UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RONNIE MAURICE STEWART, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 1:18-cv-152 (JEB)
	)	
ALEX M. AZAR II, et al.,	)	
	)	
Defendants.	)	

REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND PLAINTIFFS' UNIFIED RESPONSE IN OPPOSITION TO FEDERAL DEFENDANTS' MOTION TO DISMISS AND FEDERAL DEFENDANTS' AND COMMONWEALTH INTERVENORS' MOTIONS FOR SUMMARY JUDGMENT

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INTRODUCTION

If Defendants are to be believed, the Secretary's authority to grant a waiver under Section 1115 is limited by nothing more than the Secretary's own desires. The Secretary is free to ignore as many and whichever of Medicaid's requirements as he sees fit, so long as he determines that the project is likely to promote the objectives of the Medicaid Act. And, since according to Defendants, there are no express objectives, the Secretary is free to make them up. Finally, Defendants argue that the Secretary's waiver approvals are not reviewable by this Court. In short, under Defendants' view, the Secretary can do whatever he wants to Medicaid through his power to "waive" the Act's requirements, and these decisions are insulated from judicial review.

This is not how Congress drafts statutes. "Congress enacts laws that define and, equally important, circumscribe the power of the Executive to control the lives of the citizens." *Chamber of Commerce of the U.S.A. v. U.S. Dep't of Labor*, 885 F.3d 360, 387 (5th Cir. 2018); *see also Ctr. for Biological Diversity v. EPA*, 722 F.3d 401, 413 (D.C. Cir. 2013) ("Congress sets the policy in the statutes it enacts; [the agency] has discretion to act only within the statutory limits set by Congress."). And while Congress has seen fit, on occasion, to grant the Executive flexibility to waive or modify a statute's requirements to more effectively carry out its purposes, such delegations have never been understood to give the Executive unbounded authority to fundamentally rework the statute. For Congress's delegation to pass constitutional muster, there must be some "intelligible principle" to guide the Secretary's exercise of discretion. *Whitman v. American Trucking Ass'ns, Inc.*, 531 U.S. 457, 458 (2001).

Defendants' interpretation of the Secretary's Section 1115 authority runs roughshod over these fundamental separation of powers principles. By their own admissions, the Secretary's approval is designed to "comprehensively transform" Medicaid and result in at least 95,000 low-income Kentuckians *losing* access to medical assistance, including 19,000 traditional Medicaid

recipients, *i.e.*, parents and caregivers. *See* AR 5421 (listing eligible member months for Demonstration Year 5 without waiver); AR 5422 (listing eligible member months for Demonstration Year 5 with waiver). The Secretary's approval also rewrites the purposes of the Act to "restructure[]" Medicaid into a work-oriented program aimed at teaching people about commercial insurance.[1] Encouraging individuals to work may be a worthy policy goal, but it is manifestly *not* the goal of Medicaid, which Congress enacted to provide "medical assistance" and "rehabilitation and other services" to those individuals "whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396-1.

Defendants attempt to justify their arbitrary rewriting of the Medicaid Act by asserting that the demonstration project as a whole, and the work requirements in particular, primarily target the expansion population. But as the approval reveals, the requirements and penalties, in fact, also apply to "traditional" populations. Nor does focusing on the expansion population save the Secretary's decision. The Affordable Care Act did not expand the Secretary's Section 1115 authority or alter the Medicaid Act's purposes; it merely extended Medicaid coverage to an additional group of low-income people. Defendants may disagree with the Medicaid expansion, but they are tasked with executing the laws, not "explod[ing]" them through use of Section 1115.[2] Indeed, Congress included a provision in the Affordable Care Act requiring the Secretary, when reviewing Medicaid Section 1115 waivers, such as this one, to do so consistent with the requirements of Title XIX. Patient Protection and Affordable Care Act, Pub. L. No. 111-148,

[1] Seema Verma, *The Future Of: Healthcare*, Wall St. J. (Nov. 10, 2017), http://www.wsj.com/video/the-future-of-health-care/D5B767E4-B2F2-4394-90BB-37935CCD410C.html.

[2] Amy Goldstein & Juliet Eilperin, *Affordable Care Act Remains "Law of the Land," but Trump Vows to Explode It*, Wash. Post (Mar. 24, 2017), https://www.washingtonpost.com/national/health-science/affordable-care-act-remains-law-of-the-land-but-trump-vows-to-explodeit/2017/03/24/4b7a2530-10c3-11e7-ab07-07d9f521f6b5_story.html.

§ 10201(i), 124 Stat. 119, 922 (codified at 42 U.S.C. § 1315(d)).

Defendants sum up this case best when they observe that "the questions plaintiffs raise about community engagement . . . 'are issues to be resolved in Congress and at the polls.'" Fed. Defs.' Mem. In Supp. of Mot. to Dismiss, or in the Alternative, for Summ. J., and in Opp'n to Pls.' Mot. for Partial Summ. J., ECF No. 54, at 4 (hereinafter "Fed. Br."). Contrary to Defendants' assertion, however, Plaintiffs are not the ones asking the Court to resolve these questions. Rather, they are asking the Court to intercede to ensure that Congress, not unelected bureaucrats, is the one to answer them.

ARGUMENT

I. The Plaintiffs Have Standing To Challenge The Secretary's 1115 Waiver Grant.

Federal Defendants concede Plaintiffs have standing to bring their APA claims challenging the Kentucky HEALTH waiver as a whole (Count 8) and their Take Care Clause claim (Count 9). While including a passing reference to Plaintiffs' Dear State Medicaid Director Letter claim (Count 1), Fed. Br. at 43-44, Defendants focus their arguments on the challenges to the waiver's individual components, *id.* at 27 (challenging Counts 2 through 7). But having admitted that Plaintiffs have standing to challenge the program as a whole, the claim that Plaintiffs somehow lack standing to challenge the building blocks of that program rings hollow. At any rate, the Government is incorrect: Plaintiffs have standing to challenge each component of Kentucky HEALTH.

Plaintiffs represent a class of Kentuckians who are likely to be subject to the work requirements, premiums, and other onerous requirements when they begin on July 1, 2018. Plaintiffs may pursue their claims as long as at least one named Plaintiff has standing to bring each claim. Ky.'s Mem. In Supp. of Mot. for Summ. J. & Resp. to Pls.' Mot. for Summ. J., ECF No. 50-1, at 3 (hereinafter "Ky. Br."). *See, e.g.*, 1 William B. Rubenstein, *Newberg on Class Actions* §

2:5 (5th ed. 2011). While Defendants attempt to pick off some class representatives with respect to specific claims, they cannot show that *all* of the class representatives lack standing for any particular claim.

A. Plaintiffs Will Suffer Imminent Injury If Kentucky HEALTH Is Implemented.

Plaintiffs' injuries are sufficiently imminent to satisfy standing. Defendants' arguments boil down to the premise that Plaintiffs lack standing to stop a program that has yet to take effect. *See* Fed. Br. at 27-28. That is not the law. *See, e.g.*, *U.S. Telecom Ass'n v. FCC*, 825 F.3d 674 (D.C. Cir. 2016) (pre-enforcement challenge to regulation), *petition for cert. filed*, 86 U.S.L.W. 3195 (U.S. Sept. 28, 2017) (No. 17-498).

The D.C. Circuit in *Village of Bensenville v. FAA*, 376 F.3d 1114 (D.C. Cir. 2004), rejected this very argument. The court held that municipalities had standing to challenge the FAA's approval of Chicago's application to impose a $4.50 facility fee on passengers traveling by plane from O'Hare airport. *Id.* at 1119. That injury was sufficiently imminent, even though Chicago would not start collecting the fee for another *thirteen years*, because the FAA's order was final, and "absent action by [the court], come 2017 Chicago will begin collecting the passenger facility fee." *Id.* As a result, "the impending threat of injury to the municipalities is sufficiently real to constitute injury-in-fact and afford constitutional standing.'" *Id.* (quotation marks and alteration omitted).

Bensenville's reasoning applies equally to the health care context. Indeed, courts across the nation have held that plaintiffs had standing to challenge the Affordable Care Act's individual mandate years before implementation." *See, e.g.*, *Ass'n of Am. Physicians & Surgeons, Inc. v. Sebelius*, 901 F. Supp. 2d 19, 36 (D.D.C. 2012) (holding plaintiffs could challenge individual mandate pre-enforcement, where they showed "a substantial probability that the plaintiffs would

be adversely affected, given the finality of the act, the fact that it will take effect at a definite point in time, and the high likelihood that the plaintiffs will qualify as individuals subject to the requirement"), *aff'd.*, 746 F.3d 468 (D.C. Cir. 2014)).

Under these precedents, the Plaintiffs' injuries are imminent. The Secretary has granted Kentucky's waiver, and Kentucky HEALTH will begin in a month-and-a-half—action and timing far more imminent than in *Bensenville* or the individual mandate cases. The harms Plaintiffs face bear no relationship to the speculative harms Defendants parade in their briefing, such as the possibility that certain agency decisions may harm the environment *at some point* in the future, *Am. Petroleum Inst. v. U.S. EPA*, 216 F.3d 50 (D.C. Cir. 2000), or that the government may have targeted plaintiff's communications at some unknown time, *Clapper v. Amnesty Int'l. USA*, 568 U.S. 398 (2013), or the potential injury an inmate may experience only after—and if—he receives a new trial through habeas relief, is convicted, and receives a particular sentence, *Whitmore v. Arkansas*, 495 U.S. 149 (1990).

What is more, Plaintiffs have alleged injuries stemming from each individual piece of the Kentucky HEALTH program.

Work Requirements and Premiums. Plaintiffs have alleged a substantial likelihood that they will be subject to and injured by work requirements and premiums. Both provisions apply to most working age adults, and Defendants cannot assert that Plaintiffs will be exempted as former foster care youth or pregnant women.

There will be a handful of additional exemptions—medically frail individuals for both requirements, and full-time students, primary caregivers of a dependent, or individuals with acute medical conditions for work requirements. AR 0042. While it is possible that some Plaintiffs may be able to prove that they qualify for an exemption, such "possible changes" are "by no means

certain, or even likely to occur." *Mead v. Holder*, 766 F. Supp. 2d 16, 24 (D.D.C. 2011).

Plaintiffs have alleged facts indicating it is substantially likely that they may be unable to meet the premium and work requirements. *See, e.g.*, Penney Decl. ¶¶ 5, 15[3] (previously unable to work, and at times unable to work, due to depression or anxiety); Radford Decl. ¶ 5 (looking for a job, but noting that few exist in his town); M. Woods Decl. ¶ 8 (as a self-employed car repairman, his hours fluctuate wildly based on the amount of business he receives each week); Bennett Decl. ¶¶ 3, 8 (works two part-time jobs, but worried he will lose Medicaid if he cannot work enough hours); Spears Decl. ¶ 9 (unable to work due to ongoing medical issues), *id.* ¶ 10 (cannot pay premiums because she makes no money); Stewart Decl. ¶¶ 3, 8 (retired at age 62 because he was no longer able to do work requiring him to stand); *id.* ¶ 9 (if he pays for his premiums, other expenses will go unpaid); Branham Decl. ¶ 4 (has difficulty finding work due to lack of public transportation and no driver's license); Ballinger Decl. ¶ 8 (paying premiums will be difficult); McComas Decl. ¶ 12 (premiums will be difficult, and she has struggled to pay them in the past). *Cf. Grid Radio v. FCC*, 278 F.3d 1314 (D.C. Cir. 2002) (plaintiffs had standing to challenge policy, although exemption existed that plaintiff had not applied for, because applying for exemption was likely to be futile).

Non-Emergency Use of the Emergency Department. Plaintiffs' allegations show a substantial likelihood that they will be required to use the emergency room for sudden needs. *See, e.g.*, Ballinger Decl. ¶ 15 (prior visits to the emergency room due to spleen pain, high fever, and concussion); M. Woods Decl. ¶ 11 (visit after a work accident); Spears Decl. ¶ 11 (visits due to seizures, anaphylactic attacks, and tachycardia attacks); Allen Decl. ¶ 6 (went to emergency room

[3] Plaintiffs' Declarations are attached as exhibits to Plaintiffs' Memorandum in Support of Motion for Summary Judgment, ECF No. 33-1 (hereinafter "Pls.' Br.").

after car accident).

Defendants claim that Plaintiffs "merely speculate that they *may* someday go to a hospital's emergency department." Fed. Br. at 30. An individual's future need for health care—especially from an emergency department—cannot be stated with certainty. But Plaintiffs have identified specific medical conditions and injuries that have required urgent care in the past and are substantially likely to recur, as well as ongoing conditions, such as seizures, for which they are likely to seek urgent (though not necessarily "emergency") care. Given the nature of the injuries, Plaintiffs have alleged a "substantial probability" of injury. *Ass'n of Am. Physicians & Surgeons, Inc.*, 901 F. Supp. 2d at 36.

