The Focal Point: Advocacy & Legislative Update

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WHO Report Finds 1 Billion Worldwide with Preventable Vision Impairment

The World Health Organization's first *World Report on Vision* estimates that 2.2 billion people have vision impairment or blindness, with more than 1 billion people living with a preventable vision impairment. This includes:

- Unaddressed refractive error (123.7 million)
- Cataract (65.2 million)
- Glaucoma (6.9 million)
- Corneal opacities (4.2 million)
- Diabetic Retinopathy (3 million)
- Trachoma (2 million)
- Unaddressed presbyopia (826 million)

The burden of eye conditions and vision impairment is not borne equally. The burden tends to be greater in low- and middle-income countries and underserved populations, such as women, migrants, indigenous peoples, persons with certain kinds of disability, and in rural communities. Aging populations, changing lifestyles and limited access to eye care will dramatically increase the number of people with eye conditions, vision impairment and blindness.

The report recommends five important actions:

1. Make eye care an integral part of universal health coverage.
2. Implement integrated people-centered eye care in health systems.
3. Promote high-quality implementation and health systems research complementing existing evidence for effective eye care interventions.
4. Monitor trends and evaluate progress towards implementing integrated people-centered eye care.
5. Raise awareness and engage and empower people and communities about eye care needs. In addition, more eye care services are needed in order to prevent, detect and treat these issues.

FDA Finalizes Guidance on PDUFA Fee Waivers, Reductions and Refunds

The FDA finalized guidance providing advice to drug and biologic sponsors looking to apply for *Prescription Drug User Fee Act* (PDUFA) fee waivers, reductions and refunds. This guidance finalizes the draft guidance for industry of the same title issued in June 2018.

Specifically, the guidance explains the various types of fee waivers, reductions and refunds offered to industry, such as those for pressing public health needs, small business entities and when paying the fee would be a significant barrier to an applicant's ability to develop a drug.

The final guidance adds a section with instructions for where and how to submit written requests for fee waivers, reductions and refunds; explains that the deadline for requesting a program fee refund is 180 calendar days from the date the fee is due; and includes an appendix containing Form FDA 3971, which is to be used by small businesses for requesting a fee waiver or refund.

CDRH Proposed Guidances for Fiscal Year 2020

FDA's Center for Devices and Radiological Health (CDRH) released its FY 2020 draft and final guidance list, which CDRH intends to publish this fiscal year. CDRH divides the list between "A-list" which are prioritized device guidance documents and a smaller "B-list" which CDRH will publish as resources permit.

CDRH plans to finalize many of the previously released draft guidance topics and proposes draft guidance on unique device identification, patient-reported outcome measures used in device submissions, and computer software assurance for manufacturing, operations, and quality system software.

FDA Revises Guidance on Drug Master Files

The FDA has revised the 1989 draft guidance on drug master files (DMFs), which are submissions to FDA providing confidential, detailed information about facilities, manufacturing, processing, packaging and storing drugs. This guidance provides information about preparing and submitting DMFs. It describes DMF types, the information needed in DMF submissions, and FDA's DMF review processes.

This guidance focuses on the following submissions to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER):

- DMFs under 21 CFR 314.420 that are used to support new drug applications (NDAs), abbreviated new drug applications (ANDAs), and investigational new drug applications (INDs) under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

- DMFs and other master files under 21 CFR 601.51(a) that are used to support biologics license applications (BLAs) under the Public Health Service Act (PHS Act).

This guidance has been distributed for comment purposes only.

FDA Approves Rapid Diagnostic Test for Ebola

The FDA approved marketing of the OraQuick Ebola Rapid Antigen diagnostic test for Ebola Virus Disease (EVD). The OraQuick Ebola Test is intended for use in patients suspected of and with symptoms consistent with EVD. It may also be used in recently deceased individuals with epidemiological risk factors suspected to have died from EVD to inform decisions on safe handling of cadavers. This test is not intended for general Ebola infection screening (e.g., airport screening) or testing of individuals at risk of exposure without observable signs of infection.

France Reports First Locally-Acquired Zika Case

The European Centre for Disease Prevention and Control (ECDC) confirmed the first case of locally acquired Zika virus (ZIKV) disease in southern France. The patient is from the city of Hyeres in Var department in the country's southeast. The individual had Zika symptoms during the first half of August, and lab tests confirmed the case on Oct 1. The investigation found the patient had not traveled to any countries that have a history of Zika transmission, along with no evidence of sexual transmission. No imported infections were reported in the patient's area for 2019.

Further investigation is under way to determine how the patient contracted Zika virus, but for now, health officials suspect vector-borne transmission. Vector control measures are being implemented near the residence of the case.

Officials assess the risk of Zika spread as very low, given the lack of evidence of a more extensive cluster and the fact that decreasing temperatures as autumn progresses aren't favorable for sustaining transmission.

NIH to Launch Tick-Borne Disease Research Initiative

The National Institutes of Health (NIH) announced a five-year strategic plan to accelerate research and improve scientific understanding tick-borne diseases. Cases of infection are up in the last two decades, with an increase of almost 10,000 tick-borne disease cases from 2016 to 2017.

The NIH Strategic Plan for Tickborne Disease Research focuses on the following five scientific priorities for advancing research and development:

- Increasing fundamental knowledge of tick-borne diseases, including the biology of tick-borne pathogens and how they are transmitted to humans, evade the immune system and spread within the body.
- Improving detection and diagnosis of tick-borne diseases by developing rapid diagnostic tests that can detect a pathogen both early and late in the infection and distinguish between active and past infections.
- Supporting the development of diagnostics capable of predicting treatment success and identifying human biomarkers of infection and persistent symptoms.
- Developing new treatments for tick-borne diseases and techniques to reduce disease complications.
- Prioritizing the development of tools and resources to advance tick-borne disease research by improving scientists' access to biological samples and tick-borne disease genetic data and by supporting preclinical development of promising products.

OIG to Assess FDA's Postmarket Surveillance of Devices

The US Department of Health and Human Services' Office of Inspector General (OIG) will issue a report next year on the US Food and Drug Administration's (FDA) postmarket surveillance of medical devices, which has come under fire in recent months. OIG will assess and describe how FDA's "established passive postmarket surveillance system" identifies and tracks safety concerns and responds to them. They will also describe how elements of FDA's newer surveillance system initiatives, such as the Unique Device Identification system, are being integrated into the passive postmarket surveillance system. OIG will describe how FDA plans to integrate these initiatives into the National Evaluation System for health Technology (NEST), its in-development active postmarket surveillance system.

Upcoming Events & Deadlines

October 28:	Physician Leadership Program Nomination Deadline
November 6:	Webinar: Developing Ambassadors to Promote Your Mission
November 18:	2020 Annual Meeting: Presentation Proposal Deadline
February 18:	2020 Annual Meeting: Scientific Symposium Proposal Deadline
February 20-22:	Technician Education Seminar