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Happy New Year! (I Think?): Some 2022 Predictions For FDA's Device Center

by Steve Silverman

Former US FDA device center compliance chief Steve Silverman considers what industry can expect this year, from continued pandemic activities to enhanced facility inspections – and more.

Thank goodness COVID-19 is over!

Sorry – I began writing this column in December and I was overly optimistic. (As an aside, does anyone else think that "Omicron" sounds like a Marvel Universe villain?)

So, I'll stick to what I know a bit about – what will the US Food and Drug Administration's Center for Devices and Radiological Health focus on in 2022? In answering, I'll take the safe strategy of agreeing with others (including the CDRH). The device center will continue to handle pandemic demands while keeping the lights on (focusing on core practices like product review, quality oversight and mitigating safety risks). Here's what I think this means:

CDRH Will Keep Fighting The Pandemic

Much has already been written, including in *Medtech Insight*, about COVID-19's FDA-wide impact. There's a huge regulatory backlog, leaving little room for new initiatives. Pandemic demands have hamstrung activities across the agency, including in the CDRH.

The device center has ably met pandemic demands while handling tasks like product review, but the results of its massive workload are inevitable: time to meet with stakeholders has disappeared and it's likely that the CDRH will miss some user-fee deadlines.

Still, the center is digging out. It hoped to return to normal activities in 2021, but that goal was pushed to this year because of unexpected demands like the Delta variant. Even so, much of the center is back to normal, or close. A notable exception is the Office of Health Technology 7, which is responsible for *in vitro* diagnostics. OHT 7 has been COVID-19 Central, delaying its

return to normal.

And now there's Omicron. It's hard to predict how this variant will affect CDRH operations. For sure, Omicron will impact areas like diagnostics, which can detect the variant (sorry OHT 7). The question is, how much will Omicron, and future variants, derail core CDRH activities (think sponsor meetings and product review)? If the answer is, "not much," then the center stands a good chance of managing pandemic demands while handling traditional workflow.

Here's a key caveat: staff retention and departures will not return to normal. CDRH staff has worked 24/7 to get critical pandemic products to market and, sometimes, to get junk off the market. Now, that staff is burned out and seeing a nicer life across the FDA fence: more money, better hours and work-from-anywhere. Some staff will tap out and their departures will make the personnel problems that the CDRH already faces – hiring, training and retaining qualified staff – more dire.

Who's The Boss?

Finally: We have an FDA commissioner! Well – at least we have a nominee, which is an improvement. Robert Califf hasn't yet been confirmed, but the cards are on the table and that's where things seem to be headed. That's a good thing.

What will a new commissioner mean for the CDRH? Probably, not much. Jeff Shuren, the center's director, is experienced and a known quantity, inside and outside the FDA. The smart bet is that he'll have running room to lead the CDRH.

But that doesn't mean Califf won't have significant impact across the agency, including the CDRH. To be clear, "FDA commissioner" is a unique and critical role. The commissioner is the FDA's public face, coordinating and leading high-profile efforts (especially cross-center ones like the pandemic response). The commissioner is the focal point and an advocate before Congress, the administration and others who oversee and influence FDA.

The CDRH and the rest of the FDA will benefit from this champion. The commissioner will highlight and elevate the FDA's COVID-19 efforts, back the agency's public-health role and campaign for adequate funding. The importance of these duties can't be overstated.

For more on Califf's nomination, check out the Speaking Of Medtech podcast below. My remarks begin at the 13:45 mark.

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MDUFA V Will Pass

We will have a 2023-2027 device user-fee agreement. That prediction gets me the gold in the Obvious Olympics.

There must be device user fees – the device center can't operate without them. And the CDRH and industry will negotiate the fee agreement because the alternative, kicking the can to Congress, is a nonstarter.

So, what will MDUFA V look like? Will industry get a pure "back to basics" approach? No way. But neither will FDA get full support for its TPLC Advisory Program (TAP). Plus, agency and industry are far apart on funding – about $1 billion at last count.

That gap will narrow as the FDA and industry align on substance. Industry has already proposed to support TAP, but to delay it until the CDRH meets basic review goals. The center hasn't agreed yet, but it and industry are working hard on compromise solutions. This back-and-forth will intensify because negotiations are behind schedule (another COVID-19 "gift"). Look for an agreed package to go to Congress this month.

And this next piece is for those of you who still haven't put away your holiday decorations. Let's talk about the MDUFA Christmas tree.

Here's what you need to know: because MDUFA is must-pass, other members of Congress will attach their own legislative initiatives to it, like ornaments on a Christmas tree. These are bills that may be only indirectly related to MDUFA, but user-fee action carries them along too. It's hard to know what the ornaments will be, but the 21st Century Cures Act, version 2.0, is a safe bet. Cures 2.0 builds on the original 2016 version, with provisions for real-world evidence, pandemic preparedness, digital health and other innovations.

See our recent Speaking Of Medtech podcast below for more of my thoughts on the MDUFA V negotiations.

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Device Facility Inspections

After a full pause, fits and starts, and other setbacks, we'll be seeing more on-site device facility inspections. The FDA has already ramped up domestic inspections, using its risk model to chip away at a mountainous backlog.

Foreign inspections are another matter. As I wrote in a *July 2020 column* for *Medtech Insight*, restarting foreign inspections is a black box. It's impossible to know when foreign countries will allow US investigators to return. So, if live inspections are a must, when they'll happen is an

open question.

Remote inspections are a way to evaluate device facilities, including those that the FDA can't see in person. There's already a template for this authority: drug-facility inspections. FDA is authorized to take documents from drug facilities, either before or in place of live inspections. *With the draft Medical Device Integrity Act (MDIA)*, Congress now proposes to give FDA the same authority for devices. Maybe we'll even see a MDIA bill hanging from the MDUFA V Christmas tree.

MDIA is a good start. But it's hard to imagine why device makers would support remote document production when live inspection could add to, not replace, that production. Still, remote inspection is innovative, and parity between drug and device inspections is overdue. Plus, remote inspections can improve over time, including by clarifying and limiting when document production *plus* live inspection can occur.

See our Speaking Of Medtech podcast below for more of my thoughts on remote inspections.

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Year Of Rebuilding

This 2022 predict-o-rama could go on; I haven't even brought up real world evidence or machine learning. But leaving specifics aside, I believe that 2022 will be a CDRH rebuilding year. Look for more focus on basics like sponsor meetings and submission review. The big variable is COVID-19. What effect will Omicron have (or whatever variant comes next)? I have no idea.

But I hope that, when I repeat this exercise next year, I can truthfully write: "Thank goodness COVID-19 is over."