

FRESH-Thinking

Focused Research on Efficient, Secure Healthcare



Robert Wood Johnson Foundation

The Regulatory Component Of Health Care Reform



by Roger G. Noll

THE REGULATORY COMPONENT OF HEALTH CARE REFORM

by

Roger G. Noll

The American health care sector is extensively regulated. States play a major role, regulating insurance carriers, entry and quality in health care professions, and in some cases facilities entry through certificate-of-need requirements. The federal government also is a major player through its regulation of drugs, medical devices, and employee fringe benefit programs. Participants in the debate about reforming the American health care system generally agree that the health care regulatory system is too complex and inefficient, so that one component of reform must be a redesign of the regulatory policies and institutions. But with few exceptions reformers have not provided much detail about how regulation should be reformed, and what problems regulation

Health policy analysts broadly agree about the problems with the American health care system. First, costs are high compared with other nations at a comparable level of development, and, after an interlude in the 1990s, costs again are growing substantially faster than the rate of growth in income. If this trend is not arrested, sometime before the middle of the 21st Century the annual growth in medical care costs will equal the annual growth in gross domestic product, so that from that date on further growth in health care costs must be financed by reductions in the production of other goods and services. Second, a major source of high and rising costs is that many patients receive treatments that provide little or no health benefits, including excessive

utilization of expensive new technologies. Existing procedures for reviewing treatment decisions by providers are largely ineffective at preventing over-utilization because reviews focus on detecting unusual cases, rather than the appropriateness of common practice decisions by most physicians. Third, the administrative costs associated with the system for paying for care are excessive. A great deal is spent authenticating the validity of claims and resolving disputes arising from claims denial. Fourth, insurance coverage and access to care is incomplete. Whereas the focus of public discourse about coverage is the uninsured, another problem is the uncertainty that insurance actually will cover the costs of a major health incident.

The natural and common conclusions to draw from the recital of agreed problems are that high costs can be controlled by regulating prices, excessive treatments can be reduced by regulating the delivery of care, and universal coverage can be achieved by mandating universal coverage and regulating the minimum content of that coverage. But with few exceptions, health policy analysts provide few details about how regulation ought to be implemented – that is, what policies, structure and process of the regulatory system would be most likely to yield regulations that provide substantial benefits to society. The implicit presumption is that creating an agency with a mandate to solve the problems of high costs, over-utilization and incomplete coverage is sufficient to assure that significant progress will be made.

The absence of serious attention to the regulatory component of health care reform is surprising, for five decades of research finds that regulatory policies, in health care as well as other industries, often impose more costs than benefits on consumers. The seemingly incongruous conclusions that regulation is a necessary part of health-care reform but that the overall effect of regulation fails a benefit-cost test is understandable, for it is based on years of

frustration in trying to generate more competition and better financial incentives in the health care sector. Because health care constitutes 16 percent of GDP, providers of health care services and products constitute, by far, the largest interest groups in the American political system. Providers have succeeded in inducing the government to adopt many regulatory programs that protect them against changes in policies and institutions that they perceive as threatening to their incomes and autonomy, and they have formed extensive and effective alliances with various groups that represent particular categories of health care consumers to advocate expansion of health care for these groups.

American consumers, though dissatisfied with the American system of health care, have favorable views about doctors, hospitals and the care that they and their family members receive.¹ Consumers also generally have unfavorable views about insurance companies and HMOs (even though most report satisfaction with their own carrier), and most believe that HMO's have caused the quality of care to decline. Consumers' satisfaction with the service that they and their families receive but dissatisfaction with the system as a whole gives health care providers political leverage if providers package self-serving proposals for regulation as consumer protection initiatives that will deal with the latest newsworthy health care horror story. The alliance of consumers and suppliers has led many to conclude that significant reform of the American health care system is politically infeasible, implying that we should just pay our bills and be happy.

1. A comprehensive compendium of public opinion polls about health care can be found at: www.kaisernetwork.org/health_poll/hpoll_results.cfm?catID=9&Submit=display+subtopics.

I believe that this assessment is correct with respect to prospects for effective use of regulation as a means for solving the problems of health care. The primary message of this essay is that regulation is not likely to produce significant potential benefits in terms of controlling costs or improving efficiency. I do not regard the current reform movement as offering good prospects for eliminating existing regulations that contribute to the current problems with health care delivery, let alone to create new regulations that will deal effectively with the problems in health care that are not primarily due to existing bad regulations. This essay explains why.

WHAT IS REGULATION?

Before proceeding with an analysis of potential reforms in health care regulation, a useful beginning is to define the domain of policies to which the term regulation applies. Regulation is in part a set of rules, and these rules can have many forms. The most common types of regulation involve control of prices, limitations on entry into a market, technical requirements for products (including services) and production processes, and mandatory disclosure about product characteristics. A fifth form of regulation, which is rules to deal with discrimination on the basis of ethnicity, gender, disability and age, has important applications in the health care sector, but does not raise issues that are unique to health care and so will be ignored.

Regulation is more than a set of rules. Regulation has two additional defining characteristics: it is a non-legislative, non-judicial process for creating rules that have the force of law, and it applies to activities in which the government is not otherwise directly involved.

Regulations are not created by the legislature or the courts, which are the two entities that the Constitution authorizes to create rules that have the force of law. Instead, regulations are the

product of a rule-making authority that has been delegated its powers through legislation.

For example, in 1906 Congress delegated to the Secretary of Agriculture the responsibility to regulate the safety of food and drugs. The Secretary in turn delegated this responsibility to DOA's Bureau of Chemistry, until then a scientific research agency that, among other things, studied food quality. The Bureau became the Food, Drug and Insecticide Administration in 1927 and the Food and Drug Administration (FDA) in 1930.² The FDA was transferred from Agriculture to the Federal Security Agency in 1940, which became the Department of Health, Education and Welfare (HEW) in 1953. When HEW was divided in 1980, the FDA became part of the Department of Health and Human Services (HHS). In each transfer, the official to whom Congress delegated the authority to regulate was the head of the agency of which the FDA was a part. Technically, the statute requires that new drug applications formally must be filed with the Secretary of HHS, not the FDA.³

Another example is in the history of auto corporate average fuel economy (CAFE) standards, which illustrates the substitutability of rules by regulation and rules by statute if Congress is so inclined.⁴ In 1975, Congress passed legislation that established long-term fuel-efficiency standards for passenger cars at a fleet average for each manufacturer of 27.5 miles per

