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FDA Advisory Committee

December 17 & 18 2018

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Agenda

- About Emergent BioSolutions
- About Naloxone and Narcan Nasal Spray
- Key Points from Sponsor Joint Co-prescribing Briefing Document
- Estimating Population on Higher Risk Opioids and Adoption
- Impact of State Regulations on Narcan Nasal Spray Adoption
- Estimating Impact of FDA Regulatory Action on Adoption
- Dynamics Influencing Access and Affordability
- Capacity and Cost
- Recommendation

About Emergent BioSolutions

Emergent BioSolutions Acquired Adapt Pharma Including Narcan® (naloxone) Nasal Spray in 4Q18

Global Life Science Business Focused on Public Health Threats

- Significant scale: NYSE Listed; 1,600 employees; 19 global locations
- 11 Products and 7 Projects in Clinical Development
- Portfolio includes vaccines such as BioThrax® (anthrax vaccine); ACAM2000® (smallpox vaccine)

Supporting Expanded Access to Narcan Nasal Spray

- Leverage Emergent's two decades of expertise addressing public health threats
- Maintain affordable access for public health purchasers, health insurance systems and individuals
- Investing in supply chain capacity, awareness and pipeline

 **NARCAN**[®] (naloxone HCl)
NASAL SPRAY 4mg

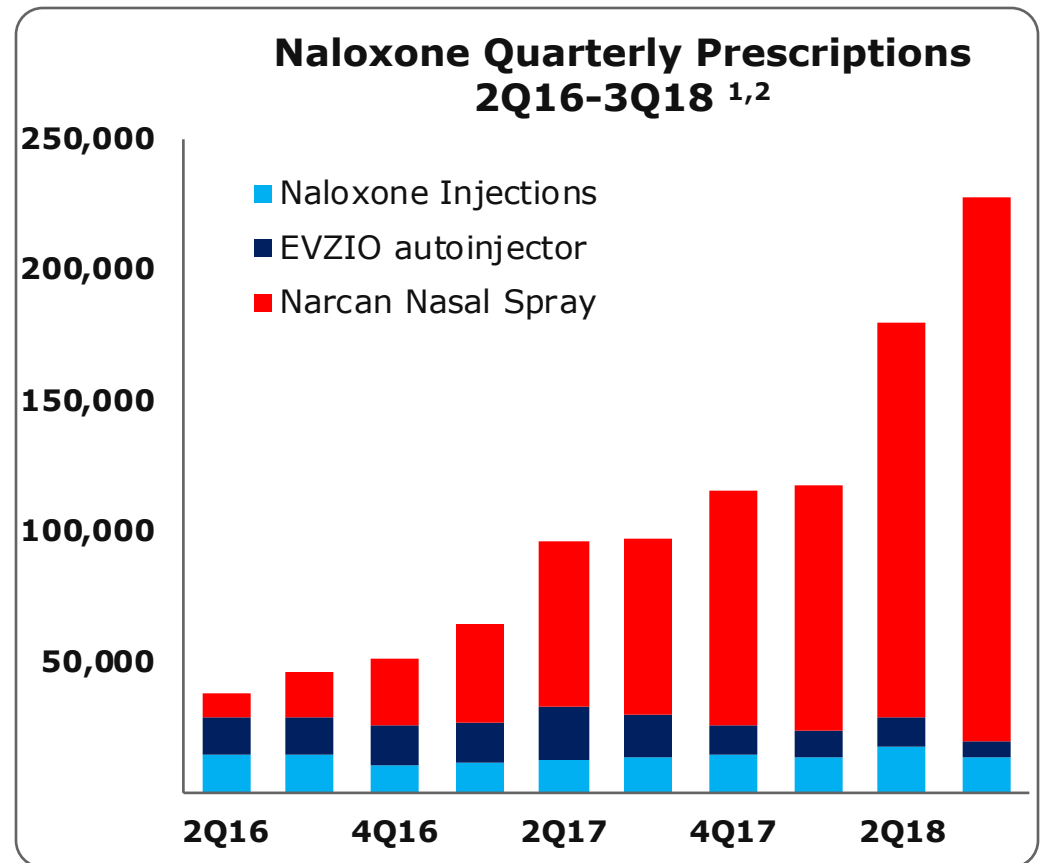
About Naloxone and Narcan Nasal Spray

Naloxone Prescriptions are Growing

- Narcan accounts for **>90%** of prescriptions
- Growth driven by affordability, accessibility and awareness

Narcan 4mg Nasal Spray

- FDA-approved for community use
- Each device delivers a 4mg/0.1 ml spray
- Supplied in carton with 2 devices
- Product shelf-life is 2 years



