Public Affairs Report

ASM Comments on FDA Guidance on Marketing In Vitro Diagnostics

ASM, in concert with the Pan American Society for Clinical Virology (PASCV), provided written comments to the FDA on their Draft Guidance for Industry and Food and Drug Administration Staff on “Commercially Distributed in vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only; Frequently Asked Questions.” This document is intended for manufacturers and distributors of RUO and IUO IVD products and addresses the marketing of these products. Because these RUO/IUO products are sometimes crucial in the molecular detection of infectious agents, ASM’s comments focused on the need for FDA flexibility in the use of RUO/IUO reagents in laboratory developed tests. To read the comments online, go to http://www.asm.org/index.php/policy/fda-iv8–2011.html

Coordinating Council on the Clinical Laboratory Workforce Meeting

ASM staff member Kimberly Walker attended the Coordinating Committee for the Clinical Laboratory Workforce (CCCLW) Meeting on 12 September in Chicago, Ill. The Council discussed various strategies for publicizing clinical laboratory careers, including visual aids. Within their strategic workgroups, they presented ideas on recruitment and retention of laboratory professionals, business models in clinical laboratories, and improving the profile of laboratory professionals. They also reviewed last quarter’s presentation by Health Resources and Services Administration’s (HRSA) Director of the Division of Public Health and Interdisciplinary Education, Joan Weiss Ph.D., RN, CRNP. The presentation discussed ways to align the Committee to compete for funding from the Division, which funds programs and institutions that can produce a diverse qualified pipeline of health professionals in underserved areas.

Letter Supporting FY 2012 R&D Funding

In September, ASM and other scientific societies signed a letter to Congress highlighting the importance of funding scientific research in the FY 2012 budget. The letter stated “making wise investments in science is critical to our public safety, national security, and economic vitality. The long-term cost to the American people of failing to appropriately fund scientific research and development will be severe and far-reaching.” The letter can be found on the ASM Public Policy website at http://www.asm.org/index.php/policy/radfy2012.html.

NSF Appoints New BIO Leadership

In August, National Science Foundation (NSF) Director Subra Suresh announced John C. Wingfield as the new head of the Directorate for Biological Sciences (BIO). Wingfield received his Ph.D. in Zoology and Comparative Endocrinology from University College of North Wales, U.K., in 1973 and first joined the NSF as a Division Director of Integrative Organismal Systems in 2010. The BIO Directorate “provides support for research to advance understanding the underlying principles and mechanisms governing life and is comprised of five offices: biological infrastructure, environmental biology, emerging frontiers, integrative organismal systems and molecular and cellular biosciences.” Wingfield replaced Joann Roskoski, who since 2009 served as the acting assistant director for BIO.

ASM/PSAB Booklet Published on Biosolids

Arguably, the development of large-scale treatment systems for domestic wastewater was one of the greatest public health advancements of the last century. Use of these treatment systems, developed by wastewater microbiologists and engineers, safely and effectively treat water sources to remove waste and fecal material and nearly eliminate the transmission of waterborne diseases like cholera. Currently, these systems are mostly used to treat human waste, despite the prevalence of disease-causing pathogens in a wide range of waste materials. Treatment systems can be adapted to treat a broad spectrum of municipal, agricultural, and industrial wastes. With concerns about future water availability and soil sustainability increasing, demand for well-designed and man-
Land Application of Organic Residuals: Public Health Threat or Environmental Benefit?

Gary King
Chair, PSAB Committee on Environmental Microbiology

HHS Financial Conflict of Interest Rules for Researchers

The Department of Health and Human Services on 25 August issued an updated Final Rule on conflict of interest, providing a framework for identifying, managing, and ultimately avoiding investigators' financial conflicts of interest.

The revised regulations (i) require investigators to disclose to their institutions all of their significant financial interests related to their institutional responsibilities; (ii) lower the monetary threshold at which significant financial interests require disclosure, generally from $10,000 to $5,000; (iii) require institutions to report to the PHS awarding component additional information on identified financial conflicts of interest and how they are being managed; (iv) require institutions to make certain information accessible to the public concerning identified SFIs held by senior/key personnel; and (v) require investigators to complete training related to the regulations and their institution's financial conflict of interest policy.

Additional details about the major changes to the regulations can be found online at http://www.ofr.gov/OFRUpload/OFRData/2011–21633_PI.pdf.