No. 10-779

In The Supreme Court of the United States

WILLIAM H. SORRELL et al.,

Petitioners,

v.

IMS HEALTH INC. et al.,

Respondents.

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

BRIEF OF COUNCIL OF AMERICAN SURVEY RESEARCH ORGANIZATIONS, INC. AS AMICUS CURIAE SUPPORTING THE BRIEF OF RESPONDENTS IMS HEALTH INC., VERISPAN, LLC AND SOURCE HEALTHCARE ANALYTICS, INC.

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INTERESTS OF AMICUS CURIAE[1]

Council of American Survey Research Organizations, Inc. ("CASRO")

CASRO is a not-for-profit trade association representing nearly three-hundred-fifty (350) United States survey research companies engaged in professional survey research regarding a wide variety of technical, scientific, pharmaceutical, health care, economic, and other public and private issues. The survey research companies' clients include virtually every manner of for-profit, not-for-profit and governmental entity. *See* Exhibit A. CASRO's members are in aggregate responsible for the overwhelming majority of the survey research, including pharmaceutical survey research, conducted each year in the United States. CASRO was formed for the purposes of creating certain values and standards for the survey research industry and establishing a spokesperson to represent the interests of the survey research industry. CASRO's principle functions are (1) to promote a rigorous code of conduct that enhances the image of survey

[1] Letters of consent have not been lodged with the Court because on January 21, 2011, Respondents lodged with the Court their "consent to the filing of amicus curiae briefs, in support of either party or of neither party," and on January 24, 2011, Petitioners lodged with the Court their "consent to the filing of amicus curiae briefs, in support of either party or of neither party." In accordance with Rule 37.6, the undersigned states that no monetary contributions were made for the preparation or submission of this brief, and this brief was not authored, in whole or in part, by counsel for a party.

research and protects the public's rights and privacy; (2) to advocate the survey research industry's effective self-regulation when legislators propose bills that threaten legitimate survey research; and (3) to champion legitimate research companies and marginalize disreputable research companies that threaten or attempt to threaten the survey research industry's reputation. *See* Exhibit A. A vast majority of CASRO's members work, whether directly or indirectly, with the pharmaceutical, medical and health care industries conducting legitimate survey research designed to improve treatment options and patient care and improve and develop pharmaceutical products and medical devices.

This case and its proper resolution are of great importance to CASRO, as upholding the Vermont Prescription Restraint Law (*see* Vt. Acts No. 80 (2007), codified at Vt. Stat. Ann. Title 18, § 4631 (2007), as amended by Vt. Acts No. 89 (2008) (referred to herein as the "Prescription Restraint Law")) would (1) threaten the legitimate business activities of Respondent IMS Health Inc., a CASRO member; (2) threaten legitimate pharmaceutical survey research by eliminating a valuable information and data resource; and (3) create the potential for restrictions on industries and businesses beyond pharmaceutical companies, pharmaceutical marketers and pharmaceutical detailers. Additional information about CASRO can be found at http://www.casro.org/.

The Survey Research Industry

The survey research industry, of which Amicus and its members are a part, is a well respected and important fixture of the commercial landscape that is essential to the development and improvement of health care in the United States and other countries. Survey research serves an important function throughout our society[2] and is utilized by universities (in the fields of medicine and social sciences, for example), corporations, research institutes, litigants, as well as governmental agencies, to assist in the analyses of technical, scientific, economic, health care, pharmaceutical, and other social, commercial, scientific and public policy issues. No other tool permits these societal constituencies to obtain comparable data and related information. Without such data many issues affecting both public and private interests could not be addressed as intelligently or resolved as reliably. There is, as one court rightly summarized the situation, "undoubtedly a compelling social interest in promoting [survey] research." *Andrews v. Eli Lilly & Co.*, 97 F.R.D. 494, 500 (N.D. Ill. 1983). *See also*, *Dow v.*

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[2] *See generally* M. Finkelstein, *Quantitative Methods in Law* (1978), quantitative techniques of proof as applied in various legal claims; H. Barksdale, *The Use of Survey Research Findings as Legal Evidence* (1957) (same); W. Finfrock & D. Spradlin, *How to Organize and Present Statistical Evidence*, 24 Prac. Law. 67, 67-68 (1978), antitrust evidence increasingly economic and statistical; I. McCarthy, *Trademarks and Unfair Competition*, Section 32:46 ff. (2d ed. 1984), important and growing role of survey evidence.

