



Minutes of Meeting – December 11, 2020

The Laboratory Advisory Committee (LAC) meeting took place by conference call at 1:00 p.m.

Members Attending: John G. Newby, Chair, American College of Pathology
Piyush K. Patel, Vice Chair, American College of Physicians
Barbara S. Caldwell, American Society of Clinical Pathology
Melissa Day, Consumer Member
Lindsey Howard, Jr., Industry
Gail McGucken, Laboratory Surveyor Scientist II, OHCQ
Thomas J. Remsberg, Pharmacist

Other Attendees: Rodney Hargraves, Deputy Director, Administrative and Support Services
Renee Scurry, Administrator, Regulatory and Administrative Services
Hope Miller, Paralegal II, Regulatory and Administrative Services
Paul Celli, Public Health Administrator, OHCQ

Members Absent: Gattu Rao, Maryland Academy of Family Physicians

Dr. Newby called the meeting to order at 1:10 p.m.

I. Review and Approval of May 28, 2020 and November 20, 2020 Meeting Minutes

The Laboratory Advisory Committee minutes from the May 28, 2020 meeting and November 20, 2020 emergency meeting were previously distributed via email. Dr. Newby first asked for a motion to accept the May 28th minutes as drafted. The motion was made by Dr. Patel and the minutes were accepted. Thereafter, Dr. Newby asked for a motion to accept the November 20th emergency meeting minutes. A motion was again made by Dr. Patel and the November 20th minutes were accepted.

II. Final Vote Tally And Response Letter For Acting Secretary Dennis Schrader Re: Request From MedChi (On Behalf Of Cepheid) For A Letter of Exception

The Laboratory Advisory Committee (“LAC”) received a request from The Maryland State Medical Society (on behalf of Cepheid) which requested the LAC to grant a Letter of Exception for Cepheid’s Xpert® Xpress SARS CoV-2, Flu A, Flu B and RSV combination test. The LAC thereafter held an emergency conference call meeting to review this request.

Briefly, the LAC is an advisory board which renders its opinion as to whether a request for excepted status should be granted a Letter of Exception. Therefore, with regard to the request by MedChi on behalf of Cepheid, the final vote recommendation is as follows: 1 – Yes, 1 – No and 6 – Yes’ with conditions. In addition, once Cepheid’s emergency use authorization for the four-in-one combination test ends, the LAC will consider the test for the point of care system as an accepted methodology.

In terms of a response, the LAC will not send a letter to MedChi. Alternatively, the Secretary will forward a letter to MedChi to inform them of the LAC’s recommendation; and there were no objections to this protocol.

III. Legislative Session 2021

The Maryland General Assembly will convene on January 13, 2021. During the legislative session the LAC may be contacted to review legislation that may have an impact on the Committee, the Department or any other legislative matter of importance.

In the event the LAC is needed to address legislation, an emergency meeting will be scheduled to review any bills that require LAC input. For example, during previous sessions, the LAC reviewed bills concerning genetic testing in the State of Maryland. The bills, if enacted, would repeal a prohibition on medical laboratories from directly or indirectly advertising to and/or soliciting business from anyone other than a physician, hospital, medical laboratory, clinic, clinical installation, or other medical facility; and would allow medical laboratories to market genetic testing products directly to consumers.

IV. Introduction of New Consumer Member Melissa Day

Ms. Melissa Day introduced herself to the Committee. Melissa Day studies the health of the environment; and has a background in analytical chemistry and environmental science. She has worked at various research institutions, to include the Smithsonian Environmental Research Center (SERC), the University of Maryland, and private certified testing labs. Currently Melissa is on a career hiatus, while she raises her 3-year-old daughter and is finishing her master's degree in Environmental Science at the University of Maryland. Melissa's husband, Webster Ye, works at MDH and thought she'd be a good fit for the LAC.

The meeting was adjourned at 1:24 p.m.

Respectfully submitted,

Renee Scurry and Hope Miller
MDH Laboratories Administration
Office of Regulatory and Administrative Services