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TABLE OF CONTENTS

TABLE OF AUTHORITIES

AMICI CURIAE

American Academy of Pediatrics, American Cancer Society, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Public Health Association, American Thoracic Society, Bazelon Center for Mental Health Law, Campaign for Tobacco-Free Kids, Child Neurology Foundation, Epilepsy Foundation, Muscular Dystrophy Association, National Health Law Program, Physicians for Social Responsibility, The ALS Association, The Leukemia & Lymphoma Society, and Truth Initiative (collectively, " ") are public health, patient, and consumer advocacy organizations and professional medical associations that represent or work on behalf of millions of patients and consumers across the country, including those who lack access to adequate health care and those who face serious, acute, and chronic diseases and health conditions. are committed to ensuring that everyone benefits from a high quality health care system and has access to comprehensive, affordable health insurance to prevent disease, manage health, cure illness, and ensure financial stability.

Publicly funded health insurance programs such as Medicare, Medicaid, and the Children's Health Insurance Program ("CHIP") play a critical role in providing that access. These programs, in turn, depend heavily on the transparency, accountability, and stability that result from the fact

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[1] Pursuant to Supreme Court Rule 37.6, state that no counsel for any party authored this brief in whole or in part and no entity or person, aside from , their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

expertise, in turn, has facilitated the construction of the regulatory foundation on which the multi-trillion-dollar American health care system depends.

are uniquely positioned to assess – and to assist the Court in understanding – the tremendous disruption that overruling would cause to publicly funded health insurance programs specifically, to the stability of this country's health care system generally, and to the health and well-being of the patients and consumers we serve. respectfully urge the Court not to go down that path. Irrespective of the Court's ultimate view on the validity of the challenged rule requiring an industry-funded at-sea monitoring program for the Atlantic herring fishery, the Court should decline Petitioners' request to use that narrow issue as a vehicle for jettisoning in its entirety, with all the far-reaching consequences such a ruling would have.

impracticable and ill-advised. Just with respect to publicly funded health insurance alone, such an outcome would require the impossible from Congress – that it draft (and continuously update) the Medicare and Medicaid statutes with the speed, technical granularity, and prescience needed to anticipate and plug

disabilities. Gabrielle Clerveau et al.,

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national and local levels, and prevent fraud and waste. And that is not all: they must incorporate the often-conflicting needs of insureds, care providers, pharmaceutical and medical device companies, and all the other stakeholders who, from time to time, may comment, complain, or sue.

The Secretary and CMS take seriously their

Medicaid, and CHIP in ways large and small.[8] This tally does not include additional language in appropriations and other bills that directed the Secretary and CMS, without amending the U.S. Code, to take certain actions or use appropriated funds in certain ways.[9]

Congress also has embedded in the statutory schemes a variety of purpose-built mechanisms to ensure the Secretary's and CMS's ongoing accountability to Congress. For example, the President's choice of CMS Administrator is subject to the advice and consent of the Senate, 42 U.S.C. § 1317(a), as is, obviously, the President's choice of Secretary. If the Secretary appoints advisory groups, the Secretary must report to Congress annually on the

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[8] SUPPORT for Patients and Communities Act, H.R. 6, 115th Cong. (2018) (enacting measures to address opioid abuse); H.R. 6042, 115th Cong. (2018) (extending timeline for implementing "electronic visit verification" requirements); Patient Right to Know Drug Prices Act, S. 2554, 115th Cong. (2018) (concerning , generic and biosimilar medications); H.R.J. Res. 123, 115th Cong. § 201 (2017) (addressing CHIP funding shortfalls); Know the Lowest Price Act, S. 2553, 115th Cong. (2018) (concerning disclosure of drug prices to Medicare Part D beneficiaries); H.R. 3823, 115th Cong. § 302 (2018) (extending Medicare demonstration project involving intravenous immunoglobin); Bipartisan Budget Act of 2018, H.R. 1892, 115th Cong. (2018) (making numerous changes); Consolidated Appropriations Act, H.R. 1625, 115th Cong. § 1301 (2018) (revising pass-through payment rules for certain drugs and biologicals); H.R. 1370, 115th Cong. § 3201 (2017) (extending and tweaking CHIP funding); H.R. 195, 115th Cong. §§ 3005-06 (2018) (concerning Medicaid and CHIP funding).

[9] , Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, H.R. 6157, 115th Cong. (2018).

groups' membership and activities. § 1314(f). Congress requires the Inspector General of Health and Human Services ("HHS") to report to Congress annually on efforts to combat waste and abuse. § 1320a-7g(2). Congress also has created other accountability mechanisms, such as a requirement that the government provide public notice and a 60-day comment period for any "rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits . . . ." § 1395hh(a)(2), (b)(1). Congress also enacted a requirement that any rule or regulation that "may have a significant impact on the operations of a substantial number of small rural hospitals" undergo a separate regulatory impact analysis. § 1302(b).

The result of all this is a dense web of statutory and regulatory frameworks – encompassing dozens of program areas – that is unavoidably complex. This Court and many others have openly acknowledged this complexity. ,
, 568 U.S. 627, 648 (2013) (tallying the number of "federal-court opinions . . . [that] have reiterated Judge Friendly's observation that Medicaid law is 'almost unintelligible to the uninitiated'") (Roberts, C.J., dissenting);
, 529 U.S. 1, 13 (2000) (describing Medicare as "a massive, complex health and safety program . . . embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations");

Medicare and Medicaid "fraction" provisions as "downright byzantine"). The complexities necessitate, in turn, that the Secretary and CMS be afforded interpretive and programmatic flexibility in implementing the statutes. "Perhaps appreciating the complexity of what it had wrought, Congress conferred on the Secretary exceptionally broad authority to prescribe standards for applying certain sections of the [Social Security] Act." , 568 U.S. at 648 (Roberts, C.J., dissenting) (quoting , 453 U.S. 34, 43 (1981)); , 534 U.S. 473, 496 n.13 (2002) ("We have long noted Congress' delegation of extremely broad regulatory authority to the Secretary in the Medicaid area . . . ."); , 508 U.S. 402, 418 & n.13 (1993) (noting broad delegation of authority to the Secretary in connection with challenge to Medicare regulation governing estimation of health providers' reasonable costs).

