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Suzanne Murrin

Deputy Inspector General

Office of Evaluation and Inspections

Office of Inspector General

Department of Health and Human Services

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Testimony of:

Suzanne Murrin

Deputy Inspector General for Evaluation and Inspections

Office of Inspector General, Department of Health and Human Services

Thank you, Chairman Bishop, Ranking Member Fortenberry, and distinguished Members of the Subcommittee. I am Suzanne Murrin, Deputy Inspector General for Evaluation and Inspections in the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS or Department). Thank you for the opportunity to discuss OIG's oversight of the Food and Drug Administration (FDA). We are grateful for the support this subcommittee has provided to OIG, which has allowed us to expand our oversight of FDA's vital programs.

OIG has long recognized the importance of overseeing FDA's efforts to protect the public by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of our nation's food supply; and regulating tobacco products. With an annual budget of approximately \$6 billion, FDA oversees the safety of products that represent about 20 percent of all U.S. consumer spending.

Since fiscal year (FY) 2015, thanks to the additional resources (\$1.5 million annually) that this subcommittee has directed be transferred to OIG, we have enhanced our oversight of FDA. We have pursued a four-part strategy: (1) provide useful, relevant information, analysis and enforcement; (2) drive positive change by working with FDA to implement our recommended improvements; (3) build OIG expertise in FDA programs; and (4) comprehensively analyze the risks confronting FDA programs to make strategic, risk-based decisions on the priority areas we should pursue.

Our work primarily focuses on how FDA could keep Americans safer by more effectively regulating the food supply, medical devices, and drug products. Through this work, OIG has driven meaningful improvements in the efficiency and effectiveness of FDA's oversight and enforcement in many ways. For example, a number of the improvements in the Food Safety

Modernization Act (FSMA) addressed OIG recommendations to improve the traceability of the food supply and the accuracy of the food facility registry, after we reported that selected food products could not be traced through the food supply chain, from a retail shelf back to a farm, and almost half of the facilities (i.e., processors, packers, manufacturers, and holders) we contacted failed to properly register with FDA.¹ These improvements strengthen FDA’s ability to quickly locate facilities during an outbreak of foodborne illness, bioterrorism, or economically motivated adulteration.

This testimony explores the improvements that FDA has made in response to OIG recommendations to improve the safety of food, medical devices, and drugs. The testimony also highlights critical OIG recommendations that FDA has yet to implement, where we continue to engage with FDA leadership and staff. Finally, we discuss areas where OIG is expanding our oversight, such as FDA regulation of tobacco products, efforts to combat the opioid crisis, and fostering drug competition.

OIG Has Identified Vulnerabilities in FDA’s Efforts To Protect Our Nation’s Food Supply

For over a decade, OIG has examined FDA’s efforts to protect our Nation’s food supply. An estimated 1 in 6 Americans get sick from contaminated foods each year, with more than 128,000 hospitalizations and 3,000 deaths. Foodborne illnesses are largely preventable, and the American public relies on FDA to ensure the safety of the food in the global supply chain for both human and animal food.² Our work has highlighted vulnerabilities in FDA’s prevention efforts and its ability to respond effectively when problems are identified. Most recently, OIG has found vulnerabilities in FDA inspections of food facilities and FDA oversight of food recalls.

FDA Needs To Ensure Routine Inspection of Food Facilities and Prompt Correction of Violations. FSMA established specific mandates governing the timeliness of food facility

¹ *Traceability in the Food Supply Chain*, OEI-02-06-00210, March 2009.

² FDA regulates over 80 percent of the U.S. food supply, including dairy, seafood, produce, packaged foods, bottled water, and some egg products. The U.S. Department of Agriculture (USDA) regulates meat, poultry, and eggs.

inspections. OIG has reviewed the frequency of FDA’s inspections and FDA’s ability to take swift and effective action when inspections identified problems³. OIG found that the overall number of food facilities inspected by FDA had decreased over time and raised concerns about FDA’s ability to meet FSMA’s tighter inspection mandates, despite successes meeting the initial, more generous inspection mandates. Moreover, FDA did not always take timely actions to ensure that facilities corrected the most significant inspection violations. When FDA did take action, it commonly relied on facilities to voluntarily correct the violations. In fact, FDA rarely took advantage of the new administrative tools provided by FSMA, such as the administrative detention of food or mandatory food recalls.

