Lundbeck
Six Parkway North
Deerfield, IL 60015
USA

Tel 847-282-1000
Fax 847-282-1001
www.lundbeck.com/us

November 1, 2021

The Honorable Ron Wyden
Chairman
U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Mike Crapo
Ranking Member
U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510

VIA ELECTRONIC MAIL (mentalhealthcare@finance.senate.gov)

Re: Policy Proposals to Address Unmet Mental Health Needs

Lundbeck thanks you for the opportunity to provide input on addressing challenges with the current behavioral health care infrastructure in the U.S. We sincerely appreciate your leadership on these important issues, your ambition to critically review where gaps in care exist, and your commitment to addressing the needs of those living with mental health conditions with effective solutions. As a pioneer at the forefront of tackling brain diseases for more than 70 years, Lundbeck shares your objectives, demonstrated by our commitment to developing and providing innovative therapies for people living with psychiatric and neurological disorders.

The ongoing COVID-19 pandemic has shown there has never been a more critical time in recent history than now to advance measures that will render meaningful impact on the mental health of Americans, as leading organizations agree this public health crisis has exacerbated a parallel mental health crisis.[1,2] The lasting effects of a COVID-19 infection are not only physical – reports continue to emerge around potentially 'COVID-induced' psychosis,[3,4] where individuals recovering from coronavirus have attempted to harm themselves or have died by suicide.[5,6]

It is because of these growing concerns that Lundbeck partnered with Mental Health America (MHA) to issue a series of four data briefs identifying geographies demonstrating significant mental health impacts amid the pandemic. The briefs – examining suicidal ideation (released May 30, 2021), severe depression (released August 11, 2021), trauma (released October 13, 2021) and psychosis (forthcoming December 2021) – analyze data collected from the more than 2.6 million

[1] United Nations Western Europe. "Covid-19: Mental Illness, a 'Parallel Pandemic.'" 1 Apr. 2021, https://unric.org/en/covid-19-mental-illness-a-parallel-pandemic/.
[2] Paz, Isabella Grullón. " Pediatricians and psychiatrists declare a national emergency in youth mental health." *The New York Times*, https://www.nytimes.com/2021/10/19/world/covid-pandemic-children-mental-health.html. 19 Oct. 2021. Accessed 1 Nov. 2021.
[3] Zhao, Yan-Jie et al. "The prevalence of psychiatric comorbidities during the SARS and COVID-19 epidemics: a systematic review and meta-analysis of observational studies." *Journal of Affective Disorders,* vol. 287 (2021): 145-157. doi:10.1016/j.jad.2021.03.016
[4] Taquet, Maxime et al. "Bidirectional Associations between Covid-19 and Psychiatric Disorder: Retrospective Cohort Studies of 62 354 COVID-19 Cases in the USA." *The Lancet Psychiatry*, vol. 8, no. 2, 9 Nov. 2020, pp. 130–140., https://doi.org/10.1016/s2215-0366(20)30462-4.
[5] Chacko, M et al. COVID-19-Induced Psychosis and Suicidal Behavior: Case Report. *SN Comprehensive Clinical Medicine.* 2, 2391–2395 (2020). https://doi.org/10.1007/s42399-020-00530-7
[6] Schoenberg, Nara. "After COVID-19, Came Panic and Paranoia. The Suicide of a Morris Businessman Shines a Spotlight on a Rare but Serious Condition: Post-COVID Psychosis." *Chicago Tribune*, https://www.chicagotribune.com/coronavirus/ct-post-covid-psychosis-suicide-morris-04262021-20210428-hixaqwawenglfion7ih7zwqqqy-story.html. 28 Apr. 2021. Accessed 1 Nov. 2021.

