MEDTECH INSIGHT
CITELINE COMMERCIAL

02 Sep 2020 | **Analysis**

US Regulatory Roundup, August 2020: Trump's HHS Throws LDT Curveball At FDA, Industry

by Shawn M. Schmitt

Here are August's 10 most popular US regulation and policy stories from *Medtech Insight*.

Policy Shift For LDTs

In a surprising mid-August move, the US Department of Health and Human Services (HHS) – the overseer of the Food and Drug Administration – *stripped the agency of authority over laboratory developed tests* (LDTs). Our reporting on the topic was of most interest to *Medtech Insight* readers last month.

In our No. 1 story, three legal experts gave their take on the *19 August policy shift*. "By the terms of the policy that was issued, it is not restricted to COVID-19 LDTs," Scott Danzis, a partner in the Washington, DC, office of the law firm Covington & Burling, said in a 25 August interview. "Moreover, we've had recent discussions with senior HHS officials who have confirmed that the intent of this policy statement is broad. It is not intended to be only applicable to COVID-19 diagnostics."

Since then, the HHS – which had clouded matters by not immediately publicly addressing the policy or offering any type of transparency around it – *has developed a FAQ sheet on the topic*.

"FDA will no longer require premarket review of tests developed by a laboratory for use solely within that lab (laboratory developed tests, or LDTs), due to a determination by the HHS Office of the General Counsel … that, absent rulemaking, the FDA lacks the legal authority to require it," *the FAQ sheet* confirmed. "The Trump administration is merely complying with the law."

The FAQ sheet goes on to say that the FDA had "rarely enforced this premarket review

requirement" for LDTs in the first place. But former agency commissioner Scott Gottlieb weighed in on Twitter on 29 August, pointing out that during his time at the FDA, from 2017 to 2019, "the agency continued to exercise enforcement discretion over most laboratory developed tests … but we also took selective enforcement actions to protect public health."

And in one of a series of 13 tweets on 22 August, Gottlieb predicted that a "plethora" of direct-to-consumer COVID-19 tests will come to market and be "processed in a central lab operating outside FDA oversight" because of the policy change.

But in its FAQ sheet, the HHS says that won't happen: "Nothing will be flooding the market as a result of this change. LDTs, by definition, cannot be sold outside of the laboratory in which they were developed. There is no reason to believe that complying with law will have any effect on the quality of LDTs. Every COVID-19 test, including LDTs, are still regulated by the federal government."

The FDA's authority over LDTs has long been an open question. The Centers for Medicare and Medicaid Services regulates LDTs under CLIA rules. But since 2014, some stakeholders have argued that LDTs have become too complex for CLIA regulation and should be FDA-reviewed. Bills to move LDT regulation to the FDA have been introduced in Congress multiple times in recent years, but have yet to pass.

"Many in the laboratory community have long asserted that FDA lacks authority under the Food, Drug and Cosmetic Act to regulate LDTs at all," attorney Danzis said, noting that the HHS statement puts pressure on lawmakers to finally develop comprehensive legislation for the diagnostics. "There is more than one bill that has been introduced in Congress. The one that's gotten the most attention is the VALID Act. I think this policy statement may put more attention and focus on that legislative effort."

The Verifying Accurate, Leading-edge IVCT Development (VALID) Act was drafted by Congress in late 2018, but time ran out that year before legislators could give the proposed law its full attention. The act – which focuses on proposed FDA requirements for premarket review, priority review, pre-certification, third-party review, and postmarket surveillance of diagnostics – was reintroduced in Congress earlier this year, but there's been little movement on it since.

Meanwhile, powerful US House Energy and Commerce Committee chair *Frank Pallone Jr. has demanded a briefing from HHS secretary Alex Azar* to explain the department's decision. Pallone said the policy shift "is deeply concerning and suggests that the Trump administration is once again interfering with FDA's regulation of medical products."

Premarket Tips From FDA

Our No. 2 story from August offered tips from FDA officials and industry experts on creating a

510(k) or other submission to make it through the review process as smoothly as possible. While the presenters focused on spinal device submissions during the 13 August virtual workshop at which they spoke, much of their advice could apply to almost any company sending a submission to the agency.

