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US FDA Strengthens Inspection Capabilities With Pandemic Alternatives – And Travel Savings

by Bowman Cox

Agency's Office of Regulatory Affairs mines third-country EU inspections and remotely delivered documents while investing travel savings, redirecting field force and preparing for new post-pandemic travel challenges.

Barely able to travel during the COVID-19 pandemic, the US Food and Drug Administration's inspectorate used the time to plow back travel savings into bolstering other activities related to quality oversight and to develop alternatives like reviewing records remotely and relying on findings of other countries' authorities that could increase effectiveness post-pandemic.

As FDA investigators surge back into the field, they can expect to gain additional flexibilities supported by recent experience in relying more on the findings of other countries' pharmaceutical inspectorates and the FDA's own remote oversight capabilities.

Judith McMeekin, associate commissioner for regulatory affairs, shared new insights recently with the Alliance for a Stronger FDA on how well some of the pandemic alternatives have worked, and what to expect for the future.

McMeekin emphasized efforts underway to strengthen the inspectorate's IT infrastructure. (Also see "*US FDA Seeks Funding To Modernize Inspection-Related Technology Systems*" - Pink Sheet, 19 Apr, 2022.)

Meanwhile, FDA has shared with the *Pink Sheet* some details of just how much money the agency saved with its inspectorate largely grounded, and how it reallocated the savings.

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Inspection Alternatives To Keep Adding Value

McMeekin told a 6 April Alliance for a Stronger FDA webinar that the various inspection alternatives enabled the agency to exceed domestic surveillance inspection goals outlined in its May 2021 *resiliency roadmap*. Meanwhile, ORA made "significant progress" on a backlog of preapproval inspections and exceeded goals on Official Action Indicated follow-up inspections. (Also see "*US FDA's Inspection Volume Projected To Return To Normal Levels In FY 2022 As Backlog Looms*" - Pink Sheet, 2 Jun, 2021.)

Looking ahead, she said ORA will continue to employ "maximum flexibility" in using alternative tools and approaches developed to get through the pandemic, while catching up on the most important inspections.

She noted the agency must still work around enduring travel restrictions in China and other countries as spikes in COVID-19 cases continue to prevent business as usual.

Unexpected Third-Country Benefits Of MRAs

McMeekin underscored the importance of US/EU and US/UK mutual recognition agreements and explained how their value increased during the pandemic.

The agreements enable the parties to rely on each other's' domestic inspection findings, while also allowing them to leverage third-country inspections conducted in other regions like Asia.

As the pandemic continued, the FDA relied increasingly on third-country inspections to defer surveillance inspections in regions where travel remained difficult and risky.

One reason for embracing such third-country reports "is that we quickly realized that third-country reports were equivalent to in-country reports and yielded the same level of assurance we needed" to classify sites and decide on application approvals, McMeekin said.

Based on this "very positive experience," she said the FDA is pursuing expansion of the MRAs to explicitly cover veterinary inspections and third-country sites.

Government Travel Retention Challenges Recapped

McMeekin acknowledged the challenge that travel poses in recruiting and retention.

"Foreign travel for our inspectorate is rigorous," she said. Investigators must endure long trips, and if they want to fly in relative comfort, they must pay for their own upgrades.

The foreign cadre typically embark on trips of several weeks in duration, sometimes to multiple countries, that begin by crossing oceans cramped in coach. In all, they typically spend 18 weeks

per year on the road.

The challenges increase with so-called short-notice or unannounced inspections, she said. In response to congressional demands, the FDA is beginning to pilot such inspections in India and China. (Also see "*US FDA Looks To Resume Unannounced Inspections In India And China*" - Pink Sheet, 13 Dec, 2021.)

To conduct unannounced inspections of remote facilities in India, "in some cases we'll be likely forced to rely on local means of transportation or taxis that are generally less safe than when our investigators are in a major city," she said.

For the many facilities that are in special economic zones, unannounced investigators will nevertheless have to wait at the zone's entry point "until the firm is contacted, and then for someone from the firm to escort our investigators."

How The FDA Invested Its Pandemic Travel Savings

Much as it did with its personnel, ORA redirected travel expense savings to an array of activities.

Some were meant to strengthen remote alternatives, others to make inspections safer during the pandemic, and still others to improve inspection-related processes.

ORA saved $19m on travel in FY 2020 and $18m in FY 2021. Also in FY 2021, the office says it "turned in" $8m in Generic Drug User Fee Act money, the agency told the *Pink Sheet*.

ORA repurposed travel funds to support:

- Development of a time reporting system from a mandate in the user fee commitment letters;
- Development of a foreign travel planning system;
- Cleaning supplies, COVID-19 testing and personal protective equipment for investigators required to do mission-critical inspections;
- Moving in-person courses to online training;
- IT enhancements to increase wireless bandwidth for international mail facilities, resident posts, laboratories and district offices;
- IT upgrades for exchanging food regulatory data with local and state authorities; and

- Upgrades of the FDA's Jamaica, NY, facilities and expansion of its Forensic Chemistry Center in Cincinnati, OH.

Spending on Inspections Plummeted

Agency data on average inspection costs and annual inspection rates suggest that inspection costs may have accounted for 75% to 85% of ORA's budget in the years leading up to the COVID-19 pandemic, then fell to 25% during the pandemic, according to *Pink Sheet* analysis.

The agency told the *Pink Sheet* that in FY 2021, the cost of domestic inspections, including for personnel and travel expenses, averaged $41,016 while foreign inspections averaged $73,366.

The average cost appears to have grown slightly over the previous decade, as the General Accountability Office reported in January 2017 that the cost of FDA's foreign inspections averaged $60,000 to $62,500 in FY 2010 and $57,600 in FY 2015.

Funding And Staffing Held Firm

The number of FDA inspections across all commodities had been trending at about 20,000 per fiscal year until the pandemic hit midway through FY 2020, when it fell below 9,000. The trend barely exceeded 7,000 in the next two fiscal years, with full recovery now expected in FY 2023.

Meanwhile, ORA's funding and staffing levels held steady through the ordeal at $1.1bn to $1.2bn and close to 5,000 workers, many of them investigators, according to data the agency presented in annual budget request documents.

By reengineering its hiring process, ORA was even able to increase its workforce by several hundred during the pandemic, according to the FDA's FY 2023 budget justification document.

A Different Focus Emerged

However, the FDA's inspectorate was by no means idled by the pandemic, as the FY 2023 budget request noted.

ORA relied on its field workforce to conduct remote regulatory assessments for many commodities in FY 2021, including more than 1,000 pharmaceutical manufacturing sites and 150 medical device sites. (Also see "*Resiliency Roadmap Update: US FDA Exceeds FY 2021 Inspection Projections*" - Pink Sheet, 29 Nov, 2021.)

There was a rush of new activity around testing imports, including dangerously fraudulent or substandard hand sanitizers manufactured to meet surging pandemic demand. (Also see "*Remote Methods Drove Most US FDA Enforcement Actions In FY 2021*" - Pink Sheet, 6 Oct, 2021.)

Additionally, ORA played key roles in assessing requests for emergency use authorization of COVID-19-related products. The office also worked with the Securities and Exchange Commission against fraudulent COVID-19 treatments.