No. 14-181

In The
Supreme Court of the United States

◆

ALFRED GOBEILLE, in His Official Capacity as
Chair of the Vermont Green Mountain Care Board,

Petitioner,

v.

LIBERTY MUTUAL INSURANCE COMPANY,

Respondent.

◆

On Writ Of Certiorari To The
United States Court Of Appeals
For The Second Circuit

◆

BRIEF OF *AMICI CURIAE* HARVARD LAW SCHOOL CENTER FOR HEALTH LAW AND POLICY INNOVATION, ET AL. IN SUPPORT OF PETITIONER

◆

CARMEL SHACHAR
Counsel of Record
ROBERT GREENWALD
HARVARD LAW SCHOOL
CENTER FOR HEALTH LAW
AND POLICY INNOVATION
122 Boylston St.
Jamaica Plain, MA 02130
(617) 390-2588
cshachar@law.harvard.edu

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF AUTHORITIES

REGULATIONS

INTEREST OF *AMICI CURIAE*[1]

Amici are the Harvard Law School Center for Health Law and Policy Innovation; Robert Greenwald, JD, Clinical Professor of Law and Director of the Harvard Law School Center for Health Law and Policy Innovation; Ameet Sarpatwari, JD, PhD, Instructor in Medicine at Harvard Medical School and Associate Epidemiologist at the Brigham and Women's Hospital; Aaron S. Kesselheim, MD, JD, MPH, Associate Professor of Medicine at Harvard Medical School and Director of the Program on Regulation, Therapeutics, And Law in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital; Gregory Curfman, MD, Editor in Chief of Harvard Health Publications at Harvard Medical School; Elliott S. Fisher, MD, MPH, Director of the Dartmouth Institute and the John E. Wennberg Distinguished Professor at Dartmouth College; David C. Goodman, MD, MS, Co-Principal Investigator at the Dartmouth Atlas of Health Care and Professor of Pediatrics and Community and Family Medicine at Dartmouth College; Mark C. Hall, JD, Professor of Law and Public Health at Wake Forest University;

---

[1] *Amici* submit this brief pursuant to Supreme Court Rule 37.4. Both parties have consented to the filing of *amicus curiae* briefs in support of either party. Pursuant to Supreme Court Rule 37.6, *Amici* state that no counsel for a party authored this brief in whole or in part and that no person or entity other than *Amici*, its members, and its counsel contributed monetarily to the preparation or submission of this brief.

Timothy Stoltzfus Jost, JD, Emeritus Professor at Washington and Lee School of Law; Charles D. MacLean, MDCM, FACP, Professor of Medicine at University of Vermont College of Medicine and Director of the Office of Primary Care & AHEC Program; Kevin Outterson, JD, Professor of Law and N. Neal Pike Scholar in Health and Disability Law at Boston University; Sara Rosenbaum, JD, Harold and Jane Hirsh Professor at the Milken Institute School of Public Health at the George Washington University; Indra Neil Sarkar, PhD, MLIS, FACMI, Assistant Professor of Health Services, Policy and Practice and Director of the Center for Biomedical Informatics and Professor at the Warren Alpert Medical School of Brown University; Russell P. Tracy, PhD and FAHA, Professor of Pathology and Laboratory Medicine and Biochemistry at University of Vermont College of Medicine and Director of the Laboratory for Clinical Biochemistry Research; Richard C. Wasserman, MD, MPH, Professor of Pediatrics at University of Vermont College of Medicine and Director of the Pediatric Research in Office Settings Program at the American Academy of Pediatrics; John Wennberg, MD, MPH, Founding Editor of the Dartmouth Atlas of Health Care and Active Emeritus Professor of Community and Family Medicine and the Dartmouth Institute at Dartmouth College; and Ira Wilson, MD, MSc, FACP, Professor and Chair of the Department of Health Services, Policy and Practice at Brown

University School of Public Health.[2] With the exception of CHLPI, which is an academic center devoted to advocating for legal, regulatory, and policy reforms to improve the health of underserved populations, all *amici* hold academic positions within major American universities, study trends within the American health care system, and require reliable health care data to further their research. All *amici* have an in depth understanding of the unique value that State-run all-payer claims databases (APCDs)[3] present for the field of health services research.

