The Impact of Provider-Identifiable Data on Healthcare Quality and Cost

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Needless to say, the arguments made, implications drawn from interviews and discussions, and conclusions made in this study solely reflects the views of the authors.

Contents

Executive Summary and Key Findings

This study examines the uses of provider-identifiable data within the US healthcare system with particular emphasis on the impact of the commercial use of this data on the market for prescription drugs. Impacts on market structure, the operation of the market, and other non-economic variables are also addressed. Additionally, the study explores the role of these data in regulatory compliance and public research.

Provider-identifiable data serves a variety of purposes in the U.S. healthcare industry. These include the marketing of prescription pharmaceutical products directly to physicians, recruitment in clinical trials, efficient distribution of free samples, evaluation of quality of care, the practice of evidence-based medicine, assistance with drug recalls, and a range of public and private sector research purposes that assess performance and increase the transparency of the national healthcare system in ways that improve the provision of health services, promote and protect public safety, and foster research.

In 2006, lawmakers in New Hampshire banned the commercial use of provider-identifiable data. Proponents of the ban argued that the commercial use of provider-identifiable data violated significant patient and physician privacy rights and increased spending for prescription drugs.

Contrary to the claims of proponents who advocate prohibiting the commercial use of provider-identifiable data, we find :

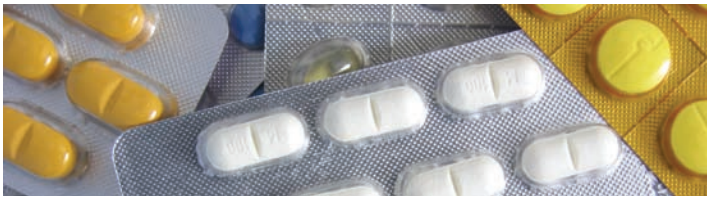
› **Access to provider-identifiable data serves as a price constraint.**
The ability of smaller and start-up companies to rapidly define and reach their market at a relatively low cost creates effective competition in the US pharmaceutical industry. A ban on the commercial use of provider-identifiable data would raise entry barriers by increasing search costs; this would deter new entrants and discourage investment in basic research and development. With reduced competition, larger firms would become further entrenched and have greater control over prices.

› **Provider-identifiable data reduces wasted physician time by reducing mismatches.**
These data enable pharmaceutical companies to focus their sales forces on physicians who are most likely to be interested in prescribing their drug. In the absence of this information, firms must either increase sales forces or market to physicians less likely to be interested in their drug, or both.

›› *If 10% of those current visits considered by physicians to be useful become useless as a result of mismatches, the costs without benefit in doctor time amounts to at least $1.4 billion annually. If 20% of these current visits become useless, these costs would amount to $2.8 billion in doctor time annually. And if 30% become mismatched, the costs increase to $4.2 billion annually.*

›› *If 10% of those current visits become useless as a result of mismatches, the lost time is equivalent to 7 million patient* visits. If 20% of these*current visits become useless, 14 million patient-visits in time would be lost annually. And if 30% become mismatched, 21 million potential patient visits would be lost.*

This excludes the costs to the pharmaceutical company. Increases in such costs resulting from these inefficiencies may be reflected over time in higher drug costs.



- **Banning commercial use of provider-identifiable data will not lower drug prices.**
  A study in Canada that compared bans on the marketing uses of prescription information with the ability to use these data indicated no impact on expenditures for prescription drugs.

- **Marketing appears ineffective in promoting the use of more expensive branded drugs if an equivalent generic is available.**
  Price differentials between the US and other countries for prescription drugs are reduced by 25% to 75% when generic drugs are included in the calculations. In 1984, generic drugs comprised 19% of retail pharmaceutical sales. By 2000, that figure had risen to 50%, and, by 2006, to 63%. In the top 10 selling drug categories, the share of the market captured by generics accounts for the majority of the market in 7 categories and continues to grow. More importantly, these price savings are accomplished rapidly, with recent introductions of generic equivalents achieving market penetration of up to 70% within three months, despite the marketing of brand-named drugs.

- **The use of provider-identifiable data helps to faster diffuse drugs that extend life expectancy.**
  The introduction of innovative new drugs increases average life expectancy by an estimated one week per year. The commercial use of provider-identifiable data allows new drugs to be introduced at a relatively faster rate in the US than in any other advanced economy. In the US, there are on average 19 new such drugs that are introduced each year and that represent significant improvements.

Overview of provider-identifiable data and its uses

Provider-identifiable data, also referred to as "prescription-level data", refers to information gleaned from the medical prescriptions written by physicians and other health professionals. This information includes the provider's identity, product information (including national drug code, dosing, strength, authorized refills, date), information on the pharmacy, the date the prescription was fulfilled, and HIPAA compliant patient demographic information. This information is appended with data on the provider: his or her name, address, specialty, and type of practice. No information that could identify the patient is collected, as directed by the Health Insurance Portability and Accountability Act and other applicable laws.

The information is extensive, covering the majority of prescriptions in the United States. IMS Health, the country's largest *health information organization* (HIO), collects, stores and legally sells and distributes provider-identifiable prescription information.[1] IMS Health receives information concerning more than 70% of prescriptions from retail pharmacies, including more than 90% of all chain pharmacies and nearly one-third of all independent pharmacies. This information is gathered from the central offices of pharmacy chains, providers of pharmacy management software, and from the pharmacies themselves. Additionally, provider-level information is also compiled from the data provided by prescription mail services, managed care and long-term care facilities, specialty retail outlets, and even food stores. Information is received from more than 115 data sources that gather prescription information from more than 37,000 pharmacies. Information is collected from over 75% of mail order outlets and more than 40% of all long-term care facilities, such as nursing homes. In all, information from approximately 57 million prescriptions is collected weekly and information from billions of prescriptions is maintained in a longitudinal database. (See figures in the Appendix for diagrams showing how HIOs collect and distribute these data.)

Provider-level information is used in concert with other data to project prescription sales from non-reporting stores. Using a combination of survey results from a sample of stores in the area, data from regularly reporting stores, and other factors such as store size, location and type, HIOs project pharmaceutical sales for most non-reporters.

[1] IMS Health Inc. offers hundreds of services and information-products that relate to pharmaceuticals and healthcare worldwide. Here, our interest is limited to provider-identifiable data.

It is important to note that the processes HIOs use to collect and validate the data is far from simple and add considerable value. At IMS Health Inc., for example, the data is standardized, and, crucially, validated at different stages. Inconsistent information is first inspected using patterns in the data and sent back to data providers for verification if all other methods prove ineffective. Provider identity is confirmed, and prescribers are matched to prescription data through other data sources. Provider specialization and location are confirmed through the use of information from various organizations such as professional associations, hospitals and state licensing boards. Third-party information service providers are used to establish the provider's identity when other avenues prove inconclusive.

The Health Insurance Portability and Accountability Act (HIPAA), the federal law which governs patient privacy, prohibits the provision of patient identifiable information to health information organizations, although a minimal level of patient information can be shared, notably year of birth and the first three digits of the patient's ZIP code. Patient identifiable information is not transmitted, and the automated information sharing systems of HIOs will not accept such information. However, an automated and highly encrypted process allows prescriptions over time to be matched to a specified albeit "de-identified" or anonymized individual.

The consequence of these steps is to ensure a very accurate and comprehensive picture of a central component of health care in the United States that at the same time protects the privacy of patients. A comparison with Medicaid and Medicare is instructive. In contrast to prescription information contained at IMS Health, for example, Medicaid's Statistical Information System covers information from approximately 17% of the American population, accounting for a far smaller share of prescription activity than the near universal sample found in the IMS database. Given its coverage of low-income families, this information is not representative of the American population. Similarly, Medicare Provider Analysis and Review (MEDPAR) data only cover 15% of the American population, although it captures a more representative sample than the Medicaid database. However, Medicare's prescription drug coverage is biased (in favor of its own formularies) and therefore does not paint an accurate picture of prescription patterns in the country. By contrast, the prescription information data systems of HIOs, covering more than 90% of prescriptions, provide a near-complete picture of many diagnoses, illnesses, and treatments for the American population as well as movements in the price of prescription pharmaceuticals—a key component of total health care costs in the country.

A 1992 study by the National Academies [2] on the National Health Care Survey examined the data needs for healthcare as the US entered the new century. The panel's report stressed the importance of data in order to evaluate and research the costs of, access to, and quality of healthcare in the country.

The report stated:

Data are needed to support analysis along each of the following dimensions:

> **Access:** there is need for information on the supply of health care providers (including information on numbers, distribution, and type) and the demand for and utilization of health care services by specific segments of the population...and by other characteristics such as health care insurance coverage status
>
> **Quality:** there is need for information concerning the health and functional status of the patient prior to and after treatment, the appropriateness of treatments or procedures provided, the degree to which health care providers resolve problems, and the satisfaction of the patient with the process.
>
> **Cost:** there is need for information on expenditures for health care services by type of provider, the cost of treatment for an episode of illness for a specific diagnosis; its distribution among provider types, and the source of payment for care provided, including how much is paid by insurance and how much is paid out-of-pocket.[3]

[2] The National Academies is made up of the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine and the National Research Council.

[3] Gooloo S. Wunderlich, ed., *Toward a National Health Care Survey*. (Washington, DC: National Academies Press, 1992) p. 63

The report encouraged the development of databases that would fulfill these purposes. The idea that a health information system has the potential to improve the performance of healthcare in the country and provide transparency remains. In August 2006, President Bush signed an executive order requiring federal agencies to share information on health care quality and price and to use information technology systems to allow the rapid exchange of this information. A decade and a half since the National Academies called for the development of a health information system, we have witnessed its progression in both the public and private spheres.

Provider-level information plays a pivotal role in improving patient access to newer and better drugs, improving quality of care, and, evidence suggests, even reducing prescription costs. Although the Center for Medicare and Medicaid Services estimates prescription drug expenditures at 10% of healthcare spending,[4] these amounts are nonetheless substantial. The varied uses of prescription-level information are relatively recent, and there is still great potential to use this information in order to research and monitor the national healthcare system. The continued use of these data reduces costs and improves quality of care, as was envisioned by the National Academy of Sciences 15 years ago.

Despite these clear benefits, recently passed and proposed legislation seeks to restrict the use of provider-identifiable data to non-commercial purposes. New Hampshire's new law (chapter number 0328) states:

> "Records relative to prescription information containing patient-identifiable and provider-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force."[5]

The prohibition against commercial use threatens the existence of critical databases maintained by HIOs such as IMS Health and Verispan, LLC.

There is no systematic evidence that pharmaceutical marketing as enabled by provider-identifiable information increases drug costs.

Proponents argue that privacy rights (patient and physician) will be advanced and healthcare costs reduced if commercial use of provider-identifiable data is banned. Contrary to these claims, our research of several academic health and economic article databases finds no systematic evidence to support the claim that pharmaceutical marketing as enabled by provider-identifiable information increases the costs of prescription drugs.

[4] Source: Center for Medicare and Medicaid Services, National Health Expenditure Data. "Table 2: National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Selected Calendar Years 1960-2005." http://www.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf

[5] An act requiring certain persons to keep the contents of prescriptions confidential. Chapter 328 of the New Hampshire Chaptered Law. www.gencourt.state.nh.us/legislation/2006/hb1346.html

We did find some anecdotal pieces from which generalizations would be unwarranted. Arguments of increased costs remain unsubstantiated and reflect a general naiveté of the likely consequences to healthcare costs and the quality of care if commercial use of provider-level data is banned. We take a careful look at these claims in what follows.

This report examines provider-level data that is collected and maintained by various HIOs and their uses by different sectors within the healthcare arena. We first closely examine private sector uses of the information, primarily for regulatory compliance, health, pharmaceutical, and epidemiological research, market analysis, and, most notably, marketing. Our findings indicate that not only are the relationships between the data and marketing poorly understood, but the impact of marketing as shaped by this information has also become the subject of many misconceptions.

We then examine uses of these data by the public, academic, and non-profit sectors. This information holds great promise for ensuring the continued high quality of healthcare and public safety in the United States. Currently, the information is underutilized in these arenas, but its use in research and monitoring of health and safety is increasing.

Finally, we examine the role these data play and promise to play in the healthcare system, especially in increasing transparency and monitoring of health, quality, access, and cost. In our conclusion, we examine the sector's efforts at self-regulation and attempts to address physician concerns about privacy through the American Medical Association's Prescribing Data Restriction Program (PDRP).

Private sector uses of provider-identifiable data and their impacts

For all the discussion of changes in the pharmaceutical industry and the rise of "excessive promotion," marketing costs borne by the pharmaceutical industry have remained relatively unchanged over the years. Between 1961 and 1978, the average ratio of marketing to sales was 12.1%. Between 1996 and 2000 the ratio rose to 14.5%.[6] These figures, however, include the cost of drug samples given away, valued at market prices. Taking this into account, the cost of samples account for over half the 14.5% figure. (See Table 1 below.) Between 1997 and 2005 the cost of marketing directed at physicians declined from 5.4% to 4.4% of revenues.[7] That is, by 2005, the cost of pharmaceutical representatives represented less than 5% of sales. Provider-level information is closely linked to the increasing use of samples and the slower growth of sale forces.

The private sector is the principal consumer of provider-level information. Prescription data is compiled by health insurance firms, managed care companies and HIOs (see Appendix). The former derive data from their own role in the purchase of prescriptions and provision of health services and use the data to monitor costs and develop drug formularies—or lists of approved drugs. HIOs, by contrast, purchase the data from pharmacies and the other suppliers of pharmaceuticals and sell the information after standardizing and verifying the information.

