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POLICY BRIEF

Updating FDA Guidance on Breakthrough Devices Program to Add Device Interoperability

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EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) has recognized that interoperability – the ability of a device to use and share information among one or more devices, systems or platforms – offers several benefits for medical devices, such as improving patient care, reducing errors and adverse events, encouraging innovation, and enabling more diverse study datasets.[1] In recognition of these benefits, the FDA should update the guidance for its Breakthrough Devices Program to clarify that third party interoperability is a consideration in designating devices under the program. This clarification would incentivize medical device sponsors to implement third party interoperability to qualify them for the Breakthrough Devices Program's benefits, including prioritized regulatory review, which ultimately would further enable patient choice and faster innovation in the medical device industry.

BACKGROUND

The FDA's Breakthrough Devices Program is a voluntary program for medical devices and device-led products that provide effective treatment or diagnosis for life-threatening diseases (like diabetes). The program is designed to accelerate the development and approval of innovative medical devices that have the potential to improve patient care or address unmet medical needs significantly. For a device to qualify for Breakthrough Device designation and receive the program's benefits, a sponsor must demonstrate that the device meets a number of criteria, including at least 1 of the following 4 qualifications:

1. The device represents breakthrough technology.
2. No approved or cleared alternatives exist.
3. The device offers significant advantages over existing approved or cleared alternatives.
4. The device availability is in the best interest of patients.[2]

Receiving a Breakthrough Device designation is a transformative milestone for device sponsors. The designation not only expedites the device's regulatory review but also signifies recognition by the FDA that the device has the potential to revolutionize disease management, thereby encouraging innovation. Moreover, it also qualifies devices for the Centers for Medicare & Medicaid Services' Transitional Coverage for Emerging Technologies (TCET) program, which incentivizes device sponsors by providing an easier pathway to reimbursement under Medicare.

Under the FDA's current Breakthrough Devices Program guidance, third party interoperability –the ability of a device to use and share information among other devices, systems or platforms, including those created by different manufacturers – is not clearly identified as a qualifier for designation. As the FDA has acknowledged in other programs and public remarks, interoperability in medical devices allows patients and providers to tailor their disease management strategies to individual preferences and needs, and enables better patient outcomes. The Breakthrough Devices Program's silence regarding interoperability creates uncertainty and risks for sponsors that otherwise have few incentives to design new medical devices with interoperability in mind, consequently hurting patient choice and stifling innovation.

This state of affairs is especially damaging in the diabetes management ecosystem. One of the leading forms of diabetes management is automated insulin dosing. Automated insulin dosing involves an interplay among 3 separate components, which can communicate with one another to individualize a patient's diabetes management strategy:

- A continuous glucose monitor (CGM), a device that automatically monitors glucose levels;
- An insulin pump, a small device that continuously delivers insulin to the patient, as an alternative to injections; and
- An automated glycemic controller (AGC), an algorithm that calculates how to automatically adjust insulin delivery in an effort to keep a patient's glucose levels in a target range and reduce the management burden on a person with diabetes. This algorithm might be embedded in the insulin pump itself, run from a separate handheld device, or live inside a smartphone app.

However, patients and providers can mostly choose only from limited bundles of pumps, CGMs, and algorithms based on manufacturer discretion and business agreements. This is because the FDA has approved just a few interoperable diabetes devices and has cleared only a single stand-alone AGC that is interoperable with multiple insulin pumps[3] and integrated CGMs (iCGMs), Tidepool Loop. And very few manufacturers offer CGMs or insulin pumps that meet interoperability standards. This limited landscape is largely the consequence of the huge regulatory undertaking for software developers and algorithm experts to get interoperable devices cleared for public use, which in practice requires preexisting contracts and partnerships with manufacturers of the other pieces of the diabetes management ecosystem. This barrier only adds to hurdles associated with market competition.

RECOMMENDATION

In response to these challenges, the FDA should update the Breakthrough Devices Program guidance to clearly indicate that third party interoperability is a feature that could qualify a device for the designation. This update would incentivize device sponsors to develop more interoperable medical devices to qualify for the Breakthrough Device designation, thereby fostering innovation and improving patient outcomes across the medical device industry.