2. For a comprehensive history of the FDA, see: <http://www.fda.gov/oc/history/default.htm>.

3. Section 505 of the Act, at: <http://www.fda.gov/opacom/laws/fdcact/fdcact5a.htm>

4. See <http://www.nhtsa.dot.gov/cars/rules/cale/overview.htm> for a history of automobile fuel efficiency regulation.

gallon to be achieved by 1985, and set lesser interim standards from 1975 through 1980. The 1975 act delegated to the Secretary of Transportation, and the Secretary of Transportation then delegated to the Administrator of the National Highway Traffic Safety Administration (NHTSA), the authority to determine the rate of progress towards attaining the fuel-efficiency standards for passenger cars from 1981 to 1984, and to create new fuel-efficiency standards for light trucks (including sport utility vehicles, or SUVs) and other vehicles. Subsequently, Congress legislated again by incorporating into all appropriations bills from 1996 through 2000 a freeze on the light truck standard at 20.7 miles per gallon. When the budget freeze was lifted in 2001, NHTSA initiated a regulatory proceeding to set new standards for light trucks, and in 2003 issued regulations that called for improvements in fuel economy for light trucks that increased the mileage standard to 22.2 mpg by 2007. In 2005, NHTSA adopted new regulations for light trucks for 2008 through 2011. The new regulations would bring overall fuel efficiency for light trucks to 23.5 mpg by 2010, and thereafter set separate standards depending on vehicle characteristics (called “reformed CAFÉ”).

In 2007, Congress passed additional legislation setting an overall fuel efficiency standard of 35 miles per gallon for all automobiles (passenger and light truck) to be achieved by 2020.⁵ The new Act authorizes the Secretary to create separate standards for passenger vehicles and light trucks within this overall constraint and standards for heavy-duty work vehicles, requiring that each standard be expressed “in the form of a mathematical function” that is based on vehicle

5. *Clean Energy Act of 2007*, weighing in at over 800 pages, available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h6eas2.txt.pdf

characteristics but allowing the Secretary to determine what those characteristics should be.⁶ In addition, it delegates to the Secretary the authority to adopt interim standards for each type of vehicle as well as the entire fleet of autos from 2011 through 2019. In a sense, Congress indirectly has delegated to NHTSA the responsibility for writing regulations that deal with the details of meeting the statutory goals, but for over 30 years has kept for itself the task of setting the overall standard. The former but not the latter is regulation.

In addition to being a non-statutory source of law, regulation refers to rules that apply to legal, socially desirable private activities that do not directly involve the government. For example, government agencies frequently produce rules regarding the qualifications of potential contractors for government procurement. An example is the reimbursement rules of the Health Care Financing Agency for Medicare and Medicaid, including the system of payment for Diagnostic Related Groups (DRGs). These rules technically are not regulations because they pertain to transaction in which the government is a direct purchaser. Indeed, HCFA has steadfastly resisted both the notion that it is a regulatory agency and attempts by Congress to give it regulatory authority.⁷

Another example is public utilities commissions (PUCs). Nearly all states have created

6. *Ibid.*, Section 102(a)(2), amending Section 32902 of Title 49 of the U. S. Code to create a new section (b)(2)(C).

7. Michael J. Astrue, "Health Care Reform and the Constitutional Limits on Private Accreditation as an Alternative to Direct Government Regulation," *Law and Contemporary Problems* Vol. 57, No. 4 (Autumn 1994), pp. 75-87.

PUCs to regulate the prices charged by privately owned electric companies; however, public utilities regulators do not control the prices of government-owned electric utilities, such as municipal utilities or federal agencies such as the Bonneville Power Authority or the Tennessee Valley Authority. Prices for municipal utilities typically are set by a city council, based on analyses and recommendations from the utility and the city's chief financial officer. The process by which those prices are set is not regulation because the entity controlling the price (the municipality) is also both the owner and a government.

The defining characteristics of regulation – rules promulgated by an agency that have the force of law and that apply to legal activities that do not directly involve government – are not just hair-splitting. Regulation as so defined raises unique concerns about the legitimacy of the delegation of law-making authority by a legislature. In the case of most forms of legislation (treaties are an exception), Article I of the U. S. Constitution designates Congress as the branch that is responsible for making laws, and Article II envisions that the President will be responsible for implementing laws, including appointing people to manage agencies and programs. That is, without generating much controversy, Congress can delegate such things as enforcement of criminal law, procurement of goods and services, or management of a public enterprise to an agency. No one expects legislators to arrest and confine criminals, construct roads and buy military aircraft, and manage the Bonneville Power Authority and the U. S. Navy. In the United Kingdom, where there is no constitutional executive branch and Members of Parliament serve as the top executives (cabinet members and one or more underlings) of government agencies, Parliamentarians are not expected to perform managerial functions. Instead, these functions are performed by high-level civil servants with extensive professional and operational experience.

By comparison, delegating law-making authority that affects legal private activity is controversial because writing laws is what legislators are elected to do. Article I, Section 8 of the Constitution enumerates the legislative power of Congress and includes the following specific authority: “To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.” The Constitution does not explicitly state that Congress can delegate this authority to the President, an agency, or anyone else. Because regulation delegates the power to make law, some pundits believe that regulation amounts to abdication by Congress of its Constitutional duty to legislate.

Delegation of the implementation of a policy to an agency creates the possibility that the legislature will lose control of the policy that was established in a statute. For expenditure programs – either procurement or direct production of goods and services – the principal mechanism for retaining policy control is the budgetary process. Legislators use the authorization stage of the budget process to shape the design and location of projects, and annual appropriations to allocate expenditures among projects. In the case of a new weapons system or federal construction activity, projects go through an initial design phase that produces a proposal to Congress to allocate funds for spending serious money to carry out the design.

Legislators can use the budgetary process to shape regulation, but only in a much more limited way than is the case for other government activities. Congress occasionally places riders in appropriations bills for regulatory agencies that prohibit the agency from spending funds on developing regulations for a particular activity, as was the case for fuel efficiency standards for SUVs from 1996 through 2001. Congress also can influence the effect of a regulation by placing restrictions on expenditures by an agency for enforcing its regulations. Notwithstanding these

possibilities, budgetary controls are not very effective as a means for controlling regulation for two reasons.

One problem Congress faces is that regulation, unlike most programs, has no design phase that produces a proposal to Congress. In the case of a new regulation, the product of the regulatory process is a rule that has the force of law, not a proposal to Congress about a potential new law or an activity that requires funding. By the time Congress knows what the agency intends to do, it is usually too late to control the outcome by using budget restrictions.

