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NOTE

THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005: WHO SHOULD PAY FOR IMPROVED OUTCOMES?

Robert A. Kerr†

INTRODUCTION

The Institute of Medicine's report "To Err is Human"¹ has been cited hundreds, if not thousands, of times since its release in 1999. In this report, it was estimated that perhaps as many as 98,000 people die each year in America due to medical error.² The report made a number of recommendations that the Institute of Medicine (IOM) hoped would address these errors.³ While some specialties of medicine, such as anesthesiology,⁴ have been successful at reducing the medical errors associated with their practice of medicine, there has not been any systematic overhaul of the delivery of health care or the remaining specialties of medicine to effectuate changes that would address the medical errors that result in so many deaths.

Among the report's recommendations, which were based on the aviation industry, was one to increase the level of medical safety research;⁵ another was to increase medical error reporting through a

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¹ TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn et al. eds., 2000).
² Id. at 26.
³ Id. at 5-14.
⁴ Mortality rates due to surgical anesthesia dropped from 1 in 852 to 1 in 6,048 administrations in the 1950s and 1960s to between 1 in 2,000 and 1 in 10,000 in the 1970s and 1980s and to 1 in 200,000 today. David A. Hyman & Charles Silver, The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?, 90 CORNELL L. REV. 893, 918 (2005).
⁵ Thomas R. McLean, The Implications of Patient Safety Research & Risk
system that would neither blame nor punish providers. A system of reporting analogous to the Federal Aviation Administration (FAA) was suggested by the IOM and has also been suggested by other scholars. This proposed system was designed ideally to encourage reporting so that institutional—not individual—problems could be alleviated. Because doctors, nurses, and other health care providers are human, accidents will happen. It is hoped that identifying errors in the processes associated with health care delivery would result in much fewer patient injuries than result from the current system. However, such a system would likely be prohibitively expensive, with some estimating such a system to cost $350 million per year.

Medication errors are a large percentage of medical errors. While it is difficult to provide an accurate count, deaths from medication errors have been estimated at seven thousand per year. Another study published in the *Journal of the American Pharmaceutical Association* estimated that patient deaths by drug misuse were 218,000 in 2000. The injuries and mortalities associated with medication error are accompanied by yearly medical costs of an estimated $37.6 billion, approximately $17 billion of which is associated with preventable error. While 7,000 deaths may not rival the number of people

*Managed Care, 26 S. ILL. U. L.J. 227, 244 (2002).*


7 Id. at 541. Following World War II, military leaders realized that planning for safety was as important as planning the mission in terms of safety. As a result, today, "civilian aviation takes a comprehensive approach to safety, with programs aimed at setting and enforcing standards, accident investigation, incident reporting, and research for continuous improvement." Id. at 72.

8 McLean, *supra* note 5, at 246.

9 Id. at 988. See also McLean, *supra* note 5, at 248.

10 Id. at 349.


killed by handguns every year, and while these deaths comprise a relatively small percentage of deaths resulting from medical error, these 7,000 deaths and other, unrecorded injuries are clearly accompanied by enormous cost. More importantly, many of these medication errors, along with other medical errors, likely can be eliminated.

On July 29, 2005, Congress passed the Patient Safety and Quality Improvement Act of 2005 (Act). This Act, established after several years of debate in Congress, creates Patient Safety Organizations (PSOs) that will analyze data collected by hospitals and providers in the hopes that doing so would help to identify problems with the process of the delivery of health care. These PSOs would collect the data in accordance with other applicable regulations, including the Health Insurance Portability and Accountability Act (HIPAA), and examine it to identify ways to prevent future injury.

Beyond the obvious problems with the PSOs’ requirement of analyzing data, such as data standardization for comparison across providers, practice areas, or both, and how to identify problem areas and near misses, the Act fails to provide funding for PSOs to carry out this work. The Act provides no funding for the establishment or maintenance of these organizations, and precludes one very prominent player in health care—health insurers—from funding PSOs. Without a government mandate to pay for the reporting and analysis of this data, there appears to be no incentive or funding to do so; creation of standards for PSOs will not necessarily result in creation of PSOs, without which the goals of the Act cannot be met. Funding should, therefore, be sought in order to accomplish the purposes of the Act.

A funding option for PSOs does exist. Pharmaceutical companies are in a unique position to step in and provide funding for PSOs. They have the resources—financial and technical—to gather and analyze

16 The National Center for Health Statistics reported that in 2002 11,829 people were killed by the intentional discharge of firearms. Kenneth D. Kochanek et al., 53 NAT’L VITAL STAT. REP., Oct. 14, 2004, at 32.
18 Id. at § 923.
19 Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936. HIPAA regulates health plans, health care clearinghouses, and health care providers who transmit health information electronically. Since most health insurers require electronic transmittal of billing information, this law applies to nearly every health care provider. HIPAA prohibits the disclosure of protected health information, meaning individually identifiable health information that is transmitted or maintained electronically or in any other medium.
20 Cf. Patient Safety and Quality Improvement Act § 923(c).
21 Id. at § 924(b)(1)(D).
the data collected. Pharmaceutical company participation can serve its own interests while achieving the goals advanced by the PSO legislation. It appears to be the best, if not only, solution to accomplishing the purposes of the Act, considering the state of the health care system in the United States.

Part I of this paper examines the unique and central role pharmaceutical companies play in the U.S. health care system. Pharmaceutical companies rely on the health care system to be profitable. In particular, they rely on the willingness of sick people to test unproven drugs that are likely to have unknown and/or severe side effects. While these patients might benefit from participating in a clinical trial to determine the safety and efficacy profile of a drug, the pharmaceutical companies are motivated by tremendous financial incentives.

Part II looks at the Patient Safety and Quality Improvement Act of 2005 (Act) and the opportunity it will afford the health care community to improve the quality of care it provides. The Act provides non-financial incentives to the health care industry by removing the stigma and fear possibly associated with reporting data. As part of this Act, Congress has mandated the creation of PSOs to collect and analyze the data. However, it has failed to provide funding for these organizations, leaving one to wonder how the government intends to accomplish the analyses and subsequent improvement in quality of care and patient safety.