Amici write to (1) explain the differences between the information the Employee Retirement Income Security Act of 1974 (ERISA) requires payers to report and the information contained in APCDs; (2) demonstrate the unique importance of state-run all-payer claims databases (APCDs) in furthering health services research and influencing health care policy; and (3) offer this Court a unique insight into the undermining effect that Respondent's proposed interpretation of the ACA would have on the national ability to study health services, which include both clinical care

---

[2] Institutional affiliations are provided for identification purposes only. This brief does not purport to present the institutional views, if any, of the named universities.

[3] APCDs are large-scale databases that systematically collect medical claims, pharmacy claims, dental claims, and eligibility and provider files from public and private payers. Thus, in the United States APCDs include data from Medicare, Medicaid, and private insurers. Countries with single payer systems have APCDs that draw solely upon the data of their national system.

as well as macro health care trends such as health care costs, and to inform health care policy.

◆

SUMMARY OF ARGUMENT

The central issue in this case is whether ERISA, 29 U.S.C. § 1001 *et seq.*, preempts state laws requiring all in-state health care payers, including self-funded insurance plans, to report claims and health care services data to the State in order to create an APCD. Specifically, the question at hand is whether ERISA preempts a Vermont statute establishing a unified health care database and requiring health insurers to report health insurance claims, enrollment information, and other information relating to health care costs, prices, quality, utilization or resources to the database. VT. STAT. ANN. TIT. 18 § 9410(a)-(d).

A divided panel of the Second Circuit held that ERISA preempts the Vermont statute and accompanying regulations requiring self-funded insurance plans to report their health care claims data to the Vermont APCD. The Second Circuit's decision was incorrect because it relies on an overly broad and outdated view of ERISA preemption and confuses the financial reporting requirements of ERISA with the type of information that health care payers are required to report to APCDs.

ERISA was not intended to shield self-funded insurance plans from all state regulation. Rather, ERISA was intended to protect the interests of beneficiaries of employee benefit plans by standardizing certain financial disclosure and reporting requirements, as well as establishing standards of conduct, responsibility and obligation for fiduciaries of these plans. By contrast, APCDs do not concern themselves with the financial soundness of employee benefit plans. Rather, they collect health care claims data intended to evaluate and improve the quality and cost of health care provided in the State. Because ERISA preempts state laws *only* "insofar as they . . . relate to any employee benefit plan," 29 U.S.C. § 1144(a), and because the APCD reporting requirements do not overlap with or undermine compliance with ERISA's financial reporting requirements, the reporting requirements of the Vermont statute should not be preempted by ERISA.

Drawing upon available data from the APCDs is crucial for improving clinical care, addressing health care cost issues, and informing health care policy. Health care claims are one of the primary sources of data for health services research in the United States. Furthermore, State APCDs are the closest resource researchers studying the American system can obtain compared to the national databases and registries available in single payer countries. Relying solely on data from government payer programs, such as Medicare and Medicaid, or from individual insurance companies, can lead to conclusions that are not applicable to all patient populations. APCDs provide researchers the ability to study disease burden, disease management, health care costs, and treatment effectiveness across the full range of patients within a State. Additionally, APCDs provide community-wide data that allow researchers to improve on the public health status of the community studied, by monitoring concerns such as achieving herd immunity through vaccination or generating policy suggestions to improve population health. APCDs have also been essential to the development and implementation of health policies and to tracking the impact of policy changes on both health and health care. The singular ability of State APCDs to monitor the performance of health care delivery systems within each State underscores that the APCDs' reporting requirements do not relate to ERISA reporting requirements.

Allowing self-funded insurance plans to use ERISA as a shield against reporting their health care claims data would undermine the ability of health care and services researchers to improve the quality of care and to address health care costs and other trends. The universal dataset available from APCDs is important because, although some insurers may be willing to share their data with researchers, health care claims data in fragmented form are less useful than a comprehensive data set and the likelihood of all insurers cooperating to share data without regulation is low. Even if the majority of insurers cooperate to form a health care claims database, it will not deliver comprehensive data to researchers, limiting the usefulness of a private health care claims database. Because of the lack of overlap between the reporting regimes as well as the important scientific value of the information available through the APCDs, this Court should reverse the judgment of the Second Circuit Court of Appeals.

