

2017R00136/BJC/JLH

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA	:	Criminal No. 20-538
	:	
v.	:	18 U.S.C. § 371
	:	
NOVARTIS HELLAS S.A.C.I.	:	

I N F O R M A T I O N

The United States charges that, at all times relevant to this Information, unless otherwise specified:

GENERAL ALLEGATIONS

Relevant Statutory Background

1. The Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, *et seq.* (the “FCPA”), was enacted by Congress for the purpose of, among other things, making it unlawful to act corruptly in furtherance of an offer, promise, authorization, or payment of money or anything of value, directly or indirectly, to a foreign official for the purpose of obtaining or retaining business for, or directing business to, any person. In addition, the FCPA’s accounting provisions, among other things, require every issuer of publicly traded securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78l, or required to file periodic reports with the United States Securities and Exchange Commission (“SEC”) under Section 15(d) of the Securities Exchange Act, 15 U.S.C § 78o(d), to make and keep books, records, and accounts that accurately and fairly reflect transactions and the distribution of the company’s

assets, and prohibit the knowing and willful falsification of an issuer's books, records, or accounts. 15 U.S.C. §§ 78m(b)(2)(A), 78m(b)(5), and 78ff(a).

NOVARTIS HELLAS and Other Relevant Entities and Individuals

2. Defendant Novartis Hellas S.A.C.I. ("NOVARTIS HELLAS") was a Greek corporation headquartered in Athens, Greece and a wholly-owned subsidiary of Novartis AG, a global pharmaceutical company based in Basel, Switzerland. Among other lines of business, NOVARTIS HELLAS sold and marketed Novartis-branded prescription drugs in Greece. Novartis AG's American Depositary Shares were listed and traded on the New York Stock Exchange under the symbol "NVS." Novartis AG was an issuer of publicly traded securities registered pursuant to Section 12(b) of the Securities Exchange Act and was required to file periodic reports with the SEC under Section 13 of the Securities Exchange Act. Thus, Novartis AG was an "issuer" within the meaning of the FCPA, 15 U.S.C. §§ 78dd-1(a) and 78m(b). NOVARTIS HELLAS's books, records, and accounts were included in the consolidated financial statements of Novartis AG filed with the SEC.

3. "Novartis Hellas Employee 1," an individual whose identity is known to the United States, was a manager at NOVARTIS HELLAS between in or about January 2011 and in or about 2015.

4. "Novartis Hellas Employee 2," an individual whose identity is known to the United States, held various positions at NOVARTIS HELLAS between in or about 2012 and in or about 2015.

The Greek Health Care System, Greek Entities, and Foreign Officials

5. Greece owned and operated state-owned and state-controlled hospitals and clinics, and these hospitals and clinics performed a state function. Individuals employed by these hospitals and clinics were “foreign officials” within the meaning of the FCPA, 15 U.S.C. § 78dd-3(f)(2)(A).

6. “Greek State-Owned Clinic,” an entity whose identity is known to the United States, was a state-owned and state-controlled medical clinic located in Athens, Greece that performed functions that Greece treated as its own, and thus was an instrumentality within the meaning of the FCPA, 15 U.S.C. § 78dd-3(f)(2)(A).

7. “Greek HCP 1,” an individual whose identity is known to the United States, was a health care provider (“HCP”), an employee of Greek State-Owned Clinic, and a “foreign official” within the meaning of the FCPA, 15 U.S.C. § 78dd-3(f)(2)(A).

Overview of the Unlawful Schemes

8. During the relevant time periods set forth below, NOVARTIS HELLAS, through its employees and agents, knowingly and willfully conspired and agreed to corruptly provide improper benefits and things of value to employees of state-owned and state-controlled hospitals and clinics in Greece (“Greek State HCPs”) and other HCPs in Greece with the intent to obtain an improper advantage and to increase sales of a certain Novartis-branded prescription drug in Greece. Specifically, NOVARTIS HELLAS sponsored Greek

State HCPs to attend international congresses as a means to bribe and corruptly influence the HCPs to increase prescriptions of Lucentis.¹

