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DOJ's Global Reach: What Every Non-U.S. Health Care and Life Sciences Company Needs to Know

With numerous recent headlines touting significant enforcement actions in the anti-corruption, antitrust, and health care arenas involving international actors, the ability of the Department of Justice (“DOJ”) to pursue foreign citizens and non-U.S.-based companies needs no introduction.¹ As former Assistant Attorney General Leslie R. Caldwell of DOJ’s Criminal Division stated in early 2016, “transnational criminal enterprises and global corporate misconduct are the new normal.” Caldwell went on to claim that DOJ can and should lead by example “by vigorously investigating and prosecuting international crime when it violates U.S. laws, and by sustaining and increasing our commitment to international collaboration in our nations’ shared struggle to safeguard our markets, our networks and our citizens.”² While there is some uncertainty about Attorney General nominee Jeff Sessions’s³ approach to international enforcement, we do not anticipate a stark departure from the priorities outlined by former Assistant Attorney General Caldwell, given the momentum of ongoing investigations and the various tools at the DOJ’s disposal, discussed herein. In fact, DOJ, in cooperation with several agencies, including the Federal Bureau of Investigation and, increasingly, in close coordination with the Food and Drug Administration’s Office of Criminal Investigations (“FDA-OCI”), is poised to boost its investigative efforts outside of the United States to enforce health care fraud cases and alleged violations of the Federal Food, Drug, and Cosmetic Act (“FDCA”).⁴

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Health care and life sciences companies are not strangers to U.S. enforcement activity, and the recent Olympus prosecution illustrates that the distance between an anticorruption case and a kickback case can be a short hop. This

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¹ See, e.g., Press Release, U.S. Dep’t of Justice, *Teva Pharmaceutical Industries Ltd. Agrees to Pay More Than \$283 Million to Resolve Foreign Corrupt Practices Act Charges* (Dec. 22, 2016), <https://www.justice.gov/opa/pr/teva-pharmaceutical-industries-ltd-agrees-pay-more-283-million-resolve-foreign-corrupt> (announcing Deferred Prosecution Agreement with Teva Pharmaceutical Industries Ltd., and a guilty plea entered by its wholly owned Russian subsidiary, for FCPA violations); Press Release, U.S. Dep’t of Justice, *Och-Ziff Capital Management Admits to Role in Africa Bribery Conspiracies and Agrees to Pay \$213 Million Criminal Fine* (Sept. 29, 2016), <https://www.justice.gov/opa/pr/och-ziff-capital-management-admits-role-africa-bribery-conspiracies-and-agrees-pay-213> (announcing Deferred Prosecution Agreement with Och-Ziff Capital Management Group LLC, and a guilty plea entered by its wholly owned African subsidiary, for FCPA violations); Press Release, U.S. Dep’t of Justice, *Medical Equipment Company Will Pay \$646 Million for Making Illegal Payments to Doctors and Hospitals in the United States and Latin America* (Mar. 1, 2016), <https://www.justice.gov/opa/pr/medical-equipment-company-will-pay-646-million-making-illegal-payments-doctors-and-hospitals> (announcing agreements by Olympus Corp. of the Americas and its subsidiary to resolve criminal charges and civil claims relating to violations of the Anti-Kickback Statute and the FCPA).

² See Remarks as Prepared for Delivery, U.S. Dep’t of Justice, *Assistant Attorney General Leslie R. Caldwell Speaks at American Bar Association’s 30th Annual National Institute on White Collar Crime* (Mar. 4, 2016), <https://www.justice.gov/opa/speech/assistant-attorney-general-leslie-r-caldwell-speaks-american-bar-association-s-30th>.

³ This article was submitted days after President Donald Trump was sworn into office, and we anticipate that Jeff Sessions will be confirmed by the Senate as the next Attorney General of the United States.

⁴ 21 U.S.C. § 301, *et seq.*

article highlights some of the tools and resources that DOJ has at its disposal for extending its law enforcement reach beyond U.S. borders—including seeking cooperation and assistance from foreign law enforcement authorities through a Mutual Legal Assistance Treaty (“MLAT”), threatening or seeking extradition of foreign citizens, and relying on the FDA’s ability to inspect, and conduct criminal investigations of, facilities outside of the U.S. that are engaged in activities subject to the FDA’s jurisdiction. The article concludes with some practical considerations for companies that have corporate offices, headquarters, or manufacturing facilities outside of the U.S., and how they can prepare themselves for inquiries, inspections, and investigations by U.S. regulators and enforcers.

