UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES EXCHANGE ACT OF 1934
Release No. 84017 / September 4, 2018

ACCOUNTING AND AUDITING ENFORCEMENT
Release No. 3964 / September 4, 2018

ADMINISTRATIVE PROCEEDING
File No. 3-18708

In the Matter of

Sanofi,

Respondent.

ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS, PURSUANT TO SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING REMEDIAL SANCTIONS AND A CEASE-AND-DESIST ORDER

I.

The Securities and Exchange Commission ("Commission") deems it appropriate that public cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 21C of the Securities Exchange Act of 1934 ("Exchange Act"), against Sanofi ("Respondent").

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the "Offer") which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission's jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings, Pursuant to 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing Remedial Sanctions and a Cease-and-Desist Order ("Order"), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds[1] that

Summary

A. These proceedings arise out of Sanofi's violations of the internal accounting controls and recordkeeping provisions of the Foreign Corrupt Practices Act of 1977 (the "FCPA") [15 U.S.C. § 78m].

B. As described below, from at least 2011 to 2015, employees and agents of Sanofi's subsidiaries in Kazakhstan, Levant (which includes the countries Jordan, Lebanon, Syria, and the region of Palestine), and the Gulf (which includes the countries Bahrain, Kuwait, Qatar, Yemen, Oman, and the United Arab Emirates) acted to provide things of value to foreign officials, including healthcare professionals ("HCPs"), in order to improperly influence them and increase sales of Sanofi products.

C. The funds used for the illicit payments were generated through fake expenses for purportedly legitimate travel and entertainment expense, clinical trial and consulting fees, product samples, round table meeting expenses, distributor discounts, and credit notes to distributors which were improperly recorded as legitimate expenses in Sanofi's books and records. Throughout this period, Sanofi failed to devise and maintain a sufficient system of internal accounting controls and lacked an effective anti-corruption compliance program with regard to Kazakhstan, Levant, and the Gulf.

D. Deficiencies in the internal accounting controls and compliance program of Sanofi also led to similar improper conduct in connection with sales in other countries in which Sanofi operates.

Respondent

E. Sanofi is a corporation organized in France. Its headquarters are located in Paris, France. Sanofi issued and maintains a class of publicly traded securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, which have traded on the New York Stock Exchange since 2002.

F. Sanofi is a global pharmaceutical company and operates in over 100 countries. Sanofi employs approximately 107,000 people worldwide, at least 28 percent of whom are designated as sales force personnel.

[1] The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

Other Relevant Entities

G. **Sanofi-Aventis Kazakhstan LLP** ("Sanofi KZ") is a company organized in Kazakhstan. Sanofi KZ engages distributors in Kazakhstan to facilitate the sale and distribution of pharmaceutical products and maintains its own sales and marketing staff to promote Sanofi pharmaceutical products.

H. **Sanofi-Aventis Liban S.A.L.** ("Sanofi Levant") is a company organized in Lebanon. Sanofi Levant engages distributors in Levant to facilitate the sale and distribution of pharmaceutical products and maintains its own sales and marketing staff to promote Sanofi pharmaceutical products.

I. **Sanofi Aventis Gulf FZE** ("Sanofi Gulf") is a company organized in the United Arab Emirates. Sanofi Gulf is responsible for pharmaceutical operations in Bahrain, Kuwait, Qatar, Yemen, Oman, and the United Arab Emirates. Sanofi Gulf engages 31 distributors across the relevant countries to facilitate the sale of Sanofi pharmaceutical products and maintains its own sales and marketing staff to promote Sanofi pharmaceutical products.

Facts

Kazakhstan

J. Between 2007 and 2011, senior managers of Sanofi KZ engaged in a scheme to bribe foreign officials to corruptly influence the award of tenders at public institutions. The funds paid to foreign officials were derived from discounts and credit notes[2] extended to several distributors who colluded with senior managers to kick back funds to Sanofi employees in Kazakhstan which were then used to pay Kazakh officials.

K. The scheme took several stages to execute. First, senior managers of Sanofi KZ identified to a distributor a public tender for pharmaceuticals that could be filled by Sanofi products. Second, the distributor submitted a bid for the public tender and, when awarded, notified Sanofi of its need to purchase products to fulfill the tender. Third, the sale price between Sanofi and the distributor included a pre-determined discount or credit note from the sale price between the distributor and the public institution. Fourth, from the amount of the discount or credit note, Sanofi and the distributor were able to designate a portion as the funds which were used to bribe Kazakh officials. Fifth, once the funds which were used to bribe Kazakh officials were earmarked, the distributor kicked back those funds to Sanofi employees who then delivered the illicit proceeds to Kazakh officials. The scheme typically involved providing a 20-30 percent discount to the distributors, a portion of which was then used as the funds from which bribes were paid to Kazakh officials. The funds kicked back to Sanofi employees were tracked in internal spreadsheets and referred to as "marzipans."

