FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SHARON NEWTON-NATIONS; MANUELA GONZALEZ; CHERYL BILBREY; HECTOR MARTINEZ; DAWN HOUSE; DANA FRANKLIN; EDWARD BONNER; D. H.; JACK BAUMHARDT; MANUEL ESPARZA,
Plaintiffs,

and

DONALD MCCANTS; PATRICIA JONES; ANNE GARRISON; TODD EATON,
Plaintiffs-Appellants,

v.

THOMAS BETLACH, Director of the Arizona Health Care Containment System; KATHLEEN SEBELIUS, Secretary of the United States Department of Human Services, in their official capacities,
Defendants-Appellees.

No. 10-16193
D.C. No. 2:03-cv-02506-EHC
OPINION

Appeal from the United States District Court
for the District of Arizona
Earl H. Carroll, Senior District Judge, Presiding

Argued and Submitted
May 10, 2011—San Francisco, California

Filed August 24, 2011

Before: Alfred T. Goodwin and Richard A. Paez, Circuit Judges, and Liam O'Grady,* District Judge.

Opinion by Judge Paez

*The Honorable Liam O'Grady, District Judge for the U.S. District Court for the Eastern District of Virginia, sitting by designation.

COUNSEL

Ellen Sue Katz, William E. Morris Institute for Justice, Jane Perkins, National Health Law Program, for plaintiff-appellants Donald McCants et al.

Tony West, Assistant Attorney General, Dennis K. Burke, United States Attorney, Mark B. Stern and Stephanie R. Marcus, U.S. Department of Justice, for defendant-appellee Kathleen Sebelius.

Timothy D. Ducar, Lorona Steiner Ducar, Ltd., for defendant-appellee Thomas J. Betlach.

OPINION

PAEZ, Circuit Judge:

Plaintiff-Appellants ("Plaintiffs") are a class of economically vulnerable Arizonans who receive public health care benefits through the state's Medicaid agency. In 2003, Arizona's Medicaid agency notified Plaintiffs that their copayments would be increased, and that these increased copayments would be mandatory, allowing providers to decline to serve them if they could not afford their copayments. The United States Secretary of Health and Human Services ("Secretary"),

pursuant to her waiver/demonstration project authority under Title XI of the Social Security Act, approved the program under which Plaintiffs' benefits were cut. Plaintiffs sued the Secretary and the Director of Arizona's Medicaid agency ("Director") (collectively "Defendants"), alleging that the heightened mandatory copayments violate Medicaid Act cost-sharing restrictions, that the waiver exceeded the Secretary's authority, and that the notices they received about the change in their health coverage was statutorily and constitutionally inadequate. The district court granted summary judgment to the Defendants on all claims. We have jurisdiction under 28 U.S.C. § 1291, and we affirm in part, reverse in part, and remand.

Factual and Procedural Background

1. Factual and Statutory Background

The Supreme Court has summarized that:

> Congress created the Medicaid program in 1965 by adding Title XIX to the Social Security Act. The program authorizes federal financial assistance to States that choose to reimburse certain costs of medical treatment for needy persons. In order to participate in the Medicaid program, a State must have a plan for medical assistance approved by the Secretary of Health and Human Services (Secretary). 42 U.S.C. § 1396a(b). A state plan defines the categories of individuals eligible for benefits and the specific kinds of medical services that are covered. §§ 1396a(a)(10), (17). The plan must provide coverage for the "categorically needy" and, at the State's option, may also cover the "medically needy."

Pharm. Research and Mfrs. of Am. v. Walsh, 538 U.S. 644, 650-51 (2003) (internal footnotes omitted). The Court explained that " 'categorically needy' groups include individ-

uals eligible for cash benefits under the Aid to Families with Dependent Children (AFDC) program, the aged, blind, or disabled individuals who qualify for supplemental security income (SSI) benefits, and other low-income groups such as pregnant women and children entitled to poverty-related coverage. [42 U.S.C.] § 1396a(a)(10)(A)(i)." *Id.* at 651 n.4. The term "medically needy" refers to "individuals who meet the nonfinancial eligibility requirements for inclusion in one of the groups covered under Medicaid, but whose income or resources exceed the financial eligibility requirements for categorically needy eligibility. [42 U.S.C.] § 1396a(a)(10)(C)." *Id.* at n.5.

