Focal Point – March 3, 2020

In this Issue:

Coronavirus Disease 2019 (COVID-19) Update

EBAA released updated COVID-19 Screening Recommendations for EBAA Member Eye Banks on March 2, 2020

The EBAA recommends that eye banks exclude/defer (rule out) potential donors for ocular tissue who in the last 28 days before donation met one or more of the following criteria:

Clinical Features		Epidemiological Risk
Any (or none)		Tested positive for or suspected of having COVID-19 within the past 28 days
Any (or none)		Traveled to an area with a Level 3 travel warning defined by the US Centers for Disease Control & Prevention within the last 28 days*
Fever **or** signs/symptoms of lower respiratory illness (e.g. cough or shortness of breath)	AND	A history of travel from affected geographic areas with widespread or sustained community transmission within the last 28 days**
Fever **or** signs/symptoms of lower respiratory illness (e.g. cough or shortness of breath)	AND	Any person, including healthcare workers, who has had close contact with a laboratory-confirmed COVID-19 patient within the last 28 days
Severe acute lower respiratory illness (e.g. pneumonia, ARDS) without alternative explanatory diagnosis (e.g. responsible organism identified by culture or other testing)	AND	No source of COVID-19 exposure within the last 28 days has been identified

The U.S. has reported 89 confirmed cases of COVID-19, including several cases of community transmission of COVID-19, four deaths in Washington state, the first reported case of COVID-19 in a healthcare worker, and the first potential outbreak in a long-term care facility. Consequently,

the CDC case definition of a person under investigation (PUI) was revised on February 27 and CDC released a CDC Health Alert Network (HAN) Health Update.

CDC has established geographic risk-stratification criteria for the purpose of issuing travel health notices for countries with COVID-19 transmission and guiding public health management decisions for people with potential travel-related exposures to COVID-19.

As of March 2, CDC has issued the following travel guidance related to COVID-19:

- China (Level 3 Travel Health Notice)
- Iran (Level 3 Travel Health Notice)
- South Korea (Level 3 Travel Health Notice)
- Italy (Level 3 Travel Health Notice)
- Japan (Level 2 Travel Health Notice)

Eye banks should be prepared for the possibility of a COVID-19 outbreak in their community. CDC has developed an Interim Guidance for Businesses and Employers to Plan and Respond to Coronavirus Disease 2019 (COVID-19), February 2020, and an Interim Guidance for Healthcare Facilities: Preparing for Community Transmission of COVID-19 in the United States.

EBAA continues to monitor the COVID-19 outbreak and will keep members informed as necessary. Check the COVID-19 Regulatory Updates page on the EBAA website for all of our advisories and guidance.

2019 National Survey of Organ Donation Attitudes and Practices Report Now Available

The U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), has released a report describing the main findings from the 2019 National Survey of Organ Donation Attitudes and Practices (NSODAP). The 2019 NSODAP is the fourth survey of national views taken on organ donation and transplantation, following prior surveys published in 1993, 2005, and 2012. The purpose of these surveys is to help HRSA better understand and track public beliefs, opinions, and behaviors related to organ donation in America.

A recording of the webinar held February 24 is also available. Some of the key findings discussed during the webinar:

- Overall support for organ donation remains high at 90%
- Belief in the benefits of organ donation remains high at 85%
- Nearly half of U.S. adults heard messaging about organ donation in the past year
- Half of U.S. adults have signed up to be organ donors, with the majority signing up at their local Department of Motor Vehicles
- Of those who have not signed up, half expressed a desire to donate organs after death

https://www.organdonor.gov/sites/default/files/about-dot/files/nsodap-organ-donation-survey-2019.pdf

eBPDR System is Now Accessible Through the FDA Industry Systems (FIS)

As of 2/17/2020, the electronic Biological Product Deviation Report (eBPDR) is accessible through FDA Industry Systems (FIS). As a result, FDA has posted updated documents to their website, including:

- Direct Recall Classification Program
- Electronic Submission of Biological Product Deviation Reports (eBPDR)
- Biological Product Deviations
- General Instructions for Completing the Biological Product Deviation Report (BPDR) - Form FDA 3486
- Instructions for Using the eBPDR System

FDA Finalizes 'Biological Product' Definition

The FDA issued a final rule amending its definition of "biological product" to incorporate changes made by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) and the Further Consolidated Appropriations Act, 2020 (FCA Act), and to provide its interpretation of the statutory term "protein."

FDA now interprets the term "protein" to mean "any alpha amino acid polymer with a specific defined sequence that is greater than 40 amino acids in size."

In addition to the final rule, FDA also released two frequently asked questions (FAQ) documents for patients and healthcare providers explaining the transition and how it will affect them.

https://www.federalregister.gov/documents/2020/02/21/2020-03505/definition-of-the-term-biological-product

CBER Raises Concerns with Promotion of RejuvaYou Cellular Products

FDA's Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research (CBER) sent an untitled letter to South Pasadena, CA-based RejuvaYou Medical Corporation, regarding the company's unapproved umbilical cord blood-derived cellular product, adipose-derived cellular product and exosome products.

RejuvaYou markets these products, administered intravenously or intranasally, as treatments for cerebral palsy, Parkinson's disease, traumatic brain injuries, end-stage lung disease and other serious illnesses. FDA noted that "Such unapproved uses raise potential significant safety concerns. Moreover, because the products are administered by various higher risk routes of administration, their use, if contaminated, could cause a range of adverse events."

