

No. 20-683

In the Supreme Court of the United States

DIRK WILKE, in his official capacity as interim State
Health Officer of North Dakota, et al.,
Petitioners,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Respondent.

**On Petition for a Writ of Certiorari to
the United States Court of Appeals
for the Eighth Circuit**

BRIEF OF RESPONDENT

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INTRODUCTION

Petitioners seek further review of the Eighth Circuit's holding that certain North Dakota statutes regulating pharmacy benefit managers (PBMs) are preempted by ERISA. As originally framed, the petition presents two questions: The first concerns the substantive scope of ERISA preemption, and the second asks whether ERISA preemption is facial or as-applied.

In the time since the petition was filed, this Court decided *Rutledge v. Pharmaceutical Care Management Association*, No. 18-540 (Dec. 10, 2020). There, the Court held that Arkansas's regulation of "maximum allowable cost lists" for generic drug reimbursements is not preempted by ERISA. In so holding, the Court reversed the Eighth Circuit's decision in *Rutledge* and abrogated *Pharmaceutical Care Management Association v. Gerhart*, 852 F.3d 722 (8th Cir. 2017).

The Eighth Circuit's resolution of the first question presented in this case was premised on *Rutledge* and *Gerhart*. See Pet. App. 6a-9a & n.2. Petitioners therefore have withdrawn (Supp. Br. 6) their request for plenary review of the second question presented and ask instead (Supp. Br. 5, 7) only for a GVR in light of *Rutledge*. Accord Pet. 3, 13.

Respondent agrees that a GVR is the appropriate course. To be clear, respondent's position on the merits is that the laws challenged here remain preempted by ERISA even after *Rutledge* because they regulate substantive benefit design and intrude upon subject matters covered by ERISA itself. They are also preempted by Medicare Part D. But because the Eighth Circuit based its holding below exclusively on the reasoning of *Rutledge* and *Gerhart*, a GVR in light of this Court's reversal in *Rutledge* is warranted.

STATEMENT

1. PBMs are third-party administrators that manage prescription-drug benefits for health plans covered by ERISA, among other benefit plans. Pet. App. 2a. Most ERISA plans choose to contract with a PBM to administer prescription drug benefits for their members to avoid the substantial cost of administering prescription-drug benefits themselves. PBMs' contracts with health plans are individually negotiated and include a variety of terms and conditions, including provisions relating to levels of access to pharmacy networks, pharmacy credentialing, pharmacy performance requirements, benefit design, pricing terms, mail-order and specialty drug requirements, and development and management of a plan's formulary. Pet. App. 2a-3a.

PBMs enter into contracts with pharmacies to ensure that their clients' plan members have the requisite level of access to prescription drugs. PBMs' contracts with pharmacies typically include provisions governing such issues as credentialing, accreditation, and insurance; pharmacy performance standards; services and access requirements; reimbursement methodology; amounts and fees chargeable to plan members; means for providing prescriptions to plan members; and grievance processes, among others.

2. This case concerns North Dakota Century Code Sections 19-02.1-16.1 ("Section 16.1") and 19-02.1-16.2 ("Section 16.2"). See Pet. App. 101a-105a.

Both statutes apply to "third-party payer[s]" and "pharmacy benefits manager[s]." Pet. App. 106a-107a. Together, they (1) regulate the ways in which plans and their PBMs are permitted to design and manage their pharmacy networks; (2) limit the fees that plans and PBMs may charge to network pharmacies, including performance-related fees; and (3) dictate numerous disclosure and recordkeeping requirements.

3. Respondent filed suit in district court challenging Sections 16.1 and 16.2 as preempted by ERISA and Medicare Part D. Pet. App. 2a. The parties cross-moved for summary judgment. Pet. App. 16a. The district court ruled largely in petitioners' favor, holding that just one provision, Section 16.2(2), is preempted by Medicare Part D. Pet. App. 53a.

The Eighth Circuit affirmed with respect to Section 16.2(2) but otherwise reversed. Pet. App. 1a-10a. Relying on its prior decisions in *Rutledge* and *Gerhart*, the court held that Sections 16.1 and 16.2 have an impermissible "reference to" ERISA plans because the laws' "definitions of and references to 'pharmacy benefits manager,' 'third-party payer,' and 'plan sponsor' mean the legislation's provisions apply to plans 'subject to ERISA regulation.'" Pet. App. 7a. The court did not address respondent's contention that Sections 16.1 and 16.2 are preempted under alternative theories.

The court further concluded that ERISA preempts Sections 16.1 and 16.2 "in [their] entirety." Pet. App. 10a n.5. Having so held, it did not pass upon respondent's argument that Sections 16.1 and 16.2 are preempted by Medicare Part D. Pet. App. 10a n.5.

ARGUMENT

Petitioners assert that the judgment below should be vacated and the case remanded to the Eighth Circuit in light of this Court's decision in *Rutledge*. Supp. Br. 5, 7; accord Pet. 3, 13. Respondent agrees that that is the appropriate course under the circumstances.

The Eighth Circuit's decision below was based on *Rutledge* and *Gerhart*. Pet. App. 6a-8a. The court stressed, in particular, that it was "bound by those panel decisions unless they are abrogated by the Supreme Court." Pet. App. 7a-8a & n.2. Because this Court has now abrogated those decisions, the Eighth

Circuit should have the opportunity reconsider the question of ERISA preemption in light of this Court's most recent guidance.

Respondent's position on the merits is that Sections 16.1 and 16.2 remain preempted under ERISA because, unlike the Arkansas law at issue in *Rutledge*, they regulate substantive benefit design and intrude upon subject matters covered by ERISA itself. But the Eighth Circuit did not reach those arguments in light of its conclusion that *Rutledge* and *Gerhart* dictated the outcome on alternative grounds. The court also did not reach respondent's parallel argument that Sections 16.1 and 16.2 are preempted by Medicare Part D. A GVR would give the Eighth Circuit an opportunity to address the full range of respondent's arguments concerning express preemption under both statutes.

CONCLUSION

The Court should grant the petition, vacate the judgment of the court of appeals, and remand for further proceedings in light of the Court's decision in *Rutledge*.

Respectfully submitted.

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