I. Mutual Legal Assistance Treaties and DOJ’s Ability to Seek Assistance from Foreign Law Enforcement Authorities

An MLAT is an agreement between two or more countries that allows them to exchange evidence and information in criminal and related matters. In the United States, they are negotiated by the State Department in cooperation with DOJ. The United States has MLATs with over 40 countries,⁵ including Japan, India, Hong Kong, Mexico, Nigeria, the Philippines, South Africa, and Thailand. The United States has also signed a Mutual Legal Assistance Agreement with China that serves a similar purpose as an MLAT.

MLATs allow DOJ to obtain information or evidence from another country that would otherwise be outside of its jurisdiction. An MLAT typically obligates a signatory country to provide for the production of documents, testimony from witnesses, execution of search and seizure requests, and seizure of forfeitable assets upon the request of the other signatory country.⁶ For example, the DOJ may use an MLAT to request the freezing of assets where there is probable cause to believe those assets are subject to forfeiture under 18 U.S.C. § 981 (civil forfeiture) or 18 U.S.C. § 982 (criminal forfeiture). The conduct that forms the basis for the request generally need not be an offense under both countries’ laws for mutual legal assistance to be provided.⁷

MLAT requests must be made directly between the authorities identified in the applicable treaty. For the United States, the designated point of contact is the Office of International Affairs in the Criminal Division of DOJ (“OIA”). For other countries, the designated authority is often the Minister of Justice, Attorney General, or Minister of Interior, or that official’s designee. When a DOJ attorney wants to obtain overseas evidence via an MLAT, he or she must contact OIA and work with OIA to prepare a formal mutual legal assistance request, which is then sent to the designated authority in the other country.⁸

DOJ need not have filed an indictment to obtain evidence pursuant to an MLAT. Nonetheless, prosecutors may seek to obtain evidence through informal means first, and then make a formal MLAT request only once it is apparent that the evidence will be needed for a formal court proceeding.⁹ Where DOJ seeks assistance in obtaining evidence from a foreign country pursuant to an MLAT, U.S. courts have found that motions to suppress such evidence will be granted only in limited circumstances. For example, in 2013, the Second Circuit denied a Fourth Amendment exclusionary rule challenge to evidence collected in Israel pursuant to an MLAT, noting that the Fourth Amendment and the exclusionary rule generally do not apply where foreign officials are acting within their own country. The Second Circuit identified two narrow exceptions to this rule, neither of which it applied in the case: (1) where the

⁵ Treaties, Agreements and Asset Sharing, U.S. DEP’T OF STATE, <http://www.state.gov/j/inl/rls/nrcrpt/2014/vol2/222469.htm>.

⁶ See, e.g., Treaty on Mutual Legal Assistance in Criminal Matters, Aug. 5, 2003, U.S.-Japan, S. TREATY DOC. NO. 108-12 (2003), <https://www.state.gov/documents/organization/191629.pdf>.

⁷ See *id.*

⁸ See Thomas G. Snow, *The Investigation and Prosecution of White Collar Crime: International Challenges and the Legal Tools Available to Address Them*, 11 WM. & MARY BILL RTS. J. 209, 227 (2002).

⁹ *Navigating The Arcane World of Mutual Legal Assistance Treaties, Letters Rogatory and Evidence-Gathering From Abroad*, FCPA PROFESSOR (May 21, 2014), <http://fcpprofessor.com/navigating-the-arcane-world-of-mutual-legal-assistance-treaties-letters-rogoratory-and-evidence-gathering-from-abroad/>.

conduct of foreign officials “is so extreme that it shocks the judicial conscience”; and (2) “where cooperation with foreign law enforcement officials may implicate constitutional restrictions,” such as where foreign law enforcement officials act as agents, or virtual agents, of U.S. law enforcement officials, or where U.S. law enforcement officials seek to evade their own constitutional obligations by cooperating with foreign law enforcement agencies.¹⁰