Allen, 672 F.2d 1262 (7th Cir. 1982). In *Cimino v. Raymark Industries, Inc.*, 751 F. Supp. 649 (E.D. Tex. 1990), the court articulated the value of survey data as a unique and important research tool:

> . . . the science of statistics is now universally accepted, exerting the most profound influence on our daily lives. 'The objective of statistics is to make an inference about a population of interest based on information obtained from a sample . . . of that population.' For example, statistical sampling plays a critical role in medical and pharmaceutical research . . . [a]s in medical research, private industries employ statistical techniques in the development and testing of new products . . . [it is used] for many diverse tasks, such as maintaining the dimension requirements for the plastic cards used in automatic bank teller machines or testing the specific gravity of laundry detergent. Statistical techniques are particularly valuable in the field of marketing . . . the insurance industry . . . education . . . in the administration and evaluation of various standardized tests . . . [and] in the political arena.

Id. at 660. The judicial process itself is a significant beneficiary of survey and public opinion research. In *Cimino*, it was reported that

> . . . [a]cceptance of statistical evidence is now commonplace in the courts . . . , it occurs frequently in Title VII employment discrimination cases, most often demonstrating a pattern or practice of discrimination on the

> part of the employer . . . , it has been used in anti-trust cases to project pre and post merger market share and market concentration. . . . [and] in trademark infringement suits [it] is useful in determining consumer product identification and confusion regarding trademarks. . . .

SUMMARY OF ARGUMENTS

Amicus' arguments are as follows: (1) the Prescription Restraint Law lays the foundation for the unfair and legally improper termination of Respondent IMS Health's subject lines of business – not only in Vermont, but throughout the United States, as two additional states currently have enacted laws restricting the use of prescriber-identifiable and patient-identifiable information, and numerous other state legislatures have proposed and are considering similar legislation during this current legislative calendar period, for the sole purpose of placing restrictions on the communications between pharmaceutical detailers and physicians; (2) the United States Court of Appeals for the Second Circuit correctly identified that the Prescription Restraint Law failed the intermediate scrutiny test elaborated by this Court in *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980), in that it did not directly advance Vermont's asserted interest and was much more extensive than was necessary to serve that interest; and (3) the Prescription Restraint Law's broad definition of "Marketing" and the limited exceptions to the

prohibitions contained therein, create the potential for restrictions on industries and businesses beyond pharmaceutical companies, pharmaceutical marketers and pharmaceutical detailers. Amicus, therefore, respectively requests that this Court affirm the judgment of the Second Circuit.

ARGUMENTS

I. The Prescription Restraint Law Effectively Terminates the Respondents' Subject Lines of Business For the Sole Purpose of Placing Restrictions on Communications Between Pharmaceutical Detailers and Physicians.

The Respondents are in the pharmaceutical market intelligence business, an area of pharmaceutical market research, and they provide certain products and services that address a variety of needs within the pharmaceutical, medical and healthcare industries. As noted above, Respondent IMS Health Inc. is a valued member of CASRO in good standing, and to CASRO's knowledge it upholds CASRO's standards of professional and ethical conduct. The products and services at issue in this case involve the Respondents' purchase of reliable, legitimate and truthful information (e.g. prescriber-identifiable information) from pharmacies and other sources; the deletion or removal of any data or information that may identify an individual patient; the aggregation of the prescriber-identifiable information with other information that is either available to the general public or obtained

through a license with a third party, but that in any event is likewise devoid of patient identities; and the creation of prescriber reference files. The prescriber reference files are then sold, licensed or transferred by the Respondents to individuals and/or entities, including, without limitation, pharmaceutical survey researchers, pharmaceutical companies, and certain not-for-profit entities or groups, including, without limitation, educational institutions, public interest groups, and law enforcement agencies. The purchasers of that data use the information to better understand individual, national and international prescribing behavior, so as to promote their respective for-profit or not-for-profit purposes.

While Amicus acknowledges that the Respondents (like all other businesses) should not and do not have an unlimited right to conduct their respective business activities, the Respondents' subject business activities now stand to be, but should not be, completely terminated as a result of, or radically restricted by, legislative efforts to limit the use of prescriber-identifiable information by one class of recipients or end-users of such information – the pharmaceutical manufacturers in the "detailing" and other direct marketing operations described below. The Respondents are a source of reliable, legitimate and truthful information that has many uses, as discussed herein, other than pharmaceutical detailing or direct marketing of pharmaceutical products performed by those end-users who are the target of the Prescription Restraint Law, and thus termination of the Respondents'

business lines is unfair, unnecessary, and draconian toward the Respondents.

