A Look Back at Ten Key FDA Initiatives Over the Past Decade

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It’s been almost 80 years since passage of the Federal Food, Drug, and Cosmetic Act of 1938, which authorized the FDA to demand evidence of safety and effectiveness for new drugs, issue standards for food safety, and conduct factory inspections. Since that time, the FDA has grown into a comprehensive federal agency, regulating $1 trillion worth of products annually, from animal drugs and feed to human drugs and medical devices.

There can be no question that the FDA’s actions impact the consuming public – and necessarily the pharmaceutical industry – in myriad ways. What follows is a snapshot of ten initiatives over the past ten years that have had (or are having) a major impact in the world of drugs and devices. We start with laws signed in 2007 and move forward in time to fairly recent Congressional and FDA activity with a brief look at FDA’s priorities in the year to come.

### 2007: Food and Drug Administration Amendments Act of 2007

President George W. Bush signed the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007. The many aspects of this law included reauthorization and expansion of the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act, which significantly raised the annual user fees paid by the industry to the FDA for new drug reviews. The amendments also reauthorized the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, both directed at research and development of treatments for children. The law further contained amendments to the citizen petition process intended to prevent delay in the approval of pending ANDAs and 505(b)(2) applications.

One of the (many) parts of the 2007 amendments that impacted the pharmaceutical industry was the significant increase in the FDA’s responsibilities, requirements, authority, and resources regarding pre- and post-market drug safety. Together with a doubling of resources allocated to the FDA’s Office of Drug Safety, the amendments added to the FDA’s authority to require post-market studies and clinical trials, safety labeling changes, and Risk Evaluation and Mitigation Strategies (REMS). This included the addition of the FDA’s authority to require application holders to conduct post-marketing studies and clinical trials “to assess a known serious risk, assess signals of serious risk, or identify an unexpected serious risk related to the use of a drug product . . . .” According to the FDA, as of fiscal year 2015, a total of 88 percent of post-marketing requirements overall and 89 percent of FDAAA post-marketing requirements were progressing according to their original schedules.

Not to be overlooked, the amendments in 2007 require the FDA to establish a database of post-marketing adverse drug reactions; more on that, below.
2008: FDA’s Sentinel Initiative

In May 2008, the FDA launched its Sentinel Initiative in response to requirements of the FDAAA that the FDA work with public and private entities to coordinate a system for providing access to existing electronic healthcare information from across multiple sources. The FDA would then use this information to help monitor safety of regulated products and take actions such as issuing safety communications or warnings. After a pilot program (“Mini-Sentinel”), the Sentinel System officially launched in 2016.

For a look back at the impact of this program—including a discussion about how, in litigation, plaintiffs’ firms try to argue that pharmaceutical companies failed to timely report a key safety signal—we invite you to view the coverage of the Sentinel Initiative in the June 2014 issue of Pro Te: Solutio.

2010: Patient Protection and Affordable Care Act/Healthcare and Education Reconciliation Act

The Patient Protection Affordable Care Act was a landmark piece of legislation affecting all levels of the healthcare industry. Passed in March 2010 along with the Healthcare and Education Reconciliation Act, the legislation changed the face of healthcare in the United States by, inter alia, imposing a regulatory overhaul and greatly expanding healthcare coverage to Americans.

With respect to the FDA in particular, the Affordable Care Act provided that manufacturers and distributors must provide the FDA with specific information concerning drug samples that they distribute, including: (1) the identity and quantity of drug samples requested; (2) the identity and quantity of drug samples distributed; (3) the name, address, professional designation, and signature of any person who makes or signs such a request; and (4) any other category of information determined appropriate by the Secretary. The FDA has also issued a Draft Guidance explaining how these provisions work in conjunction with the existing provisions of the Prescription Drug Marketing Act.