The process of standardizing and verifying the information is very complicated. Information on prescription orders from a substantial number of retail pharmacies, mail order outlets, and long-term care facilities is received by the HIO. The HIO then tracks, standardizes over 100 formats, and verifies the accuracy and quality of the information as needed through supplementary data sources such as the AMA and other associations, 3rd party data aggregators, through algorithmic procedures, and through verification with the supplier—and then transforms the information into a standardized usable file and deploys it for sales projections from non-reported outlets. Providers' records are bridged to create a meaningful prescription history. Outlet records are similarly bridged. This process, involving information from 57 million prescription transactions and hundreds of millions of data *elements is repeated weekly*. The fact that the whole process from start to finish is repeated with vast amounts of data every 7 days is one of the hidden infrastructural accomplishments of the information revolution and the health information sector it has spurred. The net effect is the construction of a near real-time data base of the prescribing and therapeutic patterns of nearly the whole of the United States. *In fact, HIO databases include the patient de-identified records of nearly 6 billion prescriptions, presenting a nearly complete drug and drug therapeutic history for the country.*

The private sector's use of the information is varied and the impact of these uses is extensive. Although the primary use of provider-identifiable information is for marketing, the information is also used by pharmaceutical firms in research, for regulatory compliance, and for continuing medical education. These data also play an important role in fostering competition in the pharmaceutical industry. All of these uses are discussed in turn below.

[6] Rosenthal, Meredith B, Ernst R. Berndt, Julie M. Donohue, Arnold M. Epstein, Richard G. Frank. "Demand Effects of Recent Changes in Prescription Drug Promotion." The Kaiser Family Foundation, publication 6085, June 2003. www.kff.org.

[7] The figures presented were calculated from: Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2006 (http://www.phrma.org/files/2006 Industry Profile.pdf), used for industry revenues and the GAO, "Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising," (Washington, DC: Government Accountability Office, November 2006) p. 13. http://www.gao.gov/new.items/d0754.pdf, used for the marketing figures. Includes costs of office- and hospital-based promotion to physicians and journal advertising by PhRMA member companies. Does not include other spending, such as events, or on targets other than physicians. Figures do not include non-PhRMA companies (although PhRMA accounts for almost all of prescription drug promotion) or data aggregator spending.

Provider-Identifiable Data, Prescription Drug Costs and the Pharmaceutical Market

The prevalent image of the commercial use of provider-identifiable data is one where physicians are identified according to their specialty and prescribing patterns by pharmaceutical sales representatives. These sales representatives then promote their drugs when visiting selected physicians. (Prescription patterns are also used to benchmark the effectiveness of these sales strategies.) A *New York Times* article paints a cynical picture: "Armed with such data, a drug sales representative can pressure a doctor to write more prescriptions for a name-brand medicine or fewer orders for a competitor's drug."[8]

Provider-identifiable data are used in pharmaceutical marketing as a means of *lowering* the costs of promotion. Simply put, focused marketing directs goods and services towards those who are most likely to be interested in them, such as high prescribers who prefer pharmaceutical therapies. The data *is* used to develop messaging and judge the appropriate frequency of contacts. In the case of pharmaceuticals, samples are provided to those physicians who most need to evaluate the drug in practice. And perhaps most importantly, provider-level data are used to efficiently disseminate new information about drugs to physicians (e.g. results of recent clinical trials).

Pharmaceutical firms use the data to "match" their product to physicians whose areas of specialization indicates a possible interest. The data is used in this way to support sales activities. It is also used for marketing research, as well as for sales management and monitoring the effectiveness of sales strategies, compensation for representatives, message development and message targeting, and tracking market share and thereby return on investment.

These seemingly simple uses play a significant role in expediting diffusion of new drugs and enabling new entrants and competitors to challenge larger and more established firms. How new drugs are adopted through the use of provider-identifiable data and the consequences of the specific patterns of diffusion are sources of controversy and misunderstanding. How these uses impact the market structure of the pharmaceutical industry and, in turn, innovation, competition and prices are altogether overlooked by those who favor banning the commercial use of provider-level data.

The issue of promotion in the pharmaceutical industry has been extensively explored. Kieth Leffler examined the economics of prescription drug marketing more than 25 years ago in the wake of similar debates about pharmaceutical promotion.[9] He pointed out that some of the first products advertised were medicines, and that concerns about pharmaceutical marketing raising drug prices are by no means new. In 1958, testimony before a Senate subcommittee argued that uninformative and misleading drug marketing was responsible for high drug prices.

Leffler felt that sales representatives have a compelling incentive to provide useful and accurate information to doctors so that they can continue marketing drugs to these clients. In addition to education and promotion, sales representatives provide goodwill and relationship management. Their visits give doctors opportunities to ask questions. Newer drugs, which are likely to generate more questions, are more likely to be promoted through drug representatives, whereas older drugs are promoted in ways that "remind" doctors of their existence, such as journal ads.[10] This is especially the case with drugs that are nearing patent expiration and/or where they are established in the market. Once drugs go off-patent, they become open to generic competition and marketed less.

[8] Stephanie Saul, "Doctors Object to Gathering of Drug Data." *The New York Times*. May 4, 2006. www.nytimes.com/2006/05/04/business/04prescribe.html?ex=1168750800&en=c209b0c8e9963f56&ei=5070

[9] Keith B. Leffler, "Persuasion or Information? The Economics of Prescription Drug Advertising." *Journal of Law and Economics*, 24 (1981)

[10] At the time Leffler found that the average age for the top 15 drugs marketed by sales reps was 5.2 years in 1977 and for the top 15 drugs advertised in journals it was 9.9 years. Keith B. Leffler, "Persuasion or Information? The Economics of Prescription Drug Advertising."

Information or Coercion? Sample Distribution, Office Visits and Education

Opponents of the commercial uses of provider-identifiable information make a number of claims about the inappropriateness of visits by pharmaceutical representatives. They argue that these visits, as enabled by provider-identifiable data, "pressure" physicians into prescribing drugs. They make the further claims that : (1) office promotion provides little informational value; (2) the promotion of many of these new drugs adds little value to medical practice; and, (3) promotions drive up prescription drugs costs beyond that which is warranted by their contribution to health outcomes.

First, and perhaps more seriously, pharmaceutical representatives are accused of providing information that is less reliable and comprehensive than other sources. Second, marketing gifts are seen as creating a sense of social obligation among physicians.[11] Each of these two accusations—distortion and coercion—must be closely examined.

Informing physicians v. distorting information: With the exception of samples, the most significant source of promotional expense is the cost associated with sales representative visits to physicians' offices. The aggregate cost of these visits amounts to nearly one-half of the retail value of samples provided by the industry.[12] *As a share of the total cost of promotion, however, direct sales calls to physician have declined during the past decade—from 36.8% of total marketing costs in 1998 to 28.2% in 2004.* This trend is expected to continue and even accelerate as media sources such as the Internet replace sales visits.[13] Recent and dramatic cuts in sales personnel by Pfizer seem to bear out this trend. In December 2006 Pfizer announced that it would reduce its 11,000 person sales force in the US by 20%; [14] in January 2007 the pharmaceutical giant announced it would implement a 30% reduction in its sales force outside of the US.[15] Competitive market forces, not legislation, appear to be reducing sales visits.

Physician "matching" v. coercion: Data are used to identify physicians who are most likely to be interested in a particular drug, based on their specializations and tendency to be early adopters. This practice is at odds with the image of pharmaceutical representatives as directing, shaping and "coercing" physician behavior. If this were true, identification of specific physicians would be less important than persuasion (through gifts, pressure, pro-drug information, etc.), and pharmaceutical firms would *make* prescribing patterns rather than expending considerable resources *finding* appropriate matches. The *use of these data* by pharmaceutical firms suggests instead that their products are being matched with physicians who are interested in pharmacological therapies. Strategy can vary from firm to firm. For example, physicians who prescribe a firm's drugs already may not be visited, but those who prescribe a competing drug in the therapeutic category may be chosen for visits.

[11] Note that other "gifts" such as dinners do not require the use of provider-identifiable information. Self-regulation by the industry has also reduced gifts to educational luncheons and dinners.

[12] The industry is, of course, evolving, as it often does. For example, vouchers that can be exchanged for drugs are increasingly replacing sample disbursement. Of course, provider-identifiable information is still necessary to identify to whom vouchers should be given.

[13] The relative share of direct-to-consumer marketing expenditures has certainly risen of late as a result of recent changes to the federal regulations guiding television advertising. GAO, "Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations." GAO—03-177 (Washington, DC: General Accountability Office, 2002) http://www.gao.gov/new.items/d03177.pdf

[14] Kevin B. O'Reilly, "Will Industry Follow Pfizer Lead on Drug Rep Cuts?" *American Medical News*, December 25, 2006. www.ama- assn.org/amednews/2006/12/25/prl21225.htm

[15] Shannon Pettypiece, "Pfizer May Reduce Spending on Workforce, Research (Part 2)." *Bloomberg.com*, January 11, 2007. http://www.bloomberg.com/apps/news?pid=20601087&sid=aTJCkryWln.Y&refer=home

Physician attitudes toward visits by pharmaceutical representatives vary considerably. A meta-analysis of 29 surveys of physicians and residents about their attitudes towards the marketing practices of the pharmaceutical industry by Ashley Wazana published in *The Journal of the American Medical Association* revealed a great degree of variation.[16] The lower and upper bounds of responses among these surveys that agreed with the question whether gifts were inappropriate were 4% and to 88% respectively. Interestingly, the lower bound of responses that agreed that gifts influence behavior was 8% and the upper bound was 13%.[17]

Biased information is, of course, the more serious claim regarding influences on prescribing behavior. Physicians largely believe that the point of visits is to promote a specific drug. One survey found that only 19% of physicians viewed pharmaceutical representatives as having adequate knowledge of alternative treatments, and various surveys have found that only 20% to 35% view representatives as having adequate knowledge overall. [18] Another survey found that only 44% of physicians find pharmaceutical representatives "credible." [19]

The various claims are at odds with one another. Majorities to large majorities of physicians believe that interactions with pharmaceutical representatives influence behavior. Pharmaceutical companies continue to prosper, hence the expenditure. Yet significant majorities of physicians are skeptical about the information provided by sales representatives. Given this, the question becomes: "What is the source of pharmaceutical rep influence?" And there is ample evidence supporting the notion that information provided by sales representatives—and not gifts or paid lunches—increases the market share of a drug.

Whether information from pharmaceutical reps increases sales of particular drugs is the source of considerable debate. At the heart of the debate is whether physicians are informed by pharmaceutical promotion or whether interactions with pharmaceutical sales representatives lead them to behave irrationally. The fact that doctors believe sales representatives provide partial and less credible information and at the same time believe that visits by representatives influence prescribing behavior is not evidence of irrationality. With a new drug, sales representatives and clinical studies are the earliest available information. Early adopters rely on

[16] Ashley Wazana, "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift." JAMA. 283 (January 19, 2000). pp. 373-380.
[17] Ashley Wazana, "Physicians and the Pharmaceutical Industry." p. 377. Also on surveys that used a Likert Scale, the lower bound was 1.6 and the upper one 1.8, where 5= "strongly agree", 4= "agree", 3= "neutral", 2= "disagree" and 1= "strongly disagree". It should be noted that some surveys show that 8% of physicians remember any particular pharmaceutical visit, and recall is necessary for reciprocity. John Mack, "Marketing's Role in Limiting Physician Access."
[18] Ashley Wazana, "Physicians and the Pharmaceutical Industry." p. 377.
[19] Source: Manhattan Research Physician Health Media Study, June 2002, cited in John Mack, "Intelligent Online Sampling Strategies." pp. 13-15. Pharma Marketing News, Special Supplement: Increase Physician Access and Detailing Effectiveness. p. 14, 2005. It should be noted that there are different types of representatives, some which are sales focused and others that are associates that discuss the health and science issues in more detail.

the information available from representatives and sample testing for themselves . Over time, as additional information becomes available, they rely less on sales representatives. However, *there is evidence that effective, therapeutically useful medications may be under-used if they are not adequately marketed*.[20] C.G. Suresh, et al. found that pharmaceutical marketing increased the use of the nucleoside adenosine for rapid heart rates much more than postgraduate education through peer group journals.[21] This can suggest two things: (1) marketing can increase sales; and, (2) information from academic sources, such as journals, and peers may be insufficient to effectively and rapidly disseminate vital performance information on even well regarded innovations.[22]

As additional treatments enter the market, a separate dynamic comes into play illustrated by this anecdote. An interview with one pharmaceutical sale representative revealed that at least one firm found themselves responding to biased (incomplete) information on a therapeutic treatment presented by a competitor.[23] Using provider-identifiable data, they noticed a sudden change in prescriptions away from their drug. In response, they reached out to physicians to explore the reason for the shift and provide a more complete picture of their drug. What holds true locally when one representative promotes a drug in a specific therapeutic class using biased and incomplete information need not hold true globally. *Some, perhaps even most, representatives may provide incomplete information, but the pool of pharmaceutical representatives in a therapeutic line comes to provide, in the aggregate, a more complete picture*. That is, a physician gets a more accurate and global picture of treatments as different representatives provide additional information on therapies offered by their firms. They are able to do so, substantially as a result of provider-identifiable data.

