Congress of the United States

Washington, DC 20515

March 12, 2024

Christopher Hunter
CEO, Acadia Healthcare
6100 Tower Circle
Franklin, TN 37067

Dear Mr. Hunter:

The United States continues to grapple with an opioid use disorder (OUD) epidemic that has left millions of Americans in need of treatment. Medication for opioid use disorder (MOUD) — particularly methadone — is considered the gold standard for treatment because evidence shows that it is safe and effective. Yet proposed federal legislation to make methadone more widely available has been subject to organized opposition by opioid treatment programs (OTPs), including the recent "Program, not a pill campaign," advanced by your organization. We write with concern that your organization's opposition to expanding methadone treatment for OUD is driven not by science, but by the profits that private-equity-backed OTPs earn when patients are only allowed to access treatment through your programs. We write to request information about the role of private equity and profit-seeking in the OTP opposition to methadone reform legislation. We urge your organization to prioritize patients over profits and support expanded access to evidence-based treatment for those suffering from OUD.

Despite some progress, the opioid epidemic has evolved, and the United States has a long way to go in combatting the opioid epidemic that has swept across the nation. In 2022, nearly 110,000 people in the United States died from a drug overdose; synthetic opioids, including fentanyl, contributed to about 75,000 fatal overdoses.[1] Those staggering figures underscore the need for more overdose prevention resources, including increased access to treatment for Americans living with OUD. In 2021, only about one in five Americans with OUD received MOUD.[2]

Methadone is one highly effective, proven medication for stabilizing patients with OUD and helping them stay in recovery. According to the National Institute on Drug Abuse describes, "[a] large number of studies . . . support methadone's effectiveness at reducing opioid use."[3] In fact, methadone has been used with great success to treat OUD since the 1970s, reducing the likelihood of dying from an opioid overdose by 50 percent or more.[4]

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[1] Noah Weiland, *U.S. Recorded Nearly 110,000 Overdose Deaths in 2022*, N.Y. Times (May 17, 2023), https://www.nytimes.com/2023/05/17/us/politics/drug-overdose-deaths.html.

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[4] Morgan Coulson, *Methadone Is an Effective Treatment for Opioid Use Disorder, So Why Aren't More Patients Using It?*, Johns Hopkins University Bloomberg School of Public Health (Sept. 26, 2023), https://publichealth.jhu.edu/2023/barriers-to-methadone-access; News Release, Methadone and buprenorphine

But few people in need of methadone treatment receive it due to restrictions on access under federal law. Methadone is the most stringently regulated of the three FDA-approved medications for opioid use disorder.[5] Currently, methadone for the treatment of OUD is only available at approximately 2,000 federally regulated OTPs, also known as methadone clinics.[6] Federal regulations allow only specially certified providers to prescribe and dispense methadone, limit where it can be dispensed, and prevent dispensing of take-home doses. These restrictions create barriers for patients seeking to maintain treatment. Over half of all census tracts do not have an OTP.[7] In many rural and remote communities, some patients must travel long distances to get treatment for withdrawal symptoms. According to the National Academies of Science, Engineering, and Medicine, "there are huge areas of the country where the nearest OTP is more than 2 hours away by car."[8] In addition to these challenges, some OTPs do not take advantage of the full regulatory flexibility available that would limit how often a patient must go to an OTP in-person.

For these reasons, there is widespread, bipartisan support for legislation to reform and liberalize how patients suffering from OUD can access methadone. The Modernizing Opioid Treatment Access Act (MOTAA) would modernize the outdated rules governing methadone, empowering board-certified addiction psychiatry and addiction medicine physicians registered with the Drug Enforcement Administration to prescribe it to patients, and allowing U.S. pharmacies to dispense it. The bill is supported by more than 100 local, state, and national organizations. As the CEO of Faces and Voices of Recovery explained in her organization's endorsement to the legislation: "As our country struggles with an overdose crisis, we should examine every possible option to expand the use of this medication. This legislation will go a long way towards destigmatizing methadone and increasing access."[9]

Despite the recognition throughout the medical community that changes to methadone regulation are long overdue, some OTPs have organized opposition to MOTAA through the "Program, not a pill" campaign. Although the campaign states that "[m]edication-assisted treatment is the best and most proven treatment option for people who want to recover or reduce the harms from OUD," and that "[m]ethadone is a highly effective medication,"[10] the campaign's broader goal is to continue to require patients to receive treatment *at* OTPs. The campaign

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[8] Methadone Treatment for Opioid Use Disorder: Improving Access Through Regulatory and Legal Change: Proceedings of a Workshop, National Academies Press (2022), https://doi.org/10.17226/26635.https://nap.nationalacademies.org/read/26635/chapter/9.

[9] Press Release, Sens. Markey, Paul and Reps. Norcross, Bacon Introduce Modernizing Opioid Treatment Access Act to Reach More Americans Suffering from Opioid Use Disorder as Annual Overdoses Surpass 100,000 Across U.S., Office of Senator Edward J. Markey (Mar. 6, 2023), https://www.markey.senate.gov/news/press-releases/sens-markey-paul-and-reps-norcross-bacon-introduce-modernizing-opioid-treatment-access-act-to-reach-more-americans-suffering-from-opioid-use-disorder-as-annual-overdoses-surpass-100000-across-us.

