Attachment A

Colorado District Court Complaint on Behalf of Medicaid Patient Denied Prior Authorization for Hetlioz

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action 1:21-cv-3175

SARAH ANDERSON,

Plaintiff,

v.

KIM BIMESTEFER, in her official capacity as Executive Director of the Colorado State Department of Health Care Policy and Financing,
TRACY JOHNSON, in her official capacity as Medicaid Director of the Colorado State Department of Health Care Policy and Financing,
PETER WALSH, in his official capacity as Chief Medical Officer of the Colorado State Department of Health Care Policy and Financing,
CHRISTY BLAKELY, in her official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,
CECILE FRALEY, in her official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,
PATRICIA LYNN GIVENS, in her official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,
SIMON HAMBIDGE, in his official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,
BREGITTA HUGHES, in her official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,
JESSICA KUHNS, in her official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,
CHAROLETTE LIPPOLIS, in her official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,
AMANDA MOORER, in her official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,
AN NGUYEN, in her official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,
DAVID PUMP, in his official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,
DONNA M. ROBERTS, in her official capacity as a member of the Colorado State Department of Health Care Policy and Financing's Medical Services Board,

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiff in this case challenges Defendants' unlawful denial of prescription drug coverage for Hetlioz (tasimelteon)—the only FDA-approved treatment for Plaintiff's Non-24-Hour Sleep-Wake Disorder ("Non-24").

2. Plaintiff is an enrollee in Colorado's Medicaid program (also known as Health First Colorado or "HFC") who suffers from Non-24, a disorder in which the body is unable to synchronize its internal circadian rhythm with the 24-hour day. Non-24 makes it extraordinarily difficult for individuals suffering from it to function in normal society, which runs on a 24-hour rhythm—including in school, work, and other obligations. Those individuals who attempt to fight their internal rhythm and follow a 24-hour day experience severe sleep deprivation, with attendant physical and mental health effects. Throughout her life, Plaintiff's Non-24 has disrupted her education, her employment opportunities, and her relationships with others.

3. After years of Plaintiff trying countless therapies to no avail, Plaintiff's doctor prescribed her Hetlioz, the only FDA-approved therapy for Non-24. When Plaintiff's doctor submitted a prior authorization request to HFC, however, the request was denied. This is because Defendants, officials of Colorado's Department of Health Care Policy and Financing ("DHCPF"), which administers HFC, have created and apply an illegal criterion that provides coverage for Hetlioz only if a Non-24 Medicaid enrollee is blind. It excludes coverage for Non-24 enrollees who are not blind, like Plaintiff. This criterion has no medical or clinical basis: blindness is not a diagnostic criterion for Non-24, and Hetlioz is indicated for *all* patients with Non-24, regardless of whether they are blind. In fact, the U.S. Food and Drug Administration (FDA) has *expressly* explained that it approved Hetlioz for all Non-24 patients, whether or not they are blind, and it rejected efforts to limit Hetlioz's approved indications to only blind patients.

4. Defendants' conduct denies Plaintiff the rights guaranteed to her by the federal Medicaid Act and is preempted by that Act. The Medicaid Act requires states that include prescription drug coverage in their state Medicaid plans to cover medically necessary drugs and, moreover, to cover all FDA-approved drugs that are covered by a rebate agreement between the drug manufacturer and the federal government (as Hetlioz is), subject to a few exceptions that are inapplicable here. 42 U.S.C. §§ 1396a(a)(8), 1396a(a)(10)(A), 1396r-8. It further requires that states make available to all categorically needy individuals the same amount, scope, and duration of services it makes available to any other categorically needy individuals. *Id.* § 1396a(a)(10)(B). Thus, the Medicaid Act does not permit Defendants' criterion, which denies Plaintiff a medically necessary drug that is covered by the Act and that Defendants *do* in fact cover for *blind* Non-24 individuals who are categorically needy.

5. Despite the setbacks and difficulties Plaintiff has faced due to Non-24, Plaintiff has persisted to create a life for herself. But that life is under constant threat of being destroyed—as it has been so many times in the past—by the effects of Plaintiff's Non-24. Plaintiff is entitled to coverage of the life-changing medication that Defendants make available to others suffering from her same condition.

PARTIES

6. Plaintiff Sarah Anderson is a 37-year-old resident of Colorado who has been diagnosed with Non-24-Hour Sleep-Wake Disorder. She is enrolled in Colorado's Medicaid Program (also known as "Health First Colorado" or "HFC").

7. Defendant Kim Bimestefer is the Executive Director of the Colorado State Department of Health Care Policy and Financing ("DHCPF"). DHCPF is an agency of the State of Colorado and is the sole state agency responsible for administering Health First Colorado. Col.

Rev. Stat. §§ 25.5-1-105, 25.5-4-104, 25.5-1-201(1)(1). Ms. Bimestefer is sued in her official capacity.

8. Defendant Tracy Johnson is the Medicaid Director for DHCPF. Dr. Johnson is sued in her official capacity.

9. Defendant Peter Walsh is the Chief Medical Officer for DHCPF. Dr. Walsh is sued in his official capacity.

10. Defendant Christy Blakely is a member of DHCPF's Medical Services Board. The Medical Services Board has authority to adopt rules for Colorado's Medicaid Program—including the type of benefits a Medicaid recipient may obtain. Colo. Rev. Stat. § 25.5-1-303(1)(a), (3). Dr. Blakely is sued in her official capacity.