Prescription-level data and the distribution of samples: Provider-identifiable data allows pharmaceutical marketers to allocate valuable samples to physicians who would be most likely to prescribe them for patients. Samples are an essential part of both marketing and therapy. Samples allow physicians to try and evaluate new treatments without having to prescribe a full course (insurance usually requires 30-90 day cycles for many prescriptions and does not determine co-pay by the size of the prescription). Samples also allow doctors to "fine tune" treatments by determining whether individuals experience adverse reactions, calibrating dosage, and evaluating the claims of the pharmaceutical representative without having the patient purchase the drug.[24]

> A greater share of physicians believe that they receive too few samples than believe that they receive too many.

It should be noted that provider-identifiable information is not used for the provision of samples only through sales representatives. With only 43% of pharmaceutical representatives ever getting past the receptionist and only 36% of samples delivered to the physician directly, according to some studies, provider-identifiable information is not used to determine specific physicians to whom to direct mail samples.[25]

[20] C. G. Suresh, D. Greene, and M. O. Coupe, "Use of adenosine and effectiveness of pharmaceutical marketing." *Lancet*. 341. 1993.
[21] C. G. Suresh, D. Greene, and M. O. Coupe, "Use of adenosine and effectiveness of pharmaceutical marketing."
[22] It should be noted that a lot of activity by pharma representatives directly support education, e.g., providing articles, sponsoring educational lectures, and bringing experts who provide in-service education.
[23] Interview with anonymous pharmaceutical sales representative.
[24] Interview with Ruth Szmarag, M.D. Conducted November 7, 2006.
Rate of pharmaceutical representative-physician face to face interactions from "The Accel Report: Through Our Customers' Eyes", cited in John Mack, "Marketing's Role in Limiting Physician Access." *Pharma Marketing News, Special Supplement: Increase Physician Access and Detailing Effectiveness*. p. 4, 2005. Sample delivery figures from IMS Health Inc., cited in John Mack, "Intelligent Online Sampling Strategies." *Pharma Marketing News, Special Supplement: Increase Physician Access and Detailing Effectiveness*. 2005. p. 13
[25] Rate of pharmaceutical representative-physician face to face interactions from "The Accel Report: Through Our Customers' Eyes", cited in John Mack, "Marketing's Role in Limiting Physician Access." Pharma Marketing News, Special Supplement: Increase Physician Access and Detailing Effectiveness. p. 4, 2005. Sample delivery figures from IMS Health Inc., cited in John Mack, "Intelligent Online Sampling Strategies." Pharma Marketing News, Special Supplement: Increase Physician Access and Detailing Effectiveness. 2005. p. 13

Doctors use samples to evaluate new drugs. 25% of physicians require samples before they prescribe a drug so that they can evaluate the drug's impact first. To a lesser extent, samples are also used to assist patients who cannot afford drugs, with 29% of samples being dispensed to indigent patients and 13% to elderly ones. (Many pharmaceutical firms run patient assistance programs that provide free medicine to low-income patients.) In fact, a larger share of physicians (70%) believe they should receive more samples than those who feel that they receive too many (40%).[26] (There is good reason to believe that this mismatch would increase without access to provider prescription patterns.) [27]

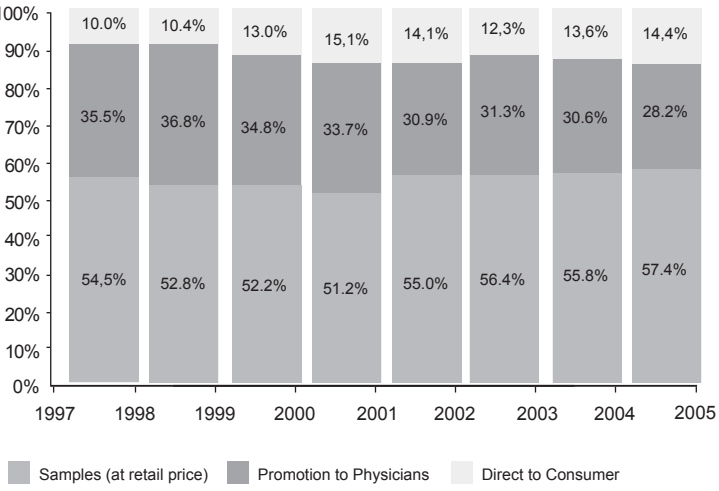


Figure 1: Expenditure on Prescription Drug Promotion (by Category 1997-2004)[28]

Expenditures on samples, measured in terms of their retail price, have grown substantially. Between 1997 and 2004, these expenditures increased by an average of 13% annually while expenditures on promotion to physicians (sales force, journal advertising, expenditures, etc.) grew at 9%. In fact, it should be noted that many figures on promotional expenditures, as a share of total pharmaceutical sector costs, include the retail price of samples. As the chart below indicates, samples account for the largest component of promotion.

The Value of New Drugs and Pharmaceutical Promotion

One of the principal functions of provider-identifiable information is support for the rapid introduction of new drug therapies. Opponents of the commercial uses of provider-level data object to this effect, claiming there are few real benefits, *on the whole*, to new drugs and their speedier introduction. They argue that the use of this information to promote new drugs simply adds costs without improvement in patient outcomes. According to this view, the billions spent on research and development each year result in a slight tweaking of existing drugs (or ones which have little benefit over existing drugs). Anti-cholesterol drugs are, by this account, the exception rather than the rule.

[26] John Mack, "Intelligent Online Sampling Strategies." p. 13

[27] The industry is, of course, changing. Alternative methods of providing samples—e-detailing, or web-based detailing, and the use of vouchers that can be redeemed at pharmacies, are becoming more prevalent. These nonetheless require provider-identifiable data for better segmentation, especially if these are to become fuller substitutes to office visits. Interview with Scott Rose, Director, Sales Force Incentives and Business Reporting, Eli Lilly and Company, January 18th, 2007.

[28] Source: PhRMA and IMS Health Inc.

While it is easy to anecdotally point to instances of new drugs that offer little value beyond existing ones (although many dimensions such as frequency of dosage have to considered), the issue of whether new drugs *on average and/or in the aggregate* offer little benefit cannot be so evaluated. Furthermore, the question of whether even "me-too" drugs offer no benefit is unclear. It is well recognized that any individual drug, regardless of its value, works only in a percentage of eligible patients. It is only with the availability of other therapeutic options that the majority of patients can be effectively treated. If new drugs bring new benefits then their speedy introduction brings these benefits sooner; in this way the *commercial* uses of provider identifiable data play a critical and positive role in the health of Americans. Thus deeply implicated in these debates are two related questions: What exactly is provider-identifiable information being used to diffuse? And what are the consequences of the diffusion of these drugs?

What Makes a New Drug New? : The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research breaks down new drug applications (NDAs) approved by calendar year (1990-2004) according to therapeutic potential and type of chemical innovation.[29] Therapeutic potential is divided between "priority review" and "standard review," where "priority review" indicates the new drug "represents a significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease." "Standard review" indicates that the new drug "appears to have therapeutic qualities similar to those of one or more already marketed drugs." With no apparent trend over the time period, priority review drugs account for around 23% of the NDAs and, also with no apparent trend over time, this amounts to a little over 19 new drugs a year. These therapeutic potentials, of course, are estimates that may never be realized or that may be surpassed. Although many new drugs are classified as minor innovations, it is impossible to conclude from these data that those NDAs that are ultimately subject to "standard reviews" were intended by the pharmaceutical company to be a minor innovation. In fact, the research and development process is unpredictable, and many leading drugs fail to reach the marketplace. For this reason, and due to research shared in peer-reviewed publications early in the research process, various alternatives are simultaneously in development. This accounts for the flow of competing products that follow a break-through product.

Basic research conducted with the intention of generating a revolutionary new product may only yield so-called minor innovations or, worse yet, no measurable results at all. This is part of the risk associated with pharmaceutical innovation in general. Developing new drugs for specific treatments is a very risky business. In some cases, drugs developed not only show little benefit in drug trials but actually exhibit more harmful effects than beneficial ones. An unfortunate example of this is the drug torcetrapib developed by Pfizer to treat heart disease at a cost of nearly a billion dollars. Due to deaths in clinical trials among those taking the drug, it was abandoned in 2006 and written off as a complete loss.[30] And similarly, in the case of research to treat Alzheimer's disease, decades and billions of dollars have resulted in only a small number of products.

[29] See http://www.fda.gov/cder/rdmt/pstable.htm
[30] Alex Berenson and Gardiner Harris "End of Drug Trial Is a Big Loss For Pfizer and Heart Patients" New York Times, December 4, 2006

When the NDAs are broken down by type of chemical innovation, around 34% are classified as a ?new molecular entity.?[31] But again, this does not translate to 34% of pharmaceutical research aiming to develop "new drugs" and the remaining 66% aiming to modify already existing drugs. More radical innovations are likely to be costlier, requiring more research and development resources. Also, major innovations are likely to be riskier and hence less likely to survive to the approval stage, as seen in the *torcetrapib* case.

In short, the majority of new drugs actually approved are not new molecules expected to offer revolutionary improvements over existing treatments. The proportion of significant breakthroughs to total innovations for the pharmaceutical sector may well be greater than for other sectors. With the total number of patents granted by the United States Patent Office well over 200,000 a year, it is unlikely that more than a small fraction of these innovations represent significant breakthroughs.[32] Or, more comparably, we could think about what proportion of new products brought to market in other sectors represent significant breakthroughs.[33]

It is also important not to dismiss the 77% of new drugs approved that are classified as having "therapeutic qualities similar to drugs on the market" as adding little or no real benefit. Many of these drugs are referred to as "me-too" drugs. One effect of the introduction of such drugs may be to increase competition for an existing drug. Dr. Henry Grabowski, a Duke University economist who has long studied the economics of the pharmaceutical industry, notes that the introduction of such drugs gives large purchasers of drugs—such as governments and insurance companies—leverage when negotiating with pharmaceutical companies.[34] He also *notes that just because a drug is first in class doesn't make it best in class. That is, a "me-too" drug may be more effective than the original drug in its class*. In the case of statins for hypercholesterolemia, a follow-up product to the market innovator quickly achieved and sustained market leadership.

When drugs are said to be therapeutically similar they are similar in the aggregate. Two drugs could be regarded as therapeutically similar if they, for instance, both lower cholesterol in 50% of patients. However, the individuals in the 50% taking the first drug could be different than the 50% taking the second drug. Optimally, we could get an effectiveness of 100% if those not affected by the one drug are affected by the other. If the effect is independent and random in the two cases we could see 75% of the patents positively affected by using some combination of the two drugs.

[31] The other classifications being: new ester, new salt, or other noncovalent derivative; new formulation; new combination; new manufacturer; new indication; and drug already marketed, but without an approved NDA.
[32] For counts of US patent applications and patents granted see www.uspto.gov/web/offices/ac/ido/oeip/taf/ h_counts.htm
[33] For counts of US patent applications and patents granted see www.uspto.gov/web/offices/ac/ido/oeip/taf/ h_counts.htm
[34] Interview with Henry Grabowski.

And, most pessimistically, if the two drugs are therapeutically identical at the individual level, we would see only 50% positively affected. The extreme cases are unlikely. It is more reasonable to assume that the addition of a "me-too" drug to a class of similar drugs raises the treatment potential of that class of drugs by some degree. Actually quantifying the total benefits to patients of additional drug choices in a class could be difficult as the benefits include such nebulous gains as preferring the side effects of one drug over another. But these gains are very real to individual patients. Crawford and Shum, who explored the problem of matching the right anti-ulcer prescription drug to the right patient, found that there are substantial differences in drug efficacy among the anti-ulcer drugs across patients.[35] Chintagunta, Jiang, and Jin, who explored doctor and patient learning among different cox-2 inhibitors, also found that learning which drugs in a class are right for them is important to patient satisfaction.[36]

It would be surprising if there were not *some* new drugs introduced and marketed that held little benefit or were even inferior compared to existing drugs Undoubtedly there are instances of for-profit pharmaceutical companies that develop drugs without any real benefits to consumers solely to enter a lucrative market. However, it would appear that, overall, new drugs brought to the market should not be simply viewed as little different from existing drugs with demand only induced by marketing. But what are the benefits of new drugs and are they worth their costs?

Are New Drugs Worth the Price? There is little question that retail prices of new drugs are higher than existing drugs, especially generics. The important issue is whether the net benefits of newer drugs are greater than the net benefits of existing drugs. The question has been explored in the scholarly literature using econometric techniques.

[35] Gregory S. Crawford and Matthew Shum. "Uncertainty and Learning in Pharmaceutical Demand," *Econometrica*, 73n4 (July 2005), 1135-1174.
[36] Pradeep K. Chintagunta ,Renna Jiang,Ginger Z. Jin "Patient Learning and Advertising in the Diffusion of Cox-2 Inhibitors"

Frank Lichtenberg's work captures the value of some of the benefits of new drugs.[37] Specifically, he analyzed data from the 1996 Medical Expenditure Panel Survey (MEPS) to investigate the relationship between the age of drugs prescribed to treat specific conditions and outcomes, including mortality, morbidity, and total non-drug medical expenditures. The morbidity measures included whether an individual missed work or school or spent days in bed due to a condition for which a drug was prescribed. In addition to controlling the condition for which the drug was prescribed, several other factors were controlled for. These included year that the condition began, number of conditions the patient had, patient age, income, education, race, gender, sex, whether the patient was covered by Medicare, Medicaid, or private insurance, and percentage of prescription costs self-paid. In addition, the impact of drug age on morbidity and non-drug health expenditures was also assessed in a second set of calculations using individual fixed effects. In this way, the effects of drug age were estimated from the variations within individuals (who have more than one drug-treated condition) instead of across individuals. This approach, essentially, holds the individual constant and controls for all individual specific factors. The benefits of newer drugs—greater patient choice, decreased workdays lost, increased workforce participation, lower non-drug medical expenditures, decreased mortality, and increased quality of life—significantly exceed their costs.