Non-Emergency Medical Transportation. Plaintiffs have sufficiently alleged that they will be injured by the loss of non-emergency transportation. Several Plaintiffs lack a driver's license and/or vehicle and do not have access to public transportation. *See, e.g.*, Branham Decl. ¶ 4 (no driver's license or public transportation); Bennett Decl. ¶ 6 (cannot drive due to cataracts in both eyes and glaucoma); McComas Decl. ¶ 10 (no car); Spears Decl. ¶ 12 (cannot drive, and seeking transportation assistance from her mother imposes difficulties on her mother); Radford Decl. ¶ 5 (no car). When they require medical treatment—and are not able to prevail on a friend or relative to drive them—they will be required to rely on NEMT. This is sufficient to confer standing.

Lockouts and Waiver of Retroactive Coverage. Plaintiffs alleged that they will lose their Medicaid coverage due to the Kentucky HEALTH lockouts if they fail to comply with the program's administrative requirements. *See, e.g.*, Allen Decl. ¶ 8 (fear of being locked out of Medicaid for failure to report because her husband's income varies each week); Spears Decl. ¶¶ 4, 9 (fear of being locked out because she struggles to work for medical reasons); M. Woods Decl. ¶¶ 5, 8 (income varies wildly because he is self-employed, and it would be difficult to report

income changes within required timeframe); S. Woods Decl. ¶¶ 3, 8 (same); McComas Decl. ¶ 11 (income varies due to unpredictable work hours, and it would be difficult to report income changes). Plaintiffs face a substantial likelihood of losing health coverage for up to six months due to a lockout period and, without retroactive eligibility, will have gaps in coverage.

The Commonwealth argues that certain of Plaintiffs' injuries are self-inflicted and therefore cannot support standing because Plaintiffs could "merely" follow the reporting requirements or choose not to use the emergency room. Ky. Br. at 7, 8. That is not the law. *See, e.g.*, *Mead*, 766 F. Supp. 2d at 20, 24 (holding plaintiffs could challenge individual mandate even though they could have chosen to comply with the insurance requirements and therefore avoid the penalty); *Okla. Dep't of Envtl. Quality v. EPA*, 740 F.3d 185, 190 (D.C. Cir. 2014) ("The possibility of an alternative remedy, of uncertain availability and effect, does not render its injury self-inflicted"). The theoretical ability to comply with a law does not undermine a plaintiff's ability to challenge it.

B. Plaintiffs' Injuries Will Likely Be Redressed By The Requested Relief.

Kentucky argues that the Governor's threat to withdraw the Commonwealth from the Medicaid expansion entirely *if* Plaintiffs prevail in this suit somehow vitiates Plaintiffs' ability to bring suit in the first place. Ky. Br. at 3.

The Governor's bullying, however, does not strip the Plaintiffs of standing here. The Supreme Court and the D.C. Circuit have held that injuries are redressable even if there is no guarantee that the plaintiff will ultimately receive the benefit in question due to a party's subsequent actions. For example, a real estate developer had standing to challenge a racially discriminatory rezoning denial that prohibited the developer from building integrated housing; the developer's injury was redressable because it removed an "absolute barrier," even if invalidating the rezoning denial did not guarantee the developer would ultimately be able to secure needed

federal subsidies or carry through with construction. *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 261-62 (1977); *see also Teton Historic Aviation Found. v. U.S. Dep't of Defense*, 785 F.3d 719, 724-25 (D.C. Cir. 2015) (purchaser of aircraft parts showed redressable injury even if it could not prove that invalidating Department of Defense policy would force the Department to sell or accept the purchaser's bid.); *cf. Fla. Bankers Ass'n v. U.S. Dep't of Treasury*, 19 F. Supp. 3d 111 (D.D.C. 2014) (permitting challenge to IRS's reporting requirement, even though invalidating requirement would provide no permanent guarantee against future requirements), *vacated on other grounds*, 799 F.3d 1065 (D.C. Cir. 2015), *cert. denied*, 136 S. Ct. 2429 (2016).

These principles should apply with even more force here, where the Governor's attack on Plaintiffs' standing is based on his own browbeating. If the Commonwealth's view of the law were correct, government officials could avoid judicial reckoning through any number of bullying proclamations—simply making the threat would insulate governmental action from judicial scrutiny. That is not—and cannot be—the law. And it is conduct that should not be rewarded.

If Plaintiffs prevail, the Governor will have to await any decision on appeal and decide whether to proceed with a decision that will take Medicaid coverage away from hundreds of thousands of Kentuckians. Moreover, he would certainly face a challenge that he cannot lawfully rescind Medicaid coverage for the mandatory expansion population. *See, e.g.*, 42 U.S.C. § 1396a(a)(10)(A)(i) (requiring the state to "provide . . . for making medical assistance available" to mandatory populations); *id.* § 1396a(a)(10)(A)(i)(VIII) (categorizing the "expansion" population as a mandatory category of beneficiaries); *Nat'l Fed. of Indep. Business v. Sebelius*, 567 U.S. 519, 580-86 (2012) (holding that the federal government may not compel states to take up the Medicaid expansion in the first place by threatening to withhold all federal Medicaid

funding, but leaving intact the statutory scheme otherwise treating the expansion population as mandatory once covered); Op. Denying Mot. to Transfer, ECF No. 42 (hereinafter "Transfer Op.") ("[i]f the state decides to cover the expansion group . . . those individuals become part of the state's mandatory population"). The possibility that the current Governor will end the expansion is dependent on multiple future decisions of governmental and judicial actors; the requested relief remains at least "likely, as opposed to merely speculative." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (quotation omitted).

C. Plaintiffs Have Standing To Challenge The Dear State Medicaid Director Letter.

Finally, to the extent Defendants challenge Plaintiffs' standing vis-à-vis the Dear State Medicaid Director (DSMD) Letter, the challenge fails. Fed. Br. at 43-44. Plaintiffs' injuries flow not just from the approval of Kentucky HEALTH, but also from the Letter on which that approval expressly relies. *See* AR 0008-09. Plaintiffs thus have standing to challenge both the approval *and* the rule invoked to support the approval. *See Ark Initiative v. Tidwell*, 64 F. Supp. 3d 81, 96 (D.D.C. 2014), *aff'd*, 816 F.3d 119 (D.C. Cir. 2016). As this Court has held, redressability is satisfied where vacating guidance would prevent the plaintiff from having to challenge the same guidance in reference to future agency decisions. *See Scenic Am., Inc. v. U.S. Dep't of Transp.*, 983 F. Supp. 2d 170, 181 (D.D.C. 2013). Plaintiffs have established injury consistent with Article III's commands.

II. The Secretary's Section 1115 Waiver Grant Is Judicially Reviewable.

Defendants face a "heavy burden" to overcome the "strong presumption that Congress intends judicial review of administrative action." *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670-72 (1986); *see also Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967) (APA "embodies the basic presumption of judicial review" of agency action), *abrogated on other*

grounds by Califano v. Sanders, 430 U.S. 99 (1977). A decision is unreviewable "in those rare circumstances where statutes are drawn in such broad terms that in a given case there is no law to apply." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). The Secretary's decision does not fit that "very narrow" exemption, *Heckler v. Chaney*, 470 U.S. 821, 830 (1985), reserved for actions "committed to agency discretion by law," 5 U.S.C. § 701(a)(2).

All federal courts to face the question have found that the Secretary's decision to grant a Section 1115 waiver is judicially reviewable. *See Beno v. Shalala*, 30 F.3d 1057, 1067 (9th Cir. 1994) ("the granting of an exemption from statutory requirements is not an area of agency discretion traditionally unreviewable," and Section 1115 does not fit that mold because it "allows waivers only for the period and extent necessary to implement experimental projects which are 'likely to assist in promoting the objectives' of the AFDC program; the AFDC program's objectives are set forth with some specificity");[4] *see also, e.g.*, *Newton-Nations v. Betlach*, 660 F.3d 370, 380 (9th Cir. 2011); *C.K. v. N.J. Dep't of Health & Human Servs.*, 92 F.3d 171, 183 (3d Cir. 1996); *Aguayo v. Richardson*, 473 F.2d 1090, 1105 (2d Cir. 1973).

This case is a far cry from those in which courts have held statutory questions to be unreviewable. The statute at issue in *Webster v. Doe*, 486 U.S. 592 (1988), upon which the Secretary relies, Fed. Br. at 11, "exhibit[ed] the Act's extraordinary deference to the Director in his decision to terminate individual employees." *Id*. at 601. The statute gave wide latitude to terminate an employee "whenever [the CIA Director] shall deem such termination necessary or advisable in the interests of the United States." 50 U.S.C. § 403(c). Unlike the bald grant of

[4] This discussion belies Federal Defendants' claim that the Ninth Circuit "brushed aside the statutory language." Fed. Br. at 12.

discretion in *Webster*, the Secretary's Section 1115 waiver authority is pegged to time-limited experiments that promote objectives set out in the Medicaid Act. *See* Part III.C, *infra*. The Secretary's Section 1115 waiver grant is therefore judicially reviewable.

III. The Secretary Cannot Use Section 1115 To Achieve The Executive's Goal Of Fundamentally Restructuring The Medicaid Act.

A. Deference Is Not Appropriate In Cases Of Deep Economic And Political Significance.

Defendants argue that, even if the Secretary's actions are reviewable, they are entitled to *Chevron* deference. Fed. Br. at 13; Ky. Br. at 16. But the Supreme Court has made clear that agencies are not entitled to deference on a question "of deep 'economic and political significance' that is central to [a] statutory scheme." *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (quoting *Util. Air. Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2444 (2014)). That is especially true when "an agency claims to discover in a long-extant statute an unheralded power to regulate a significant portion of the American economy," and asserts that power in a way that would "bring about an enormous and transformative expansion," in the agency's authority "without clear congressional authorization." *Util. Air Regulatory Grp.*, 134 S. Ct. at 2444. This is exactly what HHS has done here: It asks this Court to read into the isolated terms "waive compliance with" and "objectives" a power to, without Congress, transform the Medicaid program state-by-state. In other words, the Secretary now asks this Court, under the guise of deference, to look the other way and allow the agency to make good on President Trump's promise to "explode" the ACA and its Medicaid expansion, *see* Goldstein & Eilperin, *supra* note 2, and use "administrative actions[] to fundamentally transform Medicaid."[5]

[5] Seema Verma, *Lawmakers Have a Rare Chance to Transform Medicaid. They Should Take It*, Wash. Post (June 27, 2017), https://www.washingtonpost.com/opinions/lawmakers-have-a-rare-chance-to-transform-medicaid-they-should-take-it/2017/06/27/f8e5408a-5b49-11e7-9b7d-14576dc0f39d_story.html?utm_term=.11a4dfe727df.

As those statements highlight, this case involves questions of deep economic and political significance. Indeed, as this Court has already acknowledged, while Kentucky is first in line, the questions raised here "carr[y] national consequences, particularly in light of CMS's invitation to other states to use Section 1115 waivers in a similar way." Transfer Op. at 14. Given the significant consequences, and the breadth and novelty of the Secretary's interpretations, the Court should proceed directly to the statutory interpretation question. *King*, 135 S. Ct. at 2489.[6]

At any rate, even if the Court applies the *Chevron* framework, the Secretary's interpretations do not warrant deference because they are "inconsisten[t] with the design and structure of the statute as a whole." *Util. Air Regulatory Grp.*, 134 S. Ct. at 2442 (alteration in original). And even if this Court holds that the relevant provisions are ambiguous (and they are not), CMS's interpretations of the statute are unreasonable. *See, e.g.*, *ACA Int'l v. FCC*, 885 F.3d 687, 698 (D.C. Cir. 2018).

Defendants' citation to *Pharmaceutical Research & Manufacturers of America v. Thompson*, 362 F.3d 817 (D.C. Cir. 2004), does not change this outcome. Fed. Br. at 13. In that case, the Court of Appeals concluded that state plan amendments (SPAs) are generally the kind of agency action that can be entitled to *Chevron* deference. *Pharm. Research*, 362 F.3d at 822. But that does not mean *every* approval receives deference; courts must still apply the *Chevron* framework to determine if deference is warranted in a particular case. *See Cal. Ass'n of Rural Health Clinics v. Douglas*, 738 F.3d 1007, 1014 (9th Cir. 2013) ("we . . . do not defer to CMS's

[6] To the extent that the Secretary relies on the DSMD letter (and studies cited therein) to justify his decision to grant Kentucky's waiver request, and the DSMD letter is found to be nonbinding guidance as opposed to a substantive rule, the Secretary's decision also is not entitled to *Chevron* deference under the Supreme Court's decision in *United States v. Mead Corp.*, 533 U.S. 218, 234 (2001) ("interpretations contained in policy statements, agency manuals, and enforcement guidelines . . . are beyond the *Chevron* pale" (internal quotations and citation omitted)).

approval of the challenged SPA," because the statute was unambiguous); *Christ the King Manor, Inc. v. Sec'y U.S. Dep't of Health & Human Servs.*, 730 F.3d 291, 313 (3d Cir. 2013) (where "HHS's approval of a SPA rests on [incorrect] interpretation, it is not a permissible construction of the statute entitled to deference under *Chevron*" (internal quotation marks omitted)). Thus, Defendants' argument that all Section 1115 approvals are entitled to deference misconstrues the decisions in *Pharmaceutical Research.* and in *Chevron* itself.