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Fax 847-282-1001
www.lundbeck.com/us

users who accessed MHA's online screening tools in 2020 and 2021, and collectively they represent the largest dataset ever gathered from a help-seeking population experiencing mental health conditions during the COVID-19 pandemic. Key findings to date include a significant increase in the rate of those scoring at-risk for Post-Traumatic Stress Disorder (PTSD) in 2020 and the first half of 2021 (93%) compared with prior data from 2019 alone (84%).[7] Additionally, 62% of individuals screened for depression were found to report severe or moderately severe symptoms[8] and, among those scoring with severe symptoms, 70% had not previously been diagnosed with a mental health condition and 67% had never before received any kind of mental health treatment.[8]

To better support the needs of millions of Americans with brain diseases now and into the future, Lundbeck supports the below policy concepts and evidence-based solutions to enhance mental health care across the following areas identified in the Committee's request for information:

Strengthening the Workforce

While the current behavioral health workforce shortage has created significant wait times for patients with any kind of coverage and made receiving treatment in the near-term a difficult task,[9] a 2020 *Health Affairs* article explains that the shortage is "even more notable in state Medicaid programs, particularly in rural areas [as,] on average, rural and frontier counties have 1.8 and 1.5 licensed behavioral health providers, respectively, per 1,000 Medicaid enrollees, compared with 6.4 in urban counties."[10] Low Medicaid reimbursement rates have been shown to discourage providers from participating in the program,[11] and a 2018 *National Bureau of Economic Research* study found that increasing Medicaid reimbursement rates for several primary care services encouraged more providers to take part in the program.[12] Though that same study showed Medicaid beneficiaries did not expand their treatment beyond primary care over a six-year period, behavioral health outcomes were improved through increased access to and attention given by primary care providers, producing a 9.7% decrease in mental illness and a 15.2% decrease in substance use disorder treatment.[12] **Lundbeck encourages the Committee to advance policy to meaningfully spur states to increase behavioral health provider reimbursement within their Medicaid programs.**

Further, federal funding to underwrite community-based peer-support programming – proven to be a particularly effective tool for the depression community[13] – within Medicare would be another substantial access improvement. Peer support is provided by an individual with lived mental health experience who participates on a care team on a non-clinical basis, providing the

[7] Reinert, M. & Nguyen, T. (October 2021). "Trauma and COVID-19: Communities in Need Across the U.S." Mental Health America, Alexandria VA.
[8] Reinert, M, Nguyen, T & Bhardwaj, J. (July 2021). "Severe Depression and COVID-19: Communities in Need Across the U.S." Mental Health America, Alexandria VA.
[9] Harrar, Sari. "Inside America's Psychiatrist Shortage." *Psycom*, 2 June 2021, https://www.psycom.net/inside-americas-psychiatrist-shortage.
[10] "Battling The Mental Health Crisis Among The Underserved Through State Medicaid Reforms, " *Health Affairs Blog*, February 10, 2020. DOI: 10.1377/hblog20200205.346125
[11] Biener, Adam I., and Selden, Thomas M. (2017). "Public And Private Payments For Physician Office Visits." *Health Affairs*. 36:12, 2160-2164
[12] Maclean, Johanna et al. "Reimbursement Rates for Primary Care Services." *National Bureau of Economic Research*, Oct. 2018, https://www.nber.org/system/files/working_papers/w24805/w24805.pdf.
[13] Pfeiffer, P. N. et al. (2011). Efficacy of Peer Support Interventions for Depression: A Meta-Analysis. *General Hospital Psychiatry*, 33(1), 29–36. http://doi.org/10.1016/j.genhosppsych.2010.10.002.

