# The Focal Point: Advocacy & Legislative Update

## January 21, 2020

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## In This Issue



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### CDC Releases Interim Guidance on 2019 Novel Coronavirus (2019-nCoV) Outbreak in Wuhan, China

The Centers for Disease Control and Prevention (CDC) is closely monitoring an outbreak caused by a novel coronavirus in Wuhan City, Hubei Province, China. Chinese authorities identified the new strain of coronavirus, which is in the same family as the deadly severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). Symptoms of coronaviruses can range from fever and coughing to severe pneumonia and renal failure, and in some cases lead to death.

China's National Health Commission have confirmed nearly 300 cases in China, with the majority reported in Wuhan, central China's largest city. Five cases were reported in the capital Beijing, 14 in Guangdong, in southeast China, and two more in Shanghai, a global financial hub. Suspected cases have also been reported in Yunnan, Sichuan, Guangxi and Shandong provinces. The death toll rose to six Tuesday evening, after the Wuhan Municipal Health Commission confirmed that a 66-year-old male and a 48-year-old female died on January 20.

A number of countries are actively screening incoming travelers from Wuhan and there have been three exported cases confirmed in Thailand, one in Taiwan, one in Japan, and one in South Korea. Health officials in Australia and the Philippines are also probing suspected cases of the virus there**.** The outbreak comes ahead of the Lunar New Year holiday during which hundreds of millions of people are expected to travel.

Most of the infected patients have been traced to the Huanan Wholesale Seafood Market, which has been shut down for disinfection since January 1. The market also sold other live animals, including birds, rabbits and snakes -- suggesting a possible zoonotic origin to the outbreak.

Chinese authorities report fifteen medical personnel are among those infected, and two people in Guangdong province in southern China caught the virus from family members, confirming human-to-human transmission. The World Health Organization (WHO) has called a meeting for Wednesday to consider declaring a global health emergency.

The CDC released a Health Alert Network (HAN) Health Update and interim guidance for health care professionals and public health partners on January 17, 2020.

Patients in the United States who meet the following criteria should be evaluated as a Patient Under Investigation (PUI) for 2019-nCoV:

1. Fever AND symptoms of lower respiratory illness (e.g., cough, shortness of breath) –and in the last 14 days before symptom onset,
   - History of travel from Wuhan City, China -or-
   - Close contact with a person who is under investigation for 2019-nCOV while that person was ill.

2. Fever OR symptoms of lower respiratory illness (e.g., cough, shortness of breath) –and in the last 14 days before symptom onset,
   - Close contact with an ill laboratory-confirmed 2019-nCoV patient.

Starting Friday, travelers from Wuhan to the United States will undergo entry screening for symptoms associated with 2019-nCoV at three U.S. airports that receive most of the travelers from Wuhan, China: San Francisco (SFO), New York (JFK), and Los Angeles (LAX) airports.

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## FDA Seeks Comments Related to Human Tissue Intended for Transplantation

FDA is soliciting comments concerning the collection of information related to regulations under part 1270 (21 CFR part 1270) to prevent the transmission of human immunodeficiency virus, hepatitis B, and hepatitis C, through the use of human tissue for transplantation. Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor.

The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet provisions intended to ensure appropriate screening and testing of human tissue donors and to ensure that records are kept documenting that the appropriate screening and testing have been completed.

The Center for Biologics Evaluation and Research (CBER) estimates that 383 tissue establishments, of which 262 are conventional tissue banks and 121 are eye tissue banks distribute a total of 2,141,960 conventional tissue products, and 130,987 eye tissue products per year with an average of 25 percent of the tissue discarded due to unsuitability for transplant. In addition, they estimate 29,799 deceased donors of conventional tissue and 70,027 deceased donors of eye tissue each year.

Based on a review of the information collection since their last OMB approval, FDA has made no adjustments to their estimated annual recordkeeping burden. Fax written comments on the collection of information by February 10, 2020.