9. During the relevant time periods set forth below, NOVARTIS HELLAS, through its employees and agents, also knowingly and willfully conspired and agreed to cause certain payments to be falsely recorded in Novartis AG's books, records, and accounts. Specifically, NOVARTIS HELLAS falsely recorded as legitimate advertising and promotion expenses: (a) corrupt payments related to the international congresses described above; and (b) improper payments to HCPs related to an epidemiological study intended to increase sales of certain Novartis-branded prescription drugs. These records were consolidated into Novartis AG's financial records and used to support Novartis AG's financial reporting to the SEC. As such, NOVARTIS HELLAS, through its employees and agents, caused these payments to be falsely recorded in Novartis AG's books, records, and accounts.

10. During this time period, NOVARTIS HELLAS recognized at least \$71.48 million in profits, as calculated for the purposes of the U.S. Sentencing Guidelines, from sales of Lucentis in Greece and from sales of Novartis-branded prescription drugs related to the epidemiological study.

¹ Lucentis was a prescription drug sold by NOVARTIS HELLAS in Greece that is approved for several indications, including to treat adults with neovascular (wet) age-related macular degeneration.

Details of the International Medical Congress Scheme

11. Between in or about 2012 and in or about 2015, NOVARTIS HELLAS paid for public and private ophthalmologists in Greece to attend international “medical congresses.” These congresses were organized by various medical associations in the United States and Europe, and typically took place over several days in a destination city in the United States or Europe.

12. By sponsoring Greek State HCPs to attend congresses, NOVARTIS HELLAS paid for the costs associated with that Greek State HCP’s attendance, such as airfare, hotel accommodations, and congress registration fees. NOVARTIS HELLAS typically paid for travel costs associated with congresses through third-party travel agencies. For each individual Greek State HCP, the total cost to NOVARTIS HELLAS for attendance of an international congress often exceeded \$6,000.

13. NOVARTIS HELLAS’s policies stated that the purpose for sending HCPs to congresses was to provide scientific or educational information. In reality, however, sales employees at NOVARTIS HELLAS, including Novartis Hellas Employee 1, sometimes used international congresses to improperly influence and induce Greek State HCPs to increase prescriptions for Lucentis.

14. As part of the scheme, NOVARTIS HELLAS maintained internal documentation noting that HCPs with the highest potential and highest propensity to prescribe Lucentis would receive “investments,” such as

sponsorships to attend international congresses, while HCPs with lower potential and less propensity to prescribe Lucentis would receive no such “investments.”

15. The use of congresses as a means to improperly influence and induce Greek State HCPs to prescribe Lucentis was discussed and documented at NOVARTIS HELLAS. For example, on or about September 27, 2012, NOVARTIS HELLAS’s Lucentis Brand Team held a meeting to discuss the sales strategy for Greek State HCPs. Among other attendees, Novartis Hellas Employee 1 and Novartis Hellas Employee 2 participated in the meeting. In the written minutes from this meeting (the “Minutes”), a section entitled “Increase Pressure in [sic] HCPs” reflected NOVARTIS HELLAS’s intent to use specific international congress sponsorships to corruptly influence Greek State HCPs. In particular, the Minutes stated that Greek State HCPs “must understand that their participation in [specific congresses in the United States and Europe] will be cancelled if sales performance is not improved significantly.”

16. The Minutes further explained that NOVARTIS HELLAS’s message that it would withdraw its international congress sponsorships based on poor Lucentis sales performance “must also be discussed with [sales] REPs in the next Sales team [meeting]. REPs must make clear to their [HCP] customers that Lucentis is facing real difficulties in the market and for this reason there will be serious consequences.”

17. The Minutes referred to a certain U.S.-based ophthalmology association that organized a congress in the United States (the “U.S. Academy”).

Sales employees in NOVARTIS HELLAS's ophthalmology business unit sent selected HCPs, including Greek State HCPs, to the U.S. Academy's congress, and employees of NOVARTIS HELLAS traveled to the United States and, while located in the United States, facilitated the attendance of the Greek State HCPs at the U.S. Academy's congress as a method to corruptly influence the HCPs.

