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

In *Stewart v. Azar*, 313 F. Supp. 3d 237 (D.D.C. 2018), this Court concluded that the approval of Kentucky HEALTH was arbitrary and capricious because, in part, the Secretary "failed to 'adequately analyze'... whether the project would cause recipients to *lose* coverage[, and] whether the project would help *promote* coverage." *Id.* at 262 (emphasis in original). The Court vacated the approval and remanded to the Secretary so that he could "adequately *consider* the effect of any demonstration project on the State's obligation to help provide medical coverage." *Id.* at 272 (emphasis in original). As Plaintiffs' opening brief showed, instead of following the Court's instructions, the Secretary engaged in an "exercise of supplying reasons to support a pre-ordained result." *Food Mktg. Inst. v. ICC*, 587 F.2d 1285, 1290 (D.C. Cir. 1978). All the evidence in the record indicates that tens of thousands of people will lose medical coverage as a result of Kentucky HEALTH. The Secretary once again made no attempt to grapple with this evidence.

Rather, the Secretary responds that any losses in coverage that the project may produce are wholly irrelevant because without Kentucky HEALTH, the Commonwealth will no longer cover the expansion population at all. In so doing, he has taken cost savings—which he labelled a "happy side effect" of the original approval—and moved them front and center. Without scrutiny, the Secretary is endorsing the Governor's threat to end health coverage that is essential to nearly half a million Kentuckians (and for which the State currently receives 95% federal funding—the most generous federal funding possible). Section 1115 does not permit re-approval on this basis.

In short, the Secretary's re-approval of Kentucky HEALTH suffers from the same errors that infected his initial approval. He again failed to rationally consider how the project's heightened barriers to coverage could possibly promote the Medicaid Act's central purpose of furnishing medical assistance to people whose incomes are insufficient to meet the cost of

necessary medical care. Plaintiffs respectfully request that this Court grant their motion for summary judgment and vacate the Secretary's re-approval of Kentucky HEALTH.

ARGUMENT

I. The Secretary's Re-Approval Is Reviewable And Not Entitled To Deference.

Federal Defendants seek to insulate the re-approval of Kentucky HEALTH from review by arguing that the Section 1115 waiver authority is committed as a matter of law to the absolute "judgment of the Secretary." Mem. Supp. Fed. Defs.' Mot. to Dismiss or, in the Alternative, for Summ. J. and in Opp'n to Pls.' Mot. for Summ. J., ECF No. 108-1, at 13-14 ("Fed. Br."). But, as the Secretary acknowledges, the Court has already rejected that argument, holding that his Section 1115 authority is properly subject to APA review. *Id.* at 14. Notably, the Court agreed with "every court which has considered the issue." *Stewart*, 313 F. Supp. 3d at 256 (quotation marks and brackets omitted).

Nor can the Secretary avoid meaningful scrutiny of his decision by seeking refuge under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). The Supreme Court repeatedly has held that deference is not appropriate when an agency decision touches on issues "of deep 'economic and political significance' that [are] central to [a] statutory scheme." *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (quoting *Util. Air Reg. Grp. v. EPA*, 134 S. Ct. 2427, 2444 (2014)). That is especially true where, as here, the "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 Reg. Grp.*, 134 S. Ct. at 2444 (internal quotation marks omitted). Here, the Administration has forcefully stated its intent to explode the ACA Medicaid expansion and fundamentally transform Medicaid.

As evidenced by the Kentucky HEALTH re-approval, this includes transforming Medicaid from a program designed to ensure health care coverage for needy individuals to a work program that strips their coverage in a manner inconsistent with Medicaid's fundamental purpose. The Secretary's re-approval of Kentucky HEALTH "carries national consequences . . . that will likely be felt . . . broadly across the nation." *Stewart v. Azar*, 308 F. Supp. 3d 239, 249 (D.D.C. 2018). Given the breadth of the Secretary's ambition, he cannot constrict the scope of this Court's review through the mere incantation of *Chevron. See King*, 135 S. Ct. at 2489.

Moreover, even if the *Chevron* framework applies, the Secretary's interpretations of the Medicaid Act's objectives still are not entitled to deference because they are plainly "inconsisten[t] with the design and structure of the statute as a whole." *Util. Air Reg. Grp.*, 134 S. Ct. at 2442 (alteration in original). As the Court has already pointed out, the Medicaid Act's "overarching purpose" is to "furnish [] medical assistance . . . and [] rehabilitation and other services" to low-income populations whose incomes are insufficient to the cost of cover necessary medical services. *Stewart*, 313 F. Supp. 3d at 260 (quoting 42 U.S.C. § 1396-1). The Secretary's re-approval continues to distort and discount that purpose, framing the Medicaid Act's objectives instead as promoting health and well-being, improving self-sufficiency, and saving money, all at the expense of providing coverage. No deference is owed to an agency's interpretation of a statute that is fundamentally at odds with the statute's express purpose.

Defendants' citation to *Pharmaceutical Research & Manufacturers of America v. Thompson*, 362 F.3d 817 (D.C. Cir. 2004), does not change this outcome. There, the Court of Appeals concluded that state plan amendments (SPAs) are generally the kind of agency action that can be entitled to *Chevron* deference. *Id.* at 822. But, of course, that does not mean every approval receives deference; courts still must 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) (no deference to approval of SPA because statute unambiguous); Christ the King Manor, Inc. v. Sec'y U.S. Dep't of Health & Human Servs., 730 F.3d 291 (3d Cir. 2013) (SPA approval not entitled to deference when it rests on incorrect interpretation); Beno v. Shalala, 30 F.3d 1057, 1071 (9th Cir. 1994) (stating in Section 1115 case that Chevron deference is not appropriate when agency's interpretation conflicts with the statute or appears to have been adopted for purposes of litigation and is not supported by the record). Defendants' argument that all Section 1115 approvals are entitled to deference—regardless of content, context, or scope—misconstrues Thompson and Chevron.

Equally meritless are Federal Defendants' arguments that the Secretary's decisions under Section 1115 are subject to "the utmost deference" because they entail "[p]redictive judgments" about areas that are purportedly within his unique "policy and scientific expertise." Fed. Br. at 14. As courts have recognized, "new agency policies often will involve some element of prediction about the future effects of those policies," but this does not render "any agency decision . . . by definition unimpeachable." *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 821-22 (D.C. Cir. 1983) (vacating agency action where the agency did not give "sufficient consideration to factors that may be highly relevant to" its predictive judgment) (quotation marks omitted). Rather, a predictive judgment "must be based on reasoned predictions." *Metlife, Inc. v. Fin. Stability Oversight Council*, 177 F. Supp. 3d 219, 237 (D.D.C. 2016); *see Nat'l Lifetime Ass'n v. FCC*, No. 18-1026, 2019 WL 405020, * 7 (D.C. Cir. Feb. 1, 2019) (vacating new FCC policy because the agency's predictive judgments were not supported by substantial evidence).

II. The Plaintiffs Have Standing To Pursue This Case.

Plaintiffs have standing to challenge the work requirements and premiums (and their associated consequences), which Defendants do not dispute. *Cf. Stewart*, 313 F. Supp. 3d at 252 (finding Plaintiffs have standing to challenge approval writ large where they showed injury from one component of approval). Further, having conceded that Plaintiffs have standing to challenge the project as a whole, Defendants' arguments that Plaintiffs lack standing to challenge the project's building blocks ring hollow, and regardless, are meritless for the reasons below.

Waiver of Retroactive Coverage. Defendants assert that Plaintiffs' risk of injury from the elimination of retroactive coverage is speculative. See Fed Br. at 35. However, Plaintiffs have shown a "real and immediate" threat of experiencing gaps in Medicaid coverage or losing coverage altogether. Nat. Res. Def. Council v. Pena, 147 F.3d 1012, 1022 (D.C. Cir. 1998). Furthermore, Plaintiffs suffer from chronic conditions that require regular visits to specialists and prescription medication, making it "virtually certain" that during gaps in coverage, the waiver of retroactive coverage will cause Plaintiffs to incur uncovered medical bills or forgo critical treatment altogether. See, e.g., Penney Decl. ¶¶ 7, 11 (discussing ongoing treatment needs for anxiety and depression and difficulty paying monthly premiums and meeting work requirement); Blanton Decl. ¶¶ 5, 10 (unable to work consistently due to fibromyalgia, degenerative disk disease, and Crohn's Disease); Wittig Decl. ¶¶ 3, 5, 9 (could not pay premium in July 2018, and with no savings and significant medical debts, fears being locked out of Medicaid if she cannot pay future premiums; requires ongoing treatment for migraines, arthritis, spinal disease, and depression); Humber ¶¶ 5, 8, 11 (does not have a job and did not pay premium in July 2018; needs treatment for chronic anemia and arthritis). See also, e.g., NB ex rel. Peacock v. District of Columbia, 682 F.3d 77, 83 (D.C. Cir. 2012) (finding Medicaid recipient requiring prescription inhalers for chronic asthma was "virtually certain to need Medicaid prescription coverage on a monthly basis for the foreseeable future").

Administrative Lockouts. Contrary to Federal Defendants' contention, Fed. Br. at 37, Plaintiffs allege facts that indicate a substantial probability that they will be locked out of Medicaid for failing to complete the redetermination process or to report changes in income in a timely way. E.g., Yates Decl. ¶¶ 7, 8, 9 (lacks a car, phone, and internet access, and therefore does not believe he can meet reporting requirements); Humber Decl. ¶¶ 12 (has no car or internet access, which will make it difficult to comply with reporting requirements); Kobersmith Decl. ¶¶ 4, 11, 12 ("biggest concern" is being locked out for not meeting reporting requirements because hours and income fluctuate substantially); Segovia Decl. ¶¶ 4 (lost coverage after missing recertification in past when his notice arrived late in mail).

Federal Defendants attempt to skirt this conclusion by asserting that Plaintiffs "would be exempt" from the lockout periods "if they are medically frail, pregnant, former foster care youth, or survivors of domestic violence, or if Kentucky grants them a good cause exception." Fed. Br. at 37. None of the referenced Plaintiffs currently qualifies for an exemption. The possibility that they may meet an exemption or seek a good cause exception in the future is "by no means certain, or even likely to occur," *Mead v. Holder*, 766 F. Supp. 2d 16, 24 (D.D.C. 2011), *aff'd sub nom. Seven-Sky v. Holder*, 661 F.3d 1 (D.C. Cir. 2011), and does not deprive them of standing.

Finally, Federal Defendants claim that Plaintiffs lack standing because "there is no reason to suppose that Plaintiffs cannot comply with the [reporting] requirement" by phone, online, or in person, Fed. Br. at 37, but this is doubly wrong. It is factually incorrect, as shown by certain Plaintiffs' inability to navigate any of these reporting mechanisms. *See*, *e.g.*, Pls.' Decls., *supra* at 7. Moreover, it misstates the law. "The theoretical ability to comply with a law does not undermine

a plaintiff's ability to challenge it." *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).

Non-Emergency Medical Transportation (NEMT). Federal Defendants' assertion that Plaintiffs have not sufficiently alleged that they will be injured by the loss of NEMT is similarly meritless. See Fed. Br. at 38–39. Several Plaintiffs do not have access to a car or to reliable public transportation. They anticipate needing to use NEMT in the future. See, e.g., Yates Decl. ¶ 8 (no car, and uses NEMT get to doctor's appointments); Spears-Lojek Decl. ¶¶ 9-11 (no car and has made appointments to use NEMT); Wittig Decl. ¶ 14 (relied on NEMT for several years and may need to again if existing mechanical issues cause her car to break down). Further, contrary to Defendants' supposition, none of these Plaintiffs qualify for an exemption. See AR 6762 (describing exemptions).

