Pharmaceutical & Medical Device Regulatory Update
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Pharmaceutical & Medical Device Regulatory Update

United States

New York Attorney General Announces Settlements with Three Mobile Health Application Developers

New York has made a mark on the regulatory and enforcement landscape for mobile health applications ("mobile health app") with the New York Attorney General's ("NY AG") March 23, 2017, announcement of settlements with three mobile health app developers. Two of the mobile health apps were promoted as tools to help users accurately monitor their heart rate using only their smartphone's camera. The developer of the third mobile health app claimed that it could transform a smartphone into a fetal heart monitor using only the smartphone's microphone and a pair of headphones. According to the developer, the mobile health app could be used instead of a Doppler—a type of fetal heart monitor. In the settlement agreements, the NY AG's office notes that both heart rate monitors and fetal heart monitors are regulated by the Food and Drug Administration ("FDA") as Class II medical devices, which "require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness."
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Supreme Court Hears Oral Arguments in *Sandoz Inc. v. Amgen*

By Guest Contributors Gasper J. LaRosa, Jennifer J. Chheda, and Shehla Wynne

On April 26, 2017, the U.S. Supreme Court heard oral argument in *Sandoz Inc. v. Amgen Inc.* (Nos. 15-1039, 15-1195), on appeal from the Federal Circuit's July 21, 2015, opinion interpreting various provisions of the Biologics Price Competition and Innovation Act ("BPCIA"). The parties presented two main issues to the Supreme Court: (i) whether the BPCIA's required 180-day "notice of commercial marketing" is effective if given before FDA approval of the abbreviated biologics license application ("aBLA"); and, (ii) whether, under 42 U.S.C. § 262(l)(2)(A), an aBLA applicant (here, Sandoz) is required to

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provide the reference product sponsor (here, Amgen) with a copy of its aBLA and related manufacturing information. At oral argument, the Court provided each side with an additional five minutes of argument time, underscoring the complexity of the statutory scheme at issue.
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Senate Confirms Dr. Gottlieb's Nomination as FDA Commissioner

On May 9, 2017, the Senate confirmed Dr. Scott Gottlieb as the next FDA commissioner. With a 57-42 vote, the Senate fills the commissioner position most recently held by Dr. Robert Califf, who resigned in January 2017 and was replaced in the interim by Dr. Stephen Ostroff. Dr. Gottlieb, a physician, policy analyst, and entrepreneur assured in his confirmation hearing he will make his mission "to fight for those families every single day, and ensure that FDA puts their interest first." Dr. Gottlieb also stressed he will lead the FDA as "an impartial and passionate advocate for public health" and offered to work for better efficiency and better safety while also remaining "faithful to FDA's gold standard for regulatory conduct."
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Europe

Update on Recommendations and Initiatives of EU Regulators Ahead of Brexit

On April 27, 2017, the European Medicines Agency ("EMA") held a meeting with the heads of the National Competent Authorities ("NCAs") of the European Union ("EU")/European Economic Area ("EEA") Member States to discuss the consequences of Brexit on the workload of the agency.
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UK's Regulator Announces Its Top Priorities in the Lead Up to Brexit

The Medicines and Healthcare products Regulatory Agency (MHRA), the UK's pharmaceutical and medical devices regulator, has recently released its 2017-2018 business plan. Of the 10 key priorities identified by the MHRA, life sciences companies will be particularly interested in the regulator's proposed strategy in the lead up to Brexit as well as how it intends to approach the regulation of medicines and medical devices in the UK in the interim period. In this respect, it is encouraging that the UK regulator's priorities emphasize the need for ongoing cooperation with EU regulatory procedures as well as developing, in parallel, an innovative world class, financially stable, regulatory offer based around more rapid and agile assessments. The MHRA plays a central role in medicines approvals for Europe (in 2015-2016, it was the reference EU Member State authority responsible for 43 percent of all decentralized MA applications in which applicants sought a UK authorization) and so its continuing involvement in this area is welcome.
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EMA Adopts a Guidance Concerning Periodic Safety Update Reports

On April 6, 2017, the European Medicines Agency ("EMA") issued new guidance and recommendations


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concerning periodic safety update reports ("PSURs") of nationally authorized medicinal products. These recommendations form part of the EMA's commitment to ensure continuous improvement of safety monitoring of medicinal products in the EU.

PSURs are reports submitted by marketing authorization holders that evaluate, on the basis of available safety clinical data, the benefit-risk balance of a medicinal product at a defined time following its authorization. The EMA uses the information contained in the PSURs to determine whether new risks exist and if the benefit-risk balance of a concerned medicinal product should be updated. The EMA can decide to conduct further investigations or decide to take measures to protect public health. Since 2015, the PSURs of medicinal products containing the same active substance or the same combination of active substances have been assessed jointly by the EMA in a so-called periodic safety update report single assessment ("PSUSA") procedure.
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French ANSM Clarifies Guidance Related to Raw Materials for Pharmaceutical Use

On January 31, 2017, the French National Drug and Health Product Agency ("ANSM") issued an updated FAQ related to the authorization and declaration procedures of manufacturing, import, and distribution of raw materials for pharmaceutical use ("RMPU"). In particular, the ANSM clarified the scope of the authorization/declaration procedure; only facilities that are located in French territory have to request an authorization and/or declare themselves to the ANSM. Facilities located in France where RMPU is stored on behalf of distribution companies also fall within the scope of the authorization/declaration requirement. Facilities located in other European Member States must register with the authority competent in their own jurisdiction. Furthermore, the ANSM explains that certain subcontracting relationships do not qualify as distribution activities even though a sales and purchase transaction took place. For example, distribution activities of a pharmaceutical company "for own use," where RMPU is sold to a subcontractor exclusively for the purpose of manufacturing drugs which are then entirely purchased back by the pharmaceutical company, are not subject to authorization/declaration requirement. However, if part of the RMPU is not sold back to the pharmaceutical company, this company is considered to be a distributor subject to authorization/declaration.
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Publications of Interest

China's New Cybersecurity Law and Draft Data Localization Measures Expected to Burden Multinational Companies

China's new Cybersecurity Law ("new Law") is set to come into effect on June 1, 2017, and introduces sweeping provisions that may have a significant impact on companies doing business in and with China, including life sciences companies. To provide guidance on a controversial data localization requirement introduced in the new Law, the Cyberspace Administration of China released on April 11, 2017, draft Measures for Security Assessment of Outbound Transmission of Personal Information and Important Data ("draft Measures") for public comment. The draft Measures are sparking outcry from the international community, but are expected to come into force on June 1, 2017, largely unamended. The deadline for submissions is May 11, 2017, just three weeks before the new Law takes effect.
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