18. In or about January 2013, Novartis Hellas Employee 1 prepared a presentation entitled "Action Plan KOLs" which detailed the various means through which Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to target various "Top KOLs," or Key Opinion Leaders, in ophthalmology (the "Action Plans").

19. One such Action Plan targeted Greek HCP 1, who worked at the Greek State-Owned Clinic. The Action Plan set forth how Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to use certain "actions"—including sponsorship to U.S. congresses—to induce Greek HCP 1 to prescribe Lucentis. The "Target" was to "increase" Greek HCP 1's "loyalty" to NOVARTIS HELLAS and "chan[ge] [HCP 1's] mindset about cooperation." As described in the Action Plan's "Strategy-Actions" section, Novartis Hellas Employee 1 and others at NOVARTIS HELLAS sought to achieve this objective through, among other "actions," "tak[ing] advantage of [the U.S. Academy's] congresses."

20. The Action Plan further stated that Novartis Hellas Employee 1 and others at NOVARTIS HELLAS should convey the following message to Greek HCP 1: “to get you must write. No presents anymore.”

21. The Action Plan indicated that Novartis Hellas Employee 1 would “ASK HIM ALL,” meaning that the goal was to capture 100% of Greek HCP 1’s ophthalmology prescriptions for which Lucentis could be prescribed.

22. In or about late 2013, employees of NOVARTIS HELLAS traveled to the United States and, while located in the United States, facilitated the attendance of Greek HCP 1 and others at the U.S. Academy’s congress in New Orleans, Louisiana.

23. In addition to Greek HCP 1, an Action Plan written by Novartis Hellas Employee 1 stated that NOVARTIS HELLAS’s ophthalmology business unit would “[l]ower investment [in another Greek State HCP] as a penalty for [Lucentis injection] loss” while making their “motive (large investment)” visible to the HCP. To generate increased Lucentis prescriptions from one particular Greek State HCP, another Action Plan written by Novartis Hellas Employee 1 stated that the “Implementation Plan” consisted of specific European congresses and the U.S. Academy’s congress along with a reference to “5500 grand [*sic*] for congress.”

24. In or about 2013, certain employees in NOVARTIS HELLAS’s ophthalmology business unit developed a plan that outlined the various “activities” that they intended to use to influence HCPs at a public hospital’s

ophthalmology clinic (the “Greek Hospital Clinic”). These activities included “Participation in Congress (4x INTL, 10x National).”

25. In or about 2014, Novartis Hellas Employee 1 and another manager at NOVARTIS HELLAS wrote a basketball-themed written presentation for NOVARTIS HELLAS’s Lucentis brand team (the “Presentation”). The Presentation addressed how NOVARTIS HELLAS’s Lucentis brand team should approach Greek State HCPs who preferred a competitor company’s product and who raised certain “defenses” against using Lucentis. Among other “defenses,” these HCPs indicated that the competitor company’s products were the preferred choice to treat age-related macular degeneration and were less expensive. The Presentation described how NOVARTIS HELLAS intended to overcome these “defenses” through the use of improper inducements to “convert” Greek State HCPs to prescribing Lucentis.

26. One “defense,” which was described against the backdrop of an image of a world famous basketball player’s face on a dollar bill, stated (as translated): “[the competitor company] has a large budget to invest ‘they told me, whatever you want.’” The competitor company’s strategy, as indicated in the Presentation, included sending Greek State HCPs to U.S. congresses.

27. The Presentation further explained how NOVARTIS HELLAS sought to “dissolve” this “defense” through, among other things, sending targeted Greek State HCPs to ophthalmology congresses in Europe and the United States.

This included sending ten HCPs to the U.S. Academy's congress at a cost of 67,000 euros (then equivalent to approximately \$89,000).

28. NOVARTIS HELLAS, through its employees and agents, falsely recorded the corrupt payments associated with congress sponsorships as legitimate advertising and promotion expenses in NOVARTIS HELLAS's internal accounting records. By recording these payments as advertising and promotion expenses, NOVARTIS HELLAS concealed their true and corrupt nature. These false records were consolidated into Novartis AG's financial records and used to support Novartis AG's financial reporting to the SEC. As such, NOVARTIS HELLAS, through its employees and agents, knowingly and willfully conspired and agreed with others to cause the corrupt payments to be falsely recorded as legitimate expenses in Novartis AG's books, records, and accounts.