◆

ARGUMENT

I. The Judgment Below Applies ERISA Preemption in an Overly Broad Manner that is Incompatible with Recent Case Law.

The reporting regimes required by ERISA and by the Vermont statute establishing its APCD have virtually no overlap in their focus and in the type of information they require. Furthermore, because all insurance plans will have this information already aggregated in their own databases, the Vermont statute will not substantially impact how benefits are administered to beneficiaries or mandate certain benefit structures. Therefore, under the standard articulated by this Court in prior cases such as *California Div. of Labor Standards Enforcement v. Dillingham Constr., N.A.*, the Vermont statute and its accompanying regulations should not be preempted by ERISA. 519 U.S. 316 (1997).

A. ERISA's Preemption Clause was Intended Only to Prevent Impact to the Administration of Benefits of Employee Benefit Plans.

ERISA regulates employee benefit plans, including self-funded health care insurance plans. In creating ERISA, Congress intended to establish the regulation of such plans, which included self-funded health insurance plans, "as exclusively a federal concern." *Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504, 523 (1981). As this Court previously concluded, "the goal [of ERISA's preemption clause] was to minimize the administrative and financial burden of complying with conflicted directives among States or between States and the Federal Government . . . , [and to prevent] the potential for conflict in substantive law." *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 656-57 (1995). To prevent such conflicts, Congress included a preemption provision in ERISA, which this Court interpreted to mean that a State law is preempted if "it has a connection with or reference to such a[n employee benefit] plan." *Shaw v. Delta Airlines, Inc.*, 463 U.S. 85, 97 (1983).

Nevertheless, this Court has repeatedly cautioned that even in cases "where federal law is said to bar state action in fields of traditional state regulation . . . [the Court has] worked on the 'assumption that the historic policy powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'"

Travelers, 514 U.S. at 655 (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 229 (1947)). Therefore, this Court limited ERISA preemption to only "state statutes that mandate[ ] employee benefit structures or their administration." *Dillingham Constr.*, 519 U.S. at 328 (quoting *Travelers*, 514 U.S. at 658). Because of the limitations upon the preemption provision, ERISA preserves a role for state regulations that do not overlap with or burden compliance with ERISA's requirements or core purposes.

B. ERISA's Core Reporting Requirements Relate Only to Financial Reporting.

The Second Circuit panel noted that reporting was a "core ERISA function[ ] subject to a uniform federal standard." *Liberty Mut. Ins. Co. v. Donegan*, 746 F.3d 497, 505 (2d Cir. 2014). However, the ERISA reporting requirements cover mostly financial information, such as a statement of assets and liabilities, changes in fund balances, disclosures about changes made in the plans, actuarial statements, and certain financial commitments, including loans, leases, and transactions. *See* 29 U.S.C. § 1023. The information reported is used to generate a summary plan description for plan participants and a financial annual report to the Secretary of Labor. *See* 29 U.S.C. § 1021-30.

By contrast, the Vermont statute requiring insurers to report information to the State's APCD asks for very different data. It seeks information on medical claims data, health services provided to beneficiaries, charges and payments for medical services, and the demographic information of the beneficiaries. Vt. Stat. Ann. tit. 18 § 9410(c)-(d) (Supp. 2014); Reg. H-2008-01, 21-040-021 Vt. Code R. (2008). The Vermont statute is designed to obtain valuable health care claims data, not to investigate the financial soundness of the State's health care plans. As discussed below, claims data, aggregated across all payers, are uniquely valuable in the information they provide on the state of the American health care system. The value of the data further underscores the difference between the reporting requirements found in ERISA and the reporting requirements mandated by the Vermont statute. Fundamentally, the Vermont statute does not actually impact ERISA's core reporting function because it focuses on entirely different data.