Part III provides the rationale for expecting and looking to pharmaceutical companies to provide the funding for PSOs. As outlined in Part I, pharmaceutical companies rely on the health care industry to make money. However, their mere involvement in the industry results in a significant amount of medical error and associated cost. Pharmaceutical companies ought to have an interest in seeing medical errors caused by their products reduced. Not only does medical error cause morbidity and mortality in the patients pharmaceutical companies purport to help, these companies create an increased burden on the health care system by increasing costs because of the adverse events caused by their products. However, there are disincentives for pharmaceutical companies to improve patient safety and quality of care, such as decreased utilization of their products as a result of proper use of their drugs and decreased need for their drugs resulting from treating fewer adverse events.

Lastly, Part IV looks at the other participants in the health care system and argues that they are not in a position to fund PSOs. Consumers, providers, health insurers, employers, and the government all interact with and affect the utilization of health care in the U.S. Each has a vested interest in seeing improvements in patient safety and quality of care. Each, however, is limited—or has chosen to limit their
participation, in the case of the government—in their ability to pay for PSOs. Given the inability of entities in the health care system other than pharmaceutical companies to pay for PSOs, one possible source of funding remains: large pharmaceutical companies.

I. PHARMACEUTICAL COMPANIES PLAY A CRITICAL ROLE IN HEALTHCARE IN THE UNITED STATES

Pharmaceutical and medical device manufacturers have been around for over a century. Their prominence in the health care field has arguably never been greater. Americans spend upwards of $200 billion on prescription drugs a year, constituting almost 13 percent of the $1.6 trillion Americans spent on health care in 2002. This $200 billion is only what Americans spend on health care in a year as individual consumers—it does not take into account drugs paid for by insurance companies or dispensed in doctors' offices or hospitals. This staggering amount is even more awe-inspiring in light of IMS Health’s estimation that the total worldwide sales of drugs in 2002 were $400 billion.

Not only are pharmaceuticals increasing in price, they are the fastest growing part of the health care tab. Drug spending between 1993 and 1996 experienced an average of 10.9 percent growth over that period. The reasons for this are two-fold: first, people are taking more drugs, and, second, the drugs they are taking are more likely to be brand-name pharmaceuticals as opposed to the generic brands. Take, for example, Claritin and Clarinex.

Claritin, the brand name of the drug loratadine, was a blockbuster allergy drug for Schering-Plough, scheduled to go off patent in 2002. This loss of patent meant that Schering-Plough would lose drug exclusivity—meaning that it was no longer the only company

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22 See, e.g., About Merck, Merck & Co., Inc., http://www.merck.com/about/ ("Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs.").
25 ANGELL, supra note 23, at 4-5.
26 IMS Health is a leading source of pharmaceutical statistics. See id. at 5.
27 Id.
28 Id. at xii.
29 Sheila Smith et al., The Next Decade of Health Spending: A New Outlook, HEALTH AFF., July – Aug. 1999, at 86, 91.
30 ANGELL, supra note 23, at xii.
31 Id. at 79.
that could sell loratadine—that generated $2.7 billion in sales in 2001. As Claritin approached the end of its patent, Schering-Plough launched a large campaign to switch users of Claritin to Clarinex, which contained the Claritin metabolite, instead of the Claritin drug. Roughly speaking, this means that the body is getting, in Clarinex, the same drug the body converts Claritin to after ingestion. There is no difference between the two drugs. Schering-Plough patented Clarinex, priced it lower than the still-protected Claritin (but higher than the soon-to-be generic-priced Claritin), and urged doctors to switch their patients from Claritin to Clarinex. This resulted in allowing Schering-Plough to keep some of its exclusivity and revenues originally generated by Claritin by switching prescriptions and preventing people from continuing to take loratadine with the generic version of Claritin.

While drugs are becoming more expensive, pharmaceutical companies are bringing in ever-increasing amounts of money. In 2002, combined profits for the ten pharmaceutical companies in the Fortune 500 were $35.9 billion. By comparison, the other 490 companies in the Fortune 500 had a combined profit of $33.7 billion. At the same time that pharmaceutical companies have been bringing in disgustingly large profits, they have been spending more on marketing than on research and development. While spending more on marketing and advertising than on research and development, they have cried out against price controls in the United States, arguing that the high cost of pharmaceuticals is justified by the cost to develop and bring to market new drugs. Some sources have calculated that it may cost as much as $802 million to bring a new drug to market, while other calculations indicate that it may be as little as a quarter of that. Exploring these numbers on a larger scale shows that while pharmaceutical companies may have spent $31 billion on research and development in 2002, this was only 14 percent of their entire budget (and their profits—$35.9 billion—were more than they spent on research and development). Even as these companies were spending $31 billion on

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32 Id.
33 Id.
34 Id. at 80.
35 Id. at 79.
36 ANGELL, supra note 23, at 11.
37 Id.
38 See id. at 11-12.
39 See generally id.
40 See id. at 37-51.
41 Id. at 11.
research, they were pumping over twice that much into marketing and administration ($67 billion).\(^{42}\) Along with these expenditures, pharmaceutical companies make sure that they get the most they can out of their representatives when they pass a major bill.\(^{43}\)

In fact, big pharmaceutical companies are by themselves bringing few totally new drugs, meaning drugs that are not derivatives of existing medicines, to market in a given year and even fewer new useful drugs. As an example, seventeen new active ingredients were among the seventy-eight drugs approved by the Food and Drug Administration (FDA) in 2002.\(^{44}\) Of these seventeen, the FDA rated only seven of these drugs as improvements over medicines already on the market.\(^{45}\)

Based on this very cursory snapshot of the pharmaceutical industry today, it could be very convincingly argued that pharmaceutical companies have money to spare. In fact, they have a lot of money to spare, as evidenced by the amount of money these companies spend on sales and marketing.\(^{46}\) They could reallocate some of their marketing and advertising dollars to help fund PSOs, improving patient safety and quality instead of inundating the public with fancy television ads.

A. Pharmaceutical Companies Rely on Patient and Provider Participation in Clinical Trials to Make Advancements in Pharmaceuticals

Part of the money pharmaceutical companies do spend on research and development is spent on clinical trials.\(^{47}\) This money goes to a variety of tasks that include: discovering the drug, isolating it, and then making it; providing study supplies; recruiting physicians to participate in the trial, who in turn find the patient volunteers; and collecting the data, analyzing the data, and reporting it to the FDA so that it can progress from Phase I (initial testing in humans) through to

\(^{42}\) Id. at 48.

