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Opinion: At Least It's Not Fruitcake – My Annual FDA Predictions

by Steve Silverman

Consultant (and former FDAer) Steve Silverman is back with a reflection on his predictions for 2023, and well as what he expects to see in the coming year.

You know that saying, "practice makes perfect"? That's not this article. You know those green socks your grandma knit for you (and you can't give them away)? That's this article.

This is the third time I've predicted what the US Food and Drug Administration (FDA) will do in the coming year. Last time, I hired a team of Nobel laureates to judge my predictions. Money's gotten tight, so this year's judges are five guys I found at Home Depot.

First, let's look at how I did for 2023.

2023 Predictions

The COVID-19 Public Health Emergency Will "End."

Isn't it great that we finished the pandemic? Now, all we have is a never-ending endemic (whatever that means). On the upside, the COVID public health emergency is officially over. That means that FDA's Center for Devices and Radiological Health (CDRH) can return some resources to core functions like device approval and oversight. And it can apply lessons from the pandemic – like expedited review and remote inspections – to standard operations.

Steve's grade: A

CDRH Will Enhance Its Digital Engagement.

This one was a lob at the net – nobody doubted that CDRH would go all-in on digital.

Still, I got some specifics right. I predicted that CDRH's Digital Health Center of Excellence (DHCoE) would benefit from more staff and a permanent director. Welcome Troy Tazbaz, Director of the DHCoE. (Also see "*Former Oracle Exec Joins FDA As Director Of Digital Health Center Of Excellence*" - Medtech Insight, 7 Feb, 2023.)

And I predicted that CDRH would manage authority limits while streamlining digital innovation. In March, CDRH announced predetermined change control plans (PCCPs) to bypass prior authorization for AI/ML devices. PCCPs allow updates to these devices without prior approval.

Steve's grade: A

Real-World Evidence Will Gain Momentum.

My results here are mixed. No question, real-world evidence (RWE) has gained popularity across FDA. But what role this evidence will play remains unclear.

RWE draws from patient registries, health and billing records, claims data, and similar sources to supplement traditional clinical evidence. The problem is that this data is diverse and unifying it is tricky (and sometimes impossible). An accepted RWE template doesn't exist and, until RWE shows uniformity, accuracy and reliability, it won't be an independent data source.

Steve's grade: B (no extra points for calling RWE important (too obvious))

☒ *All I Want for Christmas Is Breakthrough Device Designation.* ☒

I'm not Kreskin for predicting that CDRH's breakthrough program – which preferences devices that diagnose and treat serious diseases – would expand. The program has grown quickly since it launched with 10 devices in 2015. CDRH recently reported more than 800 participants. (Also see "*Former Oracle Exec Joins FDA As Director Of Digital Health Center Of Excellence*" - Medtech Insight, 7 Feb, 2023.)

But I missed a tricky topic last year: reimbursement. Initially, the Centers for Medicare & Medicaid Services (CMS) agreed to cover breakthrough devices, but it rescinded that decision in late 2021. CMS has revisited coverage, but there's still no clear path. Without payment certainty, the breakthrough program's long-term viability is unclear.

Steve's grade: C

Diagnostics Regulation Will Stall.

I wrote last year's column after the VALID Act (diagnostics regulation) fizzled and after Commissioner Califf announced that FDA would regulate diagnostics even without legislative support.

I pooh-poohed that plan, but FDA delivered. In late September, it issued a proposed rule ending enforcement discretion for in vitro diagnostics (IVDs), preparing to regulate them as medical devices.

No surprise, the announcement created a firestorm. It's generated thousands of comments so far, with major stakeholders weighing in, to say nothing of the expected lawsuits and the legislative static. (Also see "*FDA Receives Thousands Of Opinions On Proposal To Regulate LDTs As Comment Period Comes To A Close*" - Medtech Insight, 1 Dec, 2023.)

Steve's grade: C (I probably deserve worse, but I embrace grade inflation.)

2024 predictions

Diagnostics Regulation Will Stall (Again).

Now, it's almost 2024 and FDA intends to regulate IVDs. This ends decades of enforcement discretion. But FDA still gave stakeholders only 60 days to comment on the proposed rule.

No surprise, many comments tell FDA, "We need more time." That is, 60 days is inadequate to analyze the proposed rule, flag questions and concerns, and propose answers. This seems reasonable given the rule's scope and detail, not to mention the years that passed without FDA regulation. But FDA denied these extension requests. FDA is being tight-lipped about its reasoning. I have theories, but I want to avoid "fake news," so I'm staying mum.