11. Cecile Fraley is a member of DHCPF's Medical Services Board. Dr. Fraley is sued in her official capacity.

12. Patricia Lynn Givens is a member of DHCPF's Medical Services Board. Dr. Givens is sued in her official capacity.

13. Simon Hambidge is a member of DHCPF's Medical Services Board. Dr. Hambidge is sued in his official capacity.

14. Bregitta Hughes is a member of DHCPF's Medical Services Board. Dr. Hughes is sued in her official capacity.

15. Jessica Kuhns is a member of DHCPF's Medical Services Board. Dr. Kuhns is sued in her official capacity.

16. Charolette Lippolis is a member of DHCPF's Medical Services Board. Dr. Lippolis is sued in her official capacity.

17. Amanda Moorer is a member of DHCPF's Medical Services Board. Dr. Moorer is sued in her official capacity.

18. An Nguyen is a member of DHCPF's Medical Services Board. Dr. Nguyen is sued in her official capacity.

19. David Pump is a member of DHCPF's Medical Services Board. Dr. Pump is sued in her official capacity.

20. Donna M. Roberts is a member of DHCPF's Medical Services Board. Dr. Roberts is sued in her official capacity.

JURISDICTION AND VENUE

21. Plaintiffs bring this suit under 42 U.S.C. § 1983, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and this Court's inherent equitable powers.

22. The court's jurisdiction is invoked under 28 U.S.C. § 1331, as this case arises under the Constitution and laws of the United States. Specifically, this case arises under 42 U.S.C. §§ 1396a(a)(8), 1396a(a)(10), 1396a(a)(17), 1396r-8, and the Supremacy Clause. This court's equitable jurisdiction is also invoked. *Ex parte Young*, 209 U.S. 123, 148 (1908).

23. Venue is proper in this district under 28 U.S.C. § 1391(b)(1) and (2) because all of the actions, events, or omissions giving rise to Plaintiff's claims occurred in the District of Colorado, and the Defendants reside here.

BACKGROUND

A. Non-24-Hour Sleep-Wake Disorder.

24. Non-24-Hour Sleep-Wake Disorder ("Non-24") is a disorder in which the body is unable to synchronize its internal circadian rhythm—the process that regulates the sleep-wake

cycle—with the 24-hour day.[1] Most people have a natural circadian rhythm that is longer than 24 hours, but their bodies are able to reset that rhythm in response to daily environmental cues, like morning light (a process known as "entrainment"), and thereby maintain relatively consistent sleep/wake times.[2] Individuals with Non-24, however, lack this ability.

25. In the classic expression of this disorder, the longer-than-24-hour circadian cycle progressively delays the sleep-wake cycle by minutes or hours each day, such that individuals with Non-24 will sleep and wake at a later time each day than the day before.[3] In severe cases, the natural circadian rhythm can be up to 30 hours long, resulting in a sleep cycle that is progressively delayed by as much as 6 hours per day. The individual's cycles of body temperature and hormone rhythms also follow a non-24-hour rhythm.[4] Eventually, the individual comes "all the way around the clock" and is temporarily aligned with the 24-hour day, until the cycle starts once again.[5]

26. During the periods in which the individual's body is desynchronized from the day-night cycle, individuals with Non-24 experience insomnia and excessive daytime sleepiness.[6] Even during the times where the individual is temporarily aligned with the 24-hour day, some individuals with Non-24 continue to experience fatigue, grogginess, malaise, and disrupted sleep due to continued desynchronization of their internal circadian rhythms and other bodily clocks.[7]

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[1] Sabra M. Abbott, *Non-24-Hour Sleep-Wake Rhythm Disorder*, 37 Neurol Clin 545, 545 (2019) (Ex. A); Nat'l Org. for Rare Disorders, Non-24-Hour Sleep-Wake Disorder (2017), https://perma.cc/8SS8-M6EX.

[2] Nat'l Org. for Rare Disorders, *supra* n.1.

[3] *Id*.

[4] *Id*.

[5] *Id*. Daily jumps are not necessarily steady; many individuals display "jumping behavior," in which there are "greater delays in [patients'] rest-activity patterns when sleeping during the day compared with when sleeping at night." Abbott, *supra* n.1, at 546.

[6] Abbott, *supra*, at 546; Nat'l Org. for Rare Disorders, *supra* n.1.

[7] Nat'l Org. for Rare Disorders, *supra* n.1.

27. As the FDA has recognized, "Non-24 can be debilitating for many patients."[8] Non-24 is often associated with psychiatric disorders, including depression.[9] And over time, the symptoms of chronic sleep deprivation—including daytime sleepiness, fatigue, depression, difficulty concentrating, and memory problems—accumulate and cause "extreme difficulty for the individual attempting to maintain social and career obligations."[10]

28. ***Diagnosis of Non-24.*** A diagnosis of Non-24 is typically based on a history of periods of insomnia and/or excessive sleepiness that alternate with short asymptomatic periods, as the individual's body cycles in and out of alignment with the 24-hour day.[11] Although Non-24 is more typical in blind individuals, blindness is not a criteria for diagnosis, and there is ample documentation of sighted individuals with Non-24.[12] Indeed, one study found that approximately 6% of sighted individuals with bipolar disorder suffer from Non-24.[13]

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[8] U.S. Food & Drug Admin., Letter to Drs. Bardehann, Almashat, and Wolfe Re: Docket No. FDA-2015-P-2142 (Jan. 27, 2020) ("FDA Letter") (Ex. B); *see also* Nat'l Org. for Rare Disorders, *supra* n.1 (Non-24 "can be severely disabling").

[9] Tatsuro Hayakawa et al., *Clinical Analyses of Sighted Patients with Non-24-Hour Sleep-Wake Syndrome: A Study of 57 Consecutively Diagnosed Cases*, 28 SLEEP 945, 951 (2005), https://perma.cc/873M-RRBD; Abbott, *supra* n.1, at 546.

[10] Nat'l Org. for Rare Disorders, *supra* n.1; *see also* FDA Letter, *supra* n.8 at 2-3; Roneil G. Malkani et al., *Diagnostic and Treatment Challenges of Sighted Non-24-Hour Sleep-Wake Disorder*, 14 J. Clin. Sleep Med. 603, 608 (2018), https://perma.cc/5VKX-XXQ5 (diagnosis of Non-24 in sighted patients is often missed).

[11] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Health Disorder* 396 (5th ed. 2013) ("DSM-5") (Ex. C); *see also* Hayakawa et al., *supra* n.9, at 945 (citing the International Classification of Sleep Disorders' recommended criteria for diagnosis).