The other problem is that in nearly all cases in which Congress and an agency disagree, the source of disagreement is not about whether an activity should be regulated, but about the details of the regulation, including its stringency. To deny funds to the agency for developing or enforcing a regulation is costly to Congress if Congress desires to have the activity regulated but disagrees with the agency about the details.

Assuming that Congress prefers regulation to no regulation, all that Congress can do after a regulation is adopted is to pass a law that overrides the agency's regulation. Although Congress sometimes does use legislation to over-ride or constrain a regulation, as seen in the history of automobile fuel efficiency standards, this outcome is unusual. Substituting statutes for regulation is potentially quite costly to Congress for three reasons. First, writing a detailed regulation is time-consuming and difficult, as witnessed by the 800+ pages of the 2007 energy act that set up the new system for controlling automobile fuel economy. Second, statutory rules, once enacted, produce inflexible policies. Statutes are difficult to amend because they require the passage of another statute. The procedures within Congress for writing laws are complex, in part because Congress is a democratic institution in which members represent heterogeneous

constituencies and in part because enacting a statute involves two houses plus, because of the possibility of a veto, the President. Third, proposing a statutory change may open a Pandora's box by creating the possibility that other, unanticipated items will be attached to the legislation through floor amendments. Thus, *ex post* correction of a regulation by statute usually is not an attractive means for controlling a regulatory agency.

A final concern about regulation arises from its application to private activities that are regarded as both legal and socially desirable. The concern here is that the rights and benefits of those who are engaged in legal activity may be undermined by an attempt to regulate their behavior. For example, the courts interpret the 5th Amendment protection against expropriation of property without due process of law as requiring that regulation must not prevent regulated entities from earning a competitive return on their investments unless their products or production processes are a threat to public welfare.

As a result of these concerns about regulation as a method for achieving a policy goal, both courts and legislatures have created an array of procedural requirements for regulation that do not apply to other bureaucratic decision-making processes or to the process of writing statutes. The point of these procedural rules is to reduce the chance that an agency will promulgate a regulation that legislators or the courts will find inconsistent with either statutory policies or Constitutional rights. Procedural requirements serve the political purpose of advantaging particular interests or points of view in the regulatory process that the creators of the procedures regard as needing protection or having interests that are congruent with policy goals of the regulatory statute.

For procedural rules to work as an *ex ante* means of control over regulatory outcomes,

variation in procedures must have predictable effects on the policy content of regulations.

Conceptually, procedures affect outcomes by affecting the evidence that is available to the agency concerning the possible consequences of a regulation. An agency must be able to defend the content of a final regulation against appeals of its decisions to the courts. The ability of the agency to defend its regulations depends on the amount and quality of the information that the regulator can use as evidence in support of its decisions. Procedures determine the information that is available to regulators, and hence the regulations that they can successfully promulgate.

A necessary component of the dependence of outcomes on procedures is oversight of regulatory outcomes by the courts. Whereas courts always have jurisdiction to review regulatory rules to ascertain whether they comply with underlying statutes and the Constitution, regulatory legislation gives the courts other review rights as well, including the authority to enforce the agency's procedural rules, such as the assignment of burdens of proof to participants in the regulatory process, the standard of proof (that is, how convincing the evidence must be) for justifying a decision, and the requirements for a person or organization to have the right to participate in the regulatory process (e.g., standing) by submitting evidence and argument about proposed regulations. Failure to comply with procedural requirements is a common cause of rejection of regulations by courts.

A recent example of reversal due to procedural error – in this case, failure to satisfy the burden of proof and to follow its own procedures – is the decision by the U. S. Court of Appeals for the Ninth Circuit to vacate the fuel-efficiency standards for light trucks, which includes

SUVs.⁸ In 2006, NHTSA proposed a new set of fuel economy requirements for SUVs and other light trucks for the years 2008 through 2011. The new regulations required steady improvement from 22.2 mpg for 2007 models, but that still fell considerably short of the standards for passenger cars. The Ninth Circuit ruled that NHTSA’s new regulations were “arbitrary and capricious” (that is, NHTSA failed to bear the burden of proof that the new standards were reasonable according to the methods of economic analysis that it had developed to implement its statutory mandate) in deciding which regulations to adopt because of the agency’s “failure to monetize the value of carbon emissions, failure to set a backstop [a minimum overall standard], failure to close the SUV loophole [the difference in standards between SUVs and standard passenger vehicles], and failure to set fuel economy standards for all vehicles in the 8,500 to 10,000 gross vehicle weight rating (‘GVWR’) class.”⁹ Underpinning the decision are legal provisions about standards for writing regulations: NHTSA must offer reasonable evidence that differences in standards among types of vehicles are justified and consistent with its regulatory mandate to consider technological feasibility, economic practicality, energy consumption effects, and environmental consequences.

Recall that the original legislation not only set up separate procedures for regulating fuel-

8. *Center for Biological Diversity, et al., v National Highway Highway Traffic Safety Administration*, U. S. Court of Appeals for the Ninth Circuit, November 15, 2007, at [http://www.ca9.uscourts.gov/ca9/newopinions.nsf/775202DBA504085C88257393007B9729/\\$file/0671891.pdf?openelement](http://www.ca9.uscourts.gov/ca9/newopinions.nsf/775202DBA504085C88257393007B9729/$file/0671891.pdf?openelement).

9. *Ibid.*, pp. 14840-1.

efficiency standards for passenger cars and light trucks, but adopted a standard for the former but not the latter. Later, Congress used the appropriations process to freeze the SUV standard at 20.7 mpg while the passenger standard was 27.5 mpg. The analytical arguments by the plaintiffs about why NHTSA's rules were inconsistent with the statutory goals of the fuel-efficiency program applied with equal validity to the standards adopted by Congress in 1975 for passenger vehicles and in 1996 for light trucks, but such arguments do not constitute a valid legal challenge to a statute. The fact that Congress could write this distinction into statutes without fear of judicial reversal did not confer upon NHTSA the right to perpetuate that distinction without proving that doing so was reasonable.

This case sharply illustrates the difference between rules as regulations and rules as statutory mandates. This distinction was played out again in late 2007 as Congress amended the underlying fuel-efficiency statute, setting a target overall standard of 35 mpg (without offering evidence that this standard satisfied the statutory criteria for setting a regulation by NHTSA), retaining separate standards under this overall constraint for different types of vehicles based on their characteristics ("reformed CAFÉ"), and continuing the practice of not including medium and heavy duty vehicles in the overall standard. Whether the plaintiffs' arguments against NHTSA's proposed regulations also apply to the new rules adopted by Congress is irrelevant because laws and regulations are not subject to the same standards of judicial review.