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The evidence shows that MOTAA builds off a safe, effective, evidence-based framework. The U.S. experience during the COVID-19 pandemic illustrates that expanding access to methadone helped patients and did not lead to increased overdoses. In March 2020, the federal government put emergency measures in place, approving flexibilities that allowed patients to take home additional doses of methadone, allowing OTPs to dispense 28 days of take-home methadone doses to stable patients for the treatment of OUD, and up to 14 doses of take-home methadone for less stable patients who the OTP determined could safely handle that level of take-home medication.[12] The Substance Use and Mental Health Services Administration (SAMHSA) recently published a final rule to make those flexibilities permanent and allow more practitioners, including physician assistants and nurse practitioners, to determine if take-home doses of methadone are clinically appropriate.[13]

Pandemic-era methadone flexibilities allowed more patients with OUD to enter treatment and stay in recovery. Studies conducted nearly two years after the exemption was first granted showed that stakeholders reported "increased engagement with treatment, improved patient satisfaction, and very few incidents of misuse or diversion of medication."[14] A feared "increase in methadone-involved overdoses never materialized."[15] And "[t]he flexibility promote[d] individualized, recovery-oriented care by allowing greater access for people who reside[d] farther away from an OTP location or who lack[ed] reliable transportation."[16] As Nora Volkow, director of the National Institute of Drug Abuse, has stated, "[t]here's absolutely no reason why" physicians should not be allowed to prescribe methadone directly to patients.[17]

Given the strong clinical evidence in support of expanded methadone access, we are struggling to understand OTPs' opposition to MOTAA and their support of the "Program, not a pill campaign" advanced by Acadia Healthcare. We write to seek more information about OTPs' interest in keeping methadone treatment limited to their on-site locations, and what aspects of the for-profit OTP business model are informing clinical decisions about patient care. According to

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[14] *Id*.
[15] Lev Facher, *The fight for control of methadone, addiction treatment's 'miracle molecule'*, STAT (Oct. 20, 2023), https://www.statnews.com/2023/10/20/methadone-clinic-access-prescription/.
[16] Press Announcement, SAMHSA Extends the Methadone Take-Home Flexibility for One Year While Working Toward a Permanent Solution, SAMSHA (Nov. 18, 2021), https://www.samhsa.gov/newsroom/press-announcements/202111181000.
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publicly available information, private equity has an interest in at least seven of the eight OTPs affiliated with the "Program, not a pill" campaign.[18]

In recent years, private equity has invested heavily in addiction treatment programs. The U.S. Securities and Exchange Commission defines "private equity" as a "private fund that is managed by a private equity firm" and which, in a "typical investment strategy" takes "a controlling interest in a portfolio company and engage[s] actively in the management and direction of the business in order to increase its value."[19] According to the *Wall Street Journal*, "private-equity has become the 'driving force' in growth in methadone clinics."[20] In the mid-2000s, "roughly 60% of the clinics were nonprofits." By 2017, "nearly 60% were for-profit entities.[21] The reason, according to Marketplace, is that "[a]ddiction treatment" is "now seen as a big moneymaker" and "has become a prime investment target because of the ongoing opioid overdose crisis and improved health insurance coverage."[22]

The consequence of private equity investment in health care is to "increase health care prices and utilization — and thus costs — to both patients and the larger society." And although "[s]ome new private owners of health care facilities may adopt reforms that make care more efficient and reduce costs, thus improving value . . . in general, it's much easier, and more common, for private owners to raise prices and volumes and to focus on high-margin services."[23] Overall, there is a question of "the compatibility of [private equity's] profit maximization practices with certain public-service-oriented industries."[24] In this instance, we are concerned that there is incompatibility manifesting itself in private-equity-backed OTPs seeking to maintain their monopoly on methadone access, not because it is good for the patient, but because it is good for the bottom line. Any interference with policies that would save lives for the sake of profit is unacceptable.

To help us better understand whether, and, if so how, private-equity investment in OTPs is impacting access to and the use of methadone for OUD, we request written answers to the following questions by April 12, 2024:

1. Please provide a comprehensive overview of any private equity investment in your OTP, including the date of the investment, the geographic location(s) of the investment, the name(s) of the private equity firm(s) involved, and a summary of the non-confidential terms and conditions of the investment. Please also provide any term sheet.

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[18] Acadia Healthcare; BayMark Health Services; Behavioral Health Group; Carolina Treatment Centers; Crossroads Treatment Centers; New Season; and Western Pacific Med Corp.
[19] Cutting Through the Jargon From A to Z, U.S. Securities and Exchange Commission (last modified Sept. 5, 2023), https://www.sec.gov/education/glossary/jargon-z#P.
[20] Jeanne Whalen & Laura Cooper, *Private-Equity Pours Cash Into Opioid-Treatment Sector*, Wall St. J. (Sept. 2, 2017), https://www.wsj.com/articles/opioid-crisis-opens-opportunities-for-private-equity-firms-1504353601.
[21] *Id.*
[22] Blake Farmer, *Private equity investment is flooding into addiction treatment. Is that a good thing?*, Marketplace (Jan. 25, 2023), https://www.marketplace.org/2023/01/25/private-equity-investment-is-flooding-into-addiction-treatment-is-that-a-good-thing/.
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[24] Eva Su, *Private Equity and Capital Markets Policy*, Congressional Research Service (Mar. 28, 2022), https://www.crs.gov/Reports/R47053.

2. If there is any private equity investment in your OTP, what specific objectives or goals were outlined in the agreement between the OTP and the private equity firm(s)? How have these objectives been tracked and measured over time?
3. What is the total amount of capital that the private equity firm(s) invested in your OTP, if any? How has this investment been allocated within the OTP, and what key areas or projects have received funding as a result of the private equity investment?
4. Please provide an overview of the financial performance and profitability of the OTP before and after any private equity investment. Please include relevant financial metrics and any changes in revenue, expenses, or profit margins.
5. Has your OTP made any modifications to the criteria or guidelines for prescribing or dispensing methadone since any private equity investment? If so, please identify them.
6. Since any private equity investment, has there been any involvement by the PE firm(s) in any decisions regarding clinical practices? If so, please describe that involvement.
7. Since any private equity investment, have there been any updates or enhancements to the training programs provided to OTP staff involved in methadone prescribing and dispensing? If so, please describe them.
8. Has any private equity investment influenced patient education and counseling regarding methadone usage, potential side effects, and associated risks? If so, how?
9. Please provide data on patient outcomes specifically related to methadone treatment, both pre- and post- any private equity investment, including data on key performance indicators related to patient success rates, relapse rates, and overall satisfaction. Have there been any notable improvements or challenges in patient outcomes linked to methadone treatment since the involvement of private equity?
10. How has any private equity investment affected the OTP's compliance with state and federal regulations governing the use of methadone in opioid treatment programs? Are there any specific challenges or successes related to regulatory compliance that can be attributed to the private equity investment?

