IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

v.

ENDO PHARMACEUTICALS INC.,

Defendant.

Case No. 1:14-CR-66 (MAD)

Deferred Prosecution Agreement

Richard S. Hartunian, United States Attorney for the Northern District of New York (by First Assistant U.S. Attorney Grant C. Jaquith, appearing), Michael S. Blume, Director of the Consumer Protection Branch of the U.S. Department of Justice (by Trial Attorney Shannon L. Pedersen), and defendant Endo Pharmaceuticals Inc. ("Endo" or "Defendant") (by defense counsel Jonathan L. Stern, Esq., Arnold & Porter LLP, and Chief Executive Officer Rajiv De Silva, pursuant to authority granted by the Board of Directors of Defendant's parent company), hereby enter into the following Deferred Prosecution Agreement ("Agreement").

I. CRIMINAL INFORMATION, ACCEPTANCE OF RESPONSIBILITY, AND DEFERRED PROSECUTION

a. Endo consents to the filing, in United States District Court for the Northern District of New York, of a one count criminal information charging Endo with the introduction and causing the introduction into interstate commerce of a misbranded drug, in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1), a misdemeanor, and agrees to venue of the case in the Northern District of New York.

b. Endo admits that it is responsible for the acts of its employees, directors, officers, and agents, as set forth in the Statement of Facts below. Endo further admits that the Statement

of Facts is true and accurate, and agrees that, should the prosecution deferred pursuant to this Agreement be initiated, Endo will neither contest the admissibility of the Statement of Facts nor contradict the Statement of Facts in any such proceeding, including any guilty plea or sentencing proceeding.

c. The United States Attorney's Office for the Northern District of New York and the U.S. Department of Justice's Consumer Protection Branch (collectively, the "Government") enters into this Agreement based upon the individual facts and circumstances of this case, including: 1) the acknowledgement by Endo of its conduct and Endo's acceptance of responsibility for that conduct; 2) the cooperation by Endo in the investigation of this matter and Endo's commitment to continue that cooperation; 3) the compliance efforts by Endo, and Endo's commitment to enhanced compliance measures; 4) the remedial measures undertaken by Endo, and Endo's commitment to undertake additional remediation as identified herein; 5) the payment by Endo of $10,414,466.50 in monetary penalties; 6) the forfeiture by Endo of $10,414,466.50; 7) the commitment by Endo to full compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA"); and 8) the commitment by Endo to fulfill all of the terms of this Agreement.

d. This Agreement is effective for a period beginning on the date on which the Information is filed ("Effective Date") and ending thirty (30) months from that date (the "Term"). However, the Government agrees that, in its sole discretion, it may shorten the Term of this Agreement by no more than six (6) months. However, Endo agrees that, in the event that the Government determines, in its sole discretion, that Endo has knowingly and materially violated any provision of this Agreement, an extension or extensions of the term of the Agreement may be imposed by the Government, in its sole discretion, for up to a total additional time period of one

year, without prejudice to the Government's right to proceed as provided in Section VI below. Any extension of the Agreement extends all terms of this Agreement, including the terms of the Enhanced Compliance Program and Certifications described in Section V below, for an equivalent period.

e. The Government will recommend to the Court that prosecution of Endo on the Information be deferred for the duration of the Term of this Agreement. Endo waives its right to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Criminal Procedure 48(b), and the parties agree that, pursuant to 18 U.S.C. § 3161(h)(2), the period of delay during which prosecution is deferred is excluded from the time within which trial of the offense charged must commence. If the Court declines to defer prosecution or exclude the deferral Term from the time within which trial on the Information must be commenced, this Agreement shall be null and void.

II. THE DEFENDANT'S OTHER OBLIGATIONS:

a. Compliance with Agreement: Endo will comply in a timely manner with all of the terms of this Agreement. If Endo sells, merges, or transfers all or substantially all of its business operations, unless otherwise agreed to in writing by the Government, Endo will maintain its existence and its ability to fulfill and complete all of its obligations under this Agreement, or include in any contract for sale, merger, or transfer a provision binding the purchaser, or any successor in interest to Endo, to fulfill and complete all of Endo's obligations under this Agreement.

b. Cooperation: Endo agrees to provide complete, truthful cooperation with the Government in any investigation or prosecution of Endo and/or any of its former directors, officers, employees, agents, consultants, contractors, subcontractors, and subsidiaries, or any

other party, as follows:

1. Endo will truthfully disclose all information that is not protected by any applicable privilege or protection with respect to its activities or those of any of its former directors, officers, employees, agents, consultants, contractors, subcontractors, and subsidiaries, or any others, concerning all matters about which the U.S. Attorney's Office, Consumer Protection Branch, and law enforcement agencies designated by them, may inquire.

2. Endo will, upon request of the U.S. Attorney's Office, Consumer Protection Branch, and law enforcement agencies designated by them, provide documents, records, and/or other tangible evidence not protected by any applicable privilege or protection regarding matters about which such agencies may inquire and identify knowledgeable directors, officers, employees, agents, and/or representatives to provide information, materials, and testimony.

3. Endo (and its directors, officers, employees, agents, and representatives) will testify truthfully before the grand jury and/or at any trial or other proceeding with respect to any matters about which it may be questioned provided that the testimony sought is not protected by any applicable privilege or protection. Endo (and its directors, officers, employees, agents, and representatives) will at all times give complete, truthful, and accurate information and testimony provided that the information and testimony sought is not protected by any applicable privilege or protection. Endo (and its directors, officers, employees, agents, and representatives) will neither attempt to protect any person who has been involved in criminal activity, nor falsely implicate anyone in criminal activity.

