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8
9 **IN THE UNITED STATES DISTRICT COURT**
10 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**
11 **SAN FRANCISCO DIVISION**

12
13 **STATE OF ALABAMA**
14 **STATE OF ARKANSAS**
15 **STATE OF FLORIDA**
16 **STATE OF HAWAII**
17 **STATE OF IDAHO**
18 **STATE OF INDIANA**
19 **STATE OF ILLINOIS**
20 **STATE OF IOWA**
21 **STATE OF MARYLAND**
22 **STATE OF MINNESOTA**
23 **STATE OF MISSISSIPPI**
24 **STATE OF MISSOURI**
25 **STATE OF OKLAHOMA**
26 **STATE OF OHIO**
27 **STATE OF UTAH**
28 **STATE OF WASHINGTON**
STATE OF WISCONSIN
COMMONWEALTH OF VIRGINIA

Plaintiffs,

v.

ENDO INTERNATIONAL PLC, and
ENDO PHARMACEUTICALS INC.,

Defendants.

SETTLEMENT AGREEMENT AND
STIPULATED ORDER FOR
PERMANENT INJUNCTION AND
MONETARY RELIEF

Case No. 3:19-cv-4157

1 This Settlement Agreement and Stipulated Order (“ASO”) is made and entered into this
2 15th day of July, 2019 (“Effective Date”), by and between the undersigned States through their
3 respective Attorneys General (“Party States”), and Endo Pharmaceuticals Inc. and Endo
4 International plc (collectively “Endo”) (the Party States and Endo, collectively, the “Parties”).
5 Any State electing to join the ASO shall do so by executing a signature page that shall be annexed
6 to this ASO, with the ASO and all such counterparts collectively constituting the whole of this
7 agreement.

8 WHEREAS, Endo Pharmaceuticals Inc. is or was engaged in manufacturing, marketing,
9 and/or selling certain pharmaceuticals, including but not limited to Lidoderm[®], throughout the
10 United States;

11 WHEREAS, the Party States allege that they have reason to believe that Endo
12 Pharmaceuticals Inc. entered into an agreement that foreclosed competition from generic
13 equivalents of the brand-name drug Lidoderm[®] for a period of time in violation of federal
14 antitrust and state antitrust and consumer protection laws;

15 WHEREAS, the Party States initiated an investigation of Endo with respect to the above
16 alleged actions;

17 WHEREAS, the Party States have filed an enforcement Complaint (“Complaint”)
18 against Endo in this Court alleging such violations of federal and state laws;

19 WHEREAS, Endo denies that it engaged in any wrongful or unlawful conduct and asserts
20 that it has, at all times, operated within the law and within industry standard practices; and

21 WHEREAS, nothing in this ASO will be construed as a finding or admission of any
22 violation of law on the part of Endo;

23 The Parties have agreed to resolve the States’ concerns identified through the
24 investigation and the allegations in the Complaint by entering into this ASO, as follows:

25 FINDINGS

26 1. This Court has jurisdiction over the Parties and the subject matter of this action.
27 Endo has stipulated that, for purposes of this ASO alone, the Court has jurisdiction over Endo
28 Pharmaceuticals Inc. and Endo International plc.

1 2. Venue for these matters is proper in this Court under 15 U.S.C. § 22 and 28 U.S.C.
2 §1391(b) and (c).

3 3. The Complaint alleges that Endo engaged in violations of federal antitrust and
4 state antitrust and consumer protection laws by entering an agreement that foreclosed competition
5 from generic equivalents of the brand-name drug Lidoderm[®] and later reduced competition
6 between sellers of generic lidocaine patches.

7 4. Endo admits the facts necessary to establish the personal and subject matter
8 jurisdiction of this Court in this matter only.

9 5. Endo denies the charges in the Complaint and disputes that the Party States are
10 entitled to obtain relief.

11 6. This Order does not constitute any evidence against Endo, or an admission of
12 liability or wrongdoing by Endo, in this case or in any other litigation. This Order shall not be
13 used in any way, as evidence or otherwise, in any other litigation or proceeding; *provided*,
14 *however*, that this provision shall not prevent the Party States or Endo from using this Order in
15 any proceeding regarding enforcement or modification of this ASO or as otherwise required by
16 law.

17 7. Entry of this ASO is in the public interest. The Party States and Endo have agreed
18 to stipulate to entry of this ASO to finally resolve the claims and litigation between them.

19 **STIPULATIONS**

20 1. The Party States stipulate that they will not file litigation or any other proceedings
21 against Endo asserting, or seeking remedies based on, Released Claims, other than any legal
22 proceeding regarding enforcement or modification of this ASO.

23 2. Upon entry of this ASO by the Court, the Complaint shall be deemed dismissed
24 with prejudice.

25 **I. DEFINITIONS**

26 **IT IS ORDERED** that, as used in this ASO, the following definitions shall apply:

27 A. “505(b)(2) Application” means an application filed with the United States Food
28 and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic

1 Act, U.S.C. § 355(b)(2).

2 B. “ANDA” means an Abbreviated New Drug Application filed with the United States
3 Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic
4 Act, 21 U.S.C. § 355(j).

5 C. “Authorized Generic” means a Drug Product that is manufactured pursuant to an
6 NDA and Marketed in the United States under a name other than the proprietary name identified
7 in the NDA.

8 D. “Brand/Generic Settlement” means any agreement or understanding that settles a
9 Patent Infringement Claim in or affecting Commerce in the United States.

10 E. “Brand/Generic Settlement Agreement” means a written agreement that settles a
11 Patent Infringement Claim in or affecting Commerce in the United States.

12 F. “Branded Subject Drug Product” means a Subject Drug Product Marketed in the
13 United States under the proprietary name identified in the NDA for the Subject Drug Product.

14 G. “Commerce” has the same definition as it has in 15 U.S.C. § 44.

15 H. “Control” or “Controlled” means the holding of more than fifty percent (50%) of
16 the common voting stock or ordinary shares in, or the right to appoint more than fifty percent
17 (50%) of the directors of, or any other arrangement resulting in the right to direct the management
18 of, the said corporation, company, partnership, joint venture, or entity.