Thank you in advance for your attention to these questions. We look forward to your timely response.

Sincerely,

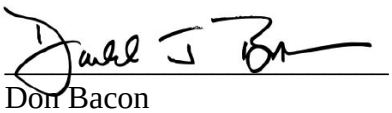
Edward J. Markey
United States Senator

Mike Braun
United States Senator

Maggie Hassan
United States Senator

Elizabeth Warren
United States Senator

Donald Norcross
Member of Congress



Don Bacon
Member of Congress

Congress of the United States

Washington, DC 20515

March 12, 2024

David K. White, Ph.D
CEO, BayMark Health Services
1720 Lakepointe Drive
Lewisville, TX 75057

Dear Mr. White:

The United States continues to grapple with an opioid use disorder (OUD) epidemic that has left millions of Americans in need of treatment. Medication for opioid use disorder (MOUD) — particularly methadone — is considered the gold standard for treatment because evidence shows that it is safe and effective. Yet proposed federal legislation to make methadone more widely available has been subject to organized opposition by opioid treatment programs (OTPs), including the recent "Program, not a pill campaign," advanced by your organization. We write with concern that your organization's opposition to expanding methadone treatment for OUD is driven not by science, but by the profits that private-equity-backed OTPs earn when patients are only allowed to access treatment through your programs. We write to request information about the role of private equity and profit-seeking in the OTP opposition to methadone reform legislation. We urge your organization to prioritize patients over profits and support expanded access to evidence-based treatment for those suffering from OUD.

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8. Has any private equity investment influenced patient education and counseling regarding methadone usage, potential side effects, and associated risks? If so, how?
9. Please provide data on patient outcomes specifically related to methadone treatment, both pre- and post- any private equity investment, including data on key performance indicators related to patient success rates, relapse rates, and overall satisfaction. Have there been any notable improvements or challenges in patient outcomes linked to methadone treatment since the involvement of private equity?
10. How has any private equity investment affected the OTP's compliance with state and federal regulations governing the use of methadone in opioid treatment programs? Are there any specific challenges or successes related to regulatory compliance that can be attributed to the private equity investment?

Thank you in advance for your attention to these questions. We look forward to your timely response.

Sincerely,

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United States Senator

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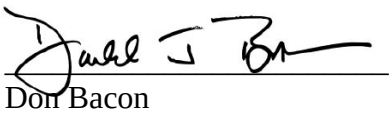

Don Bacon
Member of Congress

Congress of the United States

Washington, DC 20515

March 12, 2024

Jay Higham
CEO, Behavioral Health Group
5001 Spring Valley Road
Dallas, TX 75244

Dear Mr. Higham:

The United States continues to grapple with an opioid use disorder (OUD) epidemic that has left millions of Americans in need of treatment. Medication for opioid use disorder (MOUD) — particularly methadone — is considered the gold standard for treatment because evidence shows that it is safe and effective. Yet proposed federal legislation to make methadone more widely available has been subject to organized opposition by opioid treatment programs (OTPs), including the recent "Program, not a pill campaign," advanced by your organization. We write with concern that your organization's opposition to expanding methadone treatment for OUD is driven not by science, but by the profits that private-equity-backed OTPs earn when patients are only allowed to access treatment through your programs. We write to request information about the role of private equity and profit-seeking in the OTP opposition to methadone reform legislation. We urge your organization to prioritize patients over profits and support expanded access to evidence-based treatment for those suffering from OUD.

Despite some progress, the opioid epidemic has evolved, and the United States has a long way to go in combatting the opioid epidemic that has swept across the nation. In 2022, nearly 110,000 people in the United States died from a drug overdose; synthetic opioids, including fentanyl, contributed to about 75,000 fatal overdoses.[1] Those staggering figures underscore the need for more overdose prevention resources, including increased access to treatment for Americans living with OUD. In 2021, only about one in five Americans with OUD received MOUD.[2]

Methadone is one highly effective, proven medication for stabilizing patients with OUD and helping them stay in recovery. According to the National Institute on Drug Abuse describes, "[a] large number of studies . . . support methadone's effectiveness at reducing opioid use."[3] In fact, methadone has been used with great success to treat OUD since the 1970s, reducing the likelihood of dying from an opioid overdose by 50 percent or more.[4]

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[4] Morgan Coulson, *Methadone Is an Effective Treatment for Opioid Use Disorder, So Why Aren't More Patients Using It?*, Johns Hopkins University Bloomberg School of Public Health (Sept. 26, 2023), https://publichealth.jhu.edu/2023/barriers-to-methadone-access; News Release, Methadone and buprenorphine

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For these reasons, there is widespread, bipartisan support for legislation to reform and liberalize how patients suffering from OUD can access methadone. The Modernizing Opioid Treatment Access Act (MOTAA) would modernize the outdated rules governing methadone, empowering board-certified addiction psychiatry and addiction medicine physicians registered with the Drug Enforcement Administration to prescribe it to patients, and allowing U.S. pharmacies to dispense it. The bill is supported by more than 100 local, state, and national organizations. As the CEO of Faces and Voices of Recovery explained in her organization's endorsement to the legislation: "As our country struggles with an overdose crisis, we should examine every possible option to expand the use of this medication. This legislation will go a long way towards destigmatizing methadone and increasing access."[9]