Additionally, the Vermont statute asks only for information typically generated in health care encounters and routinely aggregated by health care plans, including self-funded insurance plans in their own administrative databases. *See* Denise Love, William Custer, and Patrick Miller, *All-Payer Claims Databases: State Initiatives to Improve Health Care Transparency*, Commonwealth Fund pub. 1439, Vol. 99 (Sept. 2010). Under the standard articulated in *Dillingham Constr.*, statutes that do not directly relate to an ERISA core function, such as reporting, may still be preempted if the State statute in question impacts how benefits are administered to beneficiaries or mandates certain benefit structures. 519 U.S. at 319. Because Liberty Mutual in this case and other self-funded insurance plans in general already aggregate this information, the Vermont statute is not onerous enough to dictate benefit structures. Additionally, the reporting requirements are broad enough to encompass a variety of benefit structures, such as traditional fee for service payment and newer forms such as capitated payments. For example, this Court found that ERISA preempted a New York law requiring employers to provide the same benefits for pregnancy-related disabilities as for other disabilities, *Shaw*, 463 U.S. at 85, as well as a state law that revoked, upon divorce, a former spouse's status as a beneficiary, *Egelhoff v. Egelhoff*, 532 U.S. 141 (2001). In both cases, this Court concluded that the regulations required plans to deliver a different package of benefits in the State in question, than in neighboring States. By contrast, in this case, the reporting requirements do not mandate that self-funded insurance plans provide certain benefits, such as providing mental health benefits or benefits to domestic partners. Instead, the reporting requirements only require that the self-funded insurance plans report the health care claims data deriving from the benefits they do offer.

II. APCDs Provide Vital and Unique Data for Health Services Research and Policy Decision Making.

APCDs are an important tool that researchers, including those based at academic medical centers and universities, use to understand cost, utilization, and quality of health care as well as to generate recommendations regarding health care policy. APCDs function as a useful source of comprehensive claims data for health services research in the United States. Health services research encompasses a broad range of important issues dedicated to improving the American health care system, including cost trends relating to price transparency, hospital, provider, and patient out-of-pocket costs, location and performance of intra-state health care markets, as well as clinical care issues including health status, disease management, pregnancy management, medication safety, hospital quality, and hospital-associated infections. Access to a comprehensive database that includes all claims in an area – not just those from public payer systems or from one or two insurers – permits rigorous efforts designed to rectify or address issues in our health care system for the benefit of patients and the improvement of the broader system.

A. APCDs are Necessary for Supporting Certain Health Services Research and Policy Decision Making.

APCDs are critical for improving the quality of health care interventions in this country, refining health care policy on the local, state, and federal level, and for understanding cost, utilization, and quality of health care. APCDs allow researchers to study a variety of health care issues, including clinical care as well as trends impacting and informing health care policy. APCDs also provide information in context to researchers, allowing them to observe important phenomena, such as practice variation among regions, through more traditional experiments.

1. APCDs Support a Variety of Important Research

APCDs are an important data source that has been used in a broad variety of health services research that has directly impacted patient care and the provision of health care services. For example, azithromycin, an antibiotic, has historically been considered free of serious adverse effects and safe to use for the treatment of upper and lower respiratory infections and some sexually transmitted infections. In 2012, an American team studying Medicaid data from Tennessee reported that patients using azithromycin had a risk of death from cardiovascular causes that was two to three times higher than the risk of individuals taking amoxicillin – another common antibiotic – or not using antibiotics. Wayne A. Ray et al., *Azithromycin and the Risk of Cardiovascular Death*, New England Journal of Medicine 366 (May 17, 2012). This study could have a serious impact on the standard course of care for common infections and was intended to help physicians and patients weigh the risks and benefits of using this antibiotic over other comparable medications. In response to this study, a team from Denmark used their country's national registries[4] to analyze the risk of cardiovascular death in individuals with no antibiotic use, with azithromycin use, and with penicillin use. *See* Henrik Svanstrom et al., *Use of Azithromycin and Death from Cardiovascular Causes*, New England Journal of Medicine 368 (May 2, 2013). They found no such risk. Access to a comprehensive dataset, akin to the APCD data, was helpful; as the researchers noted, "[g]iven the large, nationally representative study population, the results are likely to be widely generalizable to young and middle-aged adult populations" who are common users of these antibiotics. *Id.* The Danish researchers distinguished their results from the Tennessee study by noting that the risks associated with this common antibiotic may be limited to high-risk populations, *id.*, which would reflect the poorer health of the Medicaid population as compared to the general population. *See infra* pp. 20-21.