B. The Secretary Cannot Fundamentally Restructure The Medicaid Act By Rewriting The Objectives Of The Act.

The record does not support the conclusion that Kentucky HEALTH furthers the objectives of Medicaid, and therefore the Secretary's approval is arbitrary and capricious. Plaintiffs' opening brief discusses the Medicaid Act's straightforward objectives of enabling states to furnish medical assistance and rehabilitation and other services to individuals who cannot afford to pay, and it explains why the Secretary cannot ignore or overhaul those objectives using Section 1115. In an attempt to sidestep these objectives, Defendants contend there are two Medicaid programs—one for "traditional" groups and another for the ACA Medicaid expansion. Fed. Br. at 1, 23-24; Ky. Br. at 15. They argue that the purposes of the two programs differ, with Section 1396-1 establishing the purposes for the traditional group, and the Secretary deciding the purposes for the latter group. Fed. Br. at 21, 23; Ky. Br. at 16. Defendants also attempt to construe Section 1396-1 to authorize their radical transformation, but their interpretation is a perversion of the objectives of the Medicaid program.

1. Congress Has Established One, Not Two, Medicaid Programs.

Defendants read Section 1396-1's reference to "families with dependent children and . . . aged, blind, or disabled individuals," to set up their policy preference that the expansion population not be included in Medicaid in the first place. Fed. Br. at 23; Ky Br. at 15-16.

First, whether Defendants like it or not, when Congress enacted the Medicaid expansion, it did not create two programs. Congress included the expansion population in the same Medicaid provision that includes the families with dependent children and aged, blind, or disabled individuals that are listed in Section 1396-1. Specifically, Congress added Subsection VIII to Section 1396a(a)(10)(A)(i), creating another mandatory population, and assigned that population a benefit package already available to some other enrollees, 42 U.S.C. § 1396a(k). And when Congress made this change, it referred to one Medicaid program, not two. *See, e.g.*, H.R. Rep. 111-443 (I), at 204 (2010) ("Medicaid will be expanded so that anyone below 133 percent of poverty will be Medicaid eligible and that expansion will be fully federally financed."); H.R. Rep. 111-443 (II), at 977 (2010) (the expansion "strengthens the Medicaid program by improving access to primary care services and providers, and expands eligibility so that all individuals under 133 percent of the federal poverty level are assured Medicaid coverage").[7]

This is the approach Congress takes when adding mandatory populations. For example, Congress has amended Section 1396a(a)(10)(A)(i) to expand medical assistance to low-income pregnant women, emancipated children, and former foster youth. *See* Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, § 302, 102 Stat. 683, 750; Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6401, 103 Stat. 2106, 2258; Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4601, 104 Stat. 1388, 1388-166; Patient

[7] Drawing sharp lines between "traditional" and "expansion" populations is not as simple as Defendants make out. As Plaintiffs' own circumstances reveal, many people covered by the expansion are families with dependent children. Defendants' arguments rest on defining a group of "able-bodied adults," a term not used in the statute. That is because Medicaid is health insurance for all low-income people who meet the statutory eligibility requirements. Program benefits include not only treatment services for individuals who are sick or have a disability, but also preventive care (*e.g.*, check-ups and cancer screens) designed for all insured individuals. *See* 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a) (describing covered Medicaid services).

Protection and Affordable Care Act, § 2004, 124 Stat. at 283. None of these groups are mentioned in Section 1396-1; yet, it would be inconceivable for Defendants to argue that Congress intended to establish separate Medicaid programs, with differing purposes, for each of these groups.

Second, Defendants' interpretation necessarily implies that by adding the expansion population, Congress intended to dramatically expand the Secretary's Section 1115 power by untethering it from the purposes of Section 1396-1. But Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions." *Whitman*, 531 U.S. at 468. Moreover, when Congress expanded Medicaid as part of the ACA, it also amended Section 1115. Among other things, Congress added substantive limitations directing the Secretary to ensure that a waiver "that would result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing . . . will be in compliance with subchapter XIX . . . of this chapter." 42 U.S.C. § 1315(d)(2)(iii). Thus, Congress underscored its intent that waivers, such as this one, be "in compliance" with subchapter XIX, of which Section 1396-1 is a part.

Also fatal to the Secretary's "two program" argument is the fact that it was not advanced by the agency when making its decision. The DSMD Letter cited Section 1396-1 as the *sole* statutory authority for the "Medicaid program objectives." AR 0090. When explaining the approval of the work requirement components of Kentucky HEALTH, CMS identified "the authorizing language in Section 1901 of the Social Security Act" as the sole statutory basis for its interpretation of the "statutory objectives." AR 0005. Having relied on Section 1396-1 to make its decisions, CMS's new litigating position is not entitled to deference. *See, e.g.*, *Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 156-57 (1991) (interpretations raised in litigation are not entitled to deference). In short, the Secretary must abide by the objectives set out in Section 1396-1.

2. Defendants' Reading Of Section 1396-1 Ignores Both The Words And the Context Of The Statute.

After dismissing Section 1396-1, Defendants nonetheless argue that the Kentucky approval is consistent with that Section. These arguments, however, rip terms within the Section from their mooring.

First, the Secretary emphasizes the phrase "under the conditions in such State" to argue that the approval was justified by budgetary constraints. Fed. Br. at 22. But reading the phrase in full—"as far as practicable under the conditions in such State," it is clear that Congress's goal was for states to extend coverage as far as *reasonably* possible. 42 U.S.C. § 1396-1. The "conditions" clause serves as a limitation on the central goal of enabling states to furnish assistance "as far as practicable." *Id.* The isolated clause neither permits the Secretary to approve waivers based on budgetary constraints nor permits the Secretary to prioritize furnishing medical assistance among mandatory populations. *Cf. Beno,* 30 F.3d at 1069 (simple benefit cut would not be experimental, even if termed a "work incentive"). Furthermore, the citations that the Secretary relies on to argue that "budgetary" considerations are themselves objectives underscore this point: Each refers to the "efficient and proper *administration*" of the state plan and provides federal reimbursement for administrative costs, to enable the states to do the practical, logistical work of "furnish[ing]" assistance. *See* Fed. Br. at 20 (citing 42 U.S.C. § 1396a(a)(4)(A), (a)(24), (a)(42)(B)(ii)(IV); § 1396b(a)(2)(A)). These references do not support a reading of the Medicaid Act that takes as an express goal reducing and limiting *coverage* or *benefits* to save money.

Next, the Secretary asserts that Section 1396-1 contemplates entirely unspecified "other purposes" that the Secretary is free to determine. Fed. Br. at 20. The Secretary points to the language in Section 1396-1 that "there is hereby authorized to be appropriated for each fiscal year a sum sufficient to carry out the purposes of this subchapter." But the statute does not refer to

some ambiguous "additional" or "other" purposes. It uses the definite article "the" to refer to the enumerated purposes that appear immediately prior. *See Noel Canning v. NLRB*, 705 F.3d 490, 500 (D.C. Cir. 2013) ("[T]he word 'the' was and is a definite article," and "suggests specificity.").

The sheer breadth of the Secretary's "other purposes" interpretation should give the Court pause. Under the Secretary's reading, the Medicaid Act's "overarching purpose" is to "promote public health and well-being." Fed. Br. at 20. This high level reading ignores the Medicaid Act's more specific—and express—purpose of "furnish[ing] . . . medical assistance . . . and rehabilitative and other services." 42 U.S.C. § 1396-1. And while improving public health and health outcomes might be a desirable *result* of furnishing medical assistance, the Secretary has no authority to isolate that desired outcome from the specific mechanisms Congress prescribed for achieving it. *See Waterkeeper Alliance v. EPA*, 853 F.3d 527, 535 (D.C. Cir. 2017) ("Agencies are . . . bound not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes"). Defendants may believe that mechanisms other than furnishing medical assistance are more effective at improving health outcomes, but they must nevertheless abide by the choices Congress made. *See Ams. for Clean Energy v. EPA*, 864 F.3d 691, 712 (D.C. Cir. 2017) ("[T]he fact that EPA thinks a statute would work better if tweaked does not give EPA the right to amend the statute.").

Absent this tie to the words of the statute itself, the Secretary would be able to approve *any* policy that he subjectively concludes might influence health outcomes. For instance, the Secretary could authorize states to require individuals to adopt a vegetarian, low-carb diet as a condition of eligibility, because such diets could have positive health outcomes. An interpretation that rests on such expansive and nebulous concepts would allow the Secretary to expand his own authority to include areas governed by other statutes and other agencies (*e.g.*, housing, environmental

regulations, or workplace safety standards—all of which likely have stronger correlations with "health outcomes" than the Medicaid work requirements, premiums, lockouts, or coverage terminations in this case). This is certainly not what is contemplated by Section 1396-1's directive to enable each State to furnish medical assistance and rehabilitation and other services as far as practicable. *Cf. FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000) (an "agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. And in our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." (quotation marks and alterations omitted)).

Kentucky attempts to warp Medicaid's objectives through seizing on Section 1396-1's use of the word "independence," attempting to infuse the word with the concept of "economic" independence from the Medicaid program itself. Ky. Br. at 17-18. That novel interpretation finds no basis in the Medicaid statute or in any prior interpretation of the provision. Congress said the purpose of Medicaid is to furnish medical assistance "and rehabilitation and other services to help such families and individuals attain or retain capability for independence and self-care." 42 U.S.C. § 1396-1. A statutory provision must be understood from the company it keeps. *See Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 224 (D.C. 2001) ("Words draw meaning from context."). Here "independence" does not refer to being free from conflicts-of-interest (as it might in the securities laws), but rather to the possible result of receiving rehabilitation and other health services that will enable individuals to live more independently.[8] The suggestion that

[8] *See, e.g.*, 42 U.S.C. § 1396d(a)(13)(C) (defining rehabilitation services as "any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts . . . for maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level"); 42 C.F.R. § 440.130(d) (federal Medicaid agency definition for rehabilitative services); *id.* § 441.102

Congress intended this word to mean "independence from Medicaid itself" finds no basis in the statute or its history.

C. Section 1115's Authorization To "Waive" Certain Provisions Of The Medicaid Act Does Not Allow The Secretary To Fundamentally Restructure The Medicaid Act.

As explained in Plaintiffs' opening brief, the term "waive," especially when used in the context of time-limited "experimental, pilot, or demonstration projects," refers to a narrow authority not to enforce certain provisions and does not include authority to "transform" or "restructure" the statute Congress has enacted. Pls.' Br. at 13-14.

In fact, Federal Defendants assert that the Secretary did not "fundamentally modify, amend, or change statutory provisions," apparently agreeing that such actions would be unlawful. Fed. Br. at 18. The closest they come to offering an interpretation of their own is the tautological argument that the Secretary "did what Section 1115 expressly authorizes him to do—waive compliance with specific provisions of § 1396a." *Id.* However, Defendants ignore that in effect, they wrote additional eligibility criteria into Section 1396a(a)(10)(A). Defendants' reading runs directly counter to the Supreme Court's admonition that "it is unlikely that Congress would leave" such a major question "to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to 'modify' [a statutory] requirement." *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 231 (1994).

Defendants' efforts to distinguish *MCI* are unsuccessful. They focus myopically on the term "modify" and claim it is narrower than "waive." Ky. Br. at 13; *see also* Fed. Br. at 18 n.7.

(requiring Medicaid agency that provides healthcare to institutionalized beneficiaries to develop individual treatment plans that ensure the "institutional care maintains the beneficiary at, or restores him to, the greatest possible degree of health and independent functioning"); *id.* § 441.515 (defining mandatory home and community-based attendant services coverage as that which provides services in a setting appropriate to the person's disability and needs, and "community-based attendant services and supports that the individual requires to lead an independent life").

MCI's reasoning does not rest on the literal meaning of "modify." The Court went "[b]eyond the word itself," considering a narrow statutory exception to the authority to "modify," as well as the "enormous importance" of the tariff-filing requirement to the Communications Act's overall scheme. *MCI*, 512 U.S. at 228-31. The Court observed that "[r]ate filings are . . . the essential characteristic of a rate-regulated industry," and therefore, *regardless* of how broadly the term "modify" is understood, it could not encompass a "fundamental revision of the statute," such as "elimination of the crucial provision of the statute for 40% of a major sector industry." *Id*. at 231.