[2] Credit notes are monies owed to a vendor by Sanofi. The vendor may apply the credit note(s) against monies the vendor owes to Sanofi and, in some cases, the vendor was able to exchange the credit note(s) for cash from Sanofi.

L. At the time, Sanofi had no standardized commercial policy for distributor discounts and did not review the discounts provided by local management. During the relevant period, tender sales increased by over 200 percent and included top selling products of Sanofi. The distributors involved in the conduct were some of the largest distributors by sales in Kazakhstan. As a result of the improper conduct in Kazakhstan, Sanofi derived profits equivalent to approximately USD 11,580,099.

Levant

M. From 2011 to 2013, employees and agents of Sanofi Levant participated in a series of schemes to pay foreign officials to boost sales of Sanofi products through increased prescriptions. The schemes included sponsorships, gifts, donations, product samples, consulting agreements, peer-to-peer meetings, clinical studies, and grants. The schemes were executed across the various business lines in Levant and included the top selling products of Sanofi in the region. Some of the schemes involved the participation by senior managers of Sanofi Levant. The instances of improper conduct were not isolated and spanned across government agencies as well as private institutions.

N. An example of the corrupt conduct is a 2012 request by an HCP of a large public hospital in Jordan for 24 vials of Taxotere as product samples. At the time, corporate policy for product samples required a medical justification. Taxotere is a product used to treat cancer and is one of the most expensive products sold in Levant. The oncology manager requested a justification from the sales representative and was told

> [HCP] is a KOL [key opinion leader] Doctor, our Consumption in [hospital] is 124 vials, But we Don't Give Dr.s in Institution Pt.Support [in public hospital product samples for patients]. But He Asked as a Favor.

The oncology manager then approved the request. Medical Affairs was not involved in reviewing or approving the request and no justification was provided regarding the medical use or appropriateness. The quantity provided as samples was nearly 20 percent of the hospital's purchases. The HCP requesting the samples was a tender committee member at the hospital.

O. The same HCP requesting samples of Taxotere in 2012 was also provided with consulting, speaking, and clinical trial fees over a period of years despite the lack of documentation of other support to demonstrate the services had been provided. Sanofi paid to the HCP the equivalent in local currency of USD 28,900 in consulting fees and, USD 5500 in speaking fees. Sanofi also paid to the HCP USD 125,997 in clinical trial fees. The consulting fees were purportedly related to hosting events and training for HCPs in Iraq. No supporting documentation was found for any of the purported consultancy services. While the clinical trial fees were approved by Medical Affairs, the HCP has never provided reports of findings or observations. The HCP, who provided the ostensible speaking, consulting, and clinical trial services to Sanofi, requested that the consulting and clinical trial fees be paid by check to an unrelated individual. Sanofi accommodated the request to pay the unrelated individual without explanation or justification.

P. The practice of engaging as consultants influential HCPs who provided vague services was also performed with HCPs in the private sector. As an example, Sanofi Levant retained as a consultant the services of a prominent pharmacist in Lebanon for several years through 2013. The pharmacist received annual payments denominated in United States dollars of no less than USD 42,000 and in a five-year period received a total of USD 237,300. The consulting services required included preparing training programs and conducting speaking events however, evidence of the receipt of those services is sparse or nonexistent. Sanofi failed to require sufficient documentation of the performance of services before making payments to its consultants.

Q. As a result of the improper conduct in Levant, Sanofi derived profits equivalent to approximately USD 4,200,000.

The Gulf

R. In the countries comprising Sanofi Gulf, sales managers and medical representatives in the Primary Care business unit engaged in a long-standing scheme to submit false travel and entertainment reimbursement claims, pool the illicit proceeds of the false schemes, and distribute the illicit proceeds to HCPs in the private sector in order to increase prescriptions of Sanofi products.

S. The false travel and entertainment claims were made in connection with fake round table meetings with HCPs and facilitated by fake receipts issued by collusive vendors known to facilitate such activity. The scheme was quite simple and involved local sales managers. Medical representatives were instructed by their sales managers to submit a doctored receipt for a round table meeting that never occurred. Medical representatives then submitted a doctored receipt for reimbursement as a legitimate travel and entertainment expense. The sales managers approved the travel and entertainment expense submission and the medical representatives were reimbursed. Medical representatives gave the sales managers the illicit proceeds from the fraudulent reimbursement and then pooled the illicit proceeds together into a slush fund to pay HCPs. Managers tracked the incoming pool of illicit proceeds from medical representatives and the disposition of illicit proceeds to HCPs who were paid to increase prescriptions of Sanofi products.

