



January 7, 2022

Mr. Patrick Allen
Director, Oregon Health Authority
Health Policy and Analytics Medicaid Waiver Renewal Team
Attn: Michelle Hatfield
500 Summer St. NE, 5th Floor, E65
Salem, OR 97301

Re: Comments on Oregon's Draft 2022-2027 Medicaid 1115 Demonstration Application

Dear Director Allen:

Gilead Sciences, Inc. (Gilead) welcomes this opportunity to comment on Oregon's Draft 2022-2027 Medicaid 1115 Demonstration Application (the "Draft Application"). Gilead is a US-based, global biopharmaceutical company that is committed to discovering, developing, and delivering innovative therapeutics for people with life-threatening diseases in areas of unmet medical need. Our marketed products include medicines for the prevention and treatment of HIV/AIDS and treatment of liver diseases including hepatitis B and C, cancer, and COVID-19, as well as certain cardiovascular and respiratory diseases.

Gilead has significant concerns with the Draft Application, specifically its provisions relating to the adoption of a closed-formulary in the Oregon Medicaid program outpatient prescription drug benefit. As a member of both the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO), we join their critique of the Draft Application. We write separately to emphasize the following points for your consideration:

- The State cannot waive protections for access to the full range of FDA approved medications granted under SSA Section 1927.
- The requested waiver would fail to meet the essential criteria under SSA Section 1115, because it does not specify an experiment that supports the objectives of the Medicaid program.
- The state has existing authorities that it can leverage in order to manage formularies.
- The proposed waiver would undermine a crucial component of health equity.
- The proposed waiver would inhibit the coverage of drugs approved under accelerated approval pathways by substituting the state's judgment for the FDA approval process.
- The proposed waiver would result in substandard coverage for Medicaid compared to Medicare or Exchanges.

Our comments on each of these points are below.

1. The State cannot waive protections for access to the full range of FDA approved medications granted under SSA Section 1927.

In the Draft Application, Oregon seeks to “increase predictability of costs and ensure value for spending” in its Medicaid program through implementation of a “commercial-style closed formulary” and “exclusion of drugs with limited or inadequate evidence of clinical efficacy.” Oregon seeks to accomplish this through a SSA Section 1115 waiver of SSA Section “1902(a)(54) insofar as it incorporates” SSA Section 1927(d)(1)(B) – the provision of the Medicaid Rebate Statute that limits the state’s ability to exclude certain drugs from coverage. Notably, Oregon’s request would leave the remainder of SSA Section 1927, including the rebate obligation for participating manufacturers under SSA Section 1927(b), intact. There are several reasons why Oregon’s request is legally impermissible.

As a threshold matter, by its express terms, SSA Section 1115 does not permit waiver of any requirements of SSA Section 1927. Pursuant to SSA Section 1115(a)(1), the Secretary may waive compliance “with any of the requirements of section 402, 454, 1402, 1602, or 1902....” Notably, SSA Section 1927 is not among the enumerated statutes subject to waiver. This interpretation is supported by the D.C. Circuit’s holding in *PhRMA v. Thompson*, which addressed whether Section 1115 permits waivers of the rebate statute requirements:

The Social Security Act, of which the Medicaid statute is a part, authorizes HHS to approve experimental “pilot” or “demonstration” projects that the Secretary determines are “likely to assist in promoting the objectives of [Medicaid].” [42 U.S.C.] § 1315(a). Although the Act authorizes the Secretary to waive certain Medicaid requirements for such demonstration projects, it does not authorize him to waive any requirements of section 1396r-8’s [SSA Section 1927’s] rebate provision.¹

Furthermore, an almost identical closed formulary proposal was rejected by CMS in 2018 in response to the Commonwealth of Massachusetts’ SSA Section 1115 Demonstration Amendment request. Massachusetts argued that waiving the open formulary requirements would “improve [its] ability to negotiate additional supplemental rebates.”² CMS determined, however, that it would be impermissible for the Commonwealth to exclude certain Medicaid covered outpatient drugs from coverage and continue to: (a) provide drug coverage pursuant to its state plan under SSA Section 1902 and (b) claim mandatory rebates from manufacturers under SSA Section 1927(b).³ Oregon’s proposal is similarly flawed for the same reasons, among others.

Moreover, the state’s proposal to categorically deny coverage of covered outpatient drugs would undermine the congressionally-declared objective of SSA Section 1927 and its carefully designed bargain between manufacturers, the States, and the Federal government. Congress enacted SSA

¹ *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 222 (D.C. Cir. 2001).

