EYE BANK ASSOCIATION OF AMERICA

The Focal Point: Advocacy & Legislative Update
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FDA Launches Redesigned Website

The Food and Drug Administration (FDA) has launched a redesigned, more customer-centric website at FDA.gov to provide the public with health and safety information that is easier to locate and navigate.

Most URLs will change. Automatic redirects will be established, but users should update their bookmarks. In addition to helping the public make more informed decisions quickly, the site includes federal regulations, recall information, safety alerts and other regulatory actions.

The goals for the improved FDA.gov include:

- Remodeled webpages that can be viewed on any internet-ready device
- Easier access to popular content
- Updated navigation based on data and audience behavior
- Easier to find FDA content in search results
- Better consistency of FDA content across web and social channels

FDA Issues Draft Guidance on Voluntary Recalls for FDA-Regulated Products

FDA issued a draft guidance on the initiation of voluntary recalls under 21 CFR part 7 subpart C. The draft guidance, if finalized, would clarify FDA's recommendation for industry and Agency staff regarding timely initiation of voluntary recalls of all FDA-regulated products.

The guidance discusses:

- Preparations firms in a distribution chain, including manufacturers and distributors, should consider making to establish recall initiation procedures
- Timely identification of, and response to, product problems that might lead to a recall
- Promptly issuing recall communications and press releases or other public notices
- Preparations that firms in a distribution chain should consider making to ensure timely responses to a recall communication.
- How FDA assists firms with carrying out their recall responsibilities

The proposed recommendations fall under three categories—proper personnel training, thorough and organized record-keeping and adequate recall initiation procedures to ensure that voluntary recalls are initiated properly and promptly.

Comments to FDA on this draft guidance are due by June 24.

ACBTSA Recommendations for Updating the PHS Guideline

Marian Macsai, MD, EBAA's representative on the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), submitted the list of recommendations from the 50th ACBTSA meeting.

The ACBTSA met April 15-16 to receive presentations on updating the 2013 *PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation*. The Committee took note of data highlighting a significant gap between organs available for transplantation, organ utilization, and organs needed. The Committee learned that 119,000 individuals are on a transplant waiting list with 200 being added each day. Although increasing, the number of transplants per year is only 35,000. It is estimated that 20 Americans die each day while waiting for a transplant. The deficit presents a significant public health crisis and requires urgent actions to enhance options for transplant and make more organs available, by providing incentives for, not against transplant.

To improve policies around transplant so that Americans in need of organs have the greatest possible chance of receiving one, the ACBTSA recommends the following actions be taken immediately.

1. That there be continued recognition and designation of a category of potential organ donors with an augmented chance of transmission of HIV, HBV, and HCV.

2. All organ donors should be tested for HIV, HBV, and HCV using NAT along with serology.

3. That the terminology “increased risk donor” be changed because
    - Current nomenclature causes cognitive bias, potentially discouraging use of these donors and needs to be reframed not to do so.
    - It allows recalibration of the discussion with the organ transplant team, the deceased donor families, living donors, and transplant candidates based on newer science with the goal of improved, shared decision making.
        - Therefore, additional discussions should be had with donor families, transplant candidates and recipients regarding terminology prior to modification of the “increased risk donor” terminology. One suggestion made by the Committee was to change the term to “possible risk donor.”

4. Remove the following as medical/social criteria resulting in an augmented chance of donor designation

    - Women who have had sex with a man with a history of MSM behavior
    - Newly diagnosed or have been treated for syphilis, gonorrhea, Chlamydia, or genital ulcers
    - Hemodialysis
    - Hemodiluted blood specimen used for infectious disease testing
    - Child (age ≤18 months) born to a mother at increased risk for HIV, HBV, or HCV
    - Child breastfed within the preceding 12 months by mother at increased risk for HIV infection.

5. That the current 12-month risk behavior timeframe be changed to 3 months.

6. Strongly endorses universal implementation of the Uniform Donor Risk Assessment Interview (UDRAI) forms.

7. The Secretary mandate and fund a longitudinal collection of data by the OPTN from the UDRAI to determine donor and recipient risk, as well as the impact of risk assessment on the donor pool and organ utilization.