Non-Emergency Use of the Emergency Department. Federal Defendants' arguments regarding non-emergency use of the emergency department are also misguided. See Fed. Br. at 39. Plaintiffs have identified specific medical conditions and injuries that led them to seek care in the emergency room in the past and are substantially likely to recur, but which likely do not qualify as "emergent." See, e.g., Penney Decl. ¶¶ 7, 13 (prior visit for treatment of chronic depression and anxiety); Keith Decl. ¶¶ 11 (visit for ongoing vertigo condition); Wittig Decl. ¶¶ 5, 11 (visit to treat extreme pain and spasms from chronic arthritis and neuropathy); McComas Decl. ¶¶ 15 (visits to ER for rapid-onset urinary tract infections); Humber Decl. ¶¶ 10 (visits for high blood pressure and pneumonia); Ritter Decl. ¶¶ 11, 15 (visits for chronic migraine and seizure conditions); Lee Decl. ¶¶ 10 (visit for sinus infection). Given the chronic nature of their health conditions, Plaintiffs have alleged a substantial likelihood of injury. See NB ex rel. Peacock, 682 F.3d at 83-84 (finding

Medicaid recipient's past need for medical care was evidence of future need and past injury from coverage reductions predicted "both frequent and recurring" future injury).

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

The central purpose of the Medicaid Act is to furnish medical assistance to individuals whose income is insufficient to afford necessary care. In re-approving Kentucky HEALTH, the Secretary continued to manipulate the objectives of the Medicaid Act in an effort to implement the Administration's plan to "transform" Medicaid and "explode" the ACA's Medicaid expansion. See Pls.' Mot. and Mem. in Supp. of Mot. for Partial Summ. J., ECF No. 91-1, at 7-8 (Pls.' Br.). Saving money, once a "happy side effect" of the project, see Stewart, Tr. at 42:25-43:2, became the central focus of the approval. As before, Federal Defendants also approved the project to promote health and wellness—a justification the "Secretary spent much time claiming" in the original approval, Stewart, 313 F. Supp. 3d at 266, and that the Court rejected, id. at 266-68. Finally, even though the Court already expressed "doubts whether such an objective is proper," id. at 271, the Secretary again approved Kentucky HEALTH as a measure to help people achieve financial independence. Simply put, the Secretary intended from the beginning to disassemble Medicaid and engaged in an exercise of "supplying reasons to support a pre-ordained result." Food Mktg. Inst., 587 F.2d at 1290; Fed. Br. at 14. The additional explanation does not cure the APA violations this Court identified, and the Secretary's actions continue to be arbitrary and capricious.

A. Cost Considerations

The Secretary seeks to justify approval of Kentucky HEALTH by claiming that Medicaid has an additional, implicit purpose—to save the Commonwealth's money for the long run. According to the Secretary, the re-approved project's restrictive requirements will help Kentucky "stretch its limited resources" and "ensure the long-term sustainability of the [Medicaid] program."

AR 6726; Fed. Br. at 15 (arguing that measures that help "stretch limited Medicaid resources" further the objectives of Medicaid). But that is not a legitimate objective under Section 1115. As other courts have held, if the "purpose of [a Section 1115] waiver application [i]s to save money," the application cannot meet the standards of Section 1115. *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011); *Beno*, 30 F.3d at 1069. As explained below, Defendants' arguments to the contrary fail, as they are untethered from the Medicaid Act, unsubstantiated by record evidence, and unsupported by the case law. *See* Fed. Br. at 14-20.

To begin with, Defendants argue that a handful of cases recognize that saving money is a purpose of the Medicaid Act. But none of these cases support their extreme position. First, Defendants cite *PhARMA v. Walsh*, 538 U.S. 644 (2003), for the proposition that "it is a legitimate objective of Medicaid to conserve state resources via measures that reduce the likelihood of borderline groups becoming Medicaid-eligible." Fed. Br. at 16; see also Mem. Supp. Ky. Defs.' Mot. for Summ. J. and in Opp'n to Pls.' Mot. for Summ. J., ECF No. 110-1, at 11 ("Ky. Br."). But Walsh addressed a preemption challenge to a state Medicaid program feature and did not purport to define or determine the objectives of the Medicaid Act for the purpose of Section 1115. More importantly, the Medicaid program feature at issue provided reduced-cost pharmaceuticals to all individuals in the state. See Walsh, 538 U.S. at 653-54. Reducing the costs of medicine—and in doing so both providing broader access to prescription drugs and reducing unnecessary Medicaid spending—is the kind of fiscally sound policy that also promotes the provision of medical assistance. See id. at 664 (noting the state program did not restrict access to prescription drugs for Medicaid enrollees except through prior authorization as explicitly allowed by the Medicaid Act). In fact, the Court found that providing cheaper drugs to individuals not enrolled in Medicaid and cutting Medicaid costs "would not provide a sufficient basis for upholding the [supplemental drug

rebate] program if it severely curtailed Medicaid recipients' access to prescription drugs." *Id.* at 664-65. That the Medicaid Act does not preempt such a policy has no bearing on whether the Secretary's waiver authority extends to authorizing a massive benefits cut, the purpose of which is to reduce costs.

Second, Defendants cite *New York State Department of Social Services v. Dublino*, 413 U.S. 405 (1973), for the same proposition. Fed. Br. at 16. But *Dublino* also featured a preemption challenge—that time, to a state-imposed AFDC work requirement that differed from the work requirement in the federal statute. 413 U.S. at 407. Again, the question of whether a state's program conflicts with a federal program's purpose is not the same as whether a state's project is likely to affirmatively promote the federal program's purpose. Moreover, AFDC and Medicaid are fundamentally different programs, with fundamentally different purposes. *See* Part IV.D, *infra*. Whether AFDC's work requirement includes cost-savings as one of its purposes has no bearing on whether Medicaid does.

Kentucky also cites *Crane v. Mathews*, 417 F. Supp. 532 (N.D. Ga. 1976), and *California Welfare Rights Organization v. Richardson*, 348 F. Supp. 491 (N.D. Cal. 1972), for the same proposition. Ky. Br. at 11. But the stated purpose of the Section 1115 waivers in these cases was not simply to save money. Rather, the states sought to impose nominal copayments on a limited subset of the Medicaid population for a quite limited duration (one year) to determine whether the copayments would curtail *overutilization* of marginally needed health care. *See Crane*, 416 F. Supp. at 537; *Cal. Welf. Rts. Org.*, 348 F. Supp. at 495 n.3.

Next, the Secretary argues that cutting costs promotes coverage, as it enables states to continue to cover optional eligibility categories—particularly the expansion population—and optional services. Fed. Br. at 18; *see also* AR 6726, 6731-32. He bases this conclusion on *National*

Federal of Independent Businesses v. Sebelius, 567 U.S. 519 (2012) ("NFIB"), which he argues converted the mandatory Medicaid expansion coverage group to an optional coverage group. Fed. Br. at 18-20; see also Ky. Br. at 14. But Defendants misread NFIB.

In NFIB, the Court decided a constitutional question: whether it was unduly coercive for Congress to compel a Medicaid-participating state to cover the Medicaid expansion population under the threat of losing all federal Medicaid funding. The Court held that it was coercive because, prior to 2010, states did not understand they would have to cover this group as part of the Medicaid bargain. And "though Congress' power to legislate under the spending power is broad, it does not include surprising participating States with post-acceptance or 'retroactive' conditions." 567 U.S. at 584 (citation omitted and alteration adopted). As the full remedy for the unconstitutional violation, the Court prohibited the Secretary from withdrawing existing federal funds from a state that refused to expand, id. at 586, and otherwise left the Medicaid statutory scheme intact, id. at 585. NFIB established only whether requiring coverage of the expansion population without a state's opt-in was coercive. But it did not deem the expansion population an optional coverage population. And following enactment of the ACA in 2010 and the Supreme Court's NFIB decision in 2012, states, such as Kentucky, that opted-in understood the bargain. Requiring coverage of the expansion population for those states, therefore, is no more coercive than is requiring coverage of pregnant women and children. See Stewart, 313 F. Supp. 3d at 242 ("Although it may choose not to cover the ACA expansion population, . . . if the state decides to provide coverage, those individuals become part of its mandatory population." (citing NFIB, 567 U.S. at 587)). Nor may states choose to treat the expansion population differently after opting-in. See id. at 269 (noting Congress placed the expansion group "on equal footing" with traditional eligibility categories).

Defendants also cite a Frequently Asked Questions published by CMS after NFIB was decided, which indicates that states may unexpand. Fed. Br. at 18. This document is entitled to no deference from the Court. "In case after case, courts have affirmed this fairly intuitive principle, that courts need not, and should not, defer to agency interpretations of opinions written by courts." Citizens for Responsibility & Ethics in Washington v. FEC, 209 F. Supp. 3d 77, 87 (D.D.C. 2016) (collecting cases); Rural Tel. Coal. v. FCC, 838 F.2d 1307, 1313 (D.C. Cir. 1988) ("Deference to administrative expertise does not extend to judging the constitutionality of a statute or regulatory scheme." (citation omitted)); accord Miller v. Johnson, 515 U.S. 900, 922-23 (1995) (rejecting state's reliance on federal agency's interpretation of a constitutional question). Further, since the FAQ contains no reasoning, this Court should not consider CMS's standalone statement persuasive in its analysis of whether states may later withdraw coverage for a mandatory population—here, individuals with incomes below 133% of FPL. See, e.g., Texas Children's Hosp. v. Azar, 315 F. Supp. 3d 322, 338 (D.D.C. 2018) (FAQ not entitled to deference because it lacked "power to persuade"); Oceana, Inc. v. Evans, No. CIV.A.04-0811(ESH), 2005 WL 555416, at *34 (D.D.C. Mar. 9, 2005) (giving no weight to FAQ as the "document is merely an informal statement").

Even if Kentucky is free to terminate coverage for the expansion population, the Governor's threat to do so cannot turn a coverage-reducing project into a project promoting coverage. This claim—that the Secretary properly found that Kentucky HEALTH was likely to promote coverage by enabling the Commonwealth to maintain coverage for optional populations and services—would make the Section 1115 authority virtually limitless. As Plaintiffs described in their opening brief, Pls.' Br. at 16, any proposed project that cuts spending would then pass muster under Section 1115 so long as the state continued to cover some populations and/or services. Notably, optional populations currently comprise nearly 30% of the Medicaid enrollees.

See MACPAC, Mandatory and Optional Enrollment and Services in Medicaid 3 (June 2017), https://www.macpac.gov/publication/mandatory-and-optional-enrollees-and-services-inmedicaid (last visited Feb. 18, 2019). Under the Secretary's reasoning, there would be no reason for a state to cover these populations under their state Medicaid plan and grapple with the strings Congress attached. Using Section 1115, state and federal officials could consign all of these people to parallel programs of their choosing, with the state slicing and dicing coverage in any way the Secretary would allow. The Secretary's rationale would even allow him to approve a project eliminating some mandatory coverage of populations and services whenever a state threatens to pull out of the Medicaid program altogether if it does not get what it wants. This cannot be what Congress intended. See Beno, 30 F.3d at 1069 (doubting that Congress would set forth such detailed and comprehensive requirements, "require the Secretary to enforce them, and then enact a statute allowing states to evade these requirements with little or no federal agency review"); see also Stewart, 313 F. Supp. 3d at 255-56 (noting that the requirement that any project be "likely to assist in promoting" the objectives of the Medicaid program is what prevents the Secretary from allowing a state to terminate coverage for the blind). In addition, interpreting the statute to give the Secretary the unfettered authority to reject the policy priorities Congress set forth in the Medicaid Act would raise serious constitutional concerns. See Pls.' Br. at 16; see also FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) (The court must be guided to a degree by common sense as to the manner in which Congress is likely to "delegate a policy decision of such economic and political magnitude to an administrative agency" with virtually no constraint on its delegated authority).