² Office of Medicaid, Mass. Executive Office of Health & Human Services, MassHealth Section 1115 Demonstration Amendment Request at 8 (Sept. 8, 2017).

³ Letter from Tim Hill, Acting Director, CMS, to Daniel Tsai, Assistant Secretary, MassHealth at 2 (June 27, 2018).

Section 1927 to guarantee that “[s]tates that elect to offer prescription drugs . . . cover all the products of any manufacturer that agrees to provide price rebates.”⁴ As Congress made abundantly clear, “[s]tates that elect to offer prescription drug coverage under their Medicaid programs will be required to cover all of the drugs of any manufacturer entering into and complying with such an agreement, with the exception of drugs (e.g., cosmetic drugs) on a statutory list (which may be revised by the Secretary).”⁵ As the Supreme Court has emphasized, “strict adherence to the language and structure of an act is particularly appropriate where . . . a statute is the result of a series of carefully crafted compromises.”⁶

But Oregon’s proposal, which would enable the state to escape its coverage obligations under SSA Section 1927, would unravel this carefully designed bargain. That is, Oregon would continue to provide prescription drug coverage under its Medicaid state plan, and thus continue to subject manufacturers to rebate obligations, all without complying with its corresponding obligation under the Medicaid Drug Rebate Program (MDRP) – coverage of all of a participating manufacturer’s covered outpatient drugs. This would contravene the terms of the compromise Congress carefully designed between manufacturers and the government; it would be fundamentally unfair to require manufacturers to uphold their side of the arrangement and could dissuade some manufacturers from participating in the MDRP, if states were permitted to avoid their set of reciprocal requirements.

2. The requested waiver would fail to meet the essential criteria under SSA Section 1115, because it does not specify an experiment that supports the objectives of the Medicaid program.

Oregon’s draft proposal would fail to satisfy the plain language requirement of SSA Section 1115(a)(1), which only allows “Secretary [to] waive compliance with any of the requirements” of SSA Section 1902 “[i]n the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of” Medicaid. This is because the state failed to specify what would be tested by waiving the Medicaid coverage requirements, the waiver would conflict with the objectives of the Medicaid program, and the waiver proposal does not include essential beneficiary protections.

First, Oregon has failed to specify a research or experimental proposition that it seeks to test under its demonstration project as a result of the requested waiver. A waiver of compliance with SSA Section 1927 to enable a truly closed formulary would be tantamount to nothing more than a “simple benefits cut” , which, as the Ninth Circuit Court of Appeals has ruled, does not serve an experimental purpose.⁷ In particular, the Ninth Circuit has held that the Secretary, in reviewing a proposed demonstration project, “must make some judgment that the project has a research or a demonstration value. A simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy this requirement The statute was not enacted to enable

⁴ H. R. NO. 101-881, at 98 (1990).

⁵ STAFF OF H. COMM. ON WAYS AND MEANS, H. COMM. ON ENERGY AND COMMERCE, & S. COMM. ON FINANCE, 101ST CONG., SUMMARY OF MEDICARE AND MEDICAID PROVISIONS IN THE OMNIBUS BUDGET RECONCILIATION ACT OF 1990 19 (Comm. Print. 1990).

⁶ *Community for Creative Non-Violence v. Reid*, 490 U.S. 730, 748 n.14 (1989).

⁷ *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

states to save money or to evade federal requirements but to ‘test out new ideas and ways of dealing with the problems of public welfare recipients.’”⁸ Oregon has failed to set forth any meaningful research proposition or purpose that would be tested as a result of the requested waiver.

Second, under SSA Section 1115(a), a demonstration project must, in the judgment of the Secretary, be “likely to assist in promoting the objectives of ... [the Medicaid statute].”⁹ Medicaid was enacted by Congress in order to provide medical care to the needy and medically needy.¹⁰ Indeed, recently the D.C. Circuit determined in striking down CMS’ approval of an Arkansas waiver that “[T]he intent of Congress is clear’ that Medicaid’s objective is to provide health care coverage and, as a result, [CMS] ‘must give effect to [that] unambiguously expressed intent of Congress.’”¹¹ Put another way, Medicaid beneficiaries cannot be “significantly burdened—that is, for example, their eligibility significantly restricted or benefits significantly cut—in the name of saving money.”¹² If a state were allowed to deny access to otherwise-covered and potentially life-saving therapies, as Oregon contemplates here, a demonstration project would do precisely that – it would substantially limit Medicaid beneficiaries’ access to medically-necessary therapies, many of which have life-saving potential. This would undermine, as opposed to promote, the attainment of Congress’ fundamental objective in enacting the Medicaid program.