Like the Communication Act's tariff-filing requirement, Section 1396a(a)(10)(A)(i)'s eligibility requirements are an "essential characteristic" of the Medicaid program. They establish the categories of individuals that a state plan *must* cover if the state accepts federal funding, including (if the state elects to accept Medicaid expansion funds) "all individuals" in the ACA Medicaid expansion. 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII). Failure to cover a "mandatory eligibility group" under a state plan places all federal Medicaid funds received by the state in jeopardy of being withheld. *Id.* § 1396(c). Section 1396a(a)(10)(A)(i) thus plays a central role in ensuring that federal funds are used to accomplish the purposes for which they were appropriated: to furnish medical assistance and rehabilitative and other services to those who cannot afford them. *Id.* § 1396-1. The "elimination of the crucial provision of the statute,"—*i.e.*, modifying these mandatory eligibility criteria to exclude an entire category of individuals who have incomes below 133% of the federal poverty line ("FPL"), *but who do not work*—is just the kind of "fundamental revision" that Congress does not delegate to agency discretion. *See MCI*, 512 U.S. at 231.

Veering from the statutory text, Defendants support their expansive reading of the Secretary's Section 1115 authority by citing several prior Section 1115 waivers, which they assert are broader in scope than Kentucky's "modest" demonstration project. Ky. Br. at 14; Fed. Br. at

15. Critically, these prior waivers differ *in kind* from Kentucky HEALTH. Pursuant to Section 1115, they were designed to experiment with new ways to deliver care, expand coverage (*e.g.* family planning), and test payment models to improve quality of care. *See, e.g.*, Jessica Schubel, Ctr. on Budget & Policy Priorities, *Senate Health Bill Would Penalize Arizona for Its Innovative and Efficient Medicaid Program* (July 19, 2017), https://www.cbpp.org/research/health/senate-health-bill-would-penalize-arizona-for-its-innovative-and-efficient-medicaid; Tennessee Section 1115 Demonstration Approval & STCs, at 12 (Feb. 1, 2018), https://www.tn.gov/content/dam/tn/tenncare/documents/tenncarewaiver.pdf; Rhode Island Section 1115 Demonstration STCs, at 10 (Oct. 20, 2016), http://www.eohhs.ri.gov/Portals/0/Uploads/Documents/1115Waiver/RISTCswTCs120216.pdf. Whatever the scope of the Secretary's authority, it clearly cannot encompass authorizing a state to provide Medicaid coverage only to a subset of the eligible population that the state prefers or somehow deems worthy—based on work or any other basis. Such distinctions are unconnected to the Medicaid program itself and inconsistent with its objective to furnish insurance coverage to the most needy.

Moreover, the issuance of the DSMD Letter further underscores that the Secretary is attempting to exercise authority that goes far beyond a "modest" waiver. Section 1115 is intended to allow individual states to develop experiments, limited in time and scope, that are meant to improve the provision of medical care to needy people in that state. Here, the Secretary has announced a national policy initiative to impose work requirements in any state that wants them. That strays far beyond the sort of limited experiment that the statute was intended to permit.

D. Defendants' Expansive Reading Of The Section 1115 Authority Raises Constitutional Concerns Regarding The Scope Of Delegation.

To the extent Defendants suggest that the objectives of the Medicaid Act were not clearly set forth by Congress and that the Secretary either is entitled to choose those objectives or

otherwise to receive *Chevron* deference as to his interpretation of those objectives, it creates a constitutional problem where none should exist. Whatever the parameters of the non-delegation doctrine, it cannot authorize an Executive Branch official to: a) choose the objectives of a congressional statute; b) waive virtually any requirement that Congress imposed based on the Executive Branch's chosen objectives; and c) re-direct billions of dollars of federal spending to suit the Secretary's policy desires. As the Ninth Circuit held in interpreting the waiver authority, "[w]hile [the Secretary's waiver authority] obviously represents a congressional judgment that, in certain circumstances, such an override is appropriate, we doubt that Congress would enact such comprehensive regulations, frame them in mandatory language, require the Secretary to enforce them, and then enact a statute allowing states to evade these requirements with little or no federal agency review." *Beno*, 30 F.3d at 1068-69.

Under Defendants' interpretation, the *only* intelligible principle offered by Congress to govern the substance of Section 1115 demonstration projects is that the projects must be "likely to assist in promoting the objectives of" the Medicaid Act. Fed. Br. at 10-11 (quoting 42 U.S.C. § 1315). The Secretary asserts that he may invent new, competing objectives, with no statutory grounding at all, and then proscribe new Medicaid policy, based on his "overall judgment of how the [un-codified and un-defined] competing goals of the program might best be served." *Id.* at 21. Such a broad interpretation of the Secretary's authority must be rejected under the doctrine of constitutional avoidance. *See Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989) (nondelegation concerns result in "giving narrow constructions to statutory delegations that might otherwise be thought to be unconstitutional.").

IV. The Secretary's Approval Of The Kentucky Health Waiver Is Arbitrary, Capricious, An Abuse Of Discretion, And Not In Accordance With Law.

Defendants throw up a smokescreen, suggesting that Plaintiffs are demanding that the

Secretary address individually every comment in the record. Fed. Br. at 7; Ky. Br. at 28-29. Far from it. Binding precedent from the Circuit and the Supreme Court do, however, impose "strict and demanding" obligations on the Secretary, *Motor Vehicle Mfrs. Ass'n. of U.S. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 48 (1983), to engage in a "searching and careful" review of the record, to respond to significant comments and consider alternatives, and to provide adequate explanations for choices made, *Int'l Ladies' Garment Workers Union v. Donovan*, 722 F. 2d 795, 815 (D.C. Cir. 1983). Here the Secretary's review is infected by multiple fatal flaws. The analysis below focuses on: a) flaws that cut across the entire Approval Letter; b) the Secretary's legal errors; and c) the lack of substantial evidence and/or failure to respond by the Secretary that renders the approval arbitrary and capricious.

At the outset, however, Plaintiffs address Defendants' contention that the Secretary's evaluation of Kentucky HEALTH must be considered as a whole, rather than in terms of Kentucky HEALTH's component parts. Fed. Br. at 25-26; Ky. Br. at 10. Plaintiffs do not disagree that the relevant inquiry is whether the Secretary, based on the applicable law and administrative record, properly concluded that Kentucky's application represented an "experimental, pilot, or demonstration project" that is likely to promote Medicaid's objectives. 42 U.S.C. § 1315(a); *see also Beno*, 30 F.3d at 1069. That being said, whether each of Kentucky HEALTH's components is consistent with the purposes of the Medicaid Act and serves an experimental purpose obviously is relevant to whether the project as a whole meets those requirements. Moreover, this is not a situation where the Secretary is making trade-offs among legitimate program objectives, *see Cal. Welfare Rights Org. v. Richardson*, 348 F. Supp. 491, 497 (N.D. Cal. 1972); Defendants cannot use the project-as-a-whole argument to achieve Medicaid cuts and program changes that are inconsistent with Medicaid's objectives or otherwise unsupportable. Thus, it makes sense to

examine Kentucky HEALTH's components—and the Secretary's reasons for finding that they are likely to promote Medicaid's objectives and serve an experimental purpose—separately *in addition to* considering the Secretary's evaluation of the project as a whole. In fact, CMS appears to have taken a similar approach in its review of the waiver. *See, e.g.*, AR 1860, 1997-99. You can't assess the forest without looking at the trees.

A. Fatal Flaws Infect The Secretary's Waiver Approval.

The Secretary's approval suffers from multiple, overarching flaws that violate the APA. First, to the extent that the Secretary reviewed the record with a view toward advancing objectives other than those of the Medicaid program, the APA compels vacatur of the Approval Letter. Where an agency exercises discretion using the wrong legal standard (here embracing objectives other than those of the Medicaid program), the agency action must fail. *See SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943) ("[A]n [agency] order may not stand if the agency misconceived the law."). The Kentucky HEALTH request and the Approval Letter are littered with euphemistic statements about goals that Kentucky HEALTH seeks to advance—the most prevalent being "familiariz[ing] beneficiaries with a benefit design that is typical of what they may encounter in the commercial market and thereby facilitat[ing] smoother beneficiary transition to commercial coverage," AR 0004—that have nothing to do with the Medicaid Act. If, as the Government demands, the Approval Letter must be taken as a whole, the focus on objectives other than those of the Medicaid Act brings the entire Approval Letter down.

Second, Kentucky concedes that many people will be knocked off Medicaid as a result of this program; as the record shows and based on an objective view, many of the provisions of Kentucky HEALTH are designed to and have the effect of making it difficult to preserve Medicaid coverage. It is certain that some number of beneficiaries will not meet the work requirement, will not be able to pay the premiums, will be locked out, or will otherwise lose Medicaid coverage, for

some period of time or for good. The Secretary never directly addressed that Kentucky HEALTH will explicitly *reduce* Medicaid coverage, and he never weighed the coverage losses against any countervailing benefits (that must be objectives of the Medicaid program) that justify this retraction in coverage from the minimum that Congress defined in the statute.

In this regard, the Secretary's lack of analysis is reminiscent of *Beno v. Shalala*, where the Ninth Circuit vacated a waiver that failed to grapple with the impact of a benefit cut intended to be a "work incentive." 309 F.3d at 1074. On this question, the Secretary's Approval Letter is bare or conclusory at best. As the Ninth Circuit explained in *Newton-Nations*, Section 1115 requires the Secretary to consider the impact on the people whom the statute was intended to protect, and cursory statements that fail to consider aspects of the problem will not do. 660 F.3d at 381.[9]

Third, even if the above flaws were not dispositive, the record in this case presents a basic administrative law question: When there is a mountain of evidence in the record showing that an agency action will have a particular result, does an agency satisfy the APA by simply disregarding the body of evidence as a whole or, with respect to certain aspects of the action, selecting snippets of the record that at best do not appear to be inconsistent with the result the agency purports to seek? However lenient one believes the substantial evidence standard to be—and the D.C. Circuit has said that the APA requires a "searching and careful" inquiry—the Government has failed it here. *Int'l Ladies' Garment Workers Union*, 722 F.2d at 815. At most, the evidence to which Defendants point to support the work requirement—bits of the record cited by Kentucky (Ky. Br.

[9] The Secretary points to "lengthy negotiations" with the Commonwealth as evidence that he adequately considered how each of the Kentucky HEALTH components would affect Medicaid enrollees. Fed. Br. at 33. However, the record indicates that the back and forth primarily concerned implementation, and CMS merely accepted the rationale provided by Kentucky at face value. *See, e.g.*, AR 1753-56 (Kentucky explaining how it plans to implement the reporting lockout); AR 1997-99 (Kentucky explaining how each of the penalties promotes the objectives of Medicaid). This is not reasoned agency decisionmaking.

at 27), including an article about a Gallup poll, an article about a study (but not the study itself), and studies looking at correlations between work, income, and health—support only the unsurprising conclusions that those who have jobs tend to be healthier than those who do not and that people find volunteering to be a meaningful experience. There is nothing in the record to suggest that compelled work will promote health outcomes, particularly for the people who will lose health care coverage as a result of the requirements. A finding here that the Secretary has met his burden would constitute an assault on science that the APA's standard of review does not allow.[10]

B. The Secretary Lacked Statutory Authority To Waive Certain Requirements.

In addition to the overall flaws—each one of which compels vacatur here—the Secretary lacked legal authority for several specific aspects of the waiver. Each is discussed in turn and each, independently, renders the Secretary's Approval Letter invalid.

The Work Requirement. Plaintiffs explained in their opening brief why Congress did not vest the Secretary with the power to approve a work requirement. Pls.' Br. at 18-21. The Medicaid Act, by its plain terms, aims to provide medical assistance to those individuals who cannot afford it. 42 U.S.C. § 1396-1. Period. Defendants' arguments to the contrary are unavailing. Defendants

[10] Nor can Defendants fall back, as they do repeatedly, on the fact that Kentucky HEALTH is designed to be an "experimental" project. Fed. Br. at 1, 3, 15-17, 18-19, 26, 32, 34; Ky. Br. at 9-10, 13 n.3, 42. As noted below, many of the claimed "experiments" have already been tried—and failed—in other contexts. A mere hypothesis that some benefit could possibly accrue to some beneficiaries—in the face of a record that shows that harm will certainly come to many—does not satisfy the test, even accounting for some measure of deference to the Secretary.

Defendants rely throughout their briefs on *Aguayo* and *C.K.*, but these cases do not engage in the "searching" assessment of the record demanded under Supreme Court and D.C. Circuit precedent. *See C.K.*, 92 F.3d at 183; *Aguayo*, 473 F.2d at 1103-05. And *Aguayo*—on which *C.K.* rests—was decided in 1973, when HHS reviewed Section 1115 waivers under federal human subject protections—meaning that HHS used technical review panels of outside experts who evaluated the research design and possible harmful effects of the experiment on its participants. *See* 42 U.S.C. § 3515b.

may desire to promote labor force participation, Ky. Br. at 23-24, but that is not a purpose of the Medicaid Act.

In addition to their overall argument about limitless discretion for the Secretary, Defendants object to Plaintiffs' choice of "work requirement" as shorthand for their preferred terminology: a "community engagement requirement." Fed. Br. at 18; Ky. Br. at 19. What is significant is not how one refers to the requirement, but the requirement itself: enrollees must participate in 80 hours of non-voluntary activities per month in order to receive Medicaid coverage. It is this aspect of Kentucky HEALTH that is at odds with Medicaid's stated purpose of furnishing medical assistance to those in need (regardless of their employment status).