Details of the Clinical Trial Scheme

Background on Clinical Trials at NOVARTIS HELLAS

29. NOVARTIS HELLAS was not responsible for Phase I, II, or III clinical trials, which relate to different phases of the process leading from a drug's discovery to government approval. However, NOVARTIS HELLAS sponsored post-approval clinical trials, known as Phase IV studies and epidemiological studies, both of which were research studies intended to answer scientific questions related to medical conditions treated by Novartis-branded prescription drugs. In this role, and depending on the study, NOVARTIS HELLAS selected Greek public and private HCPs to gather patient data for the studies.

30. Phase IV studies and epidemiological studies were designed to inform medical and clinical decisions, not to increase sales. As set forth below, however, NOVARTIS HELLAS made improper payments to HCPs related to an epidemiological study intended to increase sales of certain Novartis-branded prescription drugs.

The EXACTLY Study

31. In or about 2008, employees of NOVARTIS HELLAS responsible for marketing Novartis-branded hypertension prescription drugs developed a marketing project named “EXACTLY.” The brand managers prepared a written “Project Summary” for EXACTLY dated November 19, 2008 (the “Project Summary”). According to the Project Summary, NOVARTIS HELLAS planned to provide HCPs with free blood pressure manometers and the HCPs would provide NOVARTIS HELLAS with information related to their patients, including uncontrolled or newly diagnosed patients with hypertension. Through EXACTLY, NOVARTIS HELLAS sought to increase sales of Novartis-branded hypertension prescription drugs.

32. The Project Summary described including over 2,200 HCPs who, in turn, treated over 44,000 patients. With an anticipated return on investment (“ROI”) of 3.04, the planned investment of over 2.8 million euros (equivalent to then approximately \$3.8 million) in payments to HCPs through EXACTLY was expected to yield sales of over 8.6 million euros (the equivalent to

then approximately \$11.9 million). This projected ROI, the Project Summary explained, included over 16,000 “newly diagnosed or uncontrolled patients.”

33. On or about November 19, 2008, the Project Summary for EXACTLY was submitted to NOVARTIS HELLAS’s Country Compliance Board (“CCB”) for internal approval. As reflected in the CCB’s Program Review Meeting Minutes from on or about November 19, 2008, the CCB deemed EXACTLY to be “of high value,” but decided that all or part of the project should be converted to a “Scientific Investigation.” The CCB made this decision, in part, because EXACTLY involved collecting patient data and would thus require approval from the Greek government’s National Organization for Medicines (Ethnikos Organismos Farmakon) (the “Greek EOF”).

34. NOVARTIS HELLAS accordingly redesigned a portion of EXACTLY as an epidemiological investigational study designed “to evaluate the percentage of uncontrolled hypertensive patients” in Greece. Instead of providing free manometers to HCPs, the investigational study version of EXACTLY entailed NOVARTIS HELLAS paying participating HCPs directly. Participating HCPs were responsible for gathering patient data and completing case report forms to record data for each enrolled patient.

35. In or about February 2009, the Greek EOF approved EXACTLY as an investigational study.

36. From in or about April 2009 through in or about December 2009, NOVARTIS HELLAS and HCPs conducted the EXACTLY study which was designed to target over 2,200 HCPs and over 44,000 patients.

37. Ultimately, NOVARTIS HELLAS, through its employees and agents, made improper payments to HCPs.

38. Many of the forms that were submitted contained mistakes and inconsistencies, including forms that failed to indicate whether the patient suffered from coronary disease, which is strongly linked to hypertension — the core purported focus of EXACTLY.