When a population is covered under a state's Medicaid Plan, federal law sets limits on the amount and type of cost sharing that a state can require participants to contribute to their health care. 42 U.S.C. § 1396o; 42 U.S.C. § 1396o-1. As we explained in *Spry v. Thompson*, § 1396o provides that "subsection (a) permits a state plan to impose nominal premiums and cost sharing on mandatory populations. Subsection (b) permits a state plan to impose income-related premiums and nominal cost sharing on non-mandatory populations who are Medicaid eligible, i.e., optional, medically needy populations." 487 F.3d 1272, 1276 (9th Cir. 2007).

In addition to state Medicaid plans, the Secretary can authorize states to operate "Demonstration Projects" pursuant to 42 U.S.C. § 1315. "In the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of [the Act] . . . the Secretary may waive compliance with" certain Medicaid rules, including cost-sharing restrictions. 42 U.S.C. § 1315(a)(1). Section 1315 also authorizes the Secretary to approve "regard[ing]" demonstration project costs "as expenditures under the State plan." § 1315(a)(2)(A). When demonstration project costs are "regarded as expenditures under the State plan," the federal government can reimburse the state for some of those costs. *See Spry*, 487 F.3d at 1274-75. "Pa-

tients who are eligible for services by way of the Secretary's waiver . . . are know as 'expansion populations.' " *Phx. Mem'l Hosp. v. Sebelius*, 622 F.3d 1219, 1222 (9th Cir. 2010); *see also Spry*, 487 F.3d at 1275 ("A demonstration project may cover people who would not be eligible for Medicaid without a waiver from the Secretary. The agencies call these people 'expansion populations.' ").

States can also exceed the normal limitations on Medicaid cost sharing through 42 U.S.C. § 1396o(f) and § 1396o-1. Subsection (f) of § 1396o provides:

> No deduction, cost sharing, or similar charge may be imposed under any waiver authority of the Secretary, except as provided in [sections (a) and (b)] of this section and section 1396o-1 of this title, unless such waiver is for a demonstration project which the Secretary finds . . . (1) will test a unique and previously untested use of copayments, (2) is limited to a period of not more than two years, (3) will provide benefits to recipients of medical assistance which can reasonably be expected to be equivalent to the risks to the recipients, (4) is based on a reasonable hypothesis which the demonstration is designed to test in a methodologically sound manner, including the use of control groups of similar recipients of medical assistance in the area, and (5) is voluntary, or makes provision for assumption of liability for preventable damage to the health of recipients of medical assistance resulting from involuntary participation.

42 U.S.C. § 1396o(f). Congress later added § 1396o-1, which further relaxes the normal cost-sharing restrictions.

Arizona has a state plan that only covers mandatory Medicaid populations, the categorically needy. Arizona's state plan has never included the optional medically needy population. Until 2001, however, Arizona's Medicaid agency, the Arizona

Health Care Cost Containment System ("AHCCCS"), also operated an entirely state-funded program under which people who could be medically needy obtained coverage. *See Phx. Mem'l Hosp.*, 622 F.3d at 1226 ("During the relevant time period, the [medically needy] populations were part of the state-funded program"). This entirely state-funded program was called Medical Expense Deduction ("MED").

In October 2000, AHCCCS and the United States Department of Health and Human Services ("HHS") corresponded about Arizona's application for a § 1315 waiver. AHCCCS stated that "[c]urrently Arizona provides health care coverage with 100% state funds" to five specific groups, including the "Medically needy." AHCCCS explained to HHS: "The above groups will be 'subsumed' by this eligibility expansion. Arizona will not be operating a parallel state-funded program for these same populations and will convert all existing state-funded populations into the proposed eligibility expansion."

In November 2000, the citizens of Arizona passed Proposition 204, which expanded AHCCCS coverage to childless, non-disabled adults with incomes up to 100% of the federal poverty level. A.R.S. § 36-2901.01. The Secretary approved Arizona's § 1315 waiver application in January 2001. Under this system, AHCCCS imposed nominal and non-mandatory copayments on non-categorically needy participants, which included former MED participants and Proposition 204 populations.

In May 2003, AHCCCS requested another § 1315 waiver from the Secretary. Among other reforms, the request sought permission to increase and expand copayments for certain categories, including childless non-disabled adults with incomes up to 100% of the federal poverty level and former MED participants. AHCCCS's May 2003 request did not specify the reason Arizona sought to make these changes. AHCCCS later stated that the catalyst for the waiver request was the "Arizona legislature direct[ing] [it] to submit a Cost Sharing

Report to the Joint Legislative Budget Committee . . . in response to a deficit approaching $1 billion."

