ATTORNEY GENERAL OF THE STATE OF NEW YORK
ANTITRUST BUREAU

In the Matter of

Assurance No. 19-156

Investigation by LETITIA JAMES,
Attorney General of the State of New York, of

Emergent BioSolutions, Inc.

Respondent.

ASSURANCE OF DISCONTINUANCE

The Office of the Attorney General of the State of New York ("OAG") commenced an investigation pursuant to Section 343 of the New York General Business Law and Section 63(12) of the New York Executive Law into conduct that may be hindering the development of new potentially lifesaving treatments for opioid overdoses. This Assurance of Discontinuance ("Assurance") contains the findings of the OAG's investigation and the relief agreed to by and between the OAG, Adapt Pharma, Inc. ("Adapt"), and Emergent BioSolutions, Inc., which acquired Adapt late last year (Adapt and Emergent BioSolutions, Inc. are collectively referred to herein as "Emergent" and, together with the OAG, referred to as the "Parties").

OAG'S FINDINGS

A. Background

1. On October 26, 2017, the United States Department of Health and Human Services ("HHS") declared a national public health emergency to address the national opioid crisis.[1] Specifically, in response to a crisis that has resulted in the loss of nearly 400,000

[1] https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-addressnational-opioid-crisis.html

lives since 1999, decimated communities, ruined lives and drained public and private resources, both state agencies and federal agencies have announced and have taken actions to confront and mitigate the opioid epidemic.[2]

2. A core component of efforts by state and federal agencies to combat the opioid crisis is to improve availability and access to overdose-reversing drugs.[3] When combined with successful prevention and treatment, increasing availability and access to such overdose-reversing drugs is expected to save lives and mitigate some of the worst consequences of the opioid epidemic, while working on comprehensive solutions to the problem.

3. High-level public health care officials – including the Secretary of Health and Human Services, the United States Surgeon General, and the Commissioner of the Food and Drug Administration ("FDA") – have advocated for increased access to and availability of opioid overdose-reversing drugs as a critical tool in combating opioid overdoses.[4]

4. In particular, health care officials have supported the use of the drug naloxone to treat opioid overdoses. According to the National Institute of Drug Abuse, naloxone is both "extremely safe" and effective at very quickly countering the effects of opioid overdoses to an overdose patient.[5] In addition to its quick onset of action (working within minutes of administration), naloxone has a relatively short duration of action, *i.e*, typically being effective for an hour or two after being administered, after which time a second dose may be appropriate depending on the circumstances of the overdose, the particular drug taken, and whether the patient has obtained medical treatment.[6] This may be a substantial benefit for an overdose

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[2] https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html; https://www.cdc.gov/injury/features/prescription-drug-overdose/index.html; https://www.naag.org/publications/papers-briefs-and-other-research/nagtri-prescription-opioid-projects/prescriptionopioid-education-toolkit-for-consumer-education/attorney-general-program-and-initiatives-listed-by-state.php http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx

[3] https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/better-overdose-response/index.html

[4] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-mdunprecedented-new-efforts-support-development-over (Gottlieb statement); https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html (Adams Statement); https://www.cdc.gov/media/releases/2019/p0806-naloxone.html (Azar statement)

[5] https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio

[6] https://chemm.nlm.nih.gov/countermeasure_naloxone.htm; Wang DS, Sternbach G., Varon J., *Nalmefene: a longacting opioid antagonist. Clinical applications in emergency medicine*, J. Emerg. Med. 1998: May-Jun; 16(3):

patient because the drug is highly effective in a short period of time, and thus less likely to result in prolonged withdrawal symptoms for opioid dependent patients.

5. Since February 2016, Adapt (and now Emergent) has sold the only FDA-approved nasal naloxone product in the United States, branded as NARCAN nasal spray. NARCAN is provided in a convenient, easy to use and non-invasive nasal spray. NARCAN has become an important tool in the treatment of opioid overdoses as it can safely and effectively be used at the scene of an overdose by persons without any medical knowledge or training.

6. Notwithstanding naloxone's success in the emergency treatment of a known or suspected opioid overdose, health care professionals have advocated for the development of additional opioid-reversing drugs, particularly those targeted towards the substantial increase in overdoses and deaths caused by very-high potency synthetic opioids.[7] The drug nalmefene could potentially be developed to address these concerns.