OIG made four recommendations to FDA to address the vulnerabilities identified in this report: (1) improve its stewardship of the inspections program to ensure the better use of resources, (2) take appropriate action against all facilities with significant inspection violations, (3) improve the timeliness of its actions so that facilities do not continue to operate under harmful conditions, and (4) conduct timely followup inspections to ensure that significant inspection violations are corrected. FDA concurred with these recommendations and stated that it has taken steps to address them, including developing an FDA Management Dashboard that may implement certain aspects of our recommendation to follow up on inspection violations. OIG continues to monitor FDA’s ongoing response to these four open recommendations as well as an earlier recommendation for FDA to seek statutory authority to impose civil monetary penalties on food facilities.

OIG has also reviewed FDA’s oversight of State contractors that conduct more than half of all FDA inspections⁴. We found that in eight States, FDA failed to ensure completion of the required number of inspections. In addition, when States were responsible for correcting violations, FDA was not always informed about actions taken, and FDA was unable to determine

³ *Challenges Remain in FDA’s Inspections of Domestic Food Facilities*, OEI-02-14-00420, September 2017.

⁴ *FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability*, OEI-01-98-00400, June 2000.

that all inspection violations were remedied. As a result of this review, FDA changed how it monitors State contractors to ensure completion of all required inspections.

FDA Should Fix Deficiencies in Food Recalls. To review FDA's use of the mandatory recall authority it was granted in FSMA to recall certain harmful foods, OIG reviewed 30 food recalls. We found that FDA's food-recall process was not always effective and efficient in ensuring the safety of the Nation's food supply.⁵ Specifically, we identified deficiencies in FDA's oversight and monitoring of (1) recall initiation, (2) recall implementation, and (3) the accuracy of the recall information captured and retained in FDA's electronic Recall Enterprise System (RES). To better ensure that food recalls are quick and comprehensive, OIG recommended that FDA finalize its interim mandatory recall procedures and consider issuing guidance for FDA staff on those factors that staff should consider when determining whether there is a reasonable probability that a food could cause serious adverse health consequence or death. OIG also recommended steps ranging from specific improvements to FDA's food recall plan to establishing performance measures for the amount of time between the date FDA learns of a potentially hazardous product and the date a firm initiates a voluntary recall. Eight of the report's 14 recommendations have been implemented and OIG continues to work with FDA to seek implementation of the remaining open recommendations, including ensuring that FDA monitors food recall performance and refines operating procedures, as needed.

OIG Has Identified Risk Associated With Medical Device Safety and Security

The speed at which science and technology are evolving means that the development and oversight of medical devices presents new safety and effectiveness concerns.

FDA Needs To Further Mitigate Risk of Cybersecurity Threats to Medical Devices. Managing the cybersecurity risks associated with networked devices is an area of increasing concern to the OIG as more medical devices use wireless, internet, and network connectivity.

⁵ Because we selected a judgmental sample, the results are informative about deficiencies in FDA's food-recall oversight process but are not representative of the full population of FDA recalls.

Researchers have shown that networked medical devices approved by FDA can be susceptible to cybersecurity threats, such as ransomware and unauthorized remote access, if the devices lack adequate security controls. These networked devices include hospital-room infusion pumps, diagnostic imaging, and pacemakers. In 2018, OIG released two reports assessing FDA's oversight of premarket⁶ and postmarket⁷ cybersecurity risks to medical devices. An underlying issue of both reports was the opportunity for FDA to take further action in addressing cybersecurity threats to reduce risk to patients and the health care industry.

In response to these reports, FDA has made administrative changes to its premarket and postmarket processes. Specifically, FDA released draft guidance in 2018 that encourages device manufacturers to meet with FDA early and discuss how they are addressing cybersecurity in their device's design and development. FDA also made postmarket improvements to the procedures for handling recalls of medical devices vulnerable to cybersecurity threats, including the signing of a Memo of Agreement with the Department of Homeland Security to improve information sharing of cybersecurity vulnerabilities and coordinate response actions. We continue to recommend that FDA establish written procedures for securely sharing information about cybersecurity events with key stakeholders to ensure patient safety.

