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Mr. Freeze: Biden's Swift Move To Pause Last-Minute Trump-Era Regs

US Regulatory Roundup, January 2021

by Shawn M. Schmitt

A raft of rules that affect the medtech industry are on ice for the time being while the new Biden administration determines whether the regulations should move forward. This and other stories topped our list of most-read *Medtech Insight* articles in January.

Last-Moment Trump-Era Rules Put On Ice – For Now

A raft of rules that affect the medtech industry are paused for the time being while the new Biden administration determines whether the regulations should indeed move forward. *Our reporting on Biden's reg freeze*, and the rules it touches, was of most interest to *Medtech Insight* readers last month.

A *memo* from the White House on 20 January – Inauguration Day – to the heads of executive departments requested that they "consider" suspending action on any so-called "midnight regulations" that the Trump administration tried to finalize in its waning days and confer with the director of the Office of Management and Budget before renewing any regulatory activity.

The freeze impacted rules that had been sent to the Federal Register but were not yet published, and rules that were published but were not yet in effect. Those that weren't published were immediately withdrawn and the effective date of ones that were published was delayed for 60 days.

One recent rule issued by the US Department of Health and Human Services (HHS) that was affected by the freeze is the Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) rule, which would require the department and its agencies – including the Food and Drug Administration and the Centers for Medicare and Medicaid Services (CMS) – to review all

regulations every 10 years to determine whether they're still necessary.

SUNSET was published in the Federal Register on 19 January and had been scheduled to go into effect on 22 March. Proponents say the rule will encourage HHS agencies to routinely root out unnecessary, redundant or unclear regulations, while others say SUNSET was put in place to *"gum up the works"* for the Biden administration HHS.

A recent notice from the HHS and the FDA that aims to exempt 84 types of medical devices from premarket review also falls under the umbrella of Biden's reg freeze, an attorney told *Medtech Insight*.

The mid-January HHS/FDA *notice suspended premarket notification requirements for seven low-risk class I devices* – all of them gloves. The regulators said allowing the gloves on the market without premarket review would save time and resources, and presents no increased risk to the public. The products were initially waived under an emergency guidance to help manage the coronavirus pandemic.

But the notice goes on to say the regulators are considering waiving premarket review for another 83 moderate-risk class II devices and one unclassified device, after stakeholders give feedback during a 60-day comment period.

Despite the HHS and the FDA labeling their recent document a "notice," *King & Spalding partner Kyle Sampson says it's essentially a rule that falls under the purview of the freeze*: "It would be frozen in the sense that it would be delayed. It's already subject to the 60 day notice-and-comment period that started on January 15, and the memo from the Biden administration reset that 60-day clock to January 20. So it really just delays it a little bit more than it's already delayed, which then would give the opportunity for FDA to essentially issue a new proposed rule."

Another Trump-era regulation that's on ice for now is the Medicare Coverage of Innovative Technology (MCIT) rule from the CMS, issued on 12 January. Under MCIT, Medicare will cover a new breakthrough device or diagnostic as soon as the FDA approves it. The medtech industry had been pushing the CMS to adopt the reg for the past few years.

FDA Puts Finishing Touches On STeP Pathway

Speaking of breakthrough products, also of interest to readers in January was *news that the FDA is putting the finishing touches on a new voluntary pathway* that aims to bring innovative, novel devices to patients more quickly.

The FDA said in a 6 January final guidance document that it will stand up its Safer Technologies Program (STeP) within 60 days. The agency will begin accepting applications from interested

manufacturers on 8 March.

STeP is modeled on, and is a complement to, the FDA's popular *Breakthrough Devices Program*, an accelerated development pathway for devices that the agency finds could provide a more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, addressing an unmet need.

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.

5-Point Action Plan For AI/ML SaMD Issued By FDA

Meanwhile, the FDA in mid-January put out a *five-point action plan aimed at artificial intelligence/machine learning (AI/ML)-based software as a medical device (SaMD)*. The agency promises in the plan to draft a new guidance document and a hold a public workshop.

The FDA's action plan was developed using input from stakeholders who responded to an April 2020 discussion paper from the agency on a regulatory framework for AI/ML SaMD. The plan "builds on the agency's longstanding commitment to support innovative work in the regulation of medical device software and other digital health technologies," the FDA said.

While the new action plan is focused on SaMD, the agency said it expects "some of this work may also be relevant to other medical device areas, including software in a medical device (SiMD)."

Other Top Stories

These articles rounded out our Top 10 list in January:

- *No. 3 story*: US Rep. Angie Craig of Minnesota will work as a freshman legislator on the powerful House Energy and Commerce Committee over the next two years. Before joining Congress in 2019, Craig worked as a reporter, then as a human resources and communications executive at device maker St. Jude Medical before it was acquired by Abbott in January 2017.

- *No. 5 story*: The FDA says February 2021 is the month it will release a draft of its harmonized Quality System Regulation.

- *No. 7 story*: The FDA announced in mid-January that Boston Scientific recalled its Lotus Edge transcatheter aortic valve replacement (TAVR) system. The company discontinued manufacture of the Lotus system last November and asked that any unused systems be returned to the company.

The 10 most popular US regulation and policy stories in January are listed in the table below.

Rank	Story
1	*Biden Regulatory Freeze Could Slam Brakes On SUNSET Reg Review Rule From HHS*
2	*'STeP' By 'STeP': FDA Finalizes Accelerated Pathway For Novel Devices, Combo Products*
3	*Medtech Industry Favorite Wins Seat On Powerful House E&C Committee*
4	*FDA Suspends Premarket Notification Requirement For 7 Devices; 84 More Under Consideration*
5	*FDA Picks New Target Date For Releasing Its Draft Harmonized Quality System Regulation*
6	*FDA Issues 5-Point Action Plan For Artificial Intelligence/Machine Learning-Based SaMD*
7	*FDA Announces Recall Of Boston Scientific's Lotus Edge TAVR System*
8	*Lawyer: Biden Reg Freeze Puts On Ice Potential Premarket Review Waivers For 84 Device Types*
9	*Industry Praises CMS Final MCIT Reimbursement Rule; Urges Biden Team To Implement It*
10	*With Sun Setting On Trump Admin, HHS Finalizes Regulatory Review Rule*