\(^{43}\) Senator Durbin of Illinois noted, "[W]e have learned time and again - that hardly any major bill could go through the Senate unless it figured out a way to help drug companies." 149 CONG. REC. S8871, 8881 (daily ed. July 7, 2003). See also ANGELL, supra note 23, at 193-216.

\(^{44}\) ANGELL, supra note 23, at 16.

\(^{45}\) Id. at 16-17.

\(^{46}\) As an observation, 1 percent of the 2002 profit of Fortune 500 pharmaceutical companies – approximately $350 million – would be sufficient to fund the aviation-style reporting system thought by some scholars to be prohibitively expensive. See Hyman & Silver, supra note 4, at 988; McLean, supra note 5, at 248.

Phase III (final testing in humans) and beyond (Phase IV—post market-approval studies).\textsuperscript{48}

These studies involve hundreds of people who play roles of varying sizes in drug development. These roles include doctors and nurses, of course, but also the patients themselves, clinical data managers to process the collected data, scientists who develop and test the drug in its initial phases, biostatisticians, computer programmers, and other facilitators that enable the process to run as smoothly as possible. While these people play only a relatively small role within the scope of their participation in the life of a developed drug, without them pharmaceutical testing and development would grind to a halt. No new drugs would be isolated or developed. No new pills or incredibly toxic cancer drug would be prepared and dispensed by the pharmacist. No data would be collected and spit out in ready-to-analyze electronic formats. No biostatisticians would generate tables and graphs in an easy-to-read format outlining the successes and failures of a clinical trial. Pharmaceutical companies depend on these people—particularly patients—to help guide their drugs from discovery through to eventual FDA approval.

B. Contract Research Organizations (CROs) Perform Critical Functions as Part of a Clinical Trial

Increasingly, these middlemen, i.e., people who are not the drug developers and who are not the health care providers, actually overseeing administration of a new drug, come from contract research organizations (CROs).\textsuperscript{49} CROs are often contracted, as the name suggests, to provide support services for a pharmaceutical company during the clinical trial process.\textsuperscript{50} These services can even include formulating and packaging the drug during the testing phases.\textsuperscript{51} However, for the purposes of this Act, there is one area of expertise that is particularly important: data collection and analysis.


\textsuperscript{50} Id.

The largest CROs, Covance, Quintiles, Parexel, and PPD, all provide data collection and analysis for their pharmaceutical clients. As drugs pass through the clinical trial process, data regarding their safety and efficacy must be gathered to support an application to the FDA, because it is only through FDA approval that a company can capitalize on the new drug. CROs provide the staff to appropriately collect, store, question, report, and analyze that data to provide justification for FDA approval to market a drug. Pharmaceutical companies have leaned on outsourcing to these CROs to make them more efficient; as large companies with billions to spend on research, they can demand more of the CROs than they could of their own employees because the CROs depend on contracts from the pharmaceutical companies to pay their employees.

II. THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

The Act was the result of several years' work by Congress to pass a bill to improve patient safety. Along the way, the bill received bipartisan support each year it was presented to Congress but was finally passed in 2005 without providing funding to PSOs. At the same time, Congress mandated that individual identifiers be removed from the data, presumably in an effort to encourage reporting of medical errors without fear of reprisal. In establishing PSOs, Congress appears to have recognized the potential for plaintiffs' lawyers to abuse the existence of data collected by PSOs and exempted this data from discovery.


A. The Genesis of the Act

The debate over this law started in 1999\textsuperscript{57} or 2000,\textsuperscript{58} and the bill was first introduced as the Patient Safety and Errors Reduction Act\textsuperscript{59} in the 106\textsuperscript{th} Congress by Senator Jeffords, an Independent from Vermont.\textsuperscript{60} At that time, the goal of the Act was to provide for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety and for other purposes.\textsuperscript{61} This bill, ostensibly the same as the one that passed in 2005, however, failed to pass both houses of Congress and languished until 2003.

In 2005, the bill was introduced again.\textsuperscript{62} Few changes had been made to it. However, one of the notable developments surrounding the bill in 2005 was that the money it was estimated to cost in its implementation had been reduced. The House version of the bill\textsuperscript{63} in 2003 was estimated to increase discretionary spending by $104 million over five years.\textsuperscript{64} This may have been the stumbling block that prevented the two houses of Congress from coming to an agreement at that time. While this bill died in Congress without being passed by both houses, patients continued to die because of preventable medical error, even though the cost of preventable medical errors is estimated between $17 and $29 billion annually.\textsuperscript{65} When the bill finally did pass in 2005, the committee report noted that the Act "would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues."\textsuperscript{66} It did, however, estimate that it would cost $15 million in 2006 and $70 million over 2006 to 2010 (mostly on the development of the patient safety database), assuming necessary appropriation,\textsuperscript{67} but specifically noted that "PSOs would not receive funding under this bill."\textsuperscript{68}

\textsuperscript{57} 150 CONG. REC. S8617, 8631 (daily ed. July 22, 2004).
\textsuperscript{59} S. 2738, 106th Cong. § 1 (2000).
\textsuperscript{60} 150 CONG. REC. S8617, 8632 (daily ed. July 22, 2004).
\textsuperscript{61} S. 2738, 106th Cong. § 2 (2000).
\textsuperscript{64} S. REP. No. 108-196, at 16 (2003).
\textsuperscript{67} Id. at 12.
\textsuperscript{68} Id. It is unclear as to whether other specific legislation has failed in Congress because of estimates provided by the Congressional Budget Office. However, the Congressional Budget Office's web site states:

CBO's cost estimates have become an integral part of the legislative process, and committees increasingly refer to them at every stage of drafting
B. Congress Chooses to Foster an Environment Conducive to Reducing Medical Error

Finally, in 2005, Congress passed The Patient Safety and Quality Improvement Act of 2005. The stated purpose of the Act is to "provide for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety." Among the law's facilitating provisions is one that allows for reporting data to PSOs without fear of reprisal, i.e., lawsuits. The data reported to PSOs are not subject to discovery in a medical malpractice hearing, and data analyzed under the Act is not to be used to identify providers who have committed medical errors. While the Act does not specifically indicate the reason for this, it seems clear from the language of the Act that this data was to be stripped of patient identifiers so that this information could not be used against providers and so that providers are encouraged to make available and seek analyses of their data. Without the possibility that the data they provide to PSOs will be used against them to show a pattern of poor outcomes, providers can now provide this data and trust that it will be used only to effectuate the goals of the Act: to improve patient safety by reducing adverse effects.