In a March 2016 speech, former Assistant Attorney General Caldwell noted that DOJ has been actively hiring attorneys and staff at the OIA because the workload in that department had “increased exponentially” in recent years.¹¹ Although observing that mutual legal assistance is not DOJ’s only means of obtaining evidence overseas, she stated that efforts “to improve [the U.S.’s] bilateral relationships and [DOJ’s] MLAT response are essential in a world of increasingly global crime.”¹²

Most of DOJ’s recent press releases have not expressly referenced MLATs, but there is little doubt that international cooperation, both formal and informal, can be a powerful tool. DOJ’s recent prosecution of a Turkish drug wholesaler for the sale and shipment of misbranded drugs into the U.S. underscores this point. In January 2015, Sabahaddin Akman, the owner and manager of the drug wholesaler, was sentenced to 30 months of imprisonment and fined 150,000 USD for smuggling misbranded and adulterated cancer treatment drugs into the United States.¹³ Akman admitted using shipping labels that concealed the illegal nature of prescription drug shipments, shipping prescription cancer treatment drugs that required constant cold temperature without ensuring that temperature protection was maintained, and shipping a product that was determined to have no active drug ingredients from Turkey to the U.S. DOJ prosecuted the case with investigative assistance from multiple domestic and international agencies, including FDA-OCI, the Office of Inspector General for the U.S. Department of Health and Human Services, Europol, the Bonn prosecutor in Germany (Staatsanwaltschaft), the Federal Criminal Police of Germany (Bundeskriminalamt), the Dusseldorf Police, the German State Criminal Police (Landeskriminalamt), the U.S. Consulate General’s Overseas Criminal Investigations Branch in Istanbul, and the Drug Enforcement Administration.

Even without an MLAT, DOJ is often able to access documents and witnesses located outside of the United States by pushing for voluntary cooperation. Because MLAT requests can take time to execute, DOJ may contact a company or individual’s counsel to seek relevant testimony or information through informal means. In the face of DOJ programs offering leniency and credit for voluntary cooperation and disclosure, and corresponding penalties for failure to produce materials voluntarily,¹⁴ companies and individuals often feel pressured to cooperate with DOJ requests before formal MLAT requests are implemented.

II. Extradition, Red Notices, and Unique Questions for Foreign Citizens Working for Health Care and Life Sciences Companies

Extradition is the legal process by which an individual is transferred from one country to another for the purpose of facing trial or sentence. Although some countries may extradite an individual in the absence of an applicable treaty as a matter of comity, the right to seek and procure extradition is generally memorialized by contract and operates

¹⁰ *United States v. Getto*, 729 F.3d 221, 227-28 (2d Cir. 2013) (internal quotation marks and citation omitted).

¹¹ See *supra* note 2.

¹² *Id.*

¹³ Press Release, U.S. Attorney’s Office, E. Dist. of Mo., U.S. Dep’t of Justice, *Turkish Man Sentenced For Smuggling Adulterated And Misbranded Cancer Drugs* (Jan. 23, 2015), <https://www.justice.gov/usao-edmo/pr/turkish-man-sentenced-smuggling-adulterated-and-misbranded-cancer-drugs>.

¹⁴ See, e.g., U.S. DEP’T OF JUSTICE, GUIDANCE REGARDING VOLUNTARY SELF-DISCLOSURES, COOPERATION, AND REMEDIATION IN EXPORT CONTROL AND SANCTIONS INVESTIGATIONS INVOLVING BUSINESS ORGANIZATIONS (Oct. 2, 2016), <https://www.justice.gov/nsd/file/902491/download>; Press Release, U.S. Dep’t of Justice, *Criminal Division Launches New FCPA Pilot Program* (April 5, 2016), <https://www.justice.gov/opa/blog/criminal-division-launches-new-fcpa-pilot-program>; Antitrust Division Leniency Program, U.S. DEP’T OF JUSTICE, <https://www.justice.gov/atr/leniency-program>.

pursuant to international law.¹⁵ The U.S. has bilateral extradition treaties with over one hundred countries, including the Bahamas, Brazil, Burma, Canada, Hong Kong, Japan, Korea, Mexico, Panama, the United Kingdom, and South Africa.¹⁶

Extradition requirements differ based on the terms of the specific treaty, but commonly include uniform principles or requirements. One is the principle of specialty, which provides that, absent a waiver, an extradited individual may only be tried for the offense(s) for which he or she is extradited. Another is the concept of dual criminality, which requires that a person be extradited only for conduct that is criminal under the laws of *both* the requesting and surrendering country.¹⁷