T. The Primary Care business unit was responsible for several high sales volume products in the Gulf. The scheme employed by sales managers and medical representatives was executed from at least 2012 to 2015. One medical representative estimated that 70 percent of the travel and entertainment expense submissions of the Primary Care business unit were related to the scheme. From 2012 to 2015, Sanofi Gulf spent the equivalent of approximately USD 4 million for round table meetings with HCPs, although only a portion was used in the scheme.

U. In a 2015 internal audit of commercial operations in the Gulf, one of the findings concerned the lack of monitoring of outsourced distributor promotional activities. An example of a specific risk identified in the report included: "Interactions with HCPs organized by the outsourced sales force are not compliant with Sanofi guidelines. Selection of HCPs, attendance list and detailed hospitality costs were neither documented nor reviewed by Sanofi." Similar control weaknesses and failures in documentation of round table meetings conducted by distributors on behalf of Sanofi were found. Another finding identified the many internal control lapses, including

the use of cash to make payment to HCPs, surrounding round table meetings conducted by Sanofi itself and lack of documentation and approvals related to attendance of round table meetings. A full audit of the commercial operations in the Gulf had not been conducted since 2007, eight years earlier.

V. As a result of the improper conduct in the Gulf, Sanofi derived profits equivalent to approximately USD 1,751,567.

W. As a result of the conduct described above, Sanofi violated Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act. Sanofi violated Section 13(b)(2)(A) of the Exchange Act by falsely recording improper payments made by employees and agents as legitimate selling and marketing expenses, whose results were then consolidated and reported by Sanofi on its consolidated financial statements. Sanofi also violated Section 13(b)(2)(B) by failing to devise and maintain sufficient accounting controls to detect and prevent the making of improper payments to foreign officials.

Sanofi's Remedial Efforts

X. In determining to accept the Offer, the Commission considered remedial acts promptly undertaken by Respondent and cooperation afforded the Commission staff.

1. During the course of the investigation, Respondent provided regular briefings regarding the facts developed in its internal investigation in Kazakhstan, Levant, and the Gulf, and with respect to other countries. Respondent timely conveyed the facts it learned in the course of its investigation, including facts that the Commission would not have been able to readily and independently discover, produced and highlighted particularly relevant documents, promptly responded to additional requests by the Commission staff, and provided translations of documents as needed.

2. Respondent also provided information regarding its remedial efforts, enhancements to its compliance program and implementation of initiatives. Prior to the Commission's investigation, Respondent had begun independently enhancing its compliance program by, among other things, developing a centralized compliance program, revamping its internal controls and procedures over HCP expenditures, increasing the number of its compliance officers globally, enhancing the operation of local compliance committees, and placing compliance personnel in high-risk local markets. Additionally, it enhanced its (1) policies governing interactions with HCPs and government officials, gifts, travel, meetings, congresses, contributions, and ISTs; (2) anti-corruption training, audits, and due diligence procedures for third-party agents; and (3) monitoring for certain Sanofi-sponsored events for HCPs. Respondent also reports that it has terminated 121 employees, including senior local business managers, accepted resignations from another 14 employees, and disciplined 49 employees.

Undertakings

Y. Respondent undertakes to cooperate fully with the Commission in any and all investigations, litigation, or other proceedings relating to or arising from the matters described in this Order. In connection with such cooperation, Respondent shall:

1. produce, without service of a notice or subpoena, any and all nonprivileged documents and other information requested by the Commission staff subject to any restrictions under the law of any foreign jurisdiction;

2. use its best efforts to cause its current or former officers, employees, agents, and directors to be interviewed by Commission staff at such times and places as the staff reasonably may direct; and

3. use its best efforts to cause its current or former officers, employees, agents, and directors to appear and testify without service of a notice or subpoena in such investigations, depositions, hearings, or trials as may be requested by the Commission staff.

Z. Respondent undertakes to report on the status of its remediation and implementation of compliance for a period of at least two years. During this two-year period, Respondent shall conduct and prepare self reviews, as well as related follow-up, and submit written reports of the results, as set forth in the Compliance Program Review Plan ("Plan") submitted with its Offer of Settlement and report to the Commission staff as outlined below:

1. Respondent shall submit to the Commission staff a written report within six (6) months of the entry of this Order setting forth a complete description of its Foreign Corrupt Practices Act ("FCPA") and anti-corruption related remediation efforts to date, its proposals reasonably designed to improve the policies and procedures of Respondent for ensuring compliance with the FCPA and other applicable anticorruption laws, and the parameters of the subsequent reviews (the "Initial Self Report"). The Initial Self Report shall be transmitted to Charles Cain, FCPA Unit Chief, Division of Enforcement, United States Securities and Exchange Commission, 100 F St NE, Washington, DC 20549. Respondent may extend the time period for issuance of the Initial Self Report with prior written approval of the Commission staff.

