NO. 00-1471

IN THE

Supreme Court of the United States

KENTUCKY ASSOCIATION OF HEALTH PLANS, INC., *et al.*,
Petitioners,

v.

JANIE MILLER, COMMISSIONER OF THE KENTUCKY DEPARTMENT OF INSURANCE,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

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BRIEF FOR PETITIONERS

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QUESTION PRESENTED

Are state "Any Willing Provider" statutes preempted by ERISA, or are they saved from preemption because they are laws "which regulate insurance"?

PARTIES

Petitioners are the Kentucky Association of Health Plans, Inc., and Humana Health Plan, Inc., which were both plaintiffs in the district court and appellants in the court of appeals. Other petitioners are Humana Health Plan of Ohio, Inc., which succeeded plaintiff-appellant Choicecare Health Plans, Inc., and Aetna Health Inc. (OH), which succeeded plaintiff-appellant Aetna Health Plans of Ohio, Inc.

HMPK, Inc., and HPLAN, Inc., also plaintiffs-appellants below, have been succeeded by petitioner Humana Health Plan, Inc. Advantage Care, Inc. and FHP of Ohio, Inc., also plaintiffs-appellants below, are no longer parties to this action and are not petitioners in this Court.

Respondent Janie Miller succeeded to the position of Kentucky Commissioner of Insurance after the court of appeals entered judgment in this case, and is accordingly substituted as respondent pursuant to S. Ct. R. 35.3.

CORPORATE DISCLOSURE

Petitioner Kentucky Association of Health Plans, Inc., is a nonprofit corporation with no parent corporation. Aetna Inc., a publicly held company, is the parent corporation of petitioner Aetna Health Inc. (OH). Humana Inc., a publicly held company, is the parent corporation of petitioners Humana Health Plan of Ohio, Inc. and Humana Health Plan, Inc.

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JURISDICTION

The opinion and judgment of the court of appeals was entered September 7, 2000. A timely petition for rehearing and suggestion of rehearing en banc was denied by order entered November 20, 2000. Pet. App. 87a. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant provisions of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §§ 1001, *et seq.*, are reprinted at Pet. App. 88a. The Kentucky "Any Willing Provider" statutes at issue in this case are reprinted at Pet. App. 89a-91a.

STATEMENT OF THE CASE

1. Petitioners are several health maintenance organizations ("HMOs") and a Kentucky-based association of HMOs. As one means of controlling the quality and cost of health care delivery, petitioners and other HMOs have contracted with selectively-chosen doctors, hospitals, and other health care providers to create exclusive "provider networks."[1] These "participating providers" are required by

[1] It is beyond the scope of this brief to define and distinguish all the different ways that HMOs employ such networks to satisfy their care obligations for their insureds. *See* Weiner & de Lissovoy, *Razing a*

their contracts to provide health care services to the HMOs' subscribers at discounted rates and to comply with other contractual requirements.[2] In exchange for their rate discount, participating providers receive the advantage of access to the HMOs' subscribers and, consequently, increased patient volume over non-network providers who lack such access. *See* Shouldice, Introduction to Managed Care 60 (1991).

The value of network membership (and, accordingly, the amount providers will agree to discount their services) depends on the HMOs' ability to limit the number of providers in the network; the fewer the providers, the greater the patient volume for each provider. *Id.* at 72 ("the panel must be

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Tower of Babel: A Taxonomy for Managed Care and Health Insurance Plans, 18 J. Health Politics 75, 75 (1993) ("Today, even seasoned observers are unable to distinguish different health insurance plans from one another."). One point to be clear about, however, is that whereas in the past HMOs might have been understood as providing care less through a "network" of providers and more through a "staff" of paid providers – the so-called "closed" or "staff" HMO – many HMOs now rely on a combination of network-provider options and non-network care options (at higher copayments and deductibles) in the fashion of preferred-provider organizations. *See* Weiner & de Lissovoy, *supra*, at 99; Wagner, *Types of Managed Care Organizations*, *in* Essentials of Managed Health Care 17, 18 (Kongstvedt ed. 2001) ("Today, an observer may be hard pressed to uncover the differences between products that bill themselves as HMOs, PPOs, or managed care overlays to health insurance."). As used in this brief, the term HMO will encompass the older-style "pure" or "closed" or "staff" HMOs – which provide care from providers employed directly by the HMO – as well as the now-more-common arrangements for meeting care obligations through a mixture of networks and non-network provider options. It also bears noting that even HMOs that offer non-network care options have incentives to limit the number of providers that are in their networks, so that they can offer cost incentives to encourage use of their in-network providers. *See, e.g.*, Wagner, *supra*, at 20, 28; Shouldice, Introduction to Managed Care 60 (1991).

[2] Unless otherwise specified, this brief will use the term "contract" to refer to the provider contracts, and the term "policy" will refer to the contractual relationship between the HMO and its insureds, who will also be referred to as "subscribers."

small enough to enable member providers to increase their patient volume significantly"). The ability of the HMO to decide for itself which providers may join its networks is fundamental to the entire enterprise of managing the quality and costs of health care: "[T]he selection of a network of physicians, hospitals, pharmacies, laboratories, and other providers who will furnish services of adequate quality for a specified fee is essential. In selecting a network, MCOs seek to screen out providers whose quality does not meet plan standards and whose practice styles are costly." Rosenblatt, Law & Rosenbaum, Law and the American Health Care System 555 (1997).

Petitioner HMOs make their provider networks available to ERISA-governed employee health benefit plans in two different ways. First, each contracts with ERISA plans to enroll plan beneficiaries as direct subscribers in the HMO. Second, they also make their provider networks available to self-funded employee benefit plans, for which the HMOs provide only administrative services and bear no risk.

2. The laws of the Commonwealth of Kentucky include two provisions that prohibit petitioners from guaranteeing network exclusivity to providers in exchange for rate discounts. These provisions – known generally as "Any Willing Provider" ("AWP") statutes – essentially require petitioners to open their networks to any provider willing to meet the terms of participation. When initially enacted in 1994, the general AWP law was directed at and governed only "health benefit plan(s)." Ky. Rev. Stat. § 304.17A-110(3) (1994). The legislature subsequently recodifed the law and changed the phrase "health benefit plans" to "health insurers," adding a definition of the latter as:

> any insurance company; health maintenance organization; self-insurer or multiple employer welfare arrangement not exempt from state regulation by ERISA; provider-sponsored integrated health delivery

> network; self-insured employer-organized association, or nonprofit hospital, medical-surgical, dental, or health service corporation authorized to do transact health insurance business in Kentucky.

Id. § 304.17A-005(23). The law now provides:

> A health insurer shall not discriminate against any provider who is located within the geographical coverage area of the health benefit plan and who is willing to meet the terms and conditions for participation established by the health insurer . . . .

Id. § 304.17A-270. In addition to this general AWP law, in 1996 the Legislature enacted another AWP provision specifically addressed to contracts between "health benefit plan[s]" – including HMOs – and chiropractors. *See id.* § 304.17A-171(2). Although still targeted in terms to "health benefit plans," the chiropractic AWP statute does not otherwise differ in substance from the general AWP law.[3]

The purpose and effect of these AWP laws is to require petitioners and other HMOs to throw open their closed provider networks to any provider in the geographic area willing to abide by the terms of their network contracts. Because an HMO's ability to control costs and quality depends in large part on its ability to determine for itself the providers with network access, as discussed above, *see supra* at 2-3, the unavoidable consequence of the laws is to drive up the costs of the health care services managed by HMOs and to affect their ability to regulate efficiently the quality of care offered

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[3] The same Act that established the chiropractic AWP law also included other restrictions on petitioners' freedom to contract with chiropractors. *See* Ky. Rev. Stat. § 304.17A-171(1) & (3)-(8). The court below remanded the issue of whether those provisions are preempted by ERISA. Pet. App. 4a n.3.

by network providers.[4] As the Federal Trade Commission opined in commenting on another state's AWP laws:

> Although the law may be intended to assure consumers greater freedom to choose where they obtain services, it appears likely to have the unintended effect of denying consumers the advantages of cost-reducing arrangements and limiting their choices in the provision of health care services.

F.T.C., Opinion Letter to Attorney General of Montana Regarding Any Willing Provider Law, Feb. 4, 1993, *quoted in* Smith & Stewart, *supra* note 4, at 799.

