The Focal Point: Advocacy & Legislative Update
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FDA Approves First Drug for Neurotrophic Keratitis

The U.S. Food and Drug Administration (FDA) approved Oxervate (cenegermin), the first drug for the treatment of neurotrophic keratitis, a rare degenerative corneal disease which occurs in less than five in 10,000 individuals.

Neurotrophic keratitis is a degenerative disease involving loss of corneal sensation, which leads to progressive damage to the top layer of the cornea, including corneal thinning and ulceration, and, in severe cases, perforation of the cornea. Cenegermin is a recombinant form of human nerve growth factor that stimulates growth and survival of corneal epithelial cells.

The safety and efficacy of cenegermin were studied in two randomized, controlled, double-blind studies involving a total of 151 patients with neurotrophic keratitis. Cenegermin eye drops were given six times daily in the affected eye(s) for 8 weeks.

Across both studies, complete corneal healing in 8 weeks occurred in 70% of patients treated with cenegermin compared with 28% of patients treated with inactive eye drops.

The most common adverse reactions in patients using cenegermin eye drops are eye pain, ocular hyperemia, eye inflammation, and increased lacrimation.

Cenegermin received priority review and had orphan drug designation. Manufactured by Dompé in Italy, the drug was previously approved in the European Union.

FDA Requests Nominations for Membership on Device Good Manufacturing Practice Advisory Committee and Panels of the Medical Devices Advisory Committee

FDA is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee and device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health.

For the Ophthalmic Devices Panel, they are looking for Ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials

Nominations for membership should be submitted electronically by logging into the FDA Advisory Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* on or before October 22, 2018.

FDA Commissioner Announces Steps to Modernize the Agency

FDA Commissioner Scott Gottlieb, MD, announced additional steps the agency is taking to modernize the agency's organizational structure and update the drug review process.

Dr. Gottlieb highlighted the changes in the Center for Drug Evaluation and Research (CDER), which operates the Office of New Drugs (OND), that will expand the number of review offices from 5 to 9

and the review divisions from 19 to 30. Ophthalmology is anticipated to have its own drug division. FDA plans to issue many more product-specific guidance documents in the future.

The role of clinical trials is also being reimagined as part of the work around modernizing drug and device regulations. New steps to improve clinical development programs include breaking down barriers to device early feasibility studies and new policy initiatives for pharmaceuticals.

Senate Passes Defense-LHHS Minibus

The Senate passed the Defense, Labor, Health and Human Services, and Education and Related Programs "Minibus" appropriations bill for FY 2019, accounting for 65 percent of all discretionary spending. The bill passed with broad bipartisan support by a vote of 85 to 7.

The legislation provides $2 billion in additional funding for the National Institutes of Health (NIH), or 5.4 percent over FY2018, to $39.08 billion. National Eye Institute (NEI) funding increased by $25 million, or 3.2 percent over FY2018, to $797 million.

Attention now turns to the House of Representatives, which has eleven legislative days until the Sept. 30 deadline to enact a funding package to avoid shutdown of the affected departments.

Denmark to Introduce 4-month Donor Deferral for MSM

Denmark will introduce new rules allowing men who have sex with men (MSM) to donate blood after a four-month deferral period following sexual contact, the Danish Minister of Health, Ellen Trane Nørby, announced on Aug. 17.

Last year, the Minister of Health directed the Danish Board of Patient Safety to modernize the country's rules on blood donation and to assess the possible effects of different deferral periods. Current Danish policy defers MSM from donation indefinitely. The four-month deferral period will take effect in 2019.

BSE Discovered in a Florida Cow

A 6-year-old beef cow in Florida tested positive for atypical H-type Bovine Spongiform Encephalopathy (BSE), commonly known as mad cow disease, according to the U.S. Department of Agriculture (USDA).

The animal was tested as part of routine surveillance of cattle that are found to be unfit for slaughter. The cow was destroyed, and "never entered slaughter channels and at no time presented a risk to the food supply, or to human health in the United States," the agency said in a statement.

This is the sixth detection of BSE in the United States. The first, found in 2003, was a case of classical BSE in a cow imported from Canada. The remaining five have been atypical BSE cases.

Alcon Pulls CyPass Micro-Stent From Global Market

Alcon (Fort Worth, TX) announced an immediate, voluntary market withdrawal of all versions of its CyPass Micro-Stent from the global market based on the results of a five-year post-approval study. Alcon advises surgeons to immediately cease further implantation of the CyPass and to return any unused devices to Alcon.

The FDA approved the CyPass in July 2016 for use in conjunction with cataract surgery in adult patients with mild to moderate primary open angle glaucoma based on the results of the 2-year

COMPASS study. The COMPASS-XT study tracked data on patients who had completed the two-year COMPASS study for an additional three years. Analysis of the resulting additional data showed patients implanted with the stent experienced statistically significant endothelial cell loss compared to the group that underwent cataract surgery alone.