CLIAC
Clinical Laboratory Improvement Advisory Committee

February 11, 2019

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's recommendations regarding the role of the laboratory in the opioid crisis.

BACKGROUND
During the November 7-8, 2018 CLIAC meeting, four presentations were given on current issues surrounding the opioid crisis and the role of the laboratory. The meeting summary can be found at https://www.cdc.gov/cliac/docs/fall-2018/CLIAC_November_2018_Summary.pdf.

After deliberating on how clinical laboratory data can add support and value to the opioid response and ways in which the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA) can improve clinical laboratory engagement in response activities, the Committee voted to provide the following recommendations to HHS.

CLIAC recommends that the CDC, CMS, and FDA convene a blue-ribbon panel (e.g. with input from the Council for State and Territorial Epidemiologists) on laboratory engagement in controlling the opioid crisis. The panel should address the following, with emphasis on standardization of scope of testing (list of analytes), different methodologies, no clear reference laboratory system, inadequate capacity (especially in the forensic area), inadequate capability to test for novel analogs ("designer opioids"):

1. How can information on the clinical and analytic properties of presumptive and definitive (confirmatory) drug testing methods be best communicated with providers who order and utilize these tests?
2. How can a list of analytes (drugs or metabolites) be standardized (e.g. nationally vs. by region), especially given the rapid change in usage patterns?

3. What incentives and regulatory approaches may improve access to definitive (confirmatory) drug testing?
4. What approaches to laboratory-based surveillance and reporting, leveraging preexisting systems for reporting public health concerns of communicable diseases, cancer, heavy metals, and HIV/AIDS (e.g. Electronic Clinical Laboratory Reporting System, New York Department of Health), might improve our ability to monitor and address the epidemic of drug misuse?
5. Investigate the feasibility for Departments of Health to require clinical laboratories to report drugs-of-abuse toxicology results (a reference laboratory system).

CLIAC is committed to providing HHS thoughtful advice related to clinical laboratory quality improvement and laboratory medicine practice. Thank you for your consideration.

If you have any questions regarding CLIAC's recommendation, please feel free to contact me via email at rarnaout@bidmc.harvard.edu or by telephone at 617-538-5681.

Sincerely,

Ramy A. Arnaout, M.D, D.Phil
Chairperson
Clinical Laboratory Improvement Advisory Committee (CLIAC)

cc:
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Director, CDC

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