7. An injectable form of nalmefene is already FDA-approved for the reversal of opioid drug effects, and according to clinical literature, has a much longer duration of action (up to 8 hours) than naloxone. This longer duration of action could avoid the need for successive dosing, but also risks extended withdrawal reactions by opioid dependent individuals.[8] Nalmefene was previously sold in the United States, but was discontinued by its manufacturer in 2008 (although according to FDA, not for safety and efficacy reasons).[9] More recently, the OAG has learned that at least four manufacturers – including Adapt/Emergent – are considering and/or

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4751; https://www.hhs.gov/about/news/2018/09/20/hhs-sponsors-development-intranasal-form-long-acting-opioidoverdose-drug.html

[7] *Id*; Volkow N., Collins F., *The Role of Science in Addressing the Opioid Crisis*, N. Engl. J. Med. 377:4 (July 27, 2017); Wang et al, *supra* note 6; https://www.drugabuse.gov/related-topics/trends-statistics/infographics/fentanyl-other-synthetic-opioids-drug-overdose-deaths ("In 2016, synthetic opioids (primarily illegal fentanyl) passed prescription opioids as the most common drugs involved in overdose deaths in the United States"); https://www.cdc.gov/drugoverdose/data/fentanyl.html ("Synthetic opioid overdose death rates (other than methadone) increased across all demographics, county urbanization levels, and numerous states")

[8] *Id*; https://www.hhs.gov/about/news/2018/09/20/hhs-sponsors-development-intranasal-form-long-acting-opioidoverdose-drug.html ("Because of the shorter half-life of naloxone compared to fentanyl derivatives, repeat dosing of naloxone often is needed to fully reverse the effects of the opioid. Longer lasting drugs can reduce the need for repeat dosing. Nalmefene acts in the same way as naloxone and studies suggest that it may work for much longer.")

[9] https://www.empr.com/home/news/baxter-discontinues-revex-injection/; https://www.federalregister.gov/documents/2017/11/03/2017-23952/determination-that-revex-nalmefene-hydrochloride-injection-01-milligram-basemilliliter-and-10

attempting to introduce a nalmefene-based opioid overdose treatment for the United States market.[10] Earlier this year, FDA granted both priority and preferential review to one company's application for a nalmefene opioid overdose treatment.[11]

B. OAG's Investigation

8. The OAG is concerned about the opioid epidemic and is taking various actions to address it[12] as well as to ameliorate its effects. This includes ensuring that there are no unnecessary impediments to bringing new opioid overdose treatments to market.

9. On or about Fall 2018, the OAG learned that prior to its acquisition by Emergent, Adapt Pharma, the manufacturer of NARCAN nasal spray, was working to develop a nasal nalmefene product and had entered into an agreement with the manufacturer of the device used with NARCAN nasal spray as part of those efforts. The OAG became aware that certain provisions of Adapt's contract with that device manufacturer might restrict the manufacturer's ability to supply similar nasal devices to other companies for the development and sale of a nasal nalmefene product. In 2019, the OAG informed Emergent of its concern that the nalmefene agreement entered into between Adapt and its NARCAN nasal device manufacturer might unnecessarily delay or impede other firms from developing or launching their own nasal nalmefene products.

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[10] https://www.purduepharma.com/news/2019/06/06/purdue-pharma-announces-first-participant-enrolled-inclinical-study-assessing-nalmefene-hcl-injection-for-the-emergency-treatment-of-known-or-suspected-opioidoverdose/; https://www.globenewswire.com/news-release/2019/04/08/1798959/0/en/Opiant-PharmaceuticalsAnnounces-Publication-of-Clinical-Pharmacokinetic-Data-Supporting-Potential-of-OPNT003-Nasal-Nalmefene-forTreatment-of-Synthetic-Opioid-Overdose.html; https://orexo.com/media/pressreleaser?releaseId=6707EE4686448F0F; https://homelandprepnews.com/stories/37390-emergent-biosolutions-awarded-nih-grant-for-opioid-treatment/

[11] FDA granted Purdue Pharma's nalmefene injection application for both fast-track designation and competitive generic therapy designation. https://www.biospace.com/article/releases/fda-grants-purdue-pharma-s-nalmefene-hclinjection-fast-track-designation-for-the-emergency-treatment-of-known-or-suspected-opioid-overdose/; https://www.purduepharma.com/news/2019/04/24/fda-grants-competitive-generic-therapy-cgt-designation-topurdue-pharmas-investigational-nalmefene-hcl-injection-for-the-emergency-treatment-of-known-or-suspectedopioid-overdose/

