UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CASE NO. 20-cr-538
UNITED STATES OF AMERICA v. NOVARTIS HELLAS S.A.C.I. Defendant.
_____/ DEFERRED PROSECUTION AGREEMENT

Novartis AG shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of Novartis AG. Such policies and procedures shall address: a. gifts; b. hospitality, entertainment, and expenses; c. customer travel; d. political contributions; e. charitable donations and sponsorships; C-3 f. facilitation payments; and g. solicitation and extortion.

d. With respect to any information, testimony, documents, records, or other tangible evidence provided to the Fraud Section and the Office pursuant to this Agreement, the Company **consents** to any and all disclosures, subject to applicable laws and regulations, to **other governmental authorities, including United States authorities and those of a foreign government,** as well as the MDBs, of such materials as the Fraud Section and the Office, in their sole discretion, shall deem appropriate.

Nothing in this Agreement restricts in any way the ability of the Fraud Section and the Office, any other federal department or agency, or any state or local government, from proceeding criminally, civilly, or administratively, against any current or former directors, officers, employees, or agents of the Company, Novartis AG, its subsidiaries or affiliates, or against any other entities or individuals. The parties to this Agreement intend that the Agreement does not confer or provide any benefits, privileges, immunities, or rights to any other individual or entity other than the parties hereto.

28. The Company 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, the Company 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 A-9 role, and **depending on the study, the Company selected Greek public and private HCPs to gather patient data for the studies.**

The EXACTLY Study 30. In or about 2008, employees of the Company responsible for marketing Novartisbranded 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, the Company planned to provide HCPs with free blood pressure manometers and the HCPs would provide the Company with information related to their patients, including uncontrolled or newly diagnosed patients with hypertension. Through EXACTLY, the Company sought to increase sales of Novartis-branded hypertension prescription drugs.

32. On or about November 19, 2008, the Project Summary for EXACTLY was submitted to the Company'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").

Periodic Risk-Based Review 5.

Novartis AG **will develop** these compliance policies and procedures on the basis of a periodic risk assessment addressing the individual circumstances of Novartis AG, in particular the foreign bribery risks facing Novartis AG, including, but not limited to, its geographical organization, **interactions with various types and levels of government officials,** industrial sectors of operation, involvement in joint venture arrangements, importance of licenses and permits in C-4 Novartis AG's operations, degree of governmental oversight and inspection, and volume and importance of goods and personnel clearing through customs and immigration.

ATTACHMENT D

REPORTING REQUIREMENTS

d. The reports will likely include proprietary, financial, confidential, and competitive business information. Moreover, 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 as otherwise agreed to by the parties in writing, or except to the extent that the Fraud Section and the Office determine in their sole discretion that disclosure would be in furtherance of the Fraud Section's and the Office's discharge of their duties and responsibilities or is otherwise required by law.

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.

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").**

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