IN THE
UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF NEW HAMPSHIRE

CASE NO. 1:06-cv-00280-PB

IMS HEALTH INCORPORATED, a Delaware corporation; and VERISPAN, LLC, a Delaware liability company,

Plaintiffs,

vs.

KELLY A. AYOTTE, as Attorney General of the State of New Hampshire,

Defendant.

BRIEF OF *AMICI CURIAE* eHEALTH INITIATIVE, NATIONAL ALLIANCE FOR HEALTH INFORMATION TECHNOLOGY, AND SURESCRIPTS, LLC IN SUPPORT OF PLAINTIFFS

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I.
INTEREST OF *AMICI CURIAE* eHEALTH INITIATIVE, NATIONAL ALLIANCE FOR HEALTH INFORMATION TECHNOLOGY, AND SURESCRIPTS, LLC

Amici are organizations devoted to advancing the use of health information technology to help transform healthcare from today's inefficient, paper-based system to a better-connected electronic system that can reduce waste, curb medical errors, and help rein in runaway costs. Each organization believes that better communication and use of healthcare information can improve patient care and safety significantly. Amici have joined together to submit this brief because their missions – and the missions of their members and stakeholders – to improve the healthcare system are threatened by the misguided New Hampshire statute at issue in this case, and other similar legislation being considered elsewhere around the country – which may be adopted if the New Hampshire Prescription Restraint Law (N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12) law is allowed to stand.

At the heart of this case lies New Hampshire's unwarranted, severe restriction of communication about physician prescribing behavior, even when the information does not disclose patient identities.[1] *Amici* assert that the Prescription Restraint Law criminalizes information exchanges that improve healthcare nationwide, while doing absolutely nothing to accomplish the New Hampshire Legislature's stated objectives.

The Prescription Restraint Law applies – subject to narrowly limited and vaguely specified exceptions – to the license, transfer, use, or sale (*i.e.*, any exchange) of patient deidentified, prescriber identifiable prescribing information that could be used "to influence or

[1] In framing this lawsuit, plaintiffs IMS Health Incorporated and Verispan, LLC chose not to challenge the New Hampshire Prescription Restraint Law as it applies to patient-identifiable data. *See* Memorandum of Law in Support of Plaintiffs' Motion for Preliminary Injunction ("Plaintiffs' Memorandum") at 1. Therefore, this *amicus* brief focuses on information that does *not* disclose patient identity, but does disclose the identity of the prescribing practitioner, which we refer to herein as "patient-deidentified/prescriber-identifiable" information or data.

evaluate the prescribing behavior of an individual health care professional."[2] Ironically, the very purpose of the vast majority of health information technology/quality improvement projects being developed around the nation today seek to do the very things the New Hampshire Legislature has forbidden – to evaluate and influence positively the treatment decisions, including the prescribing decisions, of health professionals.

The reason for this is simple. Healthcare quality in the United States is highly variable and inconsistent, with more Americans dying each year from preventable medical errors than from AIDS or breast cancer. Institute of Medicine ("IOM"), *To Err is Human: Building a Safe Health System* (1999). That is why this case is so important. Criminalizing the use of patient deidentified/prescriber identifiable data – for any reason, but especially for reasons as vague and ill-defined as those behind the Prescription Restraint Law – will undermine efforts to make health information available and transparent. Simply put, in order to improve healthcare quality and efficiency, we need to know more – not less – about what physicians do and why they do it.

In enacting the Prescription Restraint Law, the New Hampshire Legislature apparently wanted to protect patient privacy. But, in addition to the fact that patient privacy already is protected by federal and state law, this stated purpose of the New Hampshire Prescription Restraint Law is wholly inconsistent with its actual scope and content. On its face, the Prescription Restraint Law applies not only to patient-identifiable information, but also to patient-deidentified/prescriber identifiable information; that is, information that indicates prescribers' identities but does ***not*** reveal who the patients are. Prescribers and other healthcare providers do not and should not have a "privacy" interest in patient-deidentified information

[2] N.H. Rev. Stat. Ann. §§ 318:47-f.

about their professional conduct that would shield it from all scrutiny by those who have appropriate roles to play in evaluating and influencing it for the better.

Significantly, when Congress enacted the federal patient privacy law (the Health Insurance Portability and Accountability Act of 1996, or "HIPAA," 42 U.S.C. § 1320d *et seq.*), Congress was careful to distinguish between "health information" and "individually identifiable health information," finding that only the latter was worthy of protection from disclosure. This distinction made by Congress is critical to improving the quality and efficiency of the U.S. healthcare system, in that it recognizes the right of the public, healthcare payers, and a broad range of other organizations to evaluate, critique, and disclose the actual performance of physicians and other healthcare providers, and to develop new programs and services based on that performance information. In this sphere, as in many others, the key to progress is found in Justice Brandeis's observation that sunlight is the best disinfectant.[3]

The New Hampshire Legislature also thought the Prescription Restraint Law could reduce healthcare costs by limiting doctors' exposure to the influence of pharmaceutical company sales representatives. While controlling healthcare costs is a laudable and necessary goal, any connection between the Prescription Restraint Law and the goal of cost containment is imaginary, and unsupported by any rational theory of logic or healthcare economics. The Prescription Restraint Law places no restrictions whatever on pharmaceutical manufacturers or their "detailers," and ignores the approaches that other states have adopted to address perceived excesses of pharmaceutical detailing by placing restrictions on marketing and inappropriate promotional activities. Instead, the Prescription Restraint Law illogically assumes that

[3] "'Publicity is justly commended as a remedy for social and industrial diseases. Sunlight is said to be the best of disinfectants; electric light the most efficient policeman.'" *Buckley v. Valeo*, 424 U.S. 1, 67, and n.80 (1976) (quoting Louis Brandeis, *Other People's Money*, 62 (1933)).

ignorance, resulting from criminalizing the collection and use of prescribing information for broadly defined "commercial purposes," will magically result in cost reductions.

There are many theories about what needs to be done to control healthcare costs – including better management of chronic disease, increasing patient compliance with drug and other treatment regimens, expanded coverage of and access to healthcare services, and reform of our healthcare payment system, to name just a few. This Court cannot enter into, much less resolve, the multi-faceted debate over healthcare reform. But it is clear, and it is within the jurisdiction of this Court to determine, that the New Hampshire Legislature's findings are not rationally based, that criminalizing the transfer of knowledge about provider performance is not a legitimate strategy for promoting a more efficient healthcare delivery system, and that the New Hampshire Prescription Restraint Law therefore cannot withstand constitutional challenge.

Everyone who cares about our healthcare delivery system has reason to be concerned about the Prescription Restraint law, but it is particularly disturbing to proponents of improving the quality and efficiency of healthcare through increased use of health information technology.

Amicus curiae eHealth Initiative ("eHI") is a nonprofit organization whose mission is to drive improvement in the quality, safety, and efficiency of healthcare through information and information technology. eHI is focused on engaging multiple and diverse stakeholders – including hospitals and other healthcare organizations, clinician groups, consumer and patient groups, employers and purchasers, health plans, healthcare information technology organizations, manufacturers, public health agencies, academic and research institutions, and public sector stakeholders – to define and then implement specific actions that will address the quality, safety, and efficiency challenges of our healthcare system through the use of

"interoperable"[4] information technology.