Spry v. Thompson, 487 F.3d 1272 (9th Cir. 2007), also does not support the Secretary's reasoning. See Fed. Br. at 20 (citing Spry for the proposition that any Section 1115 project that

covers optional populations is likely to promote the objectives of the Medicaid Act). *Spry* did not evaluate the approval of a Section 1115 waiver. *Spry* instead found that certain Medicaid Act provisions did not apply to categories of individuals who were not described in the Medicaid Act—at the time before the ACA, childless adults without a disability. According to *Spry*, individuals who were "statutorily *ineligible* for Medicaid under federal law" could not be covered through the state Medicaid plan absent a waiver. *Spry*, 487 F.3d at 1274 (emphasis in original). Those individuals thus were not "made worse off" by the Section 1115 project providing them limited coverage, because they otherwise would have received no Medicaid coverage at all. *Id.* at 1276. In stark contrast, the Medicaid Act now describes each of the eligibility groups subject to Kentucky HEALTH, including childless adults without a disability, making every one of them statutorily *eligible* under the Medicaid Act. *See* 42 U.S.C. § 1396a(a)(10)(A)(i). Thus, the baseline for determining whether they will be "made worse off" by the project is not no coverage at all—as it was in *Spry* pre-ACA—but the coverage Congress has since provided in the Medicaid Act.

Lastly, even if this Court were to consider cost savings a permissible purpose for a Section 1115 waiver, and even if this Court were to permit Kentucky to hold the expansion population's Medicaid coverage as a bartering chip, there is no evidence in the record that Kentucky in fact lacks the funding to maintain coverage of the expansion population (or other optional groups or services) without Kentucky HEALTH. *See Stewart*, 313 F. Supp. 3d at 271. Other than bare assertions, Fed. Br. at 8, 18; Ky. Br. at 12-13, Defendants proffer no evidence in the record that the Kentucky Medicaid program is "actually at risk" of financial collapse. *See Stewart*, 313 F. Supp. 3d at 270-71. Nor do they explain why "cuts to the expansion population would be the best remedy for any budget woes." *Id.* at 271. Federal Defendants boldly assert that the answers to those critical questions "make[] no difference," as Kentucky is free to terminate the Medicaid

expansion. Fed. Br. at 19. But, as the Court noted in *Stewart*, without data on the Commonwealth's financial position, "the Secretary could not make a reasoned decision that Kentucky would truly be 'unable to maintain access for currently enrolled populations." *Stewart*, 313 F. Supp. 3d at 271. Approving Kentucky HEALTH on this basis—even assuming it were a permissible one—therefore cannot be rationally supported.

B. Health and Public Well-Being

As with the previous approval, the Secretary justified re-approval of Kentucky HEALTH with the supposed objective of promoting health and wellness. Fed. Br at 20-21; *see also* Ky. Br. at 6-9. But the Court has already pointed out that this effort to "move the target" is "little more than a sleight of hand." *Stewart*, 313 F. Supp. 3d at 266. As the Court explained, the Secretary cannot avoid the express language of Section 1396-1 by simply proclaiming that Kentucky HEALTH may improve health outcomes through greater independence and improved quality of life. *Id.* Defendants cite no authority suggesting that Section 1115 permits the Secretary to approve a project that undermines the expressly stated goals identified in Section 1396-1 (by vastly shrinking available Medicaid coverage) to further an objective not identified in Section 1396-1. *See also* Section IV.D, *infra* (noting that the record clearly contradicts the Secretary's claim that Kentucky HEALTH is likely to promote health).

The sheer breadth of Defendants' interpretation should give the Court pause, as it did before. *See Stewart*, 313 F. Supp. 3d at 267-68 (noting if "the Secretary could exercise his waiver authority solely to promote health . . . [n]othing could stop him from conditioning Medicaid coverage on consuming more broccoli (at least on an experimental basis)"). This is even more so when Defendants seem unclear about what even constitutes promoting health—whether it means improving public health, statistical improvements in individual health outcomes, or a general

immeasurable increase in wellness and mood. Compare Fed. Br. at 20 (describing goals of the Act as promoting "basic public health") with id. at 21 (mentioning "quality of life") with AR 6719 (discussing "improve[d] health and wellness") with AR 6720 ("improving health outcomes"). More importantly, the Secretary's high level reading of Medicaid's purpose to advance health and wellness ignores the Act's more specific—and express—purpose of "furnish[ing] . . . medical assistance . . . and [] rehabilitation and other services" to low-income individuals. 42 U.S.C. § 1396-1. 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) ("[A]gencies 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." (quotation marks omitted); 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."); see also Pls.' Br. at 13-14 (noting that this alternative objective would allow the Secretary to approve any policy that he subjectively concludes might influence health outcomes and wellness).

C. Self-sufficiency

Finally, Defendants retread their previous rationale that the restrictive Kentucky HEALTH requirements further the broad objective of encouraging "economic self-sufficiency" by focusing on financial independence and transitioning individuals to commercial coverage. Fed. Br. at 15; Ky. Br. at 14-19. This Court has already expressed "doubts [about] whether such an objective is proper," noting that this reading requires "excising" the term independence from its context in Section 1396-1, which "limits its objectives to helping States furnish *rehabilitation and other*

services that might promote self-care and independence." Stewart, 313 F. Supp. 3d at 271. As the Court correctly concluded, "[i]t does not follow that limiting access to medical assistance would further the same end." Id. The re-hashed rationale offered by Defendants should not cause the Court to change its assessment of this purported objective.

First, Kentucky argues that the Secretary should be able to define "independence" for the expansion population divorced from the rest of Section 1396-1 because that population is not mentioned in Section 1396-1. Ky. Br. at 17. This echoes the "two program" argument the Court already rejected. See Stewart, 313 F. Supp. 3d at 270 (stating it is "inconceivable that Congress intended to establish separate Medicaid programs, with differing purposes, for each"). Whether Defendants like it or not, when Congress enacted the Medicaid expansion, it did not create two programs. Rather, it followed the path it has used before when adding populations not mentioned in Section 1396-1. It added Subsection VIII to Section 1396a(a)(10)(A)(i) to create another mandatory population and assigned that population a benefit package already available to some other enrollees. See 42 U.S.C. § 1396a(k). See, e.g., Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, § 302, 102 Stat. 683, 750-54 (using that approach to expand coverage of pregnancy and post-partum services to low-income women); Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6401, 103 Stat. 2106, 2258-59 (expanding coverage to emancipated children to include early and periodic screening and treatment services). And when Congress enacted the Medicaid expansion, it referred to one Medicaid program, not two. See, e.g., H.R. Rep. No. 111-443 pt. II, at 977 (2010), as reprinted in 2010 U.S.C.C.A.N. 474, 499 ("Medicaid will be expanded so that anyone below 133 percent of poverty will be Medicaid eligible."); H.R. Rep. No. 111-443 pt. I, at 204 (2010), as reprinted in 2010 U.S.C.C.A.N. 123, 128 (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.").

Further, Kentucky argues that the Secretary can pursue "independence" in Section 1396-1 in whatever manner suits him because the expansion population is "able-bodied" and, thus, "wholly unlike" other Medicaid populations. Ky. Br. at 17. This argument ignores the substantial overlap between all Medicaid-eligible population groups, both in terms of characteristics and health needs. All Medicaid enrollees, whether expansion or not, have low incomes, and a significant percentage of expansion enrollees have dependent children and/or at least one chronic condition. *See* AR 6720 (explaining the expansion population includes "many parents of dependent children," who were only eligible pre-expansion if their household income was below 25% of FPL); 17897-98 (noting prevalence of chronic conditions and functional limitations among Medicaid enrollees who do not receive SSI). For all Medicaid enrollees—whether they be in good health or not—Medicaid coverage includes not only preventive care (*e.g.*, check-ups, cancer screens) but also treatment some enrollees may never need (*e.g.*, nurse-midwife, Sickle Cell, and hospice services) and rehabilitation and other services needed to help individuals attain or retain capability for independence or self-care. *See* 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a).

Second, Kentucky argues that "it makes sense to treat expanded Medicaid as a transitional program." Ky. Br. at 18. In support, the Commonwealth points out that "participation in expanded Medicaid is specifically tied to income," and people have moved out of Medicaid, presumably because their wages have increased during the current economic upturn. This argument has problems. Participation in Medicaid, whether traditional or expansion, is specifically tied to income. *See* 42 U.S.C. § 1396a(a)(10). To the extent people are churning off Medicaid due to improved wages, this is occurring in the absence of Kentucky HEALTH's restrictive eligibility

requirements—further supporting the uncontroverted evidence in the record that the vast majority of people on Medicaid who can work do work. *See* AR 20297-99.

Third, Kentucky argues that Section 1396u-1(b) alters the Court's analysis of the Medicaid Act's objectives. Ky. Br. at 17-18. It does not. As Plaintiffs have explained, Section 1396u-1(b) is a narrow provision that permits states to coordinate eligibility for Medicaid and TANF, only for people participating in both. Kentucky's approach would transform this narrow, optional provision into a free-standing objective of the entire Medicaid Act, unrelated to the primary objective described in Section 1396-1. But the mere reference to another program or goal in a single provision does not transform the core objectives of the statute. Cf. 42 U.S.C. § 1396f (establishing protections for observation of religious beliefs). Section 1396u-1(b) is better understood as an example of Congress's careful balancing of competing policy interests. As Plaintiffs have argued, when Congress imposes work requirements, it does so carefully and in a detailed manner, using provisions that explain how work requirements will interact with its other policy goals. See Pls. Br. at 35. That is precisely what Congress has done in 1396u-1(b): where the goals of Medicaid (furnishing coverage) interact with the goals of TANF (including promoting job preparation), Congress has specified how to balance the two. Indeed, while Section 1396u-1(b) permits termination for non-compliance with TANF's work requirements in limited circumstances, it also establishes outer boundaries on when that termination can occur. See Comacho v. Texas Workforce Comm'n, 408 F.3d 229, 234-35 (5th Cir. 2005). That careful balancing—in a narrow provision outside of the Secretary's waiver authority—does not grant the Secretary carte blanche to import the TANF objectives into the Medicaid program and thus, impose work requirements broadly across the program to populations that do not interact with TANF at all.

Finally, Kentucky asserts that the language of the AFDC statute is "remarkably similar" to that of Section 1396-1 and should lead the Court to find parallel meanings between the two provisions. Ky. Br. at 19. Congress refers to "self-care and independence" in the Medicaid Act and "maximum self-support and personal independence" in AFDC. But Kentucky's "argument for uniform usage ignores the cardinal rule that statutory language must be read in context since a phrase gathers meaning from the words around it." Gen. Dynamics Land Sys., Inc. v. Cline, 540 U.S. 581, 596 (2004). Here, the vastly different contexts in which these terms appear refute any argument for parallel construction. Id. at 595-96. The AFDC goals of keeping children in their own homes, "maintain[ing] and strengthen[ing] family life," and achieving "maximum selfsupport," 42 U.S.C. § 601 (1994), are nowhere to be found in the Medicaid statute, which is focused on furnishing medical assistance for people whose incomes are insufficient to cover the cost of necessary medical services. The AFDC statute included work requirements, see Public Welfare Amendments of 1962, Pub. L. No. 87-543, § 105, 76 Stat. 172, 186-88, but Medicaid does not. And the cases Kentucky cites interpret Section 601 of the AFDC statute and, therefore, offer no insight into the meaning of Section 1396-1. See C.K. v. New Jersey Dep't of Health & Human Servs., 92 F.3d 171, 178, 184 (3d Cir. 1996); Aguayo v. Richardson, 473 F.2d 1090, 1103-04 (2d Cir. 1973). Plaintiffs' interpretation—that independence in Medicaid refers to functional, not financial, independence—properly gives the statutes two distinct meanings based on their distinct language, structure, and context. See Pls. Br. at 14-15.