Research based on APCD data has also identified important discrepancies in American health services. In a 2014 study, researchers from Dartmouth College used the APCDs available in New England, including the Vermont APCD, to find that Medicaid insured children receive psychotropic prescriptions, including anti-depressants and anti-psychotics, at higher rates than commercially insured children. Shelsey J.

---

[4] The Danish registries are not strictly an APCD in that Denmark has only one payer – the Danish Government – but function as one in that they collect all health care claims for the Danish population.

Weinstein, *Small Geographic Area Variations in Prescription Drug Use*, 132 Pediatrics 3 (Sept. 2014). Overall, prescription use among Medicaid-enrolled children was sixty-two percent higher than use among the commercially insured. *Id.* Additionally, there was significant variation in the rates of these prescriptions between regional health service areas. *Id.* The findings of this study are important in considering the quality of health care received by Medicaid insured children, which may prompt changes in Medicaid coverage and health care delivery policies. As the authors of this study note, "[t]hese findings should prompt discussion about the definitions and determinants of pediatric prescribing quality." *Id.* Without access to the New England APCDs, however, the research team would have found it very difficult to gather enough consistent claims data from the commercial insurance market to make valid comparisons between Medicaid insured children and commercially insured children. Similarly, it would have been difficult for them to gather enough data to make comparisons between health service areas.

APCDs can also be used to actively monitor and improve health services. A research team based in Boston used data from Maine's APCD to develop drug claims models to predict prescription opioid abuse. Alan G. White et al., *Analytic Models to Identify Patients at Risk for Prescription Opioid Abuse*, 15 The American Journal of Managed Care 12 (Dec. 2009). The team concluded that men age eighteen to thirty-four who either filled opioid prescriptions at multiple pharmacies or refilled their opioid prescriptions early were significantly more likely to develop prescription opioid abuse issues. *Id.* The researchers explicitly noted the value of comprehensive claims data to this work, arguing that the "study demonstrates the feasibility of developing models derived from claims data variables to identify specific characteristics associated with elevated risk for prescription opioid abuse." *Id.* at 900-01. White et al. then noted that once researchers further developed these models using claims data, prescription drug monitoring programs could use these models to screen patients receiving opioid prescriptions or notify providers if patients met certain key risk factors, such as pharmacy shopping and early refills. *Id.* at 901. In fact, several state prescription drug monitoring programs have indicated an interest in using claims data as a clinical tool to help combat the opioid abuse epidemic. *Id.* Using claims data from individual insurers, or from Medicaid and Medicare only, would not have been as comprehensive and would have therefore limited the usefulness of the model they would have been able to develop.

2. APCDs Support Policy Analyses and Studies that Address Issues that Other Study Designs Cannot Address

Many laypeople conceive of medical research as the classic interventional experiments in which investigators apply a treatment to patients and perhaps contrast this group's outcome with a control group.

However, there is a significant body of health services knowledge that is best obtained from observational, population-based studies that reflect a full data set. This is particularly the case when a data system is designed to support planning and regulatory decision making affecting the performance of local and regional health care markets within the States.

The value of APCDs for this purpose was illustrated in the early 1970s by a team of researchers from the University of Vermont and other academic institutions. Using an early version of Vermont's APCD, the analysis uncovered heretofore unrecognized extensive variation among local hospital service areas in use of medical care. This included per capita medical spending, resource allocation (*e.g.*, physicians, hospital and nursing home beds), and utilization rates for elective surgery, medical hospitalizations, and physician visits. However, little or no variation was found in illness, economic status or outcomes of care. Moreover, the variation in spending and hospital bed supply could be traced in part to errors in regulatory decision making that could have been avoided if APCD data had been used. John Wennberg et al., *Small Area Analysis and the Challenge of Practice Variation*, 5 (Aug. 2015).