Finally, through SSA Section 1927, Congress also intended to provide Medicaid beneficiaries with key safeguards to protect their access to medically necessary therapies. In enacting SSA Section 1927, “Congress made it clear that Medicaid recipients should be assured access to all medically necessary covered outpatient drugs.”¹³ This guarantee has endured over the ensuing decades as SSA Section 1927 has been amended by Congress over time.¹⁴ A waiver of a state’s obligation to comply with SSA Section 1927’s coverage obligations would undercut, rather than further, Congress’ key goal of ensuring access to covered outpatient drugs.

⁸ *Id.*; cf. *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011) (finding, in examining the research value of a state’s proposal to impose cost-sharing requirements on Medicaid beneficiaries, that “[p]laintiffs’ public health expert stated that ‘[o]ver the last 35 years, a number of studies have looked at the effects of cost sharing on the poor. Of all forms of cost sharing, copayments are the most heavily studied.’ The administrative record contains no finding from the Secretary that Arizona’s demonstration project will actually demonstrate something different than the last 35-years’ worth of health policy research.”).

⁹ SSA § 1115(a).

¹⁰ See STAFF OF H. COMM. ON WAYS AND MEANS, 89TH CONG., SUMMARY OF MAJOR PROVISIONS OF H.R. No. 6675, THE “SOCIAL SECURITY AMENDMENTS OF 1965” 1 (Comm. Print 1965); see also S.R. No. 89-404, pt. 1, at 73-74 (1965) (“[the Medicaid statute] is designed to liberalize the Federal law under which States operate their medical assistance programs so as to make medical services for the needy more generally available”).

¹¹ *Gresham v. Azar*, 950 F.3d 93, (D.C. Cir. 2019).

¹² *Stewart v. Azar*, 366 F. Supp. 3d 125, 152 (D.D.C. 2019).

¹³ See 60 Fed. Reg. 48,442, at 48,454 (citing H.R. Rep. No. 881, 101st Cong., 2d Sess. 96-98 (1990)).

¹⁴ Even when Congress added SSA Section 1927(d)(4), thereby enabling states to establish formularies that meet specific requirements, it remained the case that “section 1927(d)(4)(D) provides that the State plan must permit coverage of a drug excluded from the formulary (other than any drug excluded or restricted under section 1927(d)(2)) pursuant to a prior authorization program.” 60 Fed. Reg. at 48,454.

3. The state has existing authorities that it can leverage in order to manage formularies.

In its draft application, Oregon notes that “taking a closed formulary approach” would enable its Medicaid program “to negotiate more favorable agreements with manufacturers.” However, Oregon does not need a waiver of compliance with SSA Section 1927 in order to achieve its apparent objective. Under SSA Section 1927(d)(5), states have the authority to impose prior authorization requirements for drugs based upon valid criteria through a preferred drug list (PDL) program. Under such a program, the state can negotiate supplemental rebates in a manner that encourages the use of preferred drugs over non-preferred drugs. Preferred drugs, for which the state receives supplemental rebates from the manufacturer, can be covered without prior authorization. Non-preferred drugs, for which the state does not receive supplemental rebates, are in turn subject to prior authorization.

These existing authorities have provided states ample opportunities to negotiate significant additional rebates from manufacturers. Specifically, Gilead reviewed publicly available CMS-64 reports for states with similar Medicaid enrollments as Oregon and found that Oregon received supplemental rebates that were significantly lower than the other states.¹⁵ This further suggests that the state may be able to utilize existing authority to seek additional supplemental rebates as part of its preferred drug list.

4. The proposed waiver would undermine a crucial component of health equity.

We are concerned the closed formulary component of the Draft Application would further exacerbate health inequities, conflicting with one of the objectives laid out by the state.¹⁶ The adults served by Oregon’s Medicaid program are not only low-income, but also disproportionately people of color and people with disabilities.¹⁷ In June 2020, Governor Kate Brown released a new diversity, equity, and inclusion framework of the state of Oregon, which states “[O]ur state government must take proactive and anti-racist measures to build a more equitable Oregon.”¹⁸ To redress longstanding health inequities, Oregon must ensure that Medicaid beneficiaries are able to access the medications they need, as determined by their healthcare provider.

If Oregon were permitted to limit therapies (potentially to as few as a single drug per therapeutic class), the results would be highly detrimental to Medicaid beneficiaries. Medicaid patients often have one or more chronic health conditions and require multiple, specific prescription drugs in

¹⁵ Gilead analysis of CMS-65 reports from FY2016-2020.

¹⁶ See Draft Application page 3. “Focusing our waiver application on meaningful progress toward health equity... will allow us to improve health outcomes in communities most harmed by social injustices.”

