OPIANT PHARMACEUTICALS

TESTIMONY

JOINT LEGISLATIVE BUDGET HEARING
HEALTH AND MEDICAID

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Dear Honorable Finance Chair Senator Krueger, Honorable Ways & Means Chair Assembly Member Weinstein, Senator Rivera, Assemblyman Gottfried and distinguished Members:

My name is Dr. Roger Crystal, and I am the President and Chief Executive Officer of Opiant Pharmaceuticals, which has a mission to create best-in-class medicines for the treatment of addictions and drug overdose. Prior to my business career, I worked for several years as a surgeon, specializing in ear, nose, and throat, head and neck surgery at leading institutions including Imperial College Healthcare, London and was awarded Membership of The Royal College of Surgeons of England (MRCS). I hold a BMedSci in Physiology and an MD from the University of Birmingham, UK and an MBA from the London Business School.

I am also the lead inventor of the NARCAN® Nasal Spray, a treatment for opioid overdose, holding several issued patents around this product, and led its development towards FDA approval.

More than 220 Americans are dying from overdoses every day, according to preliminary data from the Centers for Disease Control and Prevention (CDC). In December, the CDC issued a Health Alert Network calling for a swift public health response to "substantial increases in drug overdose deaths across the United States, primarily driven by rapid increases in overdose deaths involving synthetic opioids, such as fentanyl."[1]

[1] *Overdose Deaths Accelerating During COVID-19, Centers for Disease Control and Prevention*, December 17, 2020. Retrieved from: https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html and https://emergency.cdc.gov/han/2020/han00438.asp

Changes to prescribing laws to improve availability of overdose reversal medicines can reduce fatalities. One effective way to ensure that at-risk patients have access to an overdose reversal medicine is to prescribe it at the same time as an opioid prescription.

This is why Opiant strongly encourages the New York State Legislature to enact a comprehensive co-prescribing policy for an FDA-approved opioid reversal agent in the FY 2022 New York State Budget.

THE IMPACT OF THE OPIOID EPIDEMIC IN NEW YORK IS STAGGERING

This past year, the opioid epidemic has been largely overshadowed by COVID-19. Yet together, the two public-health crises have proven a deadly mix. Social isolation, job loss and depression are known precursors to addiction or relapse. And early data suggest that overdose deaths are rising. The American Medical Association has said it is "greatly concerned" by reports of increasing mortality in over 40 states.[2]

Slowly but surely, details are emerging of the human toll this is taking in New York. Based on the most recent data published by the New York State Department of Health, in the first 6 months of 2020, a staggering 2,154 people died from opioid overdoses throughout the State. In New York City alone, the total number of deaths was 1,247 people. In the first 6 months of 2020, there were

[2] *Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic*, American Medial Association, December 4, 2020. Retrieved from: https://www.ama-assn.org/system/files/2020-12/issue-brief-increases-in-opioid-related-overdose.pdf

1,427 hospitalizations due to opioid overdose throughout the State, with 633 of those hospitalizations occurring in New York City. The following media reports illustrate the scale of the lives lost to overdose across the State.

The *Albany Times Union* reported in October, 2020, that "[Albany] county confirmed 72 overdose deaths among residents in the first nine months of this year — a 44 percent increase over the same period last year and 10 more fatal overdoses than happened in all of 2019."[3]

The *Staten Island Advance* reported on October 30, 2020, that "Overdoses on Staten Island more than doubled since the beginning of the coronavirus (COVID-19) pandemic nearly eight months ago."[4]

The Onondaga County Department of Health issued a press release last month revealing that, "Over the last year, there has been a significant increase in the number of fatal opioid overdoses in Onondaga County. From January through September 2020 there was a 40% increase in opioid overdose deaths compared to the same time period in 2019… ."[5]

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[3] *Albany County overdose deaths up 44% over last year*, by Bethany Bump, Albany Times Union, October 27, 2020. Retrieved at: https://www.timesunion.com/news/article/Albany-County-overdose-deaths-up-44-over-last-15678184.php

[4] *Borough overdoses double in six months amid COVID-19 pandemic,* by Kristin F. Dalton, Staten Island Advance, October 30, 2020. Retrieved at: https://www.silive.com/coronavirus/2020/10/borough-overdoses-double-in-six-months-amid-covid-19-pandemic.html

[5] January 28, 2021, Press Release of the Onondaga County Health Department. Retrieved at: https://healthnews.ongov.net/rise-in-opioid-overdoses/

And, on February 2, 2021, Buffalo local ABC affiliate *WKBW* reported that "A new trend in 2020 has experts looking on. The county saw a 50% increase in opioid deaths where the drug was associated with fentanyl and cocaine."[6]

Action is needed if we are to save lives.