A major factor that inspired the FDA workshop seemed to be the ongoing development of the agency's *eStar portal*. eStar is an online service currently being tested through a pilot program that, when complete, will allow the agency to receive submissions in a fully digital format, ending the current requirement that digital submissions be mailed to the FDA on a CD or flash drive. But before they launch eStar, the agency wants to make sure the submissions they receive are clean and ready to go to reduce frustration all around.

Check out our *Device Week* podcast on the topic *here*.

Updates On Breast Implants, Essure

Grim news out of the FDA about breast implants and Bayer's (now defunct) Essure birth control device also captured the attention of readers last month.

In our No. 6 story, the agency said in a 20 August update that 36 women internationally have died from a type of lymphoma associated with silicone and saline breast implants, while 733 have experienced severe implant-related symptoms signaling the disease's onset.

To further aid providers and patients, the FDA has verified and publicly released its Breast-Q reconstruction module – a Medical Device Development Tool – to examine women's physical chest soundness, and psychological and sexual well-being, as well as their personal satisfaction with their implants.

And our No. 10 story from August reported on an initial dataset of social media posts that showed Bayer documented nearly 1,500 reports of adverse events associated with Essure, including 53 reports of death. The aggregated data is part of a regulatory reporting requirement from the FDA as the company continues to handle fallout from lawsuits that were brought against it from women reportedly harmed by the device.

The agency published Bayer's *spreadsheet* on 11 August as part of its ongoing efforts to evaluate the potential harm from the devices, which have been in litigation for years. Bayer is required to submit reportable adverse event data from social media posts as the company learns of the events between November 2016 and November 2020, no matter when the posts were originally made.

The FDA noted that roughly 80% of the events reported were related to potential device removal, which was expected based on data from the agency's Medical Device Reporting system.

Other Items Of Interest

Stories about a fast-acting COVID-19 test, a device shortage list, a push to "buy American," and FDA guidance documents rounded out our Top 10 list in August:

No. 3 story: The FDA granted emergency use authorization to Abbott for its $5, 15-minute rapid COVID-19 antigen test. The BinaxNOW COVID-19 Ag Card detects SARS-CoV-2, the virus that causes COVID-19. It's intended for people suspected of having the virus within the first seven days of symptom onset. Less than a day after Abbott received its EUA, *the US government agreed to buy 150 million of the BinaxNOW tests at a cost of $760m*.

No. 5 story: The FDA's first-ever *shortage list* of critical medical devices needed during the COVID-19 public health emergency was met with shrugs by two former agency officials who told *Medtech Insight* that the listing is anemic and doesn't add much value.

No. 8 story: President Trump signed an *executive order* in early August to reduce US dependence on foreign manufacturers of medical countermeasures – including medtech equipment, drugs and their components – and to induce federal agencies to buy American-made medical products only. The EO is aimed at maximizing domestic production capability for "critical inputs, finished drug products and finished devices" during public health emergencies.

No. 9 story: Nearly a year after creating a new Safety and Performance Based Pathway for 510(k)-eligible products, the FDA has finalized the first guidance documents for acceptable performance criteria, covering Foley catheters and cutaneous electrodes.

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

Rank	Story
1	*Legal Experts: HHS Policy Change Strips FDA Of Oversight For All LDTs*
2	*FDA Shares Best Tips To Alleviate Premarket Submission Pain Points*
3	*FDA Authorizes Abbott's '$5, 15 Minute' COVID-19 Antigen Test*
4	*Ex-FDA Commish Warns Of 'Limbo' For COVID-19 LDTs Granted Emergency Use Authorization*
5	*Experts Ho-Hum About FDA's First-Ever Device Shortage List*
6	*FDA: 36 Dead From Breast Implant-Associated Lymphoma Since 2019, Hundreds Sickened*
7	*Override: HHS Revokes FDA's LDT Policies*
8	*'Buy American' Exec Order Presses Government To Only Purchase US-Made Devices, Drugs*
9	*FDA Finalizes First Two Guidances For 510(k) Pathway That Uses Performance Measurements*

10	*Social Media Posts Showed Almost 1,500 Adverse Events, 53 Deaths Linked To Essure: FDA Report*