Another procedural rule that often determines the outcome of a regulatory proceeding is the allocation of the burden of proof. Congress has successfully used modifications in the burden of proof to change the outcome of a regulatory statute that otherwise was not amended. By requiring that an actor prove some fact in order to enable the regulator to take an action,

Congress can stack the deck in favor of or against that particular actor's most preferred outcome.

The Airline Deregulation Act of 1978,¹⁰ amending the Civil Aeronautics Act of 1938,¹¹ provides one example of how a seemingly small change in the burden of proof reversed a policy. Under the original Act, in order to receive a license to offer flights between a pair of cities, a prospective entrant bore the burden of proving that a regulator could reasonably conclude that without entry service would be inadequate. Proving that one could reasonably conclude that some customers were being denied service proved to be virtually impossible, so this provision led to very little entry in the airline business for forty years. In the 1978 amendments, Congress changed the procedure, shifting the burden of proof by stating that a license should be granted unless the regulator could prove by a preponderance of evidence that new entry was not in the public interest.¹² This modification caused the regulatory process to favor entry, thereby reversing the bias against entry that had protected carriers in the past. As a result, airline entry was essentially deregulated by a shift in the burden and standard of proof.

Another useful comparison is between the current regulatory burdens of proof for licensing new drugs by the FDA and new toxic chemicals by the Environmental Protection

10. Public Law 95-504.

11. Public Law 75-706.

12. "Reasonable to conclude" is a weaker standard of proof than "preponderance of evidence" in that the latter, but not the former, implies "more likely than not."

Agency. In the case of new drugs, the Food and Drug Act, as amended in 1962,¹³ requires that an entrant must prove that a drug is safe and effective. To provide this proof, the sponsor of the drug must submit an application for an Investigational New Drug (IND).¹⁴ If approved, the sponsor then completes a three-step process. In Phase I, healthy individuals receive the drug to determine whether it has adverse side-effects. If no serious side-effects are found, the drug enters Phase II, in which a small group of patients who have the diseases or conditions that the drug is intended to treat are given the drug to determine whether it is effective. If the results in Phase II are promising, the drug moves to Phase III, which includes a larger group of target patients in the clinical trial. Finally, the sponsor submits a New Drug Application (NDA), which includes the results of the clinical trials as well as a proposed description of the effects and intended uses of the drug. The FDA then has 60 days to decide whether to “file” the NDA for formal review. Typically a decision not to file the NDA is based on an incomplete application, with the FDA noting the additional information that it requires. If the NDA is filed for review, the agency has no formal time limit to decide whether to allow the drug to be marketed, although it has a target of reviewing 90 percent of all NDAs within ten months.

By comparison, the section of the Toxic Substances Control Act (TSCA) of 1976 that deals with new chemicals requires that the EPA must prove that a new toxic chemical is a “significant threat to humans” in order to prevent it from being marketed. Firms that intend to

13. Public Law 87-781.

14. See <http://www.fda.gov/fdac/special/testtubetopatient/drugreview.html> for a description of the FDA’s process for licensing new drugs.

sell a new toxic chemical must file a “pre-market notification” (PMN) with the Environmental Protection Agency (EPA). The PMN contains a complete characterization of the chemical and “available” information about its effects on humans. No specific testing is required, although the EPA can require certain tests if the amount of the chemical to be used is large. Likewise, the PMN review has nothing that corresponds to the “safety and efficacy” (the benefits must offset the risks) requirements for drugs. EPA has 90 days to respond to the PMN, which can be extended an additional 90 days if the EPA can show “good cause.” If the information is insufficient to assess the toxicity of the chemical, the EPA can restrict its use; however, it can not ban the use of the chemical without proving that it is a substantial threat to humans, which of course can not be proved if there is no relevant testing information.

These procedural differences have had a profound effect on entry. The vast majority of IND applications do not result in a new drug being licensed and marketed, but in over thirty years the EPA never has succeeded in banning any of the 75,000 new toxic chemicals that have been subjected to the PMN review provisions in TSCA. Of course, the point is not that this outcome is undesirable. Perhaps it is perfectly reasonable. Instead, the point is to show that the allocation of the burden of proof is extremely important when dealing with regulatory issues where cause-effect relations are imperfectly understood and substantial information is required to satisfy the burden of proof.

The preceding discussion shows that regulation is an inherently complex process, and that its outcomes depend on the details of the procedures that regulators are required to follow. In addition, regardless of the purpose of the particular procedures that apply in any given case, the procedural complexity of regulation makes it inherently a costly process for implementing

policy. Not only does it impose direct participation costs – submitting the evidence and arguments that are necessary to advocate a particular outcome – but it also leads to delay.

For example, consider the case of satellite radio service. In October 1990, a firm by the name of Satellite CD Radio petitioned the Federal Communications Commission (FCC) to allocate electromagnetic spectrum for the purpose of offering subscription mobile radio broadcasting service from a satellite.¹⁵ This petition triggered a three-part process: a proceeding to allocate electromagnetic spectrum to this use; a separate proceeding to determine whether satellite radio service was in the public interest and, if so, how it should be regulated; and a final proceeding to award licenses to operate. In November 1992, the FCC responded to the 1990 petition by announcing that it was ready to consider the proposed service, and invited firms other than Satellite CD Radio to submit applications for a license that included descriptions of the services that they proposed to offer. In January 1995, after considering the license applications, the FCC allocated spectrum that was sufficient to support two operators. In June of 1995 the FCC opened a rule-making proceeding to develop regulations pertaining to the services as

15. The history of satellite radio in this paragraph is distilled from two FCC documents: *Notice of Proposed Rule Making: In the Matter of Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310-2360 Mhz Frequency Band*, International Bureau Docket 95-91 and General Docket No. 90-357, June 14, 1995, and *Report and Order: In the Matter of Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310-2360 MHz Frequency Band*, International Bureau Docket No. 95-91 and General Docket No. 90-357, March 3, 1997.

proposed by the applicants. Among other things, the FCC “requested detailed information on the new service's potential economic impact on terrestrial broadcasters.”¹⁶ In February 1997, the FCC decided to proceed with licensing two carriers, adopted rules regarding their operation, and announced the procedures for a spectrum auction. In October 1997 (seven years after its initial petition), Satellite CD Radio was declared the winner of one of the licenses, and on July 1, 2002, it launched its service, now called Sirius. The second licensee, American Mobile Radio Corporation, launched its service, called XM, on September 25, 2001.