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Six Parkway North
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USA
Tel 847-282-1000
Fax 847-282-1001
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patient with guidance on resources, education, and training specific to their condition; and contributing to the creation of that patient's recovery plan. Currently, Medicaid programs in 39 states permit some kind of reimbursement for peer-support services,[14] and expanding access to the Medicare population would serve even more Americans with psychiatric conditions. **Lundbeck recommends the Committee advance S. 2144, the "PEERS Act of 2021," to grant Medicare coverage for services for peer-support specialists.**

Increasing Integration, Coordination, and Access to Care

First and foremost, access to psychiatric medications is key to realizing true parity between behavioral and physical health care. Rather than taking the form of tangible interventions – such as a surgery – an effective course of treatment for those with mental health conditions often involves a therapeutic regimen, so assurance of consistent access is paramount. When the "Six Protected Classes" were created by Centers for Medicare and Medicaid Services (CMS) guidance in 2005 – requiring prescription drug plans to cover "all or substantially all" medications within the anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants classes – the Agency acknowledged that the establishment of this policy was, in part, due to the importance of "mitigat[ing] the risks and complications associated with an interruption of therapy for these vulnerable populations."[15] Further, from a clinical perspective, the reality of significant heterogeneity of response by, for example, each individual patient on the same antipsychotic – even if they share the same diagnosis and symptoms[16,17] – exhibits the importance of access to a broad range of therapies as it ensures their ability to identify the drug(s) most effective for their person. **Lundbeck encourages the Committee to guard the Six Protected Classes beneficiary protection from any legislative or administrative changes.**

As you know, Medicare's Collaborative Care Model (CoCM) has already made a significant impact in addressing these issues of integration, coordination, and access by uniting behavioral health services with the primary care setting, resulting in substantial impacts such as a more than 40% improvement in symptoms among those living with depression.[18] In 2018 *Translational Behavioral Medicine* published a study revealing that, in three primary care practices receiving an alternative payment model, the payment produced a striking $1.08 million in net cost savings while caring for more than 9,000 Medicare, Medicaid, and dual-eligible beneficiaries over an 18-month period.[19] The reduction in subsequent health system encounters – such as hospitalizations

[14] Open Minds. "State Medicaid Reimbursement For Peer Support Services." 14 Mar. 2018, https://static1.squarespace.com/static/56d5ca187da24ffed7378b40/t/5e4e2ecc21989a778bc3db5f/1582182093508/OMCircle_ReferenceGuide_PeerSupport.pdf.
[15] Medicare Prescription Drug Benefit Manual, Ch. 6 § 30.2.5
[16] Evers, Kathinka. "Personalized medicine in psychiatry: ethical challenges and opportunities." *Dialogues in Clinical Neuroscience,* vol. 11,4 (2009): 427-34. doi:10.31887/DCNS.2009.11.4/kevers
[17] Mental Health America. "Why Do Mental Health Meds Affect People Differently?" 28 July 2021, https://screening.mhanational.org/content/why-do-mental-health-meds-affect-people-differently/.
[18] Coleman, Karen et al. The COMPASS initiative: description of a nationwide collaborative approach to the care of patients with depression and diabetes and/or cardiovascular disease. *General Hospital Psychiatry.* 2017 Jan-Feb; 44:69-76. doi: 10.1016/j.genhosppsych.2016.05.007. Epub 2016 Aug 22. PMID: 27558107.
[19] Ross, Kaile et al. (2018). "Cost savings associated with an alternative payment model for integrating behavioral health in primary care." *Translational Behavioral Medicine*. 9. 10.1093/tbm/iby054.

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– was the main generator of savings. **In general, Lundbeck supports collaborative care as a needed fundamental change across our American health care system as it upends the long-standing operation of siloed patient care to one that represents whole-patient support, thereby inherently decreasing stigma and enabling earlier, targeted interventions. We encourage the Committee to consider expanding the CoCM to Medicaid, whilst continuing to enhance the existing model in Medicare,** since a 2020 survey of providers shows there is further room for improvement. Changes to consider include increasing reimbursement for CoCM billing codes to a level that better recompenses providers for all integrated care work they perform, and better resourcing CMS to provide health care practices with the technical support they need to utilize such codes.[20]