In June 2003, HHS informed AHCCCS that, with respect to Arizona's proposal to increase cost sharing for "groups that are not eligible for Medicaid except through Section [1315] demonstration authority, there are no legal restrictions on cost sharing." Therefore, HHS advised that "[s]uch cost sharing does not involve waivers, since the affected groups are not eligible under the State plan."

On October 1, 2003, AHCCCS implemented a new rule that increased copayments on non-categorically needy participants and made those copayments mandatory. The Plaintiff class challenging the new rule in this case consists of two groups: non-disabled childless adults with incomes up to 100% of the federal poverty level, and former MED participants. The MED participants are not "categorically needy" under the Medicaid Act, but they "incur medical expenses such that their income is reduced to 40% of the federal poverty level." In addition, some people in the MED population "meet the nonfinancial eligibility requirements for inclusion in one of the groups covered under Medicaid." *Walsh*, 538 U.S. at 651 n.5.

In September 2003, AHCCS began sending notices to members of the Plaintiff class notifying them that their copayments were going to be increased. The district court record contains three such notices that were proffered by the Plaintiffs.

HHS approved Arizona's new rule on February 20, 2004, applying retroactively to October 1, 2003. HHS stated "[w]e believe that the approved demonstration project will continue to serve the purposes of Title XIX [Medicaid] because the demonstration project will continue to ensure wider health benefit coverage for low-income populations."

2. Procedural Background

Plaintiffs filed this law suit in December 2003. The complaint alleges four claims for relief: (1) Defendant Secretary's action authorizing Arizona to implement copayments exceeded his limited authority, as set forth in 42 U.S.C. § 1315 and 1396o, and was arbitrary and capricious; (2) Defendant Secretary's action failed to comport with the human participants protections required by 42 U.S.C. § 3515b, and was arbitrary and capricious; (3) Defendant Director's imposition of copayments violates the Medicaid Act, 42 U.S.C. § 1396o; and (4) Defendant Director's written notice of the health care changes violates the Due Process Clause and the Medicaid Act, 42 U.S.C. § 1396a(a)(3). Plaintiffs sought declaratory and injunctive relief.

The district court granted Plaintiffs' motion for class certification on March 17, 2004. The class members are defined as "all Arizona Health Care Cost Containment System eligible persons in Arizona who have been or will be charged copayments pursuant to Arizona Administrative Code Amended Rule R9-22-711(E)."

On April 21, 2004, the district court granted Plaintiffs' motion for a preliminary injunction, which enjoined the Director from imposing the mandatory copayments and from allowing providers to deny certain medical services because of a participant's inability to pay the heightened copayments. Thereafter, the parties filed cross motions for summary judgment.

On March 10, 2005, the district court granted Defendant Secretary's motion to stay the court's summary judgment ruling pending this court's decision in *Spry v. Thompson*, 487 F.3d 1272 (9th Cir. 2007). Our court filed the *Spry* opinion on May 21, 2007, and the district court lifted the stay on December 17, 2007. The parties re-filed cross motions for summary judgment.

On March 29, 2010, the district court denied Plaintiffs' motion for summary judgment and granted Defendants' motion for summary judgment. The district court determined that the Secretary "invoked 'expenditure authority' under 42 U.S.C. § 1315(a)(2) in allowing Arizona to offer the expanded coverage. Plaintiffs are not eligible for Medicaid under a state plan so there was no need for a waiver." Thus, "[s]ections 1396o and 1396o-1 do not apply to Plaintiffs. Defendants did not act in violation of" these sections. The court also concluded that Plaintiffs could not be considered "medically needy" within the meaning of Medicaid unless Arizona covers this optional category in its state plan. Because Arizona's state plan does not cover the "medically needy," persons who might otherwise be in this category are instead an "expansion population," just as persons who could neither be "categorically needy" nor "medically needy" under a state plan are an "expansion population."

The district court then turned to whether the administrative record demonstrated that the Secretary sufficiently considered statutorily-prescribed factors before permitting Arizona to implement its demonstration project. The district court concluded that "[w]hether cost-sharing is a reasonable means of providing care to certain expansion populations during a state fiscal shortage appears consistent with the meaning of § 1315." The district court also concluded that the Secretary's decision was consistent with the objectives of the Medicaid Act because "as a result of the demonstration project, Plaintiffs and others within the expansion populations are provided an opportunity for health care coverage . . . where coverage might not otherwise be provided." Thus, the Secretary's waiver was not contrary to law or arbitrary and capricious.

