The debate over whether the U.S. Food and Drug Administration (FDA) should regulate laboratory-developed tests continues to divide experts in the clinical diagnostics community. However, this issue was but one of many under lively discussion during the 31st annual Clinical Virology Symposium (CVS), held last April in Daytona Beach, Fla.

Other top issues discussed during the 2015 CVS included a review of developments following the 2014–2015 Ebola virus outbreak in West Africa, reemergence of human enterovirus D68 in the United States (US), and a discussion of newer technologies, particularly next-generation DNA sequencing, that are expected to have an important impact on viral diagnostic testing in clinical laboratories.

Pondering Whether To Regulate Lab-Developed Tests

In July 2014, FDA officials announced plans to extend oversight to laboratory-developed tests (LDTs), which are designed, manufactured, and used within a single laboratory—a category of diagnostic procedures that more typically falls under jurisdiction of the Centers for Medicare and Medicaid Services (CMS) (see Microbe, October 2014, p. 397). During the Sunday plenary session, participants took up this issue, and it led to a very provocative discussion of LDTs from the perspective of those working in clinical laboratories and in industry.

Angela Caliendo of Brown University Alpert School of Medicine in Providence, R.I., outlined the key principles that are guiding FDA officials who are developing those regulations, which are not expected to be implemented for several years. However, some observers argue that such testing does not need to be further regulated, and would prefer to see those anticipated regulations deferred indefinitely.

The proposed regulations are “unnecessary” and would inhibit the development of important diagnostic testing, says Alan Metz, who is president of the American Clinical Laboratory Association in Washington, D.C. In counterpoint and representing an industry view on LDTs, Andy Fish of AdvaMedDx in Washington, D.C., says that regulating such tests is both necessary and important.

Their comments and others prompted a lively discussion, during which other participants challenged many of the points made as part of the formal presentations. One important point raised during the discussion was that FDA should conduct a cost-benefit analysis of the proposed regulations.

Faux “Jeopardy” Session on Clinical Virology

That more serious debate about LDTs gave way to a very different mood during another Sunday session, in which Alex Valsamakis of Johns Hopkins Hospital in Baltimore, Md., invited partici-
pants to eavesdrop on a version of the popular television quiz show *Jeopardy*, except in this case all the questions focused on clinical virology.

The expert “contestants” for this unorthodox version of the quiz show were Eric Rosenberg of Massachusetts General Hospital in Boston, who grappled with questions pertaining to practical issues in transplant virology, and Beverly Rogers from Children’s Healthcare in Atlanta, Ga., who fielded questions regarding health economics and outcomes in clinical virology.

**Ebola: Reviewing the State of Art**

According to officials from the World Health Organization, there were more than 28,000 cases of Ebola infection leading to more than 11,000 deaths during the 2014–2015 outbreak in West Africa. In the aftermath of that outbreak, two experts who dealt directly with many of its challenges presented what is known about the biology, pathogenesis, epidemiology, clinical signs and symptoms, diagnosis, and prevention and therapy available for this deadly virus.

These scientific discussions evoked bitter-sweet memories for many of the participants who recalled Sheik Humarr Khan, who had spoken about that outbreak a year earlier during the 30th CVS. During 2014, while caring for Ebola patients in Sierra Leone, Kahn succumbed to the virus. To honor his dedicated service, Heinz Feldmann from the Laboratory of Virology at the National Institute of Allergy and Infectious Diseases (NIAID) facilities in Hamilton, Mont., presented the Kahn Memorial Lecture. In addition, Kahn was posthumously awarded the 2015 Pan American Society for Clinical Virology Award, which his brother, Sahid Khan, accepted on behalf of the family. He also shared a poignant remembrance of his brother and his lifelong service as a physician.

Later, John Schieffelin of Tulane University in New Orleans, La., described recent efforts to develop means for preventing Ebola infections and therapies for those who are infected with this deadly virus. While there are promising vaccine and drug candidates for dealing with the Ebola virus, Schieffelin emphasized the importance of completing clinical trials to develop an accurate picture of which candidate products will be safe, effective, and cost-efficient. Both he and Feldmann also provided important insights on why this outbreak was far worse than any previously reported Ebola outbreak.

