ASM Public Affairs

ASM Recommendations to Congress on FY 2016 FDA Budget

In November, ASM a letter to the House and Senate Appropriations Committees recommending increased funding for fiscal year (FY) 2016 for the Food and Drug Administration (FDA). The Bipartisan Budget Act of 2015 makes additional discretionary funds available to appropriators. ASM recommended a budget of $2.8 billion for the FDA, an increase of $200 million over FY 2015 and $160 million above currently proposed House and Senate FY 2016 funding. The FDA has broad and significant responsibilities to protect the health and safety of the public and is in urgent need of additional funding. To read the ASM’s letter go to http://www.asm.org/index.php/public-policy/documents/statements-and-testimony/137-policy/documents/statements-and-testimony/93852-fda-11-15.

ASM Supports Agriculture Research Funding

In October, ASM endorsed an action alert and signed on to a letter supported by the American Society of Agronomy, Crop Science Society of America, and Soil Science Society of America, urging Congress to fund the Agriculture and Food Research Initiative (AFRI) with the maximum level possible in fiscal year (FY) 2016. The coordinated effort, initiated before passage of the Bipartisan Budget Act of 2015, targeted House and Senate agriculture appropriations subcommittee chairs and ranking members and stressed the importance of federal funding for basic agricultural research at the Department of Agriculture. The letter asked Congress to fund AFRI with at least $335 million in FY 2016, the same as the House level. For up-to-date information on the FY 2016 budget process, please see the Public and Scientific Affairs Board public policy webpage at http://www.asm.org/policy.

In November, the ASM joined twelve other science coalitions, representing more than five hundred scientific, academic and industrial organizations and societies, in a letter urging Congress to make additional funding for science available in FY 2016. The letter addressed the additional discretionary funds accessible to appropriators following passage of the Bipartisan Budget Act of 2015, and recommended that additional funding be spent to increase federal research funding by at least 5.2% above the FY 2015 levels. A copy of the letter can be found on the ASM webpage at http://www.asm.org/images/PSAB/ScienceCoalitions-11-15.pdf.

ASM Staff Attends Meetings on Laboratory Test Payment Changes

ASM staff attended two recent important informative sessions on clinical laboratory payment rates. On 19 October, the Centers for Medicare and Medicaid Services (CMS) held the second Clinical Diagnostic Laboratory Test Panel meeting; part of the agenda focused on the Medicare Clinical Diagnostic Laboratory Test Payment System Proposed Rule (CMS-1621-P) and the definition and regulation of Advanced Diagnostic Laboratory Tests (ADLTs). On 10 November, an MLN Connects’ National Provider Call was held on the same topics. The CMS-1621-P Proposed Rule requests data on private payor rates of clinical laboratory tests from all applicable laboratories. The rule also requests that each clinical laboratory test private payor rate be re-evaluated every three years. CMS requested interested parties to provide comments on this proposed rule by 24 November 2015. To read more about the proposed changes, go to the initial notice at https://federalregister.gov/a/2015-24770.

ASM Joins the FDA Network of Experts

ASM recently joined the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH)’s Network of Experts. The Network of Experts is a network of non-FDA scientists, clinicians and engineers who provide CDRH staff with rapid access to scientific, engineering, and medical expertise when it is needed to supplement existing knowledge and expertise within the CDRH. The program is designed to provide CDRH staff with exposure to a variety of scientific viewpoints to inform their policy-making on medical devices. To read more about the Network of Experts and the other participants of the program, go to their website at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm289534.htm.

ASM Staff Attend All-Day FDA Public Workshop on NGS Diagnostic Tests

The Food and Drug Administration (FDA) held a 12 November public workshop entitled “A Standards Based Approach to Analytical Performance Evaluation of Next Generation Sequencing In Vitro Diagnostic Tests,” which ASM staff attended. The workshop was intended to draw comments to assist with the development of analytical standards for next-generation sequencing (NGS)-based in vitro diagnostic tests. Panel discussions included the introduction of PrecisionFDA, a cloud-based community platform for NGS assay evaluation and exploration. The deliberations are focused on human genetic test regulation at present, but the framework for FDA regulation of infectious disease molecular tests is expected to follow. To see the accompanying materials for the workshop, go to http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm459449.htm.

ASM Meetings and Conferences

ASM Microbe 2016: Submit Your Abstract before January 12

Time is running out to submit your abstract for the inaugural ASM Mi-