests to encourage organizations to develop competitive advantages that will make the entire space launch and travel industry more efficient. This then will allow NASA to continue focusing on the next frontier, whether it be travel to Mars or the search for exoplanets. In Tom Cremins's words, "NASA shouldn't be doing things that others can do."

### **Science Policy**

NASA does not set policy, it provides data to direct policy. It is involved in outreach and must decide the best way to convey the importance of NASA's future goals. For instance, to appeal to students and teachers they bring in an astronaut or to appeal to Congress they showcase their international relationships and ability to contribute to national security interests. NASA must

continually refine its message about its impact on the US based on changing political and funding environments.

### **Opportunities**

NASA has a science fellowship program for those with advanced degrees. There is also a program that focuses on studying and teaching overseas.

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## **Congressman Thomas Massie**

**Authors:** Seth Cassell, Ivan Kroupin

**Date:** April 26, 2018

**Meeting with:**

Congressman Thomas Massie (KY)

We met with Congressman Massie in his office in the Rayburn House Office Building. During our meeting, we covered a number of topics, but one that he was especially eager to discuss was patent protections for American innovations. He spoke of his belief that patents should be as strong as possible so as not to delegitimize the role of inventors. While he was not familiar with one of the more contentious recent patent disputes in the biotechnology field, Association for Molecular Pathology vs. Myriad Genetics, Inc, he spoke broadly about the fact that there is a bias in America for regulators to say no to those who want to protect their innovations. In response to a question, Congressman Massie also spoke specifically about Tesla's decision to make all of its patents free and open source. He disagreed with this decision by Elon Musk and said that it set precedents that would hurt "the little guys."

Congressman Massie also spoke about partisanship and how he makes voting decisions. He said that he came into Congress thinking that the terms 'partisan' and 'ideologue' were synonyms and pejorative. Subsequently, however, he has observed a difference between a partisan and an ideologue during his time in D.C., which has surprised him. He noted that a partisan is someone who always votes with his or her party, while an ideologue votes his or her conscience. He considers himself to be an ideologue and no longer views that term to be pejorative - in contrast to 'partisan'. Additionally, he said that although he makes a concerted effort to poll his constituents to understand how they feel on various issues, he does not always feel compelled to vote according to the results of such polls. He expressed that sometimes he may have a more nuanced view of issues than his constituents and feels that even if he is outvoted 2-433, his constituents will trust that he had good reasons for being in the extreme minority. His litmus test for judging whether his constituents will support him in some unconventional policy stance is whether he thinks he would be able to convince over half of a town hall meeting in which all of the constituents had come in opposing the position he intended to defend.

When asked how he made the switch from being a scientist and engineer to thinking about politics, Congressman Massie told us about a visit that Gov. John Sununu, a fellow engineer by training, made to his alma mater, MIT. Sununu spoke about the need for more scientists in government who would be focused on collecting facts to make decisions. These sentiments inspired Massie, who, after returning home to northern Kentucky, decided to embark on a career in politics.

Speaking about his tenure in office, Congressman Massie was highly critical of the House and many of the Congresspeople, specifically commenting on their tendency to vote out of a desire to be liked by other members of Congress and not ideological or pragmatic commitments. This resulted in a situation where 'patterns of voting [of the members of the House] would appear random to an outside observer' - but were in fact guided by internal politics, both within and across parties.

After the discussion in his office, Congressman Massie invited us to the mezzanine of the House of Representatives to observe the voting process in action. Though he had not been present for the debating of the content of the ballots (this occurred during our meeting with him) his assistants were present and had compiled a list of 'vote recommendations'. Congressman Massie stressed the importance of having staff which understood your political stances - especially as an ideologue who did not simply vote along party lines.

In the mezzanine we first witnessed something referred to as 'speed voting' in which representatives cast their ballots on a number of amendments to a bill with a vote occurring every two minutes. Congressman Massie provided a running commentary on the dynamics of the House and the various traditions involved in voting. The critical tone established earlier in the conversation was largely maintained with Congressman Massie discussing the degree to which members of Congress were tribal and tended not to step out of party lines - a situation reinforced by procedures within parties to coerce reluctant members.