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Opinion: Happy New Year – the Sequel

by Steve Silverman

In this op/ed, consultant and former FDA official Steve Silverman looks at what he got right – and wrong – in his predictions for 2022 and walks us through his expectations for the new year.

As Hollywood has taught us, every sequel is better than the original. Need proof? Look no further than *Police Academy 2, The Exorcist II, and Teen Wolf Too*. Classics. So what better way to ring in 2023 than to examine how *my 2022 predictions* held up? To keep the fun going, I also made some predictions for what may happen at the US Food and Drug Administration in 2023. We'll see if my educated guesses get more accurate.

2022 Predictions

I graded my 2022 predictions on what I got right and what I got wrong. A team of Swiss Nobel laureates built the grading system, so please, no reader complaints about accuracy.

CDRH Will Keep Fighting the Pandemic.

I got this one mostly right. I forecast that the FDA's Center for Devices and Radiological Health (CDRH) would continue to respond aggressively to COVID-19, while returning to normal operations. Notably, this return was much less predictable for CDRH's Office of Health Technology VII, which regulates most pandemic devices.

But my forecast also missed the mark. I wrote that COVID demands and the prospect of better work elsewhere would spur CDRH staff departures. To its great credit, staff has largely hung in and the recent device user-fee agreement promises more bodies on board.

Steve's grade: B

Dr. Robert Califf Will Be FDA's Commissioner.

I predicted this last January, after Dr. Califf had been nominated for the commissioner role. So, backing his confirmation doesn't make me Nostradamus. Still, given the time to find a commissioner and the many candidates, Dr. Califf's confirmation was no sure thing. Plus, I predicted that Dr. Califf would allow CDRH leaders to steer the center through high-profile, complex initiatives. After MDUFA V, the pandemic response, and digital promotion, I'm calling this prediction for me.

Steve's grade: A

MDUFA V Will Pass.

I forecast that Congress would pass MDUFA V, CDRH's user-fee funding package. The alternative is the collapse of the FDA's device program, so this was a safe bet. And as guessed, Congress passed MDUFA V.

But I completely missed the mark on riders (I'm in good company here). Riders are legislative initiatives that often attach to must-pass legislation like MDUFA. When that legislation passes, the riders go along with it, like ornaments hanging on a Christmas tree. Well, this year the Grinch really stole Christmas. Congress passed "skinny" device user fees that excised all riders. Some riders came back through the 2023 budget reconciliation process, but reconciliation left big regulatory gaps. (See my discussion below of failed diagnostics reform).

Steve's grade: C

FDA Will Resume Device Facility Inspections.

I predicted that FDA would resume domestic device facility inspections, which is true. I also predicted that resuming foreign device inspections would be tougher. That's also true. There's still variability among countries about when and how the FDA can inspect device sites within their borders. Look no further than China to see that these questions persist.

I was wrong on Remote Regulatory Assessments (RRAs). These are *requests* for documents and other information from device facilities that the FDA can't inspect remotely. RRA participation is voluntary and I pooh-poohed it – why would a company agree to an RRA if it doesn't replace an inspection?

But RRAs are a success – many device makers agree to them, RRA numbers have grown, and they're becoming a regular complement to facility inspections. Plus, Congress apparently is now giving FDA formal remote device inspection authority like that the agency already has for drug sites. This will only strengthen RRA popularity.

Steve's grade: B- (It would have been a C, but my Swiss team grades on a curve.)

2023 Predictions

Looking at my 2022 results, I'm rethinking my plan to become a fortune teller. I'll try to do better for 2023.

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

This is not to suggest that COVID is actually gone. We're simply rebranding it as an endemic, whatever that means. Calling COVID a public health emergency doesn't make sense because it's here to stay.

Ending the health emergency is big news for device makers selling products via emergency use authorizations or FDA enforcement discretion. These products will now only be allowed to stay on the market if they're cleared through standard device review pathways, such as PMAs and 510(k)s.

That transition will begin this year but, as the FDA has promised, there will be ample transition time. Also, device-review will be streamlined with pandemic learnings – think less clinical evidence and more real-world evidence.