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On average, Lichtenberg found the amount paid for prescriptions declines with the age of the drug prescribed.[38] In simpler words, newer drugs are more expensive. His research also found a statistically significant positive relationship between mortality and the age of drug but little relationship between either school days lost or days in bed and the age of the drug. Although a positive and highly statistically significant relationship was found between workdays lost and the age of the drug, the effect was not large.[39] But this research did establish that newer drugs bring benefits.

In contrast, Lichtenberg's subsequent study reported both a statistically significant and practically significant relationship between either hospital stays or non-drug spending to treat a condition and the age of the drug used to treat that condition. That is, those using newer drugs to treat a condition had significantly fewer hospital stays for that condition.

[37] Frank R. Lichtenberg, "Are The Benefits Of Newer Drugs Worth Their Cost? Evidence From The 1996 MEPS." Health Affairs. Sept./Oct. 2001.
[38] Frank R. Lichtenberg, "Are The Benefits Of Newer Drugs Worth Their Cost? Evidence From The 1996 MEPS."
[39] An example given is that for the an $18 increase in the cost to a newer drug to be worth it fewer workdays lost, each work lost episode would have to cost $4,500.

The total cost savings from these non-drug efforts associated with replacing a 15 year-old drug with a 5.5 year-old drug were estimated to be around $72, or 4 times the additional cost of the newer drug.

Later studies established further and greater benefits. Lichtenberg later looked at drug treatment for 47 major chronic conditions and conservatively estimated that the benefits of using newer drugs (less than 18 years old as of 1996) on increased ability to work and fewer days lost to work was over twice the cost of the newer drugs.[40] The vast majority of this benefit was due to increased ability to work (workforce participation) rather than the benefit from fewer workdays lost.

In another study, Lichtenberg examined data comparing the average age of death by condition across 52 countries over a 20-year period, from 1982-2001.[41] Using data from IMS on new drug launches,[42] age of death[43] for condition *i*, year *t*, and country *j* were compared to the number of drugs available to treat condition *i* in year *t* and country *j*. Other potentially influential factors were controlled for, such as average education, income, environmental quality and nutrition for country *j* and year *t*. *In this study Lichtenberg found that the introduction of new drugs was associated with an increase in the average annual life expectancy of one week per year.*[44]

By extrapolation, using per person expenditures for drugs among OECD nations in 1997, the author estimated that the pharmaceutical cost for an additional year of life to be about

[40] Frank R. Lichtenberg, "Availability of New Drugs and Americans' Ability to Work," *Journal of Occupational and Environmental Medicine*, Volume 47, Number 4, April 2005.

[41] Frank R. Lichtenberg, "The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data from 52 Countries, 1982–2001," International *Journal of Health Care Finance and Economics*, 5, 47–73, 2005

[42] Specifically, launches of new chemical entities are considered.

[43] Due to availability of data in the WHO mortality database, the proportion of deaths occurring at age 65 or over for condition i is used as a proxy for average age of death for condition i.

[44] The initial figure estimated directly from the models actually amounts to 3 weeks, but due to an inability to control for the impact of non-pharmaceutical medical advances for a given condition on mortality, which may be correlated with the drug advances for that condition, the author makes the following "correction". Since pharmaceutical research and development accounts for a third of total medical R&D, the author attributes only a third of the new drug effect to the new drugs. This estimate will tend to understate the actual impact of new drugs relative to other medical advances to the extent that (1) a dollar of research and development spending by pharmaceuticals is more effective at reducing mortality than is a dollar of other medical research and development spending or (2) the less correlated (than perfectly so) are drug advances and non-drug medical advances.

$6750. This, he pointed out, is far lower than estimates of the value of an additional year of life. It is safe to say the value of an additional year of life is several times this estimated cost.[45]

Another interesting result from this study was that the full benefits of the new dugs were not realized until three years after their introduction. The author hypothesized that this lag effect reflects the average diffusion time it takes for a drug to be fully adopted following its introduction.

Taken together, the benefits of newer drugs in the forms of greater choices to patients (preferences over side-effects), decreased workdays lost, increased workforce participation, lower non-drug medical expenditures, decreased mortality, and increased quality of life seem to greatly exceed the cost of the newer drugs.

The Question of Prescription Choices and Drug Prices

Much of the objection to the use of provider-identifiable information for marketing is the claim that this use drives up prescription prices. Among the principal pieces of evidence offered in support are international comparisons of prescription drugs expenditures. Research by Danzon and Furukawa raises doubts about the methodology behind these comparisons and in so doing points to a crucial but overlooked component of US prescription patterns.[46] Their research showed that previous work comparing US drug prices to prices in other nations was seriously flawed in focusing on price difference of branded products and excluding generic drugs, which are priced differently as a result of not bearing the costs of research and development, marketing, or regulatory approval, as well as facing competition from imports. Nor did these studies adjust for income and price levels. These issues are directly related to the question of the commercial use of provider-identifiable information for they: (1) specify the economic and competitive landscape in which brand name drugs are diffused through detailing; and, (2) directly challenge the claim that the use of this information raises overall drug prices by coercing prescribers.

Generics—both their effect on overall prescription drug prices and their selection through formularies, which show the limits of prescription choice—are important when considering the impacts of provider-identifiable information on the commercial diffusion of drugs. Many studies that have reported American drug prices to be much higher than those found elsewhere have not included generics. As generics will account for 60% of the volume of US drug sales in 2007, omitting them from the price comparisons could easily distort the true picture of the drug markets.

[45] W. Kip Viscusi. "The Value of Life." Discussion Paper No. 517. Harvard Law School. June, 2005 explores many estimates of the value of a statistical life for the US and other countries. For the US, the median value of a statistical life was $7 million (in 2000 dollars). If we crudely divide this by the average life expectancy, around 77 years, we come up with a figure of around $90,000 for a year.

[46] Patricia Danzon and Michael Furukawa, "Prices and the Availability of Pharmaceuticals: Evidence from Nine Countries." *Health Affairs*. October 29, 2003. http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1.pdf

Danzon and Furukawa accounted for generics in their international comparison of drug prices. (The authors also compared prices of over-the-counter (OTC) medications as well as quantities of drugs used broken down by age of the drug.) The 1999 data they used included Canada, Chile, France, Germany, Italy, Japan, Mexico, the UK, and the US. The prices used were the manufacturers' prices, including discounts (that is, not retail prices). Drug price indices for the countries broken out between branded (on-patent) drugs and generics indicated large relative differences among the countries between the two types of drugs. The price indices for the branded (on-patent) drugs were between 25% and 40% lower than the index for the US, except for Japan, which had higher prices. The price indices for generic drugs, on the other hand, were all higher than the US index, except for Canada, which had slightly lower generic prices.

When taken together, the price index including both on-patent and generic drugs indicated that compared to the US, prices were between 6 and 33% lower in the other countries, except for Japan which had higher prices. The authors also found these price differences among drugs to generally be smaller than those for other medical services. *But when the authors considered drug prices as a portion of per capita income, only France had lower drug prices relative to incomes compared to the US.* For over-the-counter (OTC) drug prices, US prices were considerably lower than those for the other countries. The authors attributed the lower generic and OTC drug prices in the US to greater competition.

Danzon and Furukawa also compared per capita quantities of drugs consumed by drug age. The differences in consumption patterns relative to the US were most striking for newer drugs. For drugs introduced within 2 years of the study, Germany had the greatest consumption relative to the US at 58% of US per capita consumption. France followed with 44%, then the UK at 32%, and Canada with 26%. For drugs introduced between 2 and 5 years of the study, the relative consumptions were France with 91%, followed by Germany with 72%, then Canada with 65%, and Italy with 44%. *The US adopts newer drugs at a significantly faster rate than do the comparison countries.*

The results indicated that compared to consumers in other countries, US consumers do seem to face higher prices for branded (on-patent) drugs. However, US consumers have access to generic drugs at lower prices. And *when differences in per capita income are 'controlled for,' that is when drug prices are considered as a proportion of average national income, the researchers concluded that US drug prices as a share of income are lower than prices in 7 of the 8 comparison countries.*

As claimed, the use of generic drugs in the US raises an important issue that impacts the alleged consequences of provider-identifiable data. The rise in the use of generics is partly due to the use of generic "defaults" by doctors and insurance formularies. That is, prescriptions often specify that a generic must be

prescribed if one exists, and insurance companies, eager to hold down costs, often channel prescriptions towards generics. Generics both limit physicians' influence on prescription choices and pharmaceutical representatives, whose customers have limited input in purchasing decisions. More importantly, these issues do not address the limits of using brand prices as a barometer of drug costs; with brand drug prices shaped by formularies, only a minority of consumers pays retail prices, a fact which speaks to their poor role as a measure of prescription drug costs.

It should be noted that not only do generics play a crucial role in the prescription drug market, but their share of the prescription drug market has also been steadily increasing for decades, as shown in Table 1. In addition to the volume growth, generic drug sales increased from 14.7% of the dollar value of all retail prescription drug sales in 2001 to 19.5% of the dollar value of all retail prescription sales in 2006.

course, puts a great deal of downward pressure on prices. Table 2 shows generic drug penetration in the top ten drug categories by volume for years 2001 to 2006.

Table 1: Share of Retail Pharmaceutical Sales

	1984	1993	2001	2002	2003	2004	2005	2006
Brands	81%	57%	50%	49%	46%	43%	40%	37%
Generics	19%	44%	50%	51%	54%	57%	60%	63%

Source: IMS, *National Prescription Audit*. Figures do not include over-the-counter drug sales. Figures for 2006 are for Jan to Oct.

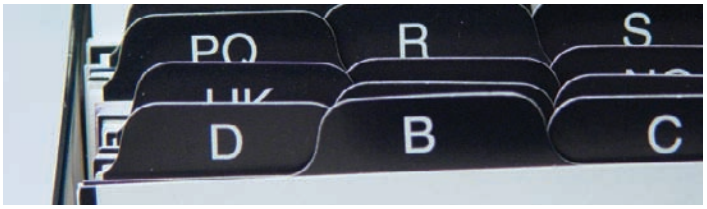
Some believe the modern generic drug market began in 1984 with the passage of the Hatch-Waxman Act, which aimed to lower entry barriers for generic pharmaceuticals.[47] At the same time the act also attempted to preserve the incentive for pharmaceutical firms to carry out research and development by extending the term of patent protection to make-up for delays caused by the FDA approval process.[48] The success of generics in the market place since this act is evident.

One study by Saha et al. looked at 40 brand name drugs that had generic substitutes introduced between July 1992 and January 1998.[49] The study found the majority the generics captured more than 50% of the market from the brand competitor *within 12 months*. Within 12 months following the introduction of the first generic, other generic competitors had entered the market in all but four cases, and in most cases many competitors had entered. This, of

[47] Richard G. Frank and Erica Seiguer. "Generic Drug Competition in the US." *Business Briefing: Pharmatech* (2003). www.touchbriefings.com/pdf/890/PT04_frank.pdf

[48] Henry G. Grabowski, "Longer Patents for Increased Genetic Competition: The Waxman-Hatch Act After One Decade," *PharmacoEconomics* 10,Suppl. 2 (1996): 110-123.

[49] Antanu Saha, Henry Grabowski, Howard Birnbaum, Paul Greenberg, and Oded Bizan "Generic Competition in the U.S. Pharmaceutical Industry," *International Journal of the Economics of Business* (February, 2006). Vol. 13, Issue 1, pp. 15-38



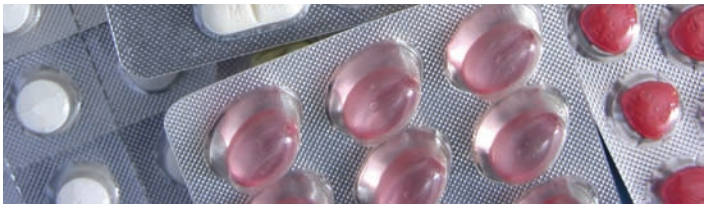


Table 2: Market Share of Generics by Top Ten Drug Categories

Drug Category	2001	2002	2003	2004	2005	2006
Codeine and COMB	98%	98%	98%	99%	99%	99%
HMG-COA Reductase Inhibitors	0%	2%	4%	6%	8%	21%
Beta Blockers	78%	72%	69%	67%	66%	65%
SSRIs	8%	20%	22%	32%	44%	51%
ACE Inhibitors	18%	34%	58%	71%	82%	85%
Proton Pump Inhibitors	0%	0%	13%	10%	11%	17%
Sythetic Thyroid Hormones	40%	41%	40%	45%	60%	66%
Anti-Seizure Disorder Medication	33%	34%	34%	37%	55%	54%
Calcium Blockers	45%	47%	47%	47%	48%	48%
Estrogen/Progestogen	34%	43%	50%	64%	66%	68%

Source: IMS, *National Prescription Audit*. Figures do not include over-the-counter drug sales. Figures for 2006 are for Jan to Oct.

With the exception of the beta blocker category, generics have been capturing ever larger portions of the drug segments.

For the sixth year in a row, growth in prescription drug expenditures has declined.

In short, marketing by pharmaceuticals does not appear to inhibit the entry or market penetration of generics to any great extent. In fact, it could be argued that marketing before patent expiration, if it led to increased demand, would make brand name drugs and their markets a more attractive target for generics. This success is borne out in the increase in overall market share of generics over the past decades as well as market shares by drug category.

