Policy Developments, Enforcement, and Priority Initiatives for 2018

Breakout Session with CDER Director Janet Woodcock, MD

By Amy E. Speros

The well-attended breakout session with Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research (CDER), featured remarks from Dr. Woodcock followed by a panel discussion on pharmaceutical industry and policy issues. Dr. Woodcock's remarks highlighted the Center's ongoing initiatives and priorities, with a strong emphasis on implementing new requirements from recent legislation, along with significant commitments for new guidance and internal modernization efforts within CDER.

Dr. Woodcock began by highlighting the Center's efforts in areas of high public focus that remain priority issues at both CDER and throughout FDA. In addressing the opioid epidemic, Dr. Woodcock indicated that CDER plans to issue guidance on development and review of non-opioid analgesics and medication-assisted addiction treatment therapies. CDER also remains committed to helping lower drug prices by facilitating speedy generic drug approvals, including its implementation efforts for enhanced generic drug development under the FDA Reauthorization Act of 2017.

Drug Quality and Security Act (DQSA) of 2014

In CDER's ongoing implementation of DQSA the agency has continued to address compounding issues by releasing guidance and a draft memorandum of understanding with the states, and the Center intends to continue its implementation plan in 2018. CDER has also held public meetings and issued initial guidance for implementation of track and trace requirements. The Center is working on additional guidance regarding serialization and grandfathered product issues as well as regulations on licensing by the end of 2018.

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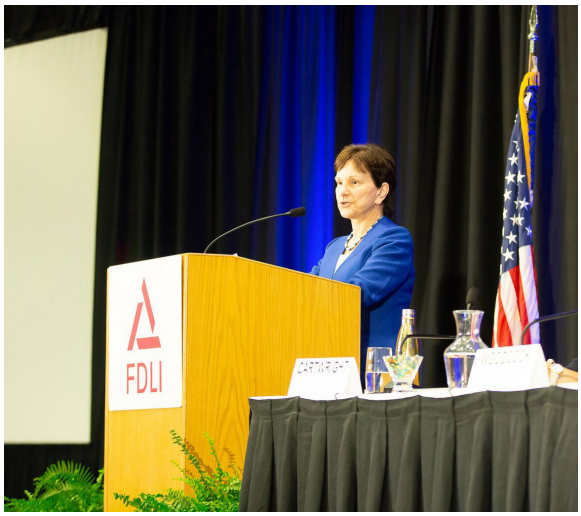
21st Century Cures Act

Initiatives stemming from the 21st Century Cures Act, including the incorporation of real world evidence into the new drug review process, were also covered. Dr. Woodcock emphasized that CDER is aligned with industry in seeking to use digital health data as much as possible. The Center is conducting studies using Sentinel data and is looking for companies to partner with to implement this initiative in future drug reviews. Dr. Woodcock also addressed patient-focused drug development, describing it as potentially the most transformative initiative at work in CDER. The Center intends to incorporate authentic patient involvement through patient meetings and a series of technical guidance documents for industry on data gathering from patient groups.

Dr. Woodcock also addressed the initiative to qualify new drug development tools, including a focus on updating and modernizing the Center's use of biomarkers and patient-reported outcome measures. She promised new guidance on novel clinical trial methodologies and indicated CDER's full support of master protocols and adaptive designs. She also highlighted the Center's plan for central oversight of surrogate endpoints to provide greater consistency and transparency in the accelerated approval process. Rounding out the 21st Century Cures discussion, Dr. Woodcock confirmed the Center's plans to offer advanced manufacturing grants to small molecule product manufacturers in an effort to enhance quality and cost savings through continuous manufacturing methods.

Modernization Efforts

Dr. Woodcock's additional discussion focused on ongoing efforts to modernize CDER to facilitate better and faster drug approvals. In the area of international harmonization, Dr. Woodcock acknowledged that drug development and clinical trials are now primarily conducted on a multinational scale, and CDER is currently working on uniform global standards with the International Conference on Harmonisation (ICH), as well as mutual recognition agreements with foreign agency counterparts on surveillance inspections.



Janet Woodcock, CDER Director

CDER is also undertaking new efforts across the Center for new drug review modernization, including a steering committee to oversee restructuring in the Office of New Drugs (OND) and an ongoing initiative to flatten the organization with increased decision-makers to relieve bottlenecks and speed review times. The nascent OND Office of Policy will play a key role in implementing consistent policies across disease areas. In the area of guidance development, Dr. Woodcock acknowledged that its prior procedures were too cumbersome and promised more concise, bulleted guidance documents that provide key advice to industry on a quicker timeline. CDER plans to release 30-40 guidance documents in 2018 based on revised procedures. CDER is also continuing its efforts to better document and relay its findings in new drug review summaries, including plans to formalize a new "uni-review" template for multiple disciplines in a single document, enhancing clarity and reducing repetition.

Finally, Dr. Woodcock highlighted the Center's ongoing reevaluation of postmarket safety assessments, which she described as a full-scale effort to review the Center's processes in a stepwise approach and initiate new pilot programs over time. Dr. Woodcock also highlighted the need for modernization of the over-the-counter drug framework to meet the demands of evolving science and indicated her hopes for congressional action in this area.

The panel discussion following Dr. Woodcock's remarks was moderated by Carla Cartwright, Director, Federal Affairs, Johnson & Johnson. During the discussion, Peter Pitts, President, Center for Medicine in the Public Interest, touched on several of the issues Dr. Woodcock addressed to offer suggestions and identify potential pitfalls, emphasizing that the goal of predictability will need to be a collaborative effort between the agency and industry. Frances Zipp, President of Lachman Consultants, focused on key issues facing generic drug manufacturers and encouraged CDER to continue issuing more simple, harmonized guidance documents to facilitate compliance. She also emphasized the need for international harmonization and guidance on continuous manufacturing, both of which could help address drug shortage issues. Daniel Kracov, Partner, Arnold & Porter LLP, highlighted the issue of off-label promotion and recent case law that has raised new constitutional issues for the agency. Mr. Kracov suggested FDA reconsider its historic bright-line rules and consider new mechanisms to voluntarily validate claims that go beyond an approved label. Margaret Anderson, Managing Director, Deloitte Consulting LLP, discussed issues facing CDER in its continual effort to accelerate drug development without sacrificing product integrity, identifying patient-focused drug development in particular as an area where CDER needed to work with industry to identify the return on investment.

During the final question-and-answer portion, an audience member asked Dr. Woodcock how CDER would align its increased guidance development efforts with the Administration's concerns regarding agency use of guidance documents more generally. Dr. Woodcock responded that industry seeks technical, not policy, guidance from FDA, and CDER will continue to meet this industry need. She also emphasized the agency's rigorous Good Guidance Practices and highlighted their nonbinding status in the broader CDER compliance framework.