Recent DOJ actions evince a strengthened commitment to holding individuals accountable for corporate crime, including those overseas. On September 9, 2015, Deputy Attorney General Sally Quillian Yates published a memorandum for all United States Attorneys and Assistant Attorneys General (commonly referred to as the “Yates Memo”) stating that DOJ would continue to seek increased individual accountability for corporate misconduct.¹⁸ Similarly, in recent confirmation hearings, Attorney General nominee Sessions suggested that, with respect to corporate fraud, “sometimes . . . the corporate officers who caused the problem should be subjected to more severe punishment than the stockholders of the company who didn’t know anything about it.”¹⁹ DOJ announced at least ten extraditions for fraud and money laundering crimes in 2015 and 2016.²⁰ Many more individuals are facing pending extradition proceedings.²¹

¹⁵ Michael John Garcia & Charles Doyle, CONG. RESEARCH SERV., 98-958, EXTRADITION TO AND FROM THE UNITED STATES: OVERVIEW OF THE LAW AND RECENT TREATIES 3 (2010), <https://fas.org/sgp/crs/misc/98-958.pdf>.

¹⁶ See Treaties of Extradition, U.S. DEP’T OF STATE, <https://www.state.gov/documents/organization/71600.pdf>.

¹⁷ In particular, the concept of dual criminality raises unique issues with respect to attempted extradition under the FDCA. Whereas many foreign countries, including European Union (“EU”) member nations, have “open” distribution systems that allow for the import and export of drugs across multinational borders, the United States has a “closed” distribution system that limits importation of drugs not approved by the FDA. For example, a drug lawfully authorized for commercial distribution in the EU also would need separate FDA approval for sale in the U.S. and would also need to meet FDA labeling requirements. See 21 U.S.C. §§ 351, 355. Accordingly, a drug found to be imported illegally under the FDCA may nonetheless be legally imported under the laws of another country, making the case for extradition difficult because dual criminality is not present. U.S. prosecutors may attempt to avoid this issue by utilizing more universal criminal charges, including mail fraud and false statements.

¹⁸ Memorandum from Sally Quillian Yates, Deputy Attorney Gen., U.S. Dep’t of Justice, to All U.S. Attorneys, *et al.*, *Individual Accountability for Corporate Wrongdoing* (Sept. 9, 2015), <http://www.justice.gov/dag/file/769036/download>.

¹⁹ Jody Godoy, *Sessions Hints Yates Memo, Fraud to Stay on DOJ Radar*, LAW360 (Jan. 11, 2017), <https://www.law360.com/articles/879816/sessions-hints-yates-memo-fraud-to-stay-on-doj-radar>.

²⁰ See, e.g., Press Release, U.S. Dep’t of Justice, *Jamaican Man First to Be Extradited to Face Fraud Charges in International Lottery Scheme* (Feb. 12, 2015), <https://www.justice.gov/opa/pr/jamaican-man-first-be-extradited-face-fraud-charges-international-lottery-scheme> (announcing extradition of Jamaican man for fraud); Press Release, U.S. Dep’t of Justice, *U.S. Citizen Extradited from Costa Rica in Connection with International-Based Business Opportunity Fraud Ventures* (Feb. 12, 2015), <https://www.justice.gov/opa/pr/us-citizen-extradited-costa-rica-connection-international-based-business-opportunity-fraud> (announcing extradition of U.S. citizen from Costa Rica for mail and wire fraud); Press Release, U.S. Dep’t of Justice, *Six Nigerian Nationals Extradited from South Africa to Mississippi to Face Fraud Charges* (July 13, 2015), <https://www.justice.gov/opa/pr/six-nigerian-nationals-extradited-south-africa-mississippi-face-fraud-charges> (announcing extradition of six Nigerian nationals from South Africa to face Internet fraud schemes); Press Release, U.S. Dep’t of Justice, *Syrian Electronic Army Member Extradited to the United States* (May 10, 2016), <https://www.justice.gov/opa/pr/syrian-electronic-army-member-extradited-united-states> (announcing extradition of Syrian national for charges including extortion and money laundering); Press Release, U.S. Dep’t of Justice, *Israeli Executive Extradited and Arraigned on Fraud Charges Involving the Foreign Military Financing Program* (Oct. 14, 2016), <https://www.justice.gov/opa/pr/israeli-executive-extradited-and-arraigned-fraud-charges-involving-foreign-military-financing> (announcing extradition of Israeli executive for fraud).

