



COLLEGE of AMERICAN PATHOLOGISTS

March 31, 2016

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2015-N-4809 for "Patient and Medical Professional Perspectives on the Return of Genetic Test Results and Interpretations "

Dear Dr. Califf:

The College of American Pathologists (CAP) appreciates this opportunity to comment on the Food and Drug Administration (FDA) discussion paper for the FDA Public Workshop on "Patient and Medical Professional Perspectives on the Return of Genetic Test Results". The CAP is a medical society serving more than 18,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. The College advocates accountable, high-quality, and cost-effective patient care. The CAP Laboratory Accreditation Program (LAP) is responsible for accrediting more than 7,000 clinical laboratories worldwide. Our members have extensive expertise in providing and directing laboratory services and also serve as inspectors in the Centers for Medicare & Medicaid Services (CMS)-deemed CAP accreditation program. The CAP welcomes the opportunity to work with the FDA on reporting of genetic test results.

The CAP has been developing guidelines on data reporting for more than 25 years so we are supportive of the FDA's efforts to ensure genetic results are provided in a format that is useful to patients and clinicians. The CAP holds that patients are best served generally when a qualified physician orders laboratory tests where such a physician directs the course of the diagnostic and therapeutic care of the patient, and that a physician should determine which clinical and anatomic laboratory services are appropriate. We agree that engagement with patient groups on how genetic results should be interpreted and returned in various testing scenarios such as well-person predictive testing (APOE, BRCA1/2), somatic mutation testing in oncology, pharmacogenetic testing and direct to consumer (DTC) genetic testing is critical for optimal patient care.

Feedback from patients and medical experts regarding preferences for reporting of genetic results is always welcomed; however, reporting of genetic results is part of the practice of pathology. Reports are specific formal medical documents from the laboratory to the referring physician and/or other health-care professionals regarding the results and interpretation of genetic testing in a patient and/or members of a family. The main goal of reports is to provide a clear, concise, accurate, fully interpretative and



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authoritative answer to a clinical question. Therefore, the genetic test report should provide a clear, concise, accurate, fully interpretative and authoritative answer to the clinical question.

DTC testing may be appropriate in some scenarios, specifically well-patient predictive testing. DTC testing, whether genetic or traditional testing, has the potential to generate useful diagnostic or prognostic information and may allow individuals to be more fully informed about their own health or disease status, predisposition to developing disease, likelihood of acquiring a disease or risk, or likelihood of transmitting a disease or risk to others. Nevertheless, DTC, as with clinical testing ordered by a licensed provider, poses a number of risks to public safety. Any genetic testing that will be used to alter medical care or treatment should be performed in a clinical setting and interpreted and reported by appropriate CLIA-certified laboratory pathologists/directors. The CAP believes that the pathologist should develop genetic test reports based on professional practice reporting guidelines recommendations.

Please contact Helena Duncan, CAP Assistant Director, Economic and Regulatory Affairs at hduncan@cap.org or Fay Shamanski, PhD, CAP Assistant Director, Economic and Regulatory Affairs at fshaman@cap.org if you have any questions on these comments.

Closing,

The College of American Pathologists

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