4. Endo (and its directors, officers, employees, agents, and representatives) will not make any public statements, in litigation or otherwise, materially contradicting the

Statement of Facts.

c. *Monetary Penalty and Forfeiture*: Endo agrees to pay a monetary penalty in the amount of $10,414,466.50 to the United States Treasury within thirty (30) days following the Effective Date of this Agreement. In addition, Endo consents to the filing of the attached Verified Complaint for Forfeiture and agrees to forfeit to the use and benefit of the United States of America $10,414,466.50 in U.S. currency, in the form of a wire transfer which it will provide within thirty (30) days of the execution of this Agreement. Endo consents to a forfeiture judgment in the amount of $10,414,466.50 being entered on the Verified Complaint for Forfeiture, with neither party considered the prevailing party. The combined monetary penalty and forfeiture amount of $20,828,933 is derived from Endo's profits from misbranded Lidoderm during the period of 2002 through 2006, considering the Sentencing Guidelines as illustrative, including culpability scoring under Guidelines § 8C2.5, the full cooperation and acceptance of responsibility by Endo, the range of sentencing multipliers, and all the facts and circumstances of this case. In connection with its payment and forfeiture of $20,828,933, Endo further agrees:

1. Nothing in this Agreement shall be deemed an agreement by the Government that the $20,828,933 amount is the maximum penalty or forfeiture that may be imposed in any future prosecution, and the Government is not precluded, in any future prosecution, from seeking a larger forfeiture amount or arguing that the Court should impose a fine, although the Government agrees that under those circumstances, they would recommend to the Court that the amount paid and forfeited pursuant to this Agreement should be offset against any forfeiture or fine the Court imposes as part of a future judgment.

2. In the event the Government determines that Endo has breached any

condition of this Agreement, none of the paid and forfeited $20,828,933 shall be returned to Endo, nor shall Endo assert any claim to the paid and forfeited $20,828,933.

III. THE GOVERNMENT'S OTHER OBLIGATIONS:

a. In exchange for and conditioned upon complete, continuing compliance by Endo with all of the terms of this Deferred Prosecution Agreement, the Government hereby agrees as follows:

1. The Government will bring no further federal criminal charges against Endo relating to the conduct committed before the date of this Agreement described in the Statement of Facts.

2. Within thirty (30) days after the expiration of the Term of deferred prosecution under this Agreement, the Government will seek dismissal of the Information.

3. The Government will not use, in any criminal or civil case, any self-incriminating information provided by Endo pursuant to its cooperation which was not previously known to the United States, or any information directly or indirectly derived therefrom, except in (i) a prosecution or other proceeding for perjury, making a false statement, or obstruction of justice; (ii) a prosecution or other proceeding for any act of violence or act of terrorism; (iii) a prosecution or other proceeding relating to any violation of the Internal Revenue Code; or (iv) any prosecution or other proceeding permitted herein as a result of failure by Endo to comply with the terms of this Agreement.

IV. STATEMENT OF FACTS

The defendant admits that it is responsible for the acts of its employees, directors, officers, and agents, and admits the following facts:

Endo Pharmaceuticals Inc. is a pharmaceutical company established in 1997. It is

incorporated in Delaware and maintains its principal executive offices in Malvern, Pennsylvania.

On October 24, 1995, the U.S. Food and Drug Administration ("FDA") designated the Lidocaine Patch 5% as an orphan drug "for relief of allodynia (painful hypersensitivity), and chronic pain in post-herpetic neuralgia." The Orphan Drug Act provides for granting special status to a product to treat a rare disease or condition, defined as one that affects fewer than 200,000 people in the United States, or one that affects more than 200,000 persons but the sponsoring company is not expected to recover the costs of developing and marketing a treatment drug. One benefit of Orphan Drug status is seven years of marketing exclusivity once FDA approves the drug for marketing. The inventor of the Lidocaine Patch called it the Lidoderm® Patch ("Lidoderm"), found a manufacturer to produce the drug, and, on May 31, 1996, filed a new drug application ("NDA") with FDA for the relief of pain associated with post-herpetic neuralgia. In November 1998, while the NDA for Lidoderm was pending, Endo obtained the exclusive United States marketing rights for Lidoderm.

On March 19, 1999, FDA approved the NDA for Lidoderm. The FDA-approved product labeling for Lidoderm provided that "LIDODERM is indicated for relief of pain associated with post-herpetic neuralgia [PHN]." FDA did not approve Lidoderm for any other indication. PHN is a type of neuropathic pain, which is generally characterized as pain, or paradoxically, sensory loss, caused by a dysfunction of the peripheral nervous system. Neuropathic pain is different from nociceptive pain, which generally is a result of an identifiable injury, such as a tissue tear or a bone fracture, and is properly regulated through the central nervous system. In the case of PHN, the dysfunction is thought to be caused by damage to the nerves resulting from the herpes zoster virus. During FDA's review of Lidoderm's NDA, FDA noted that Lidoderm was

considered safe to use at the recommended dose to treat PHN. FDA further noted that adverse events "mostly were minor complaints mild in severity" and that Lidoderm had a "fairly benign safety profile."