¹⁷ Black and Hispanic Oregonians are substantially more likely than White Oregonians to be enrolled in the Medicaid program. *Compare QuickFacts: Oregon*, U.S. Census Bureau (last updated July 1, 2019), <https://www.census.gov/quickfacts/OR> with *Medicaid Coverage Rates for the Nonelderly by Race/Ethnicity: Oregon*, Kaiser Family Foundation (2019), <https://www.kff.org/medicaid/state-indicator/nonelderly-medicaid-rate-by-raceethnicity/?currentTimeframe>. Nationwide, “nearly a quarter of nonelderly adults with Medicaid report having a disability.” M. Musumeci & K. Orgera, *People with Disabilities Are At Risk of Losing Medicaid Coverage Without the ACA Expansion*, Kaiser Family Foundation (Nov. 2, 2020), <https://www.kff.org/medicaid/issue-brief/people-with-disabilities-are-at-risk-of-losing-medicaid-coverage-without-the-aca-expansion/>.

¹⁸ <https://www.myoregon.gov/2020/06/11/oregons-equity-guidelines/> (last visited Dec. 29, 2021).

order to adequately manage those conditions.¹⁹ Such a narrow coverage policy would deprive Medicaid beneficiaries of medically necessary therapies on which they have long relied to address their conditions and co-morbidities.

Sadly, these health disparities are particularly stark with respect to HIV. The incidence rates of new HIV infection in Oregon between 2009-2018 are nearly five times higher among Black and African Americans than among Whites, and Black and African Americans are less likely to be virally suppressed than Whites.²⁰ Limiting access to HIV drugs for Medicaid beneficiaries could delay treatment initiation or interrupt therapy and exacerbate these distressing health disparities, undermining President Biden's commitment to end the HIV/AIDS epidemic by 2030.²¹ Given that Black people are both more likely to be diagnosed with a new HIV infection, more likely to not be virally suppressed, and more likely to be enrolled in Oregon's Medicaid program than other racial groups, policies and programs are needed to support vulnerable communities in achieving fair outcomes in care.²² Strong coverage and access protections are necessary to protect against potential discrimination—intentional or inadvertent—in the design and implementation of healthcare benefits, as demonstrated by the long history of complaints against health plans for discrimination against those living with HIV.²³ As discussed further below, this is why antivirals are one of Medicare's protected classes.

Similarly, despite the development of policies to support breast cancer patients, recognition of the specific effects of health disparities and inequities on Triple Negative Breast Cancer (TNBC) patients and actions to mitigate them are limited. TNBC is an aggressive form of breast cancer, is often diagnosed at later stages, and presents a higher chance at becoming metastatic than other types of cancers.²⁴ Black women are two times more likely to be diagnosed with TNBC than white women in the US.²⁵ Studies have shown that TNBC disease-specific mortality rates are often

¹⁹ See, e.g., *The Role of Medicaid for Adults with Chronic Illnesses*, Kaiser Family Foundation (Nov. 2012), available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8383.pdf>.

²⁰ Oregon Health Authority, HIV Infection in Oregon as of Dec. 31, 2018, <https://sharedsystems.dhsosha.state.or.us/DHSForms/Served/le9985.pdf>.

²¹ The White House. Fact Sheet: The Biden-Harris Administration Marks World AIDS Day 2021 With Renewed Commitments to Ending the HIV/AIDS Epidemic by 2030. December 1, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/01/fact-sheet-the-biden-%E2%81%A0harris-administration-marks-world-aids-day-2021-with-renewed-commitments-to-ending-the-hiv-aids-epidemic-by-2030/>

²² See *Id.* at 15.

²³ See, e.g., Nat'l Health Law Program, *Florida Insurance Commissioner fines Humana \$500,000* (Feb. 18, 2016) (describing litigation that resulted in a consent order in which "Humana agreed to 'maintain procedures to ensure that it does not by effect or design treat people living with HIV/AIDS less favorably than any other condition.'"), <https://healthlaw.org/news/florida-insurance-commissioner-fines-humana-500000/>; Ctr. for Health Law & Policy Innovation (CHLPI), *CHLPI Launches Groundbreaking Campaign to Enforce Health Care Rights for People Living With HIV In Seven States*, Harvard Law School (Sept. 6, 2016), <https://www.chlpi.org/chlpi-launches-groundbreaking-campaign-enforce-health-care-rights-people-living-hiv-seven-states/>.