2. Respondent shall undertake two (2) follow up reviews (the "Follow up Self Reports"), incorporating any comments provided by the Commission staff on the previous report(s), and following up on matters identified in earlier reports, to further monitor and assess whether the policies and procedures of Respondent are reasonably designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws.

3. The first Follow up Self Report shall be completed by no later than seven months after the Initial Self Report. The second Follow up Self Report shall be

completed by no later than seven months after the first Follow up Self Report. Respondent may extend the time period for issuance of the Follow up Self Reports with prior written approval of the Commission staff.

AA. Should Respondent during the period of the undertakings discover credible evidence, not already reported to the Commission staff, that questionable or corrupt payments or questionable or corrupt transfers of property or interests may have been offered, promised, paid, or authorized by Respondent entity or person, or any entity or person while working directly for Respondent, or that related false books and records have been maintained, Respondent shall undertake to promptly report such conduct to the Commission staff.

BB. The periodic reviews and reports submitted by Respondent will likely include proprietary, financial, confidential, and competitive business information. Public disclosure of the reports could discourage cooperation, impede pending or potential government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain non-public, except (1) pursuant to court order, (2) as agreed by the parties in writing, (3) to the extent that the Commission staff determines in its sole discretion that disclosure would be in furtherance of the Commission's discharge of its duties and responsibilities, or (4) is otherwise required by law.

CC. During this two-year period of review, Respondent shall provide its external auditors with its annual internal audit plan and reports of the results of internal audit procedures and its assessment of its FCPA compliance policies and procedures.

DD. During this two-year period of review, Respondent shall provide the Commission staff with any written reports or recommendations provided by Respondent's external auditors response to Respondent's annual internal audit plan, reports of the results of internal audit procedures, and its assessment of its FCPA compliance policies and procedures.

EE. Respondent shall certify, in writing, compliance with the undertaking(s) set forth above. The certification shall identify the undertaking(s), provide written evidence of compliance in the form of a narrative, and be supported by exhibits sufficient to demonstrate compliance. The Commission staff may make reasonable requests for further evidence of compliance, and Respondent agrees to provide such evidence. The certification and supporting material shall be submitted to Charles Cain, Unit Chief, FCPA Unit, Division of Enforcement, with a copy to the Office of Chief Counsel of the Enforcement Division, no later than sixty (60) days from the date of the completion of the undertakings.

FF. In determining whether to accept the Offer, the Commission has considered these undertakings.

IV.

Accordingly, pursuant to Section 21C of the Exchange Act, it is hereby ORDERED that:

A. Respondent cease and desist from committing or causing any violations and any future violations of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Securities Exchange Act of 1934 [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

B. Respondent shall, within 10 days of the entry of this Order, pay disgorgement of USD 17,531,666 and prejudgment interest of USD 2,674,479 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment is not made, additional interest shall accrue pursuant to SEC Rule of Practice 600. Respondents shall, within 10 days of the entry of this Order, pay a civil money penalty in the amount of USD 5,000,000 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. § 3717.

Payment must be made in one of the following ways:

(1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;

(2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at http://www.sec.gov/about/offices/ofm.htm; or

(3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center
Accounts Receivable Branch
HQ Bldg., Room 181, AMZ-341
6500 South MacArthur Boulevard
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying Sanofi as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Charles Cain, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Mailstop 5631, Washington, DC 20549.

C. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil

penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

D. Respondent acknowledges that the Commission is not imposing a civil penalty in excess of $5,000,000 based upon its cooperation in a Commission investigation or related enforcement action. If at any time following the entry of the Order, the Division of Enforcement ("Division") obtains information indicating that Respondent knowingly provided materially false or misleading information or materials to the Commission, or in a related proceeding, the Division may, at its sole discretion and with prior notice to the Respondent, petition the Commission to reopen this matter and seek an order directing that the Respondent pay an additional civil penalty. Respondent may contest by way of defense in any resulting administrative proceeding whether it knowingly provided materially false or misleading information, but may not: (1) contest the findings in the Order; or (2) assert any defense to liability or remedy, including, but not limited to, any statute of limitations defense.

E. Respondent shall comply with the undertakings enumerated in Section III, paragraphs Z through FF above.

By the Commission.

Brent J. Fields
Secretary