

Advocacy: What Is a Nice Scientist Like You Doing in Washington, DC?

Many members of the American Association for the Study of Liver Diseases (AASLD) are surprised to learn that their association has an active public policy presence in Washington, DC. In many ways, politics is the antithesis of science. It is emotional and reactive, not precise and hypothesis-driven. It is sometimes used to interfere with science rather than to advance it.

Yet, it can be argued that there is no more important activity in which the AASLD, or any other scientific association or society, should become involved. When done right, public policy advocacy can have a significant positive effect on the goals of the society. The budget of the National Institutes of Health (NIH) was doubled between 1998 and 2003 because of effective public policy advocacy. The fact that HIV/AIDS went from a death sentence to something approaching a chronic disease in less than 20 years is to a significant extent the result of effective advocacy. Much of the progress against cancer, heart disease, stroke, and other diseases and disorders finds its basis in public policy advocacy.

Advocates for disease research run the gamut from patients and their families, to physicians, to nonphysician researchers, and to interested private companies and non-profit organizations. They may all come to the question from a different direction, but they bring the collective experience and viewpoint of an American society that is diverse and multifaceted. Perhaps more importantly, they bring to policymakers facts, both scientific and societal, that help put the importance of healthcare research into perspective.

Advocacy, like a scientific experiment, does not always work. There are multiple reasons for failures in advocacy. Sometimes, failure is related to the quality of the request. At other times, it relates to its timeliness: asking for an appropriation from Congress the day after the bill passes

is a formula for failure. At still other times, requests can be lost in the congressional maelstrom caused by issues unrelated to the request: the perceived need to cut taxes or the exigencies of a September 11 attack or a Hurricane Katrina catastrophe. One must appreciate that the members of Congress have to develop priorities for the limited resources available.

A carefully planned and timed advocacy effort, however, can bear fruit for scientific research. That is what this article is about.

What Makes Advocacy Successful?

Advocacy on behalf of science (or anything else, for that matter) tends to be successful when the advocates take the time to learn the rules and to learn the players, and then work hard to implement what they have learned. Learning the rules in Washington is not nearly as difficult as it is sometimes portrayed. Although there are a lot of nuances and subtleties that become obvious as one moves along, and things do change and evolve from time to time, there are some basics on how the process works.

In general, a bill is introduced by a representative or a senator and referred (by the Speaker in the House and the Majority Leader in the Senate) to a committee (Table 1). The committee chair then refers it to the appropriate subcommittee, which may or may not ever consider it. Assuming they do, the members of the subcommittee have the opportunity to amend it. When action is complete in the subcommittee, the bill moves back to the full committee, which can then consider it or not consider it, again at the discretion of the chair. The same amendment process can occur, and the committee can vote to send the bill to the full House or Senate.

In both houses of Congress, the Majority Leader sets the schedule and determines which bills will come up for a vote. The House has a Rules Committee that sets the requirements for debate, whether amendments are allowed, and if so, which ones. In the Senate (sometimes known as "the world's most deliberative body"), on most bills, amendments are always in order, and debate tends to be longer.

When each house has passed a version of a bill, there are often differences between them. Those differences are resolved by a conference committee, appointed again by the Speaker of the House and the Majority Leader of the Senate, which is usually composed of members of the subcommittees that originally considered the bill. The

Abbreviations: AASLD, American Association for the Study of Liver Diseases; CDC, Centers for Disease Control and Prevention; CMS, Centers for Medicare and Medicaid Services; FDA, U.S. Food and Drug Administration; HCV, hepatitis C virus; HHS, Department of Health and Human Services; NIH, National Institutes of Health.

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Published online in Wiley InterScience (www.interscience.wiley.com).

DOI 10.1002/hep.21762

Potential conflict of interest: Nothing to report.

Table 1. Principal Committees and Subcommittees of Interest to the AASLD

Committee	Subcommittee	Relevant Jurisdiction
House Appropriations	Labor-HHS-Education	Department of Health and Human Services (includes NIH, CDC, HRSA, CMS, and FDA)
Senate Appropriations	Labor-HHS-Education	Department of Health and Human Services (includes NIH, CDC, HRSA, CMS, and FDA)
House Energy and Commerce	Health	Public health, mental health and research, biomedical research, Medicaid and national health insurance plans, and food and drugs
Senate Health, Education, Labor, and Pensions	None (all health issues are handled by the full committee)	Public health and biomedical research and development
House Ways and Means	Health	Programs that pay for health care, health delivery systems, or health research and health programs under the Social Security Act
Senate Finance	Health Care	Health programs under the Social Security Act and health programs financed by a specific tax or trust fund

NOTE. HRSA indicates the Health Resources and Services Administration.

single compromise bill that results (a “conference report”) then must pass both houses again in identical form. Only then can it be sent to the President for a signature or veto.

This is a top-down system, with the most power and discretion residing with the highest ranking members of the House and Senate: the leadership, the committee chairs, and the subcommittee chairs. However, the rank-and-file members have an important role to play as well. Their views have to be considered because decisions on approving bills at every level are made by majority vote. They are offering amendments; they are making speeches. Their power is more diffuse, but it exists nonetheless.

Just as important as learning the rules is learning the players. Every AASLD member is represented in Congress by 1 member of the House of Representatives and 2 members of the US Senate. If you do not know who they are, you need to find out. Go to www.dc-crd.com, the Web site of AASLD’s Washington advocacy firm, CRD Associates; click on “Write Congress” and follow the links to get the names of your representative and senators.

