COLLEGE of AMERICAN PATHOLOGISTS

November 20, 2024

Robert Califf, M.D.
Commissioner
US Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: FDA Draft Guidance, "Predetermined Change Control Plans for Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff": Docket No. FDA-2024-D-2338

Submitted via Electronic Submission to www.regulations.gov

Dear Dr. Califf:

The College of American Pathologists appreciates the opportunity to comment on the Food and Drug Administration (FDA) draft guidance entitled, "*Predetermined Change Control Plans (PCCP) for Medical Devices*." As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. As physicians specializing in the diagnosis of disease through laboratory methods, pathologists have a long track record of delivering high quality diagnostic services to patients and other physicians.

PCCP is documentation developed by a test developer and submitted to the FDA outlining planned modifications and assessments of those modifications to a device. The PCCP is reviewed as part of the premarket submission, negating the need for additional market submissions for future modifications. The CAP applauds the FDA for providing in the draft guidance a pathway that allows traditional test developers/manufacturers to modify test systems to keep pace with the evolving needs of pathologists and clinical laboratories. The CAP appreciates the example of updating breakpoints for Antimicrobial Susceptibility Test (AST) System Devices. The CAP has advocated for updates to these AST system devices because the lack of AST systems updates created a significant patient safety issue.

While the CAP appreciates the FDA's efforts to develop innovative approaches to regulation of traditional medical devices, we are concerned about the timing of the draft guidance in combination with the FDA's phase out of enforcement discretion for laboratory-developed tests (LDTs). The draft guidance in combination with the final rule on LDTs may result in a significant reduction in the number of highly accurate LDTs available in hospital and health system laboratories. The PCCP draft guidance requires

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developers to include specific modifications that are expected to be made over time and can be verified and validated by the FDA. It should not be an extensive list of all modifications rather a few. Moreover, the PCCP must align with the intended use, which would not include specimen types or performance changes.

Laboratories modify existing FDA approved/cleared kits and/or LDTs to meet unmet needs by adding new specimen types because of new indications or patient populations; address the technical approach of an assay that does not perform adequately, consider cost because the laboratory possesses a testing platform/equipment or the availability of reagents. LDTs have been critical for the advancement of medicine and contributed to the evolution of modern evidence-based health care services. LDTs continue to play a critical role in the advancement of medicine and clinical care for patients. We are concerned if this guidance is finalized in combination with the FDA LDT final rule, laboratories will not be able to respond to requests from physicians to provide LDTs.

Since medical practice undergoes continuous process change because of drug development and new treatments changing patient management strategies, the clinical laboratory must adapt and change in parallel to support or extend clinical practice. The CAP recognizes that quality practices in the laboratory specified by Clinical Laboratory Improvement Amendments (CLIA) are distinct from operational requirements defined by a medical device developer and approved by the FDA. Our members have extensive expertise in providing and directing laboratory services under the (CLIA) regulations, which require compliance with requirements (verification and validation of any new or modified tests or devices) through a quality system approach for overall operations and administration of the clinical laboratory. While PCCP may be an innovative approach for traditional test developers/manufacturers, it would create additional regulatory burden and uncertainty for laboratory-based developers as most clinical laboratories frequently use and modify low-risk tests to address clinical needs for their local patient populations.

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with the FDA and always stands willing to work with government agencies, industry, pathologists, and other stakeholders to support high quality laboratory operations and medical care. Please direct questions on these comments to Helena Duncan at hduncan@cap.org.

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