Significant obstacles stand in the way of realizing the promise of health information technology for improving healthcare, including the lack of healthcare system interoperability and widespread adoption of clinical data standards, outdated reimbursement policies, and lack of investment in innovation and technology. In addition, issues of privacy and security must be addressed in implementing health information technology systems and solutions. eHI was created to respond to these challenges through advocacy, education, hands-on help, and other informational activities, serving as a powerful and visible voice for the healthcare community in the public policy arena. eHi carries out its mission by working at the federal level and with states, regions, and communities across the United States.[5]

Amicus curiae National Alliance for Health Information Technology ("NAHIT") is a diverse partnership of senior executives from all healthcare sectors working to advance the adoption of clinical information technology systems to achieve measurable improvements in patient safety, quality of care, and operating performance. NAHIT comprises over 100 member organizations from all industry sectors: providers (medical groups, care providers), payers/health plans, information technology suppliers, employers/purchasers, as well as other relevant non-healthcare organizations.

NAHIT collaborates with healthcare and government leaders to shape the policy environment and accelerate the implementation of world-class, standards-based information technology aimed at creating the most effective, safe, unified, and inclusive health system

[4] "In healthcare, interoperability is the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged." National Alliance for Health Information Technology definition and explanation of healthcare interoperability, available at: http://www.nahit.org/cms/index.php?option=com_content&task=view&id=186&Itemid=157.

[5] Additional information about eHI is available at http://www.ehealthinitiative.org/.

possible. Since its founding in 2002, Chicago-based NAHIT has helped forge consensus and accelerate progress on such important initiatives as developing an industry-endorsed interoperability definition; developing barcoding and electronic health record standards; creating the Alliance Standards Directory, a public directory of health information technology standards, to promote the use of uniform standards; advocating for the creation of the National Coordinator for Health Information Technology office; co-founding the Certification Commission for Health Information Technology; and authoring *Rules of Engagement: A proven path for instilling, and then installing a CPOE approach that works.* In addition, NAHIT's CEO chaired the Commission on Systemic Interoperability.[6]

Amicus curiae SureScripts, LLC was founded in 2001 by the two associations that represent over 55,000 pharmacies in the United States: the National Association of Chain Drug Stores and the National Community Pharmacists Association. SureScripts is the largest network provider of electronic prescribing services, and serves as the infrastructure for pharmacy interoperability. SureScripts is committed to building relationships within the healthcare community and working collaboratively with key industry stakeholders and organizations to improve the safety, efficiency, and quality of healthcare by improving the overall prescribing process.

At the core of this quality improvement effort is the SureScripts Electronic Prescribing Network,™ a healthcare infrastructure that establishes electronic communications between clinicians, pharmacists, and payers, and enables the two-way electronic exchange of prescription information. The SureScripts Electronic Prescribing Network™ allows the simple and secure transmission of prescription data in a true electronic format, between the computers at the

[6] More information about NAHIT is available at http://www.nahit.org.

pharmacy and computers at the physician practice. The electronic exchange of prescription information significantly improves patient safety by reducing errors associated with illegible handwritten orders, and increases efficiency by reducing the need for phone calls, faxes and paper prescriptions.[7]

The New Hampshire law at issue in this case will have a detrimental effect on the ability of *amici* and their members and stakeholders to achieve their business objectives and thereby improve the quality of patient care in our healthcare system. It will not protect patient privacy or reduce healthcare costs. Therefore, *amici* write to assist the Court in analyzing the legal and public policy issues raised by the plaintiffs' challenge to the statute, and to persuade the Court that injunctive relief is necessary to prevent the significant harm that will result from enforcement of this misdirected law.

II.
INTRODUCTION

New Hampshire's statutory restriction on the exchange of physician prescribing information represents the first attempt in the country to stifle use of this valuable information. If this Court does not grant the plaintiffs' request for injunctive relief to stop enforcement of the law (as it applies to patient-deidentified/prescriber identifiable prescribing data), the Prescription Restraint Law will have a crippling effect on the use of healthcare information technology and the legitimate exchange of healthcare information to improve the quality and efficiency of our healthcare system. The importance of healthcare information technology to achieving these goals cannot be overstated. As the IOM concluded in 2001, "In the 20th century, brick and mortar constituted the basic infrastructure of the health care delivery system. To deliver care in the 21st century, the system must have a health information and communications technology

[7] Further information about SureScripts is available at http://www.surescripts.com/.

infrastructure that is accessible to all patients and providers." IOM, *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001). In the past several years, the President of the United States, leading members of Congress from both parties, and state governors and legislatures from nearly forty states have called for and begun to implement major initiatives in healthcare information technology. eHealth Initiative, *eHi Issue Brief: States Getting Connected: State Policy-Makers Drive Improvements in Healthcare Quality and Safety Through IT* (2006).

Even in this era of rapidly advancing medical technology, our healthcare system faces major challenges. Healthcare spending and health insurance premiums continue to rise at rates much higher than the rate of general inflation. Despite annual national health care spending of $1.9 trillion, concerns persist about preventable errors, uneven healthcare quality, and poor communication among physicians and hospitals. Office of the Actuary, Centers for Medicare and Medicaid Services, *National Health Expenditure Data* (2004), available at http://www.cms.hhs.gov/NationalHealthExpendData/. The IOM estimates that between 44,000 and 98,000 Americans die each year from medical errors occurring in healthcare facilities. *To Err is Human*, *supra*. Additional research has shown that over 770,000 people are injured or die each year in hospitals from adverse drug events. D.C. Classen, *et al.*, *Adverse Drug Events in Hospitalized Patients*, 277 J.A.M.A. 301-6 (1997).

The problems of high costs, medical errors, variable quality, administrative inefficiencies, and lack of coordination are closely connected to inadequate use of health information technology as an integral part of medical care. While many new efforts are under way to evaluate and address medical errors, including the use of health information technology, innovative techniques and strategies are essential. To make healthcare delivery better, safer, and

more efficient, the industry must develop ways to provide health information to clinicians, researchers, and various other appropriate users – when and where they need it – securely and in a manner that respects patient privacy.

Health information technology aims to create interoperable electronic health records so healthcare providers can access the patient information they need quickly and reliably. In addition, health information technology will enable providers and other organizations to collect patient care data more thoroughly and efficiently, analyze it, and use it to generate a wide range of informative reports to further improve patient care. Accordingly, over the past three years the federal government, state governments, and the healthcare industry have designated the process of transforming healthcare and improving quality through health information technology as a top priority for healthcare reform in the United States. These efforts cannot succeed unless they are national in scope.

This case is about New Hampshire's attempt to limit the exchange of prescribing information by New Hampshire pharmacies and other holders of that information, but it will prevent dissemination of New Hampshire data to those outside the state as well. And if it spawns copy-cat legislation in other states, it will have an even broader adverse effect on movement to transform healthcare and improve healthcare quality through the use of health information technology everywhere in the country.

Free exchange of patient-deidentified/prescriber-identifiable prescribing data is a crucial component of the healthcare quality improvement/health information technology movement. There is consistent evidence that – particularly in the context of drug prescribing, dispensing, and administration – medical errors can be reduced by appropriate use of computerized provider

order entry ("CPOE") and decision support systems ("DSS"). The following are a few notable examples:

- At LDS Hospital in Salt Lake City, Utah a CPOE system reduced adverse drug events by 75%. R.S. Evans, *et al.*, *A Computer-assisted Management Program for Antibiotics and Other Anti-infective Agents*, 338(4) New. Eng. J. Med. 7 (1998).
- At the Regenstrief Institute for Health Care in Indianapolis, researchers demonstrated that automated computerized reminders increased orders for recommended interventions from 22% to 46%. J.M. Overhage, *et al.*, *A Randomized Trial of 'Corollary Orders' to Prevent Errors of Omission*, 4 J. Amer. Informatics Ass'n 364-75 (1997).
- A 1998 systematic review of the literature assessing the effects of 68 computer-based clinical DSS demonstrated a beneficial impact on physician performance in 43 of 65 studies, and a beneficial effect on patient outcomes in 6 of 14 studies D.L. Hunt, *et al.*, *Effects of computer-based clinical decision support systems on physician performance and patient outcomes*, 280 J.A.M.A. 1339-45 (1998).
- A new pharmacy software system implemented by the Department of Defense in 2001 that integrates and reviews information from all sources prior to prescriptions being filled has eliminated over 100,000 adverse drug interactions.

