Top Stories

FDA Issues Draft Guidance Explaining Intent Not to Regulate "Low Risk" MDDS

In a draft guidance issued on June 20, FDA announced it does not intend to enforce compliance with regulations governing medical device data systems ("MDDS") and related devices, citing low risk and a desire to avoid unnecessary barriers to new digital health technologies. Although the guidance articulates a policy for digital health systems, it applies to a fairly narrow class of devices. FDA defines "MDDS" as "hardware or software products that transfer, store, convert formats, and display medical device data." Systems that modify or control the functions or parameters of a connected medical device fall outside the scope of this definition and thus may be subject to other regulatory controls, such as premarket review and certain postmarket requirements.

In 2011, the FDA issued a regulation down-classifying MDDS from Class III (high-risk) to Class I (low-risk). Based on its experience since that time, the agency concluded the unusually low risks of MDDS merit further deregulation. The draft guidance released last week also proposes changes to FDA's 2013 draft guidance on Mobile Medical Applications, to ensure both documents reflect the new policy.

These changes come as medical devices and mobile medical apps advance to connect doctors with more patients in real time, an emerging market that some industry analysts predict could grow more than 60 percent over the next three years.

Social Media Marketing Comes Under New Scrutiny by FDA

Earlier this month, FDA set forth specific requirements for the use of social media by pharmaceutical and medical device manufacturers, packers, and distributors. In two draft guidance documents, the agency highlighted its expectations for firms engaging in product promotion through internet and social media platforms.

One draft guidance describes FDA's approach to advertising and promotional labeling on social media platforms with character space limitations. Such communications must

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Resources

- *Pharmaceutical & Medical Device Regulatory Update* Issue 9 Printable Version
- Jones Day's FDA Regulatory & Compliance Practice
- Jones Day's Health Care Practice

present both benefit and risk information about the promoted pharmaceutical or medical device. For example, a 140-character tweet on Twitter intended to describe a particular drug's benefits should also include adequate information about the product's safety risks.

- Jones Day's Life Sciences Practice

FDA issued another draft guidance with standards for correcting third-party misinformation on social media. This guidance recognizes a public health benefit associated with having firms correct misrepresentations and other false implications about their products. If a drug or device company chooses to use social media to respond to misinformation submitted by an independent third party, the company must do so in a "truthful and non-misleading manner," using relevant information that is limited and tailored to the misinformation. These guidance documents reflect FDA's efforts to expand its enforcement policies for promoting FDA-regulated products using evolving platforms attendant to the digital age. Interested parties may submit public comments on the draft documents through September 16.

CDER: Standards Needed to Promote Use of EHR Data in Clinical Research
In a recent blog post, Center for Drug Evaluation and Research ("CDER") Director Janet Woodcock discussed the importance of good data for drug development and the challenges clinical researchers face in harnessing data from electronic health records ("EHRs"). "To readily understand and combine information from different sources, we need to further standardize the data and the way it is exchanged," she wrote. Common industry standards promote interoperability between different computer systems and software, which can lead to better treatment decisions as practitioners gain access to patients' complete medical histories.

Woodcock also discussed Mini-Sentinel as a means of using electronic data to improve public health outcomes. Mini-Sentinel is a pilot program for using electronic health care data to monitor the safety of FDA-regulated products. Through Mini-Sentinel, when FDA scientists have drug safety questions, they can query the data of 18 large health care organizations participating in the program. Mini-Sentinel aggregates and analyzes the data, allowing queries to call on data from 4 billion pharmaceutical dispensing encounters and 4.1 billion patient encounters. Woodcock emphasized that the task of promoting interoperability is not limited to federal agencies, noting FDA's partnership with private standards-setting organizations.

FTC Opens New Investigations of "Pay-for-Delay" Generic Drug Deals
The Federal Trade Commission ("FTC") has recently opened new investigations into agreements between brand-name and generic drug manufacturers that purportedly delay consumer access to generic drugs, claiming such deals hurt consumers and competition. Last year, the United States Supreme Court affirmed that federal antitrust regulators may challenge such agreements, sometimes referred to as "pay-for-delay" deals, or reverse payment settlements. An FTC official said the agency's investigations could lead to lawsuits seeking disgorgement of revenues and stated its goal is to end the practice "by whatever means are available to us."

