PROPOSED TEXTUAL CHANGES

Suggested Redline to Breakthrough Devices Program Guidance

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This document outlines the suggested changes that the Food and Drug Administration could make to its existing Breakthrough Device Program guidance to incentivize more medical devices to implement third-party interoperability features. More information on these suggested changes can be found in this memo here. Suggested alterations appear in red.

c. Device Offers Significant Advantages over Existing Approved or Cleared Alternatives

In determining whether a device meets the criterion of offering "significant advantages over existing approved or cleared alternatives," FDA considers the potential, compared to existing approved or cleared alternatives, "to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self directed personal assistance), or establish long-term clinical efficiencies."

Examples of devices that have the potential to offer significant advantages over existing approved or cleared alternatives include:

- a diagnostic product intended to improve diagnosis or detection of a life-threatening or irreversibly debilitating disease or condition in a way that would lead to improved outcomes (e.g., an in vitro diagnostic product (IVD) for earlier diagnosis of preeclampsia);
- a product intended to improve or prevent a serious treatment-related side effect associated with an available product for treating a life-threatening or irreversibly debilitating disease or condition;
- a product intended to treat a life-threatening or irreversibly debilitating disease or condition that does not have a serious adverse effect associated with an available product for treating this disease/condition;
- a product intended to treat or diagnose a life-threatening or irreversible disease or condition that results in more efficient or safer clinical operation; and
- an automated insulin dosing system that allows for third party interoperability, enabling patient and provider choice to pick the components that significantly ease the burden of diabetes management and provide care that caters to individual patient needs.

d. Device Availability is in the Best Interest of Patients

In determining whether the device meets the criterion "availability [of the device] is in the best interest of patients," FDA considers whether the proposed device and indications for use provide another type of specific public health benefit.

An example of a device, the availability of which is in the best interest of patients, could be a group of molecular tests to identify a large number of potential pathogens simultaneously, including common, rare, and/or emerging pathogens. More rapid access to more detailed diagnostic information can better guide optimal patient care and may yield better patient outcomes. However, these devices also suffer major challenges not only in comparing against reference methods but also in obtaining the appropriate sample base to reliably verify the more rare pathogens in the panel. This can result in the target panel of these tests being reduced in order to generate data to support FDA marketing authorization. The Breakthrough Devices Program may facilitate the developers' ability to test new wide-scope IVDs for both common and rare pathogens, resulting in devices with a broader diagnostic scope being brought to market. Also, this program could facilitate more rapid marketing authorization of modifications to these tests as new and emerging pathogens are discovered or proposed for addition to the panels.

In addition, the criterion of being in the best interest of patients may apply when the device has a benefit for patients who are unable to tolerate available therapy, whose disease has failed to respond to available therapy, or for whom the treatment can be used effectively with other critical agents that cannot be combined with available therapy. This criterion may also apply if the device:

- avoids serious harm that can occur with available therapy;
- avoids serious harm that causes discontinuation of treatment of a life-threatening or irreversibly debilitating disease or condition; or
- reduces the potential for harmful interactions with other therapies.

In addition, this criterion may apply to a device that was designed or modified to address an unanticipated serious failure occurring in a critical component of an approved or cleared device for which there are no alternatives or for which alternative treatment would entail substantial risk of morbidity for the patient. A device may also satisfy this criterion if it provides an additional benefit, such as improved patient compliance that is expected to lead to a reduction in serious adverse outcomes. Furthermore, this criterion may apply if the device addresses an emerging or anticipated public health need, such as a device shortage or public health emergency.

A product developed by a sponsor who is working with a Federal agency on the development of medical devices to address a national security issue may be considered to meet this criterion. To support a request for designation under this criterion, it may be helpful to include a letter in the designation request from the Federal agency (e.g.,

Department of Defense, Department of Homeland Security) identifying the specific device or device type and indicating that its commercial availability is of particular importance to our national security.

Examples of devices for which availability would have been considered in the best interest of patients at the time they came to the market are as follows:

- an insulin pump that features a new mechanism to detect low blood glucose and automatically stop insulin delivery~~; and~~
- an automated insulin dosing system that allows for third party interoperability, enabling patient and provider choice to pick the components that significantly ease the burden of diabetes management and provide care that caters to individual patient needs; and
- an IVD assay that detects a genomic variant for the purposes of identifying patients with certain cancers who are eligible for treatment with a specific drug. In some situations, for those patients who do not possess the variant, a therapeutic product may have severe toxicities and be detrimental without providing benefit to the patient. For this reason, use of the assay is necessary for safe and effective use of the drug and is therefore in the best interest of patients. For more information on in vitro companion diagnostic devices, please refer to the FDA guidance, "In Vitro Companion Diagnostic Devices."

Finally, FDA may consider relevant patient experiences and perspectives when evaluating whether a device meets the designation criterion of availability being in the best interests of patients. FDA may also consider relevant patient experiences and perspectives when evaluating other designation criteria for purposes of a Breakthrough Device designation request. This may include information on the relative value of the perceived benefits and risks of a specific device to treat or diagnose a life threatening or irreversibly debilitating disease or condition. Sponsors interested in presenting patient perspective information in support of their Breakthrough Device designation request may refer to the FDA guidances "Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling" and "Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation"39 for additional information.

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