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The FDA’s Role in Incorporating Human Factors Engineering in Medical Device Design

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1. Development of FDA Oversight of Human Factors Considerations in Medical Device Design

Since first establishing its Bureau of Medical Devices in 1974, the Food and Drug Administration ("FDA") has understood the need to incorporate human factors engineering processes and design considerations into the design of medical devices. The FDA began its work on a general set of controls, or baseline standards for environmental and electromagnetic compatibility, for medical devices in anticipation of the 1976 amendments to the Federal Food, Drug, and Cosmetic Act of 1938, discussed below, which gave the FDA, for the first time, the statutory authority to regulate medical devices.

Despite its best intentions to quickly move forward with addressing additional human-factors-related concerns in the medical device industry, the FDA's efforts stalled in the early years. The FDA's human factors initiative was eventually jump-started in 1983 by an eager investigative reporter from the Denver Post, who began writing a local story about two deaths in the same hospital in a single month, both of which involved different machines, but the same model anesthesia gas machine. The media scrutiny caught the attention of the local FDA field office, and ultimately led to the FDA's investigation of the device. Unable to gather information about the ongoing investigation directly from the FDA, the reporter stirred interest in Congress and the House of Representatives' Subcommittee of Oversight and Investigation of the Committee on Energy and Commerce held hearings to consider the safety of such devices in 1984. Anesthesia Machine Failures: Hearing on Anesthesia Machine Failures before the Subcommittee on Oversight and Investigation, Comm. on Energy & Commerce, 98th Cong. (1985). During those hearings, the FDA agreed to work to minimize the dangerous use of medical devices, and the real push for extending the FDA's good manufacturing processes to cover designs of medical devices was born.

A. Overview of the FDA's Statutory Authority to Regulate Medical Devices

The FDA received authority to regulate medical devices when Congress enacted the Federal Food, Drug, and Cosmetic Act of 1938 ("FDC Act"), which, as amended in 1976 with the Medical Device Amendments, remains the fundamental enabling statute. 21 U.S.C.S. §301 et seq. (2008); 21 U.S.C.S. §360j(f); Robert Higgs, Wrecking Ball: FDA Regulation of Medical Devices (Aug. 7, 1995), p. 4. The FDC Act prohibits all interstate dealings in "adulterated" or "misbranded" devices. 21 C.F.R. §351-52.