On the day of approval, Endo announced FDA's approval of Lidoderm "to treat the pain associated with postherpetic neuralgia (PHN), a complication of shingles (herpes zoster) that affects approximately 200,000 Americans." Endo's announcement described Lidoderm as "composed of an adhesive material containing 5% lidocaine that is applied to a non-woven polyester felt backing," and as a "patch [that] provides analgesic action, reducing pain at the damaged and dysfunctional nerves" by releasing lidocaine "into the epidermal and dermal layers of the skin." Endo's announcement noted that it would launch the product later that year, and it did so. At that time, Endo had 92 employees and a contract sales force.

Lidoderm was the first proprietary, patented product that Endo launched since its founding in 1997. From the product launch in 1999 to date, Endo has marketed and sold Lidoderm in interstate commerce throughout the United States, including in the Northern District of New York.

Endo promoted Lidoderm using efficacy claims and assertions that it improved the quality of life for patients. By untitled letters in July, August, and September of 1999, FDA commented that comparative claims regarding the safety and effectiveness of Lidoderm for treatment of the pain associated with PHN would be considered misleading without adequate supporting evidence and that quality of life claims likewise would be considered misleading without substantiation from adequate and well-controlled studies.

Defendant submitted its Lidoderm launch promotional materials to FDA at the time of their first use. By untitled letter dated November 24, 1999, FDA advised the defendant that FDA

had specific objections to the launch promotional materials the defendant had submitted to FDA for Lidoderm, stating, in part:

> We object to the lack of fair balance with respect to the content and presentation of risk information in this sales aid. The efficacy claims for Lidoderm are prominently presented, by way of numerous headers and bullets, in large print throughout the sales aid. In contrast, you frequently present the risk information in small sized type, confined to the bottom of selective pages. Moreover, selective pieces of Lidoderm risk information, including the drug's bolded warning, is presented in a manner that is difficult to read, taking into account the size and coloring of the type and the background on which it is presented.

The 1999 untitled letter also advised the defendant that FDA considered the defendant's "efficacy claims [identified in the letter to be] misleading because they disclose favorable conclusions from a study, in the absence of qualifying contextual information concerning the study's limitations." The untitled letter stated:

> You present the claims "Preferred by 78% of patients vs placebo patch," and "88% of patients completed the Lidoderm phase of the study due to effective pain relief (vs 38% in placebo phase)." These claims are supported from the clinical study entitled, "Topical lidocaine patch relieves postherpetic neuralgia more effectively than a vehicle topical patch: results of an enriched enrollment study," listed as reference #2. We note that you disclose this was an enriched enrollment study. However, adequate context regarding the limitations of the study is not disclosed. Specifically, you omit the material fact that, "Limitations of enriched enrollment studies include the realization that the results are not generalizable to the entire population and the possibility that subjects may be able to identify the study treatment from placebo due to non-therapeutic features of treatment," as it is stated in discussion section of this clinical study. Therefore, we consider these efficacy claims misleading because they disclose favorable conclusions from a study, in the absence of qualifying contextual information concerning the study's limitations.

In response, Endo discontinued the promotional material at issue and submitted revised promotional material to FDA. By its letter dated January 10, 2000, FDA stated: "DDMAC [(Division of Drug Marketing, Advertising, and Communications)] has reviewed your response and finds the actions you have taken to discontinue the sales aid, and other

similar promotional materials for Lidoderm that contain the same or similar claims or presentations, to be acceptable. Therefore, we consider this matter to be closed."

In early 2001, Endo converted its sales force from part-time to full-time contract representatives. In 2002, Endo began to maintain an in-house sales force, converting contract sales representatives and district managers to Endo employees. The total number of Endo employees was 167 in 2001, and rose to 1,024 employees in 2006. For 2006, Endo reported marketing products directly to physicians through an internal sales force of approximately 590 specialty and pharmaceutical representatives. By 2010, Endo had grown to 2,947 employees, including 800 in sales and marketing.

Endo's efforts to promote and support compliance with federal laws and regulations included (1) the creation, in 2002, of Policies for Sales Representative Conduct, which required compliance with all FDA regulations governing pharmaceutical and biological products and set forth compliance expectations; (2) the adoption, in 2003, of a Code of Conduct for employees, which required each Endo employee to "act in a lawful and ethical manner at all times" and to "conduct [c]ompany business in "compliance with all applicable laws" with specific reference to the Prescription Drug Marketing Act (PDMA) and the Pharmaceutical Research and Manufacturers Association Code on Interactions with Health Care Professionals; (3) the establishment, in 2003, of a Corporate Compliance Committee; (4) the establishment, in 2004, of an Ethics and Corporate Compliance Department and the appointment of a Vice President of Corporate Compliance and Business Practices; (5) and the issuance, in 2005, of a Health Care Compliance Guide, which was designed to address a variety of customer-facing activities that could implicate federal health care laws. Endo subsequently revised the Code of Conduct and the Health Care Compliance Guide to further refine its various compliance policies. In addition,

Endo determined whether reprints of descriptions of the results of studies regarding the use of Lidoderm could be used for promotion of the product. Endo designated reprints that could not be used for promotional purposes as "restricted" reprints. Company policy prescribed the permissible uses of "restricted reprints."

Beginning in 2002, with the advent of an in-house sales force, it was Endo policy that sales representatives were not to discuss "uses or information not consistent with the approved product labeling for any Endo product with a physician, pharmacist, other health care professional or customer, regardless of whether the discussion is initiated by the health care professional or customer." Sales representatives could disseminate restricted materials, but could not discuss or promote the information contained in those materials. In addition, it was Endo policy that Endo sales representatives should make sales calls and present product information only to health care professionals who would have a reason to use the Endo product for the indications included as part of the FDA-approved product labeling.

