JULY 2012

REVIEW OF THE FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT OF 2012

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act ("FDASIA"), Pub. L. No. 112-144, 126 Stat. 993 (2012). This law is the culmination of a lengthy dialogue between industry, patient advocacy groups, and government authorities. FDASIA contains significant updates to the FDA regulatory process concerning drugs, biologics, and diagnostics, and it could have considerable short- and long-term effects on the regulated industry. (See table below for a breakdown of FDASIA; the text of the law can be found at http://1.usa.gov/MaLyxu.)

The heart of FDASIA lies within the reauthorization and introduction of user fees. Titles I through IV of FDASIA address user fees for the review of prescription drugs, medical devices, generic drugs, and biosimilars, respectively. These user fees are paid for by industry and help supplement the costs and increase the transparency of the FDA review process. Under FDASIA, these user fees are set to expire in 2017. As part of their discussions regarding user fees, industry and the FDA also negotiated performance goals that the FDA should meet. While the performance goals are not mandatory, FDASIA references them and requires the FDA to report on its progress toward meeting these goals.

FDASIA also affects market exclusivity in a number of areas. Market exclusivity protects the sponsor of an approved new drug application ("NDA") or biologics licensing application ("BLA") from new competition by either delaying approval or submission of applications from generics and other market competitors, sometimes even where the sponsor has no applicable patent rights. FDASIA measures relating to exclusivity include: six months of market exclusivity for conducting pediatric studies; five years of additional market exclusivity for qualifying antibiotics and antifungal drugs; and allowing enantiomers of a previously approved racemic mix to be eligible for the five-year new chemical entity ("NCE") exclusivity.

Further, FDASIA includes several incentives outside of market exclusivity to spur the development of innovative new drugs. The priority review voucher program has been expanded to include rare pediatric diseases, such that a sponsor receiving approval for a novel drug for an orphan pediatric indication is entitled to priority (six-month) review for any subsequent NDA or BLA. Nondilutive funding programs have also been established to support orphan drug development and to advance the FDA's Critical Path Initiative.

Finally, but importantly, FDASIA contains several provisions to help streamline and accelerate the approval process of new and innovative medicines. The law includes measures such as expediting the review of "breakthrough therapies," expanding the use of biomarkers and surrogate endpoints during clinical trials, allowing for consultations with FDA officials early in the drug development process, and updating the regulatory approval process for medical devices. Many of these provisions are the result of extensive conversation with industry experts and were focused on policies and procedures that would reduce the burden of regulatory approval without sacrificing patient safety.

The impact of FDASIA will of course lie with its implementation. Historically, the FDA has come under criticism regarding both the speed and cost of regulatory review and approval of drugs, as well as regarding delays in the issuance of industry guidelines. Looking forward, FDASIA could modernize the regulatory review process and provide greater transparency for industry stakeholders, while providing both the financial and legal support for FDA to properly execute on its mission. If implemented correctly, this law could help significantly reduce the uncertainty and cost associated with bringing a new drug to market.

SUMMARY OF FDASIA PROVISIONS AND EFFECTS

<table>
<tr><th>Title</th><th>Short Title</th><th>Effects</th></tr>
<tr><td>Title I</td><td>Prescription Drug User Fee Amendments ("PDUFA V")</td><td rowspan="4">Puts in place or reauthorizes User Fee Acts until 2017. These fees are paid by industry to help supplement the costs and increase transparency of FDA reviews for prescription drugs (PDUFA), medical devices (MDUFA III), generic drugs (GDUFA), and biosimilars (BsUFA).</td></tr>
<tr><td>Title II</td><td>Medical Device User Fee Amendments ("MDUFA III")</td></tr>
<tr><td>Title III</td><td>Generic Drug User Fee Amendments ("GDUFA")</td></tr>
<tr><td>Title IV</td><td>Biosimilars User Fee Amendments ("BsUFA")</td></tr>
<tr><td>Title V</td><td>Pediatric Drugs and Devices</td><td>Makes permanent two incentives to promote pediatric testing of new drugs: The Best Pharmaceuticals for Children Act ("BPCA") and Pediatric Research Equity Act ("PREA").
BPCA provides six months of marketing exclusivity in return for conducting pediatric studies, provided that certain conditions are met.
PREA requires that all original NDAs and BLAs, or supplements to such applications, must contain a "pediatric assessment" unless the applicant has obtained a waiver or deferral.</td></tr>
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Title	Short Title	Effects
Title VI	Medical Device Regulatory Improvements	Includes several provisions clarifying the approval of medical devices and requires the FDA to document the scientific and regulatory rationale for "significant decisions" regarding Investigational Device Exception applications, 510(k) submissions, and Pre-Market Approval applications, and institutes a possible appeals process.
Title VII	Drug Supply Chain	Enhances FDA inspection authority with regard to the drug supply chain and helps coordinate FDA efforts with non-U.S. authorities.
Title VIII	Generating Antibiotic Incentives Now	Encourages the development of antibacterial and antifungal drug products that treat pathogens that cause serious and life-threatening infections. Incentives include: • An additional five years of marketing exclusivity for an approved drug product designated by FDA as a Qualified Infectious Disease Product ("QIDP") (§ 801). • Granting priority review to an NDA for a drug designated as a QIDP (§ 802). • Granting fast-track approval for a QIDP (§ 803). • Developing clear FDA guidance and regulatory review of antibiotic and antifungal drug development (§§ 804, 806).
Title IX	Drug Approval and Patient Access	Includes several provisions designed to expedite the development and review of innovative new medicines. Measures include: • Broadening eligibility for FDA fast-track review (§ 901(b)). • Strengthening accelerated approval through the use of biomarkers and surrogate endpoints (§ 901(b)). • Expedited review of "breakthrough therapies" that may mark substantial improvements over existing treatments (§ 902). • Creation of external experts for consultation with regard to medicines for rare diseases through 2017 (§ 903). • Establishment of nondilutive funding mechanisms to support development of orphan drugs through 2017 (§ 906). • Development of a priority review voucher program for rare pediatric diseases (§ 908).
Title X	Drug Shortages	Incorporates provisions to address drug shortages, in part by enabling FDA to better manage and track drug shortages and threatened shortages.
Title XI	Other Provisions	Includes various provisions not included within other Titles. These include the following sections of interest: • Reauthorization through 2017 allowing for single enantiomers within approved racemic mixtures to be considered as New Chemical Entities (NCE) so as to qualify for a 5-year period of NCE exclusivity (§ 1101). • FDA is required to develop guidance documents regarding product promotion over the internet, including social media (§ 1121). • HHS is required to work with non-U.S. regulatory agencies to standardize and optimizing global clinical trial standards (§ 1123). • FDA is required to develop stronger guidance reports regarding nanotechnology and nanomaterials (§ 1126).

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