²¹ See, e.g., Remarks as Prepared for Delivery, U.S. Dep’t of Justice, *U.S. Attorney General Loretta E. Lynch Delivers Remarks at Press Conference with Attorney General Michael Lauber of Switzerland* (Sept. 14, 2015),

Every formal request for international extradition based on federal criminal charges must be reviewed, approved, and initiated by the OIA.²² The process is often further complicated by the geopolitical considerations involved in requesting extradition from another country. Thus, DOJ does not seek or initiate extradition proceedings for every accused individual. However, when an individual is indicted in the U.S., but refuses to submit voluntarily to U.S. jurisdiction, DOJ can request that an INTERPOL Red Notice be issued, notifying INTERPOL member countries that the individual is wanted for extradition. A Red Notice is issued based on a valid national arrest warrant, and most can be viewed only by law enforcement.²³ A request for a Red Notice is made to the INTERPOL General Secretariat and is separate from a formal request for extradition made to an extraditing country.²⁴ Each country has its own rules regarding whether to arrest or detain a listed individual, but the threat of arrest or detention while traveling—which could then lead to extradition—is often sufficient to persuade foreign citizens to submit to U.S. jurisdiction in the hopes of negotiating a shorter sentence. Conversely, individuals who choose not to surrender to U.S. jurisdiction must make the decision to remain within the boundaries of their home countries for the rest of their lives.

The case of a Canadian citizen who attempted to flee criminal charges by moving to Panama, but was ultimately detained due to an INTERPOL Red Notice, underscores the risks involved in choosing to be labeled a “fugitive.” Andrew Strempler, a Canadian citizen, ran an Internet, mail, and telephone order pharmacy named RxNorth that sold foreign prescription drugs from price-controlled markets such as Canada and the U.K. to users in the U.S. at cheaper prices. Such operations were controversial, with the FDA taking the stance that the prescription drug sales were illegal if the drugs were not FDA-approved. DOJ found that Strempler obtained prescription drugs from various source countries without properly ensuring the safety or authenticity of the drugs, some of which were found to be counterfeit.²⁵ Facing increased scrutiny from U.S. and Canadian regulators, Strempler fled Canada with his family and moved to Panama. However, local authorities in Naranja, Panama arrested him in June 2013 after INTERPOL was alerted of an outstanding U.S. warrant.²⁶ Strempler was then deported to Canada, but via a layover at Miami International Airport, where U.S. marshals arrested him after receiving notice from the Panamanian authorities. Strempler pleaded guilty to conspiracy to commit mail fraud and was sentenced to four years in prison in January 2013.²⁷

III. FDA’s Increased Appetite for Global Regulatory and Criminal Action

DOJ is not the only U.S. agency with the ability to seek information and cooperation outside of U.S. territory. Both on its own and in cooperation with DOJ, the FDA has steadily increased its activities abroad. The FDA has the ability and authority to regulate the conduct of a company outside of the United States so long as the company is introducing an FDA-regulated product into the U.S. One way in which the FDA enforces relevant laws is through on-site inspections of manufacturing facilities, which could be triggered by several distinct circumstances. When a company submits an application to the FDA to market a new product, the FDA may conduct a “pre-approval” inspection. If the FDA is made aware of a specific problem or complaint, the FDA may conduct a “for-cause” inspection. The FDA also conducts “routine” inspections to ensure compliance with relevant laws and regulations.²⁸

<https://www.justice.gov/opa/speech/us-attorney-general-loretta-e-lynch-delivers-remarks-press-conference-attorney-general> (noting pending extradition proceedings for ten defendants charged with corruption charges in the world of international soccer).

²² See U.S. DEP’T OF JUSTICE, UNITED STATES ATTORNEYS’ MANUAL § 9-15.210,

<https://www.justice.gov/usam/usam-9-15000-international-extradition-and-related-matters>.

²³ See Red Notices, INTERPOL, <https://www.interpol.int/INTERPOL-expertise/Notices/Red-Notices>.