Despite the recognition throughout the medical community that changes to methadone regulation are long overdue, some OTPs have organized opposition to MOTAA through the "Program, not a pill" campaign. Although the campaign states that "[m]edication-assisted treatment is the best and most proven treatment option for people who want to recover or reduce the harms from OUD," and that "[m]ethadone is a highly effective medication,"[10] the campaign's broader goal is to continue to require patients to receive treatment *at* OTPs. The campaign

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[9] Press Release, Sens. Markey, Paul and Reps. Norcross, Bacon Introduce Modernizing Opioid Treatment Access Act to Reach More Americans Suffering from Opioid Use Disorder as Annual Overdoses Surpass 100,000 Across U.S., Office of Senator Edward J. Markey (Mar. 6, 2023), https://www.markey.senate.gov/news/press-releases/sens-markey-paul-and-reps-norcross-bacon-introduce-modernizing-opioid-treatment-access-act-to-reach-more-americans-suffering-from-opioid-use-disorder-as-annual-overdoses-surpass-100000-across-us.

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Given the strong clinical evidence in support of expanded methadone access, we are struggling to understand OTPs' opposition to MOTAA and their support of the "Program, not a pill campaign" advanced by Behavioral Health Group. We write to seek more information about OTPs' interest in keeping methadone treatment limited to their on-site locations, and what aspects of the for-profit OTP business model are informing clinical decisions about patient care.

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[11] *Id*; https://programnotapill.com/write-congress/.
[12] *Id*.
[13] 42 CR Part 8 Final Rule – Frequently Asked Questions, SAMHSA (Jan. 31, 2024), https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/faqs.
[14] *Id*.
[15] Lev Facher, *The fight for control of methadone, addiction treatment's 'miracle molecule'*, STAT (Oct. 20, 2023), https://www.statnews.com/2023/10/20/methadone-clinic-access-prescription/.
[16] Press Announcement, SAMHSA Extends the Methadone Take-Home Flexibility for One Year While Working Toward a Permanent Solution, SAMSHA (Nov. 18, 2021), https://www.samhsa.gov/newsroom/press-announcements/202111181000.
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According to publicly available information, private equity has an interest in at least seven of the eight OTPs affiliated with the "Program, not a pill" campaign.[18]

In recent years, private equity has invested heavily in addiction treatment programs. The U.S. Securities and Exchange Commission defines "private equity" as a "private fund that is managed by a private equity firm" and which, in a "typical investment strategy" takes "a controlling interest in a portfolio company and engage[s] actively in the management and direction of the business in order to increase its value."[19] According to the *Wall Street Journal*, "private-equity has become the 'driving force' in growth in methadone clinics."[20] In the mid-2000s, "roughly 60% of the clinics were nonprofits." By 2017, "nearly 60% were for-profit entities.[21] The reason, according to Marketplace, is that "[a]ddiction treatment" is "now seen as a big moneymaker" and "has become a prime investment target because of the ongoing opioid overdose crisis and improved health insurance coverage."[22]

The consequence of private equity investment in health care is to "increase health care prices and utilization — and thus costs — to both patients and the larger society." And although "[s]ome new private owners of health care facilities may adopt reforms that make care more efficient and reduce costs, thus improving value . . . in general, it's much easier, and more common, for private owners to raise prices and volumes and to focus on high-margin services."[23] Overall, there is a question of "the compatibility of [private equity's] profit maximization practices with certain public-service-oriented industries."[24] In this instance, we are concerned that there is incompatibility manifesting itself in private-equity-backed OTPs seeking to maintain their monopoly on methadone access, not because it is good for the patient, but because it is good for the bottom line. Any interference with policies that would save lives for the sake of profit is unacceptable.

To help us better understand whether, and, if so how, private-equity investment in OTPs is impacting access to and the use of methadone for OUD, we request written answers to the following questions by April 12, 2024:

1. Please provide a comprehensive overview of any private equity investment in your OTP, including the date of the investment, the geographic location(s) of the investment, the name(s) of the private equity firm(s) involved, and a summary of the non-confidential terms and conditions of the investment. Please also provide any term sheet.

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[18] Acadia Healthcare; BayMark Health Services; Behavioral Health Group; Carolina Treatment Centers; Crossroads Treatment Centers; New Season; and Western Pacific Med Corp.
[19] Cutting Through the Jargon From A to Z, U.S. Securities and Exchange Commission (last modified Sept. 5, 2023), https://www.sec.gov/education/glossary/jargon-z#P.
[20] Jeanne Whalen & Laura Cooper, *Private-Equity Pours Cash Into Opioid-Treatment Sector*, Wall St. J. (Sept. 2, 2017), https://www.wsj.com/articles/opioid-crisis-opens-opportunities-for-private-equity-firms-1504353601.
[21] *Id.*
[22] Blake Farmer, *Private equity investment is flooding into addiction treatment. Is that a good thing?*, Marketplace (Jan. 25, 2023), https://www.marketplace.org/2023/01/25/private-equity-investment-is-flooding-into-addiction-treatment-is-that-a-good-thing/.
[23] David Blumenthal, *Private Equity's Role in Health Care*, The Commonwealth Fund (Nov. 17, 2023), https://www.commonwealthfund.org/publications/explainer/2023/nov/private-equity-role-health-care.
[24] Eva Su, *Private Equity and Capital Markets Policy*, Congressional Research Service (Mar. 28, 2022), https://www.crs.gov/Reports/R47053.

2. If there is any private equity investment in your OTP, what specific objectives or goals were outlined in the agreement between the OTP and the private equity firm(s)? How have these objectives been tracked and measured over time?
3. What is the total amount of capital that the private equity firm(s) invested in your OTP, if any? How has this investment been allocated within the OTP, and what key areas or projects have received funding as a result of the private equity investment?
4. Please provide an overview of the financial performance and profitability of the OTP before and after any private equity investment. Please include relevant financial metrics and any changes in revenue, expenses, or profit margins.
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10. How has any private equity investment affected the OTP's compliance with state and federal regulations governing the use of methadone in opioid treatment programs? Are there any specific challenges or successes related to regulatory compliance that can be attributed to the private equity investment?