For 2002, Endo had a business plan that "[could] be summarized as a 'second' launch of the brand" to continue to increase sales by increasing brand awareness and physician education, enhancing the impact of CME activities, and broadening the clinical practice and use of Lidoderm. Endo's 2002-2006 Lidoderm Product Marketing Plan noted that short-term sales development could be continued by focusing on the PHN patient population, but "the longer term opportunities for Lidoderm® [lay] in developing additional indications for the product or at a minimum developing a much broader clinical base of its use outside PHN." A marketing campaign was launched urging people to "put the patch where the pain is," and sales managers called for a 77% increase in sales. Certain sales representatives were encouraged to distribute restricted materials and to promote using Lidoderm to treat pain that resulted from a variety of

conditions. Certain sales representatives were given specific examples of what to say to encourage off-label discussion, including asking physicians about the different types of pain their patients experienced, selling the symptoms, and talking to physicians about Lidoderm's "mechanism of action" to broaden the sales base of potential prescriptions to include pain conditions other than PHN. Certain sales representatives were given call lists of physicians that that were less likely to treat patients for PHN pain (including doctors specializing in psychiatry and neurology). At the end of the year, Endo noted that the percentage of Lidoderm use for PHN diminished significantly in 2002 as the percentage of Lidoderm sales for off-label use increased.

For 2003, Endo's "Q4 2002 Lidoderm Business Review" called for a 100% increase in Lidoderm sales over those in 2002. Endo engaged a pharmaceutical marketing consultant "to provide opinions on the potential value of pursuing new indication(s) [for Lidoderm] versus further developing the product without seeking formal approval for one or more new indications," and the consultant indicated that there was a significant opportunity for growth in the Lidoderm market by exploring the utility of Lidoderm in neuropathic and chronic pain segments not involving PHN, such as for chronic back pain, osteoarthritis, fibromyalgia, diabetic neuropathy, carpal tunnel syndrome, cancer-related pain, and spinal cord injury. In planning a symposium on neuropathic pain, a marketing director described low back pain as "the golden goose" for Lidoderm. Certain sales representatives were provided instruction by sales managers and trainers in identifying off-label uses with doctors they were detailing, expanding sales conversations past just PHN, and managing off-label discussions. Certain Endo sales managers encouraged some sales representatives to promote Lidoderm in workers' compensation clinics. In August of 2003, identifying new Lidoderm customers among health care professionals treating carpal tunnel syndrome and those treating diabetic neuropathy was included in a section titled

"Big Strategic Ideas" in an Endo presentation on "Lidoderm 2004 Promotional Tactics" (and acknowledged to be "off label").

In October 2003, Endo published an internal report for a study, initiated in November 2001, meant to assess the effectiveness of Lidoderm to treat lower back pain in approximately 130 patients ("Study EN3220-006"). The results of this six-week, multicenter, open-label, nonrandomized study showed a statistically significant improvement in pain intensity and increases in patient quality of life. Endo later issued a news release announcing the results of Study EN3220-006.

In December 2003, Endo published an internal report for a second study, initiated in January 2003, meant to confirm the results of Study EN3220-006. The new study was a multicenter, multiple dose, double-blind, randomized, placebo controlled, parallel group pilot study that enrolled approximately 100 patients ("Study EN3220-011"). Study EN3220-011 failed to show a statistically significant difference in the mitigation of lower back pain between the group who received Lidoderm and the placebo control group.

Endo maintained a "Restricted Material Log" reflecting the distribution of materials concerning the use of Lidoderm for indications other than PHN to physicians by Endo's sales representatives. Certain of Endo's sales managers reviewed the Restricted Materials Logs, and certain managers criticized sales representatives when they thought the distribution of restricted materials by sales representatives was too light. Certain sales representatives promoted the use of Lidoderm for low back pain, carpal tunnel pain, osteoarthritis pain, diabetic neuropathy, and other neuropathic pain, and provided doctors with unsolicited restricted materials to further their promotional efforts, as they understood their supervisors to have instructed them to do.

On June 28, 2005, FDA sent Endo a Warning Letter concerning mailing pieces for

Lidoderm. The 2005 letter stated:

> The direct mailing pieces are false or misleading for several reasons: first, they contain unsubstantiated effectiveness claims for Lidoderm; second, they omit and minimize serious risk information associated with Lidoderm; and third, they fail to communicate an important limitation in the drug's FDA approved indication. Thus, the direct mailing pieces misbrand the drug within the meaning of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 352(a) and 321(n). These violations are a public health concern because they may encourage use of Lidoderm in circumstances other than those in which the drug has been shown to be safe and effective.

The promotional materials used by Endo made effectiveness claims for Lidoderm that FDA deemed unsubstantiated. Regarding claims that Lidoderm reduced pain intensity and improved quality of life in PHN patients, FDA concluded that:

> These claims are misleading because they are not supported by substantial evidence or substantial clinical experience. The study cited for support of these claims was an open-label, single-arm study with no concurrent control group, rather than a well controlled study.

After receiving the Warning Letter, Endo expressed to FDA that Endo believed the data substantiating the quality of life claims were scientifically rigorous and consistent with FDA's standards for substantiation. Endo also noted that the sales aids in question disclosed the fact that the study was open-label. FDA did not accept Endo's position, and therefore the company agreed to discontinue its use of that open-label study in promotional materials and revised the Lidoderm fair balance information included in promotional materials. Endo also revised its policy on restricted materials, permitting their dissemination only in response to an unsolicited request and prohibiting sales representatives from discussing their content. FDA acknowledged Endo's response to the Warning Letter and closed the matter on August 29, 2006.