C. The Act Creates Patient Safety Organizations to Facilitate Reduction of Medical Error

Most important in the context of this article is the definition of a PSO. As defined in Section 921, a PSO "means a private or public entity or component thereof that is listed by the Secretary [of Health and Human Services] pursuant to section 924(d)." Section 924(d) outlines that the Secretary shall maintain a listing of organizations that are certified by the Secretary as meeting the criteria for certification under the Act.

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70 Id. at 424.
71 Id. at § 922(e)(1).
72 Id. at § 922(a)(2).
73 Id. at § 921(4).
74 Id. at § 924(d).
Specifically, to become a certified PSO under the Act, an entity must: show that it “has policies and procedures in place to perform each of the patient safety activities described in section 921(5)”; show that its “mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery”; have qualified staff, including licensed or certified medical professionals either employed directly or by contract; have contracts of a reasonable time with more than one provider within 24 months of its initial certification; not be in whole or a part of a health insurance issuer; disclose its financial, contractual, and reporting relationships, including whether any providers have management or control over the PSO; collect patient safety data from providers in a standard manner, as much as possible; and utilize the data provided in order to provide “direct feedback and assistance . . . to effectively minimize patient risk.”

PSOs that are part of other organizations must meet additional criteria, both upon initial and subsequent certification. As part of this additional certification, these PSOs must make sure to maintain the patient safety work product separately from the remainder of the company and have security measures to protect the patient confidentiality of the data, must not make unauthorized disclosure of patient safety work product, which would thereby breach confidentiality, and must not have a conflict of interest between its missions, as required by the Act and the rest of the organization.

Of particular importance in relation to this article within this definition of a PSO are a number of caveats. One, the PSO cannot be, or be a part of, a health insurer. Two, a PSO that is part of another organization must maintain the patient safety work product separately from the rest of the company and must not breach the confidentiality. Three, the work as a PSO must not have a conflict of interest

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76 Id. at § 924(b)(1)(A).
77 Id. at § 924(b)(1)(B).
78 Id. at § 924(b)(1)(C)-(D).
79 Id. at § 924(b)(1)(E)(i)-(ii).
80 Id. at § 924(b)(1)(F).
81 Id. at § 924(b)(1)(G).
82 Id. at § 924(b)(2)(A).
83 Id. at § 924(b)(2)(B).
84 Id. at § 924(b)(2)(C).
85 Id. at § 924(b)(1)(D).
86 Id. at § 924(b)(2)(A)-(B).
within the organization. These must be kept in mind when looking at the organizations and industries involved in health care that might want or be able to fund PSOs.

III. PHARMACEUTICAL COMPANIES SHOULD FUND PSOS

Drugs contribute to medical error in a number of ways. One of the more common errors is dosing error, meaning giving a patient too much or too little of a prescribed drug. This is often caused by failing to adjust drug dosage to account for a patient’s impaired renal function, age, or size. Another common problem is prescribing patients drugs that are contraindicated, resulting in injury or worsening of one or more of a patient’s conditions. Moreover, in a Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) survey of hospital CEOs, chief medical officers, and directors of patient care services at 12 metropolitan hospitals, and employers, brokers, health plans, and medical groups, the most frequently mentioned patient safety activity was the improvement of drug safety.

Pharmaceutical companies are in the best position, as will be outlined, to make use of the Act and provide funding for PSOs. They have a vested interest, by virtue of the interactions with providers, in providing quality care and have the contacts and funding to start, at the very least, the process of analyzing data gathered from providers. Part of this vested interest is the number of adverse drug events that are the direct result of using the products these drug companies sell. For instance, a 1998 study showed that 100,000 people died as a result of a serious adverse drug reaction. This same study showed that deaths from adverse drug reactions were the fourth leading cause of death in the U.S.

As has been shown, big pharmaceutical companies have plenty of money, especially in comparison to the other industries in the United States who might be asked or who might have the interest to fund

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87 Id. at § 924(b)(2)(C).
88 Clark, supra note 12.
89 Id. at 351.
90 Id. at 350.
91 Kelly J. Devers et al., What is Driving Hospitals' Patient-Safety Efforts?, HEALTH AFF., Mar. – Apr. 2004, at 103, 107.
92 To ERR is HUMAN, supra note 1, at 28. This study defines adverse events as "an injury caused by medical management rather than by the underlying condition of the patient." Id.
93 Clark, supra note 12, at 351.
94 Id.
PSOs. They have used their money to convince the American public that the high prices they are paying for drugs is justified by the next medical breakthrough that is right around the corner and that if they lose funding—any funding—the public will not have the benefit of revolutionary, live-saving medicines. They have done this while spending more on convincing the public than actually performing the research necessary to bring these breakthrough drugs to market.

In addition, pharmaceutical companies have provided campaign funding and lobbied to have the government provide them with benefits that have increased their profitability. They continue to fight against the reimportation of cheaper drugs from Canada, and Congress passed Medicare Part D without any price controls usually available to large managed care organizations. Their efforts, in turn, lead to increased profits for the pharmaceutical companies.

It is only through true scientific analysis that cause and effect can be established. Drug companies and CROs have the experience in performing these analyses that would justify practice guidelines and changing practice patterns to improve patient safety. As drug companies know, these kinds of analyses, like those done in clinical trials, are costly. However, gathering the data and performing analyses on them justifies reliance on that information, just as in a clinical trial. Without doing a clinical trial-like analysis, the data may be considered suspect and may instead just become a new marketing tool.

