PDUFA VII Public Meeting

American Medical Association Remarks

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July 23, 2020

About the AMA

- We are the largest physician advocacy organization in the United States with approximately 256,000 members

- We represent physicians nationwide through the House of Medicine which includes:
  - 25 national medical specialty societies and associations
  - 54 state and territorial medical societies
  - 5 uniformed services

- We address the most pressing health care issues through innovative initiatives that produce products and services to remove the dysfunction in health care

- We are science and evidence-based, patient-centered, care team-focused, and actively seek common ground with others working to improve care delivery

Adequate Funding for the FDA

- AMA has long standing policy support for adequate funding for the FDA

- AMA publicly supported previous iterations of PDUFA with the primary purpose to make the drug approval process as efficient as possible without compromising standards for proof of efficacy and safety

PDUFA VI Performance

- FDA reports of FY 2018 and FY 2019 note significant progress in meeting performance goals
- Thus far, in FY 2020, FDA continues to make and report progress in performance goals despite shifting Agency staff responsibilities due to COVID-19
- The current pandemic has exposed vulnerabilities in the global medicine supply chain leading to uncertainty, drug shortages, and quality issues
  - Inspection of manufacturing facilities has been problematic
- Recognize that challenges related to clinical trial facilitation and completion will continue following COVID-19

Considerations for the Next Iteration of PDUFA

Health Equity

“You can’t fix something that you don’t measure. The goal is to improve health outcomes. To accomplish that, it is necessary to address the factors that contribute to inequities…”

-Aletha Maybank, MD, MPH,
AMA Chief Health Equity Officer

- Collect and share more accurate data related to race and ethnicity
- Create and enforce strict requirements for clinical trials to accurately resemble patient populations

Considerations for the Next Iteration of PDUFA

Drug Supply Chain and Drug Shortages

- Accelerate the development and adoption of pharmaceutical manufacturing innovations

- Require drug manufacturers to establish a plan for continuity of supply, including resiliency and redundancy in manufacturing capability, of medications and vaccines to avoid production shortages

- Require transparency from manufacturers regarding production locations of drugs and more detailed information regarding the causes and anticipated duration of drug shortages

Considerations for the Next Iteration of PDUFA

Medication Quality and Drug Safety

- Develop and enforce standards that make ingredients used to manufacture pharmaceuticals and ingredients used by patients in the United States transparent to prescribers and the general public
- Adequately conduct unannounced safety inspections abroad
- Evaluate and facilitate implementation of effective tracking systems for pharmaceuticals
- Continue modernization of the drug safety system and use of novel techniques, including real-world evidence, to maximize the usefulness of tools used for collecting adverse event information at various points during the product lifecycle

Concluding Remarks

- COVID-19 has exposed weaknesses and opportunities for improvement
- Strong support for PDUFA reauthorization
- Considerations related to:
  - Collecting race and ethnicity data and including minority populations in clinical trials
  - Strengthening the drug supply chain to ensure an uninterrupted supply of medicines
  - Advancing medication quality standards, effective pharmaceutical tracking systems, and drug safety systems

Physicians' powerful ally in patient care