19 I. “Contingent Supply Agreement” means a Supply Agreement that: (i) is contingent
20 on the Generic Filer’s inability to market the Generic Subject Drug Product on or after the
21 Generic Entry Date because (x) the FDA has not granted final approval of the Generic Filer’s
22 ANDA or 505(b)(2) Application for the Generic Subject Drug Product and/or (y) the Generic
23 Filer cannot manufacture commercial quantities of the Generic Subject Drug Product; and (ii)
24 terminates within thirty (30) days after the Generic Filer has final FDA approval and can
25 manufacture commercial quantities of the Generic Subject Drug Product using good faith,
26 commercially reasonable efforts, *provided, however*, the Generic Filer may take delivery of,
27 Market, and sell quantities of Authorized Generic ordered prior to termination of the Supply
28 Agreement *so long as* the total quantity of Authorized Generic delivered to the Generic Filer

1 following termination of the Supply Agreement: (i) does not exceed the total quantity needed by
2 the Generic Filer (as reflected in forecasts provided to the NDA Holder prior to termination of the
3 Supply Agreement) during the eight (8) months following (x) termination of the Supply
4 Agreement, if termination occurs after the Generic Entry Date, or (y) the Generic Entry Date, if
5 termination occurs before the Generic Entry Date; and (ii) is delivered within eight (8) months of
6 termination of the Supply Agreement.

7 J. “Drug Product” means a finished dosage form (e.g., tablet, capsule, solution, or
8 patch), as defined in 21 C.F.R. § 314.3(b), approved under a single NDA, ANDA or 505(b)(2)
9 Application, that contains a drug substance, generally, but not necessarily, in association with one
10 or more other ingredients.

11 K. “Endo Pharmaceuticals” means Endo Pharmaceuticals Inc., any joint venture,
12 subsidiary, division, group, or affiliate Controlled currently or in the future by Endo
13 Pharmaceuticals Inc., their successors and assigns, and the respective directors, officers,
14 employees, agents, and representatives acting on behalf of each.

15 L. “Endo International” means Endo International plc, any joint venture, subsidiary,
16 division, group, or affiliate Controlled currently or in the future by Endo International plc, their
17 successors and assigns, and the respective directors, officers, employees, agents, and
18 representatives acting on behalf of each.

19 M. “Endo” means Endo Pharmaceuticals and Endo International.

20 N. “Exception” means the following in a Brand/Generic Settlement:

21 1. compensation for saved future litigation expenses, **but only if** the total
22 compensation the NDA Holder agrees to provide to the Generic Filer during the sixty (60)
23 day period starting thirty (30) days before and ending thirty (30) days after executing the
24 Brand/Generic Settlement Agreement does not exceed a maximum limit, which is initially
25 set at seven million, two hundred sixty-two thousand, eight hundred seventy-nine dollars
26 (\$7,262,879)¹ and shall be increased (or decreased) as of January 1 of each year following

27 ¹ For avoidance of doubt, this amount is intended to be equivalent to the maximum
28 limit in the definition of Exception in the FTC Order, but is adjusted herein to reflect the
subsequent annual changes in the Producer Price Index as provided for in the FTC Order.

1 entry of this ASO by an amount equal to the percentage increase (or decrease) from the
2 previous year in the annual average Producer Price Index for Legal Services (Series Id.
3 PCU5411--5411--) published by the Bureau of Labor Statistics of the United States
4 Department of Labor or its successor;

5 2. the right to Market, as of an agreed upon Generic Entry Date: (i) Generic
6 Product(s) in the United States under an ANDA or 505(b)(2) Application (x) that is
7 controlled by the Generic Filer and was not transferred to the Generic Filer by the NDA
8 Holder, or (y) to which the Generic Filer has a license from a party other than the NDA
9 Holder; or (ii) an Authorized Generic of the Subject Drug Product; this Exception 2 shall
10 apply regardless of whether or not the Generic Filer must pay for the right to Market and,
11 if so, the terms and conditions governing such payment;

12 3. provisions to facilitate, by means other than the transfer of goods or money,
13 the Generic Filer's ability to secure or maintain final regulatory approval, or commence or
14 continue the Marketing, of a Generic Product, by, *inter alia*, providing covenants, waivers,
15 permissions, releases, dismissals of claims, and/or authorizations;

16 4. waiver or limitation of a claim for damages or other monetary relief based
17 on prior Marketing of the Generic Subject Drug Product, **but only if** the NDA Holder and
18 the Generic Filer do not agree, and have not agreed, to another Brand/Generic Settlement
19 for a different Drug Product during the sixty (60) day period starting thirty (30) days
20 before and ending thirty (30) days after the execution of the Brand/Generic Settlement
21 Agreement; or

22 5. a continuation or renewal of a pre-existing agreement between an NDA
23 Holder and a Generic Filer **but only if**: (i) the pre-existing agreement was entered into at
24 least 90 days before the relevant Brand/Generic Settlement Agreement, (ii) the terms of the
25 renewal or continuation, including the duration and the financial terms, are substantially
26 similar to those in the pre-existing agreement, and (iii) entering into the continuation or
27 renewal is not expressly contingent on agreeing to a Brand/Generic Settlement.
28

1 O. "Exempted Agreement" means a Materials Agreement or Supply Agreement that
2 meets (x) all of the conditions in subparagraphs I.O.1-I.O.4 below, and (y) either (i) the conditions
3 in subparagraphs I.O.5 and I.O.6 below or (ii) the conditions in subparagraph I.O.7 below:

4 1. the price is above the Fully Allocated Manufacturing Cost, meaning:

5 a. if the Agreement is a Materials Agreement, the Materials Price charged
6 by the NDA Holder for Materials provided through the Materials Agreement is at
7 or above the Fully Allocated Manufacturing Cost incurred by the NDA Holder per
8 unit of the relevant Materials, or

9 b. if the Agreement is a Supply Agreement, the Supply Price charged by
10 the NDA Holder for the Authorized Generic of the Subject Drug Product is at or
11 above the Fully Allocated Manufacturing Cost incurred by the NDA Holder per
12 unit of the Authorized Generic of the Subject Drug Product provided under the
13 agreement;

14 2. the Brand/Generic Settlement Agreement containing or incorporating the
15 Materials Agreement or Supply Agreement is the only Brand/Generic Settlement
16 Agreement that the NDA Holder and the Generic Filer have entered, or agreed to enter,
17 during the sixty (60) day period starting thirty (30) days before and ending thirty (30)
18 days after the execution of the Brand/Generic Settlement Agreement;

