Report from Town Hall Meeting with the FDA's Center for Devices and Radiological Health

By Kim M. Schmid and Shane V. Bohnen

With the medical device industry facing potentially concerning changes to the landscape of federal regulation, a critical dialogue began yesterday with the FDA's Center for Devices and Radiological Health (CDRH). On May 18, 2010, the CDRH held its initial "town hall" styled meeting in Bloomington, Minnesota, with Minnesota's medical device companies and other interested parties. This was the first of three meetings taking place nation wide, with the next two set for Boston and Los Angeles. More than 500 members of the medical device industry attended this inaugural meeting to hear from and speak with the Director of CDRH, Dr. Jeffrey Shuren, as well as other senior leaders from CDRH. The focus was to discuss the principles underlying CDRH's Strategic Priorities, including CDRH's review and likely revision of the 510(k) approval process. Shuren invited a continuing dialogue with industry because, as he stated, CDRH has not made any final decisions with regard to the medical device approval process, and the Agency is looking to the industry's input as to how best accomplish CDRH's key priorities for 2010.

Dr. Shuren articulated CDRH's priorities in his opening remarks, including:

1. Fully Implement a Total Product Life Cycle Approach
2. Enhance Communication and Transparency
3. Strengthen CDRH Workforce and Workplace
4. Facilitate Innovation and Address Unmet Public Health Needs

In an attempt to assuage the concerns of industry and others in attendance, Shuren emphasized that CDRH had no intention of eliminating the 510(k) pathway to the market. Rather, the emphasis of CDRH's proposed revisions to its regulation of medical devices, including the approval process, would reflect its "Total Product Life Cycle" approach. As indicated by the Agency's Strategic Priorities, this "Total Product Life Cycle" approach would permit CDRH to track information about the safety and efficacy of a device at all stages of the product's life. The proposed Unique Device Identification (UDI), like a National Drug Code (NDC), would establish a number and identification system for each particular device on the market and be used to track all stages of the device's life. As part of the Total Product Life Cycle, CDRH intends to make more information readily available about the safety and efficacy of approved devices. Additionally, CDRH is proposing to make clinical data available to the public through its website.

The build up to Dr. Shuren's meeting with Minnesota's medical device industry was the potentially sweeping nature of the Agency's proposed changes to the 510(k) program. Shuren advised the largely industry-based audience that the 510(k) program would remain under review and any final decisions regarding changes to the clearance or approval process would largely be put "on hold" until after the Institute of Medicine completed its review and issued its own recommendations for the 510(k) program. An internal group at CDRH is also engaged in an independent review of the program, and the reports and recommendations from these two groups are expected by 2011.

The CDRH is expected to release a new draft guidance document later this year regarding clinical trials. According to Shuren, this guidance will advise industry as to "best practices" for obtaining reliable clinical data, and avoiding pitfalls that have led CDRH to reject certain clinical data.

After concluding his remarks, over a dozen individuals were invited to publicly comment. The individuals who spoke included members of Congress and their staff, senior leadership from some of Minnesota's leading

medical device companies, venture capitalists, and practicing physicians. Afterward, Dr. Shuren answered more than two hours of questions from members of the audience.
In the prepared public comments and in the questions from the audience, two main concerns emerged. The first and most immediate concern was the growing lack of predictability of the 510(k) pathway to market, as example after example was offered to illustrate that the required showing for a device to be cleared had become a hidden target. In short, the device industry no longer knows what showing will be required in order to receive approval.

Hand in hand with this concern was the longer-term fear that unpredictable regulation would stifle innovation. Device leadership and investors alike spoke about the unwillingness of venture capitalists to invest in innovative new products where they cannot reliably forecast the investment needed to bring a device to market. CDRH was warned that since 83% of medical technology is funded by venture capital, the lack of clear guidance about the requirements for device approval could have disastrous consequences. CDRH received examples of companies that closed their United States operations to resume in Europe, as well as companies that simply ran out of capital and had to close permanently.

Dr. Shuren responded to these concerns by explaining that CDRH was in the process of hiring a Director of Innovation for the purpose of ensuring that CDRH's regulatory efforts do not unreasonably restrict innovation. As for the existing lack of predictability, Shuren and the other senior leadership at CDRH acknowledged that the procedures currently in place can permit inconsistent results. CDRH has hired additional policy staff to improve ways that CDRH updates and streamlines guidance for industry, as well as examine other ways in which the Agency can quickly communicate with industry.

Dr. Shuren conceded that since Minnesota was CDRH's first of three stops, the process of dialogue and problem solving had just begun. He reminded the audience that CDRH and the medical device industry remain in a "long term relationship" in which both sides should continue to work with one another, recognizing that there are and will continue to be disagreements. Nonetheless, he invited the medical device industry to collaborate with CDRH, and asked that the industry continue to help shape the landscape of regulation so that both sides could deliver safe and innovative new medical devices to the market.

Kim M. Schmid is the Managing Partner of Bowman and Brooke's Minneapolis office. In addition to her defense litigation practice where she is currently serving as National Coordinating Counsel in medical device mass tort litigation, Kim advises her clients on FDA regulatory compliance and reporting requirements. In court, Kim has tried cases and defended IDE products utilized in clinical trials as well as Class I, II and III FDA cleared devices, and pharmaceutical cases involving generics, branded, OTC and Rx medications. Kim can be reached at 612.672.3247 or kim.schmid@bowmanandbrooke.com.

Shane V. Bohnen concentrates his practice on defending medical device and pharmaceutical manufacturers in cases across the country. Shane has worked on cases involving Investigational Devices in clinical trials, as well as Class I, II and III (both PMA and 510(k)) medical devices. Shane has defended pharmaceutical cases involving generics, branded, OTC and Rx medications. Shane can be contacted at 612.656.4077 or shane.bohnen@bowmanandbrooke.com.