Thank you in advance for your attention to these questions. We look forward to your timely response.

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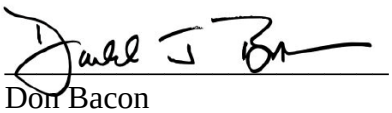

Don Bacon
Member of Congress

Congress of the United States

Washington, DC 20515

March 12, 2024

Carolina Treatment Centers
3523 Pelham Road
Greenville, SC 29615

To Whom It May Concern:

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To help us better understand whether, and, if so how, private-equity investment in OTPs is impacting access to and the use of methadone for OUD, we request written answers to the following questions by April 12, 2024:

1. Please provide a comprehensive overview of any private equity investment in your OTP, including the date of the investment, the geographic location(s) of the investment, the name(s) of the private equity firm(s) involved, and a summary of the non-confidential terms and conditions of the investment. Please also provide any term sheet.
2. If there is any private equity investment in your OTP, what specific objectives or goals were outlined in the agreement between the OTP and the private equity firm(s)? How have these objectives been tracked and measured over time?

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[19] Cutting Through the Jargon From A to Z, U.S. Securities and Exchange Commission (last modified Sept. 5, 2023), https://www.sec.gov/education/glossary/jargon-z#P.
[20] Jeanne Whalen & Laura Cooper, *Private-Equity Pours Cash Into Opioid-Treatment Sector*, Wall St. J. (Sept. 2, 2017), https://www.wsj.com/articles/opioid-crisis-opens-opportunities-for-private-equity-firms-1504353601.
[21] *Id.*
[22] Blake Farmer, *Private equity investment is flooding into addiction treatment. Is that a good thing?*, Marketplace (Jan. 25, 2023), https://www.marketplace.org/2023/01/25/private-equity-investment-is-flooding-into-addiction-treatment-is-that-a-good-thing/.
[23] David Blumenthal, *Private Equity's Role in Health Care*, The Commonwealth Fund (Nov. 17, 2023), https://www.commonwealthfund.org/publications/explainer/2023/nov/private-equity-role-health-care.
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4. Please provide an overview of the financial performance and profitability of the OTP before and after any private equity investment. Please include relevant financial metrics and any changes in revenue, expenses, or profit margins.
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7. Since any private equity investment, have there been any updates or enhancements to the training programs provided to OTP staff involved in methadone prescribing and dispensing? If so, please describe them.
8. Has any private equity investment influenced patient education and counseling regarding methadone usage, potential side effects, and associated risks? If so, how?
9. Please provide data on patient outcomes specifically related to methadone treatment, both pre- and post- any private equity investment, including data on key performance indicators related to patient success rates, relapse rates, and overall satisfaction. Have there been any notable improvements or challenges in patient outcomes linked to methadone treatment since the involvement of private equity?
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Thank you in advance for your attention to these questions. We look forward to your timely response.

Sincerely,

Edward J. Markey
United States Senator

Mike Braun
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United States Senator

Elizabeth Warren
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Donald Norcross
Member of Congress

Don Bacon
Member of Congress

Congress of the United States

Washington, DC 20515

March 12, 2024

Dr. Rupert McCormac, IV
CEO, Crossroads Treatment Centers
7806 Uplands Way A
Citrus Heights, CA 95610

Dear Dr. McCormac:

The United States continues to grapple with an opioid use disorder (OUD) epidemic that has left millions of Americans in need of treatment. Medication for opioid use disorder (MOUD) — particularly methadone — is considered the gold standard for treatment because evidence shows that it is safe and effective. Yet proposed federal legislation to make methadone more widely available has been subject to organized opposition by opioid treatment programs (OTPs), including the recent "Program, not a pill campaign," advanced by your organization. We write with concern that your organization's opposition to expanding methadone treatment for OUD is driven not by science, but by the profits that private-equity-backed OTPs earn when patients are only allowed to access treatment through your programs. We write to request information about the role of private equity and profit-seeking in the OTP opposition to methadone reform legislation. We urge your organization to prioritize patients over profits and support expanded access to evidence-based treatment for those suffering from OUD.

Despite some progress, the opioid epidemic has evolved, and the United States has a long way to go in combatting the opioid epidemic that has swept across the nation. In 2022, nearly 110,000 people in the United States died from a drug overdose; synthetic opioids, including fentanyl, contributed to about 75,000 fatal overdoses.[1] Those staggering figures underscore the need for more overdose prevention resources, including increased access to treatment for Americans living with OUD. In 2021, only about one in five Americans with OUD received MOUD.[2]

Methadone is one highly effective, proven medication for stabilizing patients with OUD and helping them stay in recovery. According to the National Institute on Drug Abuse describes, "[a] large number of studies . . . support methadone's effectiveness at reducing opioid use."[3] In fact, methadone has been used with great success to treat OUD since the 1970s, reducing the likelihood of dying from an opioid overdose by 50 percent or more.[4]

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For these reasons, there is widespread, bipartisan support for legislation to reform and liberalize how patients suffering from OUD can access methadone. The Modernizing Opioid Treatment Access Act (MOTAA) would modernize the outdated rules governing methadone, empowering board-certified addiction psychiatry and addiction medicine physicians registered with the Drug Enforcement Administration to prescribe it to patients, and allowing U.S. pharmacies to dispense it. The bill is supported by more than 100 local, state, and national organizations. As the CEO of Faces and Voices of Recovery explained in her organization's endorsement to the legislation: "As our country struggles with an overdose crisis, we should examine every possible option to expand the use of this medication. This legislation will go a long way towards destigmatizing methadone and increasing access."[9]