With respect to the human participants claim, the district court concluded that there was no violation of 42 U.S.C. § 3515b because "[p]eople in the expansion population are not made worse off by inclusion in a demonstration project less favorable to them than to the categorically and medically

needy because, without the demonstration project, they would not be eligible for Medicaid at all." (quoting *Spry*, 487 F.3d at 1276).

Finally, the district court addressed Plaintiffs' inadequate notice claim. It concluded that "[a]s Plaintiffs are not eligible for Medicaid under Arizona's state plan, any notice requirement under the Medicaid regulations would appear not to apply." And, "in the alternative," the district court concluded that "the notices overall were sufficient for purposes of due process."

Standard of Review

We review "*de novo* both the district court's grant of summary judgment and its holdings on questions of statutory interpretation." *Phx. Mem'l Hosp.*, 622 F.3d at 1224. We assess the Secretary's interpretation of Medicaid provisions following the standards set forth in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). *Id.* at 1224-25. "We first determine whether Congress has directly spoken to the precise question at issue . . . [i]f the answer is yes, then we must give effect to the unambiguously expressed intent of Congress and the agency's interpretation receives no deference." *Id.* (quoting *Chevron*, 467 U.S. at 842-43) (internal citations and quotation marks omitted). "[W]hen Congress has *not* directly spoken to the precise question at issue, we will defer to the Secretary's regulation so long as it is based on a permissible construction of the statute." *Christopher v. SmithKline Beecham Corp.*, 635 F.3d 383, 392 (9th Cir. 2011) (citing *Auer v. Robbins*, 519 U.S. 452, 457 (1997); *Chevron*, 467 U.S. at 842-43) (internal citations and quotation marks omitted).

The Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706, provides for judicial review of federal agencies' actions. We may reverse an agency action only if it is contrary to law or "arbitrary and capricious" in that:

> The agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfr. Ass'n v. State Farm Ins., 463 U.S. 29, 44 (1983).

Discussion

I. *Medicaid's Cost-Sharing Restrictions Do Not Apply to Persons Who* Could *Be Covered by a State Plan as "Medically Needy," but Are Instead Covered by a State's Demonstration Project.*

Plaintiffs argue that Defendants "cannot label persons described in the Medicaid Act as 'expansion' populations and thereby avoid the Medicaid Act's cost sharing protections." That is, for purposes of cost-sharing restrictions, the persons whom Arizona has the option of covering under its state plan as medically needy do not become expansion populations because Arizona has chosen not to cover them under the state plan. Plaintiffs argue that "the District Court's order should be reversed for those class members who are medically needy."

Defendants argue that cost-sharing restrictions "apply only to persons who are both statutorily eligible for Medicaid coverage *and* identified in the State Medicaid plan." In the absence of a state plan identifying and covering medically needy persons, these Medicaid-optional persons can be treated like an expansion population in a demonstration project.

[1] Neither Plaintiffs nor Defendants cite a provision in the Medicaid Act in which "Congress has directly spoken to the precise question at issue." *Phx. Mem'l Hosp.*, 622 F.3d at

1225. That is, Congress has not unambiguously answered the following question: are medically needy people entitled to the cost-sharing protections in § 1396o if a state covers them pursuant to a § 1315 demonstration project, and not under the state plan? "[W]hen Congress has *not* directly spoken to the precise question at issue, we will defer to the Secretary's regulation so long as it is based on a permissible construction of the statute." *Christopher*, 635 F.3d at 392 (citing *Auer*, 519 U.S. at 457; *Chevron*, 467 U.S. at 842-43) (internal citations and quotation marks omitted).

[2] Here, the Secretary argues that cost-sharing restrictions "apply only to persons who are both statutorily eligible for Medicaid coverage *and* identified in the State Medicaid plan." She argues that "[u]nder the existing State plan, [Plaintiffs] are not eligible for Medicaid and are, instead, an 'expansion population' to which the cost restrictions do not apply." The Secretary's regulations are consistent with this interpretation of the statute.

