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Steady Hands to Navigate the FDA's Balance of Innovation and Safety

▶ Nathan Brown and Howard Sklamberg bring their experience at the Food and Drug Administration to bear when counseling Akin Gump clients on pre- and post-market compliance issues and more.

CCBJ: Tell us about your individual practices.

Howard Sklamberg: I worked at the Food and Drug Administration (FDA) from 2010 to 2017, first as Director of the Office of Compliance at the Center for Drug Evaluation and Research, then in senior positions at the Office of Regulatory Affairs (ORA), and finally as Deputy Commissioner for Global Regulatory Operations and Policy. In that role, I oversaw ORA, which conducts inspections, import operations, and enforcement actions, and the Office of International Programs, which contains the foreign offices and handles bilateral and multilateral agreements. At Akin Gump, I counsel clients on a range of pre- and post-market compliance issues, drug applications, and policy development.

Nathan Brown: I went to the FDA in 2010 as Special Assistant to the Chief Counsel. I then held a similar role for the head of ORA, where I worked closely with Howard. I then served as a policy advisor on FDA issues to the Senate HELP Committee. During my stint there, the Drug Quality and Security Act (DQSA) was passed.

I focus my practice at Akin on med tech: software, diagnostics and other medical devices, as well as DQSA issues. Howard and I also advise investor clients regarding FDA-regulated companies and perform due diligence on transactions involving drug and device companies, labs and food facilities.

Have the FDA and other worldwide regulatory authorities kept pace with digitization, advances in genetics and other tech-driven changes to the industry?

Sklamberg: A few themes define how the FDA has dealt with all of the change over the past 10 years: more information for the public, encouraging innovation and more sources of information. These tools allow consumers to gain access to new products and make more choices about their health. For example, over the past year, the FDA has implemented a Nutrition Innovation Strategy, which has the potential for allowing companies to modernize labels in a way that helps consumers to eat more nutritious foods. In implementing the 21st Century Cures Act, the FDA is rewriting the traditional rule book for clinical trials, relying on more real-world evidence to make promising therapies available more quickly.

Brown: One of the challenges for the FDA is balancing innovation and safety. Its common approach is to grant enforcement discretion in emerging areas; it has used this approach, for example, with laboratory-developed tests (LDTs) and certain direct-to-consumer testing, with clinical decision support software, and in the regenerative medicine area. At the same time, the agency has taken enforcement actions against companies that it believes have crossed the line and where patient safety is at risk. We often advise companies in understanding how to navigate these gray areas.

How do you stay on top of the many legal, business and practical issues your clients face?

Sklamberg: It is important for our clients to understand not just the new programs and rules but how the FDA is implementing them. In some contexts, like during a drug's approval process, a client can seek the FDA's input. The guidance that the FDA has issued may leave unanswered questions, so it is important to know whom to speak with at the FDA.

Brown: We advise many clients to be proactive in providing input into FDA decision-making. That could be working through a trade association, providing comments to a rule, or participating in a pilot. It's useful to interact with the agency not just when you want something or have a compliance issue.

Nathan Brown, a partner with Akin Gump, focuses his practice on food and drug law, healthcare reimbursement and regulatory issues. He has served in prominent roles at the FDA. Reach him at nabrown@akingump.com.

What do you expect from the FDA as Norman Sharpless takes over the agency on an interim basis? How will emerging areas such as cell and gene therapy, combination products and continuous manufacturing play out?

Sklamberg: We expect the FDA's policy initiatives and its transparency to continue under Acting Commissioner Sharpless. He comes from a strong clinical and public health background. At the National Cancer Institute, he was an advocate for innovative therapies. He has already signaled continuity in the major areas that former Commissioner Gottlieb emphasized, such as opioids, food safety and nutrition, tobacco and e-cigarettes, and medical product innovation. Commissioners have different personal styles, but it is impossible to effectively implement change without being transparent with stakeholders. The FDA, industry and public all want everyone to know the FDA's expectations.

Brown: As another example, soon after Dr. Sharpless stepped in, he put out a statement confirming the agency's ongoing support for Congress to enact a new regulatory paradigm for in vitro clinical tests. That type of initiative will only succeed with the continued active support of the FDA and the administration.

Akin recently issued an alert on the FDA's enforcement discretion for genetic tests that qualify as LDTs. What does this more assertive stance by the FDA mean for your clients?

Brown: That action by the FDA demonstrates that enforcement discretion is not blanket protection from FDA action. In this case, the FDA had announced several months ago that it was concerned about unapproved tests that were making medication recommendations that may not be clinically validated and are not consistent with the approved drug labeling. One value of having an open dialogue with the agency is it reduces the likelihood of receiving an unwelcome enforcement action.

How're you advising clients given the murky regulatory picture on LDTs?

Brown: In short, it is evolving, as Congress considers legislation, more labs are willingly seeking FDA clearance or approval, the FDA is exercising some enforcement, and the reimbursement landscape is changing. There are many different types of tests, but it is becoming more important for sponsors of LDTs to consider a proactive regulatory strategy.

How do you assist clients struggling to deal with an evolving global patchwork of food and drug safety regulation and enforcement?

Sklamberg: It's very hard to distinguish between the domestic and international aspects of our work. Many companies rely on global supply chains. Even if you make drugs in the United States, you may get your ingredients from China and export the drugs to Europe. We advise clients on how the various regulators interact. For example, if the FDA finds a problem with your drug manufacturing quality system, you might have a problem with not just the FDA but European regulators too. The regulators share information and apply similar rules. We also advise clients on policing their global supply chains.

Howard Sklamberg, a partner with Akin Gump, concentrates his practice on regulatory compliance and strategy related to food and drug law. From January 2014 to April 2017, he served as the deputy commissioner for global regulatory operations and policy at the FDA. Reach him at hsklamberg@akingump.com.

Brown: Many companies would be happy with one set of harmonized requirements, even if they are rigorous and fairly burdensome. With regard to medical devices, there is interest among regulators and companies in greater convergence, both in terms of standards for premarket clearance and quality inspections. But these initiatives are complex and take sustained effort to accomplish.

Howard, you played a major role in the implementation of the 2011 Food Safety Modernization Act (FSMA). Has the act had unintended consequences?

Sklamberg: Implementation of FSMA has progressed in stages. The agency had a lot of input from stakeholders, including the states, before writing the major rules. The FDA knew that implementation was a gigantic change and required growers, manufacturers and importers to develop new and often complex preventive systems. The FDA's initial approach was "educate while we regulate" – teaching industry about the FDA's expectations as the agency ramped up implementation.

The results have been good so far. Our clients appreciate the guidance that the FDA has provided, such as the Technical Assistance Network. They are also learning about and preparing for new types of food inspections under FSMA. Consumers will benefit from its preventive framework. ■