Celebrating a Year of the Expedited Access Pathway Program for Medical Devices

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The U.S. Food and Drug Administration (FDA) is committed to supporting patient access to high-quality, safe, and effective medical devices of public health importance — as quickly as possible.

— Erin Cutts, B.S., Policy Lead, Q-Submission Program (acting), Office of Device Evaluation in FDA's Center for Devices and Radiological Health

For patients suffering from life-threatening conditions and who have few, if any, options, this access becomes critical. About a year ago, FDA's Center for Devices and Radiological Health created the voluntary Expedited Access Pathway (EAP) program to facilitate the development of and access to new technology for these patients who desperately need them.

The EAP program represents a collaborative approach to help manufacturers with product development and evaluation. Products in the EAP program ultimately undergo either Premarket Approval (PMA) or de novo review.

Other device programs may focus specifically on premarket review once a submission has been made. But EAP allows FDA and sponsors to focus on the early stages of product development, which can be helpful for new

products that address the unmet — and critical — life-threatening patient needs. In fact, we think the EAP program will have most impact when sponsors request EAP designation prior to beginning an IDE pivotal study. That way we can work with the sponsor to make sure the data being collected in the pivotal study are appropriate to include in the device's manufacturing submission.

— Owen Faris, Ph.D., Clinical Trials Director, Office of Device Evaluation in FDA's Center for Devices and Radiological Health.

For the devices in the EAP program, FDA, including senior leadership, maintains a high level of interaction with sponsors and provides advice on efficient device development. What does this mean? While working with the device sponsor, FDA carefully considers the risks and benefits of the new device, as well as the risks of delaying a new therapy to patients who have few or no other options. It may be appropriate to accept more initial uncertainty for devices in the EAP program so that an important technology can reach patients sooner. This uncertainty can be further addressed by collecting additional data once the device is on the market.

— Jeffrey Shuren, M.D., J.D., Director of FDA's Center for Devices and Radiological Health

Over the past year, FDA has made 29 decisions on requests for EAP designation: 17 have been accepted into the program, and 12 have been denied. These decisions were typically made in 30 days.

EAP designation requests have included devices for the heart, brain, and kidneys that are manufactured by small start-up companies and large corporations. We expect that our resources and focus on these promising technologies under the EAP program will allow them to be evaluated and enter the market more quickly, therefore providing options to the patients who need them most.

Projects should meet certain criteria to qualify for the EAP program:

- The device should treat or diagnose a life threatening or irreversibly debilitating disease or condition;
- The device should address an unmet need, which is usually shown by comparing the device to other available options; and,
- The company should have a Data Development Plan outlining what will be included in future submissions to FDA. This plan helps FDA and the company agree on the high level items up front to prevent confusion and delays later in the FDA review process.

As the program has grown in the past year, we've learned that companies who benefit most from this program are those that have a preliminary proof of principle for how their device works, but haven't undertaken formal studies to support future submissions to FDA. For these companies, discussing their Data Development Plan with the FDA and agreeing on a roadmap to their marketing application and beyond is an important part of a successful review.

So what's next? As we look forward to the EAP program's second year,we remain excited about the possibilities it presents – and to be working with industry to quickly bring new and innovative devices to patients.

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