As a bonus, CDRH will finish its return to normal operations. Premarket review and postmarket enforcement will look like they did pre-pandemic and companies will again get to meet with CDRH staff. But this is the new "normal." No one is fully shelving pandemic practices; some efficiencies and new regulatory requirements will remain. For proof, see the Omnibus spending bill, which authorizes FDA to require device shortage reports during public health emergencies.

CDRH Will Enhance Its Digital Engagement.

Announcing that CDRH will go big on digital ranks with "wow, mountains are tall" on the list of deep insights.

But some changes are noteworthy. First, CDRH will counter staffing headwinds in digital oversight. Staff shortages have constrained all of CDRH, including its Digital Health Center of Excellence. The Digital Health Center needs more people and a permanent director, both of which will be priorities next year.

CDRH also will grapple with limits to its authority. Those limits hamstrung CDRH's software precertification pilot program because the center couldn't create new market pathways for digital devices. Next year, CDRH will leverage its authority and deploy new strategies to promote

digital innovation. For example, CDRH will back change control plans for digital devices. These plans allow device companies to make specific, pre-identified changes to digital devices without triggering premarket review requirements. CDRH can deploy this new approach with its current authority and engage Congress to fill any gaps.

Real World Evidence Will Gain Momentum.

There's no question, real-world evidence (RWE) is here to stay. RWE reaches all FDA-regulated medical products (i.e., drugs and biologics, as well as devices); FDA and industry back RWE; and it's increasingly serving as an adjunct to (and eventually maybe a replacement for) traditional clinical studies.

Some quick background: RWE comes from data sources like electronic health records, claims and billing data, and disease registries. Sometimes, these sources can support product-review decisions like premarket applications and applications for expanded use. But there are obstacles. For example, RWE can be incomplete or difficult to integrate with data from other sources.

Still, CDRH is a strong RWE proponent. The center recently published a report detailing multiple RWE examples backing PMAs, 510(k)s, and other device premarket submissions. Look this year for CDRH and the rest of FDA to further embed RWE as a data source to evaluate medical products.

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

CDRH successfully promotes device innovation, and the Breakthrough Devices Program is a prime example.

The program supports devices that diagnose and treat life-threatening and debilitating diseases, while preserving basic requirements like device premarket review, good manufacturing practice, and adverse event reporting. Breakthrough devices get a lot more attention from CDRH staff, meaning more premarket meetings, expedited action, and senior-staff engagement. But there are no guaranteed results. Breakthrough designation doesn't mean that a device has a better chance of clearance or approval than devices outside the program.

Still, the numbers tell a success story. In 2015, there were about 10 devices in the breakthrough program. Last year, there were more than 160. Breakthrough designations will stay high this year, but whether that translates to better approval and clearance rates remains clouded. We already know that overall review doesn't happen faster under the breakthrough program. With more data showing more results, we'll have a better picture of whether program participants have improved odds of clearance and approval.

As important, growing breakthrough numbers will increase pressure on CDRH staff. The breakthrough program is resource-intensive. More meetings, expedited reviews, and similar measures require staff to do more work faster. Staff is already tired and spread thin after years of pandemic emergencies. Adding the demands of the breakthrough program will prolong staff's return to normal operations.

Diagnostics Regulation – Insert "InVALID" Pun Here.

I overuse the term "dumpster fire," but I can't think of a better description for in vitro diagnostic (IVD) regulation.

To recap, CDRH IVD oversight has been in limbo for years. Finally, the planets align with a compromise affirming CDRH's authority while treating IVDs differently from standard devices. The FDA is on board and industry is on board, so we've got a deal, right?

Wrong. First, VALID, the law fixing IVDs, fell off MDUFA V along with every other legislative rider. But no problem – Congress has to authorize the 2023 budget, offering another bite at the apple. Now, budget authorization is done and VALID is nowhere to be seen. But that makes sense. The budget runs past 4,000 pages, so I guess Congress just didn't have enough room.

FDA Commissioner Califf has promised to use rulemaking to deliver what Congress didn't. This begs the question why Congress was needed if the FDA could just fix this problem on its own. It's hard to see regulation having any chance of success. Apart from its glacial pace, there's the near-certain lawsuits from opponents of FDA measures. I hope to have grandchildren one day, and I'm excited to celebrate with them the arrival of IVD regulation.

I wish all of you reading this a very happy 2023. With luck, by next January, you'll have forgotten my predictions and I'll then claim total success.

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.