Catlin et al. (2007) report in *Health Affairs* that the increased use of generics has impacted overall drug spending enough that *prescription costs have grown at a slower rate than overall healthcare spending in 2005.*[50] While 2005 is the third consecutive year of slowing growth in total healthcare expenditures; prescription drug expenditure growth has been decelerating since 1999. Preliminary evidence for generic use in 2006, seen in the tables above, seems to indicate a continuation in his trend.

[50] Aaron Catlin, Cathy Cowan, Stephen Heffler, and Benjamin Washington. "National Health Spending In 2005: The Slowdown Continues," *Health Affairs*, 26, no. 1 (2007): 142-153.

The large rise in the market share of generics has not gone unnoticed in the business press. Matthew Herper writes in *Forbes* that the "generic onslaught" is likely to continue.[51] The article reports that by 2011, patents will expire for many more drugs, representing a quarter of the sales for the big pharmaceutical companies in 2006. By this point, the article concludes, generics could make-up 75% of the prescription market.

Generics also point to the fact that the American pharmaceutical market is far more competitive than commonly believed. Due to a relative decline in the prices of the drugs facing competition from new entrants, Leffler finds that "new-product entry does tend to reduce product price, and the entry success generated by pharmaceutical promotion can be presumed to be pro-competitive."[52] Given the empirical results indicating the potential benefits from promotion in launching new drugs, Leffler further concludes that *"(g)iven the large potential social benefits from the more rapid adoption of superior drug therapies, restrictions on pharmaceutical promotion appear to risk large losses in consumer welfare for the promise of unproven and perhaps nonexistent gains."*

The Impact of Provider-Identifiable Data on Market Structure

Opponents of the commercial uses of provider-identifiable data implicitly assume that these uses entrench the market power of large pharmaceutical companies. On the contrary, by easing diffusion through decreasing the costs of searching for physicians most likely to prescribe a drug, provider-information data makes it easier for new players to enter the market, making it more competitive. The logic of this dynamic is straightforward.

Search costs serve as a barrier to entry because of the resources necessary to identify a market. Providers of many new pharmaceutical therapies or diagnostic lines must identify physicians who work within the specialty and those who utilize pharmacological approaches.

An analogy is found in the financial sector where lenders can be unaware of a potential borrower's credit need and associated risks such as capacity and willingness to pay. To the extent that local banks have privileged information and new entrants do not, the banks have an advantage which serves to dissuade new entrants from extending loans, thereby reducing competition. National credit bureaus' exchange of information has helped to lower this barrier and increase competition. In a similar logic, the ability to target physicians is crucial for smaller and newer pharmaceutical firms.

[51] Matthew Herper. "The Generic Onslaught," Forbes, June 23, 2006. www.forbes.com/sciencesandmedicine/2006/06/23/drugs-patents-expiration-cz_mh_0623generics.html

[52] Keith B. Leffler, "Persuasion or Information? The Economics of Prescription Drug Advertising." *Journal of Law and Economics*, 24 (1981)

Provider-identifiable data allows new entrants to spend less on promotion, either in the form of smaller sales forces or searches. This dynamic operates when an established pharmaceutical firm enters a therapeutic line in which another firm is already established.[53] It is especially true of newer and small pharmaceutical companies.

One small pharmaceutical which produces drugs for skin disorders maintains a sales force of 40 persons.[54] Of the total population of individuals who have responsibilities writing prescriptions, the firm has an interest in less than 1.7%, that is, in approximately 24,000 specialists of the 1.46 million providers in the US. Of these 24,000, it targets 5,000 as likely to be interested in prescribing the drug. Even when the firm enters into collaborations with larger pharmaceutical companies, provider-identifiable data allow them to monitor the effectiveness of their collaboration and whether agreements are upheld.

Another firm PERC interviewed for this study stated that their *sales forces would abandon smaller states which passed legislation prohibiting the use of provider-level data for commercial purposes*. If larger states pass such legislation, they would be forced to enter into agreements with larger firms, albeit without the same capacity to monitor agreements. Smaller firms and the new entrants in the sector stand to lose disproportionately as search costs increase (and if there are economies of scale in search investments) and increase at a greater rate than for larger firms.

The competition of smaller and new players limits the ability of established firms to increase prices above costs and earn more than a reasonable rate of return. As previously mentioned, "me-too" drugs serve to provide alternatives to what would be otherwise blockbuster monopolies.

Contrary to what ban proponents imply, the use of provider-identifiable data by smaller and newer players may limit the creation of monopolies and oligopolies within a treatment line. Access to prescription-level information creates effective competition within the pharmaceutical market. This competition exerts downward pressure on prices, even in the absence of actual competition.[55]

A ban on the commercial use of provider-level data would hamper competition, discourage new entrants and thereby most likely result in increased prices for pharmaceuticals, and perhaps even dampen innovation.

[53] Interview with Scott Rose, Director, Sales Force Incentives and Business Reporting, Eli Lilly and Company, January 18th, 2007.
[54] Interview with Boris Myerson, Senior Director of Operations and CIO, Chester Valley Pharmaceuticals. November 27, 2006.

For the case described above, if the company did not have access to prescription-level data and was forced to market to specialists without knowledge of their preferences, either its marketing costs would increase nearly five-fold or its sales would dramatically decline or both. Sales visits would be less valuable and smaller pharmaceutical and biotech firms would be forced to turn to larger players. This would reduce the effective competition within diagnostic lines and across the entire pharmaceutical industry and would remove an important price constraint on larger pharmaceutical firms. In a monopolistic or oligopolistic environment, larger firms would have less incentive to rapidly diffuse innovative new drugs while they could still profit from sales of an older substitute drug. In short, *a ban on the commercial use of provider-level data would most likely result in an increase in the price of prescription pharmaceuticals and a reduction in the rate at which innovative new drugs are introduced.*

The Economic Consequences of Restrictions on the Use of Provider-Identifiable Data

Policy restrictions on the use of provider-identifiable data for marketing purposes could lead to a number of outcomes. The initial impact would undoubtedly make pharmaceutical marketing less efficient although the long-term effects are unclear. Would more physician time be wasted with less useful visits, thereby decreasing potential patient time? Would pharmaceutical companies spend more or less on marketing? Would marketing shift more toward consumers and away from physicians? Would this translate to less effective marketing? What effect would this have on longer-run strategic decisions, such as research and development budgets? Would the decreased ability to efficiently market new and competing drugs to physicians decrease competition and thereby raise drug prices?

Lost Time Through Mismatches. If provider-identifiable information is not available to help select physicians who may be interested in a new product, an increase in mismatches will occur, resulting in increased time wasted by both physicians and sales representatives. Without specific information, providers may take more time to identify optimal treatments for their patients, which wastes time. Mismatches also result in wasted time that could otherwise be used in treating patients and other health related activities.

[55] William J. Baumol, "Contestable markets: an uprising in the theory of industry structure," *American Economic Review* 72 (1982) pp. 1—15. William J.Baumol, John C. Panzar, and Robert D. Willig, *Contestable Markets and the Theory of Industry Structure.* (New York: Harcourt Brace Jovanovich, Inc. 1982). See also: "Contestable markets: an uprising in the theory of industry structure: reply," American Economic Review 73 (1983) pp. 491—6. "On the theory of perfectly contestable markets," in Joseph E. Stiglitz and G. Frank Mathewson, *New Developments in the Analysis of Market Structure.* (Cambridge, Massachusetts: The MIT Press, 1986) pp. 339—65. William J. Baumol and Robert D. Willig, "Pricing issues in the deregulation of railroad rates," in Jorg Finsinger, ed., *Economic Analysis of Regulated Markets.* (New York: St. Martin's Press, 1983) pp. 11—47. See also "Contestability: developments since the book," *Oxford Economic Papers* 38 Supplement (1986) pp. 9—36.

Surveys of doctors by Health Information Organizations (HIOs) provide considerable information on detailing visits, their length, and provider attitudes about their usefulness.

The following table summarizes some of the information from a survey of 4,738 physicians by the HIO Verispan, LLC for their *Sales Force Effectiveness 2006* survey.

Table 3: Average Number and Usefulness of Sales Force Visits

	N	Avg reps seen per week	Opinion on number of reps		
PHYSICIANS			Too many	Just right	Too Few
General practice/family med/ osteopathic med	1,038	10	41%	43%	16%
Internal medicine	**828**	**10**	**35%**	**53%**	**12%**
Cardiology	170	7	30%	59%	11%
Dermatology	**120**	**6**	**25%**	**60%**	**16%**
Pulmonology	72	6	27%	56%	17%
Neurology	**84**	**6**	**40%**	**50%**	**10%**
Gastroenterology	112	5	31%	61%	8%
Pediatrics	**492**	**5**	**20%**	**51%**	**29%**
Obstetrics/gynecology	263	5	20%	60%	20%
Psychiatry	**294**	**4**	**23%**	**58%**	**19%**
Oncology	46	3	28%	67%	5%
Ophthalmology	**268**	**2**	**18%**	**63%**	**19%**
Orthopedic surgery	138	2	9%	51%	40%
Emergency medicine	**234**	**2**	**8%**	**43%**	**49%**
General surgery	176	2	4%	42%	54%
Anesthesiology	**403**	**1.3**	**5%**	**53%**	**42%**
TOTAL	4,738	6.1	26%	52%	22%

On average, physicians receive approximately 6.1 visits per week from pharmaceutical representatives. The figure varies widely by specialization, from 10 average visits for general practitioners, family doctors, and internal medicine specialists to 2 or fewer for ophthalmologists, orthopedic surgeons, general surgeons, anesthesiologists, and emergency doctors.

The HIO Verispan, LLC study asked physicians whether they found the number of sales representative visits to be too many, just right or too few.[56] Not surprisingly, physicians who received more visits on average responded more frequently that there were too many visits while those who received fewer visits responded more frequently that there were too few visits.

[56] The question was worded as follows. "Which statement best describes how you feel about the number of pharmaceutical sales reps currently calling on you?" The possible responses were: "Far too many"; "More than necessary"; "Number is appropriate": "Fewer than necessary"; and "Far too few". For the table above, "far too many" and "More than necessary" are collapsed, as are "Fewer than necessary" and "Far too few".

These responses allow us to make a conservative estimate of mismatch costs. If we assume that "too many" visits are a proxy for visits that are not useful (an assumption which conservatively biases the measure of useful visits), we can estimate the excess costs if drug sales forces were not able to target providers as well as they do now. IMS estimates brief office visits at 4.15 minutes. We can further conservatively estimate that 10% of useful visits ("just right" and "too few") would be of little or no use as a result of a mismatch. That is, of the 74% of the 6.1 visits per week that can be estimated to be useful (or 4.5 visits per week), 0.45 would be of no use. The following table provides a basic estimate of the costs if 10% of the currently useful visits were to become unhelpful to providers as a result of mismatches and also provides estimates for the 20% and 30% scenarios.

TABLE 4: Potential Costs of Rising Mismatches

Average pharma visits per week	6.1
Useful visits as a share of total visits	74%
Useful visits per week	4.5
Total annual useful visits (@ 50 weeks)	225
Total hours (at 4.15 minutes per sales rep visit)	16
# of prescribers	1,460,000
Patient costs ($200 per visit, 20 mins per visit) per hour [57]	$600
If 10% (become non-useful), potential wasted hours per annum	1.6
Lost annual patient visits per physician	4.8
Total lost patient visits per annum	7.01 million
Estimated total annual wasted physician time costs	$1,401,600,00
If 20% (become non-useful), potential wasted hours per annum	3.2
Lost annual patient visits per physician	9.6
Total lost patient visits per annum	14.02
Estimated total annual wasted physician time costs	$2,803,200,000
If 30% (become non-useful), potential wasted hours per annum	4.8
Lost annual patient visits per physician	14.4
Total lost patient visits per annum	21.03
Estimated total annual wasted physician time costs	$4,2045,800,000

[57] The average cost of an office visit to a general practitioner was estimated to be $60 in 2001. American Medical Association, "Physician Socioeconomic Statistics," 2001. Recent surveys have placed the cost of an average doctor's visit at $200. Michelle Singletary, "Guess the cost of a routine visit to a doctor's office (answer below)." *Mcall.com*. October 25, 2006. http://www.mcall.com/business/columnists/all-d2_singletaryoct25,0,7784367.column?coll=all-randomcolumnistsbus-misc

A higher rate of mismatches would naturally increase both the wasted time and the costs.

This calculation excludes costs that would be borne by pharmaceutical companies to compensate for the loss of provider-identifiable data by increasing efforts through other marketing channels (e.g. direct to consumer advertising on television) or by increasing the size of their sales force. In either scenario, these costs would likely be passed along to the consumer. Thus, *the restriction on provider identifiable data, rather than driving prices down as proponents have argued, could actually have the reverse effect*.

Results of a Canadian Study,. An actual policy shift that occurred in the Canadian Province of Saskatchewan offers insight into effects we might expect from limiting the use of prescription-level data in marketing. In 2000, the Saskatchewan College of Pharmacists modified rules to allow the release of provider-identifiable information from pharmacies as long as no individual physician's prescription activity was identified. This allowed prescription information and identities of physicians to be released, but no individual physician's prescription information could be released. Some features of the Canadian health insurance system, as it related to prescription drugs, should be kept in mind. While the prescription drug system in Canada is *not* a single payer system, public provision of prescription drugs insurance coverage varies widely by province.[58] Nonetheless, this increase in information on the prescribing patterns of physicians being made available for marketing purposes can make for a very informative case.