[12] Abbott, *supra* n.1, at 546, 548, 550; Nat'l Org. for Rare Disorders, *supra* n.1; Hayakawa et al, *supra* n.9, at 949; FDA Letter, *supra* n.8, at 5 ("[V]isual impairment is not a component of the diagnosis.") (internal alterations omitted); Makoto Uchiyama, et al. *Delayed Phase Jumps of Sleep Onset in a Patient with Non-24-Hour Sleep-Wake Syndrome*, 19 Sleep 637, 637 (1996), https://perma.cc/2JUP-36J2 (reporting on sighted individual with Non-24).

[13] Yoshikazu Takaesu et al., *Prevalence of Circadian Rhythm Sleep-Wake Disorders and Associated Factors in Euthymic Patients with Bipolar Disorder*, PLOS ONE, July 21, 2016, at 3, https://perma.cc/V7UF-GAHX; *see also* Malkani et al., *supra* n.10 at 608 (diagnosis of Non-24 in sighted patients is often missed).

B. Hetlioz Is The Only FDA-Approved Drug to Treat Non-24.

29. The FDA has approved only one drug to treat Non-24: Hetlioz (tasimelteon). Hetlioz is approved for Non-24, regardless of whether the patient is blind.

30. Hetlioz is manufactured by Vanda Pharmaceuticals Inc. ("Vanda"). Vanda submitted a new drug application to the FDA for Hetlioz for the treatment of Non-24 in 2013. The FDA approved the application in 2014. The approval granted in 2014 applied to all patients with Non-24, regardless of visual acuity: "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."[14] Vanda Pharmaceuticals Inc., Hetlioz (tasimelteon) [package insert] at 1, 2 (Revised 2014), https://perma.cc/UD33-QGUA; *see also* Vanda Pharmaceuticals Inc., Hetlioz (tasimelteon) [package insert] at 2 (Rev. 2020) ("Hetlioz 2020 Label"), https://perma.cc/4AUV-P29K.

31. In 2015, Public Citizen requested that the FDA revise the indication for Hetlioz to "narrow the indicated population to totally blind individuals without light perception." FDA Letter, *supra* n.8, at 1, 7. The FDA denied that request, explaining that the INDICATIONS AND USAGE section of the labeling for Hetlioz—which has no reference to blind individuals—is correct. *Id.* at 2, 7. "[T]he benefits of Hetlioz therapy are not limited to those Non-24 patients who are totally blind." *Id.* at 5.

[14] Although the FDA's original approval letter to Vanda, dated January 31, 2014, contained an indication statement that the new drug application provided for the use of Hetlioz "in blind patients without light perception," the FDA later recognized that was an "incorrect indication statement." FDA Letter, *supra* n.8, at 3. Recognizing that "visual impairment is not a component of the diagnosis" of Non-24, the FDA sent a corrected approval letter to Vanda, noting that the correct indication statement was: "This new drug application provides for the use of HETLIOZ, tasimelteon 20 mg Capsules for Non-24 hour sleep-wake disorder," without a blindness requirement. *Id.* at 3-4.

32. In addition to the FDA's conclusion that Hetlioz is a safe and effective treatment for Non-24, experts have similarly confirmed the effectiveness of Hetlioz for all individuals with Non-24 and concluded that it is "mainstream for the treatment of non-24."[15]

C. The Medicaid Act Requires Coverage of Hetlioz to Treat Non-24.

1. The Medicaid Act requires participating states to make medically necessary care available, equally and with reasonable promptness, to all Medicaid enrollees.

33. In 1965, Congress enacted Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the "Medicaid Act"), establishing the Medicaid program to enable states to provide medical assistance to people "whose income and resources are insufficient to meet the costs of *necessary medical services*." 42 U.S.C. § 1396-1 (emphasis added).

34. Under Medicaid, the federal government provides federal financial assistance to a participating state for the costs incurred by that state for patient care. In return, the state must pay its share of the costs and comply with certain federal requirements.

35. One such requirement is that a participating state make "medical assistance available" to all individuals designated as categorically needy. 42 U.S.C. § 1396a(a)(10). "Medical assistance" is defined as "payment of part or all of the cost of" enumerated goods and services. *Id.* § 1396d(a). States are required to cover nine of the categories of "medical assistance." *Id.* § 1396a(a)(10). They have the option of providing the other categories of services, but if they choose to provide those services, they must do so consistent with the Medicaid Act's requirements.

36. Section 1396a(a)(10) encompasses a requirement that states provide coverage of "medically necessary" services that fall within a category covered in their Medicaid plans. *See Beal v. Doe*, 432 U.S. 438, 444-45 (1977); *Hern v. Bye*, 57 F.3d 906, 911 (10th Cir. 1995). This

[15] Shohei Nishimon et al., *Tasimelteon for Treating Non-24-h Sleep-wake Rhythm Disorder*, 20 Expert Opinion on Pharmacotherapy 1065, 1070 (2019) (Ex. D).

includes coverage for treatments in areas that a state opts to provide such coverage. *See Bontrager v. Indiana Family & Soc. Servs. Admin*, 697 F.3d 604, 608 (7th Cir. 2012); *Doe v. Chiles*, 136 F.3d 709, 714 (11th Cir. 1998); *Lankford v. Sherman*, 451 F.3d 496, 511 (8th Cir. 2006).

37. States must also provide such assistance "with reasonable promptness to all eligible individuals." 42 U.S.C. §§ 1396a(a)(8), 1396a(a)(10). Additionally, the medical assistance made available to an individual designated as categorically needy "shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual" or to "individuals not [deemed categorically needy under § 1396a(a)(10)(A)]." *Id*. § 1396a(a)(10)(B).

38. ***Prescription drug coverage***. States are not required to include prescription drug coverage in their Medicaid plans, but if a state does choose to include it, the state must comply with specific requirements in addition to those generally applicable to medical assistance. 42 U.S.C. §§ 1396a(a)(54); *see also id.* § 1396d(a)(12).

