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ΕΙΣΑΓΓΕΛΙΑ ΕΦΕΤΩΝ ΑΘΗΝΩΝ
ΓΡΑΦΕΙΟ ΕΙΣΑΓΓΕΛΙΑΣ ΕΚΚΛΗΣΙΑΣ ΔΙΑΦΘΟΡΑΣ

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U.S. Embassy
Athens, Greece

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Mrs. Meleni Raikou
Hellenic Ministry of Justice
Supreme Court
Corruption Unit
Public Prosecutor's Office
K. Loukareos 14
Athens, Greece 11522

u. A. Ερωτησίαν
18-1-17

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΔΙΚΑΙΟΣΥΝΗΣ

RE: Novartis

Mrs. Raikou:

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(U//REL TO USA, GRC) The below information provided herein is information received via initial complaint and/or during the course of our interviews with the Whistleblowers in December 2016.

Novartis AG (Novartis) is a global healthcare company that provides pharmaceutical and over-the-counter health products in over 180 countries. Novartis is organized under the laws of Switzerland, with its principal place of business located in Basel, Switzerland. Novartis issued and maintains a class of publicly traded securities registered pursuant to Section 12(b) of the Securities and Exchange Act of 1934, which are traded on the New York Stock Exchange (Ticker Symbol: NVS). Novartis is an "issuer" within the meaning of the FCPA.

Novartis conducts business in Greece solely through its subsidiaries, including, Novartis (Hellas) S.A.C.I (Novartis Greece), which is located in Metamorphosis, Athens, Greece. Among other services, Novartis Greece (NVG) conducts the sales and marketing activities of Novartis'

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pharmaceutical products in Greece. NVG is a wholly owned subsidiary of Novartis and is the largest pharmaceutical and consumer healthcare company in Greece with annual revenues in excess of \$524 million.

On or about August 23, 2016, FBI was contacted by Department of Justice (DOJ) attorneys regarding a complaint submitted to the SEC regarding bribery of, or improper payments to foreign officials, and internal controls/books and records deficiencies by NVG.

From approximately 2008 through at least 2014, NVG, by and through its employees, agents, and subsidiaries, offered and paid improper bribes to foreign officials in Greece, including regulators, physicians, and healthcare providers employed by the Greek government, in connection with its Greek operations.

During the course of this bribery scheme, NVG has made or caused to be made millions of dollars in improper payments to foreign officials to obtain or retain business in Greece. These payments were intended to, for example, to influence regulatory and formulary approvals, drug pricing, purchase decisions, prescription decisions, and the outcomes of clinical trials with respect to drugs manufactured by Novartis and sold in Greece. For example, drugs manufactured by Novartis were Aclasta, Diovan, Exelon, Exforge, Extavia, Foradil, Galvus, Eucreas, Gilenya, Onbrez, Stalevo, Trileptal, and Xolair. Under the International Pricing System, Greece serves a drug pricing reference for at least 29 other countries, including Austria, Belgium, Spain, Turkey, Bulgaria, the Czech Republic, Estonia, Hungary, Italy, Germany, Romania, Slovakia, Finland, Albania, Macedonia, Russia, Brazil, Mexico, Saudi Arabia, Bahrain, Kuwait, Iran, Algeria, Oman, Bolivia, South Korea, Jordan, Egypt, and New Zealand. Novartis' bribery scheme in Greece has generated hundreds of million dollars in revenue for Novartis and complainants believe the scheme is currently ongoing within NVG.

Complainants (hereinafter C1 and C2) are both citizens of Greece and provided the following information: C1 was employed by Novartis (Hellas) S.A.C.I (NVG) from approximately June 2008 through October 2014 as the Head of Communications and Corporate Responsibility. In this capacity, C1 was responsible for media and public relations, brand communications, and market access initiatives in Greece. C1 regularly worked with senior executives throughout NVG, including senior executives responsible for increasing NVG's access to the prescription drug sales market in Greece, in developing and implementing media and marketing strategies.

C2 was employed by NVG from approximately November 2006 through March 2013, first as a Sales Representative and later was promoted to First Line Sales Manager. In both capacities, C2 was responsible for the growing sales market for a variety of Novartis products throughout Greece. In or around March 2013, C2 transferred to Novartis' generic drug division, Sandoz, where he served in several roles, including Area Sales Manager. C2 left the company in or around December 2014.