These uses of information provide public benefit regardless of whether anyone earns money from them, and their benefits should not be disregarded or denigrated merely because they were derived through commercial enterprise.

The New Hampshire law threatens to derail healthcare quality improvement initiatives that use patient-deidentified/prescriber-identifiable prescribing information to improve patient care. The statute condemns as a *criminal* "commercial purpose" the transfer and/or use of physician prescribing data either to evaluate or to influence physician prescribing behavior. The exceptions to this broad prohibition are exceedingly narrow. The statute allows "utilization review," but only by other healthcare providers or patients' insurers, who may not have any more information about alternative medications or relevant research studies and practice guidelines than the prescribing physicians. How can physician prescribing behavior in particular, and healthcare quality in general, possibly be improved if physician prescribing behavior can be neither evaluated nor influenced by anyone else?

Many physicians welcome the information and medications they receive *gratis* from detailers, because free drugs and explanatory literature constitute a substantial benefit to the doctors' low-income patients. On the other hand, *all* doctors have the option of closing their doors to detailers if they do not wish to be the targets of drug solicitations. Stopping the flow of publicly useful prescribing data does not protect doctors from detailers. Instead, it means that physicians are more likely to get unfocused material they cannot use because it does not relate to their patients. There is no reason whatever to suppose that this legislatively imposed inefficiency will reduce costs to consumers or the State of New Hampshire. Importantly, there are alternative approaches that *can* help ensure physicians make treatment decisions based on their patients' best interests rather than pharmaceutical company solicitations, without cutting off the flow of vital healthcare information that is needed to inform treatment decisions and improve quality.

The Prescription Restraint Law is ill-conceived and poorly drafted, and it manages to jettison the "baby" (*i.e.*, beneficial uses of prescribing information to evaluate and influence

physician prescribing behavior) without even throwing out the "bathwater" (*i.e.*, perceived problems with drug detailing). This Court should enjoin its enforcement with respect to patient-deidentified/prescriber-identifiable data.

III.
BACKGROUND: BENEFITS OF PATIENT-DEIDENTIFIED/PRESCRIBER-IDENTIFIABLE DATA EXCHANGE

Critical elements of the healthcare system, including public health surveillance and reporting, emergency preparedness and response, quality-improvement initiatives, post-market adverse drug event surveillance, and clinical research, depend upon the availability and exchange of deidentified patient data. A variety of patient data that is stored in digital form in hospitals, physicians' offices, labs, and pharmacies is deidentified with algorithms, collected, summarized, analyzed, stored, communicated, and presented in a manner that helps save lives and reduce the cost of healthcare. Regional Health Information Organizations ("RHIOs"), discussed further below, are a primary vehicle for aggregating and using such data to advance quality improvement. While the law indicates that patient-deidentified/prescriber identifiable data can be used for some of these purposes, the law is broad and vague enough to prohibit them, thereby stopping the flow of prescribing data. The law will disrupt and undermine the process of implementing health information technology, and disserve the public interest by impeding quality-improvement efforts.

A. Public Health

To reduce the risks to public health from hazards such as communicable diseases, unsafe foods and medications, and terrorism, public health officials must detect threats as soon as possible after they occur, investigate the magnitude and nature of the threat, and track who is sick, with whom they have had contact, and where they were exposed to the disease, toxin, or

contaminated food or drug. Public health officials require patient-deidentified/prescriber identifiable prescription data to alert healthcare providers about confirmed or potential threats; to deliver relevant information, treatment guidelines, and interventions; to support administration of countermeasures and other responses, including treatment, prophylaxis, vaccination, and/or isolation; to monitor responses; to determine whether the responses were effective; and to develop and implement changes to improve outcomes in the future.

The following is an example cited in the Declaration of Hossam Sadek in Support of Plaintiffs' Motion for Preliminary Injunction ("Sadek Declaration"), at ¶ 21.c:

> Regional impact of bioterrorist threats on prescribing. Wisconsin researchers at the Marshfield Clinic Research Foundation used IMS Health's prescriber-level information to determine if the public demand for fluoroquinolones, such as Cipro, post-9/11 bioterrorist threats would spread to communities not directly affected by anthrax scares in New York, New Jersey, Connecticut, Pennsylvania, Virginia, Maryland and Florida.

B. Quality Initiatives

Aggregated and deidentified individual health information plays a critical role in improving clinical quality at the point where care is delivered. Such data can be used to detect and address quality variations. Public reporting of healthcare performance has been a powerful driver of quality improvement. Due in large part to reporting provided by National Committee for Quality Assurance ("NCQA"), through which patient-deidentified data was collected, patients with diabetes are now more than twice as likely to have their cholesterol controlled to recommended levels as they were in 1998. NCQA, *The State of Health Care Quality 2006* (2006). Additionally, perhaps the most dramatic success story is that of beta-blocker treatment. In 2005, more than 96% of patients who suffered heart attacks were prescribed beta-blockers to help prevent a second, and often fatal, heart attack, up from only 62% in 1996. This improvement alone has saved between 4,200 and 5,300 lives over the past 10 years. *Id.* These

improvements would not have been possible without collecting and analyzing patient-deidentified data.

Deidentified prescription data also supports pay-for-performance programs and other means of rewarding and encouraging outstanding quality. *See* Declaration of John Glaser in Support of Plaintiff's Motion for Preliminary Injunction ("Glaser Declaration") at ¶ 13 (doctors can receive additional income if their prescribing practices improve in accordance with established criteria). How can optimum care be rewarded if prescriber identities cannot be disclosed? When timely, detailed clinical data is aggregated and analyzed, it can improve care in a community or the whole nation by rationalizing the allocation of resources, steering new research, and enhancing clinician training and performance.

For example, the California Integrated Healthcare Association is a state-wide collaborative of health plans, medical groups, and other stakeholders that runs a pay-for-performance program. The program analyzes performance results at the medical group level (by aggregating data across multiple health plans), provides incentives for good care based in part on the adoption of information technology, and produces a single public scorecard comparing the performance of medical groups. Two years of data on over 200 medical groups that care for over 6 million patients shows that quality improved in nearly every clinical measure – including asthma and diabetes care, childhood immunizations, cancer screening, and cholesterol management – as a result of this program. Again, these improvements would not be possible without the use of patient-deidentified/prescriber-identifiable data.

Two relevant examples described in the Sadek Declaration (at ¶¶ 21.a and b) include:

> Asthma in low income areas. A study in New York used IMS Health's prescriber-level information to examine physician-prescribing patterns in under-served urban areas to determine patterns of under-treatment of patients with asthma. There was substantial evidence that asthma controller medications were

> underutilized, which reflected issues in both physician education and public perceptions. Feedback on the study findings was provided to physicians to engage them in implementing appropriate public health solutions.
>
> * * *
>
> Community intervention to reduce overuse of antibiotics. A research study relied on IMS Health's prescriber-level data to complete a pediatric study on the judicious use of antibiotics. The objective of the study was to assess the impact of parent and clinician education on antibiotic prescribing and carriage of penicillin-nonsusceptible streptococcus pneumoniae in children. The study resulted in a multifaceted education program that led to community-wide reductions in antibiotic prescribing.

C. Post Market Drug Event Surveillance

Once a drug is offered for sale to consumers, information about any adverse effects it may have (some of which might not have been discovered in pre-market clinical trials) is obtained through "post-market surveillance," that is, continued monitoring of a medication's safety profile after approval by the federal Food and Drug Administration ("FDA"). Post-market surveillance relies on the detection and voluntary reporting of adverse effects by healthcare professionals, but it can be significantly augmented by the use of aggregated deidentified data.