Despite the recognition throughout the medical community that changes to methadone regulation are long overdue, some OTPs have organized opposition to MOTAA through the "Program, not a pill" campaign. Although the campaign states that "[m]edication-assisted treatment is the best and most proven treatment option for people who want to recover or reduce the harms from OUD," and that "[m]ethadone is a highly effective medication,"[10] the campaign's broader goal is to continue to require patients to receive treatment *at* OTPs. The campaign

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[9] Press Release, Sens. Markey, Paul and Reps. Norcross, Bacon Introduce Modernizing Opioid Treatment Access Act to Reach More Americans Suffering from Opioid Use Disorder as Annual Overdoses Surpass 100,000 Across U.S., Office of Senator Edward J. Markey (Mar. 6, 2023), https://www.markey.senate.gov/news/press-releases/sens-markey-paul-and-reps-norcross-bacon-introduce-modernizing-opioid-treatment-access-act-to-reach-more-americans-suffering-from-opioid-use-disorder-as-annual-overdoses-surpass-100000-across-us.

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The evidence shows that MOTAA builds off a safe, effective, evidence-based framework. The U.S. experience during the COVID-19 pandemic illustrates that expanding access to methadone helped patients and did not lead to increased overdoses. In March 2020, the federal government put emergency measures in place, approving flexibilities that allowed patients to take home additional doses of methadone, allowing OTPs to dispense 28 days of take-home methadone doses to stable patients for the treatment of OUD, and up to 14 doses of take-home methadone for less stable patients who the OTP determined could safely handle that level of take-home medication.[12] The Substance Use and Mental Health Services Administration (SAMHSA) recently published a final rule to make those flexibilities permanent and allow more practitioners, including physician assistants and nurse practitioners, to determine if take-home doses of methadone are clinically appropriate.[13]

Pandemic-era methadone flexibilities allowed more patients with OUD to enter treatment and stay in recovery. Studies conducted nearly two years after the exemption was first granted showed that stakeholders reported "increased engagement with treatment, improved patient satisfaction, and very few incidents of misuse or diversion of medication."[14] A feared "increase in methadone-involved overdoses never materialized."[15] And "[t]he flexibility promote[d] individualized, recovery-oriented care by allowing greater access for people who reside[d] farther away from an OTP location or who lack[ed] reliable transportation."[16] As Nora Volkow, director of the National Institute of Drug Abuse, has stated, "[t]here's absolutely no reason why" physicians should not be allowed to prescribe methadone directly to patients.[17]

Given the strong clinical evidence in support of expanded methadone access, we are struggling to understand OTPs' opposition to MOTAA and their support of the "Program, not a pill campaign" advanced by Crossroads Treatment Centers. We write to seek more information about OTPs' interest in keeping methadone treatment limited to their on-site locations, and what aspects of the for-profit OTP business model are informing clinical decisions about patient care.

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[14] *Id*.
[15] Lev Facher, *The fight for control of methadone, addiction treatment's 'miracle molecule'*, STAT (Oct. 20, 2023), https://www.statnews.com/2023/10/20/methadone-clinic-access-prescription/.
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According to publicly available information, private equity has an interest in at least seven of the eight OTPs affiliated with the "Program, not a pill" campaign.[18]

In recent years, private equity has invested heavily in addiction treatment programs. The U.S. Securities and Exchange Commission defines "private equity" as a "private fund that is managed by a private equity firm" and which, in a "typical investment strategy" takes "a controlling interest in a portfolio company and engage[s] actively in the management and direction of the business in order to increase its value."[19] According to the *Wall Street Journal*, "private-equity has become the 'driving force' in growth in methadone clinics."[20] In the mid-2000s, "roughly 60% of the clinics were nonprofits." By 2017, "nearly 60% were for-profit entities.[21] The reason, according to Marketplace, is that "[a]ddiction treatment" is "now seen as a big moneymaker" and "has become a prime investment target because of the ongoing opioid overdose crisis and improved health insurance coverage."[22]

The consequence of private equity investment in health care is to "increase health care prices and utilization — and thus costs — to both patients and the larger society." And although "[s]ome new private owners of health care facilities may adopt reforms that make care more efficient and reduce costs, thus improving value . . . in general, it's much easier, and more common, for private owners to raise prices and volumes and to focus on high-margin services."[23] Overall, there is a question of "the compatibility of [private equity's] profit maximization practices with certain public-service-oriented industries."[24] In this instance, we are concerned that there is incompatibility manifesting itself in private-equity-backed OTPs seeking to maintain their monopoly on methadone access, not because it is good for the patient, but because it is good for the bottom line. Any interference with policies that would save lives for the sake of profit is unacceptable.

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[18] Acadia Healthcare; BayMark Health Services; Behavioral Health Group; Carolina Treatment Centers; Crossroads Treatment Centers; New Season; and Western Pacific Med Corp.
[19] Cutting Through the Jargon From A to Z, U.S. Securities and Exchange Commission (last modified Sept. 5, 2023), https://www.sec.gov/education/glossary/jargon-z#P.
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Mike Braun
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Elizabeth Warren
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Donald Norcross
Member of Congress

Don Bacon
Member of Congress

Congress of the United States

Washington, DC 20515

March 12, 2024

John Steinbrun
CEO, New Season
2500 Maitland Center Parkway
Maitland, FL 32751

Dear Mr. Steinbrun:

The United States continues to grapple with an opioid use disorder (OUD) epidemic that has left millions of Americans in need of treatment. Medication for opioid use disorder (MOUD) — particularly methadone — is considered the gold standard for treatment because evidence shows that it is safe and effective. Yet proposed federal legislation to make methadone more widely available has been subject to organized opposition by opioid treatment programs (OTPs), including the recent "Program, not a pill campaign," advanced by your organization. We write with concern that your organization's opposition to expanding methadone treatment for OUD is driven not by science, but by the profits that private-equity-backed OTPs earn when patients are only allowed to access treatment through your programs. We write to request information about the role of private equity and profit-seeking in the OTP opposition to methadone reform legislation. We urge your organization to prioritize patients over profits and support expanded access to evidence-based treatment for those suffering from OUD.