Next, Defendants contend that Congress's failure to pass two recent bills that would have imposed, or allowed states to impose, work requirements on Medicaid recipients is irrelevant. In fact, this indicates Congress's belief both that congressional action is required to impose work requirements and that such work requirements are ultimately ill-advised. *See* Pls.' Br. at 19-20. Far from being Plaintiffs' "primary evidence," however, as the Commonwealth contends, Ky. Br. at 20, this evidence should be considered together with the statutory text, structure, and history, to evaluate whether the Secretary overstepped his authority in approving the Kentucky HEALTH work requirements. Pls.' Br. at 16, 18-21.

In addition, the Commonwealth asserts that in fact "the work requirements in SNAP and TANF bolster the Secretary's decision to approve Kentucky HEALH's community-engagement program." Ky. Br. at 21; *see also* Fed. Br. at 17. The Commonwealth points to the fact that, prior to welfare reform in 1996, several states obtained waivers from the Secretary "to allow work requirements in TANF's predecessor program, AFDC." Ky. Br. at 21. The Commonwealth claims that these waivers "led to Congress' passage of work requirements for TANF and SNAP in 1996."

Id.

This characterization is inaccurate. Both SNAP and AFDC contained work requirements prior to 1996. *See* Public Welfare Amendments of 1962, Pub. L. No. 87-543, § 105, 76 Stat. 172, 186; An Act to Amend the Food Stamp Act of 1964, Pub. L. No. 91-671, § 5(c), 84 Stat. 2048, 2050 (1971). Further, that the Secretary approved waivers to allow states to impose enhanced work requirements in the AFDC context proves nothing about the validity of such waivers in Medicaid. AFDC is an entirely separate program from Medicaid, and it was created to achieve different ends. The stated purposes of AFDC included encouraging "the maximum self-support and personal independence consistent with the maintenance of continuing parental care and protection." 42 U.S.C. § 601 (1994). It is therefore no surprise that AFDC would allow for work requirements, whereas a statute passed to enable states to provide "medical assistance" to those "whose income and resources are insufficient to meet the costs of necessary medical services" would not. 42 U.S.C. § 1396-1. Thus, contrary to the Commonwealth's assertions, these AFDC waivers do not support the Secretary's authority to allow work requirements for Medicaid recipients.

As Plaintiffs set out in their opening brief, a comparison between Medicaid, on the one hand, and TANF and SNAP, on the other, underscores that Congress did not intend for Medicaid to be a work program. Pls.' Br. at 19-20. Both the TANF and SNAP statutes include work requirements. *See* 42 U.S.C. § 607; 7 U.S.C. § 2015(d), (o). Medicaid does not.

Finally, Defendants argue that it is irrelevant that CMS has never in the 50-plus year history of Medicaid approved a work requirement as a condition of Medicaid eligibility, because prior to 2014, Medicaid served only the disabled, the blind, the elderly, and families with dependent children. Fed. Br. at 19; Ky. Br. at 22. The assumption behind their arguments is that all of "these

categories of the needy" are unable to work, and therefore it would have made no sense for the Secretary to have allowed a state to impose a work requirement. Setting aside the fact that the Secretary approved Kentucky's request to impose work requirements on some families with dependent children, this assumption is false. As Defendants observe a page or two earlier in their respective briefs, Congress imposed work requirements on needy families with dependent children in AFDC, and later, TANF. Fed. Br. at 17; Ky. Br. at 21. Thus, the Secretary's prior policy of not allowing states to impose a work requirement in Medicaid must owe to reasons other than the demographics of the traditional Medicaid population.

In fact, neither the DSMD Letter nor the Approval Letter addresses the fact that previously the agency believed it was *unlawful* to approve a work requirement. To be sure, the Letters concede that there has been a policy change by suggesting "[t]his is a shift from prior agency policy regarding work and other community engagement as a condition of Medicaid eligibility or coverage, but it is anchored in historic CMS principles that emphasize work to promote health and well-being." AR 0092 (footnote omitted). But this is not merely a subtle shift of agency policy—previously the agency believed it was illegal to approve any work requirement. Pls.' Br. at 45-46 & n.21. There is no acknowledgement of this radical change, much less an explanation of it. Under *Encino Motorcars*, this failure to acknowledge the legal about-face renders the decision arbitrary and capricious. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125-26 (2016); *see also Int'l Union, United Mine Workers of Am. v. U.S. Dep't of Labor*, 358 F. 3d 40, 44 (D.C. Cir. 2004) (holding agency action arbitrary and capricious where agency merely stated a change in agency priorities and referenced a judicial decision without elaboration).

In sum, consistent with the agency's prior position articulated two years ago, and consistent with more than 50 years of practice, the Secretary lacks statutory authority to create work

requirements in the Medicaid program through his waiver authority.

Premiums. Notwithstanding the complexity of the Medicaid Act, Plaintiffs' argument that the Secretary lacked statutory authority to approve the Kentucky premiums is straightforward: The Secretary's Section 1115 waiver authority extends only to Section 1396a. Congress purposefully placed Medicaid's premium and cost sharing provisions in Sections 1396o and 1396o-1, not Section 1396a. Sections 1396o and 1396o-1 extensively describe the premiums and cost sharing that states can impose through state plan amendments or waivers. And while states are given a great deal of flexibility, Congress included some strict limits to protect access to coverage and services. *See* 42 U.S.C. §§ 1396o, 1396o-1. Thus, Sections 1396o and 1396o-1 prohibit states from imposing premiums on individuals described in Section 1396a(a)(10)(A) (*i.e.*, categorically needy groups) with household incomes below 150% of FPL, and while some cost sharing limits can be waived under the stringent criteria set forth in Section 1396o, premium protections cannot.

In arguing that Section 1115 gives the Secretary authority to waive the Medicaid Act's limits on premiums, Defendants improperly ignore the structure of the statute as a whole and the history of the relevant provisions. Fed. Br. at 38-41; Ky. Br. at 29-33. Premiums and cost sharing were originally authorized, with scant statutory discussion, in Section 1396a(a)(14). *See* Social Security Act Amendments of 1965, Pub. L. No. 89-97, § 1902(a)(14), 79 Stat. 286, 346 (1965). After two courts acknowledged the Secretary's authority to waive the Section to allow states to charge enrollees heightened cost sharing, *see Crane v. Mathews*, 417 F. Supp. 532 (N.D. Ga. 1976); *Cal. Welfare Rights Org.*, 348 F. Supp. 491, Congress added a new Section 1396o to the Medicaid Act that sets forth, in detail, the premium and cost sharing options available to states. Significantly, Section 1396o imposes independent requirements on states. *See* 42 U.S.C. § 1396o(a), (b) ("[t]he State plan shall provide . . ."). At the same time, Congress amended Section

1396a(a)(14), using wording unique among the other provisions in Section 1396a, to provide that premiums and cost sharing "may be imposed only as provided in" Section 1396o. *See* Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, 96 Stat. 324, 367.[11] With these changes, Congress expected states and the Secretary to act pursuant to the flexibilities set forth in Section 1396o, including its waiver authorities, not Section 1115. *See* H.R. Rep. No. 97-757, pt. 1, at 6 (1982) ("The Committee believes that this bill gives the States sufficient flexibility in this regard to make further exercise of the Secretary's demonstration authority unnecessary."). Defendants point out that the legislative history only mentions cost sharing and not premiums. Fed. Br. at 41; Ky. Br. at 33. This is not surprising, as the cases Congress was responding to only concerned cost sharing. However, in response to these cases, Congress did not remove only the cost sharing limits from Section 1396a—it placed detailed premium provisions in Section 1396o as well.

In the decades since 1982, Congress has consistently confirmed that the flexibilities available to states with respect to premiums and cost sharing must come from Congress, not a federal agency. Congress has amended the premium and cost sharing provisions on numerous occasions—each time establishing the substantive boundaries. *See* Omnibus Reconciliation Act of 1987, Pub. L. No. 100-203, § 4101(d)(1), 101 Stat. 1330, 1330-141 to -142 (authorizing premiums on pregnant women and infants with incomes over 150% of FPL); Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6408(d)(3)(B), (C), 103 Stat. 2106, 2269 (codified at 42 U.S.C. § 1396o(d)) (authorizing premiums for certain working individuals with

[11] If Congress intended for Section 1396o to have no independent legal significance, but to flesh out Section 1396a, it would have at least referenced Section 1396a in Section 1396o. It was logical for Congress to keep Section 1396a(a)(14) as a cross-reference to Section 1396o—that ensured that Section 1396a remained an exhaustive list of all required state plan elements.

disabilities who have incomes over 150% of FPL).[12]

As a result of all of this congressional action, Section 1396o painstakingly delineates the premiums and cost sharing states may charge to different groups of Medicaid recipients. One provision, for example, allows states to impose premiums on certain pregnant women with incomes above 150% of FPL, 42 U.S.C. § 1396o(c)(1), but prohibits the premiums from exceeding 10% of the amount by which the enrollee's income exceeds 150% of FPL, *id.* § 1396o(c)(2). Another provision addresses the premiums that may be charged to certain working individuals with disabilities whose incomes exceed 150% of FPL. *Id.* § 1396o(d). Yet another provision allows the Secretary to waive the limits on cost sharing, but not the limits on premiums, under strict conditions. *Id.* § 1396o(f). Elsewhere, in subsections (a)(3) and (b)(3), the Secretary may, through a waiver, allow states to impose heightened cost sharing for non-emergency use of the emergency room if they can ensure that non-emergency care alternatives are available to affected individuals. *Id.* § 1396o(a)(3), (b)(3). It is hard to believe that Congress would go to the trouble of spelling out in detail exactly who can be charged and how much—all with an eye to "mak[ing] further exercise of the Secretary's demonstration authority unnecessary"—if the Secretary could come along and waive these carefully delineated restrictions altogether. *See* H.R. Rep. No. 97-757, pt. 1, at 6 (1982).

When Congress enacted Section 1396o-1 in 2006 to give states even greater authority to charge cost sharing and premiums (but continuing to bar premiums on individuals with incomes below 150% of FPL), it again chose to place the new substantive limits outside of Section 1396a

[12] *See also* Ticket to Work and Work Incentives Act of 1999, Pub. L. No. 106-170, § 201(a)(3)(B), 113 Stat. 1860, 1893 (codified at 42 U.S.C. § 1396o(g)) (authorizing premiums or cost sharing on people with disabilities in ticket to work programs); American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 5006(a)(1)(B), 123 Stat. 111, 505 (codified at 42 U.S.C. § 1396o(j) (2012)) (prohibiting premiums for Native Americans).

and did not even reference them in Section 1396a(a)(14). Deficit Reduction Act of 2005, Pub. L. 109-171, § 6041-6043, 120 Stat 6, 81, 85, 86 (2006) (adding 42 U.S.C. § 1396o-1). Defendants argue that Section 1396o-1 is an exception to Section 1396o and, thus, a waiver of Section 1396o necessarily includes a waiver of Section 1396o-1. Fed. Br. at 40. However, Section 1396o-1 does more than describe exceptions to Section 1396o; it imposes additional limitations on states. *See, e.g.*, 42 U.S.C. §§ 1396o-1(a)(2)(B), (b)(1)(B)(ii) (requiring that total aggregate out-of-pocket costs imposed not exceed 5% of household income). In any case, the Secretary explicitly waived Section 1396o-1 in his Approval Letter, thus undercutting the argument that no separate waiver of Section 1396o-1 is ever necessary. AR 0014.[13]

In short, Defendants ignore Congress's clear intent to insulate the substantive limits on premiums from the Secretary's Section 1115 waiver authority. *See Ross v. Blake*, 136 S. Ct. 1850, 1858 (2016) ("When Congress amends legislation, courts must presume it intends [the change] to have real and substantial effect." (internal quotations and citations omitted)); *Beno*, 30 F.3d at 1068-69 (noting that a legislative scheme with mandatory language and detailed requirements evidenced a clear congressional intent to take certain decisions away from states).

Heightened Cost Sharing for Non-Emergency Use of the Emergency Room. The Kentucky HEALTH approval bypasses Section 1396o(f)'s waiver requirements and allows Kentucky to charge enrollees up to $75 for non-emergency use of the emergency room, an amount that exceeds the limits established in the Medicaid Act and implementing regulations. *See* 42 U.S.C. §§ 1396o-1(e), 1396o(a)(3), (b)(3); 42 C.F.R. § 447.54(b) (setting the maximum charge at $8, subject to

[13] Defendants also appear to argue that Section 1396o-1(b)(6)(B) indicates that the Secretary has the authority to waive Section 1396o-1 under Section 1115. However, this argument assumes that the Secretary had the authority to waive Section 1396o-1(b)(1)(A)'s restriction in the first place. For the reasons discussed, he did not.

increases for inflation). Defendants claim these limitations do not apply because deducting money from enrollees' *My Rewards* account is not the same as a traditional copayment or deduction. Ky. Br. at 40-41; Fed. Br. at 42. *But see* Pls.' Br. at 42.