²⁴ American Cancer Society, Triple-Negative Breast Cancer, 2019. <https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/types-of-breast-cancer/triple-negative.html>

²⁵ American Cancer Society. *Breast Cancer Facts and Figures 2019-2020*. Atlanta, GA: American Cancer Society Inc; 2021

higher if patients have Medicaid or Medicare or are lower socio-economic status;²⁶ and compared with non-Hispanic white women, Black women are 48% less likely to receive guideline adherent care and have an approximate 2-fold higher mortality incidence, resulting in a disproportionately higher risk of death from TNBC.^{27,28} Recent innovation in targeted therapies has led to advances in treatment for TNBC, yet barriers in care and treatment remain significant for minority women disproportionately impacted. Targeted policy strategies are needed to comprehensively address these barriers to ensure early TNBC diagnosis and effective treatment initiation. We are concerned however, that a closed formulary approach could create difficulty in obtaining needed therapies for some of the most vulnerable women impacted by TNBC in the state.

The two examples above illustrate the potential of the Medicaid program to remedy health inequities, but only if Medicaid beneficiaries are allowed broad and timely access to medically necessary medications and other care.

5. The waiver would inhibit the coverage of drugs approved under accelerated approval pathways by substituting the state's judgement for the FDA approval process.

Oregon's Draft Application seeks to "allow exclusion of drugs with limited or inadequate evidence of clinical efficacy." Specifically, Oregon seeks authority to deny access to "drugs coming to market through the FDA's accelerated approval pathway" on the grounds that they "have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints." Gilead strongly objects to this characterization of the accelerated approval pathway and to the exclusion of such drugs, given that the FDA instituted the accelerated approval pathway "to allow for earlier approval of drugs...that fill an unmet medical need based on a surrogate endpoint."²⁹ Exclusion of such drugs would represent a significant departure from current law, which protects access to cutting edge therapies for Medicaid beneficiaries. Oregon's Medicaid beneficiaries should not be restricted from accessing therapies approved under FDA's accelerated approval pathway as soon as they are available.

First, by attempting to limit Medicaid beneficiaries' access to these therapies, Oregon would deprive patients suffering from serious or life-threatening diseases of medicines that FDA has determined are safe and effective for their condition after a full review of available data. This barrier may negatively impact health outcomes for Medicaid beneficiaries, who are already some

²⁶ Ubbaonu C, Chang J, Ziogas A, et al. Disparities in the receipt of National Comprehensive Cancer Network (NCCN) guideline adherent care in triple-negative breast cancer (TNBC) by race/ethnicity, socioeconomic status, and insurance type. Presented at: ASCO20 Virtual; May 29-31, 2020. Accessed June 15, 2020.

<https://meetinglibrary.asco.org/record/185233/abstract>; Cho B, Han Y, Lian M, et al. Evaluation of Racial/Ethnic Differences in Treatment and Mortality Among Women With Triple-Negative Breast Cancer. *JAMA Oncol.* 2021;7(7):1016–1023. doi:10.1001/jamaoncol.2021.1254

²⁷ Lu Chen and Christopher I. Li, Racial Disparities in Breast Cancer Diagnosis and Treatment by Hormone Receptor and HER2 Status, *Cancer Epidemiol Biomarkers Prev* November 1 2015 (24) (11) 1666-1672; DOI: 10.1158/1055-9965.EPI-15-0293

²⁸ Cho B, Han Y, Lian M, et al. Evaluation of Racial/Ethnic Differences in Treatment and Mortality Among Women With Triple-Negative Breast Cancer. *JAMA Oncol.* 2021;7(7):1016–1023. doi:10.1001/jamaoncol.2021.1254

²⁹ FDA, Accelerated Approval Program. Available at: <https://www.fda.gov/drugs/information-health-care-professionals-drugs/accelerated-approval-program>

of the sickest and most vulnerable residents of the state. Moreover, accelerated approval drugs, are often the latest cures and advances in medical science. Medicaid beneficiaries would, thus, have inferior healthcare as compared to other Oregonians and Medicaid beneficiaries in other states jeopardizing health outcomes. This contravenes CMS' long-standing "commit[ment] to Medicaid beneficiaries continuing to have access to needed prescribed medications."³⁰

Second, we are also deeply concerned that Oregon's proposal to "use its own rigorous review process" to define coverage of new drugs and determine which drugs are "clinically proven, effective drugs" improperly supplants the FDA's clearly established role in the determination of safety and effectiveness of a particular drug. Drug manufacturers rely on this defined process in bringing new therapies to market. Given that Congress has granted the FDA authority to determine a particular product's efficacy, we believe they are best suited to conduct this rigorous analysis rather than the State. As one state court recently noted, "it is the FDA's job, not that of the [state] Medicaid agency, to evaluate the clinical data to determine whether a drug meets efficacy and safety standards. So long as FDA has approved the drug and the manufacturer has signed a Medicaid Drug Rebate Agreement ... the Social Security Act mandates that a state Medicaid agency cannot rely on new or different clinical data to determine whether it deems a drug worthy of coverage."³¹