²⁴ See *id.*

²⁵ Press Release, U.S. Dep’t of Justice, *Canadian Citizen Sentenced in Scheme to Defraud Consumers Purchasing Pharmaceuticals Online* (Jan. 9, 2013), <https://www.justice.gov/opa/pr/canadian-citizen-sentenced-scheme-defraud-consumers-purchasing-pharmaceuticals-online>.

²⁶ Christopher Weaver, *Former Internet Pharmacist Sentenced in Fake Drug Case*, WALL ST. J., Jan. 9, 2013, <http://www.wsj.com/articles/SB10001424127887324442304578232133556180830>.

²⁷ See *supra* note 25.

²⁸ What does FDA inspect?, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194888.htm>.

Finally, the FDA may conduct a “follow-up” inspection if a previous inspection resulted in significant observations, which are memorialized on an FDA Form 483 Notice of Inspectional Observations or in a Warning Letter. In the U.S., while “pre-approval” and “routine” inspections may be pre-announced, “for cause” and “follow-up” inspections are generally unannounced. Outside the U.S., inspections are often pre-announced due to a “potential waste of resources if the establishment is not operating or not producing the product in question, political sensitivities, availability of English speaking personnel, local holidays, etc.”²⁹

The FDA regularly conducts inspections of foreign manufacturing and processing sites for FDA-regulated products that are sold in the United States.³⁰ The FDA’s Guide to International Inspections and Travel indicates that these inspections “are essentially no different than those conducted domestically,” which are conducted in accordance with the FDA’s Investigations Operations Manual.³¹ The FDA maintains a dedicated Office of International Programs (“OIP”) within its Office of Global Regulatory Operations and Policy. OIP currently has offices in Beijing, China; New Delhi, India; San Jose, Costa Rica; Brussels, Belgium; and London, England.³² Through its foreign offices, and in close coordination with other branches of the FDA, including the Office of Regulatory Affairs, OIP collaborates with foreign regulators, obtaining foreign scientific and regulatory information and conducting inspections and investigations in foreign countries.

Refusal to cooperate with an FDA inspection overseas could result in severe consequences to pharmaceutical and medical device manufacturers. In particular, the FDCA deems adulterated a drug manufactured in a facility in which the owner/operator “delays, denies, or limits an inspection, or refuses to permit entry or inspection.”³³ For example, in December 2015, employees at Nippon Fine Chemical Co., Ltd. (“Nippon”) in Takasago City, Japan physically blocked investigators’ access to portions of a quality control laboratory and equipment used to analyze drugs by standing shoulder to shoulder in front of the area, as directed by a manager at the plant. Nippon employees also refused to allow FDA investigators to take photographs of manufacturing equipment and refused to provide copies of records documenting serious customer complaints. In response, and notwithstanding written responses from Nippon and Nippon’s counsel, the FDA placed Nippon on an Import Alert on August 8, 2016, and issued a Warning Letter to Nippon on September 26, 2016. The Import Alert provides that products from Nippon may be detained without physical inspection.³⁴ The Warning Letter further outlines significant consequences: (1) until the FDA is permitted to inspect the facility and confirm compliance with the FDA’s Current Good Manufacturing Practices, the FDA may withhold approval of new applications or supplements listing Nippon as a manufacturer; and (2) shipments of articles manufactured by Nippon are subject to refusal of admission into the United States.³⁵ The FDA recently issued similar warning letters in several other cases, two of which involved drug makers in China and one of which involved a drug maker in India.³⁶

²⁹ U.S. Dept. of Health and Human Servs. & Food and Drug Admin., Guide to International Inspections and Travel § 302.1 (2002), <http://www.fda.gov/ICECI/Inspections/ForeignInspections/ucm113565.htm>.

³⁰ See generally *id.*

³¹ See *id.* § 302.3; see also U.S. DEPT. OF HEALTH AND HUMAN SERVS, ET AL., INVESTIGATIONS OPERATIONS MANUAL (2016), <http://www.fda.gov/ICECI/Inspections/IOM/default.htm>.

³² OIP Offices, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/ucm245229.htm>. In addition to its headquarters in San Jose, Costa Rica, the Latin America office also has posts in Santiago, Chile and Mexico City, Mexico. *Id.*

³³ 21 U.S.C. § 351(j).