19 3. within fourteen (14) days after signing the Brand/Generic Settlement Agreement
20 containing or incorporating the Materials Agreement or Supply Agreement, Endo
21 Submitted to the Monitor a full and complete copy of the Brand/Generic Settlement
22 Agreement, including any Materials Agreement and/or Supply Agreement;

23 4. within fourteen (14) days after the NDA Holder provides to the Generic Filer
24 the Materials Price or Supply Price, as applicable, Endo Submitted to the Monitor
25 notification of the relevant Materials Price or Supply Price;

26 5. within thirty (30) days after beginning supply under the relevant Materials
27 Agreement or Supply Agreement, the NDA Holder Submitted to the Monitor:
28

1 a. if a Materials Agreement, a verified written statement containing (i) the
2 Fully Allocated Manufacturing Cost per unit for the Materials and (ii) a detailed
3 calculation of the Fully Allocated Manufacturing Cost for the Materials, stated
4 separately by cost component and on a per-unit basis; and

5 b. if a Supply Agreement, a verified written statement containing (i) the
6 Fully Allocated Manufacturing Cost per unit for the relevant Authorized Generic of
7 the Subject Drug Product and (ii) a detailed calculation of the Fully Allocated
8 Manufacturing Cost for the Authorized Generic of the Subject Drug Product, stated
9 separately by cost component and on a per-unit basis; and

10 6. if the NDA Holder is not Endo, the Materials Agreement or Supply Agreement,
11 as applicable, requires the NDA Holder to (i) provide the notification required by
12 subparagraphs I.O.5. and (ii) cooperate with any reasonable request by the Monitor or
13 staff of the FTC for documents and information to determine the relevant Fully Allocated
14 Manufacturing Cost, including without limitation and subject to any demonstrated legally
15 recognized privilege, providing the Monitor reasonable access to personnel, books,
16 documents, and records kept in the ordinary course of business;

17 7. notwithstanding subparagraph I.O.5. and subparagraph I.O.6., a Materials
18 Agreement or Supply Agreement in which Endo is the Generic Filer shall also be
19 considered an Exempted Agreement if it complies with subparagraphs I.O.1. to 4 **and**:

20 a. if a Materials Agreement, Endo Submits to the Monitor within thirty (30)
21 days of beginning to receive the Materials, a verified written statement containing
22 (i) Endo's best estimate of what would be the Fully Allocated Manufacturing Cost
23 per unit for the Materials if manufactured or sourced by the Generic Filer, including
24 a separate estimate of each cost component on a per-unit basis, and (ii) a
25 description of the terms and conditions of any agreement(s), offer(s), purchase
26 order(s), or price quote(s) Endo has entered into or received for supply of the
27 Materials in connection with manufacture of the Subject Drug Product and other
28

1 facts and circumstances, if any, that Endo deems relevant to understanding such
2 terms and conditions; and

3 b. if a Supply Agreement, it is a Contingent Supply Agreement and Endo
4 Submits to the Monitor within thirty (30) days of beginning to receive the
5 Authorized Generic, a verified written statement containing (i) Endo’s best estimate
6 of what would be the Fully Allocated Manufacturing Cost per unit for the Subject
7 Drug Product if manufactured by the Generic Filer and (ii) a detailed calculation of
8 the estimated Fully Allocated Manufacturing Cost, including an estimate of each
9 cost component on a per-unit basis.

10 P. “FTC” means the United States Federal Trade Commission.

11 Q. “FTC Order” means the Stipulated Order for Permanent Injunction entered in the
12 United States District Court for the Northern District of California, in *Federal Trade Commission*
13 *v. Endo Pharmaceuticals Inc.*, Civ. Action No. 17-cv-00312 (Document 25, February 2, 2017).

14 R. “Fully Allocated Manufacturing Cost” means: (1) direct costs incurred to produce
15 or, if applicable, to acquire, the Subject Drug Product or Materials, determined in accordance with
16 GAAP, as consistently applied in accordance with past practice and in the ordinary course of
17 business, including, but not limited to (x) acquisition costs or (y) if applicable, materials, labor,
18 manufacturing costs, packaging, labeling, testing, quality control, storage, insurance, and product
19 maintenance; (2) the cost to ship the Subject Drug Product or Materials to the Generic Filer, and
20 (3) administrative and overhead expenses associated with production or, if applicable, the
21 acquisition of the Subject Drug Product or Materials, including, but not limited to, administrative
22 labor costs, maintenance, information technology, quality assurance, insurance, depreciation of the
23 equipment, and depreciation of the facility, allocated in accordance with past practice and in the
24 ordinary course of business. To the extent the NDA Holder does not allocate administrative and
25 overhead expenses associated with the Subject Drug Product to the Subject Drug Product, for
26 purposes of this ASO such administrative and overhead expenses shall be deemed to be a
27 proportion of the NDA Holder’s COGS of the Subject Drug Product to the NDA Holder’s total
28 COGS (for purposes of this definition, COGS means the NDA Holder’s cost of goods sold,

1 determined in accordance with GAAP, as consistently applied in accordance with past practice and
2 in the ordinary course of business).

3 S. "Generic Entry Date" means the date in a Brand/Generic Settlement Agreement,
4 whether certain or contingent, on or after which a Generic Filer is authorized by the NDA Holder
5 to begin manufacturing, using, importing or Marketing the Generic Subject Drug Product.

6 T. "Generic Filer" means a party to a Brand/Generic Settlement who controls an
7 ANDA or 505(b)(2) Application for the Subject Drug Product or has the exclusive right under
8 such ANDA or 505(b)(2) Application to distribute the Subject Drug Product.

9 U. "Generic Product" means a Drug Product manufactured and/or sold under an
10 ANDA or pursuant to 505(b)(2) Application.

11 V. "Generic Subject Drug Product" means the Generic Product that is the subject of
12 the Patent Infringement Claim being resolved by the Brand/Generic Settlement.

13 W. "Lidoderm Settlement Agreement" means the Settlement and License Agreement
14 between Endo Pharmaceuticals Inc. and Watson Laboratories, Inc. resolving the ANDA patent
15 litigation involving the brand-name drug Lidoderm[®] that is the subject of the Complaint in this
16 action.

17 X. "Market," "Marketed," or "Marketing" means the promotion, offering for sale,
18 sale, or distribution of a Drug Product.

19 Y. "Materials" means components or ingredients used in the manufacturing of a
20 Subject Drug Product, including, but not limited to, hard-to-source excipients, hard-to-source
21 active pharmaceutical ingredients, hard-to-source packaging, devices, or kits for injectables.

