MDUFA V Public Meeting

American Medical Association Remarks

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About the AMA

- The AMA mission is to promote the art and science of medicine and the betterment of public health
- AMA was founded in 1847 to address the use of unproven therapies to treat medical conditions
- AMA is the largest physician organization in the US, with approximately 256,000 members
- AMA policy is set by its House of Delegates who represent 200 organizations including:
  - 125 national medical specialty societies and associations
  - 54 state and territorial medical societies
  - 5 delegations that represent the uniformed services
- AMA is committed to care that is based on the best science and evidence, patient-centered, and collaborative; We actively seek common ground with others working to improve health and health care

AMA Policy: Funding the FDA

- Longstanding AMA policy supports adequate funding for the FDA so that patients in the US have access to the broad range of products, including medical device and biologics under FDA jurisdiction

- AMA publicly supported previous iterations of user fee agreements to make the medical product approval process as efficient as possible without compromising standards of safety and effectiveness

MDUFA IV Performance

- FY 2018 and FY 2019 MDA reports note significant progress in meeting MDUFA IV performance goals
- Thus far, in FY 2020, FDA continues to make and report progress in performance goals in the face of enormous demands on the Agency and staff due to COVID-19
- Challenges related to product review and issuance of guidance are likely to continue throughout the COVID-19 pandemic and beyond

Vaccines

- AMA deeply appreciates the professional scientific staff of the Center for Biologics Evaluation and Research (CBER) throughout the pandemic
- A special thanks to Dr. Peter Marks for being the speaker on the first program in AMA's COVID vaccine webinar series produced to inform physicians of the vaccine review and approval process
- AMA is committed to assisting CBER and FDA in communicating timely updates to clinicians and patients to ensure a safe and effective approach to vaccines against SARS-CoV-2

Considerations for MDUFA V

Digital Health and Artificial Intelligence (AI)

- Establishment of the Digital Health Center for Excellence fulfills a major commitment made in MDUFA IV and will focus CDRH's regulatory efforts in this space
- AMA believes there is a strong need for additional clarity on the appropriate regulatory pathways for AI
- The review process must ensure that digital health products, and AI products in particular, are designed with the end users in mind: patients and physicians
- Patient safety must be paramount in any AI regulatory regime
- The AMA requests that the draft guidance "Risk Categorization Software as a Medical Device: FDA Interpretation, Policy and Considerations," which could bring clarity to this space, be moved to the highest category (Category A) in the recently published CDRH 2021 priorities for guidance documents

Considerations for MDUFA V

Appropriate Risk Considerations for AI Regulation

- AMA reiterates its previous comments to FDA that the IMDRF was not developed to consider the added dimensions of risk presented by certain types of AI, particularly continuous learning ML systems
- If FDA is to continue to rely on the IMDRF framework, AMA recommends that it be modified to account for the potential risks that come with continuous learning systems
- There must be clear standards for data necessary to demonstrate safety for products classified as high risk
- AMA urges FDA to consider new labeling approaches for AI products to include summaries of the evidence underlying the effectiveness of the algorithm and the patient populations in whom the product can be used
- The least burdensome approach to evaluation may not be the best way of ensuring patient safety and earning clinician trust, especially in the evaluation of novel AI and digital health products

Considerations for MDUFA V

Real World Evidence (RWE)

- AMA supports the continued collection and use of RWE to support regulatory decision-making where appropriate and restates it commitment to use of randomized controlled clinical trials as appropriate
- National Evaluation System for health Technology (NEST)
  - AMA applauds the progress made to date to establish NEST, engage data partners, issue methods and data quality guidance, support test cases across a wide range of clinical domains and regulatory pathways, and establish NEST 1.0
  - As NEST scales up from test cases to TPLC evaluation across the medical device ecosystem, physicians and patients will want and expect to be “in the communications loop” so that findings, favorable or unfavorable, inform shared decision-making at the point of care

Concluding Remarks

- Strong support for MDUFA reauthorization
- AMA applauds FDA for its response to the COVID-19 pandemic, particularly its:
  - actions taken to address supply chain issues, and
  - commitment to rigorous review of vaccines against the SARS-CoV-2 virus
- AMA seeks greater clarity on appropriate regulatory pathways for digital health and AI products
- AMA expresses strong support for continued funding of NEST to fully realize the return on the investments made so far

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