39. NOVARTIS HELLAS's employees also recognized that many HCPs believed that they were paid in exchange for writing prescriptions for Novartis-branded hypertension prescription drugs and not for providing data as part of a clinical study. Specifically, on or about April 15, 2010, NOVARTIS HELLAS held an internal meeting for brand managers and other personnel involved with EXACTLY "to summarize the learnings and identify next steps" (the "EXACTLY Debrief"). During the EXACTLY Debrief, which NOVARTIS HELLAS audio recorded, regarding payments that HCPs received related to EXACTLY, a number of employees and managers acknowledged the following:

- A NOVARTIS HELLAS manager stated that (as translated): "[A]lthough the microphone is recording . . . you all know this very well, I just repeat, that the doctor believes that he/she participates in a study [EXACTLY] and gets paid for what he prescribes in reality and not for what he/she writes in the study. . . Consequently, the doctor's impression was that they participate just so that they get paid for what they prescribe."

- A NOVARTIS HELLAS sales manager stated (as translated): “[T]he main issue is . . . that the doctors believe that the study was conducted in order to get paid for what they write, right?”
- A NOVARTIS HELLAS medical manager stated (as translated) that a clinical study “is a part of the marketing mix; we do not disagree that this is a type of benefit provided to the doctors. They know that they will get paid, this is what happens in reality.”
- A NOVARTIS HELLAS brand manager stated that (as translated): “To be honest, the studies were conducted in a similar way in the past as well; they were conducted as marketing projects. That’s within quotation marks. Between us.”

40. NOVARTIS HELLAS, through its employees and agents, falsely recorded these payments related to EXACTLY as advertising and promotion expenses in NOVARTIS HELLAS’s internal accounting records. By doing so, NOVARTIS HELLAS concealed their true and improper nature. These false records were consolidated into Novartis AG’s financial records and were used to support Novartis AG’s financial reporting to the SEC. As such, NOVARTIS HELLAS, through its employees and agents, knowingly and willfully conspired and agreed with others to cause the payments related to EXACTLY to be falsely recorded as legitimate expenses in Novartis AG’s books, records, and accounts.

COUNT ONE
(Conspiracy to Violate the Antibribery Provisions of the FCPA)

41. Paragraphs 1 through 8 and 10 through 28 of this Information are realleged here.

42. Between in or about 2012 and in or about 2015, within the United States and elsewhere, defendant

NOVARTIS HELLAS S.A.C.I.

together with Novartis Hellas Employee 1, Novartis Hellas Employee 2, and others known and unknown, knowingly and willfully did combine, conspire, confederate, and agree together and with each other to commit an offense against the United States, that is: while in the territory of the United States, through its employees and agents, did corruptly commit acts in furtherance of an offer, payment, promise to pay, and authorization of the giving of anything of value to a foreign official and to any person, while knowing that all or a portion of such money and thing of value would be and had been offered, given, and promised to a foreign official for purposes of: (i) influencing acts and decisions of such foreign official in his or her official capacity; (ii) inducing such foreign official to do and omit to do acts in violation of the lawful duty of such official; (iii) securing any improper advantage; and (iv) inducing such foreign official to use his or her influence with a foreign government and agencies and instrumentalities thereof to affect and influence acts and decisions of such government and agencies and instrumentalities, in order to assist NOVARTIS HELLAS in obtaining and

retaining business for and with, and directing business to, NOVARTIS HELLAS, contrary to 15 U.S.C. § 78dd-3.

Object of the Conspiracy

43. The object of the conspiracy was for NOVARTIS HELLAS and its co-conspirators to gain improper business advantages for NOVARTIS HELLAS, including increased sales of Lucentis, a Novartis-branded drug, by bribing Greek State HCPs through sponsorships to attend international medical congresses.

Manner and Means of the Conspiracy

44. The manner and means by which NOVARTIS HELLAS and its co-conspirators and others sought to accomplish the object of the conspiracy included, among other things, the following:

a. NOVARTIS HELLAS, through certain of its employees and agents, including Novartis Hellas Employee 1 and Novartis Hellas Employee 2, sponsored Greek State HCPs to attend international congresses as a means to bribe and corruptly influence the HCPs to increase prescriptions of Lucentis.

b. NOVARTIS HELLAS paid for public and private ophthalmologists in Greece to attend international “medical congresses.” These congresses were organized by various medical associations in the United States and Europe, and typically took place over several days in a destination city in the United States or Europe.

