**The Focal Point: Advocacy & Legislative Update**
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## FDA Plans to Overhaul 510(K) Pathway

The Food and Drug Administration (FDA) plans to modernize its 510(k) approval pathway by pushing medical device manufacturers to rely on predicate devices that are not older than 10 years. Under the existing framework, manufacturers can pursue expedited approval for devices that are substantially equivalent to decades-old technologies.

The agency is considering publicizing devices and manufacturers whose products are based on even older technology and potentially sunsetting older predicates.

The announcement comes after a consortium of news outlets published scathing investigations into medical device failures and how the FDA's accelerated review process may have missed problems and put consumers at risk. FDA insists they had planned the changes ahead of the news stories.

The FDA plans to finalize its guidance on establishing an alternative accelerated pathway early next year.

## FDA Issues Proposed Rule on De Novo Classification

The FDA has released the De Novo Classification Proposed Rule to clarify and streamline its de novo pathway by outlining processes and criteria for reviewing new low- to moderate-risk devices. The rule establishes the format and content of de novo requests, and the processes and requirements for acceptance, declining and withdrawal of the requests.

The De Novo classification process provides a pathway for certain new types of devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as a class III device which would require premarket approval.

If finalized, the rule will implement the de novo classification process and define the scope of regulatory procedures used by agency staff and classification panels convened by FDA when classifying and reclassifying medical devices.

The rule is open to public comment, submitted on or before March 7, 2019.

## Framework for FDA's Real-World Evidence Program

The FDA has created a framework for evaluating the potential use of real-world evidence (RWE) to help support the approval of a new indication for approved drugs and biologics, expand labels, or satisfy post-approval study requirements. The framework does not cover medical devices.

FDA defines RWD and RWE as follows:

- **Real-World Data (RWD)** are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.
- **Real-World Evidence (RWE)** is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.

Under FDA's RWE Program, evidence from traditional clinical trials will not be considered RWE. However, observational clinical studies using RWD to support product effectiveness would be covered by the RWE program.

### Keep Up to Date with ISBT 128

Version 7.20.0 of the ISBT 128 Product Description Code Database and the updated ISBT 128 Standard Terminology for Medical Products of Human Origin documents are now available to licensed facilities. All database updates are listed in the version control sheet.

The Registered Facilities Database has also been updated by ICCBBA. The database contains the names and locations of all ICCBBA-registered facilities worldwide and their assigned Facility Identification Numbers (FINs). It is available both as an Excel file (Registered Facilities.xlsx) and as a tab-delimited text file (Registered Facilities.txt).

### Epidemic Keratoconjunctivitis Outbreak Caused by Adenovirus D53

The Centers for Disease Control (CDC) details the first documented outbreak of Adenovirus D53 epidemic keratoconjunctivitis (EKC) in the United States. EKC is a contagious, severe form of viral conjunctivitis that can cause pain and blurred vision for up to 4 weeks.

The Los Angeles County Department of Public Health (LAC DPH) identified 17 patients with EKC, including 15 who had visited an optometry clinic and two who were household contacts of clinic patients. Patient specimens tested positive for human adenovirus (HAdV) type D53 (HAdV-53).

it is believed that the virus was introduced to surfaces in the exam room by a symptomatic patient, and that subsequent infection control lapses in the disinfection of tonometers and multiuse eye drop administration led to transmission to other patients.

No further cases were reported after staff member education on eye drop administration and longer slit lamp and tonometer disinfection times were implemented.

### Asian Longhorned Tick Poses a Growing Public Health Threat

The CDC reported the presence of the Asian longhorned tick, or *Haemaphysalis longicornis*, in nine US states, where it has been found on animals and people. The CDC considers the tick a new and emerging disease threat because in Asia, it transmits the severe fever with thrombocytopenia syndrome virus (SFTSV), which causes a human hemorrhagic fever, and *Rickettsia japonica,* which causes Japanese spotted fever

No evidence exists that *H. longicornis* has transmitted illnesses to humans, domestic animals or livestock in the U.S., but the species is a potential vector for several viral agents, including Heartland and Powassan viruses.

### Eye Testing May Aid Early Diagnosis of Creutzfeldt-Jakob Disease

Sporadic Creutzfeldt-Jakob disease (sCJD) is the most common prion disease in humans and has been iatrogenically transmitted through corneal graft transplantation.

Investigators used the highly sensitive real-time quaking-induced conversion (RT-QuIC) to measure postmortem prion seeding activities in the eyes and brain of 11 sCJD patients. Prion seeding was found in all eyes they tested, with the highest levels of the infectious protein in the retina. With RT-QuIC, prion seed levels generally declined in eye tissues with increased distance from the brain, and yet all corneas had prion seeds detectable. Prion seeds were also present in the optic nerve, extraocular muscle, choroid, lens, vitreous, and sclera.

These results have implications for estimating the risk for transmission of sCJD as well as for the development of diagnostic tests for prion diseases. The findings also carry implications for surgical instruments as a potential mode of transmission. For this reason, "disposable instruments are recommended for ophthalmological surgical procedures on prion disease patients."