39. If a state chooses to include prescription drug coverage in its Medicaid plan, it generally must cover prescription drugs that have been approved for safety and effectiveness by the FDA and that are covered by a rebate agreement between the drug's manufacturer and the federal government (and/or state government). 42 U.S.C. §§ 1396r-8(a)(1), 1396r-8(d)(4)(B); 1396r-8(k)(2); *see also Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652-53 (2003).

40. If a drug meets those criteria, a state may "exclude or otherwise restrict coverage of the drug" *only* in four circumstances: (1) the prescribed use is not for a medically accepted

indication, (2) the drug falls within a specified category,[16] (3) the drug is subject to such restrictions pursuant to a rebate agreement, or (4) the state has excluded coverage of the drug from a formulary that complies with statutory requirements. 42 U.S.C. § 1396r-8(d).

41. A state may establish a formulary that excludes coverage of a covered outpatient drug "with respect to the treatment of a specific disease or condition for an identified population" if, among other things: (1) the formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals, (2) "based on the drug's labeling . . ., the excluded drug does not have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary," (3) there is a publicly available written explanation of the basis for the exclusion, and (4) the state plan permits coverage of the drug pursuant to a prior authorization program that provides for the approval of the drug for any medically accepted indication within 24 hours of a request for prior authorization. *Id.* §§ 1396r-8(d)(4), 1396r-8(d)(5).

42. States that do not have formularies may also establish a prior authorization program under which states can require, "as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available . . ., the approval of the drug before its dispensing for any medically accepted indication." *Id.* § 1396r-8(d)(5); *see also id.* § 1396r-8(d)(1). The state can use such a program "to inform doctors about the availability of drugs with comparable therapeutic properties that are also more cost-effective for the state," but the

[16] These categories are: agents when used for anorexia, weight loss, or weight gain; agents when used to promote fertility; agents when used for cosmetic purposes or hair growth; agents when used for the symptomatic relief of cough and colds; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; nonprescription drugs, subject to some exceptions; covered outpatient drugs when the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; and agents when used for the treatment of sexual or erectile dysfunction. 42 U.S.C. § 1396r-8(d)(2).

"prescribing physicians retain the authority to override any suggestions." *Pharm. Research & Mfrs. of Am. v. Meadows*, 304 F.3d 1197, 1201 n.9 (11th Cir. 2002). Approval of the drug for a medically accepted indication must be provided within 24 hours of a request for prior authorization. 42 U.S.C. § 1396r-8(d)(5)(A).

D. Colorado Participates in Medicaid and Covers Prescription Drugs.

43. Colorado, like every other state, has chosen to participate in Medicaid. *See* Colorado State Plan Under Title XIX of the Social Security Act Medical Assistance Program (Aug. 31, 2021) ("Colorado State Medicaid Plan"), https://perma.cc/F22Z-TWKG. Its Medicaid Program is called Health First Colorado ("HFC"), and is administered by the Department of Health Care Policy and Financing ("DHCPF"). Col. Rev. Stat. §§ 25.5-1-105, 25.5-4-104, 25.5-1-201(1)(1).

44. Colorado has recognized its obligation to provide medically necessary care to the categorically needy and, in particular, has recognized that it is incumbent on DHCPF to establish rules providing for such care. *Id*. § 25.5-4-104 ("The state department, by rules, shall establish a program of medical assistance to provide necessary medical care for the categorically needy.").

45. DHCPF has defined "medical necessity" in regulations as a Medicaid good or service that "will, or is reasonably expected to prevent, diagnose, cure, correct, reduce, or ameliorate the pain and suffering, or the physical, mental, cognitive, or developmental effects of an illness, condition, injury, or disability." 10 Colo. Code Regs. § 2505-10:8.076.1(8). The good or service must also be "provided in accordance with generally accepted professional standards for health care in the United States"; be "clinically appropriate in terms of type, frequency, extent, site, and duration"; not be "primarily for the economic benefit of the provider or primarily for the convenience of the client, caretaker, or provider"; be "delivered in the most appropriate setting(s)

required by the client's condition"; not be experimental or investigational; and not be "more costly than other equally effective treatment options." *Id.*

46. Colorado has chosen to include prescription drug coverage in its Medicaid plan. Colo. Rev. Stat. § 25.5-5-202(1)(a)(I); *see also* Colorado State Medicaid Plan, *supra* p.12, Supplement to Attachment 3.1-A, p.3. In providing such coverage, DHCPF has not established a formulary, but rather has established a prior authorization program pursuant to 42 U.S.C. § 1396r-8. *See* Colorado State Medicaid Plan, *supra* p.12, Supplement to Attachment 3.1-A, p.3. Colorado's Medicaid plan states that "[a]ll drugs covered by the National Drug Rebate Agreements remain available to Medical Assistance Program clients, though some drugs may require prior authorization. The prior authorization process for covered outpatient drugs will conform to the provisions of section 1927(d)(5) of the Social Security Act." *Id.*

47. DHCPF developed and maintains a Preferred Drug List (PDL), which indicates the Preferred and Non-preferred Drugs in selected therapeutic drug classes. 10 Colo. Reg. § 2505-10:8.800.16.A. A "Preferred Drug" is a drug that is "payable by [Medicaid] without first obtaining a prior authorization unless otherwise required to protect the health and safety of specific members." *Id.* § 2505-10:8.800.1(DD). Those products designated "Non-preferred" require prior authorization. *Id.* § 2505-10:8.800.1(X).

48. Accordingly, DHCPF can exclude from coverage a covered drug only if (1) it is not prescribed for a medically-indicated use; (2) it falls within one of the specified categories of drugs in 42 U.S.C. § 1396r-8(d)(2); or (3) the drug is subject to restrictions pursuant to a rebate agreement. 42 U.S.C. § 1396r-8(d).