4. Petitioners filed a complaint in April 1997 in the United States District Court for the Eastern District of Kentucky against the Commissioner of the Kentucky Department of Insurance asserting, *inter alia*, that Kentucky's AWP laws are preempted by ERISA. As a general matter, ERISA broadly preempts any state law that "relate[s] to" an ERISA-governed employee benefit plan. 29 U.S.C. § 1144(a). Congress, however, chose to "save" from ERISA's preemptive force any state law "which regulates insurance." *Id.* § 1144(b)(2)(A). In other words, even if a law otherwise "relates to" an ERISA plan, it is not preempted if it is a law "which regulates insurance."

The parties cross-moved for summary judgment on the ERISA preemption count. The district court held the laws protected by the saving clause, and entered an order of final judgment under Rule 54(b) on the ERISA preemption count. Petitioners appealed to the Sixth Circuit.

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[4] Studies estimate that AWP laws increase the costs of care managed by HMOs by approximately fifteen percent. Smith & Stewart, *State Regulation of Managed Care*, *in* Essentials of Managed Health Care, *supra* note 1, at 786, 799.

The court of appeals unanimously agreed that Kentucky's AWP laws "relate to" ERISA plans. Pet. App. 7a-19a (majority, per Holschuh, D.J., sitting by designation); *id.* at 39a (Kennedy, J., dissenting). The court split, however, over whether those laws are saved from preemption under ERISA's saving clause as "laws which regulate insurance."

a. Beginning the analysis by considering whether AWP laws "regulate insurance" as a matter of "common sense," *see, e.g.*, *UNUM Life Ins. Co. of Am. v. Ward*, 526 U.S. 358, 367 (1999), the majority focused primarily on the fact that Kentucky's AWP laws apply by their terms to "insurers," Pet. App. 24a-25a. On that basis alone the court determined that the "Kentucky AWP laws are thus specifically directed toward insurers and the insurance industry and are ones that from a 'common sense view' regulate insurance." *Id.* at 25a. Adding further that the AWP laws also "deal directly with the relationship between insurers and insureds under health benefit plans," and "are part of a comprehensive subtitle of Kentucky's insurance code regulating health benefit plans," the court concluded that for those reasons as well the AWP laws are "clearly laws which, in a common sense view of the matter, 'regulate insurance.'" *Id.* at 30a.

In reaching that determination, the panel majority rejected the argument that the AWP laws do not regulate insurance because they apply in fact not just to "insurers" as traditionally understood, but also to employers that pay directly for their employees' health services. Such self-funded plans, the majority held, involve "the business of insurance." *Id.* at 26a. The court brushed aside ERISA's "deemer clause" – which explicitly prohibits states from deeming self-funded plans to be "insurance" for purposes of the saving clause, *see* 29 U.S.C. § 1144(b)(2)(B) – on the unelaborated ground that the statutory distinction between "insurance" and a self-funded employer plan "is not a distinction based upon a concept that employers who choose to be self-

insurers cannot be considered insurers subject to state regulations dealing with insurance." Pet. App. 26a.[5]

The panel majority then looked to the "three factors employed to determine whether the regulation fits within the 'business of insurance' as that phrase is used in the McCarran-Ferguson Act." *Id.* at 20a (quoting *UNUM Life Ins. Co. of Am. v. Ward*, 526 U.S. 358, 367 (1999)). The court found the first – whether the law affects the transfer or spreading of the risk against which the policyholder is insured – to be "certainly a debatable issue," *id.* at 30a, but found it satisfied simply because AWP laws allow insureds to receive covered services from providers for whose services insureds would otherwise pay directly. The panel majority reasoned that AWP laws spread the "cost component" of the policyholder's risk among all insureds, in that the policyholder is not required to shoulder all the cost when seeking care from a provider outside the network. *Id.* at 31a (quoting *Stuart Circle Hosp. Corp. v. Aetna Health Mgmt.*, 995 F.2d 500, 503 (4th Cir. 1993)).

As to the second McCarran-Ferguson factor, the court held that AWP laws govern a practice that is an "integral part of the policy relationship between the insurer and the insured," Pet. App. 35a, even while acknowledging that "it is admittedly true that the AWP laws do not change the substantive terms of the insurance coverage," *id.* at 36a. The court considered the mandatory change "from a closed pool

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[5] The court also held that the AWP statutes do not apply to HMOs that provide solely administrative services to ERISA plans, Pet. App. 26a, 28a n.14, even though both AWP laws specifically include all HMOs within their sweep and neither distinguishes among the services HMOs provide. And despite the fact that even under the court's construction the Kentucky AWP laws apply to HMOs that provide solely administrative services to non-ERISA self-funded plans – and thus bear no risk at all – the court still concluded that the AWP laws are "limited to health care 'insurers.'" *Id.* at 28a.

of providers to an open pool of providers" to be the same as "expanding covered treatment." *Id.*

Finally, bootstrapping its earlier analysis of the laws' application to HMOs and self-funded employer plans under the common-sense prong, the majority concluded that the Kentucky AWP laws are limited to entities within the insurance industry, and thus that the third McCarran-Ferguson factor is satisfied as well. *Id.*

b. Judge Kennedy dissented, rejecting the majority's conclusions at every step of the saving clause analysis. She first concluded that "the Kentucky AWP laws do not meet the common sense test because they are directed at the contracts between benefit plans and third parties, rather than being specifically directed at the insurance industry." Pet. App. 40a. And as applied to HMOs whose only role is administration, Judge Kennedy reasoned, the AWP laws are "not directed at the business of insurance, as no insurance is involved." *Id.* at 43a. In Judge Kennedy's view,

> The common sense conclusion that can be drawn from the AWP statute's coverage of entities clearly operating outside of the business of insurance is that the statute is concerned generally with regulating provider access to networks rather than specifically regulating the business of insurance.

Id. at 44a.

Judge Kennedy found the majority's treatment of the McCarran-Ferguson factors equally uncompelling. Labeling the "cost component" risk-spreading theory relied upon by the majority as "attenuated," *id.* at 55a, Judge Kennedy observed that "[t]he critical issue with respect to the risk-spreading prong . . . is whether or not the law is related to *the risks underwritten by the insurer*," *id.* at 54a (emphasis added). Health insurance policies underwrite only "the risk that [the] insured will need medical treatment for a condition

covered under the policy," *id.* at 56a, and under Kentucky's AWP laws, Judge Kennedy explained, "[t]here is no shifting of [that] risk," *id.*; *see id.* at 54a (AWP laws merely "dictat[e] how [insurers] structure their provider networks, irrespective of the risks they underwrite").

As to whether the AWP laws are integral to the insured-insurer relationship, Judge Kennedy considered the matter quite clear:

> Kentucky's AWP provisions leave the contract terms between the insurer and insured[] unaltered. The relationships directly affected by the law are those existing between insurers and third parties (*i.e.*, medical providers). . . . [T]he medical risks covered by the policy remain the same. Thus, even if an insured's preferred provider decides to join the insured's network, and complies with its terms in doing so, the medical coverage that the insurer has contracted to underwrite remains unchanged. . . . Kentucky's AWP laws do not force the insurer to offer a benefit to insureds that was not available before the law.

Id. at 59a. Finally, incorporating her discussion of the common-sense prong, Judge Kennedy concluded that the AWP laws fail the third McCarran-Ferguson factor because they "extend[] to include entities in no way involved in underwriting risks." *Id.* at 59a-60a.

SUMMARY OF ARGUMENT

A. In *Group Life & Health Insurance Co. v. Royal Drug Co.*, 440 U.S. 205 (1979), this Court held that an insurer's contracts with pharmacies to provide drugs at a fixed low cost to insureds was not part of the insurer's "business of insurance" for purposes of the McCarran-Ferguson Act, 15 U.S.C. §§ 1011, *et seq*. In so holding, the Court also devised the three-part test now employed to help determine whether state laws are saved from preemption under ERISA as laws

that "regulate insurance." The pharmacy contracts, the Court held, did not involve the spreading of any risk between insurer and insured, were not integral to any aspect of the contract between insurer and insured, and implicated entities outside the insurance industry – the pharmacies involved. Exactly the same is true of the HMO provider contracts at issue in this case, which are factually and legally indistinguishable from the pharmacy contracts at issue in *Royal Drug*. HMOs rely on provider contracts to control the costs of providing the care promised in the HMO policies, just as the insurer in *Royal Drug* relied on its provider contracts to control the costs of providing the drugs promised in its drug benefit policy.