c. By sponsoring Greek State HCPs to attend congresses, NOVARTIS HELLAS paid for the costs associated with that Greek State HCP's attendance such as airfare, hotel accommodations, and congress registration fees. NOVARTIS HELLAS typically paid for travel costs associated with congresses through third-party travel agencies. For each individual Greek State HCP, the total cost to NOVARTIS HELLAS for attendance of an international congress often exceeded \$6,000.

d. NOVARTIS HELLAS's policies stated that the purpose for sending HCPs to congresses was to provide scientific or educational information. In reality, however, sales employees at NOVARTIS HELLAS, including Novartis Hellas Employee 1, sometimes used international congresses to improperly influence and induce Greek State HCPs to increase prescriptions for Lucentis.

e. As part of the scheme, NOVARTIS HELLAS maintained internal documentation noting that HCPs with the highest potential and highest propensity to prescribe Lucentis would receive "investments," such as sponsorships to attend international congresses, while HCPs with lower potential and less propensity to prescribe Lucentis would receive no such "investments."

f. NOVARTIS HELLAS, through its employees and agents, falsely recorded the corrupt payments associated with congress sponsorships as legitimate advertising and promotion expenses in NOVARTIS HELLAS's internal accounting records. By recording these payments as

advertising and promotion expenses, NOVARTIS HELLAS concealed their true and corrupt nature.

Overt Acts

45. In furtherance of the conspiracy and to effect its object, NOVARTIS HELLAS and its co-conspirators committed or caused the commission of the following acts in the United States and elsewhere:

a. On or about September 27, 2012, NOVARTIS HELLAS's Lucentis Brand Team held a meeting to discuss the sales strategy for Greek State HCPs. Novartis Hellas Employee 1 and Novartis Hellas Employee 2 participated in the meeting at which it was discussed that Greek State HCPs "must understand that their participation in [specific congresses in the United States and Europe] will be cancelled if sales performance is not improved significantly."

b. In or about January 2013, Novartis Hellas Employee 1 prepared a presentation entitled "Action Plan KOLs" which detailed the various means through which Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to target various Key Opinion Leaders in ophthalmology. One such Action Plan targeted Greek HCP 1, who worked at the Greek State-Owned Clinic. The Action Plan set forth how Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to use certain "actions"—including sponsorship to U.S. congresses—to induce Greek HCP 1 to prescribe Lucentis. The Action Plan further stated that Novartis Hellas Employee 1 and others at NOVARTIS

HELLAS should convey the following message to Greek HCP 1: “to get you must write. No presents anymore.”

c. In or about late 2013, employees of NOVARTIS HELLAS traveled to the United States and, while located in the United States, facilitated the attendance of Greek HCP 1 and others at the U.S. Academy’s congress in New Orleans, Louisiana.

In violation of Title 18, United States Code, Section 371.

COUNT TWO
(Conspiracy to Violate the Books and Records Provision of the FCPA)

46. Paragraphs 1 through 8 and 10 through 40 of this Information are realleged here.

47. Between in or about 2009 and in or about 2010 and between in or about 2012 and in or about 2015 within the United States and elsewhere, defendant

NOVARTIS HELLAS S.A.C.I.

together with others known and unknown, knowingly and willfully did combine, conspire, confederate, and agree together and with each other to commit an offense against the United States, that is: to knowingly and willfully falsify and cause to be falsified books, records, and accounts required, in reasonable detail, to accurately and fairly reflect the transactions and dispositions of the assets of Novartis AG, an issuer within the meaning of the FCPA, contrary to 15 U.S.C. §§ 78m(b)(2)(A), 78m(b)(5), and 78ff(a).

Object of the Conspiracy

48. The object of the conspiracy was for NOVARTIS HELLAS and its co-conspirators to cause certain payments to be falsely recorded in Novartis AG's books, records, and accounts as a method to conceal the corrupt payments to Greek State HCPs in furtherance of NOVARTIS HELLAS's effort to obtain and retain business relating to Lucentis, and to conceal the improper payments to HCPs in connection with an epidemiological study intended to increase sales of certain Novartis-branded prescription drugs.