Beyond the benefits conferred upon them by the government that ought to justify their paying for PSOs, i.e., preferential treatment as a result of their lobbying efforts, they are in a unique position to do so. Their relationships with CROs, organizations that are set up to perform exactly what the Act requires of PSOs, would enable big pharmaceutical companies to build funding of PSOs into their other contracts with CROs. Alternatively, pharmaceutical companies could provide funding to providers with whom they have clinical trial con-

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95 For the 2002 federal elections, pharmaceutical companies gave over $29 million to federal office candidates. Furrow et al., supra note 24, at 507.
97 McLean, supra note 5, at 253.
98 Id.
99 See id. at 253-54. Scientifically sound methodology for measuring errors and their causes has been identified as essential to understanding the epidemiology of patient safety. Donna O. Farley et al., Assessment of the National Patient Safety Initiative: Context and Baseline Evaluation Report One 33 (2005) (the report was sponsored by the Agency for Healthcare Research and Quality).
100 Clark, supra note 12, at 354.
tracts by stipulating that a certain amount of funding provided to a physician is to be used for contracting with PSOs. At least one company, Pharmacia, has already taken steps to contribute to patient safety, although it was done well before the Act was passed.\(^{101}\) Hopefully, following passage of the Act, other companies will follow its lead.

Another possible incentive for pharmaceutical companies to pay for PSOs is the potential to find and subsequently reduce adverse events on which the company previously had insufficient data. In the wake of a Texas jury’s award of $253 million for a Vioxx®-related death,\(^{102}\) drug companies might seek out PSOs as a way to provide independent research to find side effects for which they might ultimately be liable. Surely, within the 770,000 injuries and deaths each year attributable to adverse drug events\(^{103}\) or among the 51 million prescriptions with errors or 3 million prescriptions with potentially harmful errors,\(^{104}\) there are some that could have been prevented by funding PSOs, and, by identifying them, they can take action to avoid liability without identifying patients or providers.

Drug companies could also theoretically dovetail their funding of PSOs to perform cost-effective analyses to help justify to providers and health insurers the increased costs of their products. These analyses could be done without identifying providers or patients, relying only on the raw data on outcomes and drugs provided or procedures performed.

However, these companies may have several disincentives for doing so. Analyses may uncover overuse of drugs, consequently decreasing utilization and decreased profits.\(^{105}\) Identifying medical

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\(^{101}\) The National Committee for Quality Assurance (NCQA) announced in January 2002 that it was partnering with Pharmacia "to develop a program to encourage medical groups to work together to deliver safer, more error-free health care in the office setting by addressing systemic issues such as...medication errors...." Press Release, National Committee for Quality Assurance, NCQA Partners with AMGA and Pharmacia to Develop Patient Safety Program (Jan. 9, 2002), available at http://www.ncqa.org/communications/news/amgaprogram.htm. This program was slated to "provide $500,000 to fund and evaluate medical groups' safety and error reduction initiatives, many of which are expected to become models for other organizations." \(^{102}\) Id. On April 16, 2003, Pfizer began operating with Pharmacia as a unified company under Pfizer. See Pfizer, Exploring Our History, http://www.pfizer.com/pfizer/history/2000_present.jsp (last visited May 10, 2007).

\(^{103}\) Marc Kaufman, Merck Found Liable in Vioxx Case; Texas Jury Awards Widow $253 Million, WASH. POST, August 20, 2005, at A1.

\(^{104}\) Hyman & Silver, supra note 4, at 901.

\(^{105}\) Id. at 903.

One-third of drugs may not be indicated. David A. Hyman, Regulating Managed Care: What's Wrong With A Patient Bill of Rights, 73 S. CAL. L. REV. 221,
errors might help eliminate the 77 million extra resulting prescriptions\textsuperscript{106} as well. Other studies have conversely found that where drugs should have been provided in accordance with practice guidelines, they were not, which resulted in lower utilization of drugs.\textsuperscript{107} This offers a counterargument to the drug companies' concern that they might lose revenue as a result of PSO analyses.

**IV. OTHER PLAYERS IN THE HEALTH CARE SYSTEM ARE UNABLE TO PAY FOR PSOS**

Pharmaceutical companies are not the only entities in the health care system. The other components of the health care system ought also to have an interest in reducing medical error. Patients are, in theory, the focus of the health care system, and the PSO is meant to effect changes that will benefit patients the most. Health care providers also might benefit from the use of PSOs in being able to reduce medical error rates. In the era of managed care, where providers are sometimes sharing some of the insurance risk with health insurers, this would also benefit providers by being able to reduce costs. Given the cost of medical error, health insurers would no doubt welcome a reduction in medical error. The government clearly has an interest in seeing medical error reduced, based on Congress's decision to pass the Act in the first place. Employers who fund employee health insurance plans have an interest in making sure that they, as employers, are getting the best value for their insurance dollar and that their employees miss the fewest number of days from work due to their or their loved ones' illnesses.

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\textsuperscript{106} Hyman & Silver, supra note 4, at 903.

A. Consumers Are in a Poor Position to Fund PSOs

Consumers are ill equipped to provide the funding for PSOs for several reasons. First, not only are pharmaceutical costs ballooning, health care costs skyrocketed in the last decade, and are continuing to rise.\(^{108}\) The advent of managed care has done little to control the costs of health care, and consumers, even those who have health insurance through their employers, are being asked to bear an ever-growing portion of the costs of their health care.\(^{109}\) As a result, more people are choosing to go without health insurance, instead of bearing the larger burden.\(^{110}\) This is evidenced by the fact that the number of uninsured increased between 2001 and 2002 from 41.2 million to 44.6 million.\(^{111}\)

Hand in hand with the increase in health care costs is the increase in medically-related bankruptcies. A 1999 study showed that approximately 50 percent of the 10.7 million bankruptcies in the U.S. were likely directly or indirectly attributable to health care costs.\(^{112}\) These results were despite the fact that some people declaring bankruptcy had health insurance.\(^{113}\) That so many people could find themselves in such dire straights as to resort to filing bankruptcy speaks further to consumers' inability to fund PSOs. A more recent study refutes the proposition that rising health care costs result in more bankruptcies, arguing instead that the increased rate of filing bankruptcy is "the result of an increasing propensity for American households to file bankruptcy in response to economic problems."\(^{114}\) Regardless of which position is true, the fact remains that more people are filing bankruptcies, declaring an inability to pay their debts.\(^{115}\) Clearly these people are in no position to fund PSOs when they are headed toward insolvency.

Second, consumers do not necessarily have access to the organizations that perform data collection and analysis,\(^{116}\) nor are consumers


\(^{110}\) Id. at 285.

