

May 16, 2022

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Michael Bennet
U.S. Senate
261 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
U.S. Senate
217 Russell Senate Office Building
Washington, DC 20510

Dear Representative DeGette, Representative Bucshon, Senator Bennet and Senator Burr:

The American Society for Microbiology (ASM), one of the oldest and largest life science societies with 30,000 members in the U.S. and around the world, appreciates your commitment to ensuring that diagnostic tests developed and deployed in the United States are safe, accurate and reliable. We share your goal of ensuring that tests on the market and in use in healthcare facilities meet these standards.

Laboratory-developed tests (LDTs) are widely used by clinical microbiology laboratories for the diagnosis and monitoring of myriad infectious diseases, and changes in their regulation will have far-reaching implications for these diagnostic labs. Microbiologic testing for infectious diseases (ID) is different than other diagnostic disciplines. For example, ID tests are not used as a “stand alone” diagnostic but rather, are only one part of the diagnostic work up of a patient. ID diagnostics are used to not only identify a pathogen, but also to determine the pathogen’s drug resistance, which in turn helps guide and select appropriate antimicrobial therapy and monitor treatment response. LDTs in infectious disease also play an important role when testing for uncommon infections, when new pathogens (including SARS-CoV-2) emerge, and when testing in patient populations such as pediatrics and the immunocompromised.

Furthermore, microbiologic tests go beyond patient care to assist with hospital infection control, antimicrobial stewardship, and are essential for public health and to prevent the spread of “superbugs.” Many labs use LDTs to identify infectious pathogens because there are no available commercial tests for the given condition.

One size does not fit all when it comes to the use and regulation of LDTs. As you continue to consider the Verifying Accurate Leading-edge IVCT Development (VALID) Act, we write to reiterate concerns about the bill and offer suggestions on ways to adapt the language to mitigate two specific concerns.

Implementation of a User-Fee Program for IVCT Review

Instituting user-fee program for IVCT review should consider the vast differences between large commercial test developers and individual, nonprofit laboratories at academic and other medical centers that develop LDTs. Clinical microbiology laboratories already operate on a thin margin within the health care facilities and are not profit centers. **It is unreasonable to include these laboratories in the same business category as commercial entities, and we urge you to include specific language that would exempt academic, non-profit, and laboratory entities that meet similar criteria as determined by the Secretary, from the user fee program.** If this is not done, the result could be that these laboratories completely cease infectious disease-specific test development, which will ultimately harm patients and critically reduce access to timely, accurate and reliable tests.

While we appreciate that the bill requires the Secretary to consult with scientific and academic experts, as well as health care professionals when developing a user fee program, the impact of fees associated with test review, if applied to the academic, non-profit, and small hospital-based laboratories in which our members work, would be devastating financially. This would have the unfortunate consequence of limiting the innovation of new tests, would put patients at risk and would strain the public health system.

Registration Requirement for Grandfathered and Low-risk IVCTs

Another area where we have concerns is in the registration of grandfathered and low-risk IVCTs, as this will pose a significant time and personnel burden on laboratories that are already stretched thin and short-staffed. ASM supports the concept of “grandfathering” all tests in clinical use prior to the legislation’s enactment and lifting the requirement for premarket review if they meet the criteria for such. ASM also understands that the FDA needs to know which tests are in use, even if they are not subject to review.

If the registration requirement for all grandfathered and low-risk tests remains as it is currently written in the VALID Act, it will present an unreasonable burden on academic, nonprofit and hospital-based laboratories who do not have dedicated regulatory staff and do not have the funding to hire new staff for these tasks.

Under Section 587(l)(c)(1)(a), grandfathered tests are given a one year timeframe to submit notification information for a medical device listing. ASM respectfully requests this be amended to provide a period of three years for grandfathered tests and low-risk tests to be registered with the agency.

ASM recommends the following changes to Section 587(l)(c)(1)(a):

“(A) For an in vitro clinical test that was listed as a device under section 510(j) prior to the date of enactment of this section, a person shall maintain a device listing under section 510 until such time as the system for submitting the notification information required under subsection (b) becomes available and thereafter shall submit the notification information no later than ~~1-year~~ **3 years** after the system for submitting the notification under this section becomes available.”

Use of Web-based Test Menus in Test Registration

For laboratories to more effectively meet the listing requirements found in Section 587I(b)(2), we propose maintaining an electronic, internet-based test menu on the laboratory's website and submitting the link to that test menu to the FDA. Rather than requiring laboratories to duplicate this information for the agency which contributes to the regulatory burden, FDA could access the test menu information as needed on a given laboratory's website. Patients also could access the information, either through a laboratory's website or by accessing a laboratory's test menu through the FDA's own website. We recommend keeping this requirement as simple as possible. For example, requiring laboratories to submit a summary of the analytical and clinical performance of a test is overly burdensome and seems unnecessary for the purposes of obtaining an inventory of tests.

ASM thus suggests the following revisions to Section 587I(b):

“(1) IN GENERAL.—Each person who—

(A) is a developer, a contract manufacturer (including contract packaging), contract sterilizer, repackager, relabeler, or distributor of an in vitro clinical test; and

(B) introduces or proposes to begin the introduction or delivery for introduction into interstate commerce through an exemption under section 587A(f)(2)(b) or 587A(g) or through the filing of an application under section 587B or 587D, shall submit a listing to the Secretary containing the information described in paragraph (2) in accordance with the applicable schedule described under subsection (c) or a link to a page on the entity's website that contains the same information. Such listing shall be prepared in such form and manner as the Secretary may specify in guidance. Listing information shall be submitted through the comprehensive test information system in accordance with section 587T, as appropriate.

We encourage Congress to consider our suggested ways to alleviate the aforementioned financial, regulatory and administrative burdens found within the VALID Act that would, among other aspects of the bill, be detrimental to infectious disease diagnostic testing and laboratory capacity throughout the nation.

Thank you for your attention to our views. If you have any questions, please contact Mary Lee Watts, ASM Director of Federal Affairs at mwatts@asmusa.org or 571-228-8345.

Sincerely,



Melissa B. Miller, PhD
Chair, ASM Clinical and Public Health Microbiology Committee