Joint Statement on Wireless Medical Devices

U.S. Food and Drug Administration         Federal Communications Commission

July 26, 2010

1. Innovation in broadband and wireless-enabled medical devices holds significant promise for enhancing health and reducing the costs of health care for all Americans. Examples include wireless sensors that remotely monitor heart rhythm and portable glucose monitoring systems. All Americans should be afforded the opportunity to benefit from medical technology advances with improved broadband and wireless technology.

2. Developing and integrating wireless and broadband communications technology with medical devices and applications requires agencies to assure that such devices operate in a safe, reliable and secure manner.

3. It is important for the federal government to provide leadership and encourage innovation and investment in new health care technologies that enable patients, doctors, and other health professionals to access the highest quality care.

4. The American public -- including industry, providers, patients, and other interested stakeholders -- should have clear regulatory pathways, processes, and standards to bring broadband and wireless-enabled medical devices to market. This includes clarity regarding each agency’s scope of authority with respect to these devices, predictability regarding regulatory pathways, and streamlining the application process, as appropriate, to facilitate innovation while protecting patients.

5. The FDA and the FCC agree to build upon this initiative launched today to proactively serve the national interest in finding innovative solutions to America’s health care challenges.

Food and Drug Administration (FDA)         Federal Communications Commission (FCC)
Commissioner Dr. Margaret Hamburg           Chairman Julius Genachowski