1. Prescription Data only which excludes all units shipped to Public Health **2.** IQVIA Prescription Database

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Key Points from Briefing Documents

Prescription Opioids Continue to Play a Key Role in Crisis

- 40% of opioid overdose deaths involve prescription opioids¹
- Most who use illicit opioids, first misused prescription opioids²
- 40% of opioid overdoses are witnessed, but naloxone is rarely administered³

Co-prescribing Naloxone is Widely Endorsed but Narrowly Adopted

- CDC Opioid Guideline identifies opioid prescriptions associated with higher risk of opioid overdose⁴
- Co-prescribing naloxone with these prescriptions is endorsed by multiple opioid crisis stakeholders⁵
- Adoption of naloxone co-prescribing is low and inconsistent across states⁶

Recommend FDA Consider Opioid Label Updates and Regulatory Measures to Accelerate Naloxone Adoption to Mitigate Opioid Risks

1. Seth *p* CDC MMWR 2018;67:349–358 **2.** Jones CM. Drug Alcohol Depend. Sep 2013
3. Mattson CL CDC: MMWR Aug 2018 **4.** CDC Guideline for Prescribing Opioids for Chronic Pain **5.** See Joint Sponsor Briefing Note **6.** IQVIA Data

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Analysis of Unique Patients Filling Higher Risk Prescriptions

Analyzed IQVIA Patient Claims Data for Two Years to Sep 2018

- Opioid prescription numbers are higher than patient numbers because, on average, each patient fills 3.4 opioid prescriptions annually¹
- 97.3 million unique patients filled at least one opioid prescription
- 13.5 million unique patients had an opioid daily dose >50MME (Morphine Milligram Equivalents)
- 19.2 million unique patients had concurrent use of benzodiazepine/any opioid dose (4.7 million where opioid >50 MME)
- 1.6 million unique patients had naloxone/buprenorphine or buprenorphine prescription

34.2 Million (35%) Unique Patients Filled at Least One Prescription in the 2 year period that Met CDC Higher Overdose Risk² Criteria

1. CDC Drug Surveillance Report 2018. 2. CDC Guideline Recommendation 8: history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use.

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Nationally Narcan Nasal Spray is Narrowly Adopted

Analyzed IQVIA Patient Claims Data for Two Years to Sep 2018

- 0.8% patients with an opioid daily dose >50MME filled a Narcan Nasal Spray prescription
- 1.3% patients with concurrent use of benzodiazepine/any opioid dose filled a Narcan Nasal Spray prescription
- 5.7% patients with naloxone/buprenorphine or buprenorphine prescription filled a Narcan Nasal Spray prescription

1.3% of 34 Million Patients with a Higher Risk¹ Opioid Prescription Also Filled a Narcan Prescription in the 2 Year Period

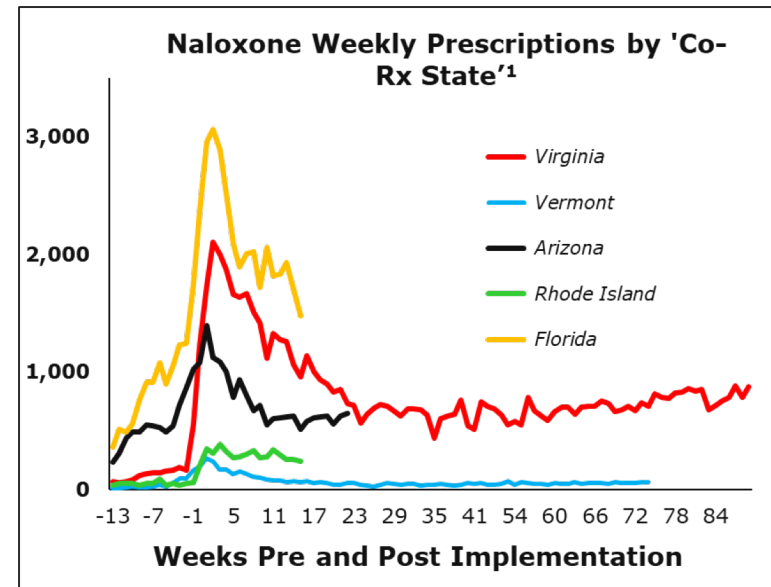
1. CDC Guideline Recommendation 8: history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use.