Once you learn who they are, go to their Web sites, and see to what committees they belong. Most liver research funding issues are handled in the House and Senate Appropriations Committees and their Labor, Health and Human Services, and Education (Labor-HHS-Education) Subcommittees. Most nonfunding issues are handled in the House Energy and Commerce Committee and its Health Subcommittee and in the Senate Health, Education, Labor, and Pensions Committee, which handles health issues without the benefit of a subcommittee. Medicare issues are handled in the House Ways and Means Committee and the Senate Finance Committee, both of which have Health Subcommittees.

However, even if your representatives are not on a committee or subcommittee of direct import to liver research, they still get a vote on the House or Senate floor. They are still part of the process, and there are many reasons to learn who they are and, more importantly, to let them learn who you are. One of the ways to do that is

to reach out to their staffs. Every elected official has staff members, and there is always someone designated to handle healthcare and health research. After you learn who your representatives are, learning who their key staff members are is next in importance.

Now that you have learned the rules and the players, all that is left is for you to make a personal commitment to become involved in advocacy. It does not take much to take the plunge. You know, for example, that the flat funding of NIH over the last 4 years has had a deleterious effect on biomedical research. Maybe 1 of your grants was reduced, or perhaps you were not funded for research that just missed a reduced payline. Members of the House and Senate need to hear those stories, and only you as an active researcher can tell them.

Whether you visit your representatives’ offices (in Washington or at home) or you call on the phone, send an e-mail, or write a letter, there are a couple of key rules that you will want to follow. You will want to make your points strongly but politely. Time is a valuable commodity, so you will want to be clear and succinct. It helps if your story is personal: for example, the impact on your research of 10% paylines and across-the-board budget cuts.

If you visit or call, it always pays for you to follow up with a short thank-you note, reiterating your major points and offering to be a resource for the office on liver-related or gastrointestinal-related issues. Keeping in touch on a regular basis puts you in a very good position when important issues arise to contact the offices again, or even for them to reach out to you.

Can You Advocate Before Government Agencies?

Our discussion above is very specific to Congress, but much of what the government does relates to actions that occur in various Executive Branch agencies, such as the NIH, the Centers for Disease Control and Prevention

(CDC), the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS). Moreover, the rules, official and unofficial, are not necessarily the same from agency to agency.

For example, the NIH and CDC are not regulatory agencies. They implement policies enacted and funded by Congress within the broad framework of Administration policy. Consequently, lobbying these agencies is possible and is often done. For example, when you go to see a division director or program officer to discuss the need for a greater research emphasis in a specific area, you are lobbying the NIH. When the AASLD goes to Atlanta to discuss with CDC officials the need to create a "home" for liver disease at the agency, they are lobbying the CDC.

The FDA is a slightly different animal, however. The FDA is a regulatory agency, and this makes its actions quasijudicial. For this reason, different rules apply. One cannot, for example, set up a meeting with the FDA to discuss a pending drug application without the prior approval of the applicant. Even if that permission is granted, FDA employees are prohibited from revealing details about an application to prevent the inadvertent disclosure of proprietary information.

The CMS falls somewhere between. However, the difficulty with lobbying the CMS really stems from the incredible complexity of the systems that it has created. If the AASLD were to want to seek a higher payment for a specific Current Procedural Terminology (CPT) code, it would quickly become caught in the maelstrom between the CMS and the American Medical Association, which has a contract to operate the Resource-Based Relative Value Update Committee, or RUC. More than 1 medical specialty society has gotten lost while being ping-ponged back and forth between these 2 entities.

Yet, despite the difficulties, successes do abound. The AASLD played an instrumental role in the issuance of the first request for applications for hepatitis C virus (HCV) research. A well-timed meeting, at which we worked together with our allies in the digestive disease field, enabled us to persuade the National Institute of Diabetes and Digestive and Kidney Diseases that its leadership was crucial in ensuring that the request for applications targeted HCV's impact on the liver, thus ensuring that much of the research funding went to hepatologists. A matching

grant of \$100,000 from the Digestive Health Foundation combined with AASLD's leadership was offered to the NIH and resulted in an additional \$5 million from multiple institute sources targeted to HCV research.

Similarly, AASLD's concern about the impact of acetaminophen resulted in our meeting with senior FDA officials in 2006 to discuss their proposal to revise labeling requirements for this drug. Following that meeting, which helped to establish AASLD's expertise on liver toxicity, changes in labeling were promulgated, and there is currently an ongoing comment period for public input.

Conclusion

The members of any organization that is interested in having an effect on public policy need to learn the rules that govern how laws and regulations are made. Then, they need to learn who the people are that are involved in making key policy decisions. Finally, they need to decide to take the initiative to get involved, make the outreach to elected and appointed officials, and make themselves a resource for those officials as they consider taking official actions that will have an impact on their research or their practice.

The AASLD works closely with other medical specialty and scientific organizations, and with patient advocacy and other groups, to advance the practice of hepatology to better treat and cure liver disease and to promote liver wellness. In the coming months, you will see the AASLD become even more active, in particular, by asking for your help in contacting legislators. The introduction of a software program called CapWiz will help the AASLD move to the next level of grassroots action. This program will enable members to reach out to their representatives with a few clicks of the mouse and enhance the role played by the association in the Washington health research advocacy community. We hope you will respond when called upon.

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