¹ The contrast between self-support and self-care bolsters Plaintiffs' interpretation that Medicaid is concerned with helping individuals attain *functional* independence and capacity to accomplish activities of daily living. For instance, federal regulations defining persons eligible for institutional-level care describe individuals whose conditions "results in substantial functional limitations in three or more of the following areas of major life activity," such as "self-care" and "capacity for independent living." 42 C.F.R. § 435.1010.

IV. The Secretary's Re-Approval Of Kentucky HEALTH Was Arbitrary And Capricious And Exceeded His Authority.

A. Re-Approval of the Kentucky HEALTH Project is What is Before the Court.

Defendants now take aim at the Court's conclusion that Kentucky HEALTH is "wholly distinct from other pieces of KY HEALTH," and that the Secretary "effectively treated the SUD program and Kentucky HEALTH as two separate demonstration projects." Fed. Br. at 27 (citing *Stewart*, 313 F. Supp. 3d at 257). However, the factors that led to the Court's finding have not changed—Kentucky HEALTH and the SUD program apply to different population groups, have different effective dates, and serve different purposes. *See Stewart*, 313 F. Supp. 3d at 257.

Defendants make much of the fact that in re-approving Kentucky HEALTH, the Secretary said: "Kentucky HEALTH, working within the larger KY HEALTH demonstration program, is likely to assist in promoting the objectives of the Medicaid program." Fed. Br. at 27-28 (citing AR 6723). However, after making that statement, the Secretary again went on to "evaluate[] independently whether Kentucky HEALTH would promote various objectives of the Act." Stewart, 313 F. Supp. 3d at 258; see AR 6723-28. And, as he did in the initial approval, the Secretary separately stated which waivers and expenditure authorities were "necessary" for Kentucky HEALTH as opposed to which were "necessary" for KY HEALTH. See AR 6738-44. Kentucky has been moving forward with the SUD program without Kentucky HEALTH in place, further revealing that the Kentucky HEALTH waivers are not "necessary" for Kentucky to provide those services. See, e.g., Letter from Andrea J. Casart, Dir., Div. of Medicaid Expansion Demonstrations, Ctr. for Medicare & Medicaid Servs., to Carol H. Steckel, Comm'r, Ky. Dep't for Medicaid Servs. (October 5, 2018) (accepting SUD Implementation Plan submitted by Kentucky and allowing Kentucky begin receiving federal funding for services under the SUD program), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/

1115/downloads/ky/health/ky-health-sud-implement-protocol-apprvl-10052018.pdf. The Secretary vaguely suggests that without Kentucky HEALTH, the Commonwealth may not have the money to continue covering those services, AR 6726, but nothing in the record shows that to be the case. Even if it were, the Secretary did not weigh the benefits of the SUD program against the coverage loss that Kentucky HEALTH would unquestionably produce. *See Stewart*, 313 F. Supp. 3d at 265; Section IV.C, *infra*.

B. Simply Labeling Kentucky HEALTH an "Experiment" Does Not Relieve the Secretary of His Obligation to Engage in Reasoned Decision-making.

Defendants repeatedly justify approval of Kentucky HEALTH by noting that it is a time-limited experiment. Plaintiffs do not contest that Congress enacted Section 1115 to allow states to carry out time-limited demonstrations designed to test novel ideas and that Congress has used the results of past projects to inform its Medicaid policy decisions. But nothing in the record indicates that Kentucky designed and the Secretary approved Kentucky HEALTH as a legitimate experiment. Rather, this is an approval in search of an experiment. See Amicus Br. of Deans, Chairs and Scholars, ECF No. 95-1, at 7 (noting that Defendants approved the project "without ensuring that their claims will be properly tested by an objective, robust, and high quality evaluation with the ability to collect and analyze evidence from a representative population

² Plaintiffs do contest any suggestion that the Secretary abides by the limits in Section 1115. Among other things, he routinely approves Section 1115 projects that no longer have experimental value. For example, even though Congress made it possible for states to use managed care and to cover a family planning eligibility category through state plan amendments (as opposed to a Section 1115 project), *see* Fed. Br. at 28, the Secretary continues to use Section 1115 to allow states to implement these very policies. In fact, CMS has recently stated that Section 1115 projects need not be innovative, experimental, or time-limited. *See* Ctrs. for Medicare & Medicaid Servs., CMCS Informational Bulletin: Section 1115 Demonstration Process Improvements 4 (2017), https://www.medicaid.gov/federal-policy-guidance/downloads/cib110617.pdf (announcing that CMS will approve certain "routine, successful" Section 1115 projects for a period of up to 10 years); *see also* Ky. Br. at 24 (noting that several states have operated all of their Medicaid programs under Section 1115 for decades).

sample"); *id.* at 16 (discussing the perils of launching Kentucky HEALTH without the evaluation design in place). In fact, there is ample reason to doubt that the true purpose of Kentucky HEALTH is experimental. *See* Pls.' Br. at 7-8. As Defendants acknowledge, CMS has allowed a number of states to maintain ongoing waivers of retroactive eligibility. Fed. Br. at 35. Similarly, many states have experimented with imposing premiums on Medicaid and CHIP enrollees, finding uniformly that premiums deter and reduce coverage. *See id.* at 30; *see also* Section IV.C, *infra*. Permitting yet another state to experiment with these features is not likely to yield additional useful information. *See, e.g., Newton-Nations*, 660 F. 3d at 381. And, while novel to Medicaid, work requirements have long been a condition of eligibility in other federal programs. The record's substantial research shows that such requirements have failed to effectively promote work, while increasing poverty, financial insecurity, and even mortality. *See* Pls.' Br. at 30, n.10.

Critically, it is not enough under Section 1115 for a project to be experimental. It must also be likely to promote the objectives of the Medicaid Act. Accordingly, even if Kentucky HEALTH were experimental, the Secretary needed to consider its impact (*i.e.*, coverage loss and promotion) on the individuals that the Medicaid program was enacted to protect. *See Newton-Nations*, 660 F.3d at 381. The Secretary cannot escape that obligation by simply declaring that the project is a demonstration, the exact outcomes of which are unknowable. *See* Fed. Br. at 22-23. Contrary to Defendants' assertions, Plaintiffs do not claim that the Secretary must perfectly predict the exact outcomes of a Section 1115 proposal. *See id*. Instead, the Secretary must reasonably weigh the evidence in the record regarding the probable outcomes of Kentucky HEALTH. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983). As described below, he did not do so here.

C. The Secretary Failed to Adequately Examine How the Project Would Affect Coverage.

Because the central objective of the Medicaid Act is to furnish medical assistance to low-income individuals, the Secretary must adequately examine whether Kentucky HEALTH "would cause recipients to lose coverage [and] whether the project would help promote coverage." *Stewart*, 313 F. Supp. 3d at 262. Ultimately, Defendants argue that the Secretary satisfied that requirement by finding that without Kentucky HEALTH, the Commonwealth would terminate coverage for the entire expansion population and perhaps (some undisclosed) optional coverage groups as well. Fed. Br. at 24. For the reasons described above, that flawed logic cannot carry the day. Instead, the Secretary needed, but again failed, to reasonably evaluate how Kentucky HEALTH would affect coverage vis-a-vis the status quo. ³

Abundant evidence in the record indicates that the project will result in massive coverage loss. *See* Pls.' Br. at 18-28. The Secretary did not engage with most of that evidence, including new evidence submitted by experts estimating how many individuals would lose coverage due to Kentucky HEALTH. *See id.* at 18-19; *see Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018) (holding that "agency cannot ignore evidence that undercuts its judgment"). Thus, the Secretary did not fulfill his duty to evaluate what effect the project would have on coverage. In an attempt to side-step this obvious deficiency in the record, Defendants emphasize that the Secretary recognized that some individuals "may lose coverage," Fed. Br. at 21; Ky. Br. at 21, and briefly discussed—and then dismissed—the evidence that 95,000 people would lose coverage, Fed. Br. at

³ Tellingly, when developing its budget projections, Kentucky assumed that the expansion population would receive coverage even without the project in place. *See* AR 5419-23.

22-24; Ky. Br. at 19-20. These aspects of the approval letter do not show a reasonable evaluation of the coverage loss. *See* Pls.' Br. at 19-20.⁴

To begin with, criticisms of the 95,000 figure are unfounded. First, the Secretary stressed that the Kentucky budget projections do not show that "95,000 individuals will completely lose coverage and not regain it." AR 6731. While that is true, it does not allow him to dismiss the figure out of hand. To be sure, the reduction in member months (in the Kentucky budget projections) is the equivalent of 95,000 individuals losing coverage for one year, not indefinitely. *See, e.g.*, AR 16707-09. It can also be expressed as 190,000 individuals losing coverage for six months, or 380,000 losing coverage for three months.

Instead of grappling with these numbers, the Secretary made the startling argument that temporary coverage loss, including due to the elimination of retroactive eligibility, does not actually constitute coverage loss or is otherwise irrelevant. AR 6731; *see also* Fed. Br. at 24; Ky. Br. at 21. That is nonsensical. Commenters did not base their concerns about coverage loss on an assumption that it would be permanent—rather, they anticipated temporary coverage loss and explained that gaps in coverage have serious health and financial consequences. *See, e.g.*, 13175 (American Lung Association warning that individuals "cannot afford a sudden gap in their care" as a result of not meeting the work requirements), 12918, 18307, 19985-86 (all expressing

⁴ Defendants also make much of the fact that in re-approving Kentucky HEALTH, the Secretary argued Section 1115 "explicitly contemplates" that a project may cause coverage loss. Fed. Br. at 21; Ky. Br. at 21-22 (citing AR 6730). In fact, the statute only contemplates that a project may "result in an impact on eligibility." 42 U.S.C. § 1315(d)(1). What is more, the provision underscores that Congress intended the Secretary to carefully consider how a proposed project could impact eligibility and coverage. *See id.* § 1315(d)(2) (requiring Secretary to issue regulations ensuring any application for a project affecting eligibility be subject to public comment and include, among other things, "*coverage projections* of the demonstration project"). Certainly, nothing in the statute relieves the Secretary of his obligation to reasonably examine whether a proposed project is likely to promote Medicaid coverage.

concerns about gaps in coverage); *see also* Amicus Br. of Am. Acad. of Ped. et al., ECF No. 99, at 19-20. The response the Secretary offered to those concerns is essentially no response at all. The Secretary also speculated that the reduction in member months is "likely attributable" in part to individuals transitioning from Medicaid to private insurance. AR 6731. However, substantial evidence in the record undermines any claim that Kentucky HEALTH will increase access to commercial coverage. *See* Pls.' Br. at 19 n.5 (citing evidence that few low-wage workers have access to commercial coverage), 30 (citing evidence that work requirements have failed to effectively promote work or financial security). And yet again, the Secretary did not attempt to quantify "how many beneficiaries might make that transition." *Stewart*, 313 F. Supp. 3d at 264.