Grootendorst looked at whether this policy shift resulted in changes to per capita drug expenditures.[59] The study utilized quarterly data on per capita drug expenditures by drug category across the Canadian provinces three years prior to the policy shift and four years after the shift. The changes in drug expenditures in Saskatchewan before and after the policy shift were compared with such changes in the other provinces which did not make the shift. Specifically, for each drug category, two comparisons were made, one with the group of provinces where provider-identifiable information was available and one where it was not.

The results indicated that following the increased availability of provider-identifiable information for marketing, drug expenditures did not rise in Saskatchewan relative to either set of the other provinces. In fact, though statistically insignificant, the data indicated a slight relative decline in expenditures when looking at all drug classes or the top nine drug categories. None of the individual drug categories saw a statistically significant increase in relative drug expenditures compared to the other provinces. However in three categories—arthritis, analgesics, and hormones—statistically significant relative declines were found. The author thus concluded that concerns that increasing the availability of provider data for marketing purposes would lead to an increase in drug expenditures appear to be unfounded and that "(i)t appears that, to the extent that the policy change increased the effectiveness and/or amount of physician 'detailing' or other promotional activities in Saskatchewan, sales increases came at the expense of competitors' sales."

The exact market dynamics, firm responses, changes in prices, quantities, and market shares were not explored in detail in the analysis of the Saskatchewan policy change, so what can be gleaned from it is somewhat general. This study and that case represent the best look at what we could expect to occur following changes in laws or policies restricting the use of provider-identifiable information for marketing. *As such, we would expect a restriction on the use of provider-identifiable information for marketing to: (1) make the marketing of pharmaceuticals less efficient, which may lead to less effective competition between pharmaceutical companies; and, (2) either have little impact on drug expenditures, or result in slightly higher expenditures in some drug classes.*

Changing Channels of Diffusion. If a ban on the commercial use of provider identifiable data made it less efficient to market to physicians, pharmaceutical companies could do one or some combination of the following: (1) shift more marketing efforts to direct-to-consumer advertising or journal advertising or (2) spend more to compensate for lost data, perhaps collecting more prescription-level data themselves for in-house use or working with their customers, managed care organizations, pharmacy benefit managers, and other health systems.

A shift to more direct-to-consumer (DTC) marketing may not be that much of a panacea for physicians. Norris et al.'s review of the literature on physicians' attitudes towards marketing indicates that while attitudes toward sale representatives and the information they provide are somewhat mixed, the "(d)octors are largely opposed to DTC advertising." [60]

[58] Saskatchewan covers 70% of the costs of prescription drugs after an $850 deductible for each 6-month period for those under 65 and not considered low-income. Alberta, by contrast, leaves prescription drug coverage the responsibility of individuals, for those under 65.

[59] Paul Grootendorst, "Disclosure of physician prescribing information and prescription drug costs: Evidence from Saskatchewan." *Journal of Pharmaceutical Marketing & Management*. 17 (2007) pp. 61-88

[60] P. Norris, A. Herxheimer, J. Lexchin, and P. Mansfield. "Drug promotion: what we know, what we have yet to learn. Reviews of materials in the WHO/HAI database on drug promotion." World Health Organization and Health Action International, 2005. A database for this can be found at http://www.drugpromo.info.

It is also unlikely that marketing via sales representatives would cease with a loss of provider-identifiable data. More likely, it would simply tend to be less efficient, more scattered, and less focused. This outcome would certainly not lead to sales reps being any less annoying to doctors. *If pharmaceutical firms compensate for the loss of provider identifiable data by hiring more sales reps—a reversal of a recent trend toward reducing sales forces, a trend enabled by access to prescription-level data for commercial purposes—then the annoyance factor is likely to increase by this type of data restriction.*

Also, as we found in the literature, less informative, more repetitive journal marketing or general advertising may not be as useful to the pharmaceutical companies introducing new drugs compared to marketing via sales representatives. The ability of sales representatives to interact with physicians and provide more detailed scientific information may be better suited for the launching of a new drug.[61]

If pharmaceutical companies are less able to introduce new drugs to the market, or if they are less able to have them adopted as fast, clear evidence exists that social welfare will be harmed (e.g. impact on average life expectancy). And if this reduced ability to market new drugs results in less incentive to invest in the development of new drugs, which currently do not provide lavish returns, then social welfare will be additionally harmed.

Currently, the open, information rich US pharmaceutical market adopts and introduces new drugs at a faster rate than do the markets in other nations. The country's regulated market has the greatest number of new drug launches with the least delays.[62]

In sum, we can therefore expect a ban on provider-identifiable information for commercial purposes to:

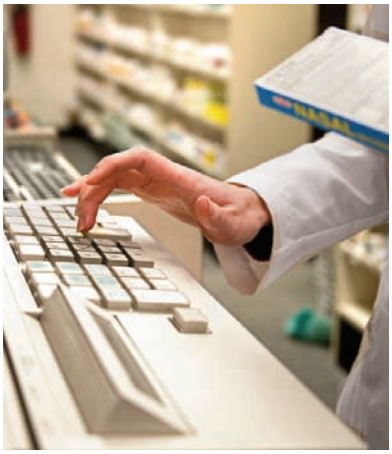
- **increase wasted physician time, as pharmaceutical representatives and doctors become increasingly mismatched;**
- **slow the speed of the introduction of new therapies and thereby limit their benefits;**
- **reduce competition in the pharmaceutical sector and make it more difficult for new players to enter the market;**
- **have no impact on pricing or even raise prices by reducing competition;**
- **increase promotional budgets as pharmaceutical firms try to compensate for the ability to target; and,**
- **have little effect on the speed of the introduction of generics.**

If drug expenditures did fall as a result of less effective direct-to-physician marketing, it would likely be due to fewer new drugs being prescribed, and it would likely lead to a shrinking of revenues from new drugs. Thus, newer drugs would be adopted less and less rapidly. If we generalize the results from the literature we would expect that overall societal health benefits would decline

[61] Keith B. Leffler, "Persuasion or Information? The Economics of Prescription Drug Advertising."
[62] P. M. Danzon and Y. R. Wang, "The impact of price regulation on the launch delay of new drugs - evidence from twenty-five major markets in the 1990s." *Health Economics*. 14 (2005) pp. 269-92.

from consumers having less access to newer drugs. And if newer drugs generated less revenue, we would expect the long-term result to be a reduction in the development of new drugs which would have negative effects on health benefits for Americans.
Finally, as noted above, the loss of third-party databases containing provider-identifiable information would also likely have anticompetitive effects as larger established pharmaceutical companies would be more able to compensate by using their own internal databases, or create them as needed. The likely consequence would be an increase in the relative market power of entrenched firms vis-à-vis their competitors and an increase in their bargaining power relative to purchasers of their goods and services, especially third-party payers.

It should be noted that these strictly economic aspects do not exhaust the uses of provider-identifiable information even in the private sector. The pharmaceutical sector extensively uses the information for research and regulatory compliance. More uses are evolving in the public and private sectors. Some of the more notable applications are discussed in the following sections.



The Role of Provider-Identifiable Data in Regulatory Compliance and Research

While commercial applications comprise the bulk of uses of provider-identifiable information, these data also play a role in research and monitoring for the sake of regulatory compliance. The comprehensiveness of the data and its longitudinal character make it ideal for these purposes, which are discussed here.

Pharmacovigilance: Adverse Reaction Monitoring and Notification

Provider-identifiable data plays a crucial role in pharmacovigilance, "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems." [63] The "detection, assessment, understanding and prevention" functions cover a wide array of issues related to medicines, such as substandard medicines, medication errors, off-label uses (or the use of medicines for purposes other than those approved by regulatory agencies), assessment of drug-related mortality, abuse and misuse of medicines, adverse interactions of medicines with chemicals, other medicines, and food. Its aims are to maintain and improve public health, specifically to:

- "improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions,"
- "improve public health and safety in relation to the use of medicines,"
- "contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including - cost-effective) use," and
- "promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public." [64]

[63] World Health Organization, The Importance of Pharmacovigilance. pp. 7-8.

Regulation in the United States requires that drugs are monitored for their quality and effectiveness in order to reduce consumer exposure to risk. Towards this end, pharmaceutical producers have pharmacovigilance obligations, comprising the elements listed above. In addition to these, pharmaceutical firms must also be able to identify and monitor providers in order to issue effective warnings and recalls if necessary. *Provider-identifiable data is essential for many of these objectives and greatly assists the others.*

To mitigate health and safety risks, whether for recalls or for other health alerts, provider-level data serve to quickly identify all parties that need to be notified.

As part of its call to restructure pharmacovigilance for a new era, the World Health Organization (WHO) established the Uppsala Monitoring Center, which manages a database of adverse drug reaction reports received from national drug monitoring centers. Detection at the Monitoring Center is partly automated through a Bayesian confidence propagation neural network, which considerably speeds up detection over earlier monitoring methods. The WHO noted that the effectiveness of such a system depends on

- "the size of the database"
- "the quality of the reports received from the contributing centers"
- "the timeliness of such reporting" and
- "an active and reliable reporting culture within participating countries."[65]

The FDA's new, computerized information database—the Adverse Event Reporting System (AERS)—receives information on adverse reactions from manufacturers, who are required to report, and voluntarily from health professionals. Moreover, the FDA's "Guidance for Industry: Development and Use of Risk Minimization Action Plans," which sets out to institutionalize practices that minimize the risk associated with prescription and biological drug products, suggests the development and institutionalization of tools for:

(i) targeted education and outreach that "increase appropriate knowledge and behaviors of key people or groups (e.g., healthcare practitioners and consumers) that have the capacity to prevent or mitigate the product risks of concern";

(ii) reminder systems that "prompt, remind, double-check or otherwise guide healthcare practitioners and/or patients in prescribing, dispensing, receiving, or using a product in ways that minimize risk"; and

(iii) performance-linked access systems.[66]

[64] World Health Organization, *The Importance of Pharmacovigilance*. pp. 7-8.

[65] World Health Organization, *The Importance of Pharmacovigilance*. p. 11.

[66] FDA, *Guidance for Industry Development and Use of Risk Minimization Action Plans* (Washington, DC: U.S. Department of Health and Human Services, March 2005) pp. 8-10.

In different ways, provider-identifiable data can play critical roles in the development and deployment of each of these tools. Prescription patterns are currently used for targeted outreach and education. The information in provider-identifiable databases can be used to remind, verify and assess healthcare practitioners. Finally, performance can be monitored and evaluated for access to treatments. Many of the elements prescribed by the Guidance are practiced through the use of provider-identifiable data. The data are used for the creation of registries that are indispensable in matching prescribing patterns to qualifications. Moreover, these data on providers can be mined to look for anomalous prescription patterns for pharmaceutical narcotics, for example, and thereby identify physicians who are engaged in abuse.

In fact, much of a manufacturer's ability to monitor post-marketing drug interactions depends critically on access to provider-identifiable data. The results from matching longitudinal prescribing patterns to an anonymized patient database allows for an examination of adverse interactions in Phase-IV or post-marketing surveillance. The FDA requires that in a Phase IV trial the drug sponsor must report on "the patient population addressed by the study, the number of patients and/or subjects to be included in the study, and the indication and dosage that are to be studied." The data permits monitoring of frequency of use, the segmentation of use by patient type, and comparisons to different therapeutic solutions.

Once an adverse reaction has been detected, either through the monitoring of consumption patterns using provider-identifiable data or through other means, physicians must be notified. It is here that provider-identifiable data proves uniquely invaluable. By definition, the data allow pharmaceutical firms to identify physicians by their prescription patterns, and thereby enables them to contact those who prescribe the drug in ways that are more likely to capture the provider's attention. Simply put, provider-level data efficiently identifies all parties that need to be notified for notification of health and safety risks, whether for recalls or for alerts concerning adverse interactions or reactions.

It should be stressed that the value of the data for pharmacovigilance lies not merely in its content, but also in the very factors that the WHO stipulates are necessary for an effective system of detection and notification. The value of the provider-identifiable databases lies in the fact that they are comprehensive, capturing the vast majority of prescriptions in the country. Furthermore, the information is verified and standardized, making it reliable and immediately usable. It is reported, for the most part, at weekly intervals, making the information very timely and allowing for faster detection of adverse events and rapid notification.

That the development of these databases by the private sector has occurred in advance of the recognition of their need by public authority speaks as much to the efficaciousness of the market in generating solutions. Many databases, private and public, from credit reporting to the national census, have come to acquire functions well beyond those intended at the time of their creation. It is questionable whether these databases could be recreated publicly without considerable time, effort and expense. (See below.) Moreover, once created, it is questionable whether they could be maintained, updated and improved to meet future needs.

Clinical Research

At Phase-IV, there is a significant overlap between pharmacovigilance and ongoing research. The prescription-level data allow "faster" research as it reduces the costs of monitoring. Given regulatory and safety requirements, as well as liability concerns, slower monitoring following market release can lead to delays in the wider introduction of new drugs, and as argued above, the faster introduction of new drugs brings considerable health benefits.

Given these relationships, use of provider-level data is essential for research purposes. For smaller pharmaceutical firms, the data also play a role in Phase-III testing, the first large-scale trial on human subjects. One interviewee confirmed that his firm uses provider-level data to identify potential candidates who are likely to have patients who might participate in clinical trials and to monitor their activity.[67] This smaller biopharmaceutical firm also uses the information to identify physicians who are working extensively in the target geographical area and would be able to identify potential participants.

[67] Interview with Boris Myerson, Senior Director of Operations and CIO, Chester Valley Pharmaceuticals. November 27, 2006.