In July 2005, a peer-reviewed journal published the results of Study EN3220-006, the earlier, open-label study using Lidoderm to treat lower back pain that had shown a statistically significant improvement in pain intensity and increases in patient quality of life. At the time of

this study's publication, Endo knew it had been unable to replicate the positive results of EN3220-006 in a double-blind, placebo-controlled study.

After Endo received the 2005 FDA Warning Letter, certain sales managers provided certain sales representatives with tips and techniques for initiating and provoking off-label discussions with doctors. In October of 2005, Endo's Lidoderm Product Manager sent an e-mail message instructing sales representatives to seize the opportunity and capitalize on the withdrawal of Vioxx® and Bextra® from the market — drugs intended to treat arthritis pain.

In June 2006, Endo published an internal study report for a third study, initiated in April 2004, to assess the effectiveness of Lidoderm to treat lower back pain in over 200 patients ("Study EN3261-001"). The results of this multicenter, multiple dose, double-blind, randomized, placebo-controlled, parallel study again failed to show a statistically significant difference in pain mitigation between the group who received Lidoderm and the placebo control group. Following the failure of Study EN3261-001, Endo ceased clinical development of an indication for Lidoderm for use in treating lower back pain.

Nonetheless, through 2006, Endo sales representatives ordered thousands of reprints of Study EN3220-006, published in July 2005, describing the use of Lidoderm to treat lower back pain — some even ordering one hundred copies at a time — to distribute when detailing health care professionals. Endo allowed its sales representatives to order and distribute the reprint of Study EN3220-006 even though Endo knew that two later, more rigorous studies had failed to replicate the favorable efficacy results discussed in the July 2005 publication and that these later studies were not available for dissemination.

Through 2006, sales and product managers noted that sales increases and growth opportunities for Lidoderm were due to intended uses such as acute pain in patients' backs,

knees, and shoulders; osteoarthritis; and other conditions lacking adequate directions for use in Lidoderm's FDA-approved labeling. Though Endo had policies regarding support for continuing medical education without commercial influence, certain Endo employees endeavored to manage the messages presented at certain educational presentations to doctors to focus on intended uses for Lidoderm other than to treat pain associated with PHN.

Responsible employees of Endo offered, marketed, and promoted Lidoderm for use for unapproved indications, and intended that Lidoderm be used for unapproved indications, as demonstrated by their activity promoting and marketing Lidoderm. The labeling of Lidoderm lacked adequate directions for intended uses not approved by FDA. As a result, Endo introduced and caused the introduction into interstate commerce of a misbranded drug, Lidoderm. This conduct during the period of 2002 through 2006 yielded significant increases in profits, including substantial payments from health care benefit programs.

V. ENHANCED COMPLIANCE PROGRAM AND CERTIFICATIONS

a. Compliance Program: Endo has in place and will maintain a Compliance Program, which governs Endo's United States branded pharmaceutical[1] business. For purposes of this Agreement, the term "Compliance Program" refers to the policies, procedures and practices that Endo has or will establish to address compliance with Federal healthcare programs and compliance with the Federal Food, Drug, and Cosmetic Act and FDA regulations regarding sales, marketing, and promotion ("FDCA Labeling Requirements") for Endo's branded pharmaceutical products. The Compliance Program consists of a Chief Compliance Officer of Endo Health Solutions Inc. who reports to the Chief Executive Officer of Endo Health Solutions

[1] For purposes of this Agreement, the term "branded pharmaceutical" means (1) Lidoderm and (2) any other drug (within the meaning of 21 U.S.C. § 321(g)) that is distributed by Endo within the United States, excluding drugs distributed by Endo's subsidiary Generics International (US Parent), Inc., doing business as Qualitest Pharmaceuticals ("Qualitest"), or any of Qualitest's subsidiaries.

Inc. and makes regular reports to the Board of Directors (or an authorized subcommittee thereof) of Endo Health Solutions Inc. (or any future parent company thereof); a Compliance Committee comprised of senior executives; and written policies and procedures governing Endo's compliance with Federal healthcare program requirements and FDCA Labeling Requirements related to Endo's branded pharmaceutical products that are marketed or sold in the United States. Endo has in place and will maintain policies and procedures that prohibit violations of Federal health care program requirements and FDCA Labeling Requirements of branded pharmaceutical products, including policies and procedures on the following subjects.

b. *Independent Medical Education*: Endo has in place and will maintain policies and procedures that address sponsorship or funding of grants (including educational grants) or charitable contributions in the United States. These Policies and Procedures shall require that Endo's funding and/or sponsorship complies with all applicable Federal health care program requirements and FDCA Labeling Requirements.

c. *Promotion of Non-FDA Approved Uses and Unsolicited Medical Information Requests*: Endo has in place and will maintain its policy that prohibits sales agents from promoting product uses that are inconsistent with what is indicated on the products' FDA-approved package labeling and to forward requests for information regarding non-FDA approved uses of Endo's products to an appropriate medical resource.

d. *Sales Compensation and Incentives:* Endo will establish and maintain policies and procedures that shall (1) require that financial incentives do not inappropriately motivate field facing sales representatives or their direct managers to engage in improper promotion, sales, and marketing of Endo's branded pharmaceutical products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation any sales that indicate promotion of non-

FDA approved uses of Endo's branded pharmaceutical products.