CO-PRESCRIBING IS A SOLUTION

There is compelling evidence that many of those currently struggling with opioid dependence and addiction were introduced to opioids through use of medically prescribed opioids used to treat chronic pain. Medically prescribed opioids remain a common gateway to illicit opioid use and are themselves frequent causes of opioid addiction and overdose, even if illicit opioids currently cause the greater number of deaths. We also now know that the population of people most likely to progress to prolonged high dose prescription opioid usage, or turn to illicit opioids, are the most distressed amongst us. This is a population that has grown with the COVID-19 pandemic and is likely to continue to grow during pandemic recovery.

The CDC recommends[7] that clinicians co-prescribe an FDA approved rescue medication, such as naloxone, to patients who are at high risk of overdose. This includes patients under past or present treatment for a substance use disorder; who are receiving a significant opioid dosage; or are also taking a benzodiazepine prescription, such as Xanax or Valium. When co-prescribing an overdose

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[6] *Overdose deaths rise in Erie County during pandemic*, by Hannah Buehler, WKBW, February 2, 2021. Retrieved at: https://www.wkbw.com/news/local-news/overdose-deaths-rise-in-erie-county-during-pandemic

[7] See CDC Guideline for Prescribing Opioids for Chronic Pain, retrieved at https://www.cdc.gov/drugoverdose/prescribing/guideline.html

rescue medicine, it also creates for clinicians an important opportunity – a *teachable moment* - to emphasize to patients and someone close to them the risks of overdose. After states began following these guidelines in 2017, rates of co-prescribing naloxone increased, with the highest co-prescription rates in states that formally implemented *required* co-prescribing regulations.[8]

In New Mexico, where co-prescribing was passed in 2018, the New Mexico Department of Health (NMDOH) reported that prescription opioid overdose deaths decreased statewide in 2019 when more than 94,000 doses of naloxone were dispensed or distributed, representing an increase of 95 percent from the year prior.[9]

Recently, Tennessee passed legislation to investigate the connection between co-prescribing and lowering the number of fatal overdoses and recognized the effectiveness of naloxone in helping to combat the opioid epidemic. As a result, in December of 2019 the State Department of Health updated their state guideline to recommend healthcare practitioners incorporate co-prescribing of naloxone into their management plan strategies to "mitigate risk...when factors that increase the risk for opioid overdose are present" and plan to introduce legislation to mandate co-prescription across the state.[10]

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[8] *Association of Naloxone Coprescription Laws With Naloxone Prescription Dispensing in the United States,* by Minji Sohn, PhD1; Jeffery C. Talbert, PhD2; Zhengyan Huang, PhD3; et al., June 21, 2019.

[9] *Naloxone helps New Mexico reduce drug overdose deaths from prescription opioids*, by Kim Riley, Homeland Preparedness News, November 13, 2020. Retrieved from: https://homelandprepnews.com/countermeasures/57503-naloxone-helps-new-mexico-reduce-drug-overdose-deaths-from-prescription-opioids/

[10] *During COVID-19, medication naloxone is a proven way to save Tennesseans from opioid overdose*, by Stephen Loyd, The Tennessean, February 4, 2021. Retrieved from: https://www.tennessean.com/story/opinion/2021/02/01/how-overdose-medication-can-save-tennesseans-opioid-overdose/4340357001/

In other words, **state legal interventions that mandate, rather than recommend**, an opioid overdose reversal agent for potentially at-risk patients have the most successful results. Yet despite recommendations to co-prescribe naloxone to patients at increased risk for opioid overdose, a new research paper published in the Journal of Internal Medicine says co-prescribing rates remain low overall. The report's authors concluded: "States, insurers, and health systems should consider implementing strategies to facilitate increased co-prescribing of naloxone to at-risk individuals."[11]

To date, New York State has not yet heeded the CDC recommendations by mandating co-prescribing. Therefore, **Opiant strongly encourages the New York State Legislature to enact a comprehensive policy to co-prescribe any FDA-approved opioid reversal agent in the FY 2022 New York State Budget.**

Co-prescribing a rescue medication with opioid prescriptions is currently mandated by legislation or regulation in Arizona, California, Florida, New Jersey, New Mexico, Ohio, Rhode Island, Vermont, Virginia, and Washington.