The process to decide to allow the firm to enter took seven years, while actually creating an operational service took less than four years for XM and less than five years for Sirius. During the eleven year wait from initial proposal to first launch, the mp3 digital audio format was invented (1993), the first portable digital radio player was introduced (1997), high-speed Internet access became generally available, Shawn Fanning introduced Napster, the first successful program for downloading large digital files (in this case, recorded music) over the Internet (1999), and the Apple iPod was launched (2001). One can only wonder whether satellite radio would have faced less of a struggle to find market acceptance had it been permitted to enter the market soon after the initial application was received, and then had launched its service in, say, 1995 (six years before the iPod and four years before the rise of audio downloading over the Internet) instead of 2001 (after the introduction of the iPod and extensive digital downloading over the Internet).

One important implication of procedural complexity, as illustrated by the satellite radio

16. *Report and Order* (1997), *Ibid.*, paragraph 6.

case, is that regulation is inherently anticompetitive. The costs of the process deter entry and innovative changes in the way services are delivered. In addition, both the Constitutional protection of sunk investments and the overall social desirability of the services that are provided by incumbents insure that regulatory procedures will not make it easy to do economic harm to established service providers, as illustrated by the FCC's two-year investigation of the concern that satellite radio might harm terrestrial radio.

Sometimes the extent to which regulatory procedures protect incumbents against competition is so extreme in favoring the regulated industry – the old method of regulating airlines is one example – that regulators (like the old Civil Aeronautics Board) are widely said to be “captured” by the regulated industry. But an important footnote to this observation is that the old CAB and many other economic regulatory agencies were *designed* to be captured. That is, the underlying statute created regulatory procedures that could not produce any other outcome. Moreover, even if the procedures of an agency are not designed to protect incumbent regulated firms against competition, some anticompetitive residual effect of regulation is inevitable because of the delay inherent in licensing a newcomer.

In most industries, the anticompetitive nature of regulation is unambiguously harmful to consumers because it leads to price-cost margins that exceed competitive levels and to production inefficiencies that increase costs. In health care, the benefits of competition are more contested because of the effects of the third-party payment system. Consumers, because they do not pay for the full costs of the care they receive, have an incentive to seek care that is not very valuable to them, and providers have an incentive to provide such care as long as the third-party payer will reimburse the expense. Regulations that discourage competition, therefore, could

reduce expenditures on treatments that are profitable but have little or no health effects.

Nevertheless, the other harmful effects of the absence of competition would still be likely to occur and to harm consumers. Among these are the under-provision of beneficial treatments due to prices that cover the costs of inefficient delivery or generate excess profits.

RATIONALES FOR REGULATION

The rationales for regulation in health include both the “market failures” that have been identified by economists as circumstances in which market outcomes are not efficient and concerns about equity. These rationales focus exclusively on outcomes in markets, and not the choice of regulatory structures and processes to solve overcome these failures effectively.

Economics offers three general categories of market failures: substantial market power, third-party effects, and incomplete information. In addition, market outcomes also may be regarded as having undesirable outcomes with respect to income distribution. All four of these rationales have found expression in the debate about health care policy, although the problem of incomplete information is by far the most important.

A third-party effect refers to a circumstance in which an economic activity creates benefits or costs for someone who is not a party to the decision to undertake the activity. The textbook example is the emission of pollutants because the harmful effects of pollution are not restricted to the people who sell and use goods that cause it. Here I ignore the issue of third-party effects, despite their importance in designing optimal policies concerning infectious diseases and the disposal of hazardous medical waste, primarily because they do not play a prominent role in debate about health care reform. In addition, in many cases the alternatives to

regulation as a means for dealing with third-party effects – banning or taxing the activity that causes third-party harm, or relying on tort litigation to compensate those who are harmed – are less effective.

The following sections focus on the other forms of market failure.

Market Power

Market power is the ability to increase profits by charging prices substantially in excess of those required to recover the efficient costs of services. For a for-profit firm, the exercise of market power typically leads to excess profits. For a non-profit entity, monopoly profits typically are dissipated in pursuing the objectives of the non-profit, which sometimes involve other costly activities that the entity perceives as its goal. In any case, the goals of non-profits, however worthy, do not alter the fact that a non-profit with market power is as likely as a for-profit firm to charge prices that exceed the competitive level.

If market power is the rationale for regulation, the goal of regulation is to cause prices to be lower (and output to be greater because people can afford to buy more) than otherwise would be the case. Historically, this form of regulation was based on setting prices on the basis of cost. Individual prices usually (but not always) were based on the cost of the associated product, but in any case all prices taken together were set so that the expected revenue of the firm recovered its costs of production, including a competitive return on investment, but no more. To implement this form of regulation, regulators audited the cost records of the firm to ascertain whether its revenues equaled its total costs, and if not, adjusted prices to bring expected future revenues and costs into balance. This procedure arose out of court decisions in the 19th Century that required

regulators to allow a firm to earn a competitive return on investment, but allowed the government to prevent monopoly profits.

While regulators still are required to allow firms to recover their costs, cost-based price regulation has been replaced by so-called “incentive regulation.” This form of regulation gives firms greater flexibility to set prices as long as prices collectively satisfy a limit based on some form of price index, and allows firms to earn super-competitive profits if they improve their efficiency. The most common form of incentive regulation is the “RPI - X” price-cap formula, where a price index of the firm's products (based on fixed quantity weights from a predetermined historical time) must not increase more rapidly than the retail price index (RPI) minus an adjustment for the historical rate of growth of productivity in the industry (X). Another form of incentive regulation is “benchmark” pricing, in which one firm's price is based on the average costs of other firms. The Medicare reimbursement system that is based on average cost per patient in a “diagnostic related group” (DRG), if adopted as a regulatory scheme for all hospital charges, would be an example of this form of regulation.

Incentive regulation schemes have largely eliminated one important disadvantage of price regulation, which is that cost-based price regulation reduces or even eliminates the incentive of the regulated firm to minimize costs. But to achieve this goal, they explicitly create an environment in which a firm will be able to exercise at least some market power – if it had market power initially. In addition, incentive regulation is not well suited for dealing with new products or technological change that dramatically alters the quality of an established product, which are common phenomena in health care. Finally, even the primary benefit of incentive regulation – providing an incentive to reduce costs – is of less significance when the regulated

entities are non-profit entities. The problem is that the goals of non-profit entities may include maximizing certain kinds of expenditures. For example, if a non-profit is essentially a “doctors’ cooperative” for staff physicians, cost-reductions in other dimensions may be dissipated in higher costs for physicians’ services.