Endo shall not provide any financial reward (through compensation, including incentive compensation or otherwise) or discipline (through employment action of any kind) to its sales representatives or their managers based upon the volume of Lidoderm within any given employee's territory or the area of any given manager's supervision.

e. *No Offering or Paying Illegal Remuneration*: Endo has in place and will maintain policies and procedures that prohibit Endo and its employees and representatives from engaging in any conduct that violates the federal anti-kickback statute, unless that conduct is excluded from coverage of the statute by any exception or regulatory safe harbor, including, but not limited to, the offering or paying of any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to any person to induce such person to prescribe any Endo branded pharmaceutical product for which payment may be made in whole or in part under a Federal health care program.

f. *Publication of Study Results:* Endo shall maintain standards, policies, and practices regarding full, fair, and accurate reporting and transparency of scientific data in the following ways:

(1) Endo will, in relation to Endo-sponsored studies [2] of branded pharmaceutical products not subject to paragraph (2) below, make available a summary of the results for each such study through an easily accessible, prominent link on Endo's publicly accessible corporate Internet website.

[2] As used in Subsections (1) and (3) of Section V.f. ("Publication of Study Results"), the terms "Endo-sponsored studies" and "Endo-sponsored research studies" refer to pre-marketing clinical research and post-marketing clinical research for which Endo is the sponsor (as defined in 21 C.F.R. § 50.3(e)), involving an intervention with human subjects with either a branded pharmaceutical product or a drug that becomes a branded pharmaceutical product during the duration of the agreement. These terms include Phase II and Phase III studies and trials as defined in 21 C.F.R. § 312.21(b) and (c), post-marketing clinical studies as defined in 21 C.F.R. § 312.85, and other post-marketing studies and trials sponsored by Endo. These terms do not include Phase I studies as defined in 21 C.F.R. § 312.21(a).

(2) Endo will register summary results from all applicable Endo-sponsored clinical trials of branded pharmaceutical products and report results of such clinical trials on the National Institutes of Health sponsored website (currently www.clinicaltrials.gov) in compliance with all federal requirements, and any changes to those requirements.

(3) Endo will seek to publish the results of Endo-sponsored research studies in peer-reviewed, searchable journals. In all publications about Endo-sponsored research, Endo shall acknowledge its role as the funding source.

(4) Endo will require as a condition of its funding that all researchers disclose in any publication of Endo-sponsored research Endo's support and any financial interest the researcher may have in Endo (including any interest in any Endo branded pharmaceutical products). Endo will require all authors of journal articles about Endo-sponsored research to adhere to International Committee of Medical Journal Editors ("ICMJE") requirements regarding authorship except when a journal requires an alternative procedure.

g. Notification of Purchase: Endo shall notify the Government, using the addresses provided below, within 60 calendar days following the purchase of the rights to distribute and/or market a branded pharmaceutical product Endo does not distribute or market as of the date this Agreement is executed. This notification shall include (1) the date of purchase, (2) the name of the product, (3) the name of the seller, (4) the regulatory status of the product as of the time of purchase, (5) the product's intended uses, and (6) whether the product is subject to any limitations as to marketing exclusivity under the FDCA.

h. Notice to Health Care Providers and Entities: Within 120 days after the Effective Date of this Agreement, Endo shall send, by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth below to all health care providers

and health care institutions who are currently detailed on behalf of Endo. This notice shall be dated and shall be signed by the Chief Executive Officer of Endo Health Solutions Inc. The body of the letter shall state the following:

> As you may be aware, Endo Pharmaceuticals Inc. recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion of one of its products (Lidoderm). This letter provides you with additional information about the settlement, explains the commitments of Endo going forward, and provides you with access to information about those commitments.
>
> In general terms, the Government alleged that Endo unlawfully promoted its product Lidoderm for intended uses not approved by the Food & Drug Administration (FDA) and that these activities violated the Federal Food, Drug, and Cosmetic Act and the False Claims Act. To resolve these matters, an Endo subsidiary, Endo Pharmaceuticals, Inc. (EPI) has entered into a deferred prosecution agreement and agreed to pay approximately $20.8 million as a monetary penalty and forfeiture. In addition, Endo entered into a civil settlement and agreed to pay $172.9 million to the Federal Government and State Medicaid programs to resolve False Claims Act allegations. More information about the deferred prosecution agreement and the civil settlement may be found at the following: http://www/justice.gov/ and http://endo.com/about-us/corporate-compliance-business-practices.
>
> As part of the global settlement, Endo also entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is available at https://oig.hhs.gov/compliance/corporate-integrity-agreements/ciadocuments.asp. Under this agreement, Endo agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. Endo also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by any of Endo's representatives to Endo's Compliance Department or the FDA using the information set forth below.
>
> Please call Endo at 1-855-645-5591 if you have questions about the settlement referenced above or to report any instances in which you believe that an Endo representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by an Endo representative to the FDA's Office of Prescription Drug Promotion at 301¬796-1200. You should direct medical questions

or concerns about the products to 1-800-462-3636.