While Defendants make much of the fact that the *My Rewards* account is comprised of "virtual dollars," "credits," or "points," as opposed to "actual money" contributed by enrollees, Ky. Br. at 40; Fed. Br. at 42, this distinction glosses over the fact that the "virtual dollars" function as "actual money" for enrollees. This is because Kentucky HEALTH terminated coverage of vision and dental services and over-the-counter medications for expansion enrollees, so enrollees will need "virtual dollars" to pay for these services. AR 0032-33. When Kentucky deducts $75 from an enrollee's *My Rewards* account, it leaves the enrollee with $75 less to pay for the services. AR 0034-35. Thus, by deducting "virtual dollars" from an enrollee's *My Rewards* account, Kentucky is unquestionably imposing a financial charge on that enrollee.

Moreover, by defining cost sharing to include only a traditional copayment or deduction, Defendants read the words "similar charge" out of the statute. Those words make clear that Congress intended for the term cost sharing to encompass other mechanisms beyond copays and deductions that impose financial consequences on enrollees for using services. Defendants cannot seriously contest that reducing the *My Rewards* account balance has real, financial consequences for enrollees, as the stated purpose of the policy is to use financial incentives to influence enrollees' behavior. AR 0033, 5462-63.[14] Defendants' interpretation of the Medicaid Act permits states to skirt the limits on cost sharing by simply devising a novel way to indirectly charge enrollees for the use of health services. This is not consistent with the plain language or purpose of the statute

[14] The Commonwealth also relies on Section 1396o(e). Ky. Br. at 41. But rather than support their argument, this statute illustrates congressional concern that states' cost sharing policies not result in individuals losing out on needed care because of a cost sharing amount.

and is not entitled to deference.

C. Approval Of The Kentucky HEALTH Program, And Individual Elements Thereof, Was Arbitrary, Capricious, And An Abuse Of Discretion.

In evaluating the project as a whole and each individual element, the Secretary failed to respond adequately to comments or provide a reasoned explanation for rejecting the overwhelming evidence that the Kentucky HEALTH program is neither experimental nor likely to promote the objectives the Medicaid program. Plaintiffs discuss individual aspects of the program below.

Work Requirement. As noted above, the evidence that purports to support the imposition of a work requirement is a thin reed. Defendants claim that studies in the record support the conclusion that requiring Medicaid enrollees to work or complete work-related activities to maintain their health coverage will improve health outcomes among low-income Kentuckians. *See, e.g.*, Ky. Br. at 27; Fed. Br. at 34. However, this conclusion is based on a selective and inaccurate reading of the relevant research—not, as Defendants contend, a rational predictive judgment. *See Metlife, Inc. v. Fin. Stability Oversight Council*, 177 F. Supp. 3d 219, 237 (D.D.C. 2016) ("Predictive judgment must be based on reasoned predictions.").

First, the literature does not show that working *causes* individuals' health to improve. *See, e.g.*, AR 5392-5408 (healthier people may be more inclined to volunteer and the causal "direction of effects" between health and community service is unclear); AR 5047-53 (noting possible "overestimation of the findings" since health impacts likelihood of entering or leaving work); AR 5054-60 ("causal direction of the relationship" between mental health and work is "not clear," since having such conditions makes it "harder to land a job"); AR 5386-91 ("individuals may be more likely to be found in a disadvantaged social position [such as without a job] because of their health difficulties"); *see also* Amicus Br. for Deans, Chair and Scholars, ECF No. 43-1, at 26-29. In fact, the literature highlights that people need to be healthy to work and working in low-wage,

low-status jobs—largely those available to Medicaid enrollees in Kentucky—can have a *negative* effect on health and well-being. *See, e.g.*, AR 5052; *see also* AR 5693 (noting that in 2015, the three industries that employed the most Medicaid expansion-eligible adults in Kentucky were restaurants, construction, and department stores). In addition, nothing in the literature even comes close to suggesting that requiring individuals to work or engage in work-related activities as a condition of maintaining their health coverage will improve health outcomes. *Cf.* AR 5152 (summarizing research showing that when individuals are disallowed benefits, many do not find work, their income falls, and many feel their health remains unchanged or gets worse).

Second, even if one were to assume that having a stable job *causes* an improvement in overall health, the evidence in the record indicates that work requirements in other public programs have not helped individuals obtain stable jobs. *See* Pls.' Br. at 22. In response, CMS said it had "considered [that issue] and decided to allow states to test the implementation of community engagement requirements in Medicaid . . . ." AR 0008, 09. However, "[s]tating that a factor was considered . . . is not a substitute for considering it." *Beno*, 30 F.3d at 1075. CMS offered no explanation as to why it expects the Medicaid work requirement to be effective despite all of the evidence in the record to the contrary.

Third, the Secretary did not adequately respond to significant concerns raised about the individuals who do not meet the work requirements and lose health coverage. *See* Pls.' Br. at 21-22. Defendants contend that the Secretary addressed those concerns by excluding "all but the able-bodied" through exemptions and a good cause exception,[15] and by allowing individuals to engage in activities other than work. *See* Ky. Br. at 19; *cf.* Fed. Br. at 33-34. However, Kentucky included

[15] Notably, the "good cause" exception is narrowly limited to especially extreme cases. *See infra* at 41.

many of these features in its initial application to CMS, meaning that commenters raised significant concerns about coverage losses despite these so-called protections. *See* AR 5449-51.

Fourth, the Secretary did not explain why he was rejecting the uncontroverted evidence from SNAP and TANF demonstrating that such protections do not prevent work requirements from reducing enrollment. *See* Pls.' Br. at 22, n.9. Indeed, the record indicates that SNAP and TANF enrollees who fall under one of the exemptions are often unable to secure an exemption in practice, resulting in termination of benefits. *See id.* at 23, n.11. The work requirement severely threatens these individuals' access to medically necessary care. Indeed, Kentucky expects at least 95,000 low-income individuals to lose Medicaid coverage. AR 5419-23.

It is not surprising that the Secretary did not even attempt to respond to comments questioning how eliminating coverage for enrollees who do not meet the work requirement will possibly improve their health or well-being. Instead, he appears to acknowledge that Kentucky is not concerned with how the work requirement will affect the health of individuals who lose coverage. *See* Fed. Br. at 35 n.12 ("[T]he Secretary acted well within his discretion in allowing Kentucky to test whether *those who respond to the incentive for community engagement* will enjoy similar health benefits [to individuals in the studies]." (emphasis added)). In determining that the work requirement is likely to promote the objectives of the Medicaid Act, the Secretary needed to consider its impact on the individuals that the Medicaid program was enacted to protect. *Newton-Nations*, 660 F.3d at 381. The Secretary cannot justify his failure to meet this obligation by emphasizing that the work requirement is an experiment, the exact outcomes of which are uncertain. *See* Fed. Br. at 34.

Premiums. As Plaintiffs have explained in detail, the record contains evidence of abundant, uncontroverted research findings that imposing premiums and lockout penalties on low-income

individuals in Medicaid and similar coverage programs both deters enrollment and reduces coverage. Pls.' Br. at 30. Federal Defendants' brief ignores the research, characterizing Plaintiffs' arguments about premiums as "fears" and presumptions. Fed. Br. at 36. Plaintiffs presume nothing, but instead rely on consistent record citations pointing to decades of research showing the harmful effects of the premiums on low-income people. *See* Pls.' Br. at 30-32.[16]

To avoid directly confronting this research, Kentucky contends that it is not part of the record. Ky. Br. at 34. But even if the studies themselves were not submitted to the agency, commenters *cited* and *explained* the findings of these studies. *See, e.g.*, AR 4326-27, 3740, 3865, 3692, 3827, 4326, 3487. The Secretary was not somehow relieved of his burden to respond to these findings just because not all the studies themselves were before the agency—their substance and findings certainly were. And, notably, Federal Defendants do not join in Kentucky's argument on this point.

Kentucky also attempts to reframe the evaluation of Indiana's premium requirements to support its position. Ky. Br. at 35, 42. Kentucky does not (and cannot) refute the basic findings: Indiana's premiums, which are lower than Kentucky's (2% versus up to 4% of household income), have caused thousands of individuals to lose access to services. *See* AR 4964 (incorporating in entry dated March 31, 2017, The Lewin Group, HIP 2.0 Power Account Contribution Assessment 12 (2017); Phil Galewitz, *Indiana's Brand of Medicaid Drops 25,000 People For Failure To Pay Premiums*, NPR.org (Feb. 1, 2018), https://www.npr.org/sections/health-shots/2018/

[16] The Commonwealth argues that the premium payments are optional for enrollees with incomes below 100% of FPL. *See, e.g.*, Ky. Br. at 36-37, 44. While it is true that individuals below the poverty level who cannot pay the monthly premium will not lose coverage, they will be penalized. The Commonwealth will deduct $25 from their *My Rewards* account and suspend the account for up to six months, leaving them to pay out-of-pocket for medically necessary vision services, dental services, and over-the-counter medications. They will also have to pay cost sharing in lieu of premiums for up to six months. AR 0026, 0039-40.

02/01/582295740/indianas-brand-of-medicaid-drops-25-000-people-for-failure-to-pay-premiums. For example, the evaluation shows that 23% of enrollees eligible for the program and required to pay an initial premium to enroll did not pay, and as a result, did not receive coverage. The Lewin Group, *HIP 2.0 Power Account Contribution Assessment* at 12 (2017). Kentucky points out that approximately half of that 23% reapplied and were covered at a later date. Ky. Br. at 35. However, this emphasis ignores that those individuals were uninsured for some unknown period of time, and that approximately 11.5% of otherwise eligible individuals *never* received Medicaid coverage due to the premium requirement. The evaluation also unquestionably shows that 55% of all enrollees who were not exempt from the premium requirements missed at least one monthly premium and were penalized with termination and lockout (for individuals above 100% of FPL) or loss of benefits and higher cost sharing (for individuals below 100% of FPL). *HIP 2.0, supra*, at 8-11.

Moreover, Kentucky makes the somewhat incredible argument that Indiana's premium requirements improved health outcomes among low-income individuals. *See* Ky. Br. at 35. Here, the Commonwealth mistakes correlation for causation. Indiana's evaluation compares two disparate groups—those who paid premiums and those who did not—that differ in health status, income, and other demographic factors known to correlate with care utilization. *See, e.g.*, AR 4850-4961. The evaluation does not control for these confounding factors, nor acknowledge that only the group that did not pay premiums was required to pay cost sharing for most services received, which is known to reduce utilization. The Commonwealth's claim also ignores the health care utilization patterns for the tens of thousands of individuals who lost coverage due to Indiana's premium policies.

Kentucky also asserts that the Secretary did in fact adequately respond to commenters'

concerns about coverage losses by including the "on-ramp," exemptions for pregnant women and medically frail individuals, and "good cause" exceptions (covering extreme circumstances, such as being a victim of a natural disaster or domestic violence, and exceptions required by federal anti-discrimination laws). *See* Ky. Br. at 35-36; AR 0037. The good cause exceptions do nothing to address the primary reasons that enrollees will not be able to pay the premiums—reasons that range from having no money to logistical obstacles (*e.g.*, no bank account, no transportation, no internet). *See* Pls.' Br. at 30-32 (citing evidence in the record indicating that many Kentucky HEALTH enrollees will not be able to afford monthly premiums); AR 3787, 3884, 3935, 3711-12 (highlighting logistical obstacles). In addition, Kentucky included the on-ramp and the exemptions for certain populations in its initial waiver application, meaning that commenters expressed their concerns about coverage losses with those features in mind. *See, e.g.*, AR 3694-95, 3937 (noting problems with the on-ramp). Thus, the record demonstrates that the Secretary simply disregarded significant public comments that questioned the efficacy and legality of the premium policies that HHS intended to implement all along.

Kentucky also argues that CMS reasonably determined that imposing premiums on Medicaid enrollees would familiarize individuals with commercial market policies, and as a result, reduce the rate of churn. Ky. Br. at 12, 33-34. Assuming for the sake of argument that this were a purpose of the Medicaid Act, the figures Kentucky relies upon show that many Medicaid enrollees have had private coverage and are already familiar with commercial market policies. *Id*; *see also* AR 4317-18. More importantly, educating Medicaid enrollees about commercial insurance does nothing to address what causes individuals to churn from Medicaid to private coverage (or uninsured status): fluctuating income. Nor does imposing premiums on individuals while they are enrolled in Medicaid do anything to increase their access to private coverage. The

tautology—that reducing churn improves continuity of coverage and care, AR 0006—ignores all of the evidence in the record indicating that the premiums and lockout penalties will do just the opposite, reducing continuity of coverage and care. *See* Pls.' Br. at 30-34.