22 Z. "Materials Agreement" means provisions in, or incorporated into, a Brand/Generic
23 Settlement Agreement providing for the supply of Materials to the Generic Filer by the NDA
24 Holder for securing and/or maintaining regulatory approval, or manufacturing and Marketing by
25 the Generic Filer of the Subject Drug Product, including the terms and conditions of any such
26 supply.

1 AA. "Materials Price" means the total actual per-unit price charged by the NDA Holder
2 for Materials provided through a Materials Agreement, including any transfer price and royalty to
3 be paid by the Generic Filer, net of any discounts, allowances, rebates, or other reductions.

4 BB. "Monitor" means an individual appointed pursuant to Paragraph IV of the FTC
5 Order.

6 CC. "NDA" means a New Drug Application filed with the United States Food and Drug
7 Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.
8 § 355(b), including all changes or supplements thereto that do not result in the submission of a
9 new NDA.

10 DD. "NDA Holder" means a party to a Brand/Generic Settlement that controls the NDA
11 for the Subject Drug Product or has the exclusive right to distribute the Branded Subject Drug
12 Product in the United States.

13 EE. "No-AG Commitment" means any agreement with, or commitment or license to,
14 the Generic Filer that prohibits, prevents, restricts, requires a delay of, or imposes a condition
15 precedent upon the research, development, manufacture, regulatory approval, or Marketing of an
16 Authorized Generic, *provided, however*, that agreement by the Generic Filer to pay royalties to
17 the NDA Holder for the right to Market the Generic Subject Drug Product or an Authorized
18 Generic of the Subject Drug Product, including agreement on the terms and conditions governing
19 payment of such royalties, shall not be considered a No-AG Commitment.

20 FF. "Patent Infringement Claim" means any allegation threatened in writing or
21 included in a complaint filed with a court of law that a Generic Product may infringe one or more
22 U.S. Patents held by, or licensed to, an NDA Holder.

23 GG. "Payment by the NDA Holder to the Generic Filer" means a transfer of value,
24 other than a No-AG Commitment, by the NDA Holder to the Generic Filer (including, but not
25 limited to, money, goods, or services), regardless of whether the Generic Filer purportedly
26 transfers value in return, where such transfer is either (i) expressly contingent on entering a
27 Brand/Generic Settlement Agreement, or (ii) agreed to during the sixty (60) day period starting
28

1 thirty (30) days before and ending thirty (30) days after executing a Brand/Generic Settlement
2 Agreement.

3 HH. "Subject Drug Product" means the Drug Product for which one or more Patent
4 Infringement Claims are settled under a given Brand/Generic Settlement. For purposes of this
5 ASO, the Drug Product of the NDA Holder and the Generic Filer to the same Brand/Generic
6 Settlement shall be considered to be the same Subject Drug Product.

7 II. "Supply Agreement" means provisions in, or incorporated into, a Brand/Generic
8 Settlement Agreement providing for the supply of the Subject Drug Product to the Generic Filer
9 by the NDA Holder for the Marketing by the Generic Filer of an Authorized Generic on or after
10 the Generic Entry Date, including the terms and conditions of any such supply.

11 JJ. "Supply Price" means the total actual per-unit price charged by the NDA Holder
12 for supply provided through a Supply Agreement, including any transfer price and royalty to be
13 paid by the Generic Filer for the right to sell an Authorized Generic of the Subject Drug Product,
14 net of any discounts, allowances, rebates, or other reductions.

15 KK. "U.S. Patent" means any patent issued by the United States Patent and Trademark
16 Office, including all renewals, derivations, divisions, reissues, continuations, continuations-in
17 part, modifications, or extensions thereof.

18 LL. "Verified Written Report" means a report that must be submitted to the FTC
19 pursuant to Paragraph V of the FTC Order.

20 II. RELEASED CLAIMS

21 **IT IS FURTHER ORDERED** that:

22 A. **Release.** The Group One States² and the Group Two States³ shall release and/or
23 stipulate and agree not to assert claims as follows:

24 (1) **Group One States' Released Claims:** In consideration of the injunctive
25 provisions and Settlement Amount contained herein, Group One States will be

26 _____
27 ² Group One States include: Alabama, Iowa, Indiana, Maryland, Minnesota,
Mississippi, Oklahoma, Utah, Virginia, Washington, and Wisconsin.

28 ³ Group Two States include: Arkansas, Florida, Hawaii, Idaho, Illinois, Missouri,
and Ohio.

1 deemed, upon the Effective Date, to have fully, finally, and forever released
2 Endo and affiliated entities and their current and former officers, directors,
3 employees, agents, other associated persons and attorneys (collectively
4 “Releasees”) from any and all manner of claims, counterclaims, set-offs,
5 demands, actions, rights, liabilities, costs, debts, expenses, attorneys’ fees, and
6 causes of action of any type, whether or not accrued in whole or in part, known
7 or unknown, under federal or state law, arising from the Lidoderm Patent
8 Settlement Agreement and from the facts, matters, transactions, events,
9 occurrences, acts, disclosures, statements, omissions, or failures to act arising
10 from said agreement (“Covered Conduct”) that were asserted or alleged, or
11 could have been asserted or alleged, in the Complaint by each Group One State
12 or the Attorney General of each Group One State in any capacity, including but
13 not limited his/her sovereign capacity as the chief law enforcement officer,
14 parens patriae or proprietary capacity (“Group One States’ Resolved Claims”).

15 **(2) Group Two States’ Released Claims:** In consideration of the injunctive
16 provisions and Settlement Amount contained herein, Group Two States will be
17 deemed, upon the Effective Date, to have fully, finally, and forever released
18 Releasees from any and all manner of claims, counterclaims, set-offs,
19 demands, actions, rights, liabilities, costs, debts, expenses, attorneys’ fees, and
20 causes of action of any type, whether or not accrued in whole or in part, known
21 or unknown, under federal or state law, arising from the Covered Conduct that
22 were asserted or alleged, or could have been asserted or alleged, in the
23 Complaint by each Group Two State in a law enforcement capacity or the
24 Attorney General of each Group Two State in his/her sovereign capacity as the
25 chief law enforcement officer. In addition, each Group Two State is otherwise
26 deemed to have stipulated and agreed that, in light of the terms of this ASO,
27 neither it nor its Attorney General will assert any claim in any capacity or any
28 claim on behalf of its departments, commissions, divisions, districts and other

1 agencies, and the predecessors, successors, administrators and assigns of any
2 of the foregoing against Endo arising from the Covered Conduct that were
3 asserted or alleged, or could have been asserted or alleged, in its Complaint.
4 (All claims covered by this Section II.A.(2) “Group Two States’ Resolved
5 Claims.)