Pro Te: Solutio devoted its February 2011 issue to this legislation, and tackled topics including how healthcare reform would affect tax and employee benefits; how governmental enforcement actions of fraud in the healthcare industry were ramping up; and how legal challenges to the Acts were shaping up. To fast-forward to today, the political landscape has changed in Washington, D.C., and, as with any change in administration, the priorities and laws themselves will change. Stay tuned to Butler Snow communications for coverage on developing aspects of this part of the healthcare and pharmaceutical industry.

2012: Food and Drug Administration Safety and Innovation Act

The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law by President Obama in July of 2012. FDASIA consisted of 11 titles. The first five affected pediatric therapy

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Act of 2007, regulated medical gases, and included myriad other provisions such as a 180-day generic drug marketing exclusivity, additional regulations on citizen petitions, and nanotechnology provisions.\textsuperscript{12}

FDASIA’s user fee provisions are incredibly important to the FDA, as user fees have played an increasingly vital part of the agency’s budget. In 2017, user fees accounted for more than 40 percent of the FDA’s overall budget.\textsuperscript{13}

5  2012: Medical Device User Fee and Modernization Act

The Medical Device User Fee and Modernization Act (MDUFMA III) was enacted in 2012 as part of FDASIA. User fees have been established and implemented in four parts. The Medical Device User Fee and Modernization Act (MDUFMA) first created device user fees in 2002. They were renewed in 2007 with
MDUFMA II, again in 2012 with MDUFMA III, and finally in 2017 with MDUFMA IV. MDUFMA IV will be in effect from October 1, 2017, through September 30, 2022. These provisions authorize the FDA to collect fees from medical device companies at various stages in the regulatory process – for example, when they register their establishments, when they list their devices, when they submit applications or notifications to market new medical devices in the United States, and for other types of submissions.

The FDA issues annual performance reports to Congress under MDUFMA on its progress in the timely completion of application reviews and other items.14

6 2013: Pandemic and All-Hazards Preparedness Reauthorization Act

Enacted in 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) establishes programs permitting the FDA to prepare for and respond to emergency situations, including chemical, biological, radiological, or nuclear crises, but also infectious diseases. PAHPRA reflects an amendment to the existing Emergency Use Authorization already granted the FDA.

Examples of acts permitted by PAHPRA are the authorization of emergency dispensation of products, extended expiration dating of products, and waiver of Current Good Manufacturing Practice and Risk Evaluation and Mitigation Strategies requirements.15

7 2013: Drug Quality and Security Act

Prompted by a fungal meningitis outbreak and covered in the November 2012 issue of Pro Te: Solutio,16 Congress enacted the Drug Quality and Security Act (DQSA) in 2013 to enhance the FDA’s ability to help protect consumers from exposure to counterfeit, stolen, contaminated, or otherwise harmful drugs.

The Act implemented greater regulatory oversight of drug compounding facilities. It also outlined steps for an electronic system to identify and trace certain prescription drugs throughout the United States.
to improve detection and removal of potentially
dangerous drugs from the drug supply chain. Further,
DQSA directed FDA to establish national licensure
standards and reporting obligations for wholesale
distributors and third-party logistics providers.\textsuperscript{17}

\section*{8 2016: 21st Century Cures Act}

One of the more recent initiatives – the 21st Century
Cures Act (Cures Act), enacted on December 13, 2016
– seeks to accelerate medical product development,
thereby bringing new innovations to patients faster
and more efficiently. Among the Act’s objectives are to
incorporate patient perspectives into the development
and approval of pharmaceutical products; modernize
clinical trial designs and clinical outcome assessments
to speed development and review of novel medical
products; coordinate activities in major disease areas
between the drug, biologics, and device centers;
 improve the regulation of combination products;
and provide FDA with authority to recruit and retain
scientific, technical, and professional experts. Among
others, new product development programs include:

\begin{itemize}
\item The Regenerative Medicine Advanced Therapy, which
offers a new expedited option for certain eligible
biologics products
\item The Breakthrough Devices program, designed to
speed review of certain innovative medical devices
\end{itemize}