FDA Needs To Ensure a Robust Postmarket Surveillance System for Devices. FDA has shifted safety oversight of medical devices to the postmarket setting. Meanwhile, the number of adverse event reports has increased dramatically over time. Despite the increased reliance on and need for a robust postmarket surveillance system, OIG found that manufacturers and medical device user facilities often submitted tardy and incomplete adverse event reports. Further, FDA failed to employ adverse event reports in a systemic manner to detect and address safety concerns. Based on our recommendations, FDA took steps to improve its processes for reviewing adverse event reports and ensure more timely and complete reporting by

⁶ *FDA Should Further Integrate Its Review of Cybersecurity Into the Premarket Review Process for Medical Devices*, OEI-09-16-00220, September 2018.

⁷ *The Food and Drug Administration's Policies and Procedures Should Better Address Postmarket Cybersecurity Risk to Medical Devices*, A-18-16-30530, October 2018.

manufacturers. The Uniform Surveillance System has been operational since 2015, allowing FDA to identify manufacturers with late or incomplete reports. However, OIG continues to recommend that FDA build better capacity in their automated systems for managing postmarketing requirements and provide a standardized form for annual status reports to ensure completion.

FDA's focus on overseeing the safety of devices in a postmarket setting underscores the importance of its surveillance system working well. Better information allows FDA to monitor signals of public health safety concerns and take appropriate action. It also allows FDA to be more targeted in its oversight efforts. Currently, OIG is examining FDA's evolution from its current passive postmarket reporting system to an active surveillance system that FDA believes will better protect patients.

OIG Has Identified Safety Concerns With FDA-Regulated Drugs

OIG has identified vulnerabilities with FDA's oversight of manufacturing and distributing drugs as well as particular high-risk drugs such as compounded drugs.

The Safety of Foreign Manufacturing Is Still a Concern. According to the FDA, roughly 40 percent of finished drugs and 80 percent of active drug ingredients are made in more than 150 countries. OIG work has determined that FDA made progress on achieving parity in its inspections of domestic and foreign generic drug manufacturers. However, it did not conduct all preapproval inspections. In response, FDA made all of OIG's recommended improvements to address its preapproval inspection backlog, improve its ability to track and oversee generic manufacturers, and enhance its efficiency in conducting these inspections.

OIG is now reviewing whether programmatic changes implemented since our first report, a program-based management structure that aligns staff by FDA-regulated product, have improved FDA's foreign drug manufacturer inspection process.

Drug Supply Chain Security Is Compromised by Incomplete Drug Tracing Records. OIG has developed a body of work to address safety concerns with potentially dangerous drug

products entering the drug supply chain and eventually being dispensed to patients.⁸ OIG investigations have identified instances where Federal programs paid for drugs not approved by the FDA, reinforcing the need to be able to trace the path drugs lead from manufacturer to patient.

To protect the drugs in the supply chain, pharmaceutical manufacturers, wholesaler distributors, dispensers, and repackagers are required to document each time the legal ownership of a drug is transferred from one supply chain trading partner to another. FDA can use this information to identify and investigate potentially harmful drug products and facilitate efficient recalls. OIG work raised concerns about incomplete ownership information that is required on wholesale distributors' and dispensers' documents and a lack of awareness among wholesale distributors and dispensers about several drug tracing requirements.

OIG's work also raised concerns about the inability to trace a drug's physical journey through the supply chain. Although this information is not required in tracing records (records only capture changes in legal custody), without this information, there are gaps in the record of the drug's path through the supply chain. The opportunity for harm arises each time a drug changes hands, creating opportunities for counterfeiting, tampering, or diversion. If this information was present on tracing information, it could help FDA more quickly identify where a drug product may have been compromised, determine where it is located, and then ensure that it is removed from the supply chain.

In response to OIG's recommended improvements, FDA has issued guidance clarifying several tracing requirements and has conducted education for dispensers about their obligations to exchange tracing information. OIG continues to follow up with FDA to ensure that it addresses concerns about incomplete tracing information and seeks new authority to include information about a drug's physical location on tracing records.

⁸ *Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information*, OEI-05-14-00640 (September 2017) and *Drug Supply Chain Security: Dispensers Received Most Tracing Information*, OEI-05-16-00550 (March 2018).