³⁴ Import Alert 99-32, U.S. FOOD AND DRUG ADMIN., http://www.accessdata.fda.gov/cms_ia/importalert_521.html.

³⁵ Letter from Francis Goodwin, Acting Dir., Office of Manufacturing Quality Office of Compliance Center for Drug Evaluation and Research, to Hiromichi Kaneko, General Mgr., Nippon Fine Chemical Co., Ltd., (Sept. 26, 2016), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm522801.htm>.

³⁶ Jeff Overley, *FDA Inspectors Letting Loose on Defiant Drugmakers*, LAW 360 (Nov. 4, 2016), <http://www.law360.com/articles/858520/fda-inspectors-letting-loose-on-defiant-drugmakers>.

While there are certain records and data that are beyond the FDA's inspectional authority reach, such as financial, personnel, and certain research data,³⁷ the FDA is generally permitted to conduct inspections of FDA-regulated facilities at reasonable times, within reasonable limits, and in a reasonable manner.³⁸ FDA intends to accept reasonable explanations for a delay, denial, or limitation of an FDA inspection including, for example, for facility closures due to scheduled maintenance, unavailability of key personnel, or unavailability of translated records.³⁹

The FDA has received heightened scrutiny from Congress regarding its oversight of global drug manufacturers, suggesting that global FDA inspections will only increase. In December 2015, leaders of the House Energy and Commerce Committee expressed concern that the FDA was exercising insufficient oversight with respect to drug manufacturing facilities in China and India, and asked the Government Accountability Office ("GAO") to investigate the same. Specifically, having noted that China had the largest number of foreign, FDA-registered drug manufacturing facilities (followed by India), Congress asked the GAO to look into the average inspection frequency for domestic drug manufacturers as compared to foreign drug manufacturers and the specific accomplishments of the FDA's foreign offices to date.⁴⁰ The GAO has not yet issued a report on this matter.

Similarly, FDA-OCI, the FDA's criminal investigative arm, has turned more of its attention abroad, with varied results to date.⁴¹ In one recent matter, FDA-OCI partnered with the U.S. Agency of International Development Office of Inspector General to investigate claims by a U.S.-citizen whistleblower who had worked in a research facility in India. The investigation resulted in a civil False Claims Act settlement agreement between DOJ and the U.S. subsidiary of the Indian generic pharmaceutical manufacturer, Ranbaxy Laboratories, and a criminal plea by the subsidiary to violations of the FDCA. The adulterated drugs at issue were manufactured at Ranbaxy's facilities in Paonta Sahib and Dewas, India.⁴²

By contrast, OCI undertook a four-year probe into unapproved oncology drugs as part of its effort to thwart "FUMPs" (foreign unapproved medical products).⁴³ As a result of this probe, the government brought criminal charges against suppliers and distributors of such drugs, "as well as more than two dozen doctors, nurses, office managers and clinics who bought the drugs and billed them to federal insurance programs."⁴⁴ Notwithstanding the more than 200,000 man hours spent on FUMP investigations (regarding oncology drugs, Botox, and otherwise), many were declined for prosecution or closed.⁴⁵

³⁷ 21 U.S.C. § 374(a).

³⁸ *Id.*; see also U.S. DEPT. OF HEALTH AND HUMAN SERVS. ET AL., GUIDANCE FOR INDUSTRY: CIRCUMSTANCES THAT CONSTITUTE DELAYING, DENYING, LIMITING, OR REFUSING A DRUG INSPECTION 2 (2014), <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM360484.pdf>.

³⁹ *Id.* at 6.

⁴⁰ See Letter from Fred Upton, Chairman, H.R. Rep. Comm. on Energy and Commerce, 114th Cong., to Gene L. Dodaro, Comptroller General, U.S. Gov't Accountability Office (Dec. 18, 2015), <http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Letters/20151218GAO.pdf>.

⁴¹ Accord Investigative Support, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/ICECI/CriminalInvestigations/ucm123040.htm> ("The increasing globalization of crime has created new challenges to law enforcement.").

⁴² Press Release, U.S. Dep't of Justice, *Japanese Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay \$500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA* (May 13, 2013), <https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false>; see also Second Amended Complaint at 12, *United States ex rel. Thakur v. Ranbaxy Labs. Ltd.*, Case No. JFM-07-962 (D. Md. June 15, 2012), ECF No. 45.