The capable and consistent administration of the country's publicly funded health insurance programs greatly depends on the subject matter expertise that the Secretary and CMS deploy in exercising this authority. 42 U.S.C. § 1395b-9(b)(1)-(2) (requiring CMS management staff to have superior expertise in technical or operational areas such as health care contracting, actuarial sciences, compliance, or consumer education). Pursuant to , courts have afforded deference to that expertise and to the policy determinations that the agency makes as it implements Congress's statutory framework in the face of unforeseen and unforeseeable real-world circumstances.

Petitioners challenge this deference by asking the Court to reach far beyond the narrow fisheries rule at issue in this case and jettison the doctrine completely. will not duplicate the work of others in responding to Petitioners' doctrinal arguments. Instead, focus on how has worked in the real world. Specifically, and consistent with 's public health missions, discuss courts' historical application of the doctrine to regulatory disputes involving the Medicare and Medicaid programs.

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In asking this Court to overturn , Petitioners use extreme terms to describe both the doctrine and the way in which courts purportedly have applied it. Petitioners' doctrinal assertions do not accord with the framework that and its progeny establish. Brief of Professor Thomas W. Merrill as in Support of Neither Party at 8-20, , No. 22-451 (July 21, 2023). Petitioners' portrayal also is at odds with the way in which courts have applied the doctrine to actual litigated disputes.

To illustrate the latter point, the remainder of this brief discusses four circuit court decisions that addressed challenges to agency rulemaking under the Medicare and Medicaid statutes. Contrary to Petitioners' contentions, the opinions issued by each of these four different circuits demonstrate that the doctrine, when applied consistent with 's

framework, is: (a) in accord with the requirements of

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All four circuit courts conducted a straightforward analysis and did so consistent with the framework established by this Court in and its progeny.

First, each court employed traditional tools of statutory construction to assess whether the statutory language underpinning the agency rule at issue was ambiguous or open-ended and concluded that it was. , 443 F.3d at 175 (observing that "the statute leaves considerable ambiguity as to the term 'geographic area'"); , 956 F.3d at 693-95 (finding ambiguity in the term "costs incurred" and rejecting hospitals' contention that the statute was unambiguous); , 572 F.3d at 917-23 (discussing a myriad of different ways to define

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the meaning of "geographic area");
, 572 F.3d at 921 ("Congress, through its silence" in "not specify[ing] how the Secretary should construct the [Factor], nor how often she must revise it . . . delegated these decisions to the Secretary") (quoting in parenthetical
, 38 F.3d

statutory terms, including "wages" and "wage-related"); , 933 F.3d. at 773-74 (describing agency's articulated policy reasons for its new rule defining "costs incurred"). Notably, where the agency's reasoning was inadequate or incomplete, no deference was afforded to the agency's determination. , 572 F.3d at 919-20 (concluding that Secretary had failed adequately to explain its decision to include postage costs in calculating the "Proportion").

In addition to the comprehensiveness of the courts' analyses and the fidelity of those analyses to 's framework, none of the decisions support any of the concerns advanced by Petitioners as supposedly warranting the overturn of .

First, nothing about the statutory provisions or rules at issue – or the way

noting the frequency with which Congress has "tinkered with the statutory scheme in question"); , 572 F.3d at 916, 922 (discussing two sets of statutory amendments made by Congress to the provisions at issue).

The courts likewise did not reflexively and unthinkingly defer to the agency's actions,

defining hospitals'

context of a complex and highly technical regulatory program.") (quotation marks omitted).

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Even if the post- world envisioned by Petitioners were feasible – which it is not – the circuit court opinions profiled in this brief comprise but a sliver of the many appellate and district court decisions that have upheld agency rules pursuant to 's analytical framework. For every one of those disputed rules that remains in place, overturning would open the door for the losing parties to relitigate the issue. Indeed, given the amount of money often at stake in challenges to Medicare and Medicaid rules, a post- litigation tsunami would seem all but guaranteed. , 443 F.3d at 167 (involving claim by 76 plaintiff hospitals that they would receive $812 million less in reimbursements over the next 10 years as a result of challenged rule); , 572 F.3d at 914 (involving claim by 113 plaintiff hospitals

Petitioners have put forth no basis – legal or otherwise – to support such a disruptive result. Contrary to Petitioners' stark depiction of the alleged perils and pitfalls of , the reality – as exemplified by the circuit court decisions profiled in this brief – is quite different. Properly applied, the doctrine is, in fact: (a) faithful to the Constitution and the Administrative Procedure Act; (b) workable; and (c) promotes uniformity and stability in the interpretation and implementation of often complex statutory schemes. As a result, whatever the Court's ultimate conclusion regarding the fisheries rule at issue in this case, the Court need not and should not use Petitioners' appeal on that narrow issue to overturn in its entirety.

For the foregoing reasons, respectfully request that the Court decline Petitioners' invitation to overturn .

Respectfully submitted,

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