E. DHCPF Categorically Denies Coverage for Hetlioz for Sighted Non-24 Enrollees.

49. Hetlioz meets the criteria for coverage under the Medicaid Act and Colorado's state Medicaid plan. Vanda, the manufacturer of Hetlioz, has entered into a rebate agreement with the federal government. Hetlioz is approved by the FDA to treat individuals with Non-24, regardless of visual acuity. Indeed, it is the *only* drug that is approved by the FDA to treat Non-24, and thus is medically necessary for many individuals suffering from Non-24. And it does not fall within one of the categorical exclusions from Medicaid coverage.

50. Nevertheless, DHCPF has instituted a written policy—developed and maintained by Defendants—categorically denying sighted Non-24 enrollees in HFC coverage for Hetlioz. DHCPF placed Hetlioz on Appendix P of its Preferred Drug List—which lists drugs requiring prior authorization from HFC. *See* Colorado Dep't of Health Care Policy & Financing, Health First Colorado Preferred Drug List App'x P (Oct. 1, 2021), https://perma.cc/KD7C-ML4S. Although denominated as a "prior authorization" criterion, DHCPF uses its policy to *exclude* medically indicated uses of Hetlioz from coverage. Appendix P indicates that Hetlioz will only be approved if the member (1) has a documented diagnosis of non-24-hour sleep wake disorder by a sleep specialist, *and* (2) the member is completely blind. *Id.* at A-29. Upon information and belief, DHCPF has not provided a publicly available written explanation for the basis of this criterion or identified another covered drug that is as effective as Hetlioz.

51. Thus, under DHCPF's policy, Medicaid enrollees suffering from Non-24 who are blind can obtain coverage of Hetlioz, but Medicaid enrollees suffering from Non-24 who are not blind cannot—even if their symptoms, treatment history, and physician recommendations are the same.

52. DHCPF's discriminatory policy has no clinical or medical basis. Hetlioz is medically indicated for treating Non-24, regardless of visual acuity. Indeed, the FDA has specifically stated that "the benefits of Hetlioz therapy are not limited to those Non-24 patients who are totally blind." FDA Letter, *supra* n.8, at 5.

F. DHCPF Wrongfully Denies Plaintiff Coverage for Hetlioz.

53. Plaintiff is a 37-year-old woman who suffers from Non-24. Since she was two-years-old, Plaintiff has been unable to sleep on a 24-hour schedule.

54. Dr. Jack Edinger, PhD, a sleep specialist at National Jewish Health in Denver, CO diagnosed Plaintiff with Non-24 in or about August/September 2019.

55. In April 2020, Plaintiff enrolled in Colorado's Medicaid program, Health First Colorado, after losing her job due to the COVID-19 pandemic. Thereafter, she began receiving primary care from Dr. William Harrigan of Rocky Mountain Urgent Care and Family Medicine. Dr. Harrigan confirmed Plaintiff's Non-24 diagnosis. His chart notes from December 2020 indicate that Plaintiff "carries the diagnosis of circadian rhythm sleep disorder, well documented from previous studies. She describes classic non-24[] hour sleep-wake disorder in a sighted person, ? with a stable dealy [sic] in her sleep-wake pattern with respect to the environment. She has seen sleep specialists and has tried multiple sleep aides that have not been successful. SHe [sic] uses meltanonin [sic] but mostly functions marginally day to day. She is working but it is difficult, she has pursued disability but prefers to work."

56. Beginning in September 2021, Plaintiff started seeing sleep specialist Dr. Stephen Duntley, MD of UCHealth Sleep Medicine Clinic – Anschutz Medical Campus. Dr. Duntley's progress notes from September 10, 2021 indicate that Plaintiff "presents with a prior diagnosis of [Non-24]. I reviewed her outside evaluation[s] a[t] Northwestern and National Jewish Hospital and agree with the diagnosis."

57. Plaintiff's Non-24 has severely impacted her life. Plaintiff struggled throughout school because she frequently missed days due to her inability to wake up in the mornings and excessive sleepiness during the day. She has been unable to keep a job long-term because of her inability to sleep and wake on a 24-hour schedule. Her frequent joblessness has, in turn, required her to deplete her savings to purchase daily necessities and has prevented her from buying a home and saving for retirement.

58. She has also been unable to maintain a romantic relationship and struggles with maintaining friendships generally due to her lack of energy and inability to consistently keep commitments.

59. Plaintiff has tried numerous therapies to treat her Non-24. She began taking melatonin prior to her Non-24 diagnosis. After her Non-24 diagnosis, Plaintiff began taking REM Fresh, a continuous release melatonin, nightly. Since 2017, Plaintiff has also tried light therapy—using dark amber and red lights in her room to try to entrain her sleep-wake schedule. All of these therapies were ineffective.

60. Plaintiff's primary care physician, Dr. William Harrigan, prescribed her Hetlioz on December 31, 2020. Dr. Harrigan's notes indicate that Plaintiff "is an ideal candidate for Rx with Hetlioz and we have written thsi [sic] Rx today Non 24 sleep wake disorder has not been responsive to multiple previous medications." Dr. Harrigan also noted that Hetlioz "could be life changing" for Plaintiff.

61. Plaintiff's current sleep specialist, Dr. Stephen Duntley, wrote Plaintiff an updated Hetlioz prescription on September 10, 2021, noting that Plaintiff "meets FDA requirements for medication approval."

62. Plaintiff qualifies as categorically needy under Medicaid. On September 14, 2021, Plaintiff's doctor, Dr. William Harrigan, submitted a prior authorization request to Health First Colorado, which is administered by DHCPF, for coverage for Hetlioz for Plaintiff.

63. On September 20, 2021, Health First Colorado sent a letter of denial. Letter from Health First Colorado to Sarah Anderson (Sept. 20, 2021) (Ex. E). Health First Colorado denied the request for coverage of Hetlioz for Plaintiff on the basis of Defendants' policy that "[a]pproval requires the member to be completely blind or have SMS." *Id.* at 1.