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Adoption is Higher in States Requiring Co-Rx

5 States Implemented Regulations Requiring Naloxone Prescribing with Higher Risk Opioids

- VA, VT, AZ, RI and FL ("Co-Rx States")
- WA and CA will implementing in 4Q18 and 1Q19
- Regulations are effective in accelerating adoption
- Initial spike post implementation
- 'Higher Risk Opioid' Criteria vary by State



Narcan Nasal Spray Adoption Was Up to 7 Times Higher In 'Co-Rx States'¹

- Up to 10.3% of patients with an opioid daily dose in excess of threshold filled a prescription¹
- Up to 8.1% of patients with concurrent use of benzodiazepine/any opioid dose filled a prescription¹
- Up to 8.3% patients with naloxone/buprenorphine or buprenorphine prescription filled a prescription¹

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Opioid Label Updates and Other FDA Regulatory Measures Could Expand Access

Estimated Additional 3M Patients Would Fill Narcan Nasal Spray

- Opioid label updates and other FDA regulatory measures could increase naloxone co-prescribing alongside the highest risk opioid prescriptions
- Estimates assuming;
 - FDA opioid label modification is based on CDC criteria
 - Utilizing the 5 'Co-Rx State' experience as a proxy
- Estimate that 3 million additional patients on higher risk opioid prescriptions would fill Narcan Nasal Spray prescription over 2 years

Narcan Nasal Spray Production Capacity

Significant Investment Initiated in mid-2018 to Expand Capacity

- 2018 production will be >3 million cartons (6 million devices) to meet demand
- Committed investments provide for doubling of capacity in 2019 and to up to 10 million units (20 million devices) in 2020
- On-going evaluation of additional investments to support demand increases

Managing Up-take Curve

- Developed a demand estimate assuming (i) FDA opioid label modification regulatory measure based on CDC criteria and (ii) using the 5 'Co-Rx State' experience as a proxy
- Expect to have adequate capacity to meet anticipated demand
- Plan an appropriate inventory build and to reserve units for Public Health consistent with past demand
- Recommend implementation lead-time to allow inventory build to meet expected spike in demand

Factors influencing access and adoption

Pharmacy Access

- State laws and regulations allow naloxone access without a personal prescription
- Pharmacy chains stock take-home naloxone and have in-store awareness initiatives

Financial Barrier

- Affordability to individuals, payors and public health
- Ensuring extensive health insurance with no or low out-of-pocket

Awareness of Opioid Risks and Naloxone

- Level of engagement by Payors, Pharmacists and Clinicians in identifying risk and raising awareness of opioid risks and naloxone

OTC Challenges

- Risk higher financial barrier for many without improvement in access or awareness

Narcan Nasal Spray Access & Affordability

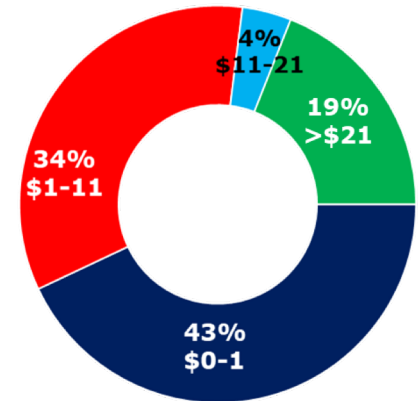
List Price & Discounted Public Interest Price

- Narcan Nasal Spray listed at \$125/carton (\$62.50/dose)
- No price increase since launch
- Discount of 40%+ is provided to all Public Health Purchasers, Medicaid, 340B, FSS to ≤ \$75 per carton (\$37.50/dose)

Extensive Insurance Coverage at Affordable Co-pays¹

- 97% of private and public insured lives cover Narcan Nasal Spray
- Narcan Nasal Spray Co-pays: 77% <\$11
- Average co-pay of \$17.65 on dispensed prescriptions YE 1Q18

Patient Co-Pays on Dispensed
Narcan Nasal Spray YE 1Q18¹



Critical to continue focus on minimizing the financial barrier to access

1. IQVIA Formulary Impact Analyzer. Co-pays on dispensed prescriptions

Suggested FDA Regulatory Option & Cost

Modification to Opioid Labels (Indication Statement or Boxed Warning).

- Sample language: “[Because of the increased risk of opioid overdose], prescribe community use naloxone to (i) patients prescribed daily opioid dose of 50 morphine milligram equivalents (MME) or greater; or (ii) patients concurrently prescribed any opioid dose and benzodiazepines; or (iii) patients with a substance use disorder.”
- Amend the Communication Plan via the Medication Guide
- Incorporate into Opioid REMS Training Materials (Blueprint Has Been Updated)

Consider an Element To Assure Safe Use (ETASU) to the Opioid REMS if Label Amendment and Communication Plan are Ineffective in Expanding Access

Based on 3 Million Demand Estimate and Narcan Nasal Spray Cost, estimated cost of \$300M over 2 Years (c. 2.5% annual spend on opioids)

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