6 The Group One States’ Resolved Claims and the Group Two States’ Resolved Claims
7 (together, the “Collective Resolved Claims”) shall not include the Excluded Claims defined
8 below. In addition, in connection with the release provided above, the Party States expressly
9 waive, release, and forever discharge any and all provisions, rights, and benefits conferred by any
10 law of any state or territory of the United States or other jurisdiction, or principle of common law,
11 which is similar, comparable or equivalent to § 1542 of the California Civil Code, which reads:

12 **Section 1542. General Release; extent.** A general release does not extend to claims
13 which the creditor does not know or suspect to exist in his or her favor at the time of
14 executing the release, which if known by him or her must have materially affected his or
her settlement with the debtor;

15 A Party State may hereafter discover facts other than or different from those which he, she, or it
16 knows or believes to be true with respect to the Collective Resolved Claims, but each Party State
17 hereby expressly waives and fully, finally, and forever settles, releases, and discharges, upon this
18 ASO becoming final, any known or unknown, suspected or unsuspected, asserted or unasserted,
19 contingent or non-contingent claim that would otherwise fall within the definition of Collective
20 Resolved Claims, whether or not concealed or hidden, without regard to the subsequent discovery
21 or existence of such different or additional facts, provided, however, that this shall not apply to
22 claims arising from documents or information intentionally withheld or concealed by Endo in
23 response to a subpoena served by a Party State in an effort to obstruct that Party State’s
24 investigation. This provision shall not in any way expand the scope of the Collective Resolved
25 Claims and shall not convert what is a limited release into a general release.

26 **B. Excluded Claims.** The release provided herein shall not have an effect on the
27 following Excluded Claims and such Excluded Claims shall not be included within the Collective
28 Resolved Claims:

- 1 (1) claims or potential claims, under federal or state laws, of persons other than the
2 Party States⁴ against Endo, including, but not limited to, any claims or
3 potential claims asserted in *In re Lidoderm Antitrust Litigation*, No. 14-md-
4 02521-WHO (N.D. Cal.);
- 5 (2) claims for alleged violations of state revenue codes;
- 6 (3) claims based on alleged breach of expressed or implied warranty claims or
7 other liability for defective or deficient products and services provided by
8 Endo;
- 9 (4) claims based on alleged failure to deliver goods or services due; or
- 10 (5) any claim for liability under common law, any statute, regulation, or rule
11 lawfully promulgated under each state’s administrative code or other enabling
12 legislation for any conduct other than the Covered Conduct, including but not
13 limited to:
- 14 i. claims regarding Medicare or Medicaid fraud, false claims, unlawful
15 kickbacks, off-label marketing, unfair or deceptive representations,
16 false advertising or product liability;
- 17 ii. claims for criminal liability; or
- 18 iii. claims for breach of this ASO.

19 C. **Res Judicata.** The ASO shall be deemed to have rendered any of the Collective
20 Resolved Claims as res judicata.

21 III. SETTLEMENT PAYMENT

22 **IT IS FURTHER ORDERED** that:

23 A. Endo Pharmaceuticals Inc. shall make a payment to the Party States in the amount
24 of U.S. \$2,265,983.59 (“Settlement Amount”) within the later of thirty (30) calendar days after
25 the Effective Date or thirty (30) calendar days after receiving written payment processing
26 instructions and any related documentation reasonably requested by Endo. The Settlement

27 ⁴ For avoidance of doubt, this ASO does not release any claims that have been or
28 could be brought by private consumers, even if those claims could have been asserted by one or
more of the Party States in their *parens patriae* capacity.

1 Amount shall be apportioned among the Party States at the sole discretion of the Party States as
2 may be agreed upon among them, and Endo shall have no responsibility for or influence with
3 respect to that allocation, which may include any or all of the following: (i) payment of
4 attorneys' fees and expenses; (ii) antitrust or consumer protection law enforcement; (iii) for
5 deposit into a state antitrust or consumer protection account (e.g., revolving account, trust
6 account), for use in accordance with the state laws governing that account; or (iv) for such other
7 purpose as the Attorneys General deem appropriate, consistent with the various states' laws.⁵

8 The Party States shall provide Endo Pharmaceuticals Inc. with written payment processing
9 instructions for payment of the Settlement Amount by electronic transfer.

10 B. Endo Pharmaceuticals Inc. warrants that, as of the date of this Settlement
11 Agreement, it is not insolvent, nor will its Settlement Payment render it insolvent within the
12 meaning of and/or for the purposes of the United States Bankruptcy Code. If (i) a case is
13 commenced with respect to Endo under Title 11 of the United States Code (Bankruptcy), or a
14 trustee, receiver or conservator is appointed under any similar law, and (ii) a court of competent
15 jurisdiction enters a final order determining the Settlement Payment, or any portion thereof, by
16 or on behalf of Endo Pharmaceuticals Inc., to be a preference, voidable transfer, fraudulent
17 transfer or similar transaction, and (iii) pursuant to an order of a court of competent jurisdiction
18 monies paid by Endo Pharmaceuticals Inc. pursuant to this Settlement Agreement are either not
19 delivered or are returned to Endo Pharmaceuticals Inc. or the trustee, receiver, or conservator
20 appointed by a court in any bankruptcy proceeding with respect to Endo Pharmaceuticals Inc.,
21 then the releases given and judgment entered in favor of Endo pursuant to this Settlement
22 Agreement shall be null and void.

23 IV. PERMANENT INJUNCTION

24 **IT IS FURTHER ORDERED** that:

25 A. In connection with any actions in or affecting Commerce, Endo shall cease and
26

27 ⁵ As deemed appropriate in the discretion of the Attorney General of Hawaii,
28 Hawaii's portion of the Settlement Amount may also be distributed to state agencies and entities
whose programs provided funding, directly or indirectly, for Lidoderm and Lidocaine
prescriptions, which programs were not completely funded through general fund appropriations.