Because the products are intended for nonhomologous uses, these products would be regulated as drugs as defined in section 201(g) of the FD&C Act [21 U.S.C. 321(g)] and biological products as defined in section 351(i) of the PHS Act [42 U.S.C. 262(i)].

In order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]. Such licenses are issued only after a demonstration that the product is safe, pure, and potent. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug (IND) application in effect as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312].

The untitled letter also said that it appears that the company treats patients with exosomes, which were part of a separate public safety alert from FDA last December. Exosomes for clinical use in humans are also regulated as drugs and biological products under section 351 of the PHS Act and the FD&C Act and are subject to premarket review and approval requirements.

https://www.fda.gov/media/135196/download?utm_campaign=What%27sNew2020-02-13&utm_medium=email&utm_source=Eloqua

FDA Consolidates Nonclinical Immunotoxicity Evaluation Guidance

The FDA issued a new draft guidance consolidating its recommendations on nonclinical safety evaluations for immunotoxicity and withdrew an earlier 2002 guidance on the topic. It does not cover biologics, adjuvanted vaccines and cell and gene therapies.

The guidance applies to new drugs, therapeutic proteins and recombinant/plasma-derived blood proteins regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) but does not apply to cell and gene therapies, adjuvanted vaccines or other types of biologics.

The topics addressed include multiple aspects of immune suppression, modulation, and stimulation, including carcinogenicity assessment and developmental and juvenile animal studies.

https://www.fda.gov/media/135312/download

FDA Finalizes eCTD Guidance

The FDA finalized the seventh revision to its guidance on making regulatory submissions in electronic common technical document (eCTD) format, finalizing a draft version released in July 2019 and replacing the previous final version from January 2019.

This guidance describes how sponsors and applicants must organize the content that they submit to the Agency electronically for all submission types under section 745A(a) of the FD&C Act. This guidance also references several technical specification documents and the Electronic Common Technical Document Conformance (eCTD) Guide, which provide additional details regarding the organization of content for electronic submissions. These include the following submission types:

- Certain investigational new drug applications (INDs)
- New drug applications (NDAs)
- Abbreviated new drug applications (ANDAs)
- Certain biologics license applications (BLAs)

Within the guidance, FDA says it will exempt all Type III drug master files (DMFs) from eCTD requirements, in addition to noncommercial investigational new drugs (INDs).

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications-0

USPSTF Recommends HCV Screening for All US Adults Ages 18-79

The US Preventive Services Task Force (USPSTF) today expanded its recommendation for one-time hepatitis C virus (HCV) screening to include all asymptomatic US adults ages 18-79 years, including pregnant women, who do not have known liver disease. This recommendation updates and expands the Task Force's 2013 guidance, which stated that one-time screening should include adults born between 1945 and 1965, with periodic screening of those at continued risk.

It is a B-level recommendation, indicating that the USPSTF "concludes with moderate certainty" that screening for HCV will have a substantial net benefit. The B level is also important because the Affordable Care Act requires that private insurers and Medicaid cover preventive services recommended at an A or B level by the USPSTF with no deductibles or copayments.

Among reasons for the change, authors cite the almost 3.8-fold increase in cases in the last decade, largely because of more injection drug use and better monitoring.

The recommendation was published online March 2 in *JAMA*.

EPA Registers First Disinfectants to Reduce the Spread of *Candida auris*

The U.S. Environmental Protection Agency (EPA) announced the availability of 11 products that can be used to disinfect surfaces against the multidrug-resistant fungus *Candida auris*, an emerging pathogen that has proven difficult for healthcare facilities to eradicate.

The new products EPA is registering, which include sporicidal and germicidal sprays and wipes, will help hospitals and healthcare facilities reduce the spread of the pathogen, which can cause severe and deadly invasive infections, persists on healthcare surfaces, and spreads easily between patients. EPA worked collaboratively with CDC to ensure product effectiveness against C. *auris.*

In addition to the new EPA-registered products, disinfectants with an EPA claim for *C. difficile* (List K) have been used effectively against *C. auris*. View CDC's web page on infection prevention and control on what products to use if registered products are unavailable.

View information from EPA on *C. auris*.
View information from CDC on *C. auris*.

Ethos Seeks to Ease Concerns of .ORG Community

Ethos Capital, the private equity firm seeking to buy the rights to operate the .ORG domain registry, on Feb. 21 offered a set of legally binding concessions to .ORG registrants concerned about the proposed sale.

Specifically, Ethos has offered to add an amendment in the form of a Public Interest Commitment. They will cap price hikes for initial or renewal registrations of .ORG domain names at no more than 10% for the next eight years, and establish a .ORG Stewardship Council with the authority to veto proposed modifications to .ORG registry policies on censorship, freedom of expression and use of .ORG registration and user data. Notably, the council would not have veto authority on future price hikes.

ASAE and other nonprofit groups have expressed concern that, should the sale to Ethos Capital go through, the private equity firm could hike fees on the nearly 10.5 million registered .ORG names held by associations and other nonprofit groups. California's attorney general and four members of Congress have also requested more information to evaluate the deal's potential impact on .ORG stakeholders.
https://www.keypointsabout.org/pressrelease