The Chief Compliance Officer (or a designee) shall maintain a log of all compliance-related calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message.

i. *Log, Certification and Board Resolution:* Endo shall provide the Log required above and the following Certification and Board Resolution to the Government on an annual basis over the term of this Agreement. Each one-year period, beginning with the one-year period following the Effective Date of this Agreement, shall be referred to as a "Review Period." Endo shall provide the Log, Certification, and Board Resolution to the Government within 120 calendar days following the end of each Review Period as follows:

First Assistant U.S. Attorney
U.S. Attorney's Office
Northern District of New York
445 Broadway, Suite 218
Albany, New York 12207

Director, Consumer Protection Branch
U.S. Department of Justice
450 5th Street, NW
Washington, DC 20530

j. *Endo's Annual Certification:* Pursuant to paragraph V.i, the Chief Executive Officer of Endo Health Solutions Inc. shall conduct a review of the effectiveness of Endo's Compliance Program as it relates to the marketing, promotion, and sale of branded pharmaceutical products during the preceding Review Period. Based on his or her review, the Chief Executive Officer of Endo Health Solutions Inc. shall submit to the Government a signed certification stating that, to the best of his or her knowledge, during the period [insert time period]: (1) Endo's Compliance Program continued to include the policies and procedures set forth in the section of this Agreement

entitled Enhanced Compliance Program and Certifications, and (2) Endo has fully complied with the Reportable Event reporting requirements of this Agreement, as described below. The certification by the Chief Executive Officer of Endo Health Solutions Inc. shall summarize the review described above that he or she conducted to provide the required certification. If the Chief Executive Officer of Endo Health Solutions Inc. is unable to provide any part of this certification regarding Endo's compliance as specified in this Agreement, he or she shall provide a detailed explanation for why he or she is unable to provide such certification. The Certification shall be sworn to under the penalty of perjury and shall set forth that the representations contained therein may be provided to, relied upon and material to the government of the United States, and that a knowing false statement could result in criminal or civil liability for the signatory.

k. Annual Board of Directors Resolution: Pursuant to paragraph V.i, the Board of Directors of Endo Health Solutions Inc. (or any future parent company thereof), or a designated Committee thereof (the "Board"), shall conduct a review of the effectiveness of Endo's Compliance Program as it relates to the marketing, promotion, and sale of Endo branded pharmaceutical products during the preceding Review Period. This review shall include, but not be limited to, updates and reports by the Chief Compliance Officer of Endo Health Solutions Inc. and other compliance personnel. The Board shall evaluate the effectiveness of the Compliance Program, including, among other means, by receiving updates about the activities of the Chief Compliance Officer and other compliance personnel and updates about adoption and implementation of policies, procedures, and practices requiring compliance with applicable federal health care program requirements and FDCA Labeling Requirements regarding Endo's branded pharmaceutical products. The Board review shall not require the retention of third party experts. Based on its review, the Board shall submit to the Government a resolution (the "Board

Resolution") that summarizes its review and oversight of Endo's compliance with Federal health care program requirements and FDCA Labeling Requirements for Endo's branded pharmaceutical products and, at a minimum, includes the following language:

> The Board of Directors (or a designated Committee of the Board) has made a reasonable inquiry into the operations of Endo Pharmaceutical Inc.'s Compliance Program for the time period [insert time period], including the performance of the Chief Compliance Officer and the Compliance Committee as it relates to the marketing, sales and promotion of Endo's branded pharmaceutical products. The Board has concluded that, to the best of its knowledge and after reasonable inquiry, Endo has implemented an effective Compliance Program to meet federal health care program requirements and the Federal Food, Drug, and Cosmetic Act and FDA regulations regarding sales, marketing, and promotion regarding Endo's branded pharmaceutical products.

If the Board is unable to provide any part of this statement, it shall include in the resolution an explanation of the reasons why it is unable to provide such a statement about the effectiveness of Endo's Compliance Program.

l. *Reportable Events:* Fifteen days after the end of each calendar quarter (that is, by January 15 for the calendar quarter ending December 31, April 15 for the calendar quarter ending March 31, July 15 for the calendar quarter ending June 30, and October 15 for the calendar quarter ending September 30), Endo shall submit a report to the Government in writing, to the addresses described in paragraph V.i, stating whether any Reportable Events have been determined to have occurred during the preceding calendar quarter, and providing updated information about Reportable Events that occurred during any other calendar quarters. A Reportable Event is any matter that a reasonable person would consider a probable violation of the FDCA, 21 U.S.C. § 331(a) or (k), related to the misbranding of an Endo branded pharmaceutical product. A Reportable Event may be the result of an isolated event or a series of occurrences. The written report to the Government shall include: (1) a complete description of the Reportable Event,

including the relevant facts, identity of persons involved, and legal authorities implicated; (2) a description of Endo's actions taken to investigate and correct the Reportable Event; and (3) a description of any further steps Endo plans to take to address the Reportable Event and prevent it from recurring. Any Reportable Event determined to have occurred by Endo shall be promptly reported to the CEO of Endo Health Solutions Inc. The first calendar quarter for which a report shall be due under this Paragraph is the quarter ending June 30, 2014.

m. *Requests for Extensions of Time:* Endo may submit a timely written request for an extension of time to provide any required Log, Certification, Board Resolution, or report. A written request is timely if received by the Government at least five business days prior to the date by which the Log, Certification, Board Resolution, or report is due. Timely requests for extension will not be unreasonably denied.