In 42 C.F.R. § 435.300 et seq., the Secretary "specifies the option for coverage of medically needy individuals." Section 435.814 states that "[t]he State plan must specify the income standard for the covered medically needy groups." 42 C.F.R. § 435.814. In 42 C.F.R. § 435.4, the Secretary defines terms that are used throughout the governing regulations. "Medically needy refers to families, children, aged, blind, or disabled individuals, and pregnant women listed under subpart D of this part who are not listed in subparts B and C of this part as categorically needy but who *may be eligible for Medicaid under this part because their income and resources are within limits set by the State under its Medicaid plan.*" 42 C.F.R. § 435.4 (emphasis added).

[3] These regulations are consistent with the Secretary's argument that Plaintiffs cannot be medically needy within the meaning of the Medicaid program unless the State elects to cover that class and defines it accordingly. *See also Spry*, 487

F.3d at 1277 ("Expenditures being 'regarded as eligible' for Medicaid for purposes of calculating hospital reimbursement is not the same thing as an individual being 'eligible' for Medicaid benefits."). In contrast to the regulatory definition of medically needy, "[c]ategorically needy refers to families and children, aged, blind, or disabled individuals, and pregnant women, described under subparts B and C of this part who are eligible for Medicaid." 42 C.F.R. § 435.4. The regulation itself defines this group, which exists without reference to state law.

[4] The regulations therefore support the Secretary's interpretation that where, as here, a state has not defined its "medically needy" population pursuant to the Medicaid Act, persons who are not mandatorily covered by the state plan are expansion populations not protected by the § 1396o cost-sharing limits. Because § 1396o is ambiguous and "the Secretary's regulation . . . is based on a permissible construction of the statute," we are obligated to defer to the Secretary's position under the strictures of *Chevron* deference.[1] *Christopher*, 635 F.3d at 392 (internal citations and quotation marks omitted). *See also Phx. Mem'l Hosp.*, 622 F.3d at 1227 (holding that the Secretary's decision was not arbitrary or capricious when he found that, for federal reimbursement purposes, hospitals could not count patients who were covered by an entirely state-funded arm of AHCCCS, despite the fact that some of those patients could have been treated as medically needy). Thus, the district court properly granted summary judgment to Defendants on this claim.

[1]The Secretary's regulatory interpretation also appears to be consistent with prior practice. In a 2003 letter from HHS to AHCCCS about Arizona's waiver application, HHS stated: "In August 2001, Rhode Island received approval to 'flip' optional populations out of their Medicaid State plan and into their [1315] in order to impose cost sharing in excess of levels allowed in Medicaid."

II. *The Secretary's Approval of Arizona's Heightened Cost Sharing in its Demonstration Project Did Not Comply with 42 U.S.C. § 1315.*

Plaintiffs argue that the Secretary's § 1315 wavier was arbitrary and capricious insofar as the administrative record does not satisfy the standard this court established in *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994). In *Beno*, we held that the Secretary's § 1315 waiver that enabled a state-wide benefits cut to recipients of AFDC was arbitrary and capricious.[2] We explained that "§ 1315(a) plainly obligates the Secretary to evaluate the merits of a proposed state project, including its scope and potential impact on AFDC recipients." *Id.* at 1068. We reasoned:

> While § 1315 obviously represents a congressional judgment that, in certain circumstances, such an override is appropriate, we doubt that Congress would enact such comprehensive regulations, frame them in mandatory language, require the Secretary to enforce them, and then enact a statute allowing states to evade these requirements with little or no federal agency review.

Id. at 1068-69.

[5] In assessing whether the Secretary's waiver in *Beno* was arbitrary or capricious, we explained that for the Secretary to act within her § 1315 authority, the administrative record must demonstrate that she "examine[d] each of th[ree] issues." *Id.* at 1069. First, whether the project is an "Experimental, Pilot or Demonstration Project." *Id.* Second, whether the project is "Likely To Assist in Promoting The Objectives Of The Act." *Id.* Third, "the extent and period" for which she finds the project is necessary. *Id.* at 1071.

[2]The Secretary is empowered to make both AFDC and Medicaid demonstration waivers under 42 U.S.C. § 1315(a).