Public sector and academic uses of provider-identifiable data

As it is used for regulatory compliance, provider-identifiable data shows considerable promise in improving our understanding of healthcare interventions. The data are valuable, given their comprehensiveness, timeliness, and accuracy. Perhaps the chief limitation of provider-identifiable data lies in the fact that they are underused outside of commercial marketing. As with many databases developed by the private sector, we see an increase in demand by government, academia and other public entities. Significant positive impacts result when utilization of the information by the public sector and academia grow. The uses of these data have made considerable contributions to improvements in access and quality of healthcare as well as cost management.

The public uses of these data include monitoring health behavior, assessments of treatment patterns, and promotion of best practices. The interventions developed using these data have improved the well-being of the target populations. In academic research, these data have contributed to studies of public health, evaluation of treatments, identification of the determinants of physician behavior, and health economics. While these data are currently underused for these purposes, they are being increasingly deployed for improved understandings of health as well as for better public health policy. A ban on the commercial uses of this information, by making it financially unviable to collect and maintain, threatens these positive trends and will hamper the development of a new and positive methods of delivering health benefits while reducing the social costs of doing so.

Monitoring, Assessment of Treatment Patterns and Promotion of Best Practices

The health impact of less than optimal treatments can be significant. Provider-identifiable data greatly assists in the development of overviews of treatments and allows academic researchers and public health officials to identify sub-optimal treatments and associated physicians. Targeted education and awareness campaigns can then improve health by diffusing best treatment practices.

This dynamic is not hypothetical. A collaboration between Merck and the New York City Asthma Partnership used provider-identifiable data to examine prescription patterns for asthma for children in New York city boroughs. Asthma is the most common cause of hospitalization of children under 14. The survey identified the under-prescription of asthma medications in low-income areas in the city, especially in the Bronx. The results were used to educate targeted physicians on asthma treatments and contributed to decreasing rates of hospitalization for asthma among children ages 0-14.

The data also have been used to identify over-prescription and thereby limit use of prescription drugs. One study examined the impact of the use of fluoroquinolone, a broad-spectrum antibiotic associated with fluoroquinolone-resistant E. Coli and methicillin-resistant Staphylococcus aureus (MRSA), in hospitals

and in the community.[68] This study found a strong association between the two and revealed a positive link between hospitals and communities, but more importantly led to the conclusion that hospital interventions to reduce drug resistance had to take into account prescription patterns in the community. The study used aggregated prescriber-identifiable data from IMS to measure antibiotic use patterns in the community. A similar study examined the use of antibiotics among children and penicillin-resistance Streptococcus pneumoniae, again with provider-identifiable data, and used the data to benchmark educational interventions and develop guidelines for the use of antibiotics.[69] Utilizations of these data to reduce inappropriate drug use are ignored by opponents of provider-identifiable information sharing. Although these utilizations are infrequent, they do validate very strong public health benefits.

A study by Ronald Cossman et al. used IMS's Xponent database to investigate rural population health.[70] Using prescriptions as proxies for disease, they were able to estimate rates of heart disease, stroke and diabetes at the county level, something for which no other source of information was available. Diane Wysowski et al. used IMS provider data to investigate the use of oral anti-diabetic drugs.[71] These studies help to evaluate the prevalence of different types of treatment and even measure the incidence of disease.

Public health officials and academia have also used these data for purposes of notification. In a 2000 study at Stanford University researchers found that prescription patterns had not significantly changed after a comprehensive study discovered negative effects in the use of α-blockers to treat hypertension. The patterns were measured using aggregate provider-level data to examine treatment patterns. The results led to a more aggressive education program

These data have also been used to examine public responses to bioterrorism scares. Belongia et al. used such data to look at how the dispensing of anthrax-related antimicrobial agents changed following the 2001 anthrax scare.[72] These data can be used to monitor our reactions to terrorist threats in the future.

Academic Uses of Provider -Identifying Information

Academic uses of provider-identifiable data are becoming more prevalent. The fact that this information has come to be used in academic research at a slower pace than it has been used in commerce follows a pattern found in other data spheres. For example, government data originally intended to calculate reapportioning of legislative seats, or monitor tariffs on exports and imports, were later found to have a myriad of valuable uses. In recent years, provider-identifiable data has witnessed a similar trajectory.

Lee Vermeulen, director of the Center for Drug Policy in the Department of Pharmacy at the University of Wisconsin Hospital and Clinics, believes *there may be [at least] 1,000 papers in health services and biomedical research journals using IMS data at both aggregate and disaggregated levels (a small number of which have been cited throughout this paper*).[73] These data are used to identify and analyze various patterns of medication use.

[68] Conan MacDougall, et al., "Hospital and Community Fluoroquinolone Use and Resistance in Staphylococcus aureus and Escherichia coli in 17 US Hospitals." CID. 41(2005) pp. 435-440.
[69] Edward Belongia, et al "A Community Intervention Trial to Promote Judicious Antibiotic Use and Reduce Penicillin-Resistant Streptococcus pneumoniae Carriage in Children." Pediatrics. 108 (2001) pp. 575-583.
[70] Ronald E. Cossman, et al. "Drugs, Diagnosis and Death: A Test of Pharmaceutical Data Validity in Estimating Rural Population Health." Draft July 2006.
[72] Diane K. Wysowski, George Armstrong, and Laura Governale. "Rapid Increase in the Use of Oral Antidiabetic Drugs in the United States, 1990 –2001," Diabetes Care. 26 (June 2003) pp. 1852-1855.
[72] Edward Belongia, B. Kieke, R. Lynfield, J.P. Davis Besser. "Demand for prophylaxis after bioterrorism-related anthrax cases, 2001." Emerging Infectious Disease (2005) Available from http://www.cdc.gov/ncidod/EID/vol11no01/04-0272.htm

There are studies looking at what types of providers write certain types of prescriptions to gain a better understanding of how to improve outcomes. Any number of subjects have been covered in these papers, ranging from economic to clinical subjects. Vermeulen emphasizes that it is crucial to recognize that there is no central repository anywhere that offers researchers an accurate picture that is as robust as is possible with the IMS data. He states, "There simply is nowhere else a system that captures a record of medication use. Without that [the IMS data] we are down to calling patients on the telephone, or using a survey. And patients are not the best historians; they are not very used to relating their experiences."

As the use of pharmaceuticals increases with the development of new ways to treat various conditions, the use of provider-level data seems crucial to the future of health research. More importantly, the data are being used for the study of healthcare costs, quality and access along the lines suggested by the National Academies 15 years ago.

The Atlas Project at Dartmouth University's Medical School "works to accurately describe how medical resources are distributed and used in the United States. The project offers comprehensive information and analysis about national, regional, and local markets, as well as individual hospitals and their affiliated physicians, in order to provide a basis for improving health and health systems."[74] The project seeks to study and assess the relationship between inputs into healthcare and outcomes, as well the costs of generating these outputs with the hope of identifying more efficient ways of providing quality health care. The very types of data provider-identifiable information affords—specialization, age, certifications, type of practice, prescribing patterns—can be analyzed in conjunction with information about patients, the region, and health expenditures to paint an accurate picture of how things work and what works in healthcare.[75]

The research promises to help change physician practice patterns as well as public health policy. The data have shown that spending on health care and health care quality are poorly related, although greater spending is related to more health care.[76] Additionally, the data have focused attention on variations in health care provision.

[73] From a personal Interview.
[74] The Dartmouth Atlas Project, http://www.dartmouthatlas.org.
[75] Interview with Elliott Fisher, M.D., M.P.H., Dartmouth Medical School, The Atlas Project. Conducted December 5, 2006.
[76] Interview with Elliott Fisher, M.D., M.P.H.

Can provider-identifiable data survive without commercial applications?

Opponents of the use of provider-identifiable data believe that loss of income from restrictions on its commercial use will not threaten the existence of the HIO databases. HIOs will simply reorient their services towards research and public health. This shift is unlikely to compensate for the loss of revenues, even enough to maintain the existing database. And whatever shift may likely occur, it will occur slowly, given the fact that the use of this information by the public sector and academia is currently sporadic.

In addition to the above, some opponents fail to understand or underestimate the systems (e.g., software programs, projection methodologies, report formats, quality control processes and human expertise associated with each of these) which must be developed and maintained to make provider-identifiable information available, and the costs associated with that development and maintenance. Some believe the information can be collected for aggregate data purposes, but reside in databases at the prescriber level and be released at that level for researchers. Their notion of producing the information is based on either Google or based on information services such as Lexis/Nexis and Dialog. However, assuming the requisite systems exist, extracting the information requires database expertise, programming skills, experience with the data, and a combination of automated and manual quality control processes—most of which would not exist if the costs were not subsidized by commercial use of the data.

The initial development costs of prescription databases are significant, as are the recurring costs of data acquisition, infrastructure development and maintenance, and the expenses of support and outreach for data providers. The costs relate to the purely technical elements of the system and do not include factors such as regulatory compliance, human resources, the costs of associated with financial and law departments, and other overhead expenses.

The technical costs comprise the data itself (that is, a large enough volume of prescription information to support national, regional, state, county and local level analyses at the prescriber-level) and support for data providers; the data facilities and infrastructure; regular upgrades in software and communications technology; costs of production and transforming raw data into a usable form;

and expenses associated with supporting clients in their access and use of the data. Equally important is the fact that this data is collected regularly, making each piece more valuable, as it constitutes dynamic or time series information. *These data and the resources deployed to collect, maintain, and add value represent a considerable investment, and it is unlikely that it can be publicly duplicated.*

First, public collection of data is the product of a regulatory process for which data collection was a by-product. Data on imports and exports are gathered as a result of the need to collect tariffs. Census data is collected out of the need to reapportion electoral districts. It is questionable whether a direct attempt to collect data by public sources can be successful, given concerns of excessive state monitoring. Second, the value of these databases also stems from the fact that there are private sector incentives to standardize and add value to them through the development of new analytics and new uses.

Excluding overhead costs and the costs of associated sales functions, the amount invested in an HIO database over a 10-year period is hundreds of millions of dollars.[77] *The costs of the embedded knowledge built over time and the expertise of the employees and experts associated with the database is considerable. It is very unlikely that any organization could replicate these resources in any reasonable period of time. Even if we assume that non-commercial uses, even by commercial entities do not need the same level of quality of data and that researchers themselves have the expertise concerning the data and its use, the costs remain considerable.*

As noted above, while the actual uses of prescription data are extensive and the potential uses even more so, the principal applications are commercial by pharmaceutical firms (although it is difficult to extract in financial terms their reliance on this data for monitoring and compliance purposes from other uses). Revenues from the non-profit sector covered less than 1% of the technical costs of the database in 2005.

Moreover, covering costs may be insufficient to preserve the quality of the database and the associated services that have been developed in anticipation of revenues from its commercial uses.

Conclusion: Health Care Transparency

A study by Harold Glass and Bruce Rosenthal (2004) looked into the characteristics of physicians who are early adopters.[78] Their findings help to identify socio-demographic correlates of prescribing patterns. On the face of it, it would seem odd that some factors (e.g., gender) would matter in the earlier or later prescription of new drugs. Some factors (notably age) seem predictable, although for reasons that may have little to do with medicine. And some (such as the age of the medical school) suggest a need for closer examination. Glass and Rosenthal note, "It is probably impossible at present to replicate this study outside the U.S. because of the absence of widespread individual physician-prescribing data."

The observation points to more than simply the fact that unique research is enabled by provider-identifiable data. Rather, it speaks to a tension between two competing pressures in the regulation of information about physicians' prescription patterns. On the one hand, the system faces demands by some providers that their identity and behavior be kept private. On the other, there is a public interest in access to information related to health care, including physician prescribing patterns. This interest is not limited to examinations of physician behavior in the wake of catastrophic failures but also includes issues such as: Are best practices being followed? What treatment patterns may explain differential access to health care or differential outcomes of health care? Is money being spent appropriately?

The call by the National Academies 15 years ago for the creation of national healthcare databases was motivated by the idea that greater transparency in the system can help improve access, quality and costs. For complicated historical reasons, the private sector databases of HIOs, and prominently among them, provider-identifiable databases, have emerged as a major component of this system as it evolves. This information remains substantially underused in government, academic, non-profit and other public health sectors, but we are witnessing a steadily increasing use of this information by these non-commercial sectors.