CLAIMS FOR RELIEF

COUNT I
42 U.S.C. § 1983
Exclusion of qualified individuals from covered medical assistance under the Medicaid Act in violation of 42 U.S.C. §§ 1396a(a)(8) and 1396a(a)(10)(A)

64. Plaintiff incorporates and re-alleges the foregoing paragraphs as though fully set forth herein.

65. The Medicaid Act requires participating states, including Colorado, to make "medical assistance available" to all individuals designated as categorically needy. 42 U.S.C. § 1396a(a)(10); *see also id.* § 1396a(a)(8) (requiring states to provide medical assistance "with reasonable promptness to all eligible individuals"). When a state chooses to cover prescription drugs in its Medicaid plan—as Colorado has done, "medical assistance" includes all FDA-approved drugs covered by a rebate agreement, subject to four exceptions. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003); 42 U.S.C. § 1396d(a)(12); *id.* § 1396r-8; Colorado State Medicaid Plan, *supra* p.12, Supplement to Attachment 3.1-A, p.3. And while a state "may *condition* drug coverage for medically accepted indications upon certain prior authorization procedures being followed, the agency may not *exclude* coverage, i.e. deny reimbursement, for a covered drug. . . pursuant to the . . . prior authorization program established

by the state." *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1336 (S.D. Fla. 2006) (emphasis in original). Rather, the state must provide approval of a medically indicated use of the drug within 24 hours. 42 U.S.C. § 1396r-8(d)(5).

66. None of the four exceptions permitting exclusion of coverage (*i.e.*, exclusion from the scope of "medical assistance") applies here. Using Hetlioz to treat Non-24 in *all* individuals, including those who are not blind, is a medically accepted indication. Hetlioz is not on the list of restricted drugs set forth in § 1396r-8(d)(2). There is no agreement between Vanda, Hetlioz's manufacturer, and the State of Colorado or the federal government to restrict coverage. And the PDL established by Defendants is not a Medicaid drug formulary because DHCPF does not provide a publicly written explanation for exclusions from the PDL, and does not exclude only drugs that do not have a significant, clinically meaningful therapeutic advantage over other drugs included in the formulary. 42 U.S.C. § 1396r-8(d)(4)(C); *see also* Colorado State Medicaid Plan, *supra* p.12, Supplement to Attachment 3.1-A, p. 3 (stating that "[a]ll drugs covered by the National Drug Rebate Agreements remain available to Medical Assistance Program clients, though some drugs may require prior authorization").

67. Even if the PDL could be characterized as a Medicaid formulary, Hetlioz would still be within the scope of "medical assistance" Colorado must provide to enrollees, including Plaintiff. The Medicaid Act permits exclusion of a drug from a formulary "with respect to the treatment of a specific disease or condition for an identified population" only if (1) "based on the drug's labeling, . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary," and (2) "there is a written explanation (available to the public) of the basis for the exclusion." 42 U.S.C. § 1396r-8(d)(4)(C). Because

Hetlioz is the *only* FDA-approved drug to treat Non-24, there is no drug that has a greater clinically meaningful therapeutic advantage over Hetlioz. And Defendants have not provided a publicly available written explanation of the basis of Hetlioz's exclusion.

68. Moreover, even if a drug is excluded from a Medicaid formulary, states must still "permit[] coverage of [the] drug excluded from the formulary . . . pursuant to a prior authorization program" that provides for "the approval of the drug" for "any medically accepted indication" within "24 hours of a request for prior authorization." 42 U.S.C. §§ 1396r-8(d)(4)(D), (d)(5).

69. Accordingly, the "medical assistance" to which Plaintiff is entitled includes coverage of Hetlioz for all Non-24 enrollees—whether or not the PDL is considered a formulary. Defendants' categorical denial of coverage for Hetlioz for sighted Non-24 enrollees deprives Plaintiff of her right to "medical assistance" under the Medicaid Act and, *ipso facto*, of her entitlement to that assistance "with reasonable promptness." Plaintiff is entitled to a declaration that Defendants' policy denying coverage for Hetlioz for sighted Non-24 Medicaid enrollees is unlawful. Plaintiff is also entitled to an injunction (1) enjoining Defendants from denying coverage for Hetlioz to qualified Medicaid enrollees who are diagnosed with Non-24 and who are not blind, and (2) requiring Defendants to reprocess and approve coverage for Hetlioz for Plaintiff.

COUNT II
42 U.S.C. § 1983
Denial of medically necessary medical assistance under the Medicaid Act in violation of 42 U.S.C. § 1396a(a)(10)(A)

70. Plaintiff incorporates and re-alleges the foregoing paragraphs as though fully set forth herein.

71. The Medicaid Act, 42 U.S.C. 1396a(a)(10)(A), "prohibits states from denying coverage of 'medically necessary' services that fall under a category covered in their Medicaid plans." *Alvarez v. Betlach*, 572 F. App'x 519, 521 (9th Cir. 2014); *see also Beal v. Doe*, 432 U.S.

438, 444-45 (1977); *Bontrager v. Indiana Family & Soc. Servs. Admin*, 697 F.3d 604, 608 (7th Cir. 2012); *Doe v. Chiles*, 136 F.3d 709, 714 (11th Cir. 1998); *Lankford v. Sherman*, 451 F.3d 496, 511 (8th Cir. 2006). This includes medically necessary drugs, where a state has included prescription drug coverage within its Medicaid plan. *See Ryan v. Birch*, 2017 WL 3896440, at *3-*4 (D. Colo. Sept. 5, 2017) (finding Medicaid enrollees adequately pled claim under 42 U.S.C. §§ 1396a(a)(10)(A) and (B) based on Colorado DHCPF's application of prior authorization criteria that denied enrollees coverage for medically necessary drugs).

72. Hetlioz is the *only* FDA-approved drug to treat Non-24, and, necessarily, is medically necessary for Medicaid enrollees suffering from Non-24, including Plaintiff. *See Weaver v. Reagen*, 886 F.2d 194, 200 (8th Cir. 1989); *Visser v. Taylor*, 756 F. Supp. 501, 507 (D. Kan. 1990); *Pinneke v. Preisser*, 623 F.2d 546, 549 (8th Cir. 1980); *Jeneski v. Myers*, 163 Cal. App. 3d 18, 33 (Ct. App. 1984).