Manner and Means of the Conspiracy

49. The manner and means by which NOVARTIS HELLAS and its co-conspirators sought to accomplish the object of the conspiracy included, among other things, the following:

a. NOVARTIS HELLAS, through its employees and agents, falsely recorded the corrupt payments associated with congress sponsorships as legitimate advertising and promotion expenses in NOVARTIS HELLAS's internal accounting records. The false books and records failed to accurately reflect the true nature of the transactions and disposition of Novartis AG's assets.

b. NOVARTIS HELLAS, through its employees and agents, falsely recorded improper payments related to EXACTLY as advertising and promotion expenses in NOVARTIS HELLAS's internal accounting records.

The false books and records failed to accurately reflect the true nature of the transactions and disposition of Novartis AG's assets.

Overt Acts

50. In furtherance of the conspiracy and to effect its object, NOVARTIS HELLAS and its co-conspirators committed or caused the commission of the following acts in the United States and elsewhere:

a. On or about September 27, 2012, NOVARTIS HELLAS's Lucentis Brand Team held a meeting to discuss the sales strategy for Greek State HCPs. Novartis Hellas Employee 1 and Novartis Hellas Employee 2 participated in the meeting at which it was discussed that Greek State HCPs "must understand that their participation in [specific congresses in the United States and Europe] will be cancelled if sales performance is not improved significantly."

b. In or about January 2013, Novartis Hellas Employee 1 prepared a presentation entitled "Action Plan KOLs" which detailed the various means through which Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to target various Key Opinion Leaders in ophthalmology. One such Action Plan targeted Greek HCP 1, who worked at the Greek State-Owned Clinic. The Action Plan set forth how Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to use certain "actions"—including sponsorship to U.S. congresses—to induce Greek HCP 1 to prescribe Lucentis. The Action Plan further stated that Novartis Hellas Employee 1 and others at NOVARTIS

HELLAS should convey the following message to Greek HCP 1: “to get you must write. No presents anymore.”

c. In or about late 2013, employees of NOVARTIS HELLAS traveled to the United States and, while located in the United States, facilitated the attendance of Greek HCP 1 and others at the U.S. Academy’s congress in New Orleans, Louisiana.

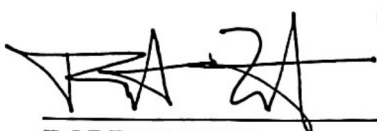
d. NOVARTIS HELLAS, through its employees and agents, falsely recorded the payments associated with Greek HCP 1’s attendance at the U.S. Academy’s congress as advertising and promotion expenses. By doing so, NOVARTIS HELLAS concealed their true and corrupt nature. These false records were consolidated into Novartis AG’s financial records and used to support Novartis AG’s financial reporting to the SEC.

e. From in or about April 2009 through in or about December 2009, NOVARTIS HELLAS and HCPs conducted the EXACTLY study which was designed to target over 2,200 HCPs and over 44,000 patients. Ultimately, NOVARTIS HELLAS, through its employees and agents, made improper payments to HCPs related to EXACTLY, which was intended to increase sales of certain Novartis-branded prescription drugs.

f. NOVARTIS HELLAS, through its employees and agents, falsely recorded these payments related to EXACTLY as advertising and promotion expenses in NOVARTIS HELLAS’s internal accounting records. By doing so, NOVARTIS HELLAS, concealed their true and improper nature. These

false records were consolidated into Novartis AG's financial records and were used to support Novartis AG's financial reporting to the SEC.

In violation of Title 18, United States Code, Section 371.

 6/22/2020

ROBERT ZINK
Chief, Fraud Section
Criminal Division
U.S. Department of Justice

_____
CRAIG CARPENITO
United States Attorney
District of New Jersey

CASE NUMBER: 20-cr-538

United States District Court
District of New Jersey

UNITED STATES OF AMERICA

v.

NOVARTIS HELLAS S.A.C.I.

INFORMATION

18 U.S.C. § 371

CRAIG CARPENITO
UNITED STATES ATTORNEY
NEWARK, NEW JERSEY

BERNARD J. COONEY
SENIOR TRIAL COUNSEL
JOSHUA L. HABER
ASSISTANT U.S. ATTORNEY
(973) 645-2823