⁴³ Sarah N. Lynch, *FDA Criminal Office Draws Fire From Agents and Doctors Over Drug Import Crackdown*, REUTERS, Sept. 8, 2016, <http://www.reuters.com/investigates/special-report/usa-fda-cases/>.

⁴⁴ *Id.*

⁴⁵ *Id.*

While OCI is subject to the same constitutional jurisdictional hurdles as the FDA, hinging on whether a proposed activity affects interstate commerce, at least some in Congress seem eager for OCI to take on a larger international role. In March 2016, leaders of the House Energy and Commerce Committee sent a number of inquiries to FDA Commissioner Robert Califf regarding the FDA's investigation into heparin manufactured in China, noting that perpetrators who added a contaminant to the drug had still not been found.⁴⁶ Given this enhanced focus on international criminal acts that affect U.S. consumers and patients, ex-U.S. companies should be wary of more aggressive and efficient criminal investigations in which OCI partners with the well-tested DOJ.

IV. Navigating the International Reach of U.S. Enforcers: Practical Tips for Non-U.S. Companies

The increasingly global trend in DOJ enforcement actions suggests that health care and life sciences companies need to be prepared for enhanced scrutiny when their businesses have U.S. contacts. A company subject to scrutiny by DOJ may need to respond to searches and seizures, make witnesses available for interviews or testimony, and produce documents to U.S. regulators. Listed below are a few ways in which multinational health care and life sciences companies can be prepared to respond to, and minimize the risks of, potential U.S. enforcement and investigative actions abroad:

- **Make sure all international subsidiaries, affiliates, and other corporate entities know what to do when responding to a request or visit from a U.S. regulator.** In many cases, a company will find that it is the target of a DOJ inquiry only when regulatory officials show up at its doorstep. Companies under scrutiny will also need to respond to U.S. subpoenas or demands for documents.
 - Ensure that local company executives or legal officers know that any unusual requests or visits should be immediately reported to the global legal department. Affiliates and subsidiaries should be aware that a local regulator may be acting upon the bidding of a U.S. enforcer. Similarly, when a subpoena or demand for information is executed pursuant to an MLAT or otherwise, the U.S. regulators involved may not be immediately evident.
 - Create a dawn raid plan. Companies should circulate a protocol for how local employees should respond to regulatory inquiries where they may not be able to obtain immediate guidance from headquarters.
 - Conduct mock inspections and searches and seizures to make sure employees are aware of what to expect and how to act according to protocol. Run-throughs are particularly important for companies with manufacturing facilities that may be subject to FDA inspections.
 - Train the local legal team regarding what a request from a U.S. regulator may look like in their jurisdiction.
 - Document and file any requests and responses provided, so that the company maintains a clear record of the interaction.
- **Anticipate and plan for data privacy issues involved in transferring data internationally.** There are a host of data privacy issues to consider when transferring data to the U.S. from another country. In China, for example, rigorous state secrecy laws regulate the transfer of information and forbid exporting documents deemed by the state to constitute a "state secret," regardless of whether it is required by another country's laws or regulator.
 - Consider data access and transfer issues before establishing data systems. For example, data privacy issues should be considered when choosing a location for data servers and hosting email.

⁴⁶ See Letter from Fred Upton, Chairman, H.R. Rep. Comm. on Energy and Commerce, 114th Cong., to Robert M. Califf, Comm'r, Food and Drug Admin. (Mar. 29, 2016), <https://energycommerce.house.gov/sites/repUBLICans.energycommerce.house.gov/files/documents/114/letters/20160329FDA.pdf>.

- Before transferring information across country borders, consult with a data privacy or e-discovery expert about the potential risks involved.
- Consider international data privacy issues before discussing document production parameters with DOJ. DOJ attorneys will expect the company's counsel to navigate these issues prior to any document production.
- **Ensure training programs address both local and global legal risks and that they are administered to overseas entities and employees.** In addition to providing a protocol for visits from regulatory officials, companies should conduct training on local and global laws that apply to their operations. Training should be administered on a regular basis to account for changes in the law, adapted to include region-specific risks, and administered to all relevant employees.