Market power has three sources: natural monopoly, legal monopoly, and anticompetitive behavior.

Natural monopoly arises when the minimum efficient scale of a firm is too large relative to demand for more than a small number of firms to operate. As a result, each firm in the market is able to charge super-competitive prices. Natural monopoly has provided the rationale for regulating local public utilities. In the health care sector, the most plausible natural monopoly is acute care hospitals in rural areas and small cities.

Regulation of hospitals on the basis of natural monopoly is unlikely to have a major effect for several reasons. Most important is the fact that there is no evidence that hospital market power is an important source of the overall high costs of health care.¹⁷ Assuming that the empirical studies that find a significant effect of concentration on prices are correct, lack of hospital competition is a significant but small source of high costs in localities that account for

17. This sentence avoids attempting to characterize a large, complex and often conflicting literature on the relationship between hospital market structure and service prices. Nevertheless, several studies have shown that, when holding other market characteristics fixed, prices are higher in highly concentrated markets (that is, three or fewer hospitals), notwithstanding the fact that the lowest prices are found among rural monopoly hospitals.

perhaps 30 percent of the population. In addition, in the best of circumstances regulating the prices of hospitals effectively would be very difficult because of the complex nature of the products hospitals offer and the rapid rate of change in treatment technologies. Moreover, hospitals are small entities economically compared to public utilities (which is the only industry in which price regulation succeeds in constraining costs), so that the direct cost of imposing price regulation are relatively large compared to the scale of the enterprise.

The second source of market power is legal impediments to competitive entry. Probably the most important example of a legal monopoly in the health care sector is patents for drugs and medical devices. Another legal source of market power is entry regulation, such as professional licensing laws and certificate of need regulation for hospitals and major investments by provider institutions in expensive medical technologies, such as magnetic resonance imaging and particle accelerators for radiation therapy.

Legal restrictions on competition are highly problematic as a rationale for regulation. With respect to patent monopolies, the point of the legal restriction is to create an incentive to innovate. Consequently, the optimal regulated price must exceed the average manufacturing and marketing cost of a drug. Assuming for the sake of argument that the profits of drug companies exceed the amounts that are necessary to induce drug innovation, or, alternatively, that drug companies over-invest in drug innovation, a regulator would need to know how much of a markup of price over manufacturing and marketing costs is necessary to induce appropriate innovation. Here $RPI - X$ would have to become $RPI - X + Z$, where Z is sufficient to recover the optimal research and development add-on (including the cost of new drug review). If such a regulatory process were created, legislators would be likely to create procedures that give

substantial weight to the interests of the drug companies in picking a value for Z, in part because new drugs are socially beneficial even if they are over-priced and no legislator would want to be responsible for killing off drug innovation.

Entry regulation is implausible as a valid rationale for price regulation. The stated rationale for entry restrictions in health care is that in its absence investment in health care facilities will exceed the amount that is socially desirable. This over-investment then will lead to a combination of excessive utilization (providing more treatment than is desirable) and higher prices driven by higher average cost per patient. Presumably the proposal to add price regulation to entry regulation is based on the presumption that the former serves its purpose, but has the undesirable side-effect of causing prices to be higher than otherwise would be the case because of its effect on market concentration. To my knowledge, there is no empirical evidence to support this conclusion. Most but not all research on the effects of certificate of need regulation conclude that it has not had substantial effects on prices, expenditures and the quality of care. But even if one believes the minority of studies that conclude that CON regulation reduces the incidence of some types of treatments (an effect others call a reduction in access to care), one still faces the problem of designing a cost-effective system of price regulation. Moreover, at best CON regulation is a binding constraint in only some markets in some states, so that unless CON is adopted nationwide – a proposal that can not be supported from the research findings about its effects – it can not justify applying price regulation to all hospitals in even a single state, let alone the entire nation.

The third source of market power is anticompetitive behavior, such as collusion among horizontal competitors or “leveraging” whereby a firm uses its market power in one product to

create market power for its affiliate in a related market. Some famous examples of leveraging are the practices by the old American Telephone and Telegraph Company to use its monopoly in local service to obtain market power in long distance service by refusing to allow its long-distance competitors to connect to its local networks, and by Microsoft to use its monopoly in operating systems for personal computers to obtain market power in Internet browsing and related products by bundling them together as a single product.

Many participants in the policy debate about health care believe that anticompetitive behavior is an important source of market power and higher prices in health care. The two anticompetitive practices that are most often mentioned are horizontal mergers among hospitals and vertical arrangements between hospitals and physicians associations. A few years ago, another potential threat to competition was the proposal to create physicians' unions to engage in collective bargaining for fees with third-party payers. My reading of the research literature is that there is evidence that hospital merger policy has been too permissive, but no conclusive evidence that vertical relations between physicians and hospitals are either good or bad for consumers. In fact, the lack of a systematic effect may explain why many such relationships have been dissolved in recent years. In addition, although there is no direct evidence on physicians' unions, there is evidence in the past – before antitrust policy was applied to professional organizations – that restrictions on competition arising from the rules of professional organizations (notably, optometrists, lawyers and real estate brokers) did lead to substantially higher prices.

Even if the research evidence indicates that anticompetitive behavior is a source of market power and high prices, the solution to this problem is better antitrust enforcement, not to

overlay weak antitrust enforcement with price regulation. If antitrust enforcement persistently is too weak in the health care sector, one should bear in mind that the cause is not the identities of the officials who currently occupy the top jobs in antitrust enforcement agencies, but a deeper political cause. That is, if antitrust enforcement is weak in health care, it is because elected officials either want it to be weak or do not care. These are the same officials who will pass the statute to impose regulation, and the political incentives they will face in establishing and managing the regulatory institution will not differ materially from the political incentives they face in overseeing antitrust policy.

Distributive Justice

A centerpiece of critiques about the U. S. health care system is its unfairness. Although an element of this unfairness is the relationship between income and access to care, the problems are deeper and more complicated than simply this effect alone. In addition, the U. S. system of employment-based health care for the working non-poor population creates additional inequities because heterogeneous employees often face little or no choice in health insurance. Moreover, because employee health insurance is an untaxed benefit, further inequities arise among individuals due to differences in their tax status. A final concern arises from the treatment of high-risk individuals, who may lose insurance or face extremely high premiums. If the goal of insurance is to spread the risk of very high health care costs, the insurance system fails to do this for individuals who have costly chronic illness.