There are at least 2 ways in which the FDA could update its Breakthrough Devices Program guidance to clarify that interoperability could qualify a device for the designation:

- The FDA could add an example demonstrating that interoperability could qualify a device under Section III.B.2.c of the guidance, which details how a device can qualify for designation if it "offers significant advantages over existing approved or cleared alternatives."
- Alternatively, the FDA could add an example demonstrating that interoperability could qualify a device under Section III.B.2.d of the guidance, which details how a device can qualify for the designation if "device availability is in the best interest of patients."

Sample language executing both versions of these changes is included here.

The FDA should consider making one or both of these updates for several reasons. Key among them is that third party interoperability is a feature that satisfies both criteria. Section III.B.2.c states that a device can be approved for the designation if it "offers significant advantages over existing approved or cleared alternatives." Interoperability does just that by limiting the need for patients to hack into their own devices to achieve the advantages of efficiency and individualized patient care that come with being able to choose the right device for their own needs, versus being forced into a closed device ecosystem. As applied to diabetes management, third party interoperability would allow patients to choose and use pumps, CGMs, and algorithms from different manufacturers – such as being able to pair a Dexcom CGM with a Medtronic pump – depending on their individual diabetes management needs.

Additionally, Section III.B.2.d states that a device can be approved for the designation if "device availability is in the best interest of patients." Interoperability meets this criterion as well: the FDA has already acknowledged that it is in the best interest of patients because it allows them to pick and choose the components that make the best sense for them, ultimately leading to better patient outcomes.[4] As applied to people with diabetes, every person has a unique physiology, meaning that the combination of components that allow for the best outcomes for them will vary. True interoperability of diabetes devices will lead to an increase in patient choice and, consequently, better outcomes for the people living with diabetes who would best respond to outcomes currently outside the ranges of bundled devices.

Moreover, clarifying that third party interoperability qualifies a device as a breakthrough device would create further incentives for device sponsors to build true third-party interoperability into their products.

A modest clarification of existing guidance would remove the risk of misinterpretation that contributes to the failure of device sponsors to incorporate interoperability into innovative devices, thereby enabling what the medical community and the FDA have already confirmed is in the best interest of public health. This clarification would alter the calculus for device sponsors, making it more worthwhile for them to engage with the rigorous regulatory approval process involved in determining whether they can safely incorporate third party interoperability, versus developing their own closed device ecosystems instead.

While we have shared how interoperability will specifically affect the diabetes ecosystem, the impact of this language stretches to all corners of the medical devices industry. The concept of interoperability fostering innovation is applicable in all aspects of medical devices, and we hope that the encouragement of third-party interoperability will foster innovation and patient choice for the larger medical community.

For more information about this proposal, please see this document that outlines the specific language changes for the FDA to implement this proposal.

ENDNOTES

1 *See* "Medical Device Interoperability," Food and Drug Administration, accessed September 2023, https://www.fda.gov/medical-devices/digital-health-center-excellence/medical-device-interoperability#:~:text=What%20is%20Medical%20Device%20Interoperability,products%2C%20technologies%2C%20or%20systems.

2 *See* "Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff," Food and Drug Administration, September 15, 2023, https://www.fda.gov/media/162413/download.

3 Insulin pumps manufactured with interoperable technology are known as "alternate controller enabled," or ACE, pumps. The FDA approved the first ACE pump for public use in 2019. *See* "FDA authorizes first interoperable insulin pump intended to customize treatment through their individual diabetes management devices," Food and Drug Administration, February 14, 2019, FDA authorizes first interoperable insulin pump intended to allow patients to customize treatment through their individual diabetes management devices.

4 *See* Alain D. Silk, "Diabetes Device Interoperability for Improved Diabetes Management," *Journal of Diabetes Science and Technology* 10, no. 1 (January 2016): 175–7, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4738204/. Dr. Silk is the FDA's former Branch Chief for Diabetes Diagnostic Devices.

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