The two grounds suggested for distinguishing HMO provider contracts from the *Royal Drug* provider contracts are without merit. The first is that HMOs, unlike the insurer in *Royal Drug*, typically limit the number of providers who may enter into such contracts. That supposed distinction has nothing to do with the question resolved in *Royal Drug* and at issue again here, which is whether the practice of entering into *any* such contracts is an "insurance" practice. The second is that HMO provider contracts affect the HMO policy relationship more directly because HMOs spread a different kind of risk than did the traditional insurance policy at issue in *Royal Drug*. That argument, too, is incorrect: HMOs, just like traditional insurance plans, insure against the risk of financial loss arising from the need to obtain care. And HMOs use provider contracts to control their own costs of underwriting such losses, in just the same way the insurer in *Royal Drug* used pharmacy provider contracts to control its underwriting costs. *Royal Drug*'s conclusion that such cost control measures, while sound business practices, are not *insurance* practices, governs here.

B. Nothing in the ERISA saving clause precedents that have followed *Royal Drug* changes the analysis or result of

the case in respect to whether an insurer's provider contracts are "insurance." The critical question under the "common sense" test is whether the law regulates the "insurance practices" of "insurers." *Rush Prudential HMO, Inc. v. Moran*, 122 S. Ct. 2151, 2159 (2002). AWP laws do not regulate insurance as a matter of common sense because they are not targeted at insurance practices, nor even exclusively at insurers. By barring HMOs from entering limited network contracts with providers, AWP laws control the conduct of the providers who would seek to enter into such agreements (and thereby obtain a financial advantage over competitors) as much as they regulate the HMOs themselves. They are also irrelevant to the "insurance" that HMOs provide, *viz.*, protection against the risk of loss arising from the need to pay for medical care. An HMO's duty to protect against such loss by providing care is wholly unaffected by its decision about whom to contract with to provide such care. The laws this Court has previously found to be laws that regulate insurance as a matter of common sense all regulated the terms of the insurance policy itself. AWP laws, by contrast, regulate non-insurance contracts between non-insurers and insurers, and thus are not laws that regulate insurance from a common-sense view of the matter.

To "test" the result of the common-sense inquiry, the Court applies the same factors *Royal Drug* applied in concluding that an insurer's provider contracts are not an insurance practice. Application of those factors naturally leads to the same result here. Provider contracts are no more about risk spreading – the essential element of insurance, according to *Royal Drug* – today than they were two decades ago. Nor do AWP laws change anything "integral" to the HMO policy relationship. AWP laws require that an HMO allow any provider willing to accept a network contract's terms to join the network, but they in no way ensure that the subscriber's provider of choice will join the network. To the contrary, providers must be both able and willing to join the network,

and there are many reasons providers would not choose to join a given network. And AWP laws obviously regulate entities outside the insurance industry – the providers themselves. The provider contracts targeted by the laws are not limited to "insurers," and they do not involve "an insurance practice."

Finally, there is no merit to any suggestion that the *Royal Drug* factors are not relevant to, or operate more narrowly in, the ERISA saving clause context. This Court has repeatedly looked to these factors in saving clause cases, including just last Term in *Rush Prudential*. The *Royal Drug* analysis of "insurance" is highly relevant in any ERISA saving clause case; in this one, it is conclusive.

ARGUMENT

BECAUSE AN HMO'S CONTRACTS WITH THIRD-PARTY PROVIDERS ARE NOT "INSURANCE," THE AWP LAWS THAT REGULATE THOSE CONTRACTS ARE NOT SAVED FROM PREEMPTION AS LAWS THAT "REGULATE INSURANCE"

ERISA broadly preempts any state law that "relates to" employee benefit plans, 29 U.S.C. § 1144(a), in the sense that the law has either a "connection with" or a "reference to" such plans, *Cal. Div. of Labor Stds. Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 324, 329 (1997). There is no serious dispute that the Kentucky AWP laws at issue here "relate to" employee benefit plans under these twin standards, as the court below unanimously determined. Pet. App. 10a-19a. AWP laws "bear[] indirectly but substantially on all insured benefits plans," *Rush Prudential*, 122 S. Ct. at 2159 (quoting *Met. Life v. Massachusetts*, 471 U.S. 724, 739 (1985)), by precluding them from purchasing medical coverage from HMOs with limited provider networks. In this respect they affect both plan administration and plan benefits, and thus have a "connection with" ERISA plans. Pet. App. 19a; *see* U.S. Pet. Br. 7-8 (agreeing that AWP laws

have "connection with" ERISA plans). In addition, the Kentucky Act's explicit "exclusion of self-insured ERISA plans from its coverage" satisfies the "refers to" prong of the preemption analysis, Pet. App. 15a, because the exclusion singles out ERISA plans for differential treatment, *id.* at 13a (citing *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 830 (1988)).

Though AWP laws therefore would normally be preempted on these grounds, ERISA "saves" from such preemption those laws that specifically "regulate[] insurance." To fall within the compass of the saving clause, the law must do more than just regulate *insurers*; it is only when "insurers are regulated *with respect to their insurance practices*" that "the state law survives ERISA." *Rush Prudential*, 122 S. Ct. at 2159 (emphasis added). Accordingly, the question in any insurance saving clause case is whether the practice the state law regulates is an "insurance practice," or is some other practice an insurer (or other entity) may choose to pursue.

To answer that question, this Court takes a "commonsense view of the matter," *id.* (quoting *Metropolitan Life*, 471 U.S. at 740), but confirms that view by examining three principles enunciated in cases interpreting the closely analogous McCarran-Ferguson Act provision protecting state laws that regulate the "business of insurance": whether the practice being regulated is one that affects the spreading of risk across all insureds; whether the practice is integral to the policy relationship between the insurer and insured; and whether the practice involves entities outside the insurance industry. *See, e.g., id.*; *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 48-49 (1987).

The first McCarran-Ferguson case to identify the factors now employed in the saving clause inquiry was *Group Life & Health Insurance Co. v. Royal Drug Co.*, 440 U.S. 205 (1979). *See Union Labor Life Ins. Co. v. Pireno*, 458 U.S. 119, 129 (1982) ("*Royal Drug* identified three criteria rele-

vant in determining whether a particular practice is part of the 'business of insurance'"). In that case, the Court applied the three factors to determine that a contract between a health insurer and a third party to provide pharmacy services to insureds is not "insurance." 440 U.S. at 212.

The question in this case is in substance identical to the question in *Royal Drug*: whether an HMO's contract with a third party to provide services to ERISA plan beneficiaries is an "insurance" practice. The Kentucky laws at issue here purport to regulate such third-party contracts by barring HMOs from limiting the number of providers with whom the HMOs will contract. If the practice of entering such contracts is an "insurance" practice, then the state laws regulating that practice are laws that "regulate insurance," and they are saved from preemption by ERISA. But *Royal Drug* already held that the practice of entering such contracts is *not* an "insurance" practice for purposes of the McCarran-Ferguson Act. And inasmuch as that very holding laid the foundation for the ERISA saving clause analysis, the result must be the same in the ERISA context as well.

A. This Court Already Held In *Royal Drug* That Third-Party Provider Agreements Identical To Those Regulated By Kentucky's AWP Laws Are Not The "Business of Insurance"

The question in this case – whether HMO contracts with third-party service providers are "insurance" – was answered by this Court in the negative on indistinguishable facts in *Royal Drug*.

1. The insurance company in *Royal Drug* provided a benefit in the form of prescription drugs. In exchange for their premium payments, insureds were promised that they could obtain prescription drugs for no more than $2. 440 U.S. at 212, 216 n.14. To satisfy the obligation to its insureds, the insurance company offered to enter into contracts with pharmacies, pursuant to which each pharmacy would

agree to provide prescription drugs to the insurance company's insured for $2, and the insurance company would pay the pharmacy directly for the cost of the drug. *Id.* at 209. Thus, "only pharmacies that [could] afford to distribute prescription drugs for less than this $2 markup [could] profitably participate in the plan." *Id.* Several large pharmacy chains accepted the contracts and joined the network.