This unfair and unnecessary legislative approach has been adopted by two other states (e.g. Maine and New Hampshire) that have enacted, and numerous other state legislatures are currently considering, legislation similar to the Prescription Restraint Law. The Respondents have legally challenged both the Maine and New Hampshire statutes; the Maine statute has been struck down and the New Hampshire statute has been upheld, and Respondents' petition for a writ of certiorari to this Court was denied without comment. This Court's ruling will determine whether New Hampshire, Maine and Vermont and the other state legislatures considering legislation similar to the Prescription Restraint Law (such as New York and Massachusetts) will be allowed to terminate the Respondents' subject business activities, not based on otherwise harmful, illegal, unethical or improper conduct on the part of the Respondents, but rather for a particular use of Respondents' products – pharmaceutical detailing and direct marketing to physicians – by certain of their clients; that result is and would be unfair, unnecessary and overbroad.

II. The Prescription Restraint Law Fails to Consider the Varied Uses of Prescriber-Identifiable Information and the Varied Businesses and Industries Using and Relying on Prescriber-Identifiable Information, thus Wrongly Depriving those Users of those Uses.

The Prescription Restraint Law, in the name of making pharmaceutical detailing less effective, does not actually regulate pharmaceutical detailing, but instead would terminate Respondents' and similar businesses' subject lines of business. As a result, as the Second Circuit noted:

> Because Section 17 is an attempt to influence the prescribing conduct of doctors by restricting the speech of others – namely data miners and pharmaceutical manufacturers – it does not directly advance the state's interests in protecting public health and reducing health care costs. Instead the statute restricts protected speech when uttered for purposes the government does not approve of in order to reduce the effectiveness of marketing campaigns and, ultimately, alter the behavior of prescribers, who are not regulated by the statute. This route is too indirect to survive intermediate scrutiny.

IMS Health Inc. v. Sorrell, 630 F.3d 263 (2d Cir. 2010). For the reasons discussed below, Respondents' data, while it certainly can be used to assist the marketing efforts of pharmaceutical detailers, has a number of non-marketing uses by pharmaceutical manufacturers

as well as many businesses and industries using and relying on such information. The curtailment of these uses helps to illustrate the dangers in regulating speech indirectly, and why the Second Circuit was correct in finding that the Prescription Restraint Law fails to meet the third prong of the test elaborated in *Central Hudson*.

One of the arguments advanced by Petitioner, which was accepted by the United States District Court for the District of Vermont in its analysis of the value of Respondents' products and services, is unduly narrow and incomplete. The District Court stated that "Pharmaceutical manufacturers are essentially the only paying customers of the data vendor industry." *IMS Health Inc. v. Sorrell*, 01:07 – CV 2009 WL 1098474 (D. Vt. Apr. 23, 2009) (Murtha, J.) at *11. Further, the District Court stated "Put simply, if PI data *(prescriber-identifiable data)* did not help sell new drugs, pharmaceutical companies would not buy it." *Sorrell*, 2009 WL 1098474 at *11.

The District Court's narrow focus on pharmaceutical detailing prevented the District Court from considering and valuing the varied uses and benefits of prescriber-identifiable information and the related products and services of the Respondents. The District Court, like the Vermont legislature, appeared to focus its analysis on the assumed unpopularity of a certain group of end-users of the prescription reference files (i.e. pharmaceutical detailers), and the uses of the prescription reference files by such end-users

(i.e. pharmaceutical detailing and direct marketing of prescription drugs).

Prescriber-identifiable information has substantial value to the general public and the pharmaceutical industry well beyond pharmaceutical detailing or direct marketing of prescription drugs. Prescriber-identifiable information and the related products and services of the Respondents are used by pharmaceutical and medical device manufacturers and others to evaluate, improve and develop pharmaceutical products and medical devices; to evaluate and identify trends and risks in the options for the treatment and care of the general public; to evaluate, improve and develop best practices for the pharmaceutical, medical and health care industries; to evaluate, improve and develop truthful communications regarding treatment options, trends, and best practice; and to address global health care issues.

For example, Amicus and its members and the pharmaceutical survey research industry of which Amicus and its members are a part, utilize and rely on the prescriber-identifiable information and the related products and services of the Respondents in conducting their research, including, without limitation, conducting surveys with identified physicians concerning various treatment and care options, best practices and trends; and concerning pharmaceutical products and medical devices utilized within a physician's practice. For example, in performing pharmaceutical survey research for a pharmaceutical or medical device manufacturer, the pharmaceutical survey

researchers will often contact physicians from a list of physicians that may be provided by the manufacturer of the drug or device. The physician list and contact information are usually obtained by the manufacturer from third party data providers including the Respondents. Pharmaceutical survey researchers do not perform any pharmaceutical detailing or direct advertising, marketing, or promotion of a manufacturer's products or devices. Indeed, the ethical codes of Amicus and other marketing research trade organizations expressly prohibit the researchers from (a) marketing, selling or promoting products and services to the physicians and other data subjects and (b) identifying the surveyed physicians and other data subjects to the researchers' manufacturer clients. Amicus' members in good standing are expected to zealously adhere to those prohibitions. Researchers seek solely the opinions, experiences and ideas of physicians related to the subject matter of the survey. As noted above, pharmaceutical survey research and pharmaceutical marketing research themselves – the businesses of Amicus' members – are benign, socially productive endeavors that heavily use the Respondents' data and similar data. Depriving these various users of such data would unnecessarily, unfairly and wrongly injure their businesses and deprive the public of their valued services.