Third, we also object to Oregon's unfounded assertion that accelerated approval drugs may have "limited or inadequate clinical efficacy." Both Congress and the FDA have made clear that nothing about accelerated approval dilutes the FDA's approval standards. In 2016, the 21st Century Cures Act incorporated FDA's existing regulatory program for accelerated approval³² into statute, expressly providing, "Nothing in this section shall be construed to alter the standards of evidence" for approval.³³ Like all other drugs approved under New Drug Applications, drugs approved through the accelerated approval pathway are subject to a demanding standard of review — demonstration of "substantial evidence" of effectiveness.³⁴ Instead of altering the approval standard, the program is intended to encourage FDA "to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs."³⁵ It should also be noted that surrogate endpoints commonly used as the basis for granting accelerated approval are thoroughly evaluated and must be reasonably likely to predict clinical benefit in patients who are very ill and without good options.³⁶ By denying Medicaid patients access to therapies that rely on surrogate endpoints, the state could effectively discriminate against individuals with rare diseases or few treatment options and compromise the health of Oregon Medicaid members.

In response to a question about whether the accelerated approval pathway provides for a less rigorous standard, the FDA confirmed that it does not:

³⁰ See CMS, Medicaid Drug Rebate Program Notice, Release No. 172, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015).

³¹ *Ark. Dep't of Human Servs. v. Sarepta Therapeutics, Inc.*, 2021 Ark. App. 330, 2021 Ark. App. LEXIS 356.

³² See 57 Fed. Reg. 58697 (Dec. 11, 1992) (FDA's final regulations establishing the accelerated approval program).

³³ 21 U.S.C. § 356(e)(2).

³⁴ 21 U.S.C. § 355(d)(5).

³⁵ 21 U.S.C. § 356(e)(1).

³⁶ FDA. Accelerated Approval. Available at: <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval>

Approval under this rule requires ... that the effect shown be, in the judgment of the agency, clinically meaningful, and of such importance as to outweigh the risks of treatment. ***This judgment does not represent either a "lower standard" or one inconsistent with section 505(d) of the act,*** but rather an assessment about whether different types of data show that the same statutory standard has been met.³⁷

Senior Biden Administration FDA officials also recently reiterated that all drugs, regardless of the pathway, are held to the same approval standards.³⁸

Congress has clearly outlined the circumstances under which the FDA can consider a drug for accelerated review. Specifically, the FDA must determine “that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit ... taking into account the severity, rarity, or prevalence of the condition and availability or lack of alternative treatments.”³⁹

Fourth, Gilead is further concerned about the Draft Application because the accelerated approval pathway has been vital for patients suffering from a wide range of serious diseases where alternative therapies do not exist, including cancer and HIV. According to Dr. Richard Pazdur, director of the FDA’s Oncology Center of Excellence (OCE), “[t]he FDA has successfully applied accelerated approval in oncology over the past three decades, making innovative therapies available to patients years earlier than they would otherwise have been available.”⁴⁰ Further, studies have found that drugs approved through the accelerated approval process have provided larger health gains compared to drugs approved through the traditional approval process.⁴¹

Beyond cancer, the accelerated approval pathways can help patients with rare disease with no approved treatment to date, such as a Hepatitis D virus (HDV) and Hepatitis B virus (HBV) co-infection. The HDV-HBV co-infection is the most severe form of chronic viral hepatitis due to its more rapid progression towards hepatocellular carcinoma and liver related death.⁴² Patients with HDV have a mortality rate of 20 percent, the highest mortality rate of any viral hepatitis.⁴³ Further, the risk of developing cirrhosis is three times higher in HDV infected patients compared to those

³⁷ 57 Fed. Reg. at 58944 (emphasis added).

³⁸ B. Wang, Woodcock, Marks: Expedited Approval Paths Do Not Lower FDA Standards, Inside Health Policy (Aug. 28, 2019), <https://insidehealthpolicy.com/daily-news/woodcock-marks-expedited-approval-paths-do-not-lower-fda-standards>.

³⁹ 21 U.S.C. § 356(e)(2), (c)(1)(A).