Eighteen independent pharmacies filed an action challenging the third-party pharmacy provider contracts under the Sherman Act as a retail drug price-fixing conspiracy and as a concerted refusal to deal. The insurance company defended on the ground that its provider contracts were exempt from the Sherman Act because they constituted the "business of insurance" under § 2(b) of the McCarran-Ferguson Act. *Id.* at 208.

This Court rejected the insurance company's argument, identifying three reasons for concluding that an insurer's third-party provider contracts are *not* "the business of insurance." Those reasons became identified in later cases as the "three criteria relevant in determining whether a particular practice is part of the 'business of insurance.'" *Pireno*, 458 U.S. at 129.

a. The first reason third-party provider contracts are not insurance, the Court explained, is that they lack an "indispensable characteristic of insurance": the "underwriting or spreading of risk." *Royal Drug*, 440 U.S. at 212. Though later cases have indicated that none of the three factors ultimately discussed in *Royal Drug* is "necessarily determinative in itself," *Pireno*, 458 U.S. at 129; *see, e.g.*, *Rush Prudential*, 122 S. Ct. at 2163 (declining to consider risk-spreading factor); *UNUM Life Ins. Co. of Am. v. Ward*, 526 U.S. 358, 373 (1999) (same), at least as applied to an insurer's third-party contracts, the risk-spreading factor is conclusive. Citing basic insurance law authorities, the Court in *Royal Drug* explained:

> The primary elements of an insurance contract are the spreading and underwriting of a policyholder's risk. "It is characteristic of insurance that a number of risks are accepted, some of which involve losses, and that such losses are spread over all the risks so as to enable the insurer to accept each risk at a slight fraction of the possibility of liability upon it." 1 G. Couch, Cyclopedia of Insurance Law § 1:3 (2d ed. 1959). See also R. Keeton, Insurance Law § 1:2(a) (1971) ("Insurance is an arrangement for transferring and distributing risk"); 1 G. Richards, The Law of Insurance § 2 (W. Fredman 5th ed. 1952).

440 U.S. at 211. The Court also drew upon its own precedents for the significance of risk-spreading in identifying an "insurance practice." The Court observed that *SEC v. Variable Annuity Life Insurance Co.*, 359 U.S. 65 (1959), had held that sales of annuity contracts by life insurance companies were not "insurance" – even though such sales "were regulated as [insurance] under state law and involved actuarial prognostications of mortality" – because "they placed all the investment risk on the annuitant and none on the company." 440 U.S. at 212. Accordingly, the Court explained, the annuities sold by the life insurance companies in *Variable Annuity Life* "involved 'no true underwriting of risks, *the one earmark of insurance* as it has been commonly conceived of in popular understanding and usage.'" *Id.* (quoting 359 U.S. at 73) (emphasis added). The Court also quoted another of its precedents noting that the "effect of insurance – indeed it has been said to be its fundamental object – is to distribute the loss over as wide an area as possible." *Id.* at 212-13 (quoting *German Alliance Ins. Co. v. Lewis*, 233 U.S. 389, 412 (1914)). The Court concluded from these authorities and precedents that the existence of risk-underwriting is "a critical determinant in identifying insurance." *Id.* at 213.

The Court then explained why an insurance company's contracts with third-party providers do not spread or underwrite risk and therefore are not insurance. The insurance company in *Royal Drug* argued that third-party provider contracts do underwrite risk because they assure that the insurer will indemnify the insured against the financial loss arising from the need to purchase drugs. That argument was incorrect, the Court stated, because it "confused" the insurance company's obligations to its policyholders, which were to make prescription drugs available for a $2 copayment, with the insurance company's provider contracts, which "serve[d] only to minimize the costs [the insurer] incur[red] in fulfilling its underwriting obligations." *Id.* at 213; *see id.* at 216 n.14 ("[T]he benefit Blue Shield provides its policyholders is the assurance that they can obtain drugs in return for a direct maximum payment of $2 for each prescription. The Pharmacy Agreements are separate contractual arrangements between Blue Shield and certain pharmacists fixing the cost Blue Shield will pay for the drugs."). Third-party provider agreements "thus do not involve any underwriting or spreading of risk, but are merely arrangements for the purchase of goods and services by [the insurer]," *id.* at 214 – arrangements that simply "reduce the costs to the [insurers] of meeting their underwriting obligations to their policyholders," *id.* at 222. Noting the "important distinction" between risk *underwriting* and risk *reduction*, the Court explained that even though contracting with providers to control the total amount of its liability for benefit obligations may reduce the insurer's own risk of monetary loss, because provider contracts do not spread the risk more widely among insureds, "there is no underwriting of risk." *Id.* at 214 n.12. In sum, third-party provider contracts merely

> enable [the insurer] to minimize costs and maximize profits. Such cost-saving arrangements may well be sound business practice, and may well inure ultimately to the benefit of policyholders in the form of

> lower premiums, but they are not the "business of insurance."

Id. at 214.[6]

b. Having determined that an insurer's third-party provider contracts are not insurance simply because they do not involve risk spreading, the Court went on to confirm that conclusion by considering "[a]nother commonly understood aspect of the business of insurance": "the contract between the insurer and the insured." *Id.* at 215. The "core of the 'business of insurance,'" the Court explained, is the "relationship between insurer and insured, the type of policy which could be issued, its reliability, interpretation and enforcement." *Id.* at 215-16 (quoting *SEC v. Nat'l Sec., Inc.*, 393 U.S. 453, 460 (1969)). Not only are third-party provider contracts "not between insurer and insured," the Court observed, but they cannot be said to "so closely affect the reliability, interpretation, and enforcement of the insurance contract" as to place them in the class of "insurance" practices. *Id.* at 216 (internal quotation marks omitted). This argument, the Court held, "proves too much." *Id.*

> At the most, the petitioners have demonstrated that the [provider contracts] result in cost savings to [insurers] which may be reflected in lower premiums if the cost savings are passed on to policyholders. But, in that sense, every business decision made by an insurance company has some impact on its reliability, its ratemaking, and its status as a reliable insurer. . . .

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[6] Further confirming the distinction between risk underwriting through spreading and risk reduction through cost control, the Court quoted from a House Report that accompanied the drafting of McCarran-Ferguson: "'The theory of insurance is the distribution of risk according to hazard, experience, and the laws of averages. These factors are not within the control of insuring companies in the sense that the producer or manufacturer may control cost factors.'" 440 U.S. at 221 (quoting H.R. Rep. No. 78-873, at 8-9 (1943)).

> If [the Act] were interpreted in the broad sense urged by the petitioners, almost every business decision of an insurance company could be included in the "business of insurance."

Id. at 216-17; *see id.* at 232 ("If agreements between an insurer and retail pharmacists are the 'business of insurance' because they reduce the insurer's costs, then so are all other agreements insurers may make to keep their costs under control – whether with automobile body repair shops or landlords."). "Such a result," the Court concluded, "would be plainly contrary to the statutory language, which exempts the 'business of insurance' and not 'the business of insurance companies.'" *Id.* at 217. What properly matters, the Court explained, is whether the insurer satisfies its obligation under the insurance contract: "So long as th[e] promise [to provide drugs for $2 maximum] is kept, policyholders are basically unconcerned with arrangements made between [the insurer] and participating pharmacies." *Id.* at 214.[7]

c. A final reason provider agreements are not the "business of insurance," the Court held, is that they "involve parties wholly outside the insurance industry." *Id.* at 231. Specifically addressing a case involving the provider contracts of a group health organization that would now be called an

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[7] This was so, the Court held, even though the pharmacy provider contracts were "indirectly referred to in the insurance policies," because the only actual obligation of the insurer was to provide the $2 drug benefit, and the provider contracts were merely the insurer's way of satisfying that obligation. 440 U.S. at 216 n.14. And, the Court added, even if "some type of provider agreement is necessary for a service benefit plan to exist," to say that the agreement is therefore "insurance" still proves too much: "Assume, for example, that an indemnity insurer must have a line of credit or other commercial arrangement with a bank in order to pay off monetary claims. Despite the fact that the line of credit is 'necessary' for the insurer to fulfill its obligations, it is nevertheless not the 'business of insurance.'" *Id.* at 214 n.9.

HMO,[8] the Court held that, while it may have been debatable whether such organizations are themselves the "business of insurance," it is "next to impossible to assume that Congress could have thought that agreements (even by insurance companies) which provide for the purchase of goods and services from third parties at a set price are within the meaning of that phrase." *Id.* at 230. Accordingly, the fact that provider contracts "involve the mass purchase of goods and services from outside the insurance industry" provided additional confirmation that such contracts are not themselves the "business of insurance." *Id.* at 224.