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The consequence of private equity investment in health care is to "increase health care prices and utilization — and thus costs — to both patients and the larger society." And although "[s]ome new private owners of health care facilities may adopt reforms that make care more efficient and reduce costs, thus improving value . . . in general, it's much easier, and more common, for private owners to raise prices and volumes and to focus on high-margin services."[23] Overall, there is a question of "the compatibility of [private equity's] profit maximization practices with certain public-service-oriented industries."[24] In this instance, we are concerned that there is incompatibility manifesting itself in private-equity-backed OTPs seeking to maintain their monopoly on methadone access, not because it is good for the patient, but because it is good for the bottom line. Any interference with policies that would save lives for the sake of profit is unacceptable.

To help us better understand whether, and, if so how, private-equity investment in OTPs is impacting access to and the use of methadone for OUD, we request written answers to the following questions by April 12, 2024:

1. Please provide a comprehensive overview of any private equity investment in your OTP, including the date of the investment, the geographic location(s) of the investment, the name(s) of the private equity firm(s) involved, and a summary of the non-confidential terms and conditions of the investment. Please also provide any term sheet.

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[19] Cutting Through the Jargon From A to Z, U.S. Securities and Exchange Commission (last modified Sept. 5, 2023), https://www.sec.gov/education/glossary/jargon-z#P.
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[23] David Blumenthal, *Private Equity's Role in Health Care*, The Commonwealth Fund (Nov. 17, 2023), https://www.commonwealthfund.org/publications/explainer/2023/nov/private-equity-role-health-care.
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Thank you in advance for your attention to these questions. We look forward to your timely response.

Sincerely,

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Maggie Hassan
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Donald Norcross
Member of Congress

Don Bacon
Member of Congress

Congress of the United States

Washington, DC 20515

March 12, 2024

Mark Hickman
CEO, Western Pacific Med Corp
4544 San Fernando Road
Glendale, CA 91204-5015

Dear Mr. Hickman:

The United States continues to grapple with an opioid use disorder (OUD) epidemic that has left millions of Americans in need of treatment. Medication for opioid use disorder (MOUD) — particularly methadone — is considered the gold standard for treatment because evidence shows that it is safe and effective. Yet proposed federal legislation to make methadone more widely available has been subject to organized opposition by opioid treatment programs (OTPs), including the recent "Program, not a pill campaign," advanced by your organization. We write with concern that your organization's opposition to expanding methadone treatment for OUD is driven not by science, but by the profits that private-equity-backed OTPs earn when patients are only allowed to access treatment through your programs. We write to request information about the role of private equity and profit-seeking in the OTP opposition to methadone reform legislation. We urge your organization to prioritize patients over profits and support expanded access to evidence-based treatment for those suffering from OUD.

Despite some progress, the opioid epidemic has evolved, and the United States has a long way to go in combatting the opioid epidemic that has swept across the nation. In 2022, nearly 110,000 people in the United States died from a drug overdose; synthetic opioids, including fentanyl, contributed to about 75,000 fatal overdoses.[1] Those staggering figures underscore the need for more overdose prevention resources, including increased access to treatment for Americans living with OUD. In 2021, only about one in five Americans with OUD received MOUD.[2]

Methadone is one highly effective, proven medication for stabilizing patients with OUD and helping them stay in recovery. According to the National Institute on Drug Abuse describes, "[a] large number of studies . . . support methadone's effectiveness at reducing opioid use."[3] In fact, methadone has been used with great success to treat OUD since the 1970s, reducing the likelihood of dying from an opioid overdose by 50 percent or more.[4]

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[1] Noah Weiland, *U.S. Recorded Nearly 110,000 Overdose Deaths in 2022*, N.Y. Times (May 17, 2023), https://www.nytimes.com/2023/05/17/us/politics/drug-overdose-deaths.html.

[2] News Release, Only 1 in 5 U.S. adults with opioid use disorder received medications to treat it in 2021, National Institute on Drug Abuse (Aug. 7, 2023), https://nida.nih.gov/news-events/news-releases/2023/08/only-1-in-5-us-adults-with-opioid-use-disorder-received-medications-to-treat-it-in-2021.

[3] *How effective are medications to treat opioid use disorder?*, Nat'l Institute on Drug Abuse (Dec. 3, 2021), https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder.

[4] Morgan Coulson, *Methadone Is an Effective Treatment for Opioid Use Disorder, So Why Aren't More Patients Using It?*, Johns Hopkins University Bloomberg School of Public Health (Sept. 26, 2023), https://publichealth.jhu.edu/2023/barriers-to-methadone-access; News Release, Methadone and buprenorphine

But few people in need of methadone treatment receive it due to restrictions on access under federal law. Methadone is the most stringently regulated of the three FDA-approved medications for opioid use disorder.[5] Currently, methadone for the treatment of OUD is only available at approximately 2,000 federally regulated OTPs, also known as methadone clinics.[6] Federal regulations allow only specially certified providers to prescribe and dispense methadone, limit where it can be dispensed, and prevent dispensing of take-home doses. These restrictions create barriers for patients seeking to maintain treatment. Over half of all census tracts do not have an OTP.[7] In many rural and remote communities, some patients must travel long distances to get treatment for withdrawal symptoms. According to the National Academies of Science, Engineering, and Medicine, "there are huge areas of the country where the nearest OTP is more than 2 hours away by car."[8] In addition to these challenges, some OTPs do not take advantage of the full regulatory flexibility available that would limit how often a patient must go to an OTP in-person.