Regulation is one proposed solution to the problem of these inequities. In the field of regulation, the relevant concept is called cross-subsidy through rate-averaging. The basic idea is

that everyone is required to have insurance (much like auto insurance in most states) and that almost everyone pays the same price, which exceeds the average cost of service among the entire population. Low-income households receive a discount. The difference between the cost of serving them and the price they pay is made up by charging more to others. Among the non-poor, the chronically healthy pay the same price as the chronically ill; rates and coverage can not be adjusted on the basis of expected costs.

To implement this system requires comprehensive regulation of health insurance prices. Regulators not only must set prices, but must develop a system that prevents insurance companies that have atypically healthy populations from experiencing windfall profits while insurers that have atypically sick populations go bankrupt. Under a single-price system with discounts for the poor, insurers have a powerful incentive to induce the sick and the poor to do business elsewhere, which in turn becomes the basis for still more regulatory intervention.

Cross-subsidization is a ubiquitous feature of economic regulation – not just in the U. S., but everywhere. Yet it is a horrendously inefficient policy that has high costs and delivers little or no benefits.

One obvious source of cost is that the subsidies for the poor and the chronically ill are based on a very narrow tax – essentially, a sales tax on mandatory health insurance for everyone else. If the mandatory coverage rule is actually enforced, the tax is similar to a head tax – equal in magnitude for all but the subsidized – except that it also is a tax on being healthy. If it were a pure head tax, at least it would be efficient, if ridiculously inequitable; however, because it taxes being healthy (or, more precisely, making expenditures that improve one's health but that are not fully covered by insurance), it also creates distortions that raise the overall cost of health care

and hence insurance premiums. Another source of cost is that it intensifies the moral hazard problem associated with insurance, which is that patients and their health care providers are encouraged to increase treatments beyond the level that produces significant health benefits.

By far the superior alternative to cross-subsidization through price regulation is a direct subsidy for those who need it, because they are either poor or unhealthy, with the revenues coming from a more broadly based tax. Such a system would not add to the distortions inhering in whatever health-care financing system is in place for the rest of the population, and so would be less costly than imposing price regulation everywhere and then using cross-subsidies to cure these two inequities.

Information Imperfections

The most important cause of excessive costs in the health care system is imperfect and asymmetric information. Physicians possess superior but imperfect information about the conditions of a patient and the likely consequences of treatment strategies. Patients, insurers¹⁸ and regulators can become more informed and thereby do a better job than otherwise would be possible in figuring out which treatments make sense for which person, but in the end, because optimal treatment strategies vary among patients and hinge on information that is not plausibly

18. For most of the discussion in this section, “insurers” includes any entity that accepts advance payments by consumers in return for promising to pay a large proportion of their future health care expenditures. If the distinctions among insurers matters, I will refer to them by type, such as HMOs or traditional fee-for-service insurance.

observable by everyone, none of these other actors are likely to be highly effective at second-guessing the treatment decisions of a physician unless the physician falls far outside the norms for the profession.

In addition, patients lack information about providers. One fascinating piece of public opinion pertains to the approach of patients to picking physicians. If given the choice between a doctor with a questionable overall performance record and a strong recommendation from a friend or relative, and another doctor with a strong overall performance record but who is unknown to friends and relatives, people divide roughly equally between which doctor they would select. Put another way, patients rely heavily on their experience and the experience of people they know in evaluating doctors. This phenomenon explains why people who are HMO patients simultaneously have favorable views of their own physician and hospital, but unfavorable views of the quality of service at HMOs in general.¹⁹

The reliance and faith that patients have in their own physicians is probably unavoidable and, in any case, a good thing to the extent that confidence in a treatment strategy affects its

19. Another fascinating tidbit of public opinion reflects the success of the campaign against HMOs. A substantial fraction of people who are satisfied with their care and who are members of HMOs falsely believe that they have traditional insurance, and a substantial fraction of people who are dissatisfied with their care and who have traditional insurance falsely believe that they are members of an HMO. When reporting errors are corrected, the two forms of health care financing have essentially no difference in reported patient satisfaction, yet most people believe that HMOs have caused a decline in the quality of care and ought to be more heavily regulated.

effectiveness. But this attachment creates many problems.

The first problem is that patients may be insufficiently responsive to evidence that their physician provides inappropriate treatment – either low quality treatment, or more or less treatment than is regarded as standard by the norms of the profession. Because this problem arises in all systems of health care provision, it poses no special challenge for proposed reforms, and so will not be examined here. Suffice to say that the tendency for excessive attachment does not imply that a public system of information collection and dissemination, combined with public disclosure requirements by providers, is unnecessary or undesirable. Imperfect responsiveness does not imply zero responsiveness. Most consumers periodically do switch providers and a significant fraction (nearly half) report that they might be willing to switch in response to information that another provider was superior. In general, the government has a good record in collecting and disseminating information when this process is disconnected from regulation, although such a system could be designed to be ineffective if its procedures caused unfavorable or comparative information to be suppressed.

Another problem arising from the attachment of patients to physicians is potential moral hazard on the part of both the provider and the insurer (notwithstanding the traditional moral hazard problem associated with the patient). The physician's moral hazard aligns with that of the patient – provide too much care. The insurer's moral hazard problem is to pay for too little care.²⁰ Inevitably, the third-party payer bears the burden of attempting to fix the tendency of

20. I realize that this use of the term is unconventional, but if moral hazard is *ex post* behavior that deviates from the *ex ante* efficient provision of service at the competitive price, under-

doctors and patients to favor more treatment than is justified, considering its cost. In the case of traditional insurance carriers, the response is to deny or to limit payments for services rendered. In the case of HMOs, the response is to limit the autonomy of physicians in making treatment decisions. Indeed, these payers have an incentive to go too far because they may benefit financially from refusing to pay or to provide treatment even if it is medically justified.

For denial of treatment to be profitable, the payer/insurer must expect that the chances of succeeding in denying treatment are sufficiently high to justify the cost of doing so. That is, the patient's chance of successfully challenging the decision of the payer are low enough that the cost of fighting challenges (both wins and losses) is less than the cost of providing care. In addition, one of two other conditions must be met: a profitable patient has no alternative source of insurance so the payer will not lose the business, or the patient has too high an expected future cost of care to be a profitable customer in the future. Both of these conditions hinge on the patient's lack of choices – in the first case no close substitute for the insurance coverage offered by the denying carrier, and in the second case no option or ability to pay an appropriate risk-adjusted premium in the future.

