FDA from the Podium

Dr. Margaret Hamburg, Commissioner of Food & Drugs, recently addressed Food and Drug Law Institute (FDLI) 2014 Annual Conference attendees on April 23, 2014 in Washington, D.C. Acknowledging that May would mark her 5th year in office as Commissioner, she took the opportunity to reflect upon her years in office and share her visions of the Agency's top priorities.

Some of her notable accomplishments were her unbending desire to "open ourselves up as an agency," and to, "ensure that [FDA's] vital work is done with the best possible input from stakeholders, and with the trust and confidence of the public [the Agency] serves." True, the Agency is not as transparent as glass, but transparency movement has brought understanding to what FDA does as well as how the Agency works (this is perhaps most evident in the several public-private partnerships in different segments of our industry). Simple changes, such as more frequent updates to the FDA website and use of social media have also advanced the notion of transparency. And the Agency has begun to really listen. Dr. Hamburg made note of FDA's recent feedback sessions on patient-centered medicine as well as the numerous public meetings with patient advocacy groups across a spectrum of specific diseases.

Dr. Hamburg, building upon the foundation of Agency success stories took an opportunity to stress that attention is now turning to certain initiatives to which industry should take note. This is not chest-beating by the Agency or an attempt to renew long since dying initiatives; what she relayed next shows the intensity with which the Commissioner's Office is driving change. According to Hamburg, the recent initiatives that are at the forefront of the Agency include:

- Implementation of the final rule for Unique Device Identification (UDI) to ensure a consistent way of identifying and tracking medical devices (implementation for Class III devices is Sept. 24, 2014);
- Issuance of the final guidance for mobile medical applications, clarifying FDA oversight on certain groups of software applications;

If you are a medical device manufacturer, mobile application developer or any entity operating in an Agency to the medical device space, consider your options for remaining current on moving and shifting regulatory developments.

Whether struggling with the unique device identifier hierarchy for certain products, dealing with related labeling challenges or determining where a mobile application sits on the regulatory spectrum to determine applicability of certain FDA requirements, Regulatory Compliance Associates® Inc. stands ready to support you and your company. Armed with consultants serious about compliance and having years in the trenches as quality and regulatory leaders, RCA can help you establish a sustainable compliance solution and remain at the forefront of the ever-evolving regulatory landscape.