73. Even under DHCPF's own regulations, Hetlioz is medically necessary. DHCPF defines medical necessity as treatment that is "reasonably expected to . . . correct, reduce, or ameliorate the pain and suffering, or the physical, mental, cognitive, or development effects" of an illness or condition. 10 Colo. Code Regs. § 2505-10:8.076.1(8). The FDA has specifically found that Hetlioz has benefits for all Non-24 patients, whether blind or not. FDA Letter, *supra* n.8, at 5-6. And as to Plaintiff, specifically, Plaintiff's doctor has concluded that Hetlioz is reasonably expected to reduce or ameliorate the pain and suffering and effects Plaintiff has experienced for decades due to Non-24.

74. The FDA's approval—as well as expert opinions[17]—also establish that Hetlioz is not "experimental or investigational," is being "provided in accordance with generally accepted

[17] *See, e.g.*, Nishimon et al., *supra* n.15, at 1070 (Hetlioz is "mainstream for the treatment of non-24.").

professional standards for health care in the United States," and is "clinically appropriate." 10 Colo. Code Regs. § 2505-10:8.076.1(8).

75. Furthermore, given the unique and documented benefits Hetlioz can provide to individuals with Non-24, there is no basis for concluding that Hetlioz is "primarily for the economic benefit of the provider or primarily for the convenience of the client, caretaker, or provider." *Id.* Plaintiff's doctor—who does not stand to benefit economically from Plaintiff taking Hetlioz—prescribed Hetlioz because no other treatment has been effective in treating Plaintiff's Non-24 to allow her to live a normal life.

76. Finally, Hetlioz is not "more costly than other equally effective treatment options" because there is *no* other FDA-approved drug to treat Non-24, and no other treatment options have been effective for Plaintiff. *Id.*[18]

77. Accordingly, Defendants' policy of systematically denying coverage for Hetlioz for sighted Medicaid enrollees diagnosed with Non-24 denies Plaintiff medically necessary care in violation of the Medicaid Act.

78. Plaintiff is entitled to a declaration that Defendants' policy denying coverage for Hetlioz for sighted Non-24 Medicaid enrollees is unlawful. Plaintiff is also entitled to an injunction (1) enjoining Defendants from denying coverage for Hetlioz to qualified Medicaid enrollees who are diagnosed with Non-24 and who are not blind, and (2) requiring Defendants to reprocess and approve coverage for Hetlioz for Plaintiff.

[18] DHCPF's regulation also requires that the Medicaid good or service be "delivered in the most appropriate setting(s) required by the client's condition." *Id.* That portion of the regulation is irrelevant here.

COUNT III
42 U.S.C. § 1983
Violation of Medicaid comparability requirement under 42 U.S.C. § 1396a(a)(10)(B)

79. Plaintiffs incorporate and re-allege the foregoing paragraphs as though fully set forth herein.

80. 42 U.S.C. § 1396a(a)(10)(B) guarantees to the categorically needy that states will make available to them the "same amount, duration, or scope" of medical assistance as is made available to any other categorically needy individual. *See also* 42 C.F.R. § 440.240. In other words, it prohibits states from "provid[ing] benefits to some categorically needy individuals but not to others." *Rodriguez v. City of New York*, 197 F.3d 611,615 (2d Cir. 1999). This comparability requirement "applies equally to mandatory and optional medical services." *Lankford v. Sherman*, 451 F.3d 496, 505 (8th Cir. 2006).

81. Defendants' policy makes coverage for Hetlioz available to some categorically needy individuals—enrollees who suffer from Non-24 and are blind—but not to others—enrollees who suffer from Non-24 and are not blind. There is no medically justifiable basis for such differential treatment. Blindness is not a diagnostic factor for Non-24. *See supra* p.7. Nor is blindness relevant to the approved indication for Hetlioz. Hetlioz is medically indicated "for the treatment of Non-24 in adults." Hetlioz 2020 Label, *supra* p.8, at 2. And the FDA has specifically recognized that "the benefits of Hetlioz therapy are not limited to those Non-24 patients who are totally blind." FDA Letter, *supra* n.8, at 5.

82. By discriminating among similarly situated Medicaid recipients on the basis of categorical restrictions that are not based upon prevailing clinical standards, Defendants have violated Plaintiff's right to receive the same "amount, duration, and scope" of medical assistance as other categorically needy individuals under the Medicaid Act. Accordingly, Plaintiff is entitled to a declaration that Defendants' policy denying coverage for Hetlioz for sighted Non-24 Medicaid

enrollees is unlawful. Plaintiff is also entitled to an injunction (1) enjoining Defendants from denying coverage for Hetlioz to qualified Medicaid enrollees who are diagnosed with Non-24 and who are not blind, and (2) requiring Defendants to reprocess and approve coverage for Hetlioz for Plaintiff.

COUNT IV
Equitable Preemption
Conflict with 42 U.S.C. §§ 1396a(a)(8), (a)(10)(A), (a)(10)(B), (a)(17)

83. Plaintiffs incorporate and re-allege the foregoing paragraphs as though fully set forth herein.

84. The Supremacy Clause makes the United States Constitution and constitutionally authorized federal statutes "the supreme law of the land." U.S. Const. art. VI, cl. 2. Accordingly, where a state official's actions conflict with federal law, those actions are preempted. Federal courts have power in equity to enjoin state action that conflicts with federal laws. *Ex parte Young*, 209 U.S. 123, 148 (1908); *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 328 (2015).

85. As set forth above, the Medicaid Act requires states to provide "medical assistance"—including, at a minimum, medically necessary goods and services—to do so with reasonable promptness, and to do so equally among the categorically needy. 42 U.S.C. §§ 1396a(8), 1396a(10)(A), 1396a(10)(B). Additionally, it requires states to use "reasonable standards" for determining "the extent of medical assistance under the plan which . . . are consistent with the objectives of this subchapter." *Id.* § 1396a(a)(17).