Second, the Secretary argued that the reduction in member months is now an overestimate due to "changes made to the demonstration at approval." AR 6731. Even assuming that the initial approval included changes significant enough to affect that number in a meaningful way, *cf. Stewart*, 313 F. Supp. 3d at 263-64, the Secretary once again neglected to calculate a bottom-line estimate of coverage loss "with these reforms in mind," *id.* at 264. Federal Defendants claim that merely mentioning the 95,000 figure in the approval letter obviated any need to provide a bottom-line estimate. *See* Fed. Br. at 23, 21. Not so. As this Court explained, the Secretary "failed to consider an important aspect of the problem" when he approved Kentucky HEALTH "with no idea

⁵ Defendants continue to assert that the exemptions, good cause exceptions, on-ramps, and other "guardrails" would minimize any coverage loss. Fed. Br. at 25-27, 37-38; Ky. Br. at 21, 30-31, 41. Plaintiffs addressed those unsupported claims in detail in their opening brief, *see* Pls.' Br. at 20-21, highlighting that these purported safeguards were "baked in" to the concerns commenters raised about coverage loss, *see Stewart*, 313 F. Supp. 3d at 263. Defendants offer no response. The Secretary does take issue with Plaintiffs' point that in using the exemptions to justify approval, he improperly limited his review to only vulnerable individuals. *See* Fed. Br. at 25. Tellingly, in arguing that he considered the effect of Kentucky HEALTH on all enrollees, the Secretary again points directly to the exemptions, *see id.*, which by definition apply only to a subset of enrollees that he determined to be particularly vulnerable. *See*, *e.g.*, AR 6726.

of how many people might lose Medicaid coverage." *Stewart*, 313 F. Supp. 3d at 264 (quotation marks omitted). The Secretary simply repeated that error – nothing in the record indicates that he bothered to calculate how many people might lose Medicaid coverage due to Kentucky HEALTH.

Because the Secretary failed to provide a bottom-line estimate of coverage loss, Federal Defendants now take the position that it would have been impossible for him to develop that estimate. Fed. Br. at 22. But, several non-governmental agencies with far less access to data than the Secretary managed to do so. See Pls.' Br. at 19, n.4. What is more, nothing in the record indicates that the Secretary made any attempt to grapple with any of those expert projections. See Am. Wild Horse Pres. Campaign v. Perdue, 873 F.3d 914, 923 (D.C. Cir. 2017) (agency must "examine all relevant factors and record evidence"). While Kentucky now attacks one of them, asserting that the estimate developed by public health academics is not relevant because it is based on data from SNAP, not Medicaid, Ky. Br. at 20 (citing ECF No. 44), this post hoc claim does not change the fact that the Secretary impermissibly ignored the estimate altogether. See Michigan v. EPA, 135 S. Ct. 2699, 2710 (2015) (noting that "a court may uphold agency action only on the grounds the agency invoked when it took the action"); Bellion Spirits, LLC v. United States, 335 F. Supp. 3d 32, 42 (D.D.C. 2018) (agency must "present its reasons for rejecting significant contrary evidence and argument) (internal quotations omitted). Moreover, the academics explained why the SNAP data is relevant—SNAP and Kentucky HEALTH serve similar populations and include similar work requirements. ECF. No. 44 at 18; see also AR 6774 (individuals meeting SNAP work requirements deemed to meet Kentucky HEALTH requirements), 93-94 (urging states to "align" Medicaid and SNAP work requirements).

Finally, Defendants contend the Secretary properly found that many aspects of Kentucky HEALTH, including the premium requirements, administrative lockout, waiver of retroactive

eligibility, and elimination of NEMT, are likely to promote coverage by better preparing individuals for commercial plans. Of course, promoting private coverage is not the same as promoting Medicaid coverage and is not a goal of the Medicaid Act. See Pls.' Br. at 14. In any event, nothing in the record suggests that Kentucky HEALTH would actually further that goal. The figures Kentucky relies upon show that many Medicaid enrollees have recently had private coverage and are already familiar with commercial insurance policies. See Ky. Br. at 27. In addition, educating Medicaid enrollees about commercial insurance does nothing to address what causes churn between Medicaid and private coverage (or, more likely, uninsured status): fluctuating income. The record belies any claim that Kentucky HEALTH would increase individuals' access to private insurance, but it does show that Kentucky HEALTH would create additional gaps in coverage and reduce access to care, with devastating health and financial consequences for low-income individuals. See, e.g., Pls.' Br. at 32 (citing record evidence on the consequences of coverage loss).

In short, far from correcting "the deficiencies this Court perceived," Fed. Br. at 27, the Secretary repeated the same mistakes, again failing to adequately consider the substantial record evidence indicating the project would result in massive coverage loss and would not promote Medicaid coverage. As before, this failure renders the re-approval arbitrary and capricious. *See Stewart*, 313 F. Supp. 3d at 260.

Work Requirements. Kentucky argues that Plaintiffs improperly focus on the "alleged consequences" of the work requirements. Ky. Br. at 25. The Commonwealth misunderstands the relevant inquiry, which centers on precisely that question: did the Secretary reasonably examine the likely effect of the project on Medicaid coverage? See Stewart, 313 F. Supp. 3d at 262. Far from "proffering mostly policy-based objections," Ky. Br. at 25, Plaintiffs pointed to voluminous

evidence in the record indicating that the work requirements would strip many thousands of individuals of coverage, Pls.' Br. at 21-22. Kentucky now tries to discount some of that evidence, arguing that data from Arkansas, which reveal that a large percentage of Medicaid enrollees subject to work requirements did not meet them, are "wholly irrelevant to this analysis." Ky. Br. at 26-27. Kentucky contends that "one demonstration project cannot be discredited by two months' worth of data from an entirely separate demonstration project." *Id.* However, the Secretary himself has emphasized the parallels between the Arkansas and Kentucky work requirements. See Mem. Supp. Fed. Defs.' Mot. to Dismiss at 4, Gresham v. Azar, No. 1:18-cv-01900 (D.D.C. Nov. 30, 2018), ECF No. 37-1 (arguing that "the relevant features of the Arkansas project are not materially different from the measures that the Secretary addressed in the new Kentucky letter"). And Defendants have had no qualms about pointing to interim data from an "entirely separate demonstration project," Ky. Br. at 26, in their attempts to justify approval of other Kentucky HEALTH features, see id. at 29, 40; Fed. Br. at 30-31. In short, no rational explanation exists for why the Arkansas data would not be instructive to the Secretary, and nothing in the record indicates that the Secretary attempted to grapple with the Arkansas data in the record and available when approving Kentucky HEALTH.⁶ See State Farm, 463 U.S. at 43 (court cannot infer agency reasoning from "mere silence").

Instead, the Secretary ignored that data (as well as expert projections about how many individuals would lose coverage due to the Kentucky HEALTH work requirements) and blindly maintained that individuals "should" have no trouble meeting the work requirements and keeping

⁶ At the time of public comments, there was two months of data from Arkansas. When the Secretary re-approved Kentucky HEALTH, he had access to five months of data and knew that over 12,200 people had been terminated for failure to comply with the work requirements. *See* Ark. Dep't of Human Servs., Arkansas Works Program August–October 2018 Reports.

their coverage. *See*, *e.g.*, AR 6730. Defendants emphasize that aspect of the re-approval and rely on the fact that enrollees need not work to satisfy the work requirements. *See* Fed. Br. at 25-26; Ky. Br. at 41. However, as Plaintiffs explained, commenters highlighted that requirements such as these will nevertheless cause massive coverage loss, as many of the barriers that prevent people from working likewise prevent them from volunteering, completing job training, or attending school. *See* Pls.' Br. at 22; *see also* AR 15484, 25358-60, 20265-66. Defendants' only response is that some Plaintiffs are meeting the work requirements. Fed. Br. at 26. Even if the Secretary were correct, and six of the sixteen Plaintiffs are currently meeting the requirements, over 60% of Plaintiffs would still be at risk of losing coverage, which was precisely commenters' point—the work requirements will cause a large percentage of enrollees to lose Medicaid coverage. *See also* AR 14908-13, 16709-11, 19960-63, 12885 (explaining that the added administrative burden of reporting work hours will trip up individuals who are working enough hours).

Premiums. Record evidence overwhelmingly shows that the Kentucky HEALTH premiums and associated consequences will deter and reduce enrollment in Medicaid. *See* Pls.' Br. at 23. Defendants point to nothing in the record suggesting otherwise and simply reiterate the nature of the premium requirements, *see* Fed. Br. at 30, which have not changed materially since commenters expressed their well-founded concerns about them. Federal Defendants' contention that Kentucky HEALTH requirements, including premiums, were designed to "minimize effects on coverage," Fed Br. at 25, 30, is no answer to the robust evidence in the record that—regardless of the project's purported intentions—the requirements will result in coverage loss.

Kentucky attacks Plaintiffs' presentation of the data from Indiana, *see* Pls.' Br. at 24 (citing Indiana data at AR 13463-65), but does not (and cannot) refute the basic conclusion that premiums have reduced Medicaid coverage and access to care. *See* Ky. Br. at 28-29. Kentucky first highlights

that Indiana dis-enrolled "only" five percent of Medicaid enrollees for failure to pay premiums. Ky. Br. at 28. Notably, that figure (which is actually seven percent) totaled 13,550 individuals over the first 22 months of the project. AR 13452, 13465. Another 46,176 individuals were denied Medicaid coverage because they did not pay the initial monthly premium. AR 13467. Kentucky highlights that approximately half of those individuals eventually reapplied and accessed coverage, Ky. Br. at 29, but ignores that all 46,176 individuals went without Medicaid coverage for some period (ranging from two to 21 months), and that approximately 23,000 individuals *never* received Medicaid coverage due to the premium requirements. In total, 29% of individuals who were eligible for Medicaid and needed to pay a premium, did not pay at least once, meaning they were denied coverage or later dis-enrolled for failure to pay. AR 13452. Nor is it "deceptive" to say – exactly as the evaluation does – that 55% of individuals required to pay a monthly premium missed at least once. *See* AR 13463. All of those individuals faced consequences for failure to pay. *Id*.

Plaintiffs do not rely only on data from Indiana. *See* Ky. Br. at 28. They also pointed to comments citing well over a dozen other studies, several of which are cumulative literature reviews, finding that premiums reduce and deter coverage among low-income individuals. Pls.' Br. at 23 (citing AR 19976, 15485, 26310-11, 18613-14). Despite Kentucky's protestations, Ky. Br. at 28, those studies are part of the administrative record and should have been considered by the Secretary. Not only did commenters describe the results of the studies they cited and also specifically ask that CMS add them to the administrative record, AR 19998, 15482, 18616, they also attached copies of many of the studies, *see*, *e.g.*, AR 13139-49, 19778-92, 19749-59, 15995-16002, 16258-65, 25309-19, 14008-13.

Kentucky also seems to claim that by exempting individuals eligible for transitional medical assistance and survivors of domestic violence (who were provided a good cause exception

in the initial approval), the Secretary further reduced the risk of coverage loss. Ky. Br. at 30. However, the Secretary did not suggest that those narrow changes would impact coverage loss, did not provide a concrete estimate of their effect on coverage, and did not make these adjustments in response to the Court's directive to adequately consider coverage loss. *See* AR 8383-86 (email from Kentucky officials requesting permission to exempt survivors of domestic violence more than one month before the Court's decision); 7706 (email from CMS indicating it does not have the authority to impose the premium requirements on the TMA group).

Defendants' claims that the premiums "are expected" to affirmatively promote coverage *see* Fed. Br. at 30, are equally unpersuasive. First, Federal Defendants argue that the prior administration approved similar premium requirements in other states, but that has no bearing on whether imposing premiums is likely to promote coverage. In any case, the record shows that when states impose premiums in Medicaid, many enrollees are not able to pay them. *See, e.g.*, AR 19977-78, 16712-14, 3739-40, (highlighting data from Indiana, Michigan, and Iowa). Second, Defendants point to interim evidence from Indiana, which they argue shows that the very act of submitting premiums somehow causes people to engage in healthy behaviors. Fed. Br. at 30-31; Ky. Br. at 29; AR 6734-35. However, even if that implausible claim were supported by any evidence in the record, *cf.* Pls.' Br. at 31-33; Section IV.D, *infra*, promoting healthy behaviors is not the equivalent of promoting Medicaid coverage.