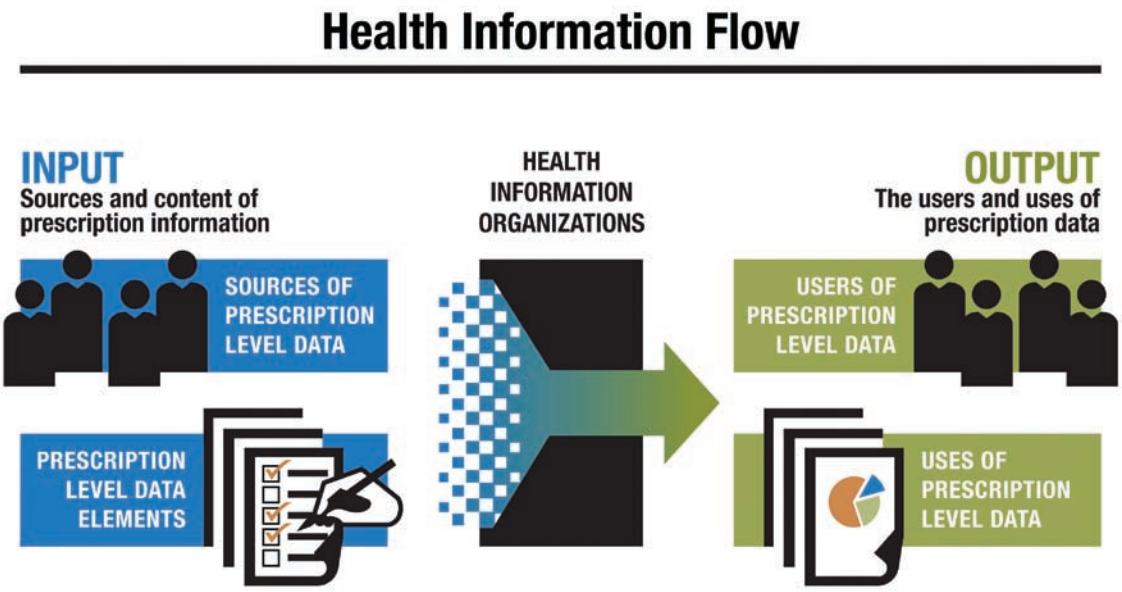
At the same time, physician concerns about the improper use of prescriber-identifiable information must be met. Furthermore, a desire to be spared targeted sales visits and other commercial offers is a concern to which the pharmaceutical industry should be responsive. (Note that a ban of provider-identifiable data for marketing purposes will not stop pharmaceutical representative visits, only stop the targeting of physicians on the basis of this information.) The American Medical Association's Prescribing Data Restriction Program (PDRP) offers a compromise between competing demands. The PDRP allows physicians to have provider-identifiable information relating to their prescribing practices kept from pharmaceutical sales representatives and other individuals who use the information in sales related activities. Rather than mandate a general practice across the profession, the program enables those who object to the sharing of these data to limit access through a sign up process available on the AMA website. The PDRP is freely available to all M.D.s and D.O.s (Doctor of Osteopathic Medicine) regardless of AMA membership.

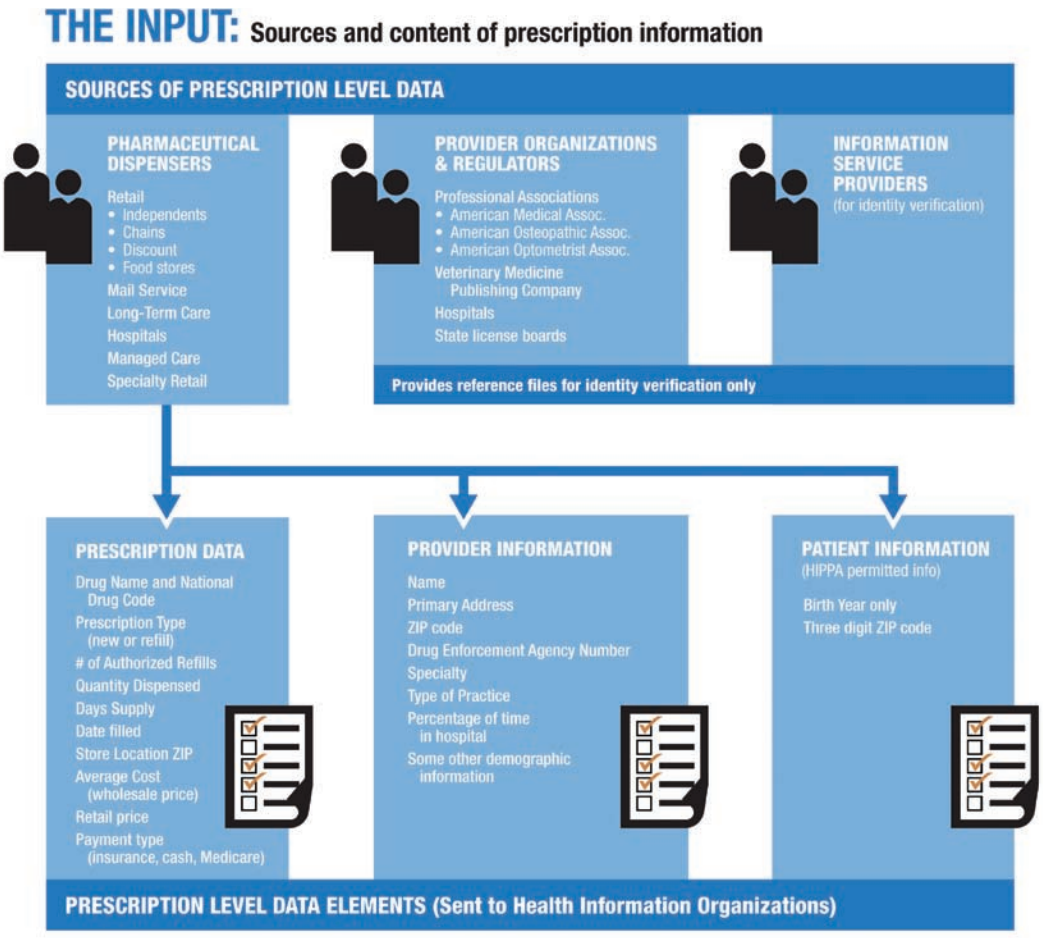
There is enforcement power behind the program. The AMA's licensing agreement for access to its Masterfile of all physicians in the United States requires pharmaceutical firms to prohibit their sales force from accessing provider-identifiable information of those physicians who sign up. As noted above, AMA files are integral components of the provider-identifiable databases of HIOs. At stake for the firm is its license to the AMA's Masterfile and its license to the HIO's provider-identifiable databases. (The information would remain available to pharmaceutical companies and others for research and other non-marketing purposes, as well as for some marketing uses that are unconnected with office solicitations.)

[77] This costs comprises the initial investment in equipment (but excludes the costs HIOs have incurred in replacing information technology), client costs, data costs, and the costs of software development. Based on interviews with IMS.
[78] Glass, Harold E. and Bruce Rosenthal, "Demographics, Practices, and Prescribing Characteristics of Physicians Who Are Early Adopters of New Drugs." P&T, November 2004.

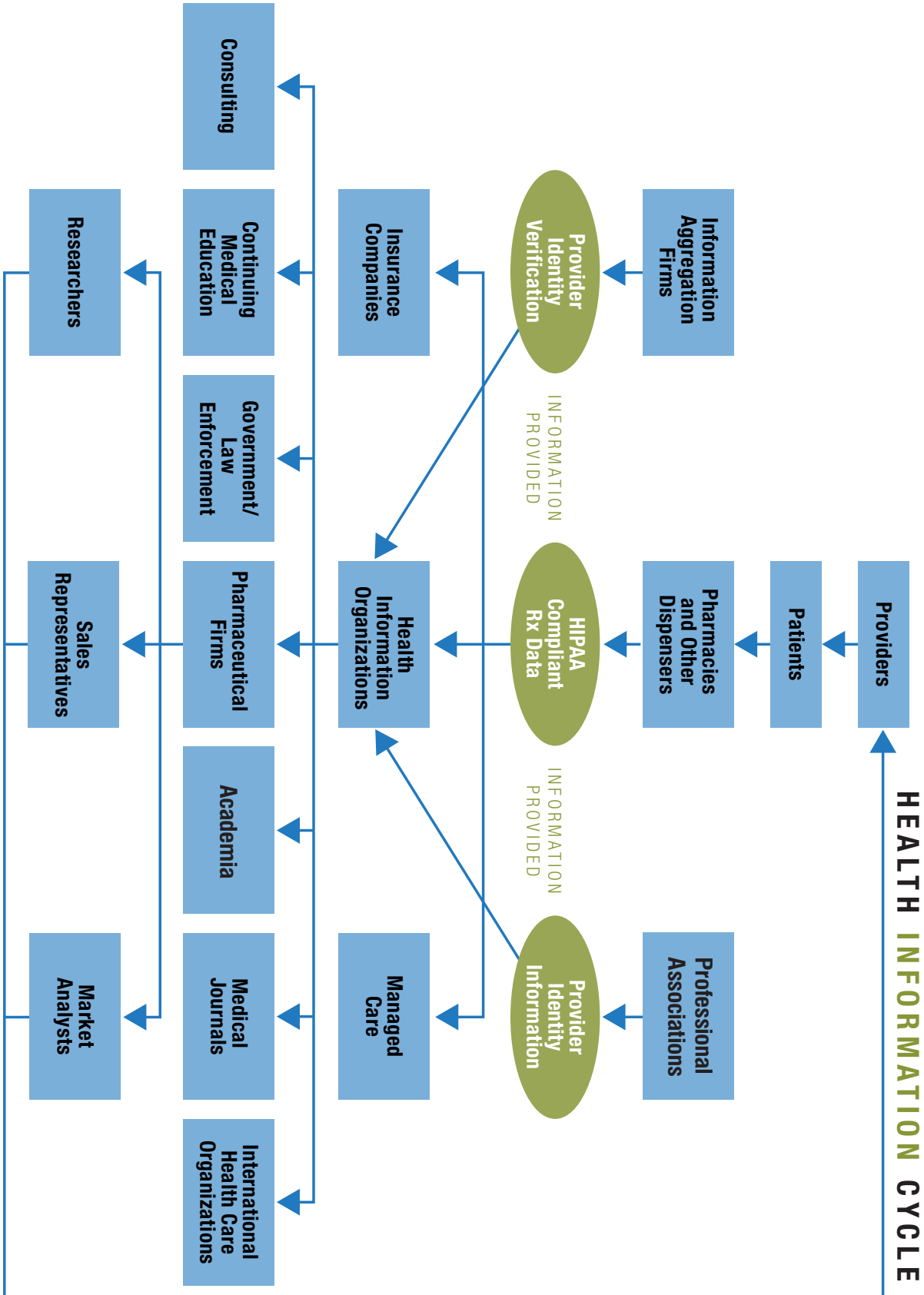
This approach squares the interests of those physicians who feel strongly about the sharing of provider-identifiable data and the public's interest in transparency of the system. Moreover, it also allows physicians the option of continuing to receive visits from pharmaceutical representatives. Finally, it preserves the significant research benefits of the use of provider-identifiable data.

Appendix A


Health Information Flow
INPUT
Sources and content of prescription information
HEALTH INFORMATION ORGANIZATIONS
OUTPUT
The users and uses of prescription data
SOURCES OF PRESCRIPTION LEVEL DATA
PRESCRIPTION LEVEL DATA ELEMENTS
USERS OF PRESCRIPTION LEVEL DATA
USES OF PRESCRIPTION LEVEL DATA


THE INPUT: Sources and content of prescription information
SOURCES OF PRESCRIPTION LEVEL DATA
PHARMACEUTICAL DISPENSERS
Retail
• Independents
• Chains
• Discount
• Food stores
Mail Service
Long-Term Care
Hospitals
Managed Care
Specialty Retail
PROVIDER ORGANIZATIONS & REGULATORS
Professional Associations
• American Medical Assoc.
• American Osteopathic Assoc.
• American Optometrist Assoc.
Veterinary Medicine Publishing Company
Hospitals
State license boards
INFORMATION SERVICE PROVIDERS
(for identity verification)
Provides reference files for identity verification only
PRESCRIPTION DATA
Drug Name and National Drug Code
Prescription Type (new or refill)
# of Authorized Refills
Quantity Dispensed
Days Supply
Date filled
Store Location ZIP
Average Cost (wholesale price)
Retail price
Payment type (insurance, cash, Medicare)
PROVIDER INFORMATION
Name
Primary Address
ZIP code
Drug Enforcement Agency Number
Specialty
Type of Practice
Percentage of time in hospital
Some other demographic information
PATIENT INFORMATION
(HIPPA permitted info)
Birth Year only
Three digit ZIP code
PRESCRIPTION LEVEL DATA ELEMENTS (Sent to Health Information Organizations)

Appendix B


HEALTH INFORMATION CYCLE
Providers
Patients
Pharmacies and Other Dispensers
Professional Associations
Information Aggregation Firms
Provider Identity Verification
HIPAA Compliant Rx Data
Provider Identity Information
INFORMATION PROVIDED
INFORMATION PROVIDED
Health Information Organizations
Insurance Companies
Managed Care
Pharmaceutical Firms
Sales Representatives
Researchers
Consulting
Continuing Medical Education
Government/ Law Enforcement
Academia
Medical Journals
Market Analysts
International Health Care Organizations

Appendix C

THE OUTPUT: The Users and Uses of Prescription Data	USERS OF PRESCRIPTION LEVEL DATA								
	Pharmaceutical firms • Large • Small and new biotechs • Generic drug manufacturers			**Federal government** • Regulatory agencies (DEA, FDA, CDC, Medicare, Medicaid) • Research bodies (GAO, BEA, FRB) • Security (DHS)			**Academia**	**Continuing medical education (CMEs)**	**Medical journal publishers**
	Large	Small	Generic	Regulatory agencies	Research bodies	Security			
Marketing									
Physician identification	x	x							
Sample provision	x	x							
Sales benchmarking for brands	x	x	x						
Benchmarking for generics			x						
Pre-production market research by startups		x							
Regulatory compliance and risk management									
Monitoring use patterns	x	x		x	x	x	x		
Identification of notification targets (e.g., for recalls)	x	x							
Promote best practices	x	x		x					
Research									
Identifying treatment patterns	x	x		x	x		x		
Monitoring of disease instances	x	x		x	x	x	x		
Identify pharmaceutical abuse patterns				x					
Assess effectiveness	x	x			x		x		
Interaction effects	x	x		x			x		
Phase III clinical testing		x							
Outcomes research: drug therapy vs. other therapy	x	x							
Education									
Identify physicians by specialty	x	x						x	x
Identify physicians by prescription patterns	x	x						x	x
National statistics development (Prices and expenditures)				x	x				
National security									
Bioterrorism preparedness						x			
Monitor diagnostic patterns						x			
Monitor public response						x			

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