The Vaccine Safety Datalink ("VSD"), developed in 1990 by the Centers for Disease Control and Prevention in partnership with seven large health maintenance organizations to monitor vaccine safety continually, is an example of a large-linked database and includes information on vaccine administration to more than six million people. All vaccines administered within the study population are recorded. Available information includes vaccine type, date of vaccination, concurrent vaccinations (those given during the same visit), the manufacturer, lot number, and injection site. Medical records are then monitored for potential adverse events resulting from immunization. Uses of the VSD project database include

examining potential associations between vaccines and a number of serious conditions, and testing new vaccine safety hypotheses advanced in medical literature.

In September 2005, the FDA contracted with four healthcare industry organizations to help the FDA conduct post-market surveillance of prescription drugs by using data from large volumes of patient records. UnitedHealth Group, which has a database of 11 million patients; the Kaiser Foundation Research Institute of Oakland, California; Nashville, Tennessee-based Vanderbilt University; and Harvard Pilgrim Health Care of Wellesley, Massachusetts, will work with FDA to monitor drug safety and effectiveness.

D. Clinical Research

Aggregation of deidentified data can be a key tool to enhance development of efficient and effective therapeutic agents and products such as drugs, biologic products (*e.g.*, vaccines,

enhance the process of organizing and conducting clinical research trials, including the development of research protocols, review of human research subject protections, recruitment of participants, and selection of research sites. Information technology also can be used to optimize the safety of clinical studies, by facilitating the timely reporting of safety data, as well as the sharing and analysis of data by the FDA, the National Institutes of Health, and other agencies that may have oversight responsibilities.

E. Regional Health Information Organizations

The existing healthcare system involves a wide range of stakeholders, the vast majority of which do not currently use electronic systems to capture clinical and administrative data. For those that do have electronic systems, the information generally exists in non-standard formats, provided by many different vendors, that cannot easily be exchanged. As a whole, the healthcare

system forces clinicians to make decisions on incomplete or inaccurate information, which can lead to harmful errors in patient care, unnecessary treatments and tests, and wide variations in the quality of care provided. Moreover, the inability of the health system to exchange information securely, easily, and in a timely manner makes it extremely difficult to aggregate data for critical public health and research purposes.

To address this lack of interoperability and the health problems that result, a number of regional collaborations have been formed with the explicit goal of supporting the exchange and use of healthcare information that improves the quality of care for patients.. These collaborations, often referred to as "Regional Health Information Organizations" or "RHIOs," involve a diverse array of stakeholders in the delivery of healthcare, including hospitals and clinics, physicians and other healthcare providers, purchasers, payers, state and local governments, laboratories, pharmacies, and consumer groups. Each RHIO has evolved as a grass-roots organization, based on local factors: the priorities of its partners, the nature of the local marketplace and the influence of regional stakeholders, and state and local laws and regulations. As a result, RHIOs vary tremendously in their size, governance structures, and technical approaches. Many small states, including Rhode Island, Vermont, Connecticut and Delaware, have formed state-level RHIOs to advance quality improvement.

RHIOs are using technology to facilitate the exchange and use of both administrative and clinical data to bring better information to the point of care, and to help integrate and coordinate patient care. Through a RHIO, physicians can find appropriate dosing calculations and selection of drugs, catch potentially harmful interactions between drugs, and transmit prescriptions reliably to nurses, pharmacists, and patients themselves. RHIOs also are evolving to support the data aggregation needs of public health, disease management, research, and quality reporting

efforts, all of which depend on deidentified patient information and are critical to realizing the expected benefits of health information technology to improve our healthcare system.

IV.
ARGUMENT

A. THE STATE HAS NOT SHOWN ANY LEGITIMATE JUSTIFICATION FOR THE STATUTORY RESTRICTIONS ON USE OF PATIENT DEIDENTIFIED DATA, OR THAT ALTERNATIVES TO ACHIEVE THE ARTICULATED LEGISLATIVE OBJECTIVES ARE UNAVAILABLE.

1. The State's Interests in Restricting the Exchange of Patient-Deidentified/ Prescriber-Identifiable Data Are Insufficient.

The Court is being asked to decide in this case whether the State of New Hampshire legitimately can stop pharmacies, insurers, and other possessors of patient-deidentified/prescriber-identifiable prescribing information from communicating that data to anyone who intends to use it for the legislatively defined "commercial purpose" of evaluating or influencing physician prescribing behavior – even if the prescribing data does ***not*** identify patients. The Prescription Restraint Law cuts off all patient deidentified/prescriber identifiable prescribing data at the source (except in very narrowly limited circumstances). As *amici curiae* eHI, NAHIT, and SureScripts explain in this brief, choking off vital health information exchange in this way is so *inimical* to the public policy goal of improving healthcare services that the statute cannot be seen to have even a rational basis – particularly since the New Hampshire Prescription Restraint Law does nothing whatsoever to protect patient privacy (beyond existing protections), or to restrict direct pharmaceutical marketing to physicians – which apparently formed the impetus for this legislation. Therefore, *amici* believe the statute cannot pass constitutional muster no matter what standard the Court uses to analyze it.[8]

[8] We defer to the plaintiffs' arguments regarding the level of scrutiny to be applied.

a. Patient privacy is *not* implicated by the exchange of deidentified data, so the State cannot legitimately invoke patient privacy concerns to justify legislation that drastically curtails the beneficial exchange of deidentified data; on the contrary, wise public policy *promotes* such exchange.

i. Patient-deidentified data poses no threat to patient privacy, so restricting exchange of patient-deidentified/prescriber identifiable data advances no legitimate state interest in protecting patient privacy.

Amici wholeheartedly support the protection of patient privacy. After all, everyone is a patient at one time or another, so this issue affects us all directly as individuals. Protection of patient privacy also is crucial to maintaining patient confidence in the healthcare system of which *amici* are a part. But the information at issue in this litigation already has been patient-deidentified when it is transferred or sold by the pharmacies, insurers and others who obtain it directly from physicians or pharmacies. *See* Declaration of Robert J. Hunkler in Support of Plaintiffs' Motion for Preliminary Injunction at ¶ 6; Declaration of James Mahon in Support of Plaintiffs' Motion for Preliminary Injunction at ¶ 8; Declaration of Jody Fisher in Support of Plaintiffs' Motion for Preliminary Injunction at ¶ 3; Sadek Declaration at ¶ 2. Nevertheless, as the New Hampshire Attorney General concedes, the Prescription Restraint Law prohibits transfer or use of provider prescribing data to evaluate or influence physician prescribing behavior, ***even if the data has been patient deidentified***. *See* Defendant's Memorandum of Law in Support of its Objection to Plaintiff's [sic] Motion for Preliminary Injunction ("Defendant's Memorandum") at 40 (the Legislature intended the law "to *independently* cover both patient-identifiable information and prescriber-identifiable data") (emphasis added).

By definition, patient deidentified data does ***not*** implicate patient privacy interests, because it does not disclose who the patient is. *See* 42 U.S.C. § 1320d(6) (defining "individually identifiable health information" to include only information that "identifies the individual" or

"with respect to which there is a reasonable basis to believe that the information can be used to identify the individual"). *See also* Markle Foundation, *The Architecture for Privacy in a Networked Health Information Environment*, in *The Connecting for Health Common Framework* (April 2006), available at http://www.connectingforhealth.org/, at 1 (the concept of privacy in the medical context "should be understood as an individual's right to control personal information").