2. The HMO provider contracts regulated by Kentucky's AWP laws are indistinguishable from the pharmacy provider agreements at issue in *Royal Drug*. Just like the insurer in *Royal Drug*, petitioners promise pharmacy, health, hospital, and other medical services to their members, either for no cost or markedly reduced costs, in exchange for advance premium payments. Just like the insurer in *Royal Drug*, petitioners arrange to satisfy that obligation by entering into con-

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[8] The case is *Jordan v. Group Health Assoc.*, 107 F.2d 239 (D.C. Cir. 1939). According to the *Royal Drug* Court's description of the entity in that case:

> Group Health was organized as a nonprofit corporation to provide various medical services and supplies to members who paid a fixed annual premium. To implement the plan, Group Health contracted with physicians, hospitals, and others, to provide medical services. These groups were compensated exclusively by Group Health. By contracting with the various medical groups directly, Group Health was able to obtain services at a lower cost than if each member contracted separately. The plan, therefore, was somewhat similar to the Pharmacy Agreements in this case.

440 U.S. at 227-28. While staff HMOs like Group Health are "somewhat similar" to the Pharmacy Agreements in *Royal Drug*, the provider network contracts frequently employed by HMOs today, *see supra* note 1, are indistinguishable from them.

tracts with pharmacies, doctors and hospitals, pursuant to which petitioners promise specified payments in exchange for the provision of services to petitioners' members. Just like the insurer in *Royal Drug*, petitioners' HMO policies do not promise the provision of care by any particular doctor, only that care will be provided at the cost (if any) to the insured specified in the policy. If the pharmacy provider contracts at issue in *Royal Drug* were not the "business of insurance," then neither are the provider contracts here.

Two related arguments have been advanced for distinguishing the *Royal Drug* provider agreements on their facts from petitioners' provider agreements. Both arguments are meritless.

a. The principal ground identified by the court below for distinguishing the agreements is that HMO provider networks are intentionally limited, whereas the insurer in *Royal Drug* "did not restrict the number of providers in question." Pet. App. 32a. Thus, the majority below reasoned, the "benefit conferred on the insureds by the Kentucky AWP statutes – removal of restrictions on the number of providers – was already present in *Royal Drug*." *Id.*

That "distinction" wholly misses the point: if what insurers were doing in *Royal Drug* was *not* the "business of insurance," a law requiring insurers to do exactly what the insurers in *Royal Drug* were doing is not a law regulating the "business of insurance." Indeed, *Royal Drug* itself explicitly uses the example of a limited network to prove why the open network in that case was not "insurance." As the Court explained, the provider contracts offered to all licensed pharmacies were "legally indistinguishable" from the situation in which

> an insurance company enter[s] into a contract with a large retail drug chain whereby its policyholders could obtain drugs under the policies only from stores operated by this chain. The justification for such an

> agreement would be administrative and bulk-purchase savings resulting from obtaining all of the company's drug needs from a single dealer. Even though these cost savings might ultimately be reflected in lower premiums to policyholders, would such a contract be the "business of insurance"?

440 U.S. at 215. If a contract limited to a single pharmacy chain to obtain a price advantage by assuring the chain increased volume is not the "business of insurance," neither is a set of contracts limited to certain providers in order to obtain a price advantage by assuring the providers increased volume.

In short, contrary to the view of the court below, the question *Royal Drug* asks is simply whether contracts between an insurer and a network of third-party providers – whether limited or not – are the business of insurance. *Royal Drug* explicitly answers that question no, and that answer must govern here.

b. The other ground offered for distinguishing HMO provider contracts with those of the insurer in *Royal Drug* is that HMO provider contracts affect the insurer-insured relationship more directly, including the specific risk the HMO subscriber is insuring against. As the Fourth Circuit has explained the argument, although "facially" an AWP law "only directly affects providers, it indirectly affects the insured's choice of provider and the consequent cost to the insured if he or she deems an excluded provider to be better qualified for treatment of a specific illness or accident. In this way it affects the risk that an insured must bear." *Stuart Circle Hosp. Corp. v. Aetna Health Mgmt.*, 995 F.2d 500, 504 (4th Cir. 1993). Elaborating its analysis of the relevant "risk," the court explained that by limiting the number of providers available to provide promised care, an HMO compels the insured to bear "all or part of the cost of the doctor or hospi-

tal *that is not preferred by the insurer*." *Id.* at 503 (emphasis added).

That analysis essentially suggests that HMO provider contracts can be distinguished from the *Royal Drug* pharmacy provider contracts because HMO *policies* insure against a different kind of risk – specifically, the risk of needing to pay for care from a provider preferred by the insured, as opposed to simply the risk of needing to pay for care at all. That is a fundamental misapprehension of HMO policies, which do not in fact differ in kind from the drug benefit policy at issue in *Royal Drug*.

The fact is that HMOs, like traditional indemnity health insurers, simply insure against the risk that a policyholder will get sick or hurt and need "specified health care." *Rush Prudential*, 122 S. Ct. at 2160 (quoting *Pegram v. Herdrich*, 530 U.S. 211, 218 (2000)). The "risk" inherent in all forms of insurance concerns loss, *see* Mehr & Cammack, Principles of Insurance 18 (7th ed. 1980), and the loss at issue in this context is the imposition of a financial obligation arising out of injury or illness, *see* Weiner & de Lissovoy, *supra* note 1, at 81 ("Health insurance plans exist mainly because of the consumer's desire to share the financial risk arising from expenses associated with treating (or preventing) an illness or injury."); Note, *Group Health Plans: Some Legal and Economic Aspects*, 53 Yale L.J. 162, 172 (1943) ("the underlying risk-distribution function of" HMO-style plans is "to insure the potential patient against the unpredictable occurrence of sickness"). Whereas traditional indemnity insurers cover a financial obligation arising from needed medical care by providing cash payment for the care, HMOs cover that obligation simply by providing the care itself. *Rush Prudential*, 122 S. Ct. at 2160. Thus, contrary to the *Stuart Circle* court's conception of HMOs, the "risk" HMOs insure against is not the loss arising out of a desire to pay one provider rather than another for particular care. No health insurance

policy deals with that kind of risk. What they underwrite is the loss arising from the need to pay for care at all. *See* Note, *The Legal Problems of Group Health*, 52 Harv. L. Rev. 809, 814-15 (1939) ("it seems clear that, in the case of the cooperative health associations, indemnification against medical cost rather than the unique services of the physicians is the principal object of the relationship").

The terms of HMO policies themselves bear this out. *Cf. Pireno*, 458 U.S. at 131 (a "fundamental principle of insurance" is that "the insurance policy defines the scope of risk assumed by the insurer from the insured"). The *Stuart Circle* court itself correctly describes "the 'policyholder's risk'" under typical HMO policies as including "the types of illness and injury that the insurance contract covers, [the] provision for treatment, and the cost of the treatment." 995 F.2d at 503. Nowhere do any of those standard "risk" terms include coverage for loss arising out of the unavailability of a *particular provider*. Petitioners' HMO policies are to the same effect: as all three judges below recognized, the HMO policies in this case do *not* promise care *from a particular provider*, any more than indemnity insurers promise to pay cash from a particular bank. *See* Pet. App. 36a (maj. op.) ("it is admittedly true that the AWP laws do not change the substantive terms of the insurance coverage"); *id.* at 56a (dissent) ("The insurance policies and the contingencies it underwrites, *i.e.*, the risk that the insured will need medical treatment for a condition covered under the policy, remain the same, regardless of Kentucky's AWP law."); J.A. 65a-76a (covered medical services of exemplary petitioner HMO policy). Petitioners' HMO policies underwrite the insured's risk of financial loss from medical expenses simply by promising to provide the needed care – just like the insurance policy in *Royal Drug* underwrote the risk of financial loss from prescription drug expenses by promising that the insured would receive needed drugs at a fixed price.