[12] https://ag.ny.gov/press-release/2019/attorney-general-james-joins-38-state-coalition-urging-congress-removefederal; https://ag.ny.gov/sites/default/files/oag_opioid_lawsuit.pdf; https://ag.ny.gov/press-release/2018/attorneygeneral-underwood-and-governor-cuomo-announce-suit-against-purdue-pharma; https://ag.ny.gov/pressrelease/2018/ag-schneiderman-sues-fentanyl-maker-insys-therapeutics-inc-dangerous-and

10. In light of the OAG's concerns, and Emergent's interest in working with the OAG and the State of New York to find other drugs that might contribute to the amelioration of the opioid crisis, Emergent has agreed to use its best efforts to negotiate altered terms of its contract with its nasal device supplier to ensure that its contract does not prevent or restrict Emergent's manufacturing partner from selling nasal devices for nasal delivery of nalmefene to other companies that wish to develop a nasal nalmefene product. In addition, while the parties renegotiate that contract, Emergent agrees not to enforce any term of the contract that would restrict its manufacturing partner from supplying nasal devices for nasal delivery of nalmefene to other firms that seek to develop a nasal nalmefene product.

11. The OAG finds the relief and agreements contained in this Assurance appropriate and in the public interest. THEREFORE, the OAG is willing to accept this Assurance pursuant to Executive Law § 63(15), in lieu of further pursuing its investigation.

IT IS HEREBY UNDERSTOOD AND AGREED, by and between the Parties:

RELIEF

12. Emergent agrees to use its best efforts to renegotiate and revise its contract with its manufacturing partner so that the manufacturing partner is permitted to sell its nasal devices for nasal delivery of nalmefene to firms other than Emergent that seek to develop a nasal nalmefene product.

13. Emergent also agrees that during the renegotiation of such contract, it will not enforce any provision that has the effect of prohibiting its manufacturing partner from selling its nasal devices for nasal delivery of nalmefene to firms other than Emergent that seek to develop a nasal nalmefene product. Emergent will provide the OAG with any modified contract with its nasal device supplier resulting from this Assurance within three days of it being executed.

14. Emergent also agrees that for three years after the execution of this Assurance, if it enters into any type of agreement, arrangement or understanding, whether formal or informal, pertaining to nalmefene with its NARCAN nasal device supplier that restricts its NARCAN nasal

device supplier from selling or otherwise supplying nasal devices to another company for the purpose of developing or selling a nasal nalmefene product, Emergent will submit a copy or summary of such agreement to the OAG within thirty days of entering into such agreement, arrangement, or understanding.

15. If a court of competent jurisdiction determines that Emergent (the "Respondent") has violated the Assurance, the Respondent shall pay to the OAG the reasonable cost, if any, of obtaining such determination and of enforcing this Assurance, including without limitation legal fees, expenses, and court costs.

16. The OAG has agreed to the terms of this Assurance based on, among other things, the representations made to the OAG by the Respondent and its counsel and the OAG's own factual investigation as set forth in Findings, paragraphs 1- 11 above. The Respondent represents and warrants that neither it nor its counsel has made any material representations to the OAG that are inaccurate or misleading. If any material representations by Respondent or its counsel are later found to be inaccurate or misleading, this Assurance is voidable by the OAG in its sole discretion.

17. Acceptance of this Assurance by the OAG is not an approval or endorsement by the OAG of any of Respondent's policies practices or procedures, and the Respondent shall make no representation to the contrary.

18. All terms and conditions of this Assurance shall continue in full force and effect on any successor, assignee, or transferee of the Respondent. Respondent shall include any such successor, assignment or transfer agreement a provision that binds the successor, assignee or transferee to the terms of the Assurance. No party may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without the prior written consent of the OAG.

19. Nothing contained herein shall be construed as to deprive any person of any private right under the law.

20. Any failure by the OAG to insist upon the strict performance by Respondent of any of the provisions of this Assurance shall not be deemed a waiver of any of the provisions hereof, and the OAG, notwithstanding that failure, shall have the right thereafter to insist upon the strict performance of any and all of the provisions of this Assurance to be performed by the Respondent.

21. Respondent acknowledges that it has entered this Assurance freely and voluntarily and upon due deliberation with the advice of counsel.

22. This Assurance shall be governed by the laws of the State of New York without regard to any conflict of laws principles.

23. The effective date of this Assurance shall be December 31, 2019.

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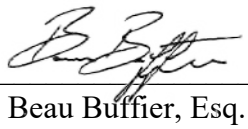
By: 

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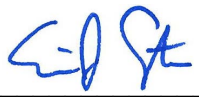
By: 

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