With respect to the first issue—experimental value—we explained that the "Secretary must make some judgment that the project has a research or a demonstration value. A simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy this requirement." *Id.* at 1069. With respect to the second issue, "the AFDC program's main objective is to support needy children . . . Thus, in determining that a state project is 'likely to further the goals of the Act,' the Secretary must obviously consider the impact of the state's project on the children and families the AFDC program was enacted to protect." *Id.* at 1070. We did not resolve the parties' conflicting interpretations of what the third issue—examination of the project's necessary extent and period—obligates the Secretary to do. *Id.* at 1072 ("[W]e need not resolve this issue of statutory interpretation or determine the precise meaning of § 1315(a)'s 'extent and period' language.").

Having set forth these rules, *Beno* considered whether the administrative record was sufficient under its limited APA review. We explained that "while formal findings are not required, the record must be sufficient to support the agency action, show that the agency has considered the relevant factors, and enable the court to review the agency's decision." *Id.* at 1074. We found that the administrative record "contain[ed] a rather stunning lack of evidence that the Secretary" considered the relevant factors. *Id.* Thus, we concluded that the Secretary's waiver was arbitrary and capricious. *Id.* at 1076.

[6] The administrative record in the present case does not demonstrate that the Secretary made the requisite findings required by *Beno*. Plaintiffs accurately point out that "the extent of the Secretary's discussion in the record of why the copayments were approved" is one statement in the 2004 retroactive approval letter. In that letter, HHS stated that Arizona's demonstration project "will continue to ensure wider health benefit coverage to low-income populations." There is no evidence that the Secretary made "some judgment that the

project has a research or a demonstration value." *Beno*, 30 F.3d at 1069. Indeed, it is questionable whether the Secretary could have made such a finding. Plaintiffs' public health expert stated that "[o]ver the last 35 years, a number of studies have looked at the effects of cost sharing on the poor. Of all forms of cost sharing, copayments are the most heavily studied." The administrative record contains no finding from the Secretary that Arizona's demonstration project will actually demonstrate something different than the last 35-years worth of health policy research.

[7] Moreover, the administrative record reveals that the purpose of Arizona's waiver application was to save money. AHCCCS stated that "[i]n January 2002, in response to a deficit approaching $1 billion, the Arizona legislature identified several areas where the state could save money in all state programs. The legislature discussed a number of cost saving measures specific to AHCCCS . . . . In the 2002-2003 Appropriations legislation, the Arizona legislature directed AHCCCS to submit a Cost Sharing Report." The Secretary's obligation under § 1315 to "make some judgment that the project has a research or a demonstration value" cannot be satisfied by "[a] simple benefits cut, which might save money, but has no research or experimental goal." *Beno*, 30 F.3d at 1069.

[8] The Secretary's second obligation under *Beno* is to "consider the impact of the state's project on the" persons the Medicaid Act "was enacted to protect." *Id.* at 1070. The Secretary's sparse statement that "the approved demonstration project will continue to ensure wider health benefit coverage to low-income populations" does not satisfy this obligation. *See Beno*, 30 F.3d at 1075 ("Stating that a factor was considered is not a substitute for considering it.") (internal quotation marks and citation omitted). We explained in *Beno* that the administrative record "must be sufficient to support the agency action . . . and enable the court to review the agency's decision." *Id.* at 1074. The Secretary's single statement in the

record is not sufficient for this court to review the agency's consideration of the impact Arizona's demonstration project would have on the economically vulnerable.

[9] In sum, the administrative records here and in *Beno* are comparably sparse. There is little, if any, evidence that the Secretary considered the factors § 1315 requires her to consider before granting Arizona's waiver. Thus, the Secretary's decision was arbitrary and capricious within the meaning of the APA insofar as it "entirely failed to consider an important aspect of the problem."[3] *Motor Vehicle Mfrs.*, 463 U.S. at 43. We therefore reverse the district court's ruling on this claim, and we remand with directions to vacate the Secretary's decision and remand to the Secretary for further consideration consistent with this opinion.

III. *The Secretary's Approval of Arizona's Heightened Cost Sharing in its Demonstration Project Did Not Violate 42 U.S.C. § 3515.*

Plaintiffs argue that in approving Arizona's cost-sharing demonstration project, the "Secretary failed to comply with the requirements of federal funding activities involving human participants." Plaintiffs argue that "the uncontroverted evidence is that copayments are a barrier to health care for the [Plaintiff] class; cause low-income persons to forego or limit essential and effective medical services and prescription drugs; and result in emergency room and other hospitalizations."