Starting in the 1990s, this group began the Dartmouth Atlas Project, which extended the practice variation analysis to the entire United States Medicare population. *The Dartmouth Atlas of Health Care*, available at http://www.dartmouthatlas.org/. Using the Dartmouth Atlas Project, researchers have been able to identify when practice variation reflects a failure to deliver appropriate care, a divergence between physician opinion and the desires of informed patients, and an overuse of unwarranted services. Wennberg at 5-6. However, before the advent of APCDs the range of possible analyses this team could undertake was limited, restricted to single-payer or to exclusively hospital-based care using hospital registries.

The Dartmouth Atlas Project illustrates that unwarranted variation is a ubiquitous phenomenon, affecting all States. Uncovering this variation depends on population-based data. It is impossible to identify practice variation trends using experimental data or by using non-comprehensive claims data. Regional health care decision making cannot be studied in a laboratory because of the many "real world" pressures and factors that affect and influence these decisions. APCDs are thus essential for uncovering unwarranted practice variation and helping the States achieve a central objective of health care public policy by improving the effectiveness of health care and the efficiency of use of scarce and expensive hospital resources. *Id.* at 25.

B. Relying on Claims from Individual Insurers Results in Suboptimal Research.

Data from a single type of payer may only represent a fragmented portion of the American health care system. For example, Medicaid represents a poorer, sicker population than the norm, Medicare represents an older population, and fully insured plans represent only a fraction of the commercially insured. Therefore, APCDs are one of the only data sources to provide researchers health care claims from the entire population in a State. The size of APCDs also provides datasets large enough to allow researchers to power certain important observational analyses that may not be available to more limited, payer-specific databases. Such observational analyses are one essential form of quantitative health services research.

1. Self-Funded Insurance Plans Serve a Different Population than Other Health Insurance Programs.

A database that included only claims from government payer programs, or even one that included claims from government payer programs and fully insured plans, would not be complete and therefore unable to approximate the health status of the American population as a whole. The population enrolled in self-funded insurance plans is a significant portion of health care users in this country and tends to be significantly younger and healthier than other populations.

As of 2014, fifteen percent of employees who obtained health insurance through their employers in small firms (3-199 workers) were enrolled in self-funded insurance plans. Gary Claxton et al., "Employer Health Benefits: 2014 Annual Survey," *Kaiser Family Foundation and Health Research & Education Trust*, 6 (Sept. 10, 2014), available at http://files.kff.org/attachment/2014-employer-health-benefits-survey-full-report. Eighty-one percent of employees at larger firms were enrolled in plans that were either partially or completely self-funded. *Id.* The larger the employer the more likely its employees are to be enrolled in a self-funded insurance plan. *Id.* at 174. Overall, sixty-one percent of employees who receive insurance through their employers are covered by a self-funded insurance plan. *Id.*

Removing a significant percentage of privately-insured individuals from health care databases significantly skews the remaining data to represent a sicker population. This is because, even controlling for income, Medicaid enrollees are much more likely to be significantly sicker and more disabled than their privately-insured counterparts. For example, among Medicaid enrollees at one hundred percent or less of the federal poverty level, thirty-eight percent were in fair or poor health, twenty-six percent reported physical or mental chronic conditions, and thirty-six percent were unable to work or could only pursue limited work due to their health. Kaiser Family Foundation, "Medicaid Enrollees are Sicker and More Disabled than the Privately-Insured" (Mar. 14, 2013), available at http://kff.org/medicaid/slide/medicaid-enrollees-are-sicker-and-more-disabled-than-the-privately-insured/. By contrast, among commercially insured individuals at one hundred percent or less of the federal poverty level, only twelve percent were in fair or poor health, thirteen percent reported physical or mental chronic conditions and only six percent were unable to work or could only pursue limited work due to their health. *Id.* Similarly, because Medicare mostly covers elderly patients, its population skews much older than the commercially insured.