Thus, it simply makes no sense to assert that the Prescription Restraint Law promotes patient privacy by restricting the use of patient-deidentified/prescriber-identifiable data. No restriction on dissemination of patient-deidentified data can be justified on privacy grounds. *Id.* (medical data can provide "tremendous benefits," and "patients may miss out on some of the benefits if data controls in the name of confidentiality over-restrict the uses and dissemination of information"); *id.* at 6 ("medical data, particularly when enabled by electronic health records, has the potential to transform the way patients receive care, and to introduce a far greater degree of efficiency and effectiveness of our nation's medical care system"); *id.* at 7 ("it is essential for our privacy and information laws to maximize the potential that can be offered by medical data. . . . [I]f information is not shared or disseminated at all, then patients themselves will be the losers").

ii. ***Congress did not restrict the exchange or use of patient-deidentified data, and the HIPAA privacy regulations specifically exempt patient-deidentified data from their scope to encourage use of such data and to acknowledge there is no privacy interest in patient-deidentified data.***

When the United States Congress enacted HIPAA, it plainly recognized the benefits to be derived from the exchange of patient-deidentified health information, and that such exchanges do not implicate the patient privacy that Congress intended to protect. This is evident from Congress's decision to define "health information" (42 U.S.C. § 1320d(4)) separately from "individually identifiable health information" (42 U.S.C. § 1320d(6)), and to provide that ***only***

disclosures of "individually identifiable health information" can be subject to statutory penalties (including fines of up to $250,000 and imprisonment for up to 10 years) as HIPAA violations. *See* 42 U.S.C. § 1320d-6; *see also* 64 Fed. Reg. 59918-01, 59920 (November 3, 1999) ("*Congress recognized the need for minimum national health care privacy standards to protect against inappropriate use of* ***individually identifiable health information*** by passing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, which called for the enactment of a privacy statute within three years of the date of enactment") (emphasis added).

Similarly, in formulating and adopting the federal Department of Health and Human Services ("DHHS") regulations that established and provided for implementation of the specific HIPAA patient privacy requirements, DHHS expressly recognized the crucial importance of deidentified health data to improving our healthcare system:

> There are many instances in which such individually identifiable health information is stripped of the information that could identify individual subjects and is used for analytical, statistical and other related purposes. ***Large data sets of de-identified information can be used for innumerable purposes that are vital to improving the efficiency and effectiveness of health care delivery***, such as epidemiological studies, comparisons of cost, quality or specific outcomes across providers or payers, studies of incidence or prevalence of disease across populations, areas or time, and studies of access to care or differing use patterns across populations, areas or time. Researchers ***and others*** often obtain large data sets with de-identified information from providers and payers (including public payers) to engage in these types of studies. ***This information is valuable for public health activities*** (e.g., to identify cost-effective interventions for a particular disease) ***as well as for commercial purposes*** (e.g., to identify areas for marketing new health care services).

65 Fed. Reg. at 59946 (emphasis added).

When DHHS issued the final HIPAA privacy rule on December 28, 2000, DHHS declared that such uses of deidentified health data should be encouraged:

- "A number of examples were provided of how valuable such de-deidentified information would be for various purposes. *We expressed the hope that covered entities [i.e., entities subject to the HIPAA privacy requirements], their business partners, and others* ***would make greater use*** *of de-identified health information than they do today*, when it is sufficient for the purpose, and that such practice would reduce the burden and the confidentiality concerns that result from the use of individually identifiable health information for some of these purposes." 65 Fed. Reg. 82462-01, 82543 (December 28, 2000) (emphasis added).

- "The comments on this topic almost unanimously supported the concept of de-identification and efforts to expand its use . . . ." 65 Fed. Reg. at 82708.

- "[W]e believe that the fact that we allow de-identified information to be disclosed without regard to the policies, procedures, and documentation required for disclosure of identifiable health information will provide an incentive to encourage its use where appropriate." 65 Fed. Reg. at 82716.

Accordingly, the HIPAA privacy regulations expressly provide that they do ***not*** apply to patient-deidentified data. 45 Code Fed. Regs. §§ 164.502(d), 164.514(a), (b).

The New Hampshire statute prohibiting the sharing and use of patient-deidentified/prescriber identified prescribing data is directly contrary to the public policy favoring free exchange of deidentified health information to improve patient care, which was recognized by Congress and articulated by DHHS in connection with the HIPAA federal healthcare privacy laws.

iii. *The New Hampshire Prescription Restraint Law is inconsistent with purpose and scope of the HIPAA privacy regulations.*

The Prescription Restraint Law arguably runs contrary to HIPAA by "stand[ing] as an obstacle to the accomplishment and execution of the full purposes and objectives"[9] of HIPAA – which include protecting patient privacy *without* limiting the many beneficial uses of patient-deidentified information. HIPAA preempts all contrary state laws unless they are "more

[9] 45 Code Fed. Regs. § 160.202.

stringent" that HIPAA, *i.e.,* they are more protective of the privacy of individually identifiable health information, or provide greater rights for consumers with respect to accessing and controlling their own individually identifiable health information. 45 Code Fed. Regs. §§ 160.202, 160.203(b). The HIPAA preemption regulations reflect Congress's goal in enacting HIPAA to establish a "floor" of privacy and consumer access rights, while allowing the states to provide higher levels of protection if they chose to do so.

The Prescription Restraint Law purports to go beyond the threshold protections of HIPAA, but in fact it does nothing to increase patient confidentiality. Rather, it imposes totally unwarranted restrictions on exchange of patient-deidentified/prescriber-identifiable data. Perversely, instead of protecting patient privacy, the New Hampshire Prescription Restraint Law will interfere with the critical consumer protection aim of using information about prescribing patterns and drug usage to reduce medical errors and otherwise improve healthcare quality. Thus, the Prescription Restraint Law undermines the interrelated patient-protection goals of HIPAA and the emerging quality improvement/health information exchange movement.

The Prescription Restraint Law's inconsistency with the intent of HIPAA supports the plaintiffs' contention that the law is unconstitutional. Even assuming for the sake of argument that the communications at issue here may constitute "commercial" speech, when a statute that restricts such speech is inconsistent with other legislative enactments and policies, it cannot "directly advance" a legitimate government interest as required to pass First Amendment muster under the U.S. Supreme Court's decision in *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York*, 447 U.S. 557 (1980). *See Greater New Orleans Broadcasting Association, Inc. v. United States*, 527 U.S. 173, 188-196 (1999); *Rubin v. Coors Brewing Company*, 514 U.S. 476, 486-491 (1995). In *Rubin*, the Court found that the challenged

statute's "exemptions and inconsistencies bring into question the purpose of the labeling ban," and "the irrationality of this unique and puzzling regulatory framework ensures that the labeling ban will fail to achieve [its] end." The same is true here with respect to the Prescription Restraint Law's ban on exchange or use of patient-deidentified/prescriber identifiable prescribing data, which should be freely available to improve patient care.

iv. ***There is a groundswell of support for the growing quality-improvement/health information exchange movement, because it will facilitate better patient care.***

Government entities and private organizations and individuals across the country are committing tremendous energy and resources to creating secure, efficient systems for exchanging health information to promote and facilitate better patient care. Many patients see doctors in a variety of settings for different conditions. Physicians and the healthcare organizations within which they practice cannot possibly provide the best possible care for patients – much less obtain reimbursement from public or private payers for services that must be shown to be medically necessary – if healthcare providers have only fragmented information about their patients' medical histories and other treatments the patients may be receiving elsewhere. It is difficult (in many cases impossible) for patients to keep track of all this information themselves. Workable health information exchange systems are the obvious solution to this problem, as many national leaders recognize.

