FDA Regulatory and Compliance Monthly Recap

MARCH 2017

KEY FINDINGS

Gottlieb confirmed as President Trump's pick to lead FDA

Gottlieb's nomination will head to the Senate for confirmation on April 5, 2017. A former FDA official, he has extensively discussed the need to cut drug prices and update the drug approval process.

President Donald Trump officially selected Dr. Scott Gottlieb, a partner at venture capital firm New Enterprise Associates and resident fellow at the American Enterprise Institute, to spearhead the FDA. Gottlieb was in the running against biotech executive Balaji Srinivasan, investor Jim O'Neill and Dr. Joseph Gulfo, a former senior fellow at the Progressive Policy Institute and the Mercatus Center at George Mason University.

Gottlieb has experience with the FDA, having served in several senior roles between 2003 and 2007, including as Deputy Commissioner for Medical and Scientific Affairs (2005-2007) and Director of Medical Policy Development (2003-2004). In these roles, Gottlieb facilitated talks that ultimately led to a system in which generics makers pay a fee to speed up the review of their products. He also served as a senior adviser to the CMS administrator, helping to implement the Medicare Drug Benefit. In 2013, he was appointed to serve on the Federal Health Information Technology Policy Committee.

He has ties to several pharmaceutical companies, including GlaxoSmithKline, Valeant Pharmaceuticals and Vertex Pharmaceuticals. In an ethics disclosure form filed with the HHS, Gottlieb said he would recuse himself from matters in which he has financial connections to healthcare companies and divest his holdings in these companies. He also said he'd resign from multiple corporate boards and consulting positions.

Gottlieb has signaled a desire to modernize the FDA's approval process and accelerate the introduction of generics in order to lower drug costs. He's discussed the need for agency departments to copy the cancer

division's efforts to approve drugs more rapidly, linking faster approvals to lower prices. He's also talked about restructuring the rules for generic drugs, which he says brand-name companies have leveraged to create "monopolies in perpetuity." Gottlieb has also pointed to the need to add competition in instances in which old drugs are provided by one generics maker, allowing others to buy the drug and hike the price.

Gottlieb completed a residency at the Mount Sinai Hospital and is a graduate of the Mount Sinai School of Medicine and of Wesleyan University. He needs to be confirmed by the Senate before taking up his position.

FDA, EMA forge mutual recognition framework for pharmaceutical inspections

Amid increasing scrutiny of foreign pharmaceutical manufacturers, the U.S. and the EU agreed to amend their mutual recognition agreement to allow drug regulators to use each other's inspections. The agreement follows years of FDA observations of EU inspection practices.

The U.S. and the EU agreed to amend the Pharmaceutical Annex to the 1998 U.S.-EU Mutual Recognition Agreement in order to permit regulators in both regions to use each other's GMP inspections of pharmaceutical manufacturing facilities. The goal of the amended agreement is to mitigate the duplication of inspections, while lowering inspection costs and allowing regulators to direct resources to other regions where there may be greater risk.

Under the 2012 Food and Drug Administration Safety and Innovation Act, the FDA was granted the power to enter mutual recognition agreements if it determines foreign inspectors are capable of conducting inspections that meet U.S requirements. The amended agreement is born out of almost three years of cooperation under the Mutual Reliance Initiative. Since 2014, the EMA and the FDA have been observing each other's inspection practices in order to explore the risks and benefits of mutual recognition. The FDA observed 14 audits under the EU's Joint Audit Program, in which two EU nations audit the regulatory authority of another EU country.

The amended agreement comes as both the FDA and foreign inspectors, such as the U.K. Medicines & Healthcare products Regulatory Agency (MHRA), have been increasing the number of inspections of foreign drug makers. In FY2016, the FDA conducted 78 inspections of foreign human drug facilities, an uptick from 69 in FY2015.

FDA issues MAPP on CDER consultations with Controlled Substance Staff

The MAPP outlines protocols for consultations between the CDER and the CSS to assess the abuse potential, dependence, scheduling and abuse-deterrent properties of new drugs and biologics. It also defines the role of the CSS within the CDER's abuse assessment and drug scheduling process.