Finally, CMS's approval of Kentucky HEALTH did not even claim to have determined that the premiums have experimental value. *See* AR 0001-10; *Beno*, 30 F.3d at 1074. The Secretary now attempts to justify the approval by noting that CMS has previously allowed states to impose heightened premiums and reasonably concluded the policies "were worth testing." Fed. Br. at 37. To the contrary, the fact that these policies have been tested many times before defeats any argument that they retain any experimental value. *See Newton-Nations*, 660 F.3d at 381.[17]

Lockouts. The record does not demonstrate that the Secretary reasonably determined that the reporting and redetermination lockouts, which Defendants agree do nothing more than add "an additional consequence" for failure to meet existing administrative requirements, Ky. Br. at 6, are likely to promote the objectives of the Medicaid Act and are experimental.

While the Secretary did not need to respond directly to every comment received, he was required to "consider evidence bearing on the issue before" him and articulate a "rational connection between the facts found and the choice made." *Foster v. Mabus*, 103 F. Supp. 3d 95, 105, 109 (D.D.C. 2015). He did not do so here. As Plaintiffs outlined in their initial brief, commenters provided evidence showing that the lockouts will reduce coverage and access to health services, leading to worse health outcomes. Pls.' Br. at 34-35. Defendants argue that the on-ramp, the exemptions for pregnant women and medically frail individuals, and the "good cause"

[17] As Plaintiffs explained in their opening brief, the premium enrollments were not challenged in prior cases, so the lawfulness of Secretary's ability to increase premiums through his Section 1115 waiver authority is a question of first impression for this Court. Pls.' Br. at 30 n.15.

exceptions show that the Secretary adequately considered the commenters' concerns.[18] Ky. Br. at 36; Fed. Br. at 35-36. Notably, Kentucky included the on-ramp, the population exemptions from the redetermination lockout, and the "good cause" exceptions from the reporting lockout in its application to CMS—the Secretary did not add them at the approval stage. AR 5453, 5415-16. Thus, the comments expressed concerns that the lockouts would reduce coverage despite the existence of these policies. *See* Pls.' Br. at 45-46. In addition, as described above in the context of premiums, the good cause exceptions do not get at the everyday challenges that prevent low-income individuals from meeting administrative deadlines. *See, e.g.*, AR 0239, 5683, 3452 (Comment 219457), 3180 (Comment 269373). If, as Defendants appear to claim, the lockouts are limited to such a small group of enrollees and are simply to cure (due to the on-ramp and good cause exceptions), then they cannot possibly offer a meaningful incentive to enrollees to follow existing requirements. *See* AR 0006, 5415. The Secretary could not have reasonably found that lockouts are both likely to influence enrollees' behavior and inconsequential.

The affirmative rationale the Secretary provided for concluding that the lockouts are likely to promote the objectives of the Medicaid Act does not withstand even minimal scrutiny. Defendants rely on nothing more than vague conclusory statements in the Approval Letter that the lockouts will strengthen enrollees' "engagement in their personal health care plan," familiarize them with private insurance, and "protect program integrity." Fed. Br. at 27 n.8; Ky. Br. at 49 (citing AR 0005-07). It is simply illogical to claim prohibiting individuals from accessing

[18] Kentucky also points to the requirement that it complete ex parte redeterminations for at least 75% of enrollees as evidence that the Secretary adequately responded to issues raised in the comments. Ky. Br. at 38 (citing AR 0028). However, Kentucky already does these. In an average month, Kentucky completes ex parte redeterminations for over 80% of enrollees, but still terminates 3904 enrollees for failure to complete their renewal forms. AR 2902. Thus, even with the ex parte redeterminations requirement, many Kentucky HEALTH enrollees will face a redetermination lockout each month.

Medicaid coverage for up to six months will educate them about commercial market policies, thereby reducing churn and improving continuity of care. AR 0006; *see also* Pls.' Br. at 34-36. In addition, while the Secretary contends that he properly credited the claims made by Kentucky that the lockout periods are necessary to preserve program integrity, Fed. Br. at 36, nothing in the record suggests that the already existing penalties—termination of coverage, and in the case of fraud, fines, imprisonment, and lockouts—have failed to ensure program integrity in Kentucky.

Similarly, the Secretary did not adequately explain his decision to reverse CMS's 2016 determination that redetermination lockouts are inconsistent with the objectives of the Medicaid Act. AR 0239-40 (rejecting Indiana's request to impose a redetermination lockout). To avoid directly confronting the 2016 determination, Kentucky simply claims that CMS's prior position is irrelevant, as it was based on the particular facts and circumstances in Indiana. Ky. Br. at 42, 36. However, Kentucky ignores CMS's blanket statement that "[a]uthorizing a lockout for individuals at any income level who do not complete their annual eligibility redetermination is not consistent with the objectives of the Medicaid program, which include ensuring access to affordable coverage." AR 0239. CMS pointed to challenges that prevent low-income individuals from completing the redetermination process, such as frequent moves, health conditions, and language access issues. Certainly, low-income individuals in Kentucky also face these challenges. In addition, in reaching its decision, CMS did highlight that 5% of Indiana enrollees do not complete the renewal process, and as a result, could be subject to the lockout. AR 0240. According to the record, the figure is even worse (8% of enrollees) in Kentucky. AR 2902. *See Encino Motorcars, LLC*, 136 S. Ct. at 2126 ("[A]n [u]nexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." (internal citation omitted)).

Finally, nothing in the record indicates that the Secretary concluded that the lockouts will yield any useful information. *See Beno*, 30 F.3d at 1069. Contrary to Defendants' arguments, the requirement that Kentucky evaluate how the lockouts affect enrollees does not transform the lockouts into an experiment. Fed. Br. at 35. While every experiment must have an evaluation, not every evaluation is part of an experiment.

Retroactive Eligibility. The record does not demonstrate that the Secretary reasonably concluded that the waiver of retroactive coverage is experimental and likely to promote the objectives of the Medicaid Act. *See* Pls.' Br. at 38-39. In approving Kentucky HEALTH, CMS made conclusory statements that the waiver would give enrollees an incentive to obtain and maintain health coverage even when healthy, thereby reducing gaps in coverage and increasing continuity of care. *Id.* at 38 (citing AR 0004, 0006). As Plaintiffs explained in their opening brief, the record does not support these claims. *Id.*

Rather than directly confronting the substantial and uncontroverted evidence in the administrative record indicating that eliminating retroactive coverage will reduce continuity of coverage and increase gaps in coverage, *see id*. at 38-39, Defendants point to CMS's previous decisions allowing other states to waive retroactive coverage, Fed. Br. at 37 & n.13; Ky. Br. at 46. That CMS's prior approvals have gone unchallenged has no bearing on whether or not the Kentucky HEALTH waiver of retroactive eligibility was arbitrary and capricious. *See* Ky. Br. at 42 (prior approvals based on individual facts). In fact, the prior approvals indicate that eliminating retroactive coverage in Kentucky is not an experiment that is likely to yield useful information. *See Beno*, 30 F.3d at 1069-71.

Kentucky further contends that CMS adequately responded to comments raising concerns about the effect of the waiver on Medicaid enrollees and providers by pointing to other features of

Kentucky HEALTH that it argues will mitigate the need for retroactive eligibility. Ky. Br. at 38. In particular, Kentucky cites the on-ramps for individuals locked out of coverage and the requirement that Kentucky complete 75% of eligibility renewals using an automatic process. *Id*. Even assuming Plaintiffs can make use of the on-ramps (*see* Part IV.C, *supra*), they will not have coverage for any treatment received between disenrollment and re-enrollment; in turn, they will forego treatment during the coverage gap or will incur substantial medical debt they cannot afford. Nor does Kentucky explain how the requirement of automatic eligibility renewals will aid those who will inevitably be locked out. Pls.' Br. at 38-39.

Kentucky next argues that CMS did not need to respond to the remaining categories of comments highlighting that the waiver of retroactive eligibility will create financial problems for medical providers and exacerbate coverage gaps due to existing administrative issues in Kentucky. The Commonwealth called the comments "speculative" and "of limited relevance" and claimed that the Special Terms and Conditions ("STCs") otherwise addressed them. Ky. Br. at 39 n.25. This characterization of the comments is inaccurate. *See* Pls.' Br. at 39 (citing concrete, significant comments in administrative record as to providers' financial burden of providing uncompensated care and frequent clerical and tracking errors that result in inadvertent termination or denials of enrollment). Defendants also fail to explain how the STCs addressed these comments. As a result, CMS's approval of the Kentucky HEALTH waiver of retroactive coverage was arbitrary and capricious. *See Bimini Superfast Operations LLC v. Winkowski*, 994 F. Supp. 2d 106, 119 (D.D.C. 2014) (agency decision is arbitrary and capricious when: "(i) the agency's explanation runs counter to the evidence before the agency" (citation omitted)).

Finally, Defendants argue that in waiving Section 1396a(a)(34), CMS also waived any requirement under Sections 1396a(a)(10) and 1396d(a) to retroactively provide medical assistance.

However, none of these provisions indicates that waiving the obligation to provide retroactive care under one provision automatically waives the obligation to do so under the others. Rather, the two provisions are independent, and only one was waived. Because the provisions of Sections 1396a(a)(10) and 1396d(a) remain in effect under, and still apply to, Kentucky HEALTH, Defendants' grant of a waiver of retroactivity is "not in accordance with law," is "in excess of statutory . . . authority," and is arbitrary and capricious. *Bimini*, 994 F. Supp. 2d at 119; 5 U.S.C. § 706(2).

Non-Emergency Medical Transportation (NEMT). There is agreement that the Secretary's approval letter offered no rationale for waiving NEMT except for the desire to require enrollees to "experience something like the commercial marketplace." Ky. Br. at 44; *see* AR 0116. This is not a legitimate objective of Medicaid. *See* Part IV.A, *supra*. Because the *agency* gave no other explanation for the NEMT waiver, it is arbitrary and capricious. *See Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993) (requiring agency to "state the main reasons for its decision and indicate it has considered the most important objections" (quoting *Simpson v. Young*, 854 F.2d 1429, 1435 (D.C. Cir. 1988))); *Beno*, 30 F.3d at 1069 (requiring explanation that waiver is experimental, as opposed to a "simple benefits cut").

Federal Defendants nevertheless argue that the waiver is valid because it was "based on the Secretary's evaluation of the Commonwealth's conclusion that the expansion population, unlike the traditional population, did not need or use NEMT." Fed. Br. at 36 (citing AR 5478). Setting aside that the agency did not in fact "state" that this was one of the "main reasons for its decision," *Pub. Citizen*, 988 F.2d at 197, the record contradicts Defendants' purported rationale. From June 2014 to June 2015, expansion enrollees used NEMT close to *140,000* times. AR 5478. The figure underscores that eliminating NEMT will reduce access to medically necessary services.

The Commonwealth also argues that eliminating NEMT will not reduce access to care, claiming that data from Indiana show that a greater percentage of persons *with* NEMT services than *without* NEMT services reported missing a medical appointment because of transportation barriers. Ky. Br. at 44. However, that report cautions that "[t]he populations with and without state-provided NEMT are not readily comparable due to large differences in demographics and healthcare needs." AR 4909. Put differently, the conclusion that Kentucky wishes to draw—that providing NEMT does not increase access to care—is unsupported by the evidence cited.

The Commonwealth also argues that commenters' concerns regarding an increase in emergency room visits and other costs are conclusory and speculative, and as a result, did not require a response. Ky. Br. at 45. To the contrary, these concerns had ample support in the record. *See* AR 3748 at n.29. Kentucky also attempts to dismiss concerns that eliminating NEMT will disproportionately affect women, persons of color, and individuals with significant health needs. Ky. Br. at 44 n.27. But again, this is not unsubstantiated opinion—it is the conclusion reached by the researchers charged with evaluating the Iowa NEMT waiver.[19] The agency's failure to address these "important" objections makes the resulting decision to eliminate NEMT arbitrary and capricious. *See, e.g.*, *Foster*, 103 F. Supp. at 108.

V. The DSMD Letter Violates The APA's Procedural And Substantive Constraints On Agency Decisionmaking.

Federal Defendants assert that CMS's announced policy on work requirements is

[19] Suzanne Bentler et al; *Non-Emergency Medical Transportation and the Iowa Health and Wellness Plan* at 26, University of Iowa (Mar. 2016) ("Females, black respondents, those enrolled in their plan longer, and those in poor health had an increased likelihood of having an unmet NEMT need."), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ia/Wellness-Plan/ia-wellness-plan-nemt-rpt-mar-2016.pdf. This study was cited in the record, *see* AR 3749 at n.30, and was before the agency as it was submitted as part of Iowa's 1115 waiver evaluation and is posted on CMS's own website.

unreviewable, not final agency action, or otherwise not subject to APA review because it is merely a "general statement of policy." Fed. Br. at 43-47. But even accepting that description, "the Supreme Court has made clear [that] such 'as applied' challenges are the appropriate means by which a party may challenge a broad agency policy document." *See Ark Initiative*, 64 F. Supp. 3d at 96 (quotation marks omitted).[20] Accordingly, for all the reasons articulated above, *see* Part IV.C, *supra*, the DSMD Letter's meager discussion of its change in position "cross[es] the line from the tolerably terse to the intolerably mute." *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 928 (D.C. Cir. 2017). The Letter's citation to a handful of studies does not make up for this deficiency. The Letter fails to: (1) explain why the agency's prior view of the same question was faulty; (2) explain how the agency weighed reliance on that prior position; (3) mention a single alternative course of action that the agency considered; or (4) acknowledge that it interprets the statute in a new way that expands the agency's authority. Any one of these lapses *alone* would suffice to set the Letter aside, given the agency's obligations to address these very factors when changing positions. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009).