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## FDA Revokes Emergency Authorization on Ebola, Zika Tests

Emergency Use Authorizations on two Ebola tests and one for the Zika virus have been revoked by the FDA because it cleared the tests via more permanent pathways.

FDA revoked both of OraSure's Authorizations on October 10, 2019, under the Federal Food, Drug, and Cosmetic Act in consideration of a De Novo classification request granted to OraSure for the OraQuick Ebola Rapid Antigen Test on October 10, 2019.

FDA revoked DiaSorin's Authorization on October 28, 2019, under the FD&C Act, in consideration of the premarket clearance of DiaSorin's LIAISON XL Zika Capture IgM II assay, which FDA determined to be substantially equivalent to a legally marketed class II predicate device on October 28, 2019.

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## FDA Approves Micafungin Injection for Pediatric Patients with Candidemia

The FDA has approved the first antifungal drug to specifically treat invasive candidiasis in pediatric patients younger than 4 years of age. Candidiasis in newborns is associated with 20 percent mortality and significant morbidity and mortality in infants.

A supplemental new drug application for micafungin injection (Mycamine, Astellas Pharma Inc.) was approved to treat candidemia, acute disseminated candidiasis, *Candida* peritonitis, and abscesses without meningoencephalitis and/or ocular dissemination in infants younger than 4 months of age.

The drug's safety in this population was assessed in 168 pediatric patients who received varying doses of micafungin in 9 clinical trials. The approved dose for MYCAMINE in neonates and young infants less than four months is 4 mg/kg once daily. The safety and effectiveness of the micafungin injection has not been established for candidemia with meningoencephalitis and/or ocular dissemination among infants younger than 4 months, as these may require a higher dose.

This is an expanded indication for the micafungin injection, which was first approved to treat adults with esophageal candidiasis back in 2005, and in 2008 for adults with candidemia, acute disseminated candidiasis, *Candida* peritonitis, and abscesses. A pediatric indication for the drug was approved in 2013, but for children 4 months and older.

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## NSA Discovers Critical Vulnerability in Microsoft Windows Clients and Servers

The US National Security Agency (NSA) has discovered a major flaw in Windows 10 that could have been used by hackers to create malicious software that looked legitimate. Microsoft has issued a patch and recommends that it be installed as soon as possible to fix the vulnerability on all Windows 10 and Windows Server 2016/2019 systems.

The bug is in Windows' CryptoAPI (Crypt32.dll) file, which helps developers cryptographically "sign" software and data or generate digital certificates used in authentication. If the verification check itself isn't trustworthy, attackers can exploit that fact to remotely distribute malware or intercept sensitive data.

The vulnerability affects all versions of Windows 10 as well as Windows Server 2016 and 2019. Eye banks running affected operating systems should turn to Windows Update to find and install the security patch, which will be contained in the latest Cumulative Update. You can also download the patch for your specific version of Windows 10 and Windows Server 2016 or 2019 from Microsoft's Security Update Guide.

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## New Legislation Would Extend Medicare Coverage of Immunosuppressive Drugs for Kidney Transplants

New legislation released late December would extend Medicare coverage of immunosuppressive medications for kidney transplant recipients past the 36-month cut-off currently in place to cover the medications for the life of the transplant patient.

The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2019 (HR 5534) was introduced in the US Senate by Sens Bill Cassidy (R-LA) and Dick Durbin (D-IL); and in the House of Representatives by Reps Ron Kind (D-WI) and Michael Burgess (R-TX).

Transplant recipients are required to take immunosuppressive medications for the life of their transplanted organ to prevent rejection. Currently, Medicare covers these medications for just 36 months after the transplant and many recipients are unable to afford their medications after the 36-month limit. This often leads to the unnecessary failure of the transplanted kidney, which can result in another transplant or dialysis.

Extending coverage through the duration of the transplanted organ will lead to better transplant recipient health outcomes and cost savings to the Medicare program. The average cost of a year of dialysis therapy is more than 30 times the cost of a year's supply of the most commonly used immunosuppression medications prescribed to prevent kidney rejection.