VI. BREACH OF THE AGREEMENT:

a. Should the Government determine that Endo, after the date it signed this Agreement, (1) has committed any further crime (whether or not charged); (2) has given materially false, incomplete, or misleading testimony or information; or (3) has materially breached any term or condition of this Agreement or any supplemental agreements with the Government, the Government will have the right, in its sole and reasonable discretion, to void this Agreement, in whole or in part. In the event of such breach, Endo (1) will not be relieved of its obligation to make the payments set forth in this Agreement nor will it be entitled to return of any monies already paid, and (2) will remain obligated to comply with the Enhanced Compliance terms set forth in paragraphs V.a through V.f of this Agreement. Endo further understands that in the event of such breach, Endo will be subject to prosecution for any federal criminal violation of which the Government has knowledge, including but not limited to the charge(s) in the Information. If Endo

breaches this Agreement, the Government will have the following remedies, among others, available to it:

1. To bring a prosecution for any federal criminal offenses to be dismissed or not prosecuted under this Agreement. Endo waives (gives up) any defense or objection to the commencement of any such prosecution that is not time-barred by the applicable statute of limitations, including time protected as the result of existing agreements between Endo and the Government to toll the applicable statute of limitations, as of the date on which Endo signed this Agreement, notwithstanding the expiration of the statute of limitations between the signing of the Agreement and the commencement of any such prosecution.

2. In connection with any such prosecution, any information, statement, and testimony provided by or on behalf of Endo, and all leads derived therefrom, may be used against Endo, without limitation and without regard to any rights Endo may have under Fed. R. Crim. P. 11(f), Fed. R. Evid. 410, the U.S. Constitution, or any other federal law or rule.

3. To utilize any information, statement, or testimony provided by or on behalf of Endo, including the Statement of Facts, in any proceeding, including at sentencing, notwithstanding U.S.S.G. §1B1.8;

4. To advocate if, and how, any particular adjustment or specific offense characteristic affects the applicable Sentencing Guidelines range without regard to any contrary stipulations contained in this Agreement;

5. To urge the sentencing Court to take Endo's breach into account when imposing sentence; and

6. To recommend any sentence the Government deems appropriate, even if such recommendation is at odds with any stipulation in this Agreement.

b. In the event the Government determines that Endo has breached this Agreement, the Government agrees to provide Endo with written notice of such breach prior to instituting any prosecution resulting from such breach. Endo shall have the opportunity to respond to the Government, in writing within fourteen (14) days of receipt of such notice, or such other later time as the Government may agree in writing, to explain the nature and circumstances of such breach, as well as the actions Endo has taken to address and remediate the situation, including whether Endo believes a breach occurred, whether such breach was material, and whether such breach was willfully committed. The Government agrees to consider such explanation in determining whether to institute a prosecution.

c. In the event the Government determines that Endo has breached this Agreement, as a contractual remedy, Endo and the Government agree that the breach may lead to the imposition of Stipulated Penalties as outlined below. At the Government's sole discretion, Stipulated Penalties may be imposed as an alternative to instituting a prosecution due to the breach of this Agreement.

1. The stipulated penalty shall be $3,000 per day for each day Endo is in breach of the Agreement (hereafter referred to as "Stipulated Penalties").

2. The Government shall notify Endo in writing of Endo's failure to comply and the Government's exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter shall set forth: (1) the obligations breached; (2) the date of the breach; (3) a description of the breach sufficient to permit Endo to cure (as described below); and (4) the amount of Stipulated Penalties claimed by the Government as of the date of the Demand Letter. Within twenty-one (21) days after receipt of the Demand Letter, or such other later time as the Government may agree in writing (the "Cure Period"), Endo shall

demonstrate (1) that no breach has occurred, (2) that the breach was not material, or (3) that Endo has cured the breach to the Government's reasonable determination. If during the Cure Period Endo fails to cure the breach or demonstrate that the breach did not occur or that the breach was not material, Stipulated Penalties calculated from the date of breach to the date of payment shall be payable to the United States within seven (7) business days of the Government's final determination provided to Endo in writing.

3. The Stipulated Penalties shall be paid by electronic fund transfer according to wire instructions that will be provided by the Government. A joint reasonable determination by the United States Attorney for the Northern District of New York and the Assistant Attorney General for the Civil Division regarding Endo's failure to comply with any of the obligations described herein will be final and non-appealable. Endo agrees that the United States District Court for the Northern District of New York shall have jurisdiction over any action to collect such a penalty.

VII. LIMITATIONS: This Agreement is between Endo and the United States Attorney's Office for the Northern District of New York and the Consumer Protection Branch of the United States Department of Justice. This Agreement does not bind any other federal, state, or local prosecuting authorities. Furthermore, this Agreement does not prohibit the United States, any agency thereof, or any third party from initiating or prosecuting any civil or administrative proceedings directly or indirectly involving the defendant, including, but not limited to, proceedings by the Internal Revenue Service relating to potential civil tax liability.

VIII. AGREEMENT MUST BE SIGNED OR CONFIRMED IN COURT: This Agreement, to become effective, must be signed by all of the parties listed below. No promises, agreements, terms, or conditions other than those set forth in this Agreement will be effective unless memorialized in

writing and signed by all parties or confirmed on the record before the Court.

RICHARD S. HARTUNIAN
United States Attorney
Northern District of New York

Grant C. Jaquith
First Assistant United States Attorney
Bar Roll No. 501396

Date: 2/21/2014

Shannon L. Pedersen
Trial Attorney, Consumer Protection Branch
U.S. Department of Justice

Date: 2/20/2014

Rajiv De Silva
Chief Executive Officer
Endo Pharmaceuticals Inc.

Date: 2/19/14

Jonathan L. Stern, Esq.
Arnold & Porter LLP
Attorney for Defendant

Date: 2/19/14