To be sure, as a practical matter provider contracts are necessary for an HMO to fulfill its policy obligations, but the "HMO is still bound to provide medical care to its members . . . regardless of the ability of physicians or third-party providers to honor their contracts with the HMO." *Rush Prudential*, 122 S. Ct. at 2162; *see supra* at 18-19 (discussing Court's rejection of same argument in *Royal Drug*). That is, the only obligation legally relevant to the HMO policy relationship is the obligation to provide care; the particular nature of the arrangements with providers the HMO makes – whether they are on a limited basis or not – are immaterial to that obligation. In the same vein, an insured may well have an interest in which doctors are available to him, but that does not bear on the risk of financial loss underwritten by the HMO, any more than the desire of an insured in *Royal Drug* to buy $2 prescription drugs from the local apothecary affected the loss underwritten there. *See* Pet. App. 54a (Kennedy, J., dissenting) ("This is not to say that at least some participants would not be disappointed by the fact that their pharmacy of choice might not have been included, if for example it was not large enough to provide prescriptions for only a two-dollar mark-up. However, the *financial* risks that Blue Shield agreed to cover remained unchanged . . . .").[9]

The underwriting of the potential financial losses imposed by medical expenses is the entirety of the "insurance" aspect of the business of HMOs. The provider contracts an HMO enters into to control its own costs of covering those expenses simply do not relate to *any* question of what risks of loss are assumed or how widely they are spread.[10] Such

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[9] AWP laws, in any event, have no direct impact on the subscriber's interest in his or her choice of provider; as discussed below, *infra* at 33-34, such laws in no way mean that a subscriber's preferred provider will become a member of the network.

[10] *See Express Scripts, Inc. v. Wenzel*, 102 F. Supp. 2d 1135, 1153 (W.D. Mo. 2000) ("Any Willing Provider statutes . . . do not require insurance companies to cover different kinds of services. Instead, they only

contracts may well be good business for HMOs, but they are not the business of *insurance*.

B. The Holding And Analysis Of *Royal Drug* Fully Apply In The ERISA Saving Clause Context

Royal Drug, of course, arose under the McCarran-Ferguson Act and not the ERISA saving clause. If *Royal Drug*'s conclusion that an insurer's third-party contracts are not part of the "insurance" aspect of their business does not answer the ERISA saving clause question whether laws regulating such contracts are laws regulating "insurance," it can only be because there is something about the analysis of "insurance" in this Court's saving clause precedents that compels a different conclusion. But if there is any substantive difference at all between the two inquiries, it does not affect analysis of an insurer's third-party provider contracts. That is, such contracts are not "insurance" under this Court's saving clause precedents for essentially the same reasons they are not the "business of insurance" under the McCarran-Ferguson factors discussed in *Royal Drug*.

As previously noted, this Court's very first ERISA saving clause precedent adverted explicitly to the three *Royal Drug* criteria to determine whether the law at issue was one that "regulates insurance." *See Metropolitan Life*, 471 U.S. at 743. But that case also initiated the tradition of beginning the saving clause inquiry with the question whether the law regulates insurance "from a common-sense view of the matter." *See UNUM*, 526 U.S. at 367 (citing *Metropolitan Life* for "common-sense" test). Each of the Court's saving clause

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require insurance companies to allow a greater number of providers to offer these services to insureds. . . . However, even without the statute, the insured would be able to see a general practitioner in the insurance company's network. Thus, in either case, the risk that the insured will need to see a general practitioner is borne by the insurance company. This is why Any Willing Provider statutes do not spread risk."), *aff'd*, 262 F.3d 829 (8th Cir. 2001).

precedents since *Metropolitan Life* has begun the saving clause analysis with this common-sense inquiry, then proceeded to "test the results" of that inquiry by reference to the more specific *Royal Drug* factors for identifying insurance laws under the McCarran-Ferguson Act. *Rush Prudential*, 122 S. Ct. at 2159.[11] It is not clear how much, if at all, the common-sense inquiry differs in substance from the three-factor *Royal Drug* analysis; what is clear is that the "combined" test "parses the 'who' and the 'what': when insurers are regulated with respect to their insurance practices, the state law survives ERISA." *Id.*

1. Kentucky's AWP laws do not regulate insurance as a matter of common sense: they regulate neither insurers exclusively, nor the insurance practices of insurers. Instead the laws regulate insurers *and providers*, by barring the latter from entering into limited network contracts with the former. And that third-party contractual relationship is not – as *Royal Drug* instructs – an *insurance* practice.

The "common-sense enquiry focuses on 'primary elements of an insurance contract[, which] are the spreading and underwriting of a policyholder's risk.'" *Rush Prudential*, 122 S. Ct. at 2159 (quoting *Royal Drug*, 440 U.S. at 211). In this respect the common-sense inquiry reflects the very heart of the *Royal Drug* analysis, and thus could hardly

[11] The court below suggested that if the common-sense test is satisfied, it is not necessary for a law to satisfy *any* of the *Royal Drug* factors. Pet. App. 38a. That cannot be correct: if the specific purpose of the factors is, as *Rush Prudential* states, to "test" and "confirm" the results of the common-sense inquiry, the failure to satisfy any of the factors means the result of the common-sense inquiry *was wrong* – the practice the law regulates has turned out on closer, more rigorous inspection not to be an insurance practice. In this sense the *Royal Drug* factors are not necessarily always of "secondary importance", Pet. App. 22a; they are factors that may provide needed specificity and guidance in hard or close cases, under which circumstances they may be more important than the common-sense test.

be expected to lead to a different result with respect to third-party provider contracts. As we have seen, HMO provider contracts do not implicate the primary elements of an insurance contract – the spreading and underwriting of risk – any more than the provider contracts in *Royal Drug* did. Put differently, the contracts regulated by the AWP laws are in no way insurance contracts. They are contracts between insurers and non-insurer third-party providers – pharmacies, doctors, hospitals, and so on. The laws govern the conduct of these non-insurers just as much as they do HMOs: providers are barred from entering into limited network contracts with HMOs to provide care to their insureds. The laws thus deprive providers of the increased patient volume (and hence income) that such networks offer. *See supra* at 2-3. The laws are written as if they regulate essentially only HMOs and other insurers, to be sure, but they plainly govern the contracts and conduct of non-insurer providers as well.[12]

AWP laws thus do not regulate insurance as a matter of common sense. The laws that this Court previously has found to "regulate insurance" under the common-sense inquiry confirm the point. *UNUM*, for example, involved a California law barring insurers from denying claims on the basis of failure to give notice of the claim unless the insurer could show actual prejudice. The law "regulates insurance"

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[12] The court below concluded that Kentucky's AWP laws satisfy the common-sense inquiry for little reason other than that they appear in the state insurance code. Pet. App. 24a-25a. This is surely incorrect: this Court has more than once held that certain practices are not the "business of insurance," "notwithstanding their classification as such for the purpose of state regulation." *Rush Prudential*, 122 S. Ct. at 2162 n.5; *see Royal Drug*, 440 U.S. at 230 n.38 (citing cases "recogniz[ing] that state regulation of a practice of an insurance company does not mean that the practice is the 'business of insurance'"). Thus the fact that the AWP laws appear in the state insurance code may be "relevant to" the common-sense inquiry, *Rush Prudential*, 122 S. Ct. at 2162 n.5, but it cannot be dispositive in and of itself.

as a matter of common sense, the Court held, because it "controls the terms of the insurance relationship" and is "applicable only to insurance contracts." 526 U.S. at 368; *id.* at 373 ("notice-prejudice is a rule of law governing the insurance relationship distinctively"). In this regard *UNUM* closely follows the seminal ERISA saving clause precedent, *Metropolitan Life*, which held that a law that regulates the specific terms of an insurance policy is, "[t]o state the obvious," a law that regulates insurance as a matter of common sense. 471 U.S. at 740. *UNUM* also presaged the Court's most recent saving clause case, *Rush Prudential*, which held that a state law affecting HMO contract terms by granting policyholders the right to an independent medical review of an HMO benefit determination is a law that regulates insurance. *See* 122 S. Ct. at 2164 (law granted "a legal right to the insured, enforceable against the HMO, to obtain an authoritative determination of the HMO's medical obligations"); *see also FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990) (state anti-subrogation law falls within saving clause because it "directly controls the terms of insurance contracts by invalidating any subrogation provisions that they contain").