Medicaid beneficiaries with mental health conditions across the U.S. would also benefit from the nationwide expansion of the Certified Community Behavioral Health Clinic (CCBHC) model, which has demonstrated that the evidence-based care it provides in its current 10 states – regardless of a patient's ability to pay – has improved access to wide-ranging treatment and recovery support services.[21] The CCBHC model makes it possible for mental health patients to be seen quickly, with the National Council of Mental Wellbeing reporting that "84% [of clinics] see clients for their first appointment within one week," with that number increasing to 93% when looking across the 10 days following a patient's first outreach[22] – a remarkably shorter wait time when compared with the nationwide average of 48 days.[22] The ability for CCBHCs to be reimbursed for non-traditional services – like community outreach and crisis response – enables the clinic to establish a local presence known to law enforcement for providing effective support, such as stabilization of an individual in crisis, rather than that person being diverted to a jail.[23] **Lundbeck encourages the Committee to facilitate such an expansion, and supports the advancement of S. 2069, the "Excellence in Mental Health and Addiction Treatment Act of 2021."**

Relatedly, more comprehensive support is needed for incarcerated or recently incarcerated individuals with behavioral health needs – according to an Urban Institute report on the population of recently-released individuals in the U.S. every year, 15% of men and more than 33% of women report having a diagnosis of depression or another mental illness,[24] though "the actual prevalence of mental health conditions is likely to be double the self-reported amount."[24] Stability achieved with a therapeutic regimen can be lost when the patient transitioning back into

[20] Docherty, Mary et al. "How Practices Can Advance the Implementation of Integrated Care in the COVID-19 ERA." Commonwealth Fund, 17 Nov. 2020, https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/practices-advance-implementation-integrated-care-covid.
[21] Siegwarth, Allison et al. "Implementation Findings from the National Evaluation of the Certified Community Behavioral Health Clinic Demonstration." ASPE, 11 Sept. 2020, https://aspe.hhs.gov/reports/implementation-findings-national-evaluation-certified-community-behavioral-health-clinic-0.
[22] National Council for Mental Wellbeing. "Leading a Bold Shift in Mental Health & Substance Use Care: CCHBC Impact Report." May 2021, https://www.thenationalcouncil.org/wp-content/uploads/2021/08/2021-CCBHC-Impact-Report.pdf.
[23] National Council for Mental Wellbeing. "Certified Community Behavioral Health Clinics." Sept. 2021, https://www.thenationalcouncil.org/wp-content/uploads/2021/08/2021-CCBHC-and-Justice-Systems-Report.pdf.
[24] Mallik-Kane, Kamala and Christy A. Visher. "Health and Prisoner Reentry: How Physical, Mental, and Substance Abuse Conditions Shape the Process of Reintegration." Urban Institute Justice Policy Center, Feb. 2008, https://www.urban.org/sites/default/files/publication/31491/411617-Health-and-Prisoner-Reentry.pdf.

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society from a detention facility experiences loss of coverage[25] or encounters utilization management tools that make adherence with their medications burdensome.[26] This gap in care can contribute to recidivism, as patients who experience problems with "medication access or continuity [have a] 3.6 times greater likelihood of a reported significant adverse event," including "incarceration in prison or detention in jail."[27] An article in the *Journal of Health Economics Outcomes Research* published earlier this year specifically found that "[long-acting injectable, or] LAI antipsychotics may have an important role in supporting patients with schizophrenia who are released from jail, especially for *bridging* [emphasis added] any intervening time between release and the implementation of community mental health support."[28] As Medicaid is often the primary source of health insurance for recently-released individuals with mental health conditions – covering about 20% of the population[24] – it is critical to ensure beneficiaries have broad access to mental health medications free from utilization management and step therapy barriers. **Lundbeck encourages the Committee to develop policy prohibiting state Medicaid programs and Medicaid Managed Care plans from exercising utilization management for behavioral healthcare upon the regimen of a recently-released individual who is – according to their prescribing provider's assessment – stable on therapy/ies at the time of release.**