In April 2004, President George W. Bush issued Executive Order 13335 calling for widespread adoption of interoperable electronic health records within 10 years, and establishing the Office of the National Coordinator for Health Information Technology. On July 25, 2006, California Governor Arnold Schwarzenegger issued Executive Order S-12-06 ordering state officials to convene a "California eHealth Action Forum," allocate funds, facilitate rapid

adoption and sustainability of health information technology, and take other specific actions – including removing barriers – to promote and implement "*a comprehensive State policy agenda for health information technology*" (emphasis in original). That executive order is available at http://gov.ca.gov/index.php/executive-order/2616/. *See also* American Hospital Association, *Health Information Exchange Projects: What Hospitals and Health Systems Need to Know* 3-5 (2006) (briefly describing federal, state, and private-sector initiatives to support improvement of patient care through health information exchange). The New Hampshire Prescription Restraint Law is a reactionary, counter-productive response to perceived problems with pharmaceutical detailing, and the law's restriction of patient-deidentified/prescriber identifiable prescribing data exchange cannot accomplish any legitimate state goal.

b. The professional conduct of licensed healthcare practitioners – including their prescribing practices – can and must be subject to evaluation and influences that promote better patient care, so prohibiting any use of patient-deidentified prescribing data that performs those functions is not a legitimate State interest.

As medical professionals, physicians always are subject to ongoing review and oversight of their professional conduct – including their prescribing behavior – by their state licensing agency (here, the New Hampshire Board of Medicine[10]), by the federal Drug Enforcement Administration, which is part of the Department of Justice,[11] and by their physician peers if they practice in hospitals, clinics, medical groups, etc.[12] As the Prescription Restraint Law

[10] *See*, *e.g.*, N.H, Rev. Stat. Ann. § 329:13-b (; http://www.nh.gov/medicine/about.html ("What Is the Board of Medicine," describing the Board of Medicine's functions, including "monitoring its licensees to ensure that they maintain a level of current medical knowledge and skill and that they practice safely and ethically") and http://www.nh.gov/medicine/consumer.html (Mission Statement of the Board of Medicine).

[11] *See* http://www.deadiversion.usdoj.gov/crim_admin_actions/index.html re DEA investigations of and actions against physicians.

[12] *See* N.H. Rev. Stat. § 329:13-b (re physician peer review); *In re "K,"* 561 A.2d 1063, 1066 (1989) ("a hospital's medical staff [must] provide 'effective mechanisms to monitor and evaluate

recognizes, physicians' prescribing behavior also is subject to utilization review by patients' health plans. Thus, physicians cannot claim any right to keep their professional conduct secret and exempt from evaluation. Although physicians' interactions with individual patients are protected by the physician-patient privilege, that simply does not apply to the patient-deidentified/prescriber-identifiable prescribing data at issue here. And patients themselves frequently share with family and friends information about who their doctors are and what medications those doctors have prescribed for them.

Physician privacy is simply not a legitimate issue in this case. Rather, the real concern here is that the statute prohibits pharmacies and insurers from providing prescriber-identifiable prescribing data to anyone other than other healthcare providers, care managers, or patients' own insurers for the purpose of evaluating or influencing (including improving) physician prescribing behavior.

Some physicians may want to avoid being approached by drug detailers (while other doctors welcome detailers; *see* Declaration of Thomas P. Wharton, M.D., F.A.C.C. in Support of Plaintiffs' Motion for Preliminary Injunction), and the Legislature may have an interest in protecting physicians from overzealous pharmaceutical marketing, but the statute at issue here does absolutely *nothing* to address the manner in which pharmaceutical companies market drugs to doctors.

The statute also makes no sense from a patient protection perspective. On its face, the statute prohibits as a "commercial purpose" any use of provider-identifiable prescribing data (other than the extremely narrow list of exceptions) that influences physician prescribing

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the quality and appropriateness of patient care and clinical performance of all individuals with delineated clinical privileges. Important problems in patient care are identified and resolved, and opportunities to improve care are addressed . . .'" (citation omitted).

behavior. The irrationality of this prohibition should have been obvious. For example, how can physicians be persuaded to help stop the alarming increase of antibiotic-resistant infections, if it is impermissible to identify over-prescribers and influence them not to prescribe antibiotics in response to ill-informed patient demand, often to treat viral infections for which antibiotics are worthless? How can physicians be educated about new drug therapies that truly may be better for their patients, or about newly discovered adverse drug interactions that could affect their patients? Using physician prescribing data to accomplish these purposes is not only good but necessary. The notion that attempting to examine and influence physician prescribing practices always is an inherently bad "commercial purpose" is simply absurd.

"Knowledge is power."[13] In order to improve patient care, our healthcare system needs to share more knowledge – including knowledge about physician prescribing behavior – not less. The New Hampshire law is a giant step backward in the march toward better patient care.

c. The New Hampshire statute will have a substantial negative impact on emerging quality-improvement/health information exchange projects.

The Prescription Restraint Law cuts off valuable prescribing data at the source, *i.e.*, the pharmacies and insurers who are in a unique position to gather it. If other states and/or the federal government adopted similar legislation, prescribing data could become unavailable to those who seek to provide particular physicians with relevant information about drugs for their patient populations, or otherwise improve physician prescribing practices – and health information technology organizations certainly will be precluded from undertaking any projects related to prescribing that were intended to be national in scope. Moreover, there is no reason to suppose that such restrictive legislation necessarily would be limited to stifling disclosure of prescribing data only. Medical device manufacturer also market to physicians. Data about

[13] Sir Francis Bacon, *Religious Meditations, Of Heresies* (1597).

physician orders for such devices may be next on the legislative "gag" list, with who knows what other misguided restrictions to follow.

At a time when consumers and knowledgeable health policy leaders are calling for greater transparency and information exchange to improve healthcare quality, New Hampshire is leading the charge in precisely the opposite direction by protecting exactly the wrong thing. The public will suffer if the nascent health information exchange movement is hobbled in this way.

2. Other Means – Which Would Not Restrict Beneficial Exchange of Patient-Deidentified Health Information – Are Readily Available To Help Ensure That Pharmaceutical Company Sales Representatives Do Not Induce Healthcare Practitioners To Prescribe Particular Medications For Reasons Other Than Their Patients' Best Medical Interests.

The Prescription Restraint Law includes in its definition of prohibited "commercial purpose" any activity that could be used to "evaluate the effectiveness of a professional pharmaceutical detailing sales force." N.H. Rev. Stat. § 318-B:12, IV. Apart from that, the statute does not address or even mention drug detailing at all, much less do anything to limit pharmaceutical marketing to prescribing practitioners.

The most direct way to limit the effect of drug detailers on doctors is for doctors to turn detailers away. Nothing impeded physicians from doing so before this statute was enacted, and they did not need the New Hampshire Legislature to excise prescribing data from the range of health information that may be exchanged – with no regard for the negative consequences of such a restriction. The American Medical Association also operates a program to assist physicians who want to keep detailers at bay. *See* Hunkler Declaration at ¶¶ 11-15. Doctors who are willing to spend their time seeking out pharmaceutical information themselves, and to forgo free medication samples that could be distributed to their low-income patients, can learn about new drugs, drug interactions, drug study data, etc. through other channels.

Doctors also can impose their own restrictions on interactions with pharmaceutical company detailers, and thereby obtain the significant benefits of such contacts – such as free medication samples and educational materials for patients – while limiting any detriments. *See* Elisabeth L. Backer, *The Value of Pharmaceutical Representative Visits and Medical Samples in Community-Based Family Practices*, Journal of Family Practice, September 2000 (some physician practices set strict limits on when and for how long detailers could speak with them; "[c]linics with specific policies for interactions with drug companies appear to derive more satisfaction from their encounters").