**Other Recent Viral Outbreaks and Threats**

Mary Anne Jackson of Children’s Mercy Hospital in Kansas City, Mo., masterfully recounted her experience in dealing with a local outbreak caused by human enterovirus (HEV) D68 during the past year. Meanwhile, Sherif Zaki of the CDC described recent unexpected deaths in epidemiologic terms, while Pablo Martinez de Salazar of the Caribbean Public Health Agency in Port of Spain, Trinidad and Tobago, described the expanding regional outbreaks being caused by the chikungunya and dengue viruses.

Infections caused by HEV D68 gave rise to very serious complications for some patients—most notably, refractory bronchospasm and respiratory failure with or without asthma. Social media as well as medical specialty listservers helped in recognizing this outbreak nationally, helping to determine its extent on the basis of the symptoms being seen, thus indicating the potential value of this approach for spotting other outbreaks in the future.

Jackson and her colleagues followed a seroepidemiology approach to track the extent of the 2014 EV D68 outbreak and to show that it was not due to a new strain of virus. Severe respiratory disease was seen more commonly, but not exclusively, among infected children who had a history of asthma, she pointed out. In addition to causing severe respiratory symptoms, some of those who were infected with the virus developed complications of the central nervous system, including a polio-like illness in a limited number of patients. However, the etiology of these complications remains unproved.

**Technology Is Improving Viral Detection and Diagnosis**

Next-generation sequencing is poised to revolutionize our ability to diagnose viral diseases, says Charles Chiu of the University of California, San Francisco. Although not yet ready for routine use in clinical laboratories, metagenomic next-generation sequencing likely soon will lead to sequencing steps that are completed in fewer than 6 hours. In turn, that speed will permit turnaround times from specimen acquisition to actionable
ASM Assumes Responsibilities for Organizing the Annual Clinical Virology Conference

In 2015, ASM assumed responsibility for organizing the annual Clinical Virology Conference, which this year was jointly sponsored by the France Foundation and the Pan American Society for Clinical Virology (PASCV).

The meeting attracted 996 individual participants, including 120 international attendees from 30 countries, as well as 56 companies whose representatives took part in the commercial exhibit. The meeting was preceded by a one-day workshop, which focused on molecular virology and was organized by Randall Hayden, Melissa Miller, and Matt Binnicker. Designed to give participants an in-depth look at practical issues facing molecular virologists, the workshop provided comprehensive overviews on verifying and validating molecular tests during one session, and the use and application of new technologies, in another session.

PASCV presented 12 young scientists with travel awards that enabled them to attend the meeting and present their research. In addition, it recognized three outstanding scientists for their contributions to the field of clinical virology. PASCV also honored Keith Jerome of the University of Washington, Seattle, with the 2015 Diagnostic Virology Award for his contributions spanning transplant virus diagnostics, host-pathogen interactions, immune evasion by herpesviruses, and other molecular diagnostics for a broad array of viruses. It also named Colleen Kraft of Emory University School of Medicine, Atlanta, Ga., the 2015 recipient of the Young Investigator Award for her research applying genomics to clinical challenges as well as studies of HIV superinfection and rhinovirus genotyping and correlation to clinical outcomes.

The scientific content of the meeting was developed and arranged by a program planning committee of 10 members from both ASM and PASCV. Program Committee members included Steven Specter (Chair), Richard Hodinka (Vice Chair), Angela Caliendo, Christine Ginocchio, Randall Hayden, Colleen Kraft, Marie Landry, Benjamin Pinsky, Gregory Storch, and Stephen Young. The speakers who presented during plenary sessions described diverse practical issues in diagnostic virology, clinical aspects of viral diseases, the laboratory diagnosis of viral infections, and novel means for preventing and treating viral infections.

Presentations from the 2015 CVS are available for purchase, with audio and slides on the ASM website at https://www.pathlms.com/asm.

This subject was examined more broadly during the American Academy of Microbiology colloquium, “Rapid Next Generation Sequencing and Bioinformatics for Enhanced Molecular Epidemiologic Investigation of Pathogens,” held in Washington, D.C., last September. The report from that colloquium is expected to be completed in early 2016.

Other experts described recent developments involving laboratory diagnostics, including Benjamin Pinsky of Stanford University in Stanford, Calif., who described the one-world implications for diagnostic virology, Kenneth Tyler of the University of Colorado in Aurora, who outlined new strategies for diagnosing viral infections of the central nervous system, and Marek Smieja of St. Joseph’s Healthcare and McMaster University in Hamilton, Ontario, Canada, who reviewed the use of multiplex testing for diagnosing infections of the gastrointestinal tract.

information for the physician in nearly that same timeframe, he suggests.

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