⁴⁰ J. A. Beaver & R. Pazdur, “Dangling” Accelerated Approvals in Oncology, N Engl J Med 384:18 (May 6, 2021), <https://www.nejm.org/doi/pdf/10.1056/NEJMp2104846?articleTools=true>.

⁴¹ J. D. Chambers et al., *Drugs Cleared Through The FDA’s Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process*, HEALTH AFFAIRS 36, NO. 8 (2017): 1408–1415, <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2016.1541>.

⁴² World Health Organization. (2021, January 28). *Hepatitis D*. Retrieved from <https://www.who.int/news-room/fact-sheets/detail/hepatitis-d>

⁴³ Romeo R, Petruzzello A, Pecheur EI, et al. Hepatitis delta virus and hepatocellular carcinoma: an update. *Epidemiol Infect.* 2018;146(13):1612-1618. doi:10.1017/S0950268818001942.

with HBV alone.^{44,45} Given that there are no approved therapies for this unmet, rare disease, Oregon should not restrict access to future medicines based on a product's regulatory pathway for approval.

Additionally, Gilead believes that by excluding accelerated approval drugs from coverage, the Oregon Health Authority effectively removes clinical decision-making from practitioners and from patients. Given the complex nature of cancer treatment, no single drug is medically appropriate to treat all cancers, as tumors respond differently depending on the cancer type, stage of diagnosis, and other factors. By attempting to interfere with Medicaid beneficiaries' current access to these therapies based on a long-standing and well-established regulatory pathway for accelerating approval of therapies to treat the most serious and unmet illness, Oregon would deny patients access to treatments their medical practitioner determines are the most appropriate, safe, and effective.

Lastly, if Oregon or other states restrict access to drugs approved through the accelerated approval pathway, this could discourage the development of innovative therapies, and ultimately deprive Medicaid beneficiaries (and others) of access to potentially life-savings drugs.

6. The proposed waiver would result in substandard coverage for Medicaid compared to Medicare or Exchanges.

In the Draft Application, Oregon states "Given that Medicare and other commercial plans are permitted to adopt closed formularies, we believe Oregon should have the same flexibility for Medicaid."⁴⁶ However, this ignores important differences between Medicaid and Medicare and commercial plans. For example, Medicare Part D beneficiaries currently have a broad choice, among multiple coverage options, with transparency into the drugs included on any individual formulary and protections against mid-year formulary changes. As a result, Medicare Part D beneficiaries can choose, on an annual basis, the formulary that best suits their medical needs. Medicaid patients have no comparable choices and will often face limited provider networks. Given that Medicaid is traditionally the "payer of last resort" any restrictions on coverage must be carefully weighed against the risk they could lead to a loss of access to medically necessary care.

Furthermore, as the Draft Application notes, Medicare Part D formularies are generally required to cover two drugs per class, while the State seeks flexibility to limit coverage to just one drug per class. In Medicare Part D, plans are only permitted to include one drug in a class when there is actually only one drug available (or only two drugs are available but one drug is clinically superior to the other for a particular category or class).⁴⁷ The significance of this difference in coverage levels cannot be overstated.

⁴⁴ Farci P, Niro GA. Clinical features of hepatitis D. *Semin Liver Dis.* 2012;32(3):228-236. doi:10.1055/s-0032-1323628.

⁴⁵ Fattovich G, Giustina G, Christensen E, et al. Influence of hepatitis delta virus infection on morbidity and mortality in compensated cirrhosis type B. The European Concerted Action on Viral Hepatitis (Eurohep). *Gut.* 2000;46(3):420-426. doi:10.1136/gut.46.3.420.

⁴⁶ Draft Application. Page 31.

⁴⁷ Medicare Prescription Drug Benefit Manual, ch. 6 § 30.2.1.

In addition, the Part D program has an exceptions and reconsideration process that provides access to off-formulary therapies as well as the six protected classes of drugs, for which Part D plans must include all, or substantially all, drugs in the class on-formulary. These classes include anti-convulsants, anti-depressants, anti-psychotics, anti-neoplastics (oncology), immunosuppressants, and anti-retrovirals (which are used to treat HIV and AIDS). The Oregon Health Authority has not suggested that it would provide such protections in its Draft Application.