Lawmakers, Industry Urge FDA to Develop Better Guidance for Compassionate Use
Pharmaceutical industry stakeholders and federal legislators are pressuring FDA to accelerate access to investigational drugs for terminally ill patients. Through the expanded access program, also known as "compassionate use," FDA allows, on a case-by-case basis, investigational drugs to be used to treat individual patients and intermediate-size groups that are otherwise ineligible for participation in clinical trials. Earlier this month, a group of Republican senators sent a letter to FDA requesting information about the uptake of this program, FDA's efforts to collaborate with manufacturers, and its plans to finalize a 2013 draft guidance. Meanwhile, industry groups, such as PhRMA, have urged FDA to improve the expanded access program with better guidance and a centralized Institutional Review Board to speed the approval of compassionate use requests. PhRMA prefers FDA's program over similar state initiatives, often called "right to try" laws (see story in the last Jones Day Update), which allow terminally ill patients to use unapproved treatments with limited clinical testing.

Other News
Supreme Court: Some Companies May Seek Exemption from ACA Contraception Mandate

India Likely to Extend Price Caps to More Drugs

340B Drug Discount Policy for Hospitals, Clinics Under Scrutiny

FDA Issues New Guidance on Global Unique Device Identification Database

CDRH Director Addresses Consumer Access to Genomic Tests

Cancer Clinic Pleas Guilty to Using Unapproved Drugs

Secretary Burwell Announces Leadership Changes at HHS

FDA Licenses First U.S. Plant to Grow Flu Vaccines from Cell Culture

FCC Officials Promote Rural Telemedicine Fund

CDRH Solicits Stakeholder Feedback, Will Begin Posting Satisfaction Ratings in August

Health Care Profits Buoyed by ACA Enrollment, Higher Drug Prices

House Democrats Urge NIH to Disclose More Demographic Data in Clinical Trials

Baylor Researchers Develop Designer T-Cells for Virus Protection in Transplants.

Regulatory Updates

FDA Issues EUA for Influenza Test
In the June 23 *Federal Register*, FDA announced an Emergency Use Authorization ("EUA") for an in vitro diagnostic device ("IVD") used to detect the novel influenza A virus (H7N9), which was detected in China in 2013. The EUA places conditions on use of the authorized IVD and follows an April 19, 2013, determination of significant potential for a public health emergency that, if occurred, would likely pose a threat to national security or the health and security of U.S. citizens living abroad. ***The authorization is effective as of April 25***.

FDA Solicits Comments on Request for 510(k) Exemption for Wheelchair Elevator
In the June 18 *Federal Register*, FDA requested comments on a petition requesting exemption from the premarket notification requirements for a wheelchair elevator device commonly known as a manually operated portable wheelchair lift. This device is used to provide a means for a disabled person to move a wheelchair from one level to another. ***Comments due July 18***.

FDA Downclassifies Blade-Form Endosseous Dental Implant
In the June 18 *Federal Register*, FDA issued a final order reclassifying the blade-form endosseous dental implant, a preamendments class III device, into class II (special controls). ***The order is effective July 18.***

FDA Issues the Following Guidance Documents
Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices. June 18 *Federal Register*. ***Comments due September 16***.

Draft Guidance for Industry on Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices. June 18 *Federal Register*. ***Comments due September 16***.

Draft Guidance for Industry on Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices. June 25 *Federal Register*. ***Comments due August 25***.

Final Guidance for Industry: Global Unique Device Identification Database. June 27 *Federal Register*.

Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology. June 27 *Federal Register*.

Draft Guidance for Industry on Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products. June 20 *Federal Register*. ***Comments due September 18***.

Draft Guidance for Industry on Uncomplicated Gonorrhea: Developing Drugs for Treatment. June 19 *Federal Register*. ***Comments due September 17***.