8. The Secretary support efforts to enhance the process of transplant candidate counseling for these donor organs. This should include not just the information provided to centers and transplant candidates, but also the ongoing shared decision making and the consent process from initial evaluation to post transplant.

9. The Secretary should support the development and use of tools and processes to educate transplant providers to enhance organ utilization.

10. All recipients regardless of donor risk profile should be tested for HIV, HBV, and HCV using NAT between 2- and 4-weeks following transplantation in order to better identify disease transmission patterns.

11. Separate from the PHS Guideline, the Committee strongly supports the Secretary taking action to remove barriers to rapid access to treatment of unanticipated donor-derived HIV, HBV, and HCV infection.

We recognize the tremendous progress that has been made to enhance transplant safety and availability since implementation of the 2013 PHS Guideline. Because the Committee appreciates the dynamic nature of the field, we think it is imperative to have ongoing review of accumulated data and scientific advancements that will guide evidence-based decisions. We look forward to hearing the response to our recommendations.

The Committee unanimously supported the recommendations.

OMB Memo Requiring Review of All Regulatory Actions May Prompt Slow Release of FDA Guidance Documents

A memo by the White House Office of Management and Budget (OMB) that requires federal agencies submit non-binding guidance to the Office of Information and Regulatory Affairs (OIRA) -- and potentially to Congress -- could throw a wrench in FDA's usual guidance-making process.

The rule which takes effect May 11, requires all federal agencies to present to OIRA a detailed analysis of the expected economic impact of guidances, statements of policy, interpretive rules and notice-and-comment rules, along with the proposed guidance or rule, at least 30 days prior to publication.

Following OIRA review, Congress will have the option of reviewing proposed guidances pursuant to the Congressional Review Act. The new requirements have the potential to slow down the guidance development process and may reduce informal agency guidances.

CBER Director Releases the FY 2018 Report

Peter Marks, MD, PhD, director of FDA's Center for Biologics Evaluation and Research (CBER), released the "FY 2018 Report from the Director," which highlights, among other topics, the agency's FY 2018 approvals, released guidance documents and several workshops, meetings and conferences.

Two gene therapy approvals topped the list for 2018: Luxturna, the first directly administered gene therapy for a specific genetic disorder, an inherited retinal disease, and Yescarta, a cell-based gene therapy for certain types of adult, large B-cell lymphoma.

FDA authorized the first two donor screening tests for the direct detection of Zika virus RNA in human plasma from individual donors - the cobas Zika Test and the Procleix Zika Virus Assay (Nucleic Acid Tests).

CBER's Office of Tissues and Advanced Therapies also released 10 new guidance documents in 2018, including six new draft guidance documents on gene therapy and a recently finalized guidance on expedited programs for regenerative medicine.

The center also launched a new program in 2018, known as INTERACT, whereby sponsors can seek a preliminary and informal consultation with the agency prior to a pre-IND meeting.

FDA Pushes Back Compliance Date for Safety Reporting Requirements for Combo Products

FDA extended the compliance date by which combination product companies must comply with certain post-market safety reporting (PMSR) requirements, in their update to the guidance for industry entitled ''Compliance Policy for Combination Product Postmarketing Safety Reporting.'' The updated guidance explains how FDA does not intend to enforce 21 CFR 4.102(c) and (d) (constituent part-based PMSR requirements), 4.104(b)(1) and (b)(2) (submission process for constituent part-based Individual Case Safety Reports (ICSRs)), and 4.105(b) (recordkeeping requirements) until:

- 31 July 2020 for combination product applicants using the FDA Adverse Event Reporting System (FAERS) and Electronic Medical Device Reporting System (eMDR) to report ICSRs.
- 31 January 2021 for combination product applicants using the Vaccine Adverse Event Reporting System (VAERS) to report ICSRs.

FDA To Hold a Data Standards Public Workshop

FDA will hold a public workshop entitled ''Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities'' on June 12, 2019. There will also be a live webcast for those unable to attend the meeting in person.

Study data standards describe a standard way to exchange clinical and nonclinical research data between computer systems. These standards provide a consistent general framework for organizing study data, including templates for datasets, standard names for variables, and standard ways of doing calculations with common variables. Establishing common study data standards enables FDA scientists to combine data from multiple studies and improves the regulatory review of electronic submissions.