Administrative Lockouts. As Plaintiffs described in their opening brief, the Secretary did not reasonably evaluate the vast evidence in the record indicating that the administrative lockouts will reduce Medicaid coverage. See Pls.' Br. at 26-27. In response, Defendants simply reiterate the very portions of the re-approval letter that Plaintiffs criticized as illogical. See Fed. Br. at 37-38; Ky. Br. at 36-37. Federal Defendants highlight that the administrative lockouts are intended to

incentivize compliance with existing requirements, but they do not point to any evidence in the record so much as suggesting they will actually have that effect. *Cf.* Pls.' Br. at 27 (citing comments explaining that the lockouts will not address the barriers that prevent compliance with existing requirements in the first place).

Kentucky argues that the Secretary addressed commenters' concerns about coverage loss by requiring the Medicaid agency to complete *ex parte* redeterminations for at least 75% of enrollees. Ky. Br. at 39 (citing AR 6757-58). Not only did the prior STCs already include that requirement, AR 28, but the record shows Kentucky is meeting that standard yet still terminates thousands of enrollees each month for failure to complete redetermination forms. AR 2902. Thus, the record shows that the *ex parte* renewals requirement will not prevent substantial coverage loss, as all of those individuals would be subject to the lockout penalty.

Federal Defendants also attempt a sleight of hand, arguing that CMS has previously allowed lockouts on certain individuals who fail to pay monthly premiums. Fed. Br. at 38. But regardless of its prior policy on lockouts for failure to pay premiums, CMS did reject redetermination lockouts specifically (as compared to premium lockouts), concluding that redetermination lockouts are inconsistent "with the objectives of the Medicaid program, which include ensuring access to affordable coverage." AR 239.

In the alternative, Federal Defendants contend that the Secretary adequately explained the change in policy by pointing to "new" data showing only 37% of Kentucky Medicaid enrollees who need to submit paperwork to complete redetermination do so. Fed. Br. at 38 (citing AR 6727). But again, Federal Defendants fail to acknowledge that CMS rejected the very reasoning this data supposedly supports when it denied Indiana's request: CMS explained that many Medicaid beneficiaries face barriers to completing the redetermination process and that locking them out of

coverage would undermine the objectives of the Medicaid Act. *See* AR 239-40. Accordingly, this unexplained inconsistency in CMS's policy gives the Court an independent reason to find the approval of the administrative lockouts arbitrary and capricious. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

Elimination of Retroactive Coverage. Defendants similarly fail to show that the Secretary adequately engaged with the substantial record evidence indicating that eliminating retroactive coverage will reduce coverage and access to services. Pls.' Br. at 37-38. Defendants instead reiterate the argument this Court has already rejected as "conclusory"—that eliminating retroactive coverage will promote coverage by encouraging individuals to enroll when they are healthy, thus reducing gaps in coverage. Fed. Br. at 36; Ky. Br. at 31-32; Stewart, 313 F. Supp. 3d at 265. While the Secretary may "expect" that outcome, Fed. Br. at 36, it is not supported by any evidence in the record. See Pls.' Br. at 25-26; see also Nat'l Lifeline Ass'n v. FCC, No. 18-1026, 2019 WL 405020, at *7 (D.C. Cir. Feb. 1, 2019) (finding that predictive judgment is only given deference when supported by substantial evidence). Federal Defendants also note that CMS has granted such waivers in the past, Fed. Br. at 35 & n.9, but these prior waivers, which were never challenged in court, have no bearing on whether eliminating retroactive coverage would promote Medicaid coverage. Stewart, 313 F. Supp. 3d at 262. Tellingly, Defendants do not cite any evaluation of these prior waivers to show that they effectively reduced gaps in coverage. In short, Defendants did not and could not have addressed Plaintiffs' central argument—in re-approving Kentucky

⁷ Kentucky argues that the Secretary did not need to respond to concerns commenters raised about the effect of eliminating retroactive eligibility on Medicaid providers, as those concerns are not "strictly relevant." Ky. Br. at 33-34. Kentucky is mistaken. As commenters clearly explained, any negative effect on Medicaid providers will reduce access to services for individuals. *See*, *e.g.*, AR 13564, 20850-51, 14041, 17464-65, 19984-85, 17397-98.

HEALTH, the Secretary unreasonably concluded that *withholding* coverage and services will *promote* the furnishing of coverage and services. Pls.' Br. at 26.

Elimination of NEMT. Federal Defendants do not dispute that eliminating NEMT will reduce access to medically necessary care, increase financial difficulties for beneficiaries, and worsen health outcomes. See Pls.' Br. at 27-28. Instead, they assert that the Secretary properly justified the waiver by citing cost considerations. Fed. Br. 39 (quoting AR 6727). Not only is that an impermissible goal, see Section III.A, supra, but the evidence in the record overwhelmingly suggests that cutting NEMT will in fact increase Medicaid costs for Kentucky. See AR 16796, 18602-03, 20717-67, 19990-91. Federal Defendants fall back on the idea that Kentucky intends to research exactly that. Fed. Br. 39. But Section 1115 does not allow the Secretary to approve any "experimental" project, see Beno, 30 F.3d at 1069, particularly where all the evidence shows the experiment will not be successful, see Dist. Hosp. Partners, L.P. v. Burwell, 786 F.3d 46, 57 (D.C. Cir. 2015) ("[A]n agency cannot fail[] to . . . offer[] an explanation for its decision that runs counter to the evidence before it." (citation and internal quotation marks omitted)).

Kentucky appears to argue that waiving NEMT will not affect access to services, citing data from Indiana's interim evaluation of its NEMT waiver showing that a larger percentage of enrollees with NEMT than without NEMT reported missing a medical appointment because of transportation barriers. Ky. Br. 40. However, as the report itself states, "[t]he populations with and without state-provided NEMT are not readily comparable due to large differences in demographics and healthcare needs." AR 4909 (emphasis added). Put differently, the report does not support the conclusion that Kentucky wishes to draw—that eliminating NEMT will not affect access to care.

D. The Secretary Could Not Have Rationally Concluded that Kentucky HEALTH is Likely to Promote Health and Well-being.

As Plaintiffs explained in their opening brief, Pls.' Br. at 28-34, the Secretary could not have reasonably determined that Kentucky HEALTH will promote health and financial well-being—even assuming, which Plaintiffs strongly contest, that such goals are permissible.

First, in evaluating the purported health and financial benefits of Kentucky HEALTH, the Secretary did not try to assert that any evidence in the record shows how eliminating retroactive coverage, imposing administrative lockouts, and eliminating NEMT would possibly improve health. *See* Pls.' Br. at 31-33. Nor do Defendants contest that the only study the Secretary cited regarding administrative lockouts does not discuss, let alone evaluate, redetermination and reporting lockouts like those approved here. *See* Pls.' Br. at 31.

With respect to how premiums and work requirements relate to health, the Secretary misread and distorted the evidence. In each case, he incorrectly imputed causation into studies showing correlation. Pls.' Br. at 29, 31-32. Pretending correlation means causation is not merely a "quibble," Fed. Br. at 31—it is an elemental error of logic. *See* Pls.' Br. at 31. *Cf. AT&T Wireless Servs., Inc. v. FCC*, 270 F.3d 959, 968 (D.C. Cir. 2001) (decision arbitrary and capricious, in part, because agency failed to explain "how it was able . . . to translate the raw signal data . . . into a finding" about harm "in the real world.").

The Secretary likewise ignored evidence—including from the very studies he relied on—that refutes the simple causal relationship he asserted. Pls.' Br. at 29, 31-32. Defendants' bare citations to studies, without explanation, cannot show whether the Secretary grappled with the limitations on what those studies actually conclude. *Compare* Fed. Br. at 41; Ky. Br. at 25-26, *with* Pls.' Br. at 29. Even if the Secretary had a rational basis for finding that work leads to improved health, he completely ignored an array of record evidence showing that work *requirements* do not

increase the number of people working or help them earn more money. Pls.' Br. at 30. This is not a case, as Kentucky suggests, of Plaintiffs merely disagreeing with the Secretary's rational judgment. Ky. Br. at 25. Rather, Plaintiffs object to the Secretary's failure to "adequately engage[] the record evidence." *Hawaiian Dredging Constr. Co. v. NLRB*, 857 F.3d 877, 885 (D.C. Cir. 2017). As a result of his inaccurate and selective reading of the evidence, there is no "rational connection between" the evidence the Secretary cited "and the choice made." *State Farm*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

Second, the Secretary entirely failed to consider the abundant evidence in the record showing that individuals who lose coverage due to Kentucky HEALTH will suffer serious health and financial consequences. Pls.' Br. at 32-33. Compounding this oversight, the Secretary neglected to estimate the magnitude of the coverage loss and therefore could not have assessed the magnitude of these harms, much less weighed them against the purported benefits. *Id*.

Defendants argue that because the Secretary cited a handful of studies, without explanation, he properly determined that Kentucky HEALTH is likely promote health and independence. *See* Fed. Br. at 41; Ky. Br. at 26. They rely on *Aguayo* and *C.K.* to assert that mere citation of studies demonstrates sufficient consideration, but those cases do not engage in the "searching" review of the record required under subsequently decided Supreme Court and D.C. Circuit precedent. *See C.K.*, 92 F.3d at 183; *Aguayo*, 473 F.2d at 1103-05. *Aguayo* pre-dates *State Farm*, which requires an agency to "examine the relevant data and articulate a satisfactory explanation for its action." 463 U.S. at 43. *C.K.* "allows [a court] to give the Secretary the benefit of the doubt and conclude that she did consider those objections," and did not "ignore[] the materials." 92 F.3d at 185. But that is not the law in this circuit, where "an agency cannot ignore evidence contradicting its

position." Butte Cty. v. Hogen, 613 F.3d 190, 194 (D.C. Cir. 2010); see also, e.g., Genuine Parts Co., 890 F.3d at 312.

In their efforts to avoid this rule, Defendants misconstrue it. They argue that because the Secretary need not respond to each comment in writing, he is free to ignore contrary evidence and obvious counter-arguments submitted by commenters. *See* Ky. Br. at 31; Fed. Br. at 40-41. But, as this Court has already concluded, "he needed to at least consider those objections." *Stewart*, 313 F. Supp. 3d at 263 (quote and alteration omitted). This is not, as Defendants claim, an "impossibly high standard for approval." Fed. Br. at 40. Rather, it is the straightforward application of the basic obligation that an agency must engage in "reasoned decisionmaking." *State Farm*, 463 U.S. at 52.

Finally, Defendants contend that considering the record evidence would require the Court improperly to referee a battle of the experts or wade through conflicting evidence. Not so. This is not a situation where both sides possess evidence the Court must weigh. The only evidence the Secretary cites is simply inapposite. The Administrative Procedure Act charges this Court with the authority and responsibility to hold the Secretary accountable for his failure to acknowledge, let alone weigh or refute, the relevant data and expert evidence in the record that contradicts his conclusion. *See Genuine Parts Co.*, 890 F.3d at 313; *United Airlines, Inc. v. FERC*, 827 F.3d 122, 130 (D.C. Cir. 2016) (vacating agency order where agency "provided no reasoned explanation for its choice of the . . . data" it used). Holding the Secretary to his burden is a core role of the judiciary here. Even assuming the Secretary was pursuing proper objectives, he failed to contend with the robust evidence presented in the comments, rendering the approval arbitrary and capricious.

E. The Secretary Lacks Authority to Approve Several Kentucky HEALTH Components.

Work Requirements. Plaintiffs' opening brief explained why the narrow authority Congress gave the Secretary to "waive" certain Medicaid provisions simply does not authorize

him to comprehensively transform Medicaid from a program that guarantees health coverage for low-income people to one that conditions health coverage on work requirements. Pls.' Br. at 34-38.