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# EMERGING INFECTIOUS DISEASES

## Pan-Resistant C. auris Found in New York City

Three patients in New York state had a strain of *Candida auris* resistant to three different classes of antifungal medications —fluconazole, amphotericin B, and echinocandins - according to a CDC report published in the *Morbidity and Mortality Weekly Report.*

*Candida auris* is a globally emerging yeast that causes outbreaks in health care settings and is often resistant to one or more classes of antifungal medications. The pan-resistant isolates were detected during susceptibility testing conducted on two sets of *C auris* isolates obtained from 801 colonized and infected patients in New York from June 2016 through August 2019.

Susceptibility tests revealed that more than 99% of the isolates were resistant to fluconazole, nearly two-thirds were resistant amphotericin B, and roughly 4% were resistant to echinocandins. Three patients' isolates became pan-resistant after receipt of antifungal medications, including echinocandins, during prolonged healthcare facility stays. The three patients were treated at separate hospitals in New York City. Subsequent investigations found no transmission of pan-resistant *C auris* to other patients or the environment.

All of the patients died, with one dying from underlying medical conditions. The role of *C auris* in the other two deaths is unclear. All three were treated with echinocandins, but the resistance to echinocandins wasn't detected until after they began receiving the drugs, which the authors said indicates that resistance likely emerged during treatment.

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### Borna Virus Blamed for Eight Encephalitis Deaths in Germany

Researchers have identified the Borna disease virus 1 (BoDV-1) in eight encephalitis patients who died in Germany between 1999 and 2019, according to a study recently published in the *Lancet Infectious Diseases,* The newly confirmed cases raise the number of published human BoDV-1 infections in the endemic area to 14. All cases were fatal.

Southern Germany, as well as Austria, Switzerland, and Liechtenstein, is home to the white-toothed shrew, which is the natural reservoir for Borna. Researchers postulate that the disease could be transmitted through house cats that have come into contact with infected shrews.

The authors say testing should occur in all patients with unknown and rapidly evolving central or peripheral nervous system disorders, and when patients may have come into contact with the infected reservoir host, the white-toothed shrew. Testing would help gain a more accurate picture of the spread of BoDV-1.

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### Cardinal Health to Recall Surgical Gowns and Packs

Cardinal Health has alerted its customers to potential quality issues affecting some of its Level 3 surgical gowns and PreSource procedural packs that contain the gowns. Customers should immediately discontinue use of affected surgical gowns and procedural packs because the manufacturer cannot provide assurance the products are sterile.

The FDA is working closely with Cardinal Health to understand and address the quality issues with these products, including the potential risks to users and patients, which specific product lots are impacted, and the potential impact on the supply chain.

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## INNOVATIONS

## Fabricated Corneal Tissue Allows Researchers to Study How Eyes Heal

University of Texas at Dallas bioengineer Dr. David Schmidtke has developed a technique in the lab for fabricating tiny strands of collagen called fibrils to facilitate further research on the eye's repair process. They came up with a way to mimic an injury model, to look at how the cells respond when there is a wound.

The researchers use microfluidic devices to inject collagen onto transparent plastic that contains small channels about the size of a strand of human hair. The collagen polymerizes as it flows through the channels, resulting in aligned fibrils that are similar in structure to the collagen fibrils that are present in corneal tissue.

The researchers plan to study how fibrils' density, elasticity and dimensionality affect keratocytes and the eye's healing mechanisms. The study was funded in part by a $1.8 million, five-year grant from the National Eye Institute.

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## CustomFlex Artificial Iris Receives Transitional Pass-Through Payment Status

The CustomFlex artificial iris was granted transitional pass-through payment status from CMS, effective Jan. 1, 2020. The HCPCS code for the device is C1839 (Iris prosthesis).

The artificial iris from VEO Ophthalmics was approved by the FDA in May 2018 and is the only iris prosthesis available in the United States for use in children and adults for the treatment of iris defects resulting from congenital aniridia, acquired defects, or conditions associated with completely or partially missing or damaged irises.