\(^{111}\) Furrow et al., * supra* note 24, at 495.


\(^{113}\) Id. at 399-400.


\(^{115}\) Id.

\(^{116}\) See Hyman & Silver, * supra* note 93, at 1452.
in a position to contract with providers or seek certification from the Department of Health & Human Services (DHHS). Since consumers are a group of individuals that wield little power individually, they are in no position to enter into the necessary arrangements to pay for PSOs. Consumers are individuals, but they do not have groups that organize them and provide representation for them as, for instance, the American Association of Retired Persons does for senior citizens. Moreover, what little negotiating power and/or influence they may have had with respect to their health care has declined. They have also been absent from patient safety improvement efforts thus far. That they have not been involved so far does not mean that they can or should not be involved moving forward. A very strong argument could be made that they absolutely should participate in ensuring quality of health care, since it is the provision of their health care that is affected.

It has been suggested that the funding for this sort of system could be financed through tort awards. However, this might punish those who are injured and result in awards that are larger than they otherwise would have been, in order for the injured party to receive as much compensation, as they would have had none of their award been earmarked for funding patient safety analyses.

B. Providers Are Already Under Pressure to Control Costs

Providers are health care professionals such as nurses, doctors, physical therapists, and physician assistants. They are, in some respects, in a similar position to that of consumers. They, too, are

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117 See Leatherman et al., supra note 107, at 28 (“[P]eople do not have the option to pay for what they want, even if what they want is better than what they have.”)

118 However, organizations such as the American Cancer Society, American Lung Association, the Institute for Healthcare Improvement, and National Patient Safety Foundation might be in a position to fund a PSO on behalf of patients. Pharmaceutical companies would be, at least to some extent, funding PSOs through this mechanism as well. See, e.g., AMERICAN CANCER SOCIETY, ANNUAL REPORT 2004: CLEAR VISION, CONFIDENT FUTURE (2004) (Pfizer and Novartis are both listed as having given at least $100,000 to the American Cancer Society).


120 FARLEY ET AL., supra note 99, at 59.

121 Liang, supra note 9, at 567. Professor Liang argues that a strict liability system of compensation should be applied to patients whose injuries are the results of the medical delivery system, and these patients would receive some percentage of the jury’s award – perhaps one-half or three-quarters – and the remainder of the award would go toward patient safety.
feeling the pinch of managed care and that industry’s efforts to rein in costs, as evidenced by a lack of resources, financial or otherwise. Providers are being faced with a variety of cost-cutting provisions, including capitation, fee-sharing, and incentives to reduce the amount of referrals or number of services they provide, even as health care costs are predicted to continue to increase at a double-digit rate. They are also faced with having to contract for lower reimbursement from large managed care companies who have the power to bargain for lower rates by virtue of their number of insured lives. In addition to responding to the pressures of managed care, medical malpractice premiums increased rapidly in the 1990s. For instance, in Dade County between 1999 and 2002, medical malpractice premium rates increased, depending on the specialty looked at in the report, between 43 and 98 percent.

Individual physicians, particularly general practitioners, have little incentive to pay for the services of a PSO and almost never compare their performance and patient outcomes with others. Not only are individual physicians likely to have smaller incomes by virtue of their smaller practice size and be ill-equipped to perform an analysis themselves, any analysis of the problems ultimately identifies a problem for which that physician is responsible. If he or she is the only physician in the office who oversees a staff of nurses, physician assistants, phlebotomists, and physical therapists, it is his or her individual act that is identified as the cause of the medical error. As the practice size increases, there may be more utility in seeking analysis of practice problems, but, again, the size of the practice may be too small to justify an expensive contract with a PSO to provide analysis of a small set of data.

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122 Financial survival is cited as the top strategic priority for health care providers by a Deloitte & Touche study. See Patterson, supra note 108, at 195. The decrease in reimbursement is also because of decreases in funding by state and federal programs as well. Michelle M. Mello et al., Fostering Regulation of Patient Safety, 30 J. HEALTH POL. POL'Y & L. 375, 411 (2005).

123 Devers et al., supra note 91, at 111.

124 Patterson, supra note 108, at 196.


126 Id.

127 Hyman & Silver, supra note 4, at 940-41.

128 Hyman & Silver, supra note 107, at 1452.

129 Hyman & Silver, supra note 4, at 961-62 ("[M]ost independent practices are too small to afford . . . technology. . . . Over and over again, one finds that providers fail to implement proven patient safety measure because they lack the incentive to bear the cost.").
Hospitals, as the largest providers in the health care food chain, clearly have the greatest incentive to undertake these studies but little to gain from doing so;\textsuperscript{130} regardless, some likely will undertake them in order to improve their processes. While some institutions are too small or financially stressed to make these investments,\textsuperscript{131} their doing so may be justified through a "business case for quality."\textsuperscript{132} Professors Hyman and Silver define a business case for quality as "when a provider can earn a profitable financial return on a quality-enhancing investment."\textsuperscript{133} However, whether error reduction and improvement of other quality measures will reduce costs and improve efficiency of care is highly controversial.\textsuperscript{134} Additionally, they may have difficulty in finding funding to establish this business case,\textsuperscript{135} even though the absence of the business case may be the most important cause of poor quality.\textsuperscript{136}

Physicians in larger organizations are more likely to report or be willing to have their data reported and receptive to changes suggested by an analysis because it reflects upon them less, personally, than when reported as part of a large institution. Health care providers working out of a hospital would likely be in a similar position, i.e., one in which reporting their data would not negatively impact them. However, unless hospitals can justify the outlay of expense involved in performing these analyses in-house or contracting them out to a PSO by recognizing a corresponding savings, there is little incentive for them to do so.\textsuperscript{137} The legislation itself provides no such incentive.