1 desist from, either directly or indirectly, or through any corporate or other device, individually or
2 collectively entering into a Brand/Generic Settlement that includes:

- 3 1. (i) a No-AG Commitment and (ii) an agreement by the Generic Filer not to
4 research, develop, manufacture, or Market the Subject Drug Product for
5 any period of time; or
- 6 2. (i) any Payment by the NDA Holder to the Generic Filer that is not an
7 Exception or an Exempted Agreement and (ii) an agreement by the Generic
8 Filer not to research, develop, manufacture, or Market the Subject Drug
9 Product for any period of time,

10 *provided, however*, that any agreement entered into by an entity prior to that entity becoming part
11 of Endo is not subject to the terms of this ASO.

12 B. In the event of a material change in the law governing the antitrust implications of
13 Brand/Generic Settlements, the Party States will consider, in good faith, modifications to this
14 ASO proposed by Endo.

15 C. Nothing in this ASO shall prohibit Endo from entering a written agreement,
16 including a Brand/Generic Settlement, for which Endo has submitted to the State Reporting and
17 Enforcement Council (“SREC”), by written communication through the Liaison States (defined
18 below), a request for prior approval of the agreement, which shall include any information
19 provided to the FTC pursuant to Paragraph III of the FTC Order, *so long as* (1) within thirty (30)
20 days of the Liaison States’ receipt of the request for prior approval under this provision, the
21 Liaison States have not notified Endo in writing that, after considering the request in good faith,
22 the SREC believes the relevant agreement raises substantial questions regarding violation of state
23 or federal antitrust law or any other applicable law that the Party States have authority to enforce
24 and of the reasons for such a belief, or (2) Endo has received, in a written communication by the
25 Liaison States, the prior approval of the SREC.

26 D. Nothing in this Section IV shall prohibit Endo from executing a written agreement
27 *so long as* such agreement contains a provision or provisions expressly stating: (1) Endo will
28 submit to the SREC by written communication through the Liaison States, a request for prior

1 approval of the agreement, and (2) the agreement is not effective, and shall not become effective,
2 until and unless (i) thirty (30) days have passed since the request for prior approval was submitted
3 to the Liaison States and the Liaison States have not notified Endo in writing that the SREC
4 believes the agreement raises substantial questions regarding violation of state or federal antitrust
5 law or any other applicable law that the Party States have authority to enforce, or (ii) the SREC
6 has approved of the agreement, as reflected in a written communication to Endo from the Liaison
7 States.

8 **V. STATES REPORTING AND ENFORCEMENT COUNCIL**

9 **IT IS FURTHER ORDERED** that:

10 A. The Party States shall have authority for enforcing this ASO as set forth herein.

11 B. The Party States shall establish a States Reporting and Enforcement Council
12 (“SREC”) consisting initially of the States of Mississippi and Minnesota. Any Party State may
13 resign from or join the SREC upon 10 days’ prior written notice to Endo. The Party States shall
14 exercise their rights under this ASO solely through the SREC, which shall have sole and
15 exclusive right and authority, among other things, to seek to enforce this ASO, to implement the
16 reporting requirements and receive from Endo the materials specified in Section VI herein
17 (Reporting and Monitoring Obligations), and to exercise any rights to access information under
18 Section VIII (Access to Information).

19 C. The SREC shall designate up to five (5) of its members to serve as the Liaison
20 States. The initial Liaison States shall be Mississippi and Minnesota. The members serving as
21 Liaison States may be changed from time to time at the discretion of the SREC, but in any event,
22 the SREC shall notify Endo within three (3) business days of the selection of any initial and
23 subsequent Liaison States, and shall provide the names and contact information for the authorized
24 representatives of any Liaison States. The SREC shall communicate with Endo, and Endo shall
25 communicate with the SREC, solely through the Liaison States concerning any matter covered by
26 or relating to this ASO, and Endo may rely exclusively on such communications with the Liaison
27 States as being on behalf of and having the full authority of the SREC. By way of clarification
28 and not limitation, Endo shall be obligated to provide only to the Liaison States any reports,

1 information, or notices required under this ASO, which Endo shall transmit by electronic mail
2 and/or overnight delivery service and which shall be effective upon transmission. The members
3 of the SREC and the Liaison States, as of the Effective Date, are identified on Exhibit A hereto
4 along with contact information for their respective representatives. All notices or
5 communications to Endo under this ASO shall be made to the individuals identified on Exhibit B
6 hereto, as may be amended in writing from time to time, and shall be made by electronic mail
7 and/or by overnight delivery service.

8 D. The SREC shall have the sole and exclusive authority on behalf of the Party States
9 to enter into and implement the terms of this ASO, as described herein. The SREC shall also
10 have the sole and exclusive authority on behalf of the Party States to seek to enforce this ASO, as
11 provided herein.

12 E. If the SREC believes that Endo is not in compliance with the terms of this ASO,
13 the SREC, through the Liaison States, shall give Endo written notice of such alleged non-
14 compliance and the reasons why the SREC believes that Endo is not complying with this ASO.
15 Endo shall have twenty (20) business days from the date of receipt of such notice to respond in
16 writing unless otherwise agreed by the Parties. If the SREC is not satisfied with Endo's response,
17 the Liaison States shall so notify Endo in writing, and Endo shall have seventy-five (75) calendar
18 days from the date of receipt of such notice to cure such alleged non-compliance. If after such
19 time, the SREC believes that Endo remains not in compliance with this ASO, the SREC may seek
20 to enforce this ASO with the Court in a civil enforcement proceeding, seeking such relief as is
21 available under applicable laws, including, if so available, fees and costs thereof, and civil
22 penalties. Such civil enforcement proceedings shall be governed by a preponderance of the
23 evidence standard, absent an applicable statutory provision or other binding legal authority to the
24 contrary.

25 F. In the event that the SREC believes that Endo remains in non-compliance with any
26 of the provisions of this ASO other than those in Section IV (Permanent Injunction) following the
27 notice and cure period provided in Section V.E., above, the SREC may seek to enforce such
28 provisions of this ASO by filing a motion in this Court, seeking such relief as is available under

1 applicable laws, including, if so available, fees and costs thereof, and civil penalties.