In response, Defendants do not contest Plaintiffs' reading of the term "waive," Pls.' Br. at 34, but instead, erroneously argue that allowing states to impose work requirements follows "the ordinary course" with respect to the use of that narrow authority. Fed. Br. at 28-29; see also Ky. Br. at 42-43. They contend that the Secretary granted states Section 1115 waivers to impose work requirements in AFDC, leading Congress to add work requirements into the SNAP and TANF statutes in 1996.8 Fed. Br. at 29; Ky. Br. at 42-43. Thus, they argue, Section 1115 gives the Secretary the authority to "experiment" at will with similar work requirements in Medicaid. Fed. Br. at 28-29; Ky. Br. at 42. But Defendants ignore two crucial facts. First, AFDC and Medicaid are distinct statutes with distinct purposes, as Plaintiffs describe in detail above. See Section III.C, supra (comparing 42 U.S.C. § 601 and 42 U.S.C. § 1396-1). Second, the AFDC statute itself long included work requirements, see Public Welfare Amendments of 1962, Pub. L. No. 87-543, § 105, 76 Stat. 172, 186-88, meaning the Secretary only approved waivers to allow states to adjust the precise nature and scope of the requirements. The history of work requirements in AFDC (and later TANF) actually underscores Plaintiffs' position: the decision to include work requirements in a particular public assistance program (or not) is a choice for Congress, not the Secretary, to make in the first instance.

Congress's steadfast refusal to incorporate work requirements wholesale into Medicaid extends through its recent failure to pass two bills that would have imposed, or allowed states to

⁸ Kentucky appears to suggest that the SNAP statute did not include work requirements prior to 1996. Ky. Br. at 42-43. That is inaccurate. *See* An Act to Amend the Food Stamp Act of 1964, Pub. L. No. 91-671, § 5(c), 84 Stat. 2048, 2050 (1971).

impose, work requirements on Medicaid enrollees. *See* Pls.' Br. at 36. Despite the Commonwealth's claims, Ky. Br. at 42, these failed attempts indicate Congress's belief that congressional action is required to impose work requirements and that such work requirements are ill-advised. *See* Pls.' Br. at 36. While not Plaintiffs' "primary evidence" of Congress's intent, Ky. Br. at 20, they should be considered together with the statutory text, structure, and history, which all support the conclusion that the Secretary exceeded his authority in approving the work requirements. Pls.' Br. at 34-38.

In fact, CMS previously agreed that the Secretary lacks authority to approve work requirements in Medicaid. See Pls. Br. at 37 n.11. Kentucky claims that CMS had not established a policy, but rather denied states' requests to impose work requirements on a case-by-case basis. That is not accurate. CMS articulated a consistent policy rooted in the clear directives of the Medicaid Act: "the Secretary does not have the authority to permit a state to require Medicaid beneficiaries to work." The Fiscal Year 2017 HHS Budget Before the Subcomm. on Health of the H. Comm. on Energy & Com., 114th Cong. 86 (2016) (responses of Sec'y of Health & Hum. Servs. Sylvia Burwell).

Finally, the purported inefficacy of "voluntary work programs" does not grant the Secretary authority to impose mandatory work requirements. Ky. Br. 45-47. First, the record does not support the Secretary's conclusions that voluntary programs were "not strong enough." *See, e.g.*, AR18851-52, 20184-85, 12829, 14787-88. Second, states do not need a waiver to implement voluntary work initiatives, so that the Secretary has "allowed" them, Ky. Br. at 45-46, does not go to the scope of the Section 1115 waiver authority. Most importantly, the purported inefficacy of these voluntary initiatives has no bearing on the outer bounds of statutory authority—here, the Secretary's limited authority to approve waivers for projects likely to promote the purposes of

Medicaid. In light of the Medicaid Act's purpose—to provide health coverage to low-income individuals—*voluntary* work programs, which have no impact on eligibility, are fundamentally different from *mandatory* work requirements that result in coverage loss. A shift from voluntary work incentives to mandatory work requirements is a "natural and logical next step," Ky. Br. at 47, only if the core purpose of Medicaid were to shift from a guarantee of medical assistance to a goad to labor force participation. But of course, Congress drafted Section 1115 to protect against the Secretary accomplishing any such shift unilaterally. For these reasons, the Secretary did not have the statutory authority to allow Kentucky to condition eligibility for Medicaid on work or the completion of work-related activities.

Premiums. By its very text, the Secretary's Section 1115 waiver authority extends only to Section 1396a. Congress purposefully placed Medicaid's premium and cost sharing provisions outside of Section 1396a and included 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 may be waived under criteria set forth in Section 1396o, which are more stringent than those in Section 1115, premium protections can never be waived.

In arguing that Section 1115 gives the Secretary authority to waive the limits on premiums, Defendants improperly ignore the structure of the statute as a whole and the history of the relevant provisions. Fed. Br. at 30-35; Ky. Br. at 49-53. Premiums and cost sharing were originally authorized, with scant 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. After two courts acknowledged that Section 1115 gave the Secretary the power to allow states to charge enrollees heightened cost

sharing, *see Crane*, 417 F. Supp. 532; *California Welfare Rights Org.*, 348 F. Supp. 491, Congress added a new Section 13960 to the Medicaid Act and set forth, in detail, the premium and cost sharing options available to states. Contrary to Federal Defendants' claim, *see* Fed. Br. at 32, Section 13960 independently requires states to comply with the limits included therein. *See* 42 U.S.C. § 13960(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 13960. *See* Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, 96 Stat. 324, 367. 9

With these changes, Congress expected states and the Secretary to act pursuant to the options set forth in Section 1396o, including its waiver authorities, not Section 1115. *See* H.R. Rep. No. 97-757, pt. 1, at 6 (1982). Kentucky makes much of the fact that the legislative history only mentions cost sharing and not premiums, Ky. Br. at 52-53—unsurprisingly so, as Congress was responding to judicially upheld waivers that permitted heightened cost-sharing. But regardless of what caught Congress's attention more, Congress chose to place *both* cost-sharing and premium provisions in Section 1396o. And, as Plaintiffs described in detail, Congress has consistently confirmed that the flexibilities available to states with respect to premiums and cost sharing must come from Congress, meaning that the Secretary cannot use Section 1115 to tinker with its carefully delineated limits. *See* Pls.' Br. at 41.

In fact, when Congress enacted Section 13960-1 in 2006 to modify states' ability to charge cost sharing and premiums (but continuing to bar premiums on individuals with incomes below

⁹ If Congress intended for Section 13960 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.

150% of FPL), it again chose to place the new substantive limits outside of Section 1396a and did not even reference these limits in Section 1396a(a)(14). Deficit Reduction Act of 2005, Pub. L. No. 109-171, §§ 6041-6043, 120 Stat 4, 81-88 (2006) (adding 42 U.S.C. § 1396o-1). Defendants argue that Congress had no need to do so because Section 1396o-1 is "simply an exception to" Section 1396o, so a waiver of Section 1396o necessarily includes a waiver of Section 1396o-1. Fed. Br. at 33. 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 in fact waived Section 1396o-1, undercutting his argument that no separate waiver of Section 1396o-1 is necessary. AR 14.

Lastly, Defendants argue that this reading "would call into question demonstrations approved across multiple administrations." Fed. Br. at 31; *see also* Ky. Br. at 49. But those demonstrations were never legally challenged or upheld and have no bearing on whether the substantive limits on premiums and cost-sharing may legally be waived under Section 1115. Moreover, Defendants' interpretation of Section 1115's authority over premiums and cost-sharing would render Congress's actions meaningless. That cannot be the case. *See Ross v. Blake*, 136 S. Ct. 1850, 1858 (2016).

Heightened Cost Sharing for Non-Emergency Use of the ER. Defendants claim charging enrollees up to \$75 for non-emergency use of the emergency room comports with the Medicaid Act's restrictions on cost-sharing because deducting virtual money of "no cash value" from enrollees' My Rewards account imposes no actual "charge on beneficiaries," Fed. Br. at 40, and therefore is not cost-sharing. But My Rewards credits appear to be equivalent to dollars. See AR

6763 (allowing enrollees to transfer money remaining in their deductible account at the end of the year directly into their My Rewards account).

Crucially, Defendants' arguments elevate form over function. As Plaintiffs explained in detail, Pls.' Br. at 42-43, the *My Rewards* credits function as money for Medicaid enrollees, who use them to pay for certain medical services. *See In re Hokulani Square, Inc.*, 776 F.3d 1083, 1085-86 (9th Cir. 2015) ("[D]ictionaries mostly agree that [money] refers to a generally accepted medium of exchange."). Thus, the deductions do have real, financial consequences for enrollees, *see* AR 6764, a fact that Defendants do not contest.

Further, in taking such a narrow view of cost sharing, *see* Ky. Br. at 54, Defendants read the words "deduction" and "similar charge" out of the statute. Those words make clear that Congress intended the term "cost sharing" to encompass various financial incentives states might use to influence enrollees' use of covered services—in short, for function to overrule form. Federal Defendants cite no case law to support their interpretation of the statute. Kentucky mischaracterized *Rehabilitation Association of Virginia, Inc. v. Kozlowski*, 42 F.3d 1444 (4th Cir. 1994), which stated only the unexceptional point that "42 U.S.C. § 1396o relates to a state's ability to impose certain charges on certain plan participants for certain services," and did not specify that such charges must be directly paid out of an enrollee's pocket.

Lastly, the Commonwealth also relies on Section 1396o(e). Ky. Br. at 54. But rather than support its argument, this provision illustrates congressional concern that states' cost sharing policies not result in individuals losing out on needed care. In fact, the charges for non-emergency use of the emergency room trigger these same concerns, as enrollees may have to forgo needed vision or dental services based on the balances in their *My Rewards* accounts. Section 1396o(e),

therefore, only further demonstrates that charges for non-emergency uses of the emergency room are a form of cost sharing.

V. The State Medicaid Director Letter Is A Final Agency Action That Violates The APA.

The Secretary insists the SMD Letter is not a "final agency action" and did not require notice and comment. Fed. Br. at 42-44. This argument is meritless. Agency action is "final," and therefore subject to judicial review under the APA, if two factors are present. "First, the action must mark the consummation of the agency's decisionmaking process." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1813 (2016) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)). "[S]econd, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* Both are true of the SMD Letter.

First, the SMD Letter clearly marks the consummation of CMS's decision making process regarding its position on state efforts to impose work requirements on Medicaid coverage. The Letter unequivocally "announc[es] a new policy," AR 90, "committing to support state demonstrations that require eligible adult beneficiaries to engage in work or community engagement activities." AR 92 (emphasis added); see Fed. Br. at 43 (stating that non-final agency guidance is one that does not "commit[] CMS to a course of action"). The Letter thus reflects the "agency's settled position, a position it plans to follow in reviewing State-issued [Section 1115 proposals]." See Appalachian Power Co. v. EPA, 208 F.3d 1015, 1022-23 (D.C. Cir. 2000) (finding EPA guidance document constituted "final agency action" where the document "consist[ed] of requir[ements] State [] authorities" must satisfy in order to receive EPA approval of proposed regulatory permits).

Second, the SMD Letter has real "legal consequences." *Hawkes Co.*, 136 S. Ct. at 1813. Federal Defendants protest that "CMS itself characterizes the letter as nonbinding guidance" and

never cited the letter "as the legal authority for its approval of Kentucky HEALTH (or any other State's project)." Fed. Br. at 44. But, at the outset, courts do not accept at face value the labels an agency applies to its actions. *Appalachian Power*, 208 F.3d at 1022-24. And it "has been settled in this circuit for many years" that "the issuance of a guideline or guidance may constitute final agency action" warranting judicial review. *Barrick Goldstrike Mines Inc. v. Browner*, 215 F.3d 45, 48 (D.C. Cir. 2000); *see*, *e.g.*, *Mendoza v. Perez*, 754 F.3d 1002, 1008 (D.C. Cir. 2014) (finding guidance letters that "update[d] special procedures" for "seeking [] certification in [certain] occupations" constituted final agency action); *Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023, 1028, 1032 (D.C. Cir. 2016) (finding agency letter was final agency action because it "establishe[d] legal consequences," even though it "created no new legal obligations").

