Reaching a State of Comfortably Numb: FDA Intends to Relax Enforcement for Certain Types of Medical Devices

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When one reads the final guidance, "Medical Device Data Systems [MDDS], Medical Image Storage Devices, and Medical Image Communications Devices," the song lyrics to Pink Floyd's "Comfortably Numb" might come to mind (or, at least, they did to me):

When I was a child
I caught a fleeting glimpse
Out of the corner of my eye
I turned to look but it was gone
I cannot put my finger on it now
The child is grown
The dream is gone
I have become comfortably numb

In a policy shift that could cause a mild case of whiplash, the Food and Drug Administration (FDA) reversed, in part, its recently-issued enforcement approach for the aforementioned types of devices.[1]

This Bulletin highlights some of the key provisions of the final guidance. We also offer our own observations. We will not describe here the history of FDA's regulation of MDDS products.

- For background and context, FDA has defined a MDDS as a hardware or software product that transfers, stores, converts, formats, and displays medical device data. 21 C.F.R. § 880.6310. A "medical image storage device" is a device that provides electronic storage and retrieval functions for medical devices. 21 C.F.R. § 892.2010. Finally, a "medical image communications device" is one that provides electronic transfer of medical image data between medical devices. 21 C.F.R. § 892.2020.
- The agency distinguishes a MDDS from those devices intended for active patient monitoring. "Active" refers to "any device that is intended to be relied upon in deciding to take immediate clinical action." FDA offers the example of a nurse telemetry station that receives and displays information from a bedside hospital monitor in an ICU.
- In the new final guidance, FDA noted that, since it down-classified MDDS products from Class III (high risk) to Class I (low risk) in 2011, it has "gained additional experience with these types of technologies, and has determined that these devices present a low risk to the public."
- With this new familiarity and expertise, the agency concluded that it "does not intend to enforce compliance with the regulatory controls that apply to MDDS, medical image storage devices, and medical image communications devices."
- Therefore, the agency said that, for the aforementioned devices, it will not enforce compliance with requirements relating to establishment registration, product listing, premarket notification (i.e., a 510(k)), postmarketing reporting, and quality system regulations (QSRs)). These requirements apply to Class I devices, but FDA intends to exercise enforcement discretion.

1 See www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm401996.pdf.

AGG Observations

- The products described remain medical devices. FDA did not change the regulatory classification. Therefore, while FDA plans to exercise enforcement discretion with certain types of products, the agency has not abdicated its ability to regulate these products, such as misbranding of a product.
- It is important to recognize that FDA is very specific to those devices affected by the final guidance. All of them share a passive or static nature – e.g., storage or display of data, no modification of data. The guidance is limited. On the other hand, a device that modifies data (e.g., converting from a number to a graph) or performs active functions, such as active patient monitoring, is not covered by the enforcement discretion outlined by FDA. Thus, the device's label, labeling, and intended use (e.g., promotional materials, verbal statements) are crucial in evaluating a device's classification and regulatory requirements. The more a product claims to be instrumental in diagnosing, treating, or assisting in clinical decisions or actions, the more FDA will regulate (e.g., requiring a 510(k) or a Premarket Approval Application, QSRs).
- To continue with the Pink Floyd theme, FDA heard industry was feeling down, tried to "ease your pain" to get industry back on its feet again (i.e., to advance digital health), and "relax." However, remember to review "some information first, just the basic facts," to minimize getting hurt – so you, too, can feel comfortably numb.

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