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A 'STeP' Backward? Expert Predicts 'Slow, Quiet Death' For FDA's STeP Novel Devices Program

by Shawn M. Schmitt

Former US FDA device center compliance chief Steve Silverman worries that the new Safer Technologies Program, or STeP, has created a three-tiered device-review framework at the agency. But Silverman says his concern "may be a tempest in a teapot" because he suspects STeP might not be long for this world.

A voluntary program stood up earlier this year by the US Food and Drug Administration to get novel medical devices into the hands of patients faster might not be long for this world, an ex-agency official predicts.

The FDA began accepting applications from interested device makers in March for its *Safer Technologies Program* (STeP), an initiative that's modeled on – and is a complement to – the agency's popular *Breakthrough Devices Program*. (Also see "*'STeP' By 'STeP': FDA Finalizes Accelerated Pathway For Novel Devices, Combo Products*" - Medtech Insight, 5 Jan, 2021.)

The breakthrough program, the output of which *Medtech Insight* tracks *here*, is an accelerated development pathway for devices that the FDA finds could address an unmet need by providing a more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

But that's different from STeP, which is for devices and device-led combo products heading for a PMA, 510(k) or de novo regulatory route that aim to treat less serious conditions than the novel devices accepted into the breakthrough program. (Also see "*FDA Takes 'STeP' Forward For Medtech Innovation With Safer Technologies Program Modeled On Agency's Breakthrough Pathway*" - Medtech Insight, 20 Sep, 2019.)

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> *"How in the world is FDA going to staff STeP when the cupboards are bare for the breakthrough program?" – Steve Silverman*

In the latest episode of *Medtech Insight*'s new podcast series Speaking Of Medtech, former FDA compliance chief Steve Silverman says he's concerned that STeP has created a three-tiered device-review framework at the agency.

"First are breakthrough devices. Second are STeP devices. And bringing up the rear are the many other devices that CDRH [the Center for Devices and Radiological Health] regulates," he says. "And I use the phrase 'bringing up the rear' intentionally. I'm worried about what this three-tiered approach means for the many devices in the third group. Will the [agency's] resources dedicated to these devices match their priority?"

But Silverman – a former director of the CDRH's compliance office who's now head of The Silverman Group consulting firm – says his concern "may be a tempest in a teapot."

That's because "STeP has been around for a while and it doesn't seem to be getting any traction," he says. "Nobody's talking about it, nobody's writing about it, and neither FDA nor device makers seem to be interested in it. So STeP may die a slow, quiet death."

Indeed, an FDA spokesperson told *Medtech Insight* on 28 October that the agency has granted a mere six STeP designations since the program launched nearly eight months ago.

Listen to Silverman's full comments on STeP – and more broadly, the FDA's Breakthrough Devices Program – in the Speaking Of Medtech podcast below:

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In any event, Silverman says STeP faces a steep uphill climb to success.

"It's great to promote development of these devices and I give FDA credit for trying. But there are real challenges too," he says. "First, how in the world is FDA going to staff STeP when the cupboards are bare for the breakthrough program? And second, how do you figure out which devices qualify for STeP? Everybody thinks that their device is important. FDA has provided some broad definitions, but they encompass devices that I'm confident FDA never planned to include in STeP.

“Without answers to these and other basic questions, it’s hard to see STeP getting off the ground.”

A *final guidance document* released by the FDA in January that laid down the parameters of STeP describes two specific eligibility factors for a product’s inclusion in the program.

First, the device should not be eligible for the breakthrough program because of the “less serious nature of the disease or condition treated, diagnosed or prevented” by the product.

Second, the device “should be reasonably expected” to significantly improve the benefit-risk profile of a treatment or diagnostic by doing one or more of the following:

- Reducing the occurrence of a known serious adverse event;
- Reducing the occurrence of a known device failure mode;
- Reducing the occurrence of a known use-related hazard or use error; or
- Improving the safety of another device or intervention.