Here, regardless of how CMS characterizes the Letter, its application proves that it has legal effect. *See Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (the "most important factor" is "the actual legal effect" of the guidance). The Letter sets forth numerous specific requirements that "States *must* comply with" to receive CMS approval for a demonstration project imposing work requirements. AR 94-98 (emphasis added). These requirements include exemptions for individuals deemed "medically frail," AR 94, and provisions that "automatically" consider individuals who comply with TANF or SNAP work requirements to be complying with Medicaid work requirements, *id.*

The Secretary has consistently cited states' compliance with the terms of the SMD Letter as a basis for approving Section 1115 projects involving work requirements. *See* Pls.' Br. at 48-49 (discussing CMS's reliance on SMD Letter and the Letter's requirements in approving Kentucky, Arkansas, and Indiana waivers). And each approval invoked the Letter to dodge any real discussion about the wisdom of work requirements. Pls. Br. at 48-49. Here, the initial approval letter expressly

relied on the SMD Letter, *see* AR 8-9, and the re-approval letter, while conspicuously omitting any reference to the SMD Letter, nevertheless points to numerous components of Kentucky HEALTH that the Letter deems necessary for approval. *See* AR 6721, 6723, 6734; Pls.' Br. at 48. It is plain that the SMD Letter has direct legal consequences for any state seeking to implement work requirements: failure to comply with the Letter's requirements will result in a denial, while meeting the requirements makes a proposal eligible for approval.

The SMD Letter is thus far different from the exhortatory statement CMS made in 2012 about its "invit[ation for] states to continue to come to [CMS] with their ideas." Fed. Br. at 44. Through the SMD Letter, CMS "has given the States their 'marching orders' and expects the States to fall in line. . . ." *Appalachian Power*, 208 F.3d at 1023; *see also Ala. v. Ctrs. for Medicare & Medicaid Servs.*, 780 F. Supp. 2d 1219, 1227 (M.D. Ala. 2011) (holding CMS "Dear State Health Official" letter establishing "obligations of states who seek recovery from fraud-and-abuse defendants" was final agency as the action was one from which 'legal consequences *will* flow'" (quoting *Bennett*, 520 U.S. at 178)), *aff'd*, 674 F.3d 1241 (11th Cir. 2012). This Court therefore has authority to review the SMD Letter.

It is undisputed that notice and comment did not occur. The Secretary argues only that the Letter is exempt from those requirements because it is a "[g]eneral statement[] of policy." Fed. Br. at 44 (citing 5 U.S.C. § 553(b)(3)(A)). The only reason the Secretary provides as to why the SMD Letter is a general statement of policy (rather than a substantive rule) is that "[t]he letter 'compels action by neither the recipient nor the agency." *Id.* (quoting *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012)). But this is not the test, either under *Holistic Candlers*—which did not even address the issue of substantive rules—or any other precedent.

The correct test is well established: If an agency pronouncement "substantially curtails [the agency's] discretion," then the pronouncement "meets . . . [the] affirmative definition of a legislative rule" and must be promulgated pursuant to notice and comment procedures. *McLouth Steel Prod. Corp. v. Thomas*, 838 F.2d 1317, 1322 (D.C. Cir. 1988). To make this determination, courts look at whether the "language" in the agency's statement "strongly suggests that [the agency] will treat the [statement] as a binding norm," and, even "[m]ore critically," whether the agency's "later conduct applying [the statement] confirms its binding character." *Id.* at 1320-21.

As described in Plaintiffs' opening brief and above, both the language of the SMD Letter and CMS's conduct applying the Letter indicate that it is a substantive rule with binding effect, not a mere policy statement. *See* Pls.' Br. at 47-49. By announcing what is necessary to win CMS approval to impose work requirements, the SMD Letter "constrains the agency's discretion" over its Section 1115 decision-making. *McLouth*, 838 F.2d at 1320; *see also Gen. Elec. Co. v. EPA*, 290 F.3d 377, 385 (D.C. Cir. 2002) (holding that "Guidance Document" was a substantive rule because it imposed "obligations upon applicants to submit applications that conform to the Document"). Because the SMD Letter is a substantive rule and was issued without the required notice and comment, it must be vacated.

VI. Re-Approval Of The Kentucky HEALTH Waiver And The SMD Letter Should Be Vacated.

According to Federal Defendants, even if Plaintiffs succeed on their APA challenge, "any relief should be tailored to the sixteen individuals before the Court." Fed. Br. 41-42. But the government misunderstands a basic administrative law principle: "When a reviewing court determines that agency [action] [is] unlawful, the ordinary result is that the [action is] vacated—not that [its] application to the individual petitioners is proscribed." *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989); *see also, e.g., Illinois Pub. Telecomms. Ass'n v. FCC*, 123

F.3d 693, 693 (D.C. Cir. 1997). In fact, in several recent cases challenging unlawful agency action, this Court and others have consistently "reject[ed] the government's invitation to confine its grant of relief strictly to the plaintiffs." *NAACP v. Trump*, 298 F. Supp. 3d 209, 243 (D.D.C. 2018); *see, e.g., New York v. U.S. Dep't of Commerce*, No. 18-CV-2921, __ F. Supp. 3d __, 2019 WL 190285, at *119 (S.D.N.Y. Jan. 15, 2019), *cert. granted*, 18-966, 2019 WL 331100 (U.S. Feb. 15, 2019); *Doe 2 v. Mattis*, 344 F. Supp. 3d 16, 23 (D.D.C. 2018), *rev'd on other grounds sub nom. Doe 2 v. Shanahan*, 2019 WL 102309 (D.C. Cir. Jan. 4, 2019); *E. Bay Sanctuary Covenant v. Trump*, No. 18-CV-06810, __ F. Supp. 3d __, 2018 WL 6053140, at *20 (N.D. Cal. Nov. 19, 2018), *appeal docketed*, No. 18-17274 (9th Cir. Nov. 27, 2018); *Desert Survivors v. U.S. Dep't of the Interior*, 336 F. Supp. 3d 1131, 1136 (N.D. Cal. 2018).

To the extent that Federal Defendants intend to suggest that "Article III standing principles constrain the courts' power to enforce the statutory remedy that Congress has created for violations of the APA," *New York*, 2019 WL 190285, at *121, "that argument is too clever by half," for it implausibly "implies that the judicial review provision of the APA is inconsistent with Article III." *Id.* Rather, "the question of what relief [a court] may or must order is a 'merits' question of substantive law that is ultimately for the legislature to decide," and in the APA context, "Congress has required that agency action be reasonable and has prescribed that *courts must set it aside* where it is not." *Id.* (emphasis added); *see* 5 U.S.C. § 706(2). In other words, if Plaintiffs have established Article III standing to sue, as they have done here, "a court has both the power and the duty to order the remedy Congress created." *New York*, 2019 WL 190285, at *121. That remedy is vacatur of the Secretary's re-approval, not some individualized form of relief.¹⁰

¹⁰ Because the APA prescribes vacatur of the entire agency action as the proper remedy, not any individualized relief, Federal Defendants' argument about class certification, regardless of its merit, is also off the mark. *See* Fed. Br. 42.

As an alternative, Federal Defendants assert in a footnote that any remand should be without vacatur. *See* Fed. Br. 42 n.11. But, as this Court has previously recognized, there is no reason to deviate from the presumptive remedy of vacatur in this case. *See Stewart*, 313 F. Supp. 3d at 272-73. Conspicuously, the government offers *no* rationale in its brief for why remand without vacatur is appropriate. As Plaintiffs have explained, both *Allied-Signal* factors strongly weigh in favor of vacatur here. *See* Pls. Br. 49-51. Not only does the Secretary's re-approval suffer from fundamental deficiencies that cannot be rehabilitated on remand, but allowing the approval to remain in effect while the Secretary takes a fruitless "third look" at the waiver would result in enormous disruptions to the ability of tens of thousands of low-income Kentuckians to access medical care. In light of these severe potential harms, "preserving the status quo—including Plaintiffs' continuity of coverage—is appropriate." *Stewart*, 313 F. Supp. 3d at 273. Accordingly, the Court should vacate the Secretary's unlawful actions.

VII. Plaintiffs Have Pleaded A Justiciable Claim Under The Take Care Clause.

Plaintiffs allege that the Executive Branch's approval of Kentucky HEALTH usurps Congress's legislative power by unilaterally rewriting the Medicaid statute with the explicit intent of undermining the ACA's Medicaid expansion. Am. Compl., ECF. No. 88, ¶¶ 14, 162-83, 424-441. In response, Federal Defendants ask the Court to conclude that the Take Care Clause is categorically unenforceable. Fed. Br. at 45. The Court should reject that sweeping claim, which cannot be squared with fundamental notions of separation of powers.

Under the Take Care Clause, when legislation is enacted, the Executive has a duty to ensure that the laws are "faithfully executed." *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). That

obligation 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—such as the Secretary—exercise the President's Article II *power* to "execute" the laws, they are bound by the Article II *duty* to do so "faithfully." *Util. Air Regulatory Grp.*, 134 S. Ct. at 2446.

Defendants' citation to Mississippi v. Johnson, 71 U.S. (4 Wall.) 475, 499 (1866), does not change this conclusion. That case stands for the narrow principle that the Court may not enjoin the President, personally, to affirmatively take an official action that was committed to his discretion. Id. That the courts are, however, empowered to enjoin executive officials whose actions exceed the limits of their constitutional authority is beyond debate. See, e.g., Bowen v. Mich. Acad. of Family Physicians, 476 U.S. 667, 681 (1986) (courts will "ordinarily presume that Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command."); Chamber of Commerce of U.S. v. Reich, 74 F.3d 1322, 1328 (D.C. Cir. 1996) ("When an executive acts ultra vires, courts are normally available to reestablish the limits on his authority."). And Federal Defendants' passing assertion that the Clause is not privately enforceable runs counter to the long history of courts permitting private plaintiffs to hold executive officials accountable for *ultra vires* actions. See, e.g., Util. Air Regulatory Grp., 134 S. Ct. at 2446; Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 587 (1952); 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).

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 arrogate to themselves the legislative power vested exclusively in Congress. *See Youngstown Sheet & Tube*

Co., 343 U.S. at 587. In the administrative realm, courts have explained the relationship between the Legislative and Executive powers as requiring that "Congress must lay down by legislative act an intelligible principle, and the agency must follow it." FCC v. Fox Television Stations, Inc., 556 U.S. 502, 536 (2009) (Kennedy, J. concurring) (internal quotations omitted); see also Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 472 (2001). The Take Care Clause and non-delegation principles, therefore, 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 Congress may not 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.

That is precisely what the Secretary has done here. Because Plaintiffs have stated a claim that the Secretary has overstepped and disregarded his constitutional obligation to take care that the laws are faithfully executed, the Court should deny Federal Defendants' motion to dismiss.

CONCLUSION

Plaintiffs ask the Court to grant their motion for summary judgment; deny Defendants' motions; vacate the approval of Kentucky HEALTH or, in the alternative, sever and vacate the aspects of the approval that exceeded the Secretary's authority and/or lacked evidentiary support. Plaintiffs also ask the Court to enjoin the SMD Letter as improperly promulgated under the APA.

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CERTIFICATE OF SERVICE

I hereby certify that on February 19, 2019, I electronically filed the foregoing with the

Clerk of Court by using the CM/ECF system, which will send an electronic notice to all authorized

CM/ECF filers.

By: /s/ Jane Perkins

Jane Perkins