2 G. In the event that the SREC believes that Endo remains in non-compliance with any
3 of the provisions of Section IV (Permanent Injunction) of this ASO following the notice and cure
4 period provided in Section V.E., above, the SREC shall request that the FTC review Endo's
5 compliance with the corresponding provisions of Paragraph II of the FTC Order and consider
6 pursuing coordinated enforcement proceedings under this ASO and the FTC Order. In the event
7 that the FTC declines or fails to agree after forty-five (45) days from such a request by the SREC
8 to take action to enforce Paragraph II of the FTC Order, the SREC may then seek to enforce
9 Section IV of this ASO by filing a motion in this Court. The SREC, through the Liaison States,
10 shall provide written notice to Endo within three (3) business days of any request(s) to the FTC
11 provided herein.

12 H. Nothing in this Section V, however, prohibits the SREC from pursuing immediate
13 enforcement for alleged non-compliance with this ASO upon a showing that delay would cause
14 irreparable harm or would prevent the SREC from seeking adequate enforcement of the ASO.

15 VI. REPORTING AND MONITORING OBLIGATIONS

16 IT IS FURTHER ORDERED that:

17 A. Each Verified Written Report that Endo is required to submit to the FTC shall also
18 be submitted to the SREC by service upon the Liaison States within five (5) business days of
19 submission to the FTC.

20 B. Each Branded/Generic Settlement Agreement submitted to the FTC pursuant to
21 Section 1112(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of
22 2003 shall also be submitted to the SREC by service upon the Liaison States within five (5)
23 business days of submission to the FTC.

24 C. Endo shall consent to the FTC providing the SREC with a copy of each written
25 report that the Monitor is required to submit to the FTC under the FTC Order.

26 D. Endo shall consent to the FTC providing the SREC with copies of any and all of
27 its submissions to the FTC under the FTC Order made between February 2, 2017 and the entry of
28 this ASO ("FTC Submissions"), provided that: (a) Endo shall have five (5) business days after

1 the entry of this ASO to notify the necessary third parties of the pending disclosure; (b) such third
2 parties shall have twenty (20) business days from the entry of this ASO to assert an objection to
3 this Court; and (c) Endo's consent shall not be effective until, either: (i) twenty-six (26) business
4 days from the entry of this ASO have passed without a third party having asserted an objection to
5 this Court; or (ii) if a third party has asserted an objection, this Court has issued a ruling
6 permitting such disclosure over any such objection(s). If, after this consent is effective, the SREC
7 has requested the FTC Submissions from the FTC, but the FTC has not been willing to provide
8 them to the SREC, Endo will produce the FTC Submissions to the SREC.

9 E. Except as provided in Section VI.F. below, any agreements, information, or
10 documents submitted by Endo pursuant to this ASO ("Endo Materials") may be divulged or
11 disclosed by any Party State only to a person or entity who is an authorized representative or
12 retained consultant or expert of any Party State, who is engaged in matters pertaining to the
13 implementation or enforcement of this ASO, and who has agreed to be bound by the provisions of
14 this Section VI.D. To the extent any Party State retains private counsel to investigate or assert
15 potential claims against Endo in matters that are not related to the implementation or enforcement
16 of this ASO, then no Endo Materials may be disclosed or divulged to those private counsel.

17 F. Notwithstanding the foregoing Section VI.D,

18 1. Endo Materials may be disclosed in the course of a legal proceeding
19 between Parties to this ASO to enforce or modify this ASO, provided all parties to
20 such a proceeding take reasonable steps to prevent disclosure of such Endo
21 Materials to persons or entities who are not Parties to this ASO and Endo is given
22 at least ten (10) business days' advance written notice and a reasonable
23 opportunity to preserve the confidentiality of Endo Materials sought to be
24 disclosed;

25 2. A Party State may disclose Endo Materials in response to a discovery
26 request or other legal process in a legal proceeding to which the Party State is a
27 party, or as otherwise required by law (other than a grand jury proceeding),
28 provided the Party State shall reasonably attempt to preserve the confidentiality of

1 such Endo Materials by proceeding under any applicable protective order and/or
2 utilizing sealing procedures provided by law or court rule and by providing Endo
3 with at least ten (10) business days' advance written notice and a reasonable
4 opportunity to preserve the confidentiality of Endo Materials sought to be
5 disclosed before disclosing such Endo Materials to a third party; and

6 3. Endo Materials may be disclosed to the FTC or the United States
7 Department of Justice, provided Endo is given at least ten (10) business days'
8 advance written notice of such disclosure.

9 F. The Party States acknowledge and agree that (i) the production of Endo Materials to
10 the Party States is compelled by the terms of this ASO; (ii) Endo may mark any such Endo
11 Materials, where appropriate, as trade secrets or otherwise exempt from public disclosure
12 ("Confidential Endo Materials"); (iii) Endo does not waive any claimed exemption from public
13 disclosure under any law with respect to Confidential Endo Materials; and (iv) nothing in this
14 ASO shall prevent Endo from seeking appropriate relief under the law of any Party State
15 concerning public disclosures. In the event of a request for production of any Endo Materials
16 pursuant to any law regarding public disclosure of documents in the possession of a Party State (a
17 "Records Request Notice"), such Party State, by and through its respective Attorney General, to
18 the extent not prohibited by law, shall (a) promptly provide Endo with notice and a copy of the
19 Records Request Notice, (b) designate any Confidential Endo Materials as falling within any
20 trade secret or similar exemptions from disclosure under that Party State's applicable laws, and
21 (c) notify Endo in advance of any disclosure of any Endo Materials in order to afford Endo the
22 ability to seek appropriate relief under the Party State's law with respect to the disclosure of such
23 Endo Materials.

24 G. An enforcement action in this Court pursuant to this ASO shall be the exclusive
25 remedy for violation of this ASO. Neither the terms of this ASO nor any reports or notices
26 provided by Endo under this ASO shall operate as a waiver of any future claims by any third
27 party. Further, any such reports or notices provided by Endo to members of the SREC under this
28 ASO shall not be deemed to constitute actual or constructive notice of any claims as to any third

1 party that has not received such reports or notices. No provision in this ASO may be used as
2 evidence by Endo or by the Party States in a proceeding other than an enforcement action
3 pursuant to this ASO.

4 **VII. PROPOSED CHANGE OF CORPORATE CONTROL**

5 **IT IS FURTHER ORDERED** that:

6 A. Endo shall notify the SREC at least thirty (30) days prior to:

- 7 1. Any proposed dissolution of Endo; or
- 8 2. Any proposed acquisition, merger, or consolidation of Endo; or
- 9 3. Any other change in Endo, including, but not limited to, assignment and the
10 creation, sale or dissolution of subsidiaries, if such change might affect the
11 compliance obligations arising out of this ASO.