An alternative approach – which allows physicians to continue receiving the valuable information and samples that detailers provide – is to formulate rules for interactions between medical professionals and detailers, along with reporting requirements to help ensure that those rules are followed. The pharmaceutical industry itself has promulgated voluntary guidelines for pharmaceutical companies and their sales representatives, the "PhRMA Code on Interactions with Healthcare Professionals,"[14] which was adopted by PhRMA as of July 1, 2002 *See* http://www.phrma.org/code_on_interactions_with_healthcare_professionals/. And in 2003, the DHHS Office of Inspector General published its Compliance Program Guidance for Pharmaceutical Manufacturers, which also address detailing issues. *See* 68 Fed. Reg 23731 (May 5, 2003); http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf.

Along these same lines, other states have devised far more rational approaches than New Hampshire's to the perceived drawbacks of detailing. For example, California enacted Senate Bill 1765, codified as California Health and Safety Code Sections 119400 to 119402. Under these provisions, effective July 1, 2005, pharmaceutical manufacturers must create

[14] "PhRMA" is an acronym for the Pharmaceutical Research and Manufacturers of America.

Comprehensive Compliance Programs ("CCPs") designed to ensure compliance with the OIG Guidance and the PhRMA Code. The bill's author said the "[b]y limiting marketing practices to exclude inappropriate marketing or promotional activities,... the bill will have the effect of lowering prescription drug costs and easing public concerns about conflicts of interest between doctors and drug company sales representatives." Each drug company must certify annually, in writing, compliance with its CCP and with SB 1765, post this annual declaration on its website, and maintain a toll-free number for access to paper copies of both the declaration and the CCP itself. CCPs must establish specific annual dollar limits on gifts, promotional materials, and other items provided to healthcare professionals Samples, financial support for continuing medical education, financial support for health education sponsorships, and fair-market-value payments for consulting and other professional services are exempt provided they conform to the OIG Guidance and the PhRMA Code.

In 2003, Maine enacted Me. Rev. Stat. Ann. tit. 22, § 2698-A, which calls for pharmaceutical companies to disclose their prescription drug marketing expenditures in Maine annually to the Maine Department of Health, including (but not limited to) expenses associated with educational or informational programs, materials or seminars; and food, entertainment, and gifts valued at more than $25, or anything given for less than market value. The District of Columbia adopted a very similar law, DC Code Ann. § 48-833.01-.06, in 2004.

Since 1993, Minnesota has prohibited drug manufacturers and wholesalers from offering or giving gifts over $50 in value to practitioners, with the exception of samples for free distribution to patients, payments to sponsors of *bona fide* medical educational programs (but not to healthcare practitioners for attending such programs), reasonable *honoraria* and expenses for

faculty of educational programs, consulting fees for genuine research projects, publications or educational materials, and employee salaries and benefits. *See* Minn. Stat. § 151.461.

Vermont requires disclosure of the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotional, or other marketing activities by a pharmaceutical company to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in this state. Some exceptions apply, including (among others) samples, unrestricted grants for medical education programs, and gifts under $25. Vt. Stat. Ann. tit. 33, § 2005. Vermont also requires pharmaceutical marketers to disclose prescription drug "average wholesale prices" to health care professionals, including not only the prices of the manufacturers' own drugs, but also the prices of other drugs in the same therapeutic class, so doctors can compare drug costs when making prescribing decisions. Vt. Stat. Ann. tit. 33, § 2005a.

West Virginia requires reporting to the state council of aggregate national advertising and promotion costs for all prescription drugs (with exceptions for samples, participation in *bona fide* clinical trials, and scholarships for medical interns, residents, and fellows who are selected by sponsoring professional associations to attend significant educational, scientific, or policy-making conferences). W. Va. Code § 5A-3C-13. West Virginia law also authorizes the Legislature to "explore innovative strategies" such as "[e]stablishing counter-detailing programs aimed at educating health care practitioners . . . about the relative costs and benefits of various prescription drugs . . . ." W. Va. Code § 5-16C-9.

The New Hampshire Legislature had no rational basis for enacting a law that cannot possibly achieve its stated objectives, when sensible alternatives exist that will not squelch

beneficial health information exchange.

B. THE NEW HAMPSHIRE STATUTE IS IMPERMISSIBLY VAGUE BECAUSE IT DOES NOT ADEQUATELY INFORM AFFECTED PERSONS AND ENTITIES WHAT CONDUCT IS PROHIBITED, AND IT IS FATALLY OVERBROAD BECAUSE IT CLEARLY DOES PROHIBIT BENEFICIAL CONDUCT ENTIRELY UNRELATED TO THE EVILS THAT THE LEGISLATURE PURPORTED TO BE ADDRESSING.

Among its many flaws, the statute fails to explain how and when the purpose of a specific use or transfer of prescribing data is determined. While a pharmacy may have a general idea of what a particular buyer of patient deidentified prescribing data intends to do with the information, is the pharmacy expected to demand a detailed description of every contemplated use? What if the buyer decides to do something more with the data later? Is the pharmacy liable – criminally and civilly – for that use if it is impermissible under the statute? The statute leaves these crucial practical questions unanswered.

And, as explained above, there is no doubt that the statute will prohibit the exchange of patient-deidentified/prescriber-identifiable prescribing data for many important purposes that are designed to improve patient care, to the detriment of patients and the healthcare system – so the statute plainly is overbroad as well.

1. Key Terms in the Statute Are Undefined, and Could Have Varying Meanings.

The terms "care management," "research," and "utilization review" – among others – are all undefined in the statute. It is crucial that these terms be understood because they purport to establish the exceptions to the broad statutory prohibition on use or transfer of prescribing data. Possessors of prescribing data face *criminal* penalties if they release such information for a purpose the State decides does not qualify as one of these permitted activities. But how are pharmacies and insurers to know what is permitted? The statute purports to define what is a

"commercial purpose," but – contrary to the Attorney General's ill-informed and illogical arguments – the broad statutory definition encompasses many activities that do not involve pharmaceutical marketing, and that may or may not otherwise be considered "commercial."

According to the Attorney General, "any activity that could be used to influence or evaluate the prescribing behavior of an individual health care professional," the broadest component of the statute's "commercial purposes" definition, "relate[s] solely to the economic interests of the pharmacies and other entities that sell prescriber-identifiable prescription data for profit, and the pharmaceutical companies that use that information for marketing purposes. Any additional uses of the information by academic researchers, medical researchers, humanitarian organizations and law enforcement do not meet the definition of 'commercial purpose' and are therefore not restricted by the Act." Defendant's Memorandum at 28.[15] The statutory language belies that argument. Any activity that even "could be used" to evaluate or influence prescribing behavior meets the definition of "commercial purpose."

Moreover, it is impossible to understand the listed exceptions to the statutory definition of "commercial purpose." Does research conducted by a for-profit entity for commercial purposes qualify for the "research" exception? Is anyone who helps a physician better manage the care of one or many patients engaging in "care management"? Can pharmaceutical manufacturers conduct "utilization review" to assure appropriate use of their products? If not, why not? Are pay-for-performance programs prohibited from rewarding good prescribing

[15] The Attorney General also argues that most of the beneficial uses of prescribing data cited by the plaintiffs in their Complaint and preliminary injunction papers do not meet the statutory definition of "commercial purpose" (*see* Defendant's Memorandum at 5), but that is wrong. "Public safety news alerts," "sample medications," and communications about "innovations," "newly developed products," "life-prolonging information," "prescription drug recall programs," and "managed care's effect" (Complaint ¶ 31; Plaintiffs' Memorandum at 6-7) all "could be used to . . . influence . . . prescribing behavior of an individual health care professional." N.H. Rev. Stat. Ann. § 318:47-f.

practices, because the relevant performance data cannot be transferred? What does the exception for "as otherwise provided by law" cover? It is not even clear from the statutory language that the Board of Medicine or hospital peer review committees can use physician prescribing data "to influence or evaluate the prescribing behavior of an individual health care professional."