Perhaps the most substantial access issue – that, if resolved, would greatly improve the care physicians offer patients by reducing their administrative burden – is establishing a standardized, electronic Prior Authorization (PA/ePA) response system. When patients access a medication for the first time – whether it's a new initiation of therapy, or a current medication for the first time with a new plan or a new plan year – for which a payer requires PA, they must wait to access it until the PA is granted or, if denied or unable to wait, will face paying for the medication out of their own pocket or foregoing the medication altogether. However, the ePA process is estimated to save significant amounts of time – anywhere from 10 to 95 times faster – when compared with manual PA processing via fax, according to internal analyses at Caremark,[29] accelerating clinical decision-making and patient care. As the Committee is aware, CMS recently implemented a regulation requiring Part D plan sponsors to comply with National Council for Prescription Drug Programs standards for specific ePA transactions beginning February 1, 2021. Though 16 states have laws permitting use of ePAs as of 2020, only 14 others actually require their use, with the remainder of the U.S. lacking any such law.[30] **Lundbeck encourages the Committee to advance policy directing CMS to also create this requirement**

[24] Mallik-Kane, Kamala and Christy A. Visher. "Health and Prisoner Reentry: How Physical, Mental, and Substance Abuse Conditions Shape the Process of Reintegration." Urban Institute Justice Policy Center, Feb. 2008, https://www.urban.org/sites/default/files/publication/31491/411617-Health-and-Prisoner-Reentry.pdf.
[25] National Institute of Corrections. "Psychiatric Medication Adherence Among People Who Are Incarcerated What Do We Know?" http://www.pacenterofexcellence.pitt.edu/documents/Psychiatric%20Med%20Adherence%20Among%20People%20Who%20Are%20Incarcerated.pdf
[26] Goldman, Dana et al. "Medicaid prior authorization policies and imprisonment among patients with schizophrenia." *The American Journal of Managed Care,* vol. 20,7 (2014): 577-86.
[27] West, Joyce C. et al. "Medicaid Prescription Drug Policies and Medication Access and Continuity: Findings from Ten States." *Psychiatric Services*, vol. 60, no. 5, May 2009, pp. 601–610., https://doi.org/10.1176/ps.2009.60.5.601.
[28] Bhatta, Madhav P. et al. "Long-Acting Injectable Antipsychotic Use in Patients with Schizophrenia and Criminal Justice System Encounters." *Journal of Health Economics and Outcomes Research,* vol. 8,1 63-70. 19 May. 2021, doi:10.36469/jheor.2021.22979
[29] Caremark. "Electronic Prior Authorization Information." 2019, https://www.caremark.com/wps/portal/HEALTH_PRO_PRIOR_AUTH_INFO.
[30] Marbury, Donna. "Electronic Prior Authorization Is Catching On." *Managed Healthcare Executive*, 28 Aug. 2020, https://www.managedhealthcareexecutive.com/view/electronic-prior-authorization-is-catching-on.

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Fax 847-282-1001
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in Medicaid Managed Care, as well as to work with your Senate colleagues to extend such requirements to commercial and exchange market plans.

Individuals living with mental health conditions also face access hurdles through the practice of step therapy, a utilization management tool implemented by insurance carriers which requires that a patient "try and fail" on therapeutics preferred by the carrier before accessing the treatment originally prescribed by their provider. Step therapy is the most common type of access restriction insurers place on patients[31] and its use has grown rapidly in large employer-sponsored health plans, from 27% in 2005 to 73% in 2013.[32] A 2014 study found that people with schizophrenia and bipolar disorder who are also subject to access restrictions in their care are more likely to face hospitalization and higher overall medical costs[33] and, further, when "combined with the other social costs such as an increase in incarceration rates, these formulary restrictions could increase state costs by $1 billion annually, enough to offset any savings in pharmacy costs."[33] **Lundbeck strongly encourages the Committee to work with Senate colleagues to pass S. 464, the "Safe Step Act," to reform step therapy in federally-regulated health plans and create a timely, transparent process for patients and physicians to request exemptions to step therapy restrictions.**