One thing is clear. Parties were already lined up to sue FDA to prevent IVD regulation. Now that list will grow, and many on it will ask courts to block FDA action until they decide the agency's legal authority. The wheels of justice . . . (you know the rest), so IVD regulation is not happening next year.

CDRH Digital Activity Will Grow.

Who else is brave enough to predict that CDRH will expand its digital work? Okay, I'm not brave (in The Matrix, I'd swallow the blue pill and order a steak dinner).

2023 saw CDRH running to keep pace with digital innovation. Progress has gone from software as a medical device to machine learning and generative AI, with algorithms that even device makers don't fully understand. It's no leap to predict that this growth will continue so, to give my conviction a bit more courage, I'll be specific.

First, PCCPs (Predetermined Change Control Plans) will expand, but this growth won't reach conventional devices (i.e., non-digital products). That's because conventional devices don't iterate often or quickly. But digital devices continuously evolve and requiring prior authorization would impair timely updates.

Second, CDRH will promote digital innovation, but stay within its regulatory authority. As we saw with VALID, there's no appetite in Congress for new FDA legislation and, especially in an election year, there's no room for a legislative push. Still, CDRH will keep busy with initiatives ranging from cybersecurity to augmented and virtual reality to AI/ML devices. PCCPs shows that CDRH can work within its authority and CDRH will stay in bounds as it pursues other initiatives.

Real-World Evidence Is Still a Bridesmaid.

For sure, real-world evidence will be a hot topic. And the Grail remains: device approvals using real-world evidence alone. But like we saw in 2023, we're not there yet – problems like data reliability, generalizability, and applicability persist.

CDRH is working on these problems, but until that work is done, real-world evidence will remain a supplementary evidence type. Complicating this is competition for limited resources within CDRH. There are other priorities – like IVD regulation and digital expansion – that need resources too. With everything else going on, 2024 will not be the year that CDRH creates parity between real-world evidence and stand-alone evidence types.

CDRH Will Align (Whatever that Means) Its Quality System Regulation to ISO 13485.

Years ago, CDRH announced that it would link its Quality System Regulation to the 2016 version of ISO 13485 – an international quality standard. The new model – the Quality Management System Regulation (QMSR) – means that device makers won't need to simultaneously satisfy FDA and the international standard.

But the QMSR launch date kept slipping (and slipping and slipping). In fairness, there was a worldwide pandemic, which required some deadline shuffling. But the final QMSR will publish soon. Even then, CDRH will give stakeholders time to meet new requirements. When CDRH proposed a one-year delay, stakeholders replied that this was way too brief. Stakeholders weren't

only seeking extra time for themselves; they worried that a year wouldn't give CDRH enough transition time. That makes sense because the to-do list is massive, ranging from updating guidances and inspection programs to training CDRH and FDA field staff.

Ordinarily, a request for more time is no big deal. But CDRH can be stubborn when it decides that matters have lingered, as we saw with the IVD comment deadline. So, I wouldn't bet on CDRH allowing more than a year for the QMSR transition, especially when deadline pressures fall predominantly on it, not stakeholders.

Remote Device Inspections – Who Ordered the Nothing Burger?

This one's a bee in my bonnet (for more, see Come On In, The Water's Fine: FDA Should Fully Embrace Remote Inspections). Why hasn't CDRH promoted remote inspections, especially after COVID made foreign inspections so hard? One answer is authority; CDRH lacked formal authority to conduct remote inspections. But FDORA (user-fee legislation) fixed this, authorizing CDRH to inspect remotely. Still, there are conditions set by FDORA and a big one is FDA guidance explaining how remote inspections will occur.

Developing guidance takes time and there will be lots of questions about remote inspections. Answering them will add time and, even with a final guidance, a transition period will precede remote inspections. So, don't expect these inspections in 2024. Remote inspections will happen, but we're looking at 2025 (and later) before they happen regularly.

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They say that the third time's the charm and I'll let you decide if that's true. Regardless, I wish you all a happy, healthy, and peaceful 2024.

Steve Silverman is the president of The Silverman Group, a consultancy that serves medical product companies on regulatory, strategy, and policy issues. Steve's professional experience includes extensive time in senior FDA roles. At the FDA, Steve directed the CDRH Office of Compliance, where he led device-quality initiatives, engaged Congress and the press, and guided the office's reorganization.