Both complainants' job responsibilities placed them in a unique position to have knowledge of and access to key evidence regarding bribes paid by NVG to foreign officials in Greece, including, for example, internal Novartis emails, PowerPoint presentations, spreadsheets, and other documents detailing NVG's scheme to pay bribes to government officials in return for

prescribing Novartis products, spreadsheets containing names, amounts, and dates of payments to specific government officials, and spreadsheets showing inflated payments to media companies used to launder money for the purpose of bribing government officials. Documents detailing the business NVG expected to retain or maintain as a result of the illegal bribes were maintained as well.

During the relevant period, Novartis' pharmaceutical products were promoted in Greece by Novartis' wholly owned subsidiary, NVG. Greece operates a national healthcare system through which the government regulates the manufacture, approval distribution, and sale of prescription drugs. Greece administers its national healthcare system through various ministries, agencies and departments (collectively, "Greek Healthcare Agencies"), to include the following:

- Ministry of Health and Social Solidarity (MoH), who oversees all healthcare programs and providers in Greece. National Organization for Healthcare Services Provision (EOPYY), and agency of MoH, oversees healthcare reimbursement in Greece.
- Ministry of Labor, Social Insurance and Social Solidarity (MoL), manages health coverage and drug pricing under Greece's Social Security Fund. Service for the Control of Social Security Health Costs (YPEDYFKA), an agency of MoL, who is responsible for managing drug pricing for the Social Security Fund.
- National Organization for Medicines (EOF), regulates the healthcare industry in Greece. It is responsible for issuing licenses, drug approvals, compliance, and setting prices for reimbursement of medical services and prescription drugs. EOF works in conjunction with Social Security Fund to administer reimbursement to medical and pharmaceutical manufacturers, physicians, pharmacists, hospitals, and other healthcare providers.

From approximately 2008 through 2014, NVG, through its employees and agents, provided cash payments and international travel to influential government officials in Greece holding senior position in the Greek government, including the Greek Healthcare Agencies. NVG's payments of cash and other things of value were intended to influence these government officials to obtain or retain business, including regulatory and formulary approvals, favorable drug pricing, pharmaceutical purchasing decisions, prescription decisions, and to influence the outcome of clinical trials.

Greek Government Officials:

1. NIKO MANIADAKIS (MANIADAKIS) – Senior Consultant to MoH and Novartis and Professor and Associate Dean for the National School of Public Health
 - MANIADAKIS had direct connects with the National Organization for Medicines (EOF), who regulates the healthcare industry in Greece. Responsibilities of EOF includes issuing licenses, drug approvals, and setting and controlling pricing. MANIADAKIS used his connections within EOF to benefit Novartis Greece (NVG). From approximately 2009-2012, MANIADAKIS received 20-40K Euros per project, according to an consultancy agreement with NVG. MANIADAKIS received this money through laundering and was the main collector for MoH.

- KONSTANTINOS FROUZIS (KEY PLAYER), former Vice President and Head of Communications, Market Access, Business Development and Licensing for NVG, was in direct contact with MANIADAKIS. FROUZIS gave cash to MANIADAKIS, who then paid cash to Deputy Ministers. This money came from the Market Tax Department (Pricing and Reimbursement). The money involved in the scheme was referred to as "Black Money." The Country President of Greece/Head of Marketing & Sales and Vice President of Head of Communications were aware of this scheme and discussed efforts on how to distribute the money.

NOVARTIS LINTZERIS (LINTZERIS) – Member of Greek Parliament and former EOF President