FDA Should Ensure That Non-Patient-Specific Compounded Drugs Are Obtained From Compounders That Meet FDA Quality Standards. In response to deaths from an outbreak of fungal meningitis caused by contaminated compounded injections, Congress enhanced FDA’s authority over facilities that perform large-scale compounding of non-patient-specific drugs. OIG sought to provide FDA with insights to improve its oversight of compounders and enhance patient safety by identifying compounders that made non-patient-specific drugs without meeting FDA registration requirements. OIG referred a list of those facilities to FDA, and FDA reported using the list to target facilities for inspection. FDA also reported that some of these inspections identified “objectionable conditions” and some led to a recall. Overall, OIG determined that most hospitals obtained non-patient-specific compounded drugs from outsourcing facilities that were registered with FDA and subject to FDA oversight.

OIG Is Expanding Its Oversight To Include Curtailing Youth Tobacco Use, Combating the Opioid Crisis, and Fostering Drug Competition

Youth Tobacco Use. Tobacco use among youth is at epidemic proportions, driven by a dramatic rise in the use of e-cigarettes, even though the use of other forms of tobacco has declined. FDA’s retail compliance inspections are a critical tool for FDA’s Youth Tobacco Prevention Plan to prevent the sale and marketing of all tobacco products to youth. OIG has begun evaluating the extent of these inspections and what can be learned from the results. We are also examining FDA’s enforcement of retail tobacco regulations intended to prevent youth access to tobacco, including e-cigarettes.

Combating the Opioid Crisis. FDA plays a significant role in the national effort to combat opioid abuse. FDA has used Risk Evaluation and Mitigation Strategies (REMSs) as part of its comprehensive action plan to reduce the risk of opioid abuse with the overall goal to increase the number of prescribers who receive training on pain management and safe prescribing of opioid drugs and decrease inappropriate opioid prescribing. OIG is reviewing the

extent to which FDA held drug manufacturers accountable for mitigating the risk of opioid misuse and abuse.

Previous OIG work on the REMS program found that FDA lacked comprehensive data to determine whether REMS improve drug safety and recommended that FDA identify REMS that are not meeting their goals and take appropriate actions to protect public health.⁹

Fostering Drug Competition. OIG has a long history of work ensuring appropriate payment for prescription drugs and has recently expanded our focus to include FDA's efforts to foster drug competition as a means to reduce drug spending. As an initial step, we have begun a review that will examine the Orphan Drug status of numerous high-expenditure drugs paid under Medicare. Orphan drug status is granted by FDA as a means to provide financial incentives, including market exclusivity, for manufacturers to develop drugs to treat rare diseases. However, analysis shows that the actual use and profitability of an orphan drug can be considerably greater than expected. In the future, OIG may explore expanded use of biosimilars¹⁰ and potential savings therefrom.

Conclusion

Thank you again for the opportunity to highlight some of our work to the subcommittee today. As noted previously, a significant portion of this work would not be doable without the funding provided by this subcommittee.

Of course, in addition to the work described throughout this testimony, OIG has included FDA in its ongoing oversight of Departmental financial and cyber systems. In covering these priority areas, and other concerns at FDA, OIG will continue to pursue recommendation implementation as a central part of our work. We welcome this subcommittee's interest in

⁹ *FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety*, OEI-04-11-00510 (February 2013).

¹⁰ Biosimilars are the biological equivalent of a generic drug. Biologic drug products are usually large, complex molecules produced through a living system, such as a microorganism, plant, or animal cell.

FDA's progress toward implementing OIG's outstanding recommendations and are pleased to have this opportunity to discuss our FDA work with you.

In closing, let me say that OIG recognizes that our current FDA workplan as described in this testimony does not and cannot cover all the important issues facing FDA. Based on our risk analysis, and given the resources available, OIG has chosen to first and foremost focus on the safety of American food, medical devices, and drugs. This is where we can have the greatest positive impact. If we are able to expand our FDA oversight, potential areas for further FDA oversight include (1) assessing the progress that FDA has made on the 21st Century Cures Act commitments to help accelerate medical product development and bring new innovations and advances to patients who need them faster, and (2) a broader exploration of the intersection between FDA drug approvals and a competitive market for drugs and biologics that better constrains costs.

Thank you again for the opportunity to be here today. I welcome any questions you may have.