[10] The Human Participants provision states:

[3]Here, as in *Beno*, because we find that the Secretary's review of the first two § 1315 requirements was insufficient, we need not address whether her review satisfied the third requirement. 30 F.3d at 1072 ("[W]e need not resolve this issue of statutory interpretation or determine the precise meaning of § 1315(a)'s 'extent and period' language.").

> None of the funds appropriated by this Act . . . shall be used to pay for any research program . . . which is of an experimental nature, or any other activity involving human participants, which is determined by the Secretary or a court of competent jurisdiction to present a danger to the physical, mental, or emotional well-being of a participant . . . without the written, informed consent of each participant.

42 U.S.C. § 3515b.

[11] The statute does not speak unambiguously as to whether heightened copayments should be considered to pose a "danger to the physical, mental, or emotional well-being of a participant." Through her authority to promulgate regulations respecting § 3515b, however, the Secretary has interpreted the statute to *not* apply to the kind of danger about which Plaintiffs complain. In 45 C.F.R. § 46.101, the Secretary answers the question "[t]o what does this policy apply?" In subsection (b)(5), the Secretary "exempt[s] from this policy" "[r]esearch and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; . . . or (iv) possible changes in methods or levels of payment for benefits or services under those programs." 45 C.F.R. § 46.101(b)(5).

[12] The Secretary's regulation is "based on a permissible construction of the statute." *Christopher*, 635 F.3d at 392. While there is no doubt that the heightened copayments impose a significant hardship on Plaintiffs, public benefits programs would be hamstrung to the point of paralysis if every reduction in benefits for economically vulnerable populations violated § 3515b.[4] Thus, we defer to the Secretary's

[4]Plaintiffs' citation to *Beno* in support of their argument that § 3515b applies to the heightened copayments is misplaced. In *Beno*, this court observed that 42 C.F.R. "[s]ection 46.101(b)(5) . . . exempts research proj-

reasonable construction of the statute under *Chevron*. Accordingly, we affirm the district court's summary judgment ruling on this claim.

IV. *The Heightened Cost-Sharing Notices.*

[13] Plaintiffs argue that the notices AHCCCS sent in 2003 informing them of their increased mandatory copayments violate the requirements of due process and the Medicaid Act. The district court correctly concluded that Medicaid's notice requirements would not apply here because Plaintiffs are not covered under Arizona's state plan. Nonetheless, it is questionable whether the challenged notices satisfied minimal due process requirements, as they are similar to notices we found constitutionally deficient in *Barnes v. Healy*, 980 F.2d 572, 579 (9th Cir. 1992), and those the district court found deficient in *Rodriguez v. Chen*, 985 F.Supp. 1189, 1195 (D. Ariz. 1996).

[14] The Director argues, however, that this issue is now moot because the challenged notices were later superseded by unchallenged notices. Numerous relevant events have taken place in the years since the Director sent the 2003 notices that Plaintiffs challenged in their complaint. These intervening events include new notices sent in 2010 after the district court granted Defendants' summary judgment motion, and the notices sent in 2011 concerning Arizona's elimination of the MED and Childless Adult programs. If the alleged failure to provide adequate notice of coverage changes has not been repeated, these intervening events likely have rendered this claim moot. *See Lewis v. Continental Bank Corp.*, 494 U.S.

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ects, including most public benefits research, 'which are conducted by or subject to the approval of department or agency heads' from" § 3515b. 30 F.3d at 1070 (quoting 42 C.F.R. § 46.101(b)(5)). Moreover, because *Beno* vacated the Secretary's § 1315 waiver for being arbitrary and capricious, it did "not address plaintiffs' human subjects claim." *Id.* at 1076 n. 48. Accordingly, *Beno* does not help Plaintiffs' human participants claim here.

472, 477-78 (1990). We therefore remand this issue to the district court for a determination of whether there is an ongoing basis for this claim, and if so, whether relevant notices have satisfied constitutional due process requirements.

Conclusion

For the foregoing reasons, we affirm the district court's conclusion that Medicaid cost-sharing restrictions do not apply to Plaintiffs and that Arizona's cost sharing does not violate the human participants statute. We reverse the district court insofar as it determined that the Secretary's approval of Arizona's cost sharing satisfied the requirements of § 1315. We remand this claim with directions to vacate the Secretary's decision and remand to the Secretary for further consideration consistent with this opinion. Finally, we remand the Plaintiffs' notice claims for further consideration in light of intervening events.

AFFIRMED in part; REVERSED in part; REMANDED.

The parties shall bear their own costs on appeal.