CMS's admitted failure to follow notice-and-comment procedures is an independent reason to invalidate the substantive rules announced in the Letter. *See Nat'l Venture Capital Ass'n v. Duke*, 291 F. Supp. 3d 5, 20 (D.D.C. 2017). The Secretary's only response is to fall back on CMS's characterization of the Letter as "nonbinding guidance." Fed. Br. at 46. But the agency's label does not control. *See Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec. (EPIC)*, 653 F.3d 1, 5 (D.C. Cir. 2011) (analyzing the specific exemption from APA review invoked by the

[20] *Fund for Animals, Inc. v. U.S. Bureau of Land Management* is not to the contrary. 460 F.3d 13 (D.C. Cir. 2006) (cited in Fed. Br. at 45). It stands for the unremarkable proposition that a general statement of policy with no practical legal effect—in that case, an agency's budget request to Congress—fails to rank as final agency action. *Id*. at 22.

agency, rather than adopting the agency's characterization); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022-24 (D.C. Cir. 2000). Instead, the fact that the Letter has "actual legal effect" is the "most important factor." *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014). The Letter "appears on its face to be binding," and "is applied by the agency in a way that indicates it is binding." *EPIC*, 653 F.3d at 7 (quoting *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002)). Indeed, the Kentucky HEALTH approval makes clear that a) the Letter reflects a "deci[sion]" by the Secretary to authorize work requirements beyond simply Kentucky, and b) the "parameters" for such work requirements are set forth in the Letter. AR 0008-09.

Contrary to the Secretary's assertions, Fed. Br. at 45, the "'mandatory, definitive language'" used by the agency refers not only to existing laws but to the specific showings states must make to win future agency approval. Pls.' Br. at 48. This language is a powerful, even potentially dispositive, factor, *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1987), regardless of any disclaimers that precede it, *Appalachian Power Co.*, 208 F.3d at 1022-24. Defendants also ignore that the Letter binds the agency itself. Critically, it withdraws the agency's previously held position to reject waivers with work requirements as inconsistent with agency policy, or the Act's objectives, and, thus, takes a new "definitive legal position concerning its statutory authority." Fed. Br. at 44 (citing *CSI Aviation Servs., Inc. v. U.S. Dep't of Transp.*, 637 F.3d 408, 412 (D.C. Cir. 2011)). That the agency still maintains some case-by-case discretion does not change the character of the Letter as a binding agency document. *See McLouth Steel Prods. Corp. v. Thomas*, 838 F. 2d 1317 (D.C. Cir. 1988). The Letter is not simply "musings about what the [agency] might do in the future." *Cmty. Nutrition Inst.*, 818 F.2d at 948. Indeed, the Secretary approved Kentucky HEALTH the next day and multiple waivers almost immediately thereafter. Because it constrains agency officials and states alike, the Letter is both a final action

and substantive rule. *See Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 320 (D.C. Cir. 2011); *Broadgate Inc. v. U.S. Citizenship & Immigration Servs.*, 730 F. Supp. 2d 240, 243 (D.D.C. 2010).

The agency's subsequent actions demonstrate the binding effect of the Letter. While the Secretary asserts that each approval is supported just as if the Letter had never been issued, Fed. Br. at 46, the record belies that claim: Each waiver decision that postdates the Letter—approvals for Kentucky, Arkansas, Indiana, and now New Hampshire[21]—invokes the Letter, measures the waiver against the requirements therein, and uses it to dodge any real discussion about the wisdom of work requirements. *See* Pls.' Br. at 49-50. These "later developments show the agency to be using it as binding policy." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1057 n.4 (D.C. Cir. 1987). Even Kentucky concedes that the Kentucky HEALTH approval used the Letter as "justification for the Secretary's position." Ky. Br. at 26. In short, without reasoned explanation or the required procedures, the Letter abruptly and substantively changed the regulatory regime. Such arbitrary agency action cannot stand.

VI. The Take Care Claim Is Properly Before The Court.

At the motion to dismiss stage, Defendants do not contest that Plaintiffs' allegations that the Secretary seized exclusive legislative power state a claim under the Take Care Clause. Indeed, it is difficult to imagine a more clear-cut set of facts for the Take Care Clause than an Executive Branch that seeks to "explode" a law enacted by Congress through unilateral action.

Instead, with scant citation and no explanation, Defendants' sole response is that the Take

[21] On May 7, 2018, CMS approved New Hampshire's waiver application containing work requirements, once again relying on the Letter. *See* Letter from Seema Verma, Administrator, Dep't of Health & Human Servs. to Henry D. Lipman, Medicaid Director, N.H. Dep't of Health & Human Servs. (May 7, 2018), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nh/nh-health-protection-program-premium-assistance-ca.pdf.

Care Clause applies to the President alone and is, therefore, judicially unenforceable. Fed. Br. at 49. But Defendants' myopic focus on the President is misguided; the Take Care Clause applies to "the President . . . personally and through officers whom he appoints." *Printz v. United States*, 521 U.S. 898, 922 (1997) (citing U.S. Const. art. II, § 2). Thus, when officers exercise the President's Article II *power* to "execute" the laws, they are also bound by the Article II *duty* to do so "faithfully." *Util. Air Regulatory Grp.*, 134 S. Ct. at 2446.

That duty is clear and enforceable. The Take Care clause defines the relationship between the Executive and the Legislature. Specifically, "the President's power to see that the laws are faithfully executed refutes the idea that he is to be a lawmaker." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 587 (1952). Once laws are enacted, the Executive "shall" ensure the laws are "faithfully executed," and is therefore precluded from dispensing with, repealing, supplementing, revising, or amending those laws. *See Util. Air Regulatory Grp.*, 134 S. Ct. at 2446; *Clinton v. City of New York*, 524 U.S. 417, 438 (1998); *Angelus Milling Co. v. Comm'r*, 325 U.S. 293, 296 (1945); *Kendall v. United States ex rel. Stokes*, 37 U.S. (12 Pet.) 524, 612-13 (1838). In the administrative context, courts have explained that "Congress must lay down by legislative act an intelligible principle, and the agency must follow it." *Fox*, 556 U.S. at 536 (Kennedy, J. concurring) (internal quotations omitted); *see also Whitman*, 531 U.S. at 472. The Take Care Clause and non-delegation principles form two sides of the same coin: Congress may not delegate its legislative authority to define a law's intelligible principle and the Executive, in "faithfully execut[ing]" that law, may not exercise that core legislative power. *See Clinton*, 524 U.S. at 445-47 (line item veto unconstitutional although "Congress intended such a result," because it gave "the President the unilateral power to change the text of duly enacted statutes"). If it is unconstitutional for Congress to give away its legislative power, it is certainly unconstitutional for

the Executive to take it without permission. *See Util. Air Regulatory Grp.*, 134 S. Ct. at 2446.

The Take Care Clause, therefore, provides an important means for courts to review the actions of subordinate executive officials when, as here, they act as lawmakers and infringe on the legislative power vested exclusively in Congress. Federal Defendants' assertion that this obligation begins and ends with the President—and is unenforceable as to him—is both unfounded and dangerous, running counter to the long history of courts holding executive officials accountable for *ultra vires* actions. *See, e.g.*, *Util. Air Regulatory Grp.*, 134 S. Ct. at 2446; *Youngstown*, 343 U.S. at 587; *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935); *Angelus Milling Co.*, 325 U.S. at 296; *Kendall*, 37 U.S. at 612-13; *City of Chicago v. Sessions*, 888 F.3d 272, 277 (7th Cir. 2018). Because Plaintiffs have clearly stated a claim that the Secretary has overstepped and disregarded the constitutional requirement to take care that the laws are faithfully executed, the Court should deny Defendants' motion to dismiss.

VII. The Secretary's Approval Of The Kentucky HEALTH Waiver And The DSMD Letter Should Be Vacated.

Federal Defendants contend that "any remand should be without vacatur." Fed. Br. at 50. However, "[w]hen a Court identifies an infirmity in a rule, vacatur and remand is the 'normal' remedy." *Sec. Indus. & Fin. Markets Ass'n v. U.S. Commodity Futures Trading Comm'n*, 67 F. Supp. 3d 373, 434 (D.D.C. 2014) (citing *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014)). In order to conclude that remand without vacatur is appropriate, the court must consider two factors: "the seriousness of the deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). In this case, both *Allied-Signal* factors strongly weigh in favor of vacatur.

As to the first factor, remand without vacatur may be appropriate in cases where the agency

failure is easy to cure, but courts "have not hesitated to vacate a rule when the agency has not responded to empirical data or to an argument inconsistent with its conclusion." *Comcast Corp. v. FCC*, 579 F.3d 1, 8 (D.C. Cir. 2009). As described in Plaintiffs' opening brief and above, the deficiencies in the Secretary's approval are serious, substantive, and cannot be explained away. Moreover, to the extent that the court concludes that the Secretary misinterpreted the statute, including the scope of his waiver authority, the objectives of the Medicaid program, or any other legal error, vacatur is all but compelled. "In cases in which the agency's reasoning is 'so crippled as to be unlawful,' vacatur is generally the appropriate remedy." *Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs*, 282 F. Supp. 3d 91, 103 (D.D.C. 2017) (quoting *Radio-Television News Directors Ass'n v. FCC*, 184 F.3d 872, 888 (D.C. Cir. 1999)). In a case similar to this one, the court found that a CMS rule calculating the limit of supplemental payments to certain hospitals conflicted with the Medicaid Act. *See Children's Hosp. Ass'n of Tex. v. Azar*, No. 17-844 (EGS), __ F. Supp. 3d __, 2018 WL 1178024 (D.D.C. Mar. 6, 2018). The court explained that the rule's "deficiency is not merely procedural; rather, . . . the agency acted outside of the scope of its statutory authority under the Medicaid Act." *Id.* at *15. Because "this [was] not a case where the agency could conceivably 'be able to substantiate its decision on remand,'" the court vacated the rule. *Id.* (quoting *Allied-Signal*, 988 F.2d at 151). Vacatur is likewise warranted here.[22]

"[T]he second *Allied-Signal* factor [disruptive consequences of vacatur] is weighty only insofar as the agency may be able to rehabilitate its rationale for the regulation." *Comcast*, 579 F.3d at 9. Here, for the reasons Plaintiffs have described, the approval cannot be rehabilitated, and

[22] Defendants' insistence that the Kentucky HEALTH program must be evaluated as a whole means that, with respect to vacatur, if any aspect of the approval was flawed the entirety must be vacated. Fed. Br. at 26-27; Ky. Br. at 10. The government cannot defend the rule as a package, and then try to salvage it piecemeal.

the Court need not analyze the second factor. *See Standing Rock*, 282 F. Supp. 3d at 97. However, even if the Court evaluates this prong, it weighs in favor of vacatur. Defendants identify one potentially disruptive consequence—that Plaintiffs and other Medicaid recipients "would face the prospect of having their coverage terminated" if the waiver is invalidated. Fed. Br. at 50. As explained above, however, the prospect that Governor Bevin will terminate the expansion is highly speculative and legally questionable. Because Defendants' "forecasted harms are imprecise or speculative," there is no reason for this Court to "depart[] from the presumptive remedy of vacatur." *Pub. Emps. for Envtl. Responsibility v. U.S. Fish & Wildlife Serv.*, 189 F. Supp. 3d 1, 3 (D.D.C. 2016); *see also Standing Rock*, 282 F. Supp. 3d at 107. By contrast, *allowing* the approval to remain in effect will indisputably disrupt access to health insurance coverage and medically necessary care for hundreds of thousands of Medicaid enrollees. Vacatur will leave the status quo in place and is the appropriate remedy here.

Finally, the DSMD Letter should be vacated because the agency failed to comply with the APA's notice-and-comment requirements. "[D]eficient notice is a 'fundamental flaw' that almost always requires a vacatur." *Nat'l Venture Capital Ass'n v. Duke*, 291 F. Supp. 3d 5, 20 (D.D.C. Dec. 1, 2017); *id.* ("When notice-and-comment is absent, the Circuit has regularly opted for vacatur."); *see also Daimler Trucks N. Am. LLC v. EPA*, 737 F.3d 95, 103 (D.C. Cir. 2013).

CONCLUSION

For the reasons stated above, Plaintiffs respectfully ask that the Court grant their Motion for Summary Judgment, vacate the approval of the Kentucky HEALTH waiver, as well as the Dear State Medicaid Director Letter, and deny Federal Defendants' Motion to Dismiss Plaintiffs' Take Care claim.

Dated: May 14, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2018, I electronically filed the foregoing with the Clerk of Court, to be served on all parties of record via the CM/ECF system.

By: /s/ Jane Perkins
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