For these reasons, there is widespread, bipartisan support for legislation to reform and liberalize how patients suffering from OUD can access methadone. The Modernizing Opioid Treatment Access Act (MOTAA) would modernize the outdated rules governing methadone, empowering board-certified addiction psychiatry and addiction medicine physicians registered with the Drug Enforcement Administration to prescribe it to patients, and allowing U.S. pharmacies to dispense it. The bill is supported by more than 100 local, state, and national organizations. As the CEO of Faces and Voices of Recovery explained in her organization's endorsement to the legislation: "As our country struggles with an overdose crisis, we should examine every possible option to expand the use of this medication. This legislation will go a long way towards destigmatizing methadone and increasing access."[9]

Despite the recognition throughout the medical community that changes to methadone regulation are long overdue, some OTPs have organized opposition to MOTAA through the "Program, not a pill" campaign. Although the campaign states that "[m]edication-assisted treatment is the best and most proven treatment option for people who want to recover or reduce the harms from OUD," and that "[m]ethadone is a highly effective medication,"[10] the campaign's broader goal is to continue to require patients to receive treatment *at* OTPs. The campaign

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reduce risk of death after opioid overdose, National Institutes of Health (June 19, 208), https://www.nih.gov/news-events/news-releases/methadone-buprenorphine-reduce-risk-death-after-opioid-overdose**.**

[5] Medications for Opioid Use Disorder Save Lives, National Academies Press (2019), https://nap.nationalacademies.org/read/25310/chapter/7.

[6] Opioid Treatment Program Directory, Substance Abuse and Mental Health Services Admin., https://dpt2.samhsa.gov/treatment/directory.aspx.

[7] Paul Joudrey et al., *Methadone prescribing by addiction specialists likely to leave communities without available methadone treatment*, Health Affairs Scholar (Nov. 2023), https://academic.oup.com/healthaffairsscholar/article/1/5/qxad061/7378813.

[8] Methadone Treatment for Opioid Use Disorder: Improving Access Through Regulatory and Legal Change: Proceedings of a Workshop, National Academies Press (2022), https://doi.org/10.17226/26635.https://nap.nationalacademies.org/read/26635/chapter/9.

[9] Press Release, Sens. Markey, Paul and Reps. Norcross, Bacon Introduce Modernizing Opioid Treatment Access Act to Reach More Americans Suffering from Opioid Use Disorder as Annual Overdoses Surpass 100,000 Across U.S., Office of Senator Edward J. Markey (Mar. 6, 2023), https://www.markey.senate.gov/news/press-releases/sens-markey-paul-and-reps-norcross-bacon-introduce-modernizing-opioid-treatment-access-act-to-reach-more-americans-suffering-from-opioid-use-disorder-as-annual-overdoses-surpass-100000-across-us.

[10] https://programnotapill.com/about/.

contends that MOTAA amounts to "deregulating" methadone, which will lead to catastrophic results, inflammatorily describing it as "the most dangerous medication," which "can be misused, potentially causing fatal overdose."[11] These are the same arguments that OTPs levied against legislation to expand the number of doctors who could prescribe buprenorphine, a medication that, like methadone, is effective in treating opioid use disorder. But Congress did pass the Mainstreaming Addiction Treatment Act in 2022, taking an essential step that is already increasing patients' access to buprenorphine.

The evidence shows that MOTAA builds off a safe, effective, evidence-based framework. The U.S. experience during the COVID-19 pandemic illustrates that expanding access to methadone helped patients and did not lead to increased overdoses. In March 2020, the federal government put emergency measures in place, approving flexibilities that allowed patients to take home additional doses of methadone, allowing OTPs to dispense 28 days of take-home methadone doses to stable patients for the treatment of OUD, and up to 14 doses of take-home methadone for less stable patients who the OTP determined could safely handle that level of take-home medication.[12] The Substance Use and Mental Health Services Administration (SAMHSA) recently published a final rule to make those flexibilities permanent and allow more practitioners, including physician assistants and nurse practitioners, to determine if take-home doses of methadone are clinically appropriate.[13]

Pandemic-era methadone flexibilities allowed more patients with OUD to enter treatment and stay in recovery. Studies conducted nearly two years after the exemption was first granted showed that stakeholders reported "increased engagement with treatment, improved patient satisfaction, and very few incidents of misuse or diversion of medication."[14] A feared "increase in methadone-involved overdoses never materialized."[15] And "[t]he flexibility promote[d] individualized, recovery-oriented care by allowing greater access for people who reside[d] farther away from an OTP location or who lack[ed] reliable transportation."[16] As Nora Volkow, director of the National Institute of Drug Abuse, has stated, "[t]here's absolutely no reason why" physicians should not be allowed to prescribe methadone directly to patients.[17]

Given the strong clinical evidence in support of expanded methadone access, we are struggling to understand OTPs' opposition to MOTAA and their support of the "Program, not a pill campaign" advanced by Western Pacific Med Corp. We write to seek more information about OTPs' interest in keeping methadone treatment limited to their on-site locations, and what aspects of the for-profit OTP business model are informing clinical decisions about patient care.

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[11] *Id*; https://programnotapill.com/write-congress/.
[12] *Id*.
[13] 42 CR Part 8 Final Rule – Frequently Asked Questions, SAMHSA (Jan. 31, 2024), https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/faqs.
[14] *Id*.
[15] Lev Facher, *The fight for control of methadone, addiction treatment's 'miracle molecule'*, STAT (Oct. 20, 2023), https://www.statnews.com/2023/10/20/methadone-clinic-access-prescription/.
[16] Press Announcement, SAMHSA Extends the Methadone Take-Home Flexibility for One Year While Working Toward a Permanent Solution, SAMSHA (Nov. 18, 2021), https://www.samhsa.gov/newsroom/press-announcements/202111181000.
[17] Lev Facher, *Top U.S. addiction researcher calls for broad deregulation of methadone*, STAT News (Nov. 16, 2022), https://www.statnews.com/2022/11/16/nora-volkow-nida-broad-deregulation-methadone/.

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