Because of the difference in the underlying populations, conclusions generated from Medicare- or Medicaid-only databases may not be generalizable to the broader health care system. For example, the Dartmouth Atlas Project was able to discover a number of low cost yet high quality health care organizations to provide benchmarks for efficient use of supply-sensitive care. These benchmarks can be used to save thirty percent of Medicare spending in managing patients with chronic illnesses. Wennberg at 25. However, because the Dartmouth Atlas cannot draw upon national private insurance claims data – due to a lack of APCDs in every State – it is limited to Medicare data. Because the Dartmouth Atlas is limited to Medicare data, it is difficult to use this resource to generate national benchmarks for private insurance.

Additionally, APCDs allow researchers to perform similar benchmarking for the privately insured population in States with these databases. Health insurers and self-funded insurance plans have data on their enrollees but this data only shows a fraction of the health insurance market in their area. With just the information on their enrollees, insurers do not have a large enough sample size to perform certain necessary statistical analyses. Additionally, their enrollees may form a skewed population compared to the rest of the commercially insured population. This means any benchmarks developed based on fragmented data sets could be underpowered statistically and not reflect correct recommendations about best clinical care. In theory, insurers could cooperate to form joint databases but, in reality, competitors are unlikely to work together closely enough to create these types of databases. Indeed, researchers studying twelve health care communities across the United States concluded that "[w]hat is palpable . . . is the recognition that private market forces are limited in their ability to achieve social objectives in health care services. . . ." Len M. Nichols et al., *Are Market Forces Strong Enough to Deliver Efficient Health Care Systems?* 23 Health Affairs, 8-21, 21 (2004). Thus, State APCDs significantly facilitate researchers' ability to generate rigorous benchmarks for the commercially insured.

With sixty-one percent of the healthier commercially insured population potentially removed, APCDs will no longer provide an accurate portrait of the health of the general State population or of the enrollees of self-funded insurance plans. Researchers would be able to study health services as they relate to Medicaid and Medicare enrollees. However, they would be more limited in their ability to study the commercially insured because they would only receive fragmented datasets. This would impact their ability to generate benchmarks, clinical care recommendations, and cost trends analyses regarding this population.

Moreover, they would not be able to generate these recommendations regarding the general population. APCDs are large enough to provide an accurate portrait of the health status of a population. It is important to get a sense of the general population's health status for key public health interventions such as herd immunity resulting from vaccination campaigns, as well as the population health of the American public. Population health can be defined as "the health outcomes of a group of individuals, including the distribution of such outcomes within the group," and includes health outcomes, patterns of health determinants, and policies and interventions that link the two. David Kindig and Greg Stoddart*, What is Population Health?* 93 American Journal of Public Health 380-83, 380 (2003). Population health is a discipline that encourages providers to address upstream factors such as health promotion and care coordination in addition to direct clinical services and encourages stakeholders to improve health care delivery systems to improve health outcomes in their communities. The macro view of population health also dovetails and supports trends in health care spending to create global payment systems in both government and private payer fields, such as accountable care organizations and capitated payments. Michael A. Stoto, *Population Health in the Affordable Care Act Era*, Academy Health (Feb. 21, 2013). Population health lastly helps inform health policy across all levels.

Thus, without APCDs it would be difficult for researchers to gain a clear sense of the overall trends in the general population and to generate best care recommendations for the commercially insured. While insurers are capable of coordinating data across the system to create private APCDs, they are unlikely to do so. Thus, State-mandated APCDs represent the best method for researchers to gain access to critical information about the commercially insured system as well as about the general American population.

2. Only APCDs Are Large Enough to Support Certain Statistical Analyses.

APCDs are some of the few databases that are large enough to provide data in sufficient amounts to power certain and necessary statistical analysis to understand our complex health system. Claims data provides information that other studies are incapable of capturing. As a research team from Harvard recently noted, "[s]haring electronic medical records and other secondary health care data sets facilitates observational studies by enabling rapid capture of a greater number of persons with exposures and outcomes of interest as well as by supplying a broader spectrum of study variables than would otherwise be possible if these resources were not shared." Ameet Sarpatwari et al., *Ensuring Patient Privacy in Data Sharing for Postapproval Research*, 371 New England

Journal of Medicine 1644-49, 1644 (Oct. 23, 2014). Sharing health care data "improve[s] statistical power, permit[s] more rigorous adjustment for confounding, and enable[s] more detailed subgroup analyses to better understand treatment-effect heterogeneity." *Id.* Claims data allow researchers to study treatments once they are approved by regulatory bodies such as the Food and Drug Administration as well as to study health services phenomena that are not suited to intervention studies and randomized controlled trials.