All these precedents reflect the common-sense conclusion that a law that specifically regulates the terms of insurance policies is a law that regulates insurance. It would be almost absurd to conclude otherwise. *See United States Department of Treasury v. Fabe*, 508 U.S. 491, 504 (1993) ("There can be no doubt that the actual performance of an insurance contract falls within the 'business of insurance,' as we understood that phrase in *Pireno* and *Royal Drug*. To hold otherwise would be mere formalism."). But AWP laws concededly do *not* alter, regulate or affect the terms of insurance policies. Pet. App. 36a (maj. op.); *see supra* at 23-25 (discussing HMO policies). What they regulate are the contracts with non-insurers HMOs pursue to satisfy the obligations of their policies. They thus do not fit within this

Court's common-sense analysis of laws that regulate insurance.

To be clear: we do not argue that AWP laws do not regulate insurance on the ground that HMOs do not act as insurers. That argument has been foreclosed by *Rush Prudential*. But *Rush Prudential* makes equally clear that unless the law in issue regulates specifically the "insurance practices" of "insurers," it is not a law that regulates insurance. 122 S. Ct. at 2159.[13] AWP laws fail both sides of that equation: they regulate an HMO practice – the designation of

[13] It is easy to mistake the common-sense inquiry for an inquiry solely into the question of "who" is being regulated. The Court's description in *UNUM* of the common-sense inquiry as asking whether the regulation "homes in on the insurance industry," 526 U.S at 368, and in *Rush Prudential* as whether the regulation is "'directed toward' the insurance industry," 122 S. Ct. at 2163, might suggest that so long as the law regulates "insurers," it is a law that "regulates insurance." *Rush Prudential* squarely rejects any such understanding: what matters, *Rush Prudential* makes clear, is whether the law regulates the "insurance practices" of "insurers," "focus[ing] on the 'primary elements of an insurance contract[, which] are the spreading and underwriting of a policyholder's risk.'" *Id.* at 2159 (quoting *Royal Drug*, 440 U.S. at 211). The references to the "insurance industry" in these cases thus are best understood as another way of saying "the industry of providing insurance." As the cases illustrate, it is sometimes enough to determine that the law regulates only insurers, for the practice in question may clearly be an insurance practice *if* it is an "insurer" doing it. For example, in *Rush Prudential* there was no question that the law affected the terms of HMO policies; the real question was whether the HMOs were acting as *insurers* in issuing those policies. Thus in *Rush Prudential* the answer to the "who" question also answered the critical "what" question. But where, as here, the law regulate *more* than insurers, it is less likely to be a law that regulates insurance, for who besides insurers engages in insurance practices? Even if the law regulates only insurers, then it is only likely (but not certain) to be a law that regulates "insurance," since states frequently regulate the non-insurance practices of insurers. *See supra* note 12. The bottom line is that regardless of who is actually being regulated, a law is saved from preemption if and only if it is regulating an *insurance* practice.

limited provider networks – that is *not* an "insurance practice," and they regulate entities that are *not* "insurers," by barring non-insurer providers who want to enter into financially beneficial limited network contracts with HMOs from doing so.[14] In short, AWP laws are "concerned generally with regulating provider access to networks rather than specifically regulating the business of insurance." Pet. App. 44a (Kennedy, J., dissenting). Thus, as a matter of common sense, AWP laws are not laws that "regulate insurance."

2. It is hardly surprising that the *Royal Drug* factors should uniformly confirm the common-sense conclusion, inasmuch as the Court derived the factors in the course of concluding that indistinguishable pharmacy provider contracts are not the business of insurance.

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[14] Kentucky's AWP laws also apply to two *other* categories of entities that do not accept and spread risk. The first includes HMOs that provide only administrative services to non-ERISA employer-funded plans (*i.e.*, government and church plans). The court below held that the laws do not apply to HMOs acting as administrators to ERISA plans apparently on the ground that such a reading would be preempted by ERISA. Pet. App 26a, 28a n.14; *cf.* Pet. App. 45a. Even accepting that highly dubious reading of the laws, the statutes still would apply to every non-risk-bearing HMO providing services to state and local government plans and church plans, which are not governed by ERISA. The second category of non-insurers the statute governs are the self-funded government and church plans themselves. The Kentucky AWP laws do not apply to any plan governed by ERISA, but since government and church plans are not governed by ERISA, they are covered by the AWP laws. And any such plans governed by the law that are self-funded are not properly called "insurance": such plans involve neither the transfer nor the pooling of shared risks – but rather only the maintenance of a fund large enough to absorb predicted losses – and so they "involve[] no insurance as the term is ordinarily used in regulatory statutes or in other legal contexts." Keeton & Widiss, Insurance Law 14 (1988). Indeed, ERISA specifically bars states from deeming the self-funded plans it governs to be "insurance" for the purpose of the saving clause. 29 U.S.C. § 1144(b)(2)(B). Thus, Kentucky AWP laws explicitly bring within their sweep public-entity plans that, were they within the scope of ERISA, clearly would be designated non-insurers.

a. As discussed above, the first reason *Royal Drug* held that provider contracts are not the business of insurance is that they do not spread risk. *See supra* at 15-18. As also discussed above, the suggestion that either HMO provider contracts, or HMO insurance policies, differ from the contracts and policies at issue in *Royal Drug* is without merit. There can be no genuine dispute that HMO provider contracts do not spread or underwrite risk – the "primary element," "one earmark," the "indispensable characteristic," of insurance. Just as that fact alone sufficed in *Royal Drug* to resolve the question whether provider contracts constitute "insurance," it should suffice to answer the question here.

Despite the primacy of risk-spreading in *Royal Drug*'s conception of the practice of insurance, this Court has in two recent saving clause cases declined to address whether the law at issue governed a risk-spreading practice. *See Rush Prudential*, 122 S. Ct. at 2163; *UNUM*, 526 U.S. at 373. But in both instances, the Court held that the practice at issue "clearly satisfied" the other *Royal Drug* factors, *Rush Prudential*, 122 S. Ct. at 2163; *see UNUM*, 526 U.S. at 374 ("the remaining McCarran-Ferguson factors, verifying the common-sense view, are securely satisfied"). And that conclusion made sense in each case, for, as discussed above, the state law in each case directly regulated the terms of insurance contracts, and only insurance contracts. *See supra* at 28-29. It follows as a matter of course that such a law "regulates insurance": even under *Royal Drug*, if there is one thing that defines a law that regulates insurance in the absence of a risk-spreading analysis, it is that the law regulates the insurance contract. *See Royal Drug*, 440 U.S. at 215-16 (noting that the policy "relationship between insurer and insured" is at "the core of the 'business of insurance'"); *cf. Pireno*, 458 U.S. at 128 (same); *id.* at 136 (Rehnquist, J., dissenting) ("the Court [in *Royal Drug*] found the contractual relationship between the insurer and the insured to be the essence of the 'business of insurance'").

Evaluation of the risk-spreading factor cannot so readily be forgone here. Unlike *Rush Prudential* and *UNUM*, the common-sense inquiry and the other *Royal Drug* factors do not "clearly" or "securely" establish that third-party provider contracts are insurance practices. To the contrary, the other elements of the test strongly suggest such contracts are *not* insurance. And then there is this Court's own holding to exactly that effect in *Royal Drug*. It would be odd, indeed, for the Court to hold in this case that third-party provider contracts are "insurance" without considering the one factor the Court considered conclusive the last time it considered essentially the same question.

b. The second reason *Royal Drug* held that provider contracts are not insurance is that the terms of such contracts are not integral to the bargain between insurer and insured. *See supra* at 18-19. As already discussed, this Court has applied that factor in the context of the ERISA saving clause to find that several state laws do regulate insurance, but only where such laws directly affect the terms of the insurance policy. *See supra* at 28-29. By contrast, as we have emphasized, AWP laws do not alter any term of the bargain between insurer and insured.

The majority below fully acknowledged that "the AWP laws do not change the substantive terms of the insurance coverage," Pet. App. 36a, but concluded that the choice of provider is "integral" to the HMO policy only in the indirect sense that policyholders would be pleased to have the opportunity to obtain care from a provider of their choice, *id.* at 31a, 36a. That analysis is flawed in two respects.

