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Icy HHS/FDA Relations Could Complicate An Already Drawn-Out Quality System Reg Rewrite

US Regulatory Roundup, September 2020

by Shawn M. Schmitt

A roundup of last month's top US policy and regulation stories from *Medtech Insight*: the latest on the US FDA's Quality System Regulation harmonization efforts; the FDA's Bakul Patel talks the inevitable future of digital health; a Sanofi usability expert gives a peek at how the company's conducting human factors studies in the age of COVID-19; and more.

QSR Delay Likely As HHS/FDA Relations Turn Frosty

News that *the US Food and Drug Administration will likely miss its fourth internal target date* for releasing a draft of its revised Quality System Regulation was of most interest to *Medtech Insight* readers last month. The agency's device center director, Jeff Shuren, said in mid-September that manufacturers should "anticipate that it will be a little while longer before we're able to issue the ISO 13485 [draft] regulation."

The FDA has been harmonizing its QSR – 21 CFR, Part 820 – with international quality systems standard ISO 13485:2016 for more than two years. *Back in July* the agency set October as the latest deadline for releasing its draft. But Shuren said his Center for Devices and Radiological Health (CDRH) has had to turn much of its attention to working on matters related to the COVID-19 national health emergency – meaning the draft probably won't be out by the end of this month.

And if retooling a decades-old regulation during a pandemic wasn't difficult enough, another wrench was thrown into the works when *Department of Health and Human Services secretary Alex Azar decreed that all rules must be signed by him*. The HHS oversees the FDA, as well as 27 other

offices and agencies.

"Any prior delegation of rulemaking authority, including the authority to sign or issue a rule or a proposed rule, is rescinded," a 15 September memo from Azar to top staff said. The memo comes during a time of particularly frosty relations between the HHS and the FDA, following an *August policy shift by the HHS* to strip the agency of authority over laboratory developed tests (LDTs).

In any event, Azar's memo means that not only will the FDA likely miss its October deadline for releasing its draft QSR, but the draft could be punted all the way into 2021. So says Kim Trautman, who authored the Quality System Regulation in the 1990s as an agency staffer.

"We already have an overworked FDA, working multiple angles of COVID-19 responses to provide … the most reliable and safe human medical products – which by itself was likely reason enough for the delay in any revision to 21 CFR, Part 820," Trautman, who's now executive VP of health sciences for consulting firm NSF International, told *Medtech Insight* in our *No. 3 article from last month*.

And if "additional briefings and clearance time is needed within HHS, then it is to be expected that we will not see the proposed rule for the revision of 21 CFR, Part 820 until 2021," she said.

Only time will tell. After all, the FDA still has four more weeks to push out a draft to meet its October deadline.

Bakul Patel And The Inevitable Future Of Digital Health

Our No. 4 story from September was a *profile of the FDA's leading figure in digital health, Bakul Patel*.

Patel, director of the FDA's *new Digital Health Center of Excellence*, was instrumental in launching the agency's Pre-certification Program, also known as the pre-cert pilot. Also during his time at the FDA, a slew of guidance documents has been released that address different types of digital health products, including wellness products.

Ultimately, Patel says his goal is to prepare for the inevitable digital health future.

"I feel in the long term it will be good for the US population, it will be good for the federal agency, it will also be good for patients, because if FDA becomes an enabling factor for these technologies to be safe and effective, that's a win for everybody," he told *Medtech Insight*.

Human Factors Experts Go Extra Mile During COVID-19

In the age of coronavirus, *human factors professionals are doing their best to find their way through the pandemic* by putting unique twists on usability testing to see what works and what doesn't in

the new reality. That was the focus of our No. 8 story from September.

Because human factors studies are traditionally close-contact activities – an obvious no-no during a pandemic – experts in the field have been forced to come up with creative solutions to keep the flow of new products moving, all the while keeping everyone involved in the process as safe as possible.

Molly Story, global MED advisor for pharmaceutical and drug-device combination product manufacturer Sanofi, told *Medtech Insight* in an interview that her company has made a lot of interesting changes to the way they conduct in-person testing of products. Story was Sanofi's head of global usability engineering and risk management for more than six years before taking on her current role.

While these tests used to be performed at Sanofi without much fanfare in the past, the coronavirus has changed all that. Now, plexiglass shields separate participant from expert and face masks are mandatory. Social distancing is always observed, and testing rooms are vigorously cleaned. So there's no contact between the firm's human factors experts – also called moderators – and test participants.

"It's a tricky business, but my team has created a full policy on how to conduct these studies" as the pandemic rages on, Story said. "We're basing our policy on WHO [World Health Organization] guidelines, CDC [US Centers for Disease Control and Prevention] guidelines and local guidelines. As a result, we've completed three validation studies under COVID conditions. We did two of them 'face to face' with a lot of precautions in place, and we didn't have any trouble."

But there are limitations. Sanofi is testing only in areas where the local economies are at least "partially open," Story said, and the company refuses to test at-risk populations. "Our whole policy is pretty complicated, but we've been able to work within it."

Check out our *Device Week* podcast on this story *here*.

Other Top Stories

Stories about changes to the FDA's eMDR system, insight from legal experts about a power shift on the Supreme Court, and more rounded out our Top 10 list in September:

- *No. 5 story*: The FDA completed planned modifications to its electronic Medical Device Reporting (eMDR) system and added an extra field for MDR exemption numbers.

- *No. 6 story*: The CDRH's Jeff Shuren says the device center has been tallying up lessons learned from the pandemic, including the importance of flexibility, and the value of

engagement and of the center's Total Product Life Cycle approach.

- *No. 7 story*: If the US Senate approves President Trump's pick of Amy Coney Barrett for the Supreme Court, Affordable Care Act coverage could disappear. Two attorneys talked to *Medtech Insight* about this and other legal issues that could touch the medtech industry.

- *No. 9 story*: The safety and performance pathway and de novo clearance process are combining to reform the FDA's approach to device approvals, CDRH officials said in mid-September.

- *No. 10 story*: In a hotly anticipated decision, the US Centers for Medicare and Medicaid Services proposed a rule in late August that would give four-year conditioned coverage for breakthrough medical devices and diagnostics.

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

Rank	Story
1	*Another Delay On The Way? FDA's Shuren Says Industry Should 'Anticipate' QSR Harmonization To Take 'Little While Longer'*
2	*'Wrong Move': Gottlieb Blasts Azar's Perceived Regulatory Power Play Over FDA; HHS On Defense*
3	*HHS Secretary's Regs Sign-Off Requirement Will Kick FDA's Draft QSR Into 2021, Expert Predicts*
4	*Profile: FDA's Bakul Patel On The Inevitable Future Of Digital Health*
5	*FDA Updated Its eMDR System. Here's What You Need To Know When Submitting Adverse Events*
6	*Shuren Gives Peek Behind Curtain With 3 Lessons FDA's Device Center Learned During Pandemic*
7	*Legal Experts Predict How US Supreme Court Shake-Up Will Impact Medtech*
8	*Human Factors Experts Forge Ahead With 'Tricky' In-Person Studies In The Age Of Coronavirus*
9	*FDA Gives Insight On Changing Approval Landscape*
10	*Game-Changer? CMS Proposes Rule To Cover Breakthrough Devices On Provisional Basis*