FDA Determines Regulatory Review Periods for Drug, Biological Patents
FDA recently published determinations regarding the regulatory review periods for patent extensions of the following drug: VICTRELIS. FDA did not publish any determinations regarding the regulatory review periods for patent extensions of biologics.

FDA Withdraws Approval of 86 ANDAs
In the June 19 *Federal Register*, FDA announced its withdrawal of approval of 86 abbreviated new drug applications ("ANDAs") at the request of the multiple applicants because the drugs are no longer marketed. ***The withdrawal is effective July 21***.

FDA Deletes Four System of Records Notices
In the June 27 *Federal Register*, FDA announced it will delete four system of records notices ("SORNs") from its existing inventory of SORNs. FDA no longer uses the systems related to the SORNs it plans to delete.

Information Collection Activities

FDA Announces that OMB Has Approved Information Collections for the Following
Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))

Importer's Entry Notice

FDA Announces that the Following Collections Have Been Submitted to OMB
Current Good Manufacturing Practice Regulations for Medicated Feeds (***comments due to OMB July 21***)

Current Good Manufacturing Practice Regulations for Type A Medicated Articles (***comments due to OMB July 21***)

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (***comments due to OMB July 21***)

Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded (***comments due to OMB July 25***)

FDA Announces the Opportunity to Comment on the Following Proposed Information Collections
Requirements for Submission of Bioequivalence Data (***comments due August 25***)

Guidance: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program (***comments due August 25***)

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics
Public Workshop on the Development of New Antibacterial Products: Charting a Course for the Future, will be held July 30 in Bethesda, MD.

Public Hearing Before the Commissioner on Confidentiality of Interim Results in Cardiovascular Outcomes Safety Trials; Part 15, will be held August 11 in Silver Spring, MD.

Public Meeting on Methodological Considerations in Evaluation of Cancer as an Adverse Outcome Associated With Use of Non-Oncological Drugs and Biological Products in the Postapproval Setting, will be held September 11 in Silver Spring, MD.

Medical Devices
Public Workshop on Hemostatic Medical Devices for Trauma Use will be held September 3–4 in Silver Spring, MD.

Public Workshop on Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing will be held October 8–9 in Silver Spring, MD.

Advisory Committees
July 10–11: Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee

July 30–31: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

July 31: Blood Products Advisory Committee Meeting

August 1: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting

August 14: Pulmonary-Allergy Drugs Advisory Committee Meeting

October 16: Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting

For more comprehensive listings of FDA meetings, please visit these FDA webpages:
Meetings, Conferences, and Workshops (Drugs)

Workshops, Meetings, and Conferences (Biologics)

Workshops & Conferences (Medical Devices)

FDA Advisory Committee Calendar

Enforcement Updates

Recent Product Recalls
Recent medical product recalls include an injection due to visible particulates and guidewire devices due to damages to the core wire of the outer polymer jacket.

Click here for a complete listing of FDA Recalls.

Recent Warning Letters
In recent weeks, FDA posted warning letters issued to a medical device manufacturer and Canadian biologics manufacturer, both for violating current good manufacturing practice requirements. FDA warned that the medical device manufacturer had failed to comply with quality systems regulation requirements, and the biologics firm was not compliant with its approved biologics license application.

FDA warned a medical facility for problems involving the conduct of mammography, noting that the facility failed to meet specific requirements to practice mammography that are needed to protect women.

Click here for FDA's Warning Letters Home page (scroll down for listing of recently posted Warning Letters).

The Office of Prescription Drug Promotion ("OPDP") issued one untitled letter to a drug manufacturer for omitting risk information or material facts.

Click here for a complete listing of 2014 OPDP Warning Letters.

Recent Drug and Device Approvals

FDA allows marketing of first wearable, motorized device that helps people with certain spinal cord injuries to walk (June 26).

FDA approves Sivextro to treat skin infections (June 20).

For additional information on drug and device approvals and clearances, please visit FDA's webpages on Drug Approvals and Databases (includes biologics) and Device Approvals, Denials, and Clearances.