The requirement to cover all protected class drugs in Medicare Part D was established by Congress and the importance of open access to antiretrovirals has been reaffirmed by CMS. When Congress enacted Part D, it recognized that ensuring comprehensive access to drug treatments for patients, and ensuring prescriber choice of the full range of treatment options (including antiretrovirals) is critical. Moreover, the legislative history of the Medicare Part D program further illustrates this point. For example, a colloquy in the United States Senate among Senators Dianne Feinstein (D-CA), Max Baucus (D-MT), and Chuck Grassley (R-IA) during discussions of the Medicare Modernization Act of 2003 emphasized that one purpose of Medicare Part D is to ensure broad medication coverage for patients, especially those “who need exactly the right medicine for them.”⁴⁸ The protected classes were later codified in statute as part of the 2008 Medicare Improvements for Patients and Providers Act (MIPPA) and strengthened by the Affordable Care Act. CMS has repeatedly reaffirmed the importance of sustained access to protected class drugs, including in its final rule on modernizing Medicare Part D.⁴⁹

CMS has provided further protection for antiretroviral medications in Part D by prohibiting prior authorization and step therapy for that class.⁵⁰ This safeguard is critical because a provider’s careful selection of an effective treatment regimen for the patient, and a patient’s ability to access and start on that regimen as soon as possible after diagnosis, helps people living with HIV stay healthy and have a better chance of living nearly as long as someone without HIV.⁵¹ In contrast, delays in initiating therapy – which could occur under a closed formulary – may lead people to stop or delay engaging in care and lengthen the time for them to reach viral suppression. Immediate treatment upon diagnosis has been associated with improved virologic suppression even five years later.⁵² In fact, the Department of Health and Human Services guidelines (DHHS guidelines) recommend “initiating [antiretroviral therapy or ART] immediately (or as soon as possible) after HIV diagnosis in order to increase the uptake of ART and linkage to care, decrease the time to

⁴⁸ 149 Cong. Rec. S15887 (Nov. 25, 2003).

⁴⁹ 42 C.F.R. § 423.120(b)(2)(vi)(C).

⁵⁰ Id.

⁵¹ Marcus JL, Leyden WA, Alexeeff SE, et al., “Comparison of Overall and Comorbidity-Free Life Expectancy Between Insured Adults With and Without HIV Infection, 2000-2016,” JAMA Netw Open, June 2020, 2020;3(6):e207954, <https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2767138>.

⁵² See S. Lodi et al., *Comparative effectiveness of immediate antiretroviral therapy versus CD4- based initiation in HIV-positive individuals in high-income countries: observational cohort study*, 2 LANCET HIV E335 (2015) (demonstrating that “rapid start”, or immediate initiation of HIV therapy upon diagnosis, has been shown to suppress the virus faster, and to improve retention in care); Liz Highleyman, *RAPID Program Leads to Faster HIV Suppression*, AIDSmag, <https://www.aidsmap.com/news/jul-2015/same-day-start-antiretroviral-treatment-leads-faster-hiv-suppression-san-francisco> (2015) (stating that participants in San Francisco General Hospital’s “Rapid- start” ART program achieved an undetectable viral load within 56 days of diagnosis, compared with 119 days for those on a standard treatment schedule).

viral suppression for patients, and improve the rate of virologic suppression among persons with HIV.”⁵³

Like Medicare Part D beneficiaries, patients who obtain coverage through the health insurance exchanges can choose plans with a formulary that is best suited to their individual needs and can also change their plan during the annual open enrollment period. In addition, these patients would have access to an exceptions process to obtain their medically necessary medications.⁵⁴ Thus, for prescription drugs, the Draft Application would result in a system in which Medicaid beneficiaries receive a demonstrably lower level of access than similarly situated Oregonians who receive coverage through Medicare Part D or the health insurance exchanges under the Affordable Care Act.

Gilead has been serving and supporting people enrolled in Medicaid for years, including those in Oregon. We are dedicated to ensuring that the state’s policy decisions support health and wellbeing for these individuals, and for all vulnerable populations in Oregon. We, therefore, encourage the Oregon Health Authority to carefully reconsider its demonstration proposal, specifically by continuing to cover all medicines subject to a National Drug Rebate Agreement through the Medicaid program. This is especially critical for infectious diseases and for cancer in which many innovative life-saving therapies have been approved by the FDA via an accelerated pathway. A closed formulary clearly exceeds CMS’s authority and fails to promote the recognized objectives of the Medicaid program. Accordingly, we ask that Oregon ensure that Medicaid beneficiaries have continued access to quality, medically necessary care.

Thank you for the opportunity to provide comments on Oregon’s Draft 2022-2027 Medicaid 1115 Demonstration Application. If you have any questions about our comments, please contact Ryan Faden at ryan.faden@gilead.com.

Yours sincerely,



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⁵³ Department of Health and Human Services. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed [September 8, 2021] [Page E-1]

⁵⁴ Know Your Rights in the Health Insurance Marketplace. Available at: <https://marketplace.cms.gov/outreach-and-education/know-your-rights.pdf>.