In sum, the Vermont Legislature and the District Court failed to consider the varied uses of prescriber-identifiable information that have a direct, beneficial and significant impact on the pharmaceutical,

medical and health care industries and on the advancements and developments in healthcare, which benefits and impact will be severely restricted, if not completely lost, if this Court fails to affirm the ruling of the Second Circuit.

III. The Prescription Restraint Law's Broad Definition of "Marketing" and Limited Exceptions to the Prohibitions Contained Therein, Create the Potential for Restrictions on Industries and Businesses Beyond Pharmaceutical Companies, Pharmaceutical Marketers and Pharmaceutical Detailers.

The breadth and scope of the Prescription Restraint Law and the limited exceptions to the prohibitions contained therein have the potential effect of limiting the pharmaceutical survey research industry and other industries from using the prescriber-identifiable information and the related products and services of the Respondents for legitimate pharmaceutical survey research.

The Prescription Restraint Law prohibits the sale, licensure, exchange or use of regulated records or prescriber-identifiable information for marketing or promoting a prescription drug, unless the prescriber consents. Vt. Stat. Ann. Title 18, § 4631(d). The Prescription Restraint Law defines "marketing" to include "advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or

evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force." Vt. Stat. Ann. Title 18, § 4631(b)(5). The Prescription Restraint Law provides certain exceptions to the prohibitions contained therein, including without limitation an exception for "health care research." Vt. Stat. Ann. Title 18, § 4631(e)(1). While the Prescription Restraint Law does not define what activities constitute "health care research," it is likely that the Vermont Legislature intended for this exception to apply to clinical trials, whether bona fide or approved by the United States Food and Drug Administration or an Institutional Review Board.

The definition of "marketing," and the exception limited to "health care research," contained within the Prescription Restraint Law thus can be inferred to restrict or limit the pharmaceutical survey research industry's legitimate use of prescriber-identifiable information and the related products and services of the Respondents. As discussed above, Amicus and its membership and the pharmaceutical survey research industry of which Amicus and its membership are a part, utilize and rely on the prescriber-identifiable information and the related products and services of the Respondents in conducting their research, including, without limitation, conducting surveys with identified physicians concerning various treatment and care options, best practices and trends; and concerning pharmaceutical products and medical

devices utilized within a physician's practice. While Amicus and its members do not market or promote prescription drugs, the broad definition of "marketing" and the absence of any exception applicable to the pharmaceutical survey research industry, may be construed, by both the data providers and the Vermont Attorney General, as restricting or limiting the ability of Amicus and its members to use prescriber-identifiable information and the related products and services of the Respondents for conducting legitimate and valuable market research services. Consequently, Amicus agrees with the Second Circuit that Vermont cannot show that Prescription Restraint Law is narrowly tailored so as to meet the fourth prong of the test elaborated in *Central Hudson*.

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CONCLUSION

For the above stated reasons, Amicus Curiae respectfully requests that this Court affirm the judgment of the Second Circuit and invalidate the Prescription Restraint Law.

Respectfully submitted,

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EXHIBIT A

Founded in 1975, the Council of American Survey Research Organizations (CASRO) represents over 300 companies and market research operations in the United States and abroad.

CASRO is the "Voice and Values" of the survey research industry.

- We promote a rigorous code of conduct that enhances the image of survey research and protects the public's rights and privacy
- We advocate our industry's effective self-regulation when legislators propose bills that threaten legitimate survey research
- We champion legitimate research companies and marginalize disreputable research "pretenders" who threaten to tarnish the industry's reputation and alienate respondents

CASRO requires members to adhere to the CASRO Code of Standards and Ethics for Survey Research, a tough, internationally-cited set of standards, which has long been the benchmark for the industry.

CASRO provides its members with numerous benefits, including access to invaluable industry data, and superb staff training and networking opportunities at workshops and conferences throughout the country.

CASRO has achieved unique status among all North American associations by serving as an active representative on numerous global initiatives and as chief liaison with several leading international associations.

CASRO's "Research Career Development" initiative reaches out to colleges and universities with information and resources to attract the best and brightest students and to make the survey research profession a career of choice.

http://www.casro.org/whatis.cfm 3/30/2011