- In or around September 2013, LINTZERIS met with FROUZIS to discuss issues regarding pharmaceutical policies. During their first meeting, LINTZERIS told FROUZIS that he had a favor to ask of him. The favor was to support a friend of LINTZERIS' to strengthen his media group. This media group was MAVRIKOS MEDIA. This information was passed along to Whistleblower #1 (WB1), who was tasked with pursuing MAVRIKOS MEDIA over VOULKIDIS MEDIA. WB1 would collect money from MAVRIKOS by envelope. Between September 2013 and July 2014, WB1 met in PIRAEUS at a Greek yacht club to receive payments.
 - After the money was received, WB1 gave the money to FROUZIS at the Novartis office. Companies were created by MAVRIKOS in order to receive money from NVG. In order to show that MAVRIKOS did not receive the money into one company, smaller companies were created, to include websites which lead to fake companies.
 - In 2014 LINTZERIS managed to block other products of competitors while NVG's drug, Gileyna prospered. Other Novartis products pushed through were Seebri and Ultibro.
3. MARY GEITONA – Associate Professor in Health Economics at the University of Peloponnese and affiliate of the Greek chapter of ISPOR
- ISPOR Congresses is an annual conference held for Health Economics and studies related to Health Economics. Novartis created a list of individuals to attend the conference. Typically, each company would send two people to attend the conference. In 2011, Novartis sent 30 delegates (government officials) to Berlin, Germany. The treasurer of ISPOR at the time was MAGDALINI HATZIKOU (HATZIKOU).
 - GEITONA put together travel packages on behalf of NVG for ISPOR events. An investigation was initiated into Novartis by SEEYP, a police agency in Greece, who monitors control of healthcare and searches for corruption within hospitals; described as the "Rambo of Healthcare." The report of the investigation revealed that Novartis funded the trip of the 30 delegates and 10 Novartis employees. GEITONA denied everything in a statement. Novartis had to do "crisis management," which was led by WB1. During this investigation, FROUZIS told WB1 to use his Gmail account and not his Novartis account because "the noise"

may affect Novartis. Novartis Head told team not to issue any statement, but to draft one and hold it.

- GEIOTONA's email: marygeitona@gmail.com
4. PARASKEVI SAKKA (SAKKA) – President of the National Center for Dementia and Alzheimer's disease Association
 - Grants were given to the Alzheimer Association in order to protect prices of Novartis products. SAKKA is also categorized as a A-1 doctor for Novartis, which is a high prescribing doctor for Novartis products.

Media Companies:

1. VOULKIDIS MEDIA – A Greek media group owned and operated by EMMANOUIL VOULKIDIS (VOULKIDIS)
 - VOULKIDIS was a vendor of Novartis from approximately 2009 through 2013. Money was hand delivered from VOULKIDIS to FROUZIS through WB1. From the total amount of money paid to VOULKIDIS, 40% would be returned to FROUZIS in cash, inside an envelope and the other 60% was used for actual expenses. WB1 would meet VOULKIDIS in Vrilissia, Greece on Sunday mornings for coffee to get the money from VOULKIDIS.
2. HEALTHDAY – A Greek media company owned and operated by EFTHYMIOS K TENIDIS (KTENIDIS)
 - FROUZIS' son, DIMITRIOS FROUZIS worked for HEALTHDAY as a consultant from approximately 2011 through 2014. FROUZIS's son never showed up to work or did any work for HEALTHDAY, but was still paid.
 - Similarly to the money exchange between VOULKIDIS and FROUZIS, but in smaller amounts, KTENDIS would pay cash to FROUZIS as a 60%/40% split for services and return amount.
3. ETHOS MEDIA – A Greek media company owned and operated by KONSTANTINOS OUZOUNIS (OUZOUNIS)
4. MAVRIKOS MEDIA – A Greek company owned and operated by PANAYIOTIS MAVRIKOS.
 - MANIADAKIS was close to ETHOS MEDIA and when NVG gave business to ETHOS MEDIA, MANIADAKIS was happy and so was everyone else (NFI). MAVRIKOS MEDIA owned the publication "Akropolis." Novartis utilized ZENITH Optimedia to receive payments from newspapers. Instead of direct payments, the newspaper would pay ZENITH and ZENITH would pay Novartis. The idea behind this form of payment was to use one vendor instead of separate vendors globally. ZENITH would be used for consulting services about how to spend communication group funds and provided all invoices and logistics.

Travel Agencies:

1. HELLENIC TOURS
 - The relationship between HELLENIC TOURS and Novartis existed since its inception in 2006.
2. TRAVEL PLAN (NFI)

3. FREI TRAVEL

- NVG mainly used FREI travel agency for package pricing for NVG. The owner of FREI is NIKI GARGASOULA (GARGASOULA). FREI had control of bank accounts of NVG. Approximately 10-15 years ago, FREI was used by other companies to pay doctors. The Purchasing Department was in charge of travel plans. The Purchasing Manager was ELENI ZOCHIOU and her successor is MATINA TSIKOU (TSIKOU). TSIKOU was responsible for choosing to do business with FREI instead of HELLENIC TOURS.

Note: Itineraries were given to travel agencies used by NVG to hand out to doctors at the airport for International Congresses to show alternate plans for the trip.

Sincerely,



Aristides Papadacos
Legal Attaché
U.S. Embassy Athens