Here in New York, there are currently 2 different bills in the Legislature that would mandate co-prescribing. S1546 (Benjamin)/2567 (Fall) mandates co-prescribing at the initial opioid prescription, and every subsequent refill. If enacted, this would be the most robust co-prescribing mandate in the Country. The other measure is S2966 (Harckham)/A336 (Braunstein) which mandates co-prescribing at the first opioid prescription of each year, or when the patient presents

[11] *Individual and Community Factors Associated with Naloxone Co-prescribing Among Long-term Opioid Patients: a Retrospective Analysis*, by Stein, B.D., Smart, R., Jones, C.M. et al., Journal of Internal Medicine, February 17, 2021. Retrieved from: https://doi.org/10.1007/s11606-020-06577-5

certain risk factors. If either measure were incorporated into the budget, New Yorkers would benefit tremendously in terms of both reduced hospitalizations, as well as fewer fatal overdoses.

CMS FINAL RULE ON CO-PRESCRIBING

We would be remiss without mentioning the Center for Medicare and Medicaid services (CMS) is in the process of finalizing a rule that will, among other things, encourage states to implement co-prescribing of an FDA-approved opioid antagonist/reversal agent for at risk patients.[12] In the Final Rule, CMS states:

> "… we are finalizing, as proposed, § 456.703(h)(1)(vii)(B) to require states to establish approaches to identify beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone. Based on comments received, we are revising the final regulation text in § 456.703(h)(1)(vii)(B) to replace the proposed reference to naloxone with a reference to all FDA-approved opioid antagonist/reversal agents, so that the final regulation is broad enough to encompass additional such drugs, should FDA approve any others in the future."[13]

Clearly, the Federal Government, through this rule, is prioritizing co-prescribing as a preferred policy to be proactively enacted by states such as New York, which has no such policy in effect.

FISCAL IMPACT TO THE STATE IS NEGLIGIBLE

While co-prescribing falls in line with best practices to protect the public health, we recognize that there is a cost associated with a mandatory co-prescribing law in New York. To more fully understand this, we have to unpack the compounding costs associated with an overdose. It is not only that overdose deaths are on the rise. Many overdose patients who survive still need a longer

[12] See 85 FR 87000, December 31, 2020. Retrieved from: https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and
[13] Ibid. at page 332

duration of mechanical ventilation and sedation, and many are suffering from more severe consequences, such as liver and kidney failure. In a study[14] of 162 academic hospitals, the Beth Israel Deaconess Medical Center in Boston, found the average cost of care per opioid admission jumped 58 percent to $92,400 in a seven-year span from 2009 to 2015. As the opioid epidemic is once again picking up momentum, and with the increase in more potent synthetic opioids, we can be sure the story has continued in an even more complex and costly way since then.

The goal of opioid overdose medicine distribution strategies is to make this life-saving medication available to people most likely to observe an opioid overdose, in time to reverse respiratory depression. A 2016 study funded by the National Institutes of Health ("NIH") concluded that providing an opioid antagonist to patients reduces admissions to hospital emergency departments.[15] Researchers at the University of Michigan found broad distribution of the opioid reversal drug naloxone to be highly cost-effective in reducing fatal overdoses.[16]

CONCLUSION

We are at a time in our history where addressing systemic inequities in the healthcare system are not just a priority but an obligation of society. As we move forward, giving tools to historically

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[14] *The cost of treating opioid overdose victims is skyrocketing,* by Casey Ross, STAT, August 11, 2017. Retrieved from: https://www.statnews.com/2017/08/11/opioid-overdose-costs

[15] *Nonrandomized Intervention Study of Naloxone Coprescription for Primary Care Patients Receiving Long-Term Opioid Therapy for Pain*, by Phillip O. Coffin, MD, MIA; et. al., Annals of Internal Medicine, June 28, 2016. Retrieved at: https://www.acpjournals.org/journal/aim

[16] *Cost-effectiveness analysis of alternative naloxone distribution strategies: First responder and lay distribution in the United States,* by Tarlise Townsend, et. al., International Journal of Drug Policy, January 2020. Retrieved from: https://www.sciencedirect.com/science/article/abs/pii/S0955395919302099?via%3Dihub

underserved communities, who are disproportionality impacted by both COVID-19 and the opioid epidemic, is essential in the fight.

New Yorkers deserve access to life saving medication.

The opioid epidemic has only gotten worse in the past 11 months of the COVID-19 pandemic, and without common sense policies enacted – namely co-prescribing – we have no indication that it will get better.

Thank you for allowing us to submit this written testimony in support of including co-prescribing into the State's final enacted budget. I am available to meet with you and your staff to discuss this further.

Respectfully Submitted,

Roger Crystal, MD