FDA REGULATION OF MEDICAL SOFTWARE INNOVATION

By Yi-Kang Hu, Ph.D.

Medical device regulation plays a key role in the design, development and commercialization of new medical technologies. A comprehensive understanding of various regulatory requirements and pathways for product commercialization is therefore an essential cornerstone of successful medical device innovation. However, for companies that develop software-based medical products, identifying the appropriate regulatory pathway can be particularly challenging because the Food and Drug Administration (FDA) policy on these types of products is a confusing patchwork of exemptions and case-by-base assessments.

For example, the FDA has recently proposed to regulate a class of software products called "Medical Device Data Systems" (MDDS) that electronically collect, transfer, and store data from devices such as glucose meters or blood pressure devices. Such systems may be used to allow doctors to remotely monitor patients who require long-term care and potentially reduce the number of doctor visits. Even though MDDS are currently considered medical devices under FDA law, the FDA has not enforced medical device requirements against MDDS manufacturers under a policy of enforcement discretion. Therefore, many MDDS manufacturers may not be aware that their products are considered a medical device subject to FDA regulation.

In its proposed regulations, the FDA stated that it intends to cease its practice of enforcement discretion for MDDS manufacturers. MDDS will be regulated as Class I medical devices, and manufacturers will need to obtain premarket clearance from the FDA if their MDDS are intended for use by lay persons or perform irreversible data compression. Additionally, MDDS-like systems that do not fit the definition of MDDS in the proposed regulations may be regulated as Class III devices, the highest and most stringent level of FDA device regulation. The new policy will impact many MDDS companies who have thus far escaped regulatory oversight and may not be prepared to comply with the FDA's medical device requirements.

The proposed MDDS rule appears to be the FDA's initial step in addressing the need to bring its device regulation up to date with the rapid changes in medical technology. Future rulemakings are expected for other medical software and computer systems. To ensure their products are competitive and follow appropriate regulatory pathways for commercialization, medical software companies should seek experienced FDA counsel in the early stages of product development. ●

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