In addition, the 21st Century Cures Act clarified
FDA’s regulation of medical software; it also amended
the definition of a “device” to exclude certain
software functions.\textsuperscript{18}

To date, items completed on the Act’s “deliverables”
list include issuance of Guidances and Draft Guidances,
submission of Federal Register notices, submission of
a work plan and funding allocation to Congress, and
presentation of a meeting by NIH in August 2017 of
the Task Force on research specific to pregnant and
lactating women.\textsuperscript{19}

Pro Te: Solutio has worked diligently to cover this Act,
with articles in Fall 2016 and Spring 2017 addressing
everything from an overview of the Act to new clinical
research tools.\textsuperscript{20}

\section*{9 2017: Medical Device Reporting}

This item is not about something the FDA has done,
but about what it hasn’t done. In 2007, Congress
amended 21 U.S.C. § 360i(a) to ease the burden of
medical device reporting for manufacturers and other
reporters for Class I and Class II medical devices.
Specifically, rather than providing individual medical
device reports within 30 days of each qualifying
event, reporters would be permitted to file summary
quarterly reports of medical device reports to the
FDA. (Congress also gave the FDA authority to create exceptions for certain devices that would have to continue the usual 30-day reports.) But for unexplained reasons, more than a decade later, the FDA still has not implemented the statute.

In December 2017, the FDA announced a “proposed program for manufacturer reporting of certain device malfunction medical device reports (MDRs) in summary form.” This followed the FDA’s “Pilot Program for Medical Device Reporting on Malfunctions,” announced in 2015, which studied summary medical device reporting. Under the proposed program, reporters for certain products would be permitted to voluntarily opt-in to summary reporting. Though this may ease the reporting burden for some products, it does not reach the scope contemplated by Congress in 21 U.S.C. § 360i(a).

Ongoing: Significant Enforcement Actions

A look back at FDA initiatives over the past decade would not be complete without mention of the FDA’s efforts — conducted in conjunction with the Department of Health and Human Services and the Office of Inspector General – to investigate and prosecute fraud in the healthcare industry, including the pharmaceutical industry. Pro Te: Solutio has reported throughout the years on many different efforts by federal agencies under their respective jurisdictional domains, ranging from articles on Warning Letters, Whistleblower Actions, Healthcare Fraud, and the “Park Doctrine” involving prosecution of corporate executives, just to name a few. You can be sure we’ll cover developing trends in this important area of healthcare, moving forward.

WHAT LIES AHEAD?

We don’t have a crystal ball, and we cannot predict what lies ahead for the pharmaceutical industry or the FDA. But as a sneak peek, consider recent statements of FDA Commissioner, Scott Gottlieb, M.D., identifying these priorities for the FDA for 2018:

- Addressing the Nicotine Addiction Crisis (e.g., proposed rulemaking regarding regulation of tobacco flavors and “premium cigars”)
- Advancing drug safety (e.g., issuance of regulations on drug compounding facilities, national standards for licensing of prescription drug wholesale distributors and third-party logistic providers: “track-and-trace” requirements)
- Promoting food safety
- Empowering consumers (e.g., new proposed patient medication document for drugs or biologics each time a patient receives a medication from the pharmacy and broadening access to non-prescription drugs)
- Modernizing standards (e.g., harmonizing global standards, modernizing mammography standards, and embracing electronic submissions)
- “Looking to the future” (e.g., reducing drug cost by encouraging competition, spurring innovation, creating regulatory efficiencies in bringing products to market, and addressing the opioid addiction crisis)

Butler Snow cherishes the work we’ve done with clients on initiatives over the past ten years, and we hope that this trip down memory lane together – with the articles we’ve shared via Pro Te: Solutio reminds you of all that has flown by over the last decade. We welcome the challenges yet to come, and we will be right there with you as new issues arise. We look forward to the next decade and beyond.