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FCC And FDA Focused On Convergence Of Communications And Medical Systems

Last week, the Federal Communications Commission ("FCC") and the Food and Drug Administration ("FDA") launched a joint initiative to clarify the approval process and regulatory requirements for converged communications and health care devices. In a two-day joint meeting held on July 26-27, 2010, the two agencies solicited comments from industry representatives "to gain a better understanding of the convergence of communications technologies and medical devices, the future of wireless health technologies, and the challenges they face." The goal of the initiative is "to enhance coordination between FDA and FCC for future devices and applications, and to clarify and delineate the respective areas of expertise and jurisdiction between the agencies."

The joint collaboration implements a key recommendation of the FCC's National Broadband Plan, released in March 2010, which cautioned that a lack of clarity regarding the appropriate regulatory approach could stifle innovation, slow the application approval processes, and deter adoption of convergent technologies in the health care industry. Such technologies include, for example, mobile applications that allow individuals to monitor their health conditions, wireless patch-like sensors that transmit data to practitioners and caregivers, and neural pathway replacements that stimulate muscle movement. FCC Chairman Julius Genachowski described the joint initiative as a key component of a larger strategy for the health care industry that also seeks to increase broadband access to rural clinics and increase spectrum availability. He noted that broadband technology is especially promising for the industry because of its ability to enable remote diagnostics and health care, remote medical monitoring, and remote access to health records.

Industry representatives generally reacted positively to the meeting, noting that the current lack of clarity as to whether the FDA or FCC has ultimate authority over medical device product safety issues related to signal interference often discourages venture capitalists from investing in the industry, and that parallel approval processes for the two agencies tend to be duplicative and time-consuming.[1]

The FDA and FCC are currently seeking comments on how they may clarify and identify each agency's respective jurisdiction and how to best improve, coordinate, and simplify the regulatory approval process. The deadline for filing comments is August 16, 2010.

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[1] *See* Monica Hogan, *FDA Partners with FCC to Spur Wireless Health Technology Development*, "THE GRAY SHEET," Aug. 2, 2010; Monica Hogan, *Philips Healthcare CTO: "The Right Things are Happening" in Wireless*, "THE GRAY SHEET," Aug. 2, 2010.