Frequentist statistics[5] form the bedrock of quantitative health services research and offer guidance on what inferences can be made from sample data such as claims data. Specifically, health services researchers use frequentist statistics to evaluate whether the difference in an observed outcome between two samples can be said to reflect a non-random difference between the populations the samples represent. By convention, a 'p-value' of less than 0.05 is often required for researchers to conclude that the differences between the studied sample populations are statistically significant and hence worth reporting. A p-value is dependent upon the size of the samples, the

---

[5] Frequentist statisticians define probability as the long-run frequency of a certain measurement or observation. The more data collected, the closer a frequentist statistician can come to the "truth" of the matter. *See* Maarten H.P. Ambaum, *Frequentist vs Bayesian Statistics – a Non-Statistician's View*, Department of Meteorology, University of Reading (July 2012), available at http://www.met.reading.ac.uk/~sws97mha/Publications/Bayesvsfreq.pdf.

frequency of the outcome, and the magnitude of the difference in outcome between the samples; the larger the samples, the more frequent the outcome, and the greater the difference in outcome between the samples, the more likely a health services researcher can trust what was observed.

Statistical power refers to the ability, using frequentist statistics, to detect a non-random difference in outcome between populations from sample data with a specified level of certainty. To detect rare adverse events a very large sample is needed. For example, a Swedish team was able to identify a correlation between use of natalizumab, a monoclonal antibody used to treat Crohn's disease and multiple sclerosis, and progressive multifocal leukoencephalopathy (PML), a serious and usually fatal viral infection resulting in inflammation of the brain. Gary Bloomgren et al., *Risk of Natalizumab-Associated Progressive Multifocal Leukoencephalopathy*, 366 New England Journal of Medicine 1870-80 (May 2012). This study was important because natalizumab reduces the progression of disability in patients affected by multiple sclerosis by forty-two to fifty-four percent. *Id.* at 1871. Unfortunately, because of the risk of PML, this medication had been for a period of time voluntarily withdrawn by its manufacturer. *Id.* Because PML is a rare event, the Swedish team was only able to study this correlation by drawing upon comprehensive health care claims data from sources analogous to an APCD. Claims derived from a single payer in the United States would not have generated a sufficiently large sample of this rare occurrence.

To detect treatment effect heterogeneity, *i.e.*, how individuals respond to a particular treatment, intervention or stimulation, often a very large and diverse sample is needed. APCDs are well-suited for this statistical purpose because their population of patients are both large and diverse; they include insurance claims from Medicare (older, sicker patients), Medicaid (younger, poorer, and sicker patients), and private insurance plans. As discussed above, *supra* at pp. 20-22, it is very challenging to replicate the mix of claims data APCDs collect in a State through individual insurer databases, government payer only databases, or databases that exclude self-funded insurance plans.

III. Upholding the Judgment Below Would Undermine The Nation's Ability To Address Health Care Cost Trends and Improve Health Care Outcomes.

APCDs are a crucial source of data for researchers studying health services. These databases permit researchers to evaluate and refine standards of care for general populations, generate recommendations for the commercially insured population, understand cost spending trends in health care, and study rare occurrences.

The important value of these data to researchers only underscores the gulf between the financial data

ERISA requires employee benefit plans to report and the health care claims data APCDs gather. Because ERISA only governs financial reporting, it should not preempt the Vermont statute requiring insurers to report health care claims data to the Vermont APCD.

◆

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

CARMEL SHACHAR
Counsel of Record
ROBERT GREENWALD
HARVARD LAW SCHOOL
CENTER FOR HEALTH LAW
AND POLICY INNOVATION
122 Boylston St.
Jamaica Plain, MA 02130
(617) 390-2588
cshachar@law.harvard.edu

SEPTEMBER 2015