COLLEGE of AMERICAN PATHOLOGISTS

March 15, 2021

Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration (FDA)
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Making Permanent Regulatory Flexibilities Provided During the COVID–19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program [Docket No. 0991–ZA52]

Dear Dr. Woodcock:

The College of American Pathologists (CAP) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the *Making Permanent Regulatory Flexibilities Provided During the COVID–19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program*. 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. Pathologists are physicians who specialize in the diagnosis of disease through laboratory methods, and their primary mission is the delivery of high-quality diagnostic services to patients and other physicians.

In response to the COVID–19 Public Health Emergency (PHE), the FDA issued guidance documents providing regulatory flexibilities, including a temporary waiver of premarket notification requirements under section 510(k) of the Food, Drug, and Cosmetic Act. Impacting pathology was the FDA guidance entitled, *Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency*, intending to expand the availability of devices for remote reviewing and reporting of scanned digital images of pathology slides during this pandemic. By issuing the permanent regulatory flexibilities proposal, the Department of Health and Human Services (HHS) is permanently exempting seven (7) class I devices from the 510(k) requirement and is also proposing to exempt an additional 83 class II devices including digital pathology devices. While the CAP supports efforts to provide regulatory flexibility, we caution against moving forward with a proposal for three of the four digital pathology product codes (QKQ, PSY, and OEO)[1] because it may result in unintended consequences such

[1] PZZ – Digital Pathology Display (21 CFR 864.3700),
QKQ – Digital Pathology Image Viewing and Management Software (21 CFR 864.3700),
PSY – Whole Slide Imaging System (21 CFR 864.3700), and

as issues with lack of standardization, interoperability, and increased physician liability. In addition, there should be consideration for the affects the digital pathology systems waivers for whole slide imaging systems and management software may have on artificial intelligence (AI) tools in the future.

Regulatory reflexibility should include a framework that can assess the totality of an open system, including impact of individual components that may be waived as well as include parameters to monitor and adjudicate whether the waivers are appropriate. The current proposal to permanently exempt these digital pathology products does not satisfy these criteria. However, for digital pathology displays (product code PZZ), the FDA should move forward with permanently exempting this product from the FDA 510 (k) premarket notification requirements since the evaluation of the digital imaging scanners is an element of the institutional validation process. The CAP provides support through more stringent laboratory accreditation requirements than CLIA on validation, user training and quality management which are added controls to the current regulatory framework. As specified by the CAP Whole-Slide Imaging guidelines and CAP Accreditation Checklist, clinical laboratories must perform a validation before using these systems within the clinical laboratory. Forcing laboratories to use specific monitors adds unnecessary cost which is not supported by current evidence and is counter-productive to the adoption of this technology.

In addition, the deregulation of digital pathology components and systems should be based on robust data that are more extensive and transparent. This regulatory decision was made based on the Manufacturer and User Facility Device Experience database (MAUDE) in which medical device reports (MDRs) are submitted to the FDA by mandatory reports (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. For digital pathology codes, MAUDE reports three total adverse event reports none of which include any death related incidents within the last ten years. From a survey conducted by the CAP in September, 5.4%[2] of CAP accredited laboratories reported using WSI systems during the PHE. The current data is inadequate to assess risk these systems pose. Given this limited amount of data and other special controls, the decision to make permanent the PHE waivers for product codes (QKQ, PSY, and OEO) is premature.

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The CAP welcomes the opportunity to discuss our concerns and recommendations for implementation at your earliest. Please contact Helena Duncan at hduncan@cap.org or 202.354.7131.

Closing,

OEO – Automated Digital Image Manual Interpretation Microscope (21 CFR 864.1860)

[2] COVID-19 Pathologist Impact Survey: Summary of Findings. October 2020.www.cap.org

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Sent via regulation.gov

References

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