June 1, 2020

Silke Schlottmann
María Ines García
Division of Microbiology Devices
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: [Docket No. FDA-2020-N-1088](#) for “Reclassification of Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Assay Devices, To Be Renamed Nucleic Acid-Based Hepatitis C Virus Ribonucleic Tests;” and [Docket No. FDA-2020-N-1082](#) for “Reclassification of Certain Hepatitis C Virus Antibody Assay Devices, To Be Renamed Hepatitis C Virus Antibody Tests.”

Dear Dr. Schlottmann and Dr. Garcia:

NASTAD is pleased to provide comments regarding reclassification from Class III to Class II of nucleic acid-based hepatitis C virus (HCV) ribonucleic acid tests intended for qualitative or quantitative detection or genotyping of HCV RNA; and HCV antibody tests intended for qualitative detection of HCV.

NASTAD strongly supports the proposed order for reclassification of these tests from Class III to Class II, with appropriate special controls necessary to assure safety and efficacy. Reclassification is essential to achieve local, state, and national goals for the elimination of hepatitis C. Reclassification of these tests from Class III to Class II is likely to stimulate manufacturers to bring new tests to market, and to adapt tests for use with new sample types. We believe that reclassification will contribute to improved access to HCV testing for priority populations served by public health programs, most notably people who inject drugs (PWID) and systems-impacted (incarcerated or formerly incarcerated) people; facilitate engagement in curative treatment for active HCV; and strengthen public health surveillance of HCV.
We concur with the proposed change to the identification language for these tests. The new proposed language is accurate and clear; it also is generally consistent with the identification language for tests for related conditions, notably HIV. This will contribute to improved understanding of these tests among consumers.

We appreciate that FDA is considering, in parallel orders, reclassification of both HCV antibody and nucleic acid-based HCV tests. The diagnostic algorithm currently used in the U.S. relies on use of both, therefore harmonizing reclassification of the algorithm’s component tests supports its adoption. Broad adoption of the full diagnostic algorithm, including through reflex testing, has been challenging but is critical to identifying active infections, and for appropriately classifying cases.

However, NASTAD is concerned that the proposed orders address prescription devices only. The availability of tests that enable consumer self-testing (i.e. “home tests”) that are accessible over the counter would be of substantial value to public health efforts to increase access to HCV testing. This is essential in addressing gaps regarding accessibility to affordable testing and can be adapted for use via different testing strategies and modalities. Additionally, the need for non-prescription “self-testing” devices has been significantly enhanced as a critical means to sustain HCV testing as limits have been placed on the availability of clinical and outreach testing as a result of the COVID-19 pandemic. We urge FDA to strongly consider including non-prescription devices in the final order tests, as this could be expected to stimulate manufacturers to adapt tests for use by consumers for “home use.”

If the proposed reclassification order is adopted, it could serve to stimulate bringing new technologies to market and support us in achieving our public health goals to eliminate HCV in the U.S.

Thank you for the opportunity to provide commentary. Please contact me at slee@nastad.org with questions.

Sincerely,

Stephen Lee MD, MBA, DHSM
Executive Director
NASTAD