John Glaser, an expert in the healthcare industry in general and health information technology in particular, stated in his declaration that he "could not determine from the language of the statute whether [its] exceptions would apply to activities of organizations such as Partners HealthCare. . . . In essence, the statute contains provisions which appear to me to be self-contradictory and counter to the interests of the American people in improving the medical care that they receive. The contradictory language, if statute [sic] in Massachusetts, would cause us to cease our formulary, care management and utilization review activities." Glaser Declaration, ¶ 21. Moreover, Glaser explained, "[s]uch vague and ambiguous statutory language creates a serious threat that it not only will stop the uses of information that the Legislature intends to stop, but also numerous other uses of the information that the Legislature does not intend to stop. Many health care organizations are extremely risk averse and will exercise extraordinary care not to run afoul of legislation, such as the New Hampshire law, which imposes not only severe criminal penalties on violators, but also creates civil claims and authorizes class actions and punitive damages for violations." *Id.* at ¶ 22.

The Prescription Restraint Law is a criminal statute that utterly fails to inform those affected of what is permitted and what is prohibited, and thus it is fatally vague. *Reno v. American Civil Liberties Union*, 521 U.S. 844, 871-872 (1977); *Grayned v. City of Rockford,* 408 U.S. 104, 108-109 (1972). Moreover, its effect of stopping far more communication than the

Legislature apparently intended is yet another reason why it is unconstitutional. *Thompson v. Western States Medical Center*, 535 U.S. 357, 376-77 (2002).

2. As a Practical Matter, It Is Impossible to Make Bright-Line Distinctions Among Promotional, Educational, and Quality Improvement Activities.

The most obvious example of the overlap among promotional, educational, and quality-improvement purposes is informing physicians about new drugs. Of course, pharmaceutical companies want to sell their products, but physicians need to know when new drugs come on the market, because those new medications may be more effective, or have fewer side effects, or provide alternatives for patients who had adverse reactions to prior medications. As John Glaser of Partners HealthCare explained, "We use [prescribing] information to help educate doctors about breakthrough drugs that have become available and that may offer their patients better alternatives to the drugs that currently are being prescribed, drugs that are more cost effective than the drugs that are being prescribed and drugs that are safer than the drugs that are being prescribed." Glaser Declaration at ¶ 11.

In addition, "research using prescriber-identifiable prescription data can help pharmaceutical companies develop new drugs by showing how individual prescribers are using existing drugs. This information can help focus or alter healthcare research that is needed for development of other drugs." Declaration of Göran Ando in Support of Plaintiffs' Motion for Preliminary Injunction at ¶ 17. As Mr. Ando also explained, "it is difficult or impossible to distinguish between much of the 'health care research' that pharmaceutical companies do from marketing and promoting of pharmaceutical products." *Id.*

If a patient gets a new drug that works better for him or her, that is an improvement in patient care – and the information exchange process by which pharmaceutical companies learn

what new drugs are needed, and physicians learn what new drugs are available, is not an unmitigated evil to be thwarted by the Legislature.

By defining impermissible "commercial purposes" broadly to include use or transfer of prescribing data to evaluate or influence physician prescribing behavior, the New Hampshire Legislature has taken a nonsensical approach to the problems it purported to address. Its ill-informed, scattershot approach has outlawed beneficial healthcare quality improvement activities, and missed the mark entirely in aiming to ameliorate the perceived negative effects of pharmaceutical marketing to healthcare practitioners. Thus, the law is unconstitutional under *Central Hudson* and *Rubin*, *supra.*

3. Many Beneficial Organizations Derive Revenue From Their Efforts to Influence Physician Behavior at the Point of Care, Which Should Not Be Prohibited Because They Promote Better Patient Care.

"Commercial purposes" can and often do promote the public good. To be successful, businesses must earn money. Even nonprofit organizations need revenue that exceeds their expenditures in order to survive. Thus, organizations involved in developing and implementing quality improvement/health information exchange systems need and are entitled to derive revenue from activities that may be aimed at influencing physicians to prescribe new or different medications to their patients, or to avoid prescribing practice that could harm patients – because the patients will receive better care and better medical outcomes as a result.[16] *Amici* are such organizations, but there are also many others. The New Hampshire law hurts them and ultimately harms everyone by impeding accomplishment of their public-health goals.

[16] As expert John Glaser stated, "The health organizations in which I have been active recognize that both physicians and manufacturers can improve the quality of care to patients everywhere and increase their profitability by constantly improving the quality of the products and services that they deliver and that one very effective means of achieving this objective is through collection, analysis, and use of information about the prescribing practices of individual physicians." Glaser Declaration at ¶ 18.

V.
CONCLUSION

The law at issue here is bad medicine – literally and figuratively. This misdirected statute will harm the citizens of New Hampshire by depriving them of the patient-care benefits to be derived from appropriate exchange of patient-deidentified/prescriber-identifiable prescribing data, while the law will do nothing to increase protection of patient privacy or to remedy any perceived problems created by pharmaceutical marketing practices.

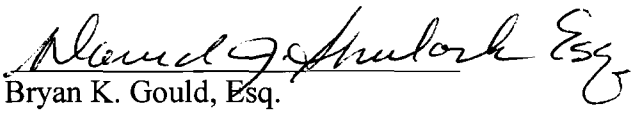
For all the foregoing reasons, the Court should grant the plaintiffs' Motion for Preliminary Injunction to prevent enforcement of the statute as to patient-deidentified/prescriber-identifiable prescribing data.

Respectfully submitted,

eHEALTH INITIATIVE, et al.

By Their Attorneys,
BROWN, OLSON & GOULD, P.C.

Date: November 30, 2006

By: 

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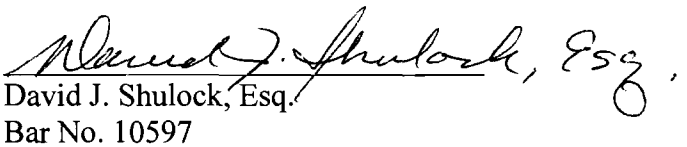
I hereby certify that the within document was this day forwarded via U.S. Mail, postage prepaid, to Patricia Acosta, Esq., Hunton & Williams, Barclays Financial Center, 1111 Brickell Ave., Ste. 2500, Miami, FL 33131, to Donald B. Ayer, Esq., Jones Day, 51 Louisiana Ave., NW, Washington, DC 20001-2113, to James P. Bassett, Esq., Orr & Reno, PA, One Eagle Sq., PO Box 3550, Concord, NH 03302-3550, to Craig S. Donais, Esq., Getman Stacey Schulthess & Steere, PA, Three Executive Park Dr., Ste. 9, Bedford, NH 03110, to Richard W. Head, Esq., NH Attorney General's Office (Consumer Protection), 33 Capitol Street, Concord, NH 03301-6397, to Stephen J. Judge, Esq., Wadleigh Starr & Peters, 95 Market St., Manchester, NH 03101, to Thomas R. Julin, Esq., Hunton & Williams, Barclays Financial Center, 1111 Brickell Ave., Ste. 2500, Miami, FL 33131, to Garry R. Lane, Esq., Ransmeier & Spellman, PO Box 600, Concord, NH 03302-0600, to Charles R. A. Morse, Esq., Jones Day, 222 East 41st St., New York, NY 10017-6702, to David A. Rienzo, Esq., NH Attorney General's Office, 33 Capitol Street, Concord, NH 03301-6397, and Jeffrey C. Spear, Esq., Orr & Reno, PA, One Eagle Sq., PO Box 3550, Concord, NH 03302-3550.

Date: November 30, 2006



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[18] Assented to Motion for Pro Hac Vice Admission is pending.