Furthering the Use of Telehealth

It comes as no surprise that, during this ongoing pandemic, telehealth – and particularly CMS's March 2020 announcement of expanded telehealth coverage policies tied to the COVID-19 Public Health Emergency[34] – has played a remarkable role in ensuring accessibility and continuity of care for patients encountering the health care system.[35] Still, several improvements are needed: for one, if Medicare patients would – beginning January 1, 2024 – lose access to the expanded list of telehealth services granted if CMS's Calendar Year (CY) 2022 Medicare Physician Fee Schedule (MPFS) proposed rule is finalized in its current form. **In that event, Lundbeck would encourage the Committee to direct CMS to make permanent all telehealth services in Medicare and to continue providing increased reimbursement to the providers working to serve the program's current record number of beneficiaries,[36] thereby ensuring that adequate care is available for each senior.**

CMS's CY 2022 MPFS proposed rule also contained the Agency's plan to implement directives from the Consolidated Appropriations Act of 2021, which require that a provider have rendered

[31] Chambers, James D., et al. "Specialty Drug Coverage Varies across Commercial Health Plans in the US." *Health Affairs*, vol. 37, no. 7, 2018, pp. 1041–1047., https://doi.org/10.1377/hlthaff.2017.1553.
[32] Chung, Adrienne et al. "Does a 'One-Size-Fits-All' Formulary Policy Make Sense?" *Health Affairs Blog, Health Affairs.* 2 June 2016, https://www.healthaffairs.org/do/10.1377/hblog20160602.055116/full/.
[33] Seabury, Seth A et al. "Formulary restrictions on atypical antipsychotics: impact on costs for patients with schizophrenia and bipolar disorder in Medicaid." *The American Journal of Managed Care* vol. 20,2 e52-60. 1 Feb. 2014
[34] Verma, Seema. "Early Impact of CMS Expansion of Medicare Telehealth during COVID-19." *Health Affairs Blog, Health Affairs*, 15 July 2020, https://www.healthaffairs.org/do/10.1377/hblog20200715.454789/full/.
[35] Koonin, LM et al. "Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic — United States, January–March 2020." MMWR Morb Mortal Wkly Rep 2020;69:1595–1599. DOI: http://dx.doi.org/10.15585/mmwr.mm6943a3external icon.
[36] Gaudette, Étienne, et al. "Health and Health Care of Medicare Beneficiaries in 2030." *Forum for Health Economics and Policy*, vol. 18, no. 2, 2015, pp. 75–96., https://doi.org/10.1515/fhep-2015-0037.

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USA **www.lundbeck.com/us**

an in-person service to the beneficiary within the six months that precede a mental health telehealth service, as well as require that in-person visits occur at least once every six months thereafter. While it is important for there to be regular contact between a patient with a mental health condition and their provider – particularly as there are data showing less patient abandonment of ongoing treatment when it is carried out face-to-face, versus over the telephone[37] – sustaining an every-six-months requirement during a declared national Public Health Emergency is counter to best public health practices to reduce transmission of disease. **Lundbeck encourages the Committee to consider revising the 2021 law, directing CMS to enforce the in-person requirements only during periods of time when there is not a declared Public Health Emergency.**

Again, thank you for the opportunity to provide input on this important legislative effort, and Lundbeck looks forward to continuing this dialogue with your offices. Please contact me at HRST@lundbeck.com if I can elaborate on the points discussed above, or be of further assistance.

Sincerely,

Heather Strawn

Heather Strawn
Vice President, Government Affairs
Lundbeck Pharmaceuticals LLC

[37] Mohr, David C et al. "Effect of telephone-administered vs face-to-face cognitive behavioral therapy on adherence to therapy and depression outcomes among primary care patients: a randomized trial." *JAMA,* vol. 307,21 (2012): 2278-85. doi:10.1001/jama.2012.5588