The FDA published a manual of policies and procedures (MAPP) describing procedures for the Center for Drug Evaluation and Research (CDER) when consulting with Controlled Substance Staff (CSS) on drug abuse potential and drug labeling, scheduling and liability. As part of the review process, CSS is responsible for assessment of abuse potential, dependence liability and schedule for investigational new drug applications (INDs), new drug applications (NDAs), biological licensing agreements (BLAs) and abbreviated NDAs (ANDAs). It is also responsible for assessing all applications submitted for any compound that contains a stimulant, depressant or hallucinogenic effect on the central nervous system, including those with possibly abuse-deterrent properties.

Using clinical trial data, CSS determines whether a drug necessitates additional studies to address questions about abuse potential. Sponsors of NDAs are required to provide all information collected during IND development pertaining to abuse and dependence. CSS uses this information to make labeling recommendations. In

addition, CSS may conduct evaluations to ascertain whether a drug warrants control under the CSA, and may draft scheduling recommendations. CSS is also responsible for assessing marketed drugs when new safety data related to abuse or dependence is submitted to the FDA. The MAPP notes that in certain cases, although rarely, the Office of Generic Drugs may need to consult CSS, including on cases in which a new scheduling recommendation is needed or when a generic product references a drug for an abuse-deterrent opioid product.

Per the MAPP, for preapproval consultations the CDER will provide the desired completion date, and justification for the date, including the user fee goal date. It will also be responsible for coordinating industry meeting requests and consultation with CSS in a timely manner. CDER will also consult CSS when putting together sponsor communications related to abuse potential. In terms of postapproval consultations, CDER will alert the CSS if postmarketing adverse events are reported related to abuse or dependence, and will include CSS in meetings on the abuse, scheduling, dependence and Risk Evaluation and Mitigation Strategies (REMS). It will also consult CSS on labeling revisions for abuse, scheduling, dependence or abuse deterrence, and talk with CSS when writing risk communications on the issues.

FDA publishes draft list of class II devices exempt from premarket notification

The list signals the first steps in the FDA's implementation of the 21st Century Cures Act and follows the FDA's last round of exemptions in 2015.

As part of its implementation of the 21st Century Cures Act, the FDA issued a draft list of class II medical devices that will be exempt from 510(k) notification. Under Section 3054 of the Cures act, the FDA is required to publish a notice in the Federal Register outlining the types of class II devices it determines are no longer required to report under section 510(k) of the Federal Food, Drug & Cosmetic Act.

Per the FDA, the devices identified as exempt are believed to be adequately well understood and don't present risks that warrant premarket notification review. From time to time, the agency exempts devices from premarket notification review in order to lessen regulatory loads on the medical device industry and cut regulatory costs. The last time devices were exempted was in 2015.

This time around, the FDA has exempted devices such as basic diagnostic tests and assays, chromatography techniques and equipment such as umbilical clamps, obstetrical forceps and certain types of ophthalmoscopes. The agency notes that exemption from premarket notification doesn't mean a device is exempt from other statutory or regulatory requirements. The FDA may also opt to partially limit the exemption to specific devices for a listed device type. For example, an exemption may be granted to endoscopic magnetic retrievers but be limited to those that are for single use.

In considering which devices to exempt, the FDA takes into account whether a review is needed to provide reasonable assurance of safety and efficacy. Before finalizing the list, the FDA will review any comments on the draft to ascertain whether the list should be modified.

For more information on any of these FDA regulatory and compliance updates, please contact Scott S. Liebman at sliebman@loeb.com.

Loeb & Loeb LLP's FDA Regulatory and Compliance Practice

Loeb & Loeb's FDA Regulatory and Compliance Practice comprises an interdisciplinary team of regulatory, corporate, capital markets, patent and litigation attorneys who advise clients on the full spectrum of legal and business issues related to the distribution and commercialization, including marketing and promotion, of FDA-regulated products. Focusing on the health and life sciences industries, including pharmaceuticals, biologics, medical devices, wellness products, dietary supplements and organics, the practice counsels clients on regulatory issues, compliance-related matters and risk management strategies; advises on laws and regulations related to product advertising and labeling; counsels on FDA exclusivity policies and related Hatch-Waxman issues; and provides representation in licensing transactions and regulatory enforcement actions.