\textsuperscript{130} Mello et al., supra note 122, at 398.
\textsuperscript{132} Hyman & Silver, supra note 4, at 957-63. See also Becher & Chassin, supra note 131, at 169.
\textsuperscript{133} Hyman & Silver, supra note 4, at 957. See also Becher & Chassin, supra note 131, at 169.
\textsuperscript{134} Epstein et al., supra note 105, at 407.
\textsuperscript{135} However, even with support for these sorts of studies, hospitals may not implement processes that will ultimately save them money. While it has been shown that computerized physician order entry (CPOE) systems reduce adverse drug events, the investment in a CPOE may be difficult to justify under short-term cost pressures and where the benefit occurs over a longer time period. See David F. Doolan & David W. Bates, Computerized Physician Order Entry Systems in Hospitals: Mandates and Incentives, HEALTH AFF., July – Aug. 2002, at 180. See generally Leatherman et al., supra note 107.
\textsuperscript{136} Hyman & Silver, supra note 4, at 957-58.
\textsuperscript{137} See id. at 988 ("The Patient Safety Act is built on the false premise that goodwill alone is sufficient to motivate health care providers to study their mistakes and improve their systems.").
Hospitals also have a disincentive to prevent medication errors because injuries caused by medications add approximately forty-seven hundred dollars to the cost of a hospitalization, although some physicians believe that the problem of medical errors has been overestimated. Medical institutions also may not implement systems to report their data because the patients feel the benefits directly, and the institutions themselves do not. However, some scholars argue that spending more on patient safety initiatives now makes up for traditional underspending in this area.

Regardless of whether providers choose to report their data, this legislation makes it easier for them to do so without fear of reprisal. Instead of having to worry about the information being reported as discoverable or providing a source of clients, this law specifically excludes reported information from discovery. It can, however, be obtained through the normal discovery process, i.e., as part of a single patient’s file and not as an entire data set. Additionally, it has been argued that if providers really do care about patient safety, they should be paying for these sorts of analyses. Indeed, some patient safety data has been generated by hospitals on patient satisfaction surveys, but this is a far cry from independent statistical analysis of empirical data provided by a hospital.
C. Health Insurers Are Precluded by the Act from Funding PSOs

As mentioned before, health insurers are precluded from providing the funding for PSOs.\textsuperscript{148} It is unclear from the legislative history what the impetus for this section of the Act was. One might hypothesize that Congress was concerned that allowing health insurers, such as managed care organizations, to do so would have created a conflict of interest.

If insurers provided funding to PSOs to perform analyses on patient safety work product, in theory, a temptation would be created to use that data for their purposes to identify providers who cause more errors and then preclude these providers from being able to provide health care through their health plan, under the auspices of providing better health care. However, even if a particular error can be traced back to a particular physician it may not necessarily mean that physician was the actual cause of the error. Institutional errors are thought to cause more injuries than individual errors.\textsuperscript{149} Scapegoating a particular physician runs counter to the goal of anonymity that underlies Section 922 of the Act.

A more cynical view of the clause precluding health insurers from funding PSOs is that their lobby "convinced" Congress to add this part of the Act to prevent cries from physicians and consumers to have health insurers pay for these sorts of analyses, since it might be a natural function for them. However, there is nothing in the legislative history to show this to be the case. Also, health insurers, as payers, are more concerned with cost than benefit to the patient.\textsuperscript{150} There is no incentive for them to fund PSOs when doing so may result in increased safety that might decrease their bottom line.

One way to get around the prohibition on health insurers funding PSOs would be to incentivize its plan physicians to report their data to and contract with PSOs. This would enable providers to increase patient safety and participate in the voluntary reporting. Health insurers could, theoretically, receive a benefit from providing this funding through reduced outlays for medical errors caused by their providers that were previously undiscovered. Indeed, some insurers have pro-

\textsuperscript{148} Patient Safety and Quality Improvement Act § 924(b)(1)(D).
\textsuperscript{149} Clark, supra note 12, at 350 (citing S.M. Dovey et al., \textit{A Preliminary Taxonomy of Medical Errors in Family Practice}, 11 QUALITY & SAFETY IN HEALTH CARE 233 (2002)). Clark notes that 82.6 percent of medical errors reported were caused by health care systems' dysfunctions. It should be noted that this data might be skewed because this data was gathered only from family physicians and because doctors reporting errors might be more likely to report medical errors that are not the result of their actions but that rather can be blamed on extrinsic factors.
\textsuperscript{150} Hyman & Silver, supra note 4, at 960.
vided financial incentives to physicians for improving patient satisfaction or quality of care.  

D. Government Has Chosen not to Provide Funding for PSOs

The federal government would be a natural source of funding for PSOs, at the very least to get the ball on reporting moving. Indeed, the federal government does perform analyses on its own for the programs it administers for the Veteran’s Administration (VA).  

Congress could have made allowances for PSOs in the Act; instead, it thrust this task upon the Agency for Healthcare Research and Quality (AHQR) without increasing its budget for the coming year. Although its budget is small, $60 million of it earmarked was for patient safety. Part of this funding goes towards the Patient Safety Research Coordinating Center, established to facilitate interactions among patient safety grantees. However, many believe the agency funding for patient safety is insufficient based on the estimated level of the problem. The $60 million falls short of the $100 million rec-

\[151\] Epstein, supra note 105, at 406. This study also noted that, anecdotally, the amount of money being used as an incentive is growing substantially. Id. Another option might be to have data reported to accrediting organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Indeed, JCAHO announced the day the law was signed that it “expects to create or become part of a Patient Safety Organization under the auspices of its new International Center for Patient Safety and seek federal approval under a new process to be created by the Department of Health and Human Services.” Press Release, Joint Commission on Accreditation of Healthcare Organizations, Joint Commission Hails Enactment of Patient Safety and Quality Improvement Act of 2005 (July 29, 2005) (on file with author).

\[152\] See Hyman, supra note 4, at 933-37.


\[155\] FARLEY ET AL., supra note 99, at 17. Interestingly, in this report it identified “major stakeholder groups” for a patient safety initiative; managed care organizations were not included, although patients, providers, patient safety organizations, and the state and federal governments were. Id. at 4.

\[156\] Id. at 6.

\[157\] Id. at 11.
ommended by the IOM report. Additionally, most of the funding spent by the AHQR thus far has been focused on traditional peer review journal articles.

Some have suggested that this sort of initiative should come from the government under the direction of the National Institutes of Health. While the government does have other efforts in the area of patient safety, it has not yet resolved to pay for the sort of analyses this law requires, and the funding given to other federal agencies for patient safety was minimal. Other authors have noted that without a commitment to substantial funding by the federal government for health care information technology, identified by the IOM’s report as a key to reducing medical error, there is unlikely to be substantial change in the rate of medical errors.