First, it fundamentally misapprehends both the operation of HMO networks and the effect of AWP laws. HMO provider networks are often explicitly limited in size in order to control quality and cost, but they are also *implicitly* limited by the terms of the network contracts. In *Royal Drug*, for example, the network was nominally open to any pharmacy

willing to join, but in fact only high-volume chains could afford to provide drugs for the small, $2 mark-up required by the contracts. Similarly, the terms of HMO network contracts may price some or many providers out of the network, or impose practice conditions providers are unwilling to accept. A provider may also choose not to join a network simply because he or she is already a member of one or more other networks, or because he or she does not want to accept the management inherent in managed care. The critical point is this: AWP laws do not change *any* of those realities. That is, they require neither that HMOs open up their networks to all providers regardless of contract terms, nor that HMOs allow insureds to obtain care from any provider of their choice who has not joined the network. "The result," as Judge Kennedy correctly observed below, "is that although Kentucky's AWP laws make it *marginally* more likely that a policyholder's benefit plan network will contain their preferred doctor, they will still be restricted to the doctors in their benefit plan network regardless of the membership or non-membership of their preferred doctor." Pet. App. 51a (emphasis added). Accordingly, even the indirect effect the majority found to be so "integral" on the insurer-insured bargain occurs *only* when an insured's preferred provider "is both willing to join [the insured's] particular provider network and able to meet its requirements." *Id.* at 56a. To say that providing such a speculative, marginal benefit to an insured is "integral" to the entire policy, is to drain the second *Royal Drug* factor of any real meaning.

Second, even if AWP laws did work to give a substantial number of insureds a significantly broader range of providers to choose from, it is wrong to assume that the size and membership of the HMO's provider network is "integral" – or even germane – to the *contract of insurance* between insurer and insured. The nature of network options is certainly no more integral to an HMO policy than the pharmacy network options were integral to the insurance policies in *Royal*

Drug. As discussed above, *supra* at 25, many of the insureds in that case doubtless would have preferred to obtain drugs for $2 from their local druggists, rather than only from one of the large chains able to contract with the insurer. And yet the Court easily concluded that the insurer's decision to effectively limit insureds' options to one of the large providers was immaterial to the insurer-insured bargain: because the essence of that bargain was underwriting the risk of needing to pay for drugs, which was fully satisfied so long as the insurer made drugs available, insureds were "basically unconcerned" with the arrangements made by the insurer to control the costs of making drugs available. 440 U.S. at 214. So it is here: HMO policyholders may wish to obtain network service from a local doctor or pharmacist as much as the insureds did in *Royal Drug*, but that desire is not "integral" to the risks of loss that HMOs agree to accept, which is what the insurer-insured bargain is all about.

c. The final reason *Royal Drug* held that provider contracts are not insurance is that they involve entities outside the insurance industry – specifically, the providers with whom insurers contract. *See supra* at 19-20. This factor has been construed as examining whether the practice regulated by the law involves an "arrangement[] between insurance companies and parties outside the insurance industry." *Pireno*, 458 U.S. at 133. If the "targets of the law" are not "limited to entities within the insurance industry," then it is not a law that regulates insurance. *Rush Prudential*, 122 S. Ct. at 2164.

As demonstrated above in our discussion of the commonsense inquiry,[15] the targets of AWP laws are not limited to

[15] Recent cases have treated the third *Royal Drug* factor as effectively identical to the common-sense inquiry into whether the law is "directed specifically to the insurance industry." *Rush Prudential*, 122 S. Ct. at 2162; *see id.* at 2164 (finding third factor "satisfied for many of the same reasons that the law passes the commonsense test"); *UNUM*, 526

HMOs; they include the doctors and other providers who seek the advantage of membership in limited networks. This Court's cases have uniformly recognized that contracts with such non-insurance entities fall outside the "business of insurance," even if they might be understood as within the "the broader 'business of insurance companies.'" *Hartford Fire Ins. v. California*, 509 U.S. 764, 783-84 (1993) (holding that agreements between insurers and reinsurers are within the business of insurance) (citation omitted); *see Pireno*, 458 U.S. at 131 (insurer's contract with providers to conduct peer review is outside the business of insurance); *Royal Drug*, 440 U.S. at 231. *None* of the Court's saving clause precedents has found a law regulating contracts between insurers and non-insurers (other than insurance policies themselves) to be a law that regulates insurance. A law regulating contracts that amount to "the mass purchase of [medical] services from outside the insurance industry," *Royal Drug*, 440 U.S. at 224, simply cannot be a law that regulates insurance. AWP laws thus plainly fail the third *Royal Drug* factor as well.[16]

3. The foregoing discussion confirms the relevance of *Royal Drug*'s analysis and specific holding to the ERISA saving clause context. The Court continues to apply the

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U.S. at 373 (relying entirely on common-sense discussion to explain why third factor met).

[16] To the extent the third *Royal Drug* factor now mirrors the common-sense inquiry, *see supra* note 15, it bears noting that the common-sense inquiry is not, in fact, limited exclusively to an examination of "who" is regulated by the law, *see supra* at 28-31 & n.13. The common-sense question ultimately is whether the law targets the *practice of insuring*. As discussed above, that inquiry may be well illuminated by evidence that the law applies only to insurers, but such evidence will not be sufficient in all cases: the law must regulate the *insurance* aspect of what insurers do. Because AWP laws regulate a practice (of both HMOs and providers) that is other than insurance, it necessarily fails the third *Royal Drug* factor for the same reasons it fails the common-sense inquiry.

Royal Drug factors in saving clause cases, and nothing in the Court's application of the factors in that context, nor in the common-sense inquiry that has been overlaid upon them, alters the conclusion that an insurer's contracts with third-party providers are not insurance.

There is thus no merit to the suggestion of the court below that this Court's decision in *United States Department of Treasury v. Fabe*, 508 U.S. 491 (1993), categorically diminishes the relevance of *Royal Drug*'s approach and holding in ERISA saving clause cases. Pet. App. 35a. In *Fabe*, this Court compared the scope of the two clauses of McCarran-Ferguson Act § 2(b): "The first clause commits laws 'enacted . . . for the purpose of regulating the business of insurance' to the States, while the second clause exempts only 'the business of insurance' itself from the antitrust laws." *Id.* at 504. The Court pointed out that the language of the first clause was not as "narrowly circumscribed" as the second, in that laws "*enacted for the purpose of* regulating the business of insurance" would cover more laws than just those that "specifically relate[] to the business of insurance." *Id.* (emphasis added). *Royal Drug*, the Court observed, construed only the narrower reference in the second clause. *Id.* at 505.

That discussion in no way suggests that *Royal Drug*'s conception of laws that "specifically relate to the business of insurance" is somehow narrower than the saving clause conception of laws that "regulate insurance." Indeed, the language of the saving clause bears a much greater resemblance to the narrower, second clause of McCarran-Ferguson § 2(b) addressed in *Royal Drug* than it does to the broader first clause. The saving clause saves laws that actually *do* "regulate insurance," not those enacted with the broader "*purpose* of regulating the business of insurance." The close linguistic similarity between the saving clause and the McCarran-Ferguson language addressed in *Royal Drug* is surely why this Court has continued to rely on the *Royal Drug* factors

for saving clause analysis, with no suggestion in any post-*Fabe* case that they are to be applied in the saving clause context more narrowly than they would apply under § 2(b).[17]

Finally, it bears emphasis that *Fabe* itself specifically restates *Royal Drug*'s holding "that an insurer's agreements with participating pharmacies to provide benefits to policyholders [are] not part of the 'business of insurance.'" *Id.* at 503. If *Fabe* itself did not circumscribe the authority of the *Royal Drug* factors in saving clause cases – and it plainly did not – then its reaffirmance of *Royal Drug*'s basic holding only underscores the continued force of that holding in the saving clause context.

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be reversed.

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[17] For the same reason, the Solicitor General's suggestion that the term "insurance" used in the saving clause invokes a broader definition of "insurance practices" than does the phrase "*business of* insurance" used in McCarran-Ferguson, *see* U.S. Pet. Br. 16, is incorrect. No precedent of this Court has suggested that the phrases have any materially different meaning. The *only* support offered for that argument is that the Court has added the common-sense inquiry to the analysis of insurance practices under the ERISA saving clause, *see id.*, as if that alone proves that "insurance" under the saving clause is broader than "the business of insurance." But the cases plainly have not employed a common-sense analysis in order to invoke a broader category of insurance practices than would be defined by McCarran-Ferguson. To the contrary, the cases specifically rely on the McCarran-Ferguson factors to "test" or "confirm" the common-sense inquiry, establishing – not refuting – the parallel between the statutes. *See also supra* note 11.

Respectfully submitted,

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