12 B. Endo shall notify the SREC within ten (10) days after any filing by Endo of a petition
13 in bankruptcy.

14 C. Endo shall submit any notice required under this paragraph to the SREC by service
15 upon the Liaison States.

16 **VIII. ACCESS TO INFORMATION**

17 **IT IS FURTHER ORDERED** that:

18 A. For the purpose of determining or securing compliance with this ASO, subject to and
19 without limiting any legally recognized privilege, and upon written request with reasonable
20 advance notice, Endo shall:

- 21 1. timely respond to and cooperate with the SREC's reasonable request for
22 production of documents or information related to compliance, including
23 permitting any duly authorized representative of the SREC to access, during
24 office hours and in the presence of counsel, all facilities and access to inspect
25 and copy all non-privileged business records and documentary material (which
26 may be redacted for privilege) related to compliance with this ASO, including
27 without limitation electronically stored information as defined in Rule 2.7(a)(1)
28 and (2), 16 C.F.R. § 2.7(a)(1), and books, ledgers, accounts, correspondence,

1 memoranda, written justifications, economic models, and other records and
2 documents (in whatever form such records and documents are kept) in the
3 possession or under the control of Endo, which copying services shall be
4 provided by Endo in a timely manner at the request of the authorized
5 representative(s) of the SREC;

6 2. permit any duly authorized representative of the SREC to interview officers,
7 directors, or employees of Endo, who may have counsel present, regarding any
8 such matters; and

9 3. agree to accept service of process of any motion filed with the Court hereunder
10 and, subject to any objections Endo may assert, cooperate with any subpoenas
11 issued by a Party State in connection with any motion to enforce this ASO.

12 B. The SREC shall to the fullest extent possible coordinate any requests for information
13 under this Section with the FTC and Department of Justice, if involved. The SREC shall make
14 any and all requests for information hereunder solely through the Liaison States.

15 **IX. EFFECT OF SETTLEMENTS WITH OTHER STATES**

16 **IT IS FURTHER ORDERED** that:

17 A. The Party States shall permit California to join the enforcement and reporting
18 provisions of this multistate ASO upon the submission of an amended California ASO by
19 California and Endo reflecting that California's enforcement authority and each of Endo's
20 notification and reporting obligations, including but not limited to the provisions reflected in
21 Paragraphs IV.B, IV.C, and V through VIII (with the exception of VI.F regarding confidentiality)
22 of the California ASO, shall be replaced by the corresponding provisions of this ASO.

23 B. If following the filing or entry of this ASO, Endo enters into a similar settlement
24 agreement with another state, or a series of similar agreements with individual states, the Party
25 States shall coordinate their enforcement actions, and Endo's reporting obligations with such
26 other state(s). The Parties will use their best efforts to negotiate an agreement among and
27 between Endo, the Party States, and California, and the other settling states to coordinate
28 enforcement authority and Endo's notification and reporting obligations under the respective

1 settlement agreement(s) and Endo and the Party States will submit any such agreement to this
2 Court as an amendment to this ASO.

3 **X. JURISDICTION**

4 **IT IS FURTHER ORDERED** that this Court shall retain jurisdiction over these matters
5 for purposes of construction, modification, and enforcement of this ASO.

6 **XI. TERMINATION**

7 **IT IS FURTHER ORDERED** that this ASO shall terminate on February 2, 2027.


8 **XII. DISMISSAL WITH PREJUDICE**

9 **IT IS FURTHER ORDERED** that the Complaint shall be and hereby is dismissed with
10 prejudice. Each party to bear its own costs aside from the Settlement Amount paid to the Party
11 States.

12 **SO ORDERED** this _____ day of _____, 2019


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FOR ENDO PHARMACEUTICALS INC.:

By: 
Name: Paul Compagnelli
Title: President & CEO

Date: 7/15/19

FOR ENDO INTERNATIONAL PLC:

By: 
Name: Paul Compagnelli
Title: President & CEO

Date: 7/15/19

By: 

Date: 7/15/2019

George G. Gordon
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**COUNSEL FOR ENDO PHARMACEUTICALS INC. AND
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Contact Information for Endo Pharmaceuticals Inc.
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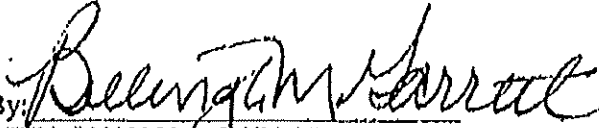
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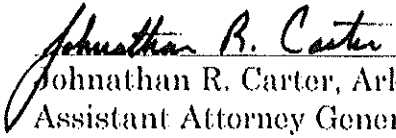
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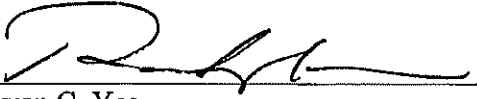
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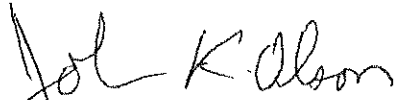
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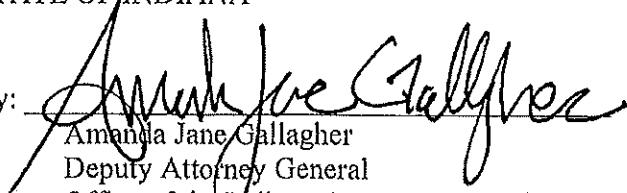
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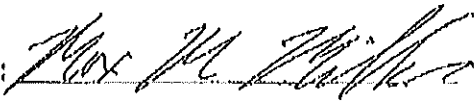
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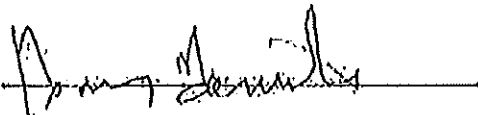
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A handwritten signature in black ink, appearing to read "Gary Hohlok", is written over a horizontal line.

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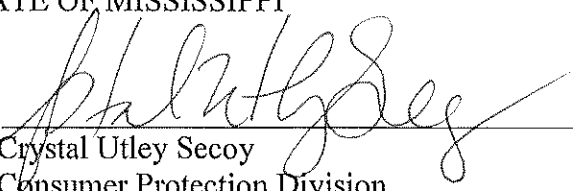
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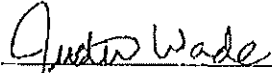
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