State governments could provide funding, but they too are facing a health care crisis with costs escalating. While some state governments have pursued initiatives, the number has been small and the programs limited. Since the federal government has appeared to opt out of providing funding on its own outside of its VA programs, PSO funding must come from either the state governments or the private sector. Florida, for example, beginning in 2004, requires its Agency

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158 Id. at 17.
159 Id. at 65-66.
160 Liang, supra note 9, at 561.
162 Farley et al., supra note 99, at 11.
163 See generally To Err is Human, supra note 1.
164 Patterson, supra note 108, at 207.
166 See Jill Rosenthal & Maureen Booth, Nat’l Acad. for State Health Policy, State Patient Safety Centers: A New Approach to Promote Patient Safety (2004). This report looked at patient safety centers in six states that are backed by state legislation. They noted, among other things, that the level and reliability of funding is an issue in most states; fees, grants, and appropriations provide primary support for these patient safety centers. Id. at 13. Another conclusion of this report was that “[s]tate patient safety centers would be logical models to serve as PSOs.” Id. at 28. Fewer than twenty states have adverse event reporting systems, but most were in place before 2000. Farley et al., supra note 99, at 28. However, these reporting systems are subject to the tight and shrinking state budgets. Id. at 29.
for Health Care Administration to gather patient safety information from its hospitals. 167 A number of states have also set up organizations to study patient safety. 168 Other steps have been taken by state governments to incentivize providers to invest in error reduction. 169 However, even if governments do decide to fund PSOs, it should be noted that state medical boards have historically been incapable of monitoring and ensuring quality. 170

E. Employers Lack Appropriate Incentives to Fund PSOs

As mentioned in Part IV(A) on consumers, employers are feeling strapped to provide health insurance to their employees. Not only have employers moved away from providing fee-for-service health insurance 171 and towards cost-controlling managed care health insurance, 172 in recent years they have passed on increasing amounts of the cost of health insurance to their employees. 173 Employers have also moved towards consumer-driven health care plans that force the employees to make decisions regarding their health care plan in an effort to control the employer’s costs. 174 Doing so, however, does not address the problems of increasing costs of health care, uninsurance, and underinsurance. 175 Based on this evidence, it is unlikely that an employer would provide funding for a PSO to provide an analysis of those providers that care for its employees. Moreover, there is little incentive for an employer to pay for analyses of a provider when it is unlikely that a provider would care for every one of its employees. This disincentive might also apply to health care insurers as long as employers are switching health care plans often. Employers would, in

168 Mello et al., supra note 122, at 385.
169 Id.
170 See, e.g., Sidney M. Wolfe, Bad Doctors Get a Free Ride, N.Y. TIMES, Mar. 4, 2003, at A25 (noting that state medical boards have failed to discipline the small minority of doctors who are responsible for multiple malpractice payouts).
171 Fee-for-service health insurance provided patients with virtually unlimited access to medical resources, resulting in doctors administering unnecessary tests and procedures. Pendo, supra note 109, at 277-78.
172 Id. at 277.
173 Id.
174 Id. at 291-92.
175 Id. at 292.
effect, be subsidizing the increase in patient quality of care for other patients, not their employees, of that provider, some of whom likely would be covered under another employer’s health care insurance. Also, because it is unlikely that all their employees will see the same provider, they could end up paying for analyses of a large number of providers.

Employer groups offer more opportunity to affect health care quality and cost. Employer groups, such as Leapfrog and the Pacific Business Group on Health, may take the lead and fund PSOs. These groups are collections of large employers that in recent years have been pooling their health care dollars to force providers to increase quality and provide better services to their employees. They could, in theory, fund these analyses up front and reduce their overall costs by tying compensation to low-error or error-free services. However, there has been no evidence yet of their response to the Act in funding PSOs, even though Leapfrog has initiated a voluntary, Web-based hospital quality and safety survey.

CONCLUSION

Pharmaceutical companies have taken too much from the American economy for far too little in return. The return on investment is increasingly woeful. It is time for large drug companies to put their marketing dollars forth as a sacrificial lamb on the altar of patient safety. They can find other ways to peddle drugs; no doubt they will find ways to increase cost effectiveness to make up for the marketing budget lost by funding PSOs.

Other players in the consumption and delivery of health care are unable to fund PSOs based on their position or the applicable law. Of the members of the health care industry, only pharmaceutical companies are in a position fund PSOs. Since the government has, at this

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176 The Leapfrog Group is a group of 170 companies and organizations that buy health care and who look to reduce medical error and encourage public reporting of health care quality. See The Leapfrog Group Fact Sheet, http://www.leapfroggroup.org/about_us/leapfrog-factsheet (last visited Sept. 17, 2006).

177 The PBCH is a business coalition of 50 purchasers, including Bank of America, Cisco Systems, FedEx, DirectTV, Lowe’s, Pacific Gas & Electric Company, Stanford University, Verizon Communications, and Wells Fargo & Company, who, to be eligible for membership, must have at least 2,000 benefits-eligible covered lives, and who seek solutions to the health care issues facing purchasers. See Pacific Business Group on Health, http://www.pbgh.org (last visited Sept. 18, 2006).

178 See Hyman & Silver, supra note 107, at 1472-73.

179 See id. at 1480. See also Mello, supra note 122, at 415.

time, decided not to undertake this venture, the mantle of funding PSOs has fallen to the private industry. Not only do big drug companies have the resources to do so, but they also have the personnel and/or contacts within the industry who have the specialized skills required in order to accomplish the analyses required to generate meaningful and useful data.

While this proposal is not a panacea to solving the problem of improving patient safety and who pays for it, it is at least a small start that can help guide and shape future, perhaps larger, efforts. This law is too new for there to be any way to judge efforts already underway under its auspices. Perhaps time will show that providers are more willing than previously thought to pay for these studies; perhaps employers will find a way to justify expenditures in this field; or perhaps consumers and patients will band together to speak with a loud enough voice in protest of the magnitude of medical injury such that their legislative or elected representatives will finally step in and do something besides enact underfunded legislation. It remains to be seen what the impact of this law will be. As it stands now, with no funding to perform needed analysis, there is little chance that it will succeed without private industry stepping forward and paying the bill.