86. Because Colorado has elected to include prescription drug coverage in its Medicaid plan, the "medical assistance" it provides includes all FDA-approved drugs covered by a rebate agreement, subject to four exceptions. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003); 42 U.S.C. § 1396d(a)(12); *id.* § 1396r-8.

87. Hetlioz meets the criteria for coverage: it is FDA approved, it is subject to a rebate agreement, and none of the four exceptions permitting exclusion of coverage applies. Indeed, Defendants provide coverage of Hetlioz for blind Non-24 Medicaid enrollees. There is no clinical or medical basis for Defendants' differential treatment of blind and sighted Non-24 enrollees.

88. Defendants' categorical exclusion of Hetlioz for sighted Non-24 Medicaid enrollees from coverage therefore directly conflicts with the Medicaid Act, and their actions are preempted.

89. Plaintiff has no adequate remedy at law.

90. Accordingly, Plaintiff is entitled to an injunction (1) enjoining Defendants from denying coverage for Hetlioz to qualified Medicaid enrollees who are diagnosed with Non-24 and who are not blind, and (2) requiring Defendants to reprocess and approve coverage for Hetlioz for Plaintiff.

COUNT V
Equitable Preemption
Conflict with 42 U.S.C. § 1396r-8(d)

91. Plaintiffs incorporate and re-allege the foregoing paragraphs as though fully set forth herein.

92. The Supremacy Clause makes the United States Constitution and constitutionally authorized federal statutes "the supreme law of the land." U.S. Const. art. VI, cl. 2. Accordingly, where a state official's actions conflict with federal law, those actions are preempted. Federal courts have power in equity to enjoin state action that conflicts with federal laws. *Ex parte Young*, 209 U.S. 123, 148 (1908); *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 328 (2015).

93. The Medicaid Act requires states that elect to include prescription drug coverage in their Medicaid plans to cover prescription drugs that have been approved for safety and effectiveness by the FDA and that are covered by a rebate agreement between the drug's

manufacturer and the federal government (and/or state government). 42 U.S.C. §§ 1396r-8(a)(1), 1396r-8(d)(4)(B); 1396r-8(k)(2); *see also Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652-53 (2003).

94. If a drug meets those criteria, a state may "exclude or otherwise restrict coverage of a covered outpatient drug" *only* in four circumstances: (i) the prescribed use is not for a medically accepted indication, (ii) the drug falls within a specified category,[19] (iii) the drug is subject to such restrictions pursuant to a rebate agreement, or (iv) the state has excluded coverage of the drug from a formulary that complies with statutory requirements. 42 U.S.C. § 1396r-8(d).

95. Hetlioz meets the criteria for coverage: it is FDA approved, it is subject to a rebate agreement, and none of the four exceptions permitting exclusion of coverage applies. Hetlioz is medically indicated "for the treatment of Non-24 in adults." Hetlioz 2020 Label, *supra* p.8, at 2. Hetlioz is not on the list of restricted drugs set forth in § 1396r-8(d)(2). There is no agreement between Vanda, Hetlioz's manufacturer, and the State of Colorado or the federal government restricting coverage. And DHCPF has not established a drug formulary. Defendants' refusal to cover Hetlioz for sighted Non-24 Medicaid enrollees therefore conflicts with, and is preempted by, federal law.

96. Even if the PDL established by DHCPF could be characterized as a Medicaid formulary, Defendants' categorical refusal to cover Hetlioz for sighted Non-24 enrollees would still be preempted by the Medicaid Act. The Medicaid Act permits states to exclude coverage of

[19] These categories are: agents when used for anorexia, weight loss, or weight gain; agents when used to promote fertility; agents when used for cosmetic purposes or hair growth; agents when used for the symptomatic relief of cough and colds; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; nonprescription drugs, subject to some exceptions; covered outpatient drugs when the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; and agents when used for the treatment of sexual or erectile dysfunction. 42 U.S.C. § 1396r-8(d)(2).

the drug from a formulary "with respect to the treatment of a specific disease or condition for an identified population . . . *only if*, based on the drug's labeling . . ., the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion." 42 U.S.C. § 1396r-9(d)(4)(C) (emphasis added).

97. Moreover, even if a state properly excludes a drug from a formulary, the Medicaid Act still requires it to cover the excluded drugs pursuant to a prior authorization program that provides for approval of medically-indicated uses of the drug within 24 hours of the request for prior authorization. 42 U.S.C. § 1396r-8(d)(4), (d)(5).

98. On information and belief, DHCPF has not provided a public, written explanation of the basis for its exclusion of Hetlioz for sighted Non-24 Medicaid enrollees from any alleged formulary. Additionally, there is no other drug (much less one on formulary) that is approved to treat Non-24. And Defendants do not cover Hetlioz for sighted Non-24 patients pursuant to their prior authorization program. For all of these reasons, Defendants' actions conflict with federal law and are preempted.

99. Plaintiff has no adequate remedy at law.

100. Accordingly, Plaintiff is entitled to an injunction (1) enjoining Defendants from denying coverage for Hetlioz to qualified Medicaid enrollees who are diagnosed with Non-24 and who are not blind, and (2) requiring Defendants to reprocess and approve coverage for Hetlioz for Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs respectfully request that the Court enter judgment in their favor, and that the Court:

(a) Declare that Defendants' policies or practices denying coverage for Hetlioz for sighted Non-24 Medicaid enrollees are unlawful;

(b) Enjoin Defendants from continuing to implement any policies or practices denying coverage for Hetlioz for sighted Non-24 Medicaid enrollees;

(c) Require Defendants to reprocess and approve coverage for Plaintiff;

(d) Award Plaintiff her attorney fees and costs pursuant to 42 U.S.C. § 1988; and

(e) Award such other relief as is just and proper.

DATED: 11/24/2021 By: */s/ Paul W. Hughes*

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