The absence of close substitutes is exacerbated by employer-based insurance that offers employees few if any choices and which seeks only to minimize the cost of the insurance fringe benefit to the employer. Unless the labor market is frictionless, an employer can benefit by signing up an insurer with a lower premium but with a propensity to deny valid claims, and then

provision by the third-party payer is as much moral hazard as is over-consumption by the patient.

offering no close substitutes for that insurer to employees.²¹

The problem of imperfect adjustment of premiums reflects many things, but one is still another source of asymmetric information, in this case on behalf of consumers. Insurers know the actual experience of their patients in seeking treatment – what conditions they have had and what treatments they received. They do not know very much about the behavior of the patient that affects health status and the preferences of the patient concerning health care. In essence, insurers, if given the option, would calculate future expenditures on the basis of current health status and recent expenditure history, which is partly but inexactly related to tastes for treatment. The associated problem here is adverse selection: people whose true expected expenditures are greater than insurers estimate buy coverage, while people with lower expected expenditures reject coverage. This creates an incentive for the insurer/payer to reduce the amount and quality of care so that patients with above-normal tastes for treatment will leave the program, but in so doing they reduce the quality of care for everyone.

21. A frictionless labor market is one in which employees can switch employers immediately and without cost in response to a small change in their total compensation. In the example here, the employer who signs on with an insurance carrier that denies reimbursement for reasonable claims has cut total compensation. Whereas in the long run an employer will be forced to increase take-home pay or other benefits, or improve insurance coverage, to retain and attract employees, in the short run at least some of the cost savings from lower insurance can pass through to higher profits if existing employees do not all respond immediately to a *de facto* cut in their total compensation package.

An interesting feature of these information-related problems is that more choice through greater competition does not fully solve them. Providing more options generally reduces problems associated with moral hazard by sharpening the incentive of insurers to deny care only when it has low value, not just when it saves money, and by creating a system in which, at least in the long run, consumers pay higher premiums if they have a propensity for excessive treatment and/or to patronize physicians who seek to provide it. This insight is the conceptual foundation of “consumer choice” health care proposals.

But a greater number of options also exacerbates problems associated with adverse selection. Patients facing numerous choices can select insurers who make the biggest error in underestimating their true demands, and the maximum expected error increases in the number of choices (and premium offers) available unless errors are perfectly correlated among insurers. To the extent that insurers are constrained in the degree to which they can set individualized risk-adjusted premiums, more choice increases the incentive to try to shed high-cost patients by denying treatment that plausibly is justified because these patients are more likely to switch. Even a patient who wins appeals for denial of coverage may switch just to try to avoid hassles in the future, so that a strategy to deny valid treatments even when the denial is certain to be reversed may be profitable. Whether this strategy is profitable depends on the ability of an insurer effectively to target the most costly patients and the costs of fighting challenges that subsequently are reversed.

The implication of the preceding analysis is that no system of health care that is based on private insurance is likely to be very efficient. Adverse selection and moral hazard can be affected by the details of the system, but they are not likely to be eliminated, and the

administrative costs of the private health care financing system are likely to be excessive because they are driven by the attempt to solve these problems as well as the prospect for at least short-term financial gain from denying care. In short, all systems are infected to some degree by a tendency to spend too much on care and on the administrative process to weed out excesses.

To return to the topic of this essay, the question remains whether regulation can make any headway in reducing these two types of costs. One can conceptualize the regulatory problem in two ways. In the first case, the regulatory problem is to establish and to enforce standards of care – that is, to establish a regulatory system for reviewing decisions by physicians about the appropriateness of their treatment decisions. In the second case, the regulatory problem is to establish and enforce standards for payment decisions by insurers. For integrated HMOs, the two forms of regulation are basically the same; however, as one moves from the integrated HMO model towards the traditional fee-for-service model, the two systems diverge.

The first example – standards of care – is most appropriately regarded as a form of information regulation, and is similar to many quality review systems that are already in place. The goal for such a program that is most likely to be reached is to weed out bad actors – that is, physicians whose behavior departs substantially from the norms of the profession. Beyond this, attempts to assess the validity of treatment decisions on a massive scale – and to put bite into those decisions by either affecting payments to levying fines on providers – appears to me to be impossible for two reasons. The first is the vast number of these transactions, running in the billions annually. Although proving a negative is impossible, I can not imagine that there is any hope of creating an effective system of second-guessing decisions by physicians and enforcing standards through financial incentives that would cause a substantial change in behavior that

would be worth the cost of implementing it. The second reason is that it would be anathema to health care providers, who could be expected successfully to enlist the support of their patients in opposing it.

A distant cousin of a system for regulating standards of care is the proposal to replace medical malpractice litigation with a regulatory body that evaluates malpractice claims, creates formulas for making malpractice awards (replacing jury verdicts), and establishes standards for care (perhaps through the precedent established by cases). The details of this proposal can vary: is the system strictly “no-fault,” if not, can it punish physicians for misbehavior, if so does it separate the punishment from the reward to patients (which is not done by using a contributory negligence standard and “pain and suffering” as criteria for awarding damages in malpractice), and does it take into account special circumstances about the patient (such as probability of impending death) in determining fault? Here I will separate the details of a reformed malpractice system (that is, a change in standards for liability, punishment and awards) from whether the institution for implementing them is a court or a regulator.

My expectation is that a regulator will be substantially more favorable to providers than a court. One reason is procedural: a regulatory system will bend over backwards to protect the rights of physicians. The second reason is informational: regulators bear the burden of proof that the information supports their decisions, whereas the burden on the adjudicator of facts, whether a jury or a judge, is generally much lower. Because the physician has superior information about the circumstances that gave rise to a treatment decision, a regulator will face a greater challenge to reach a finding that contradicts that of the physician than would a judge or jury. The final reason is political. Legislation transferring authority over malpractice to a

regulator will include procedural requirements, and provider organizations are likely to have great influence in constructing these procedures. The effect will be to protect their interests.

An overall assessment of this proposal does not hinge solely on the effects of regulation, but on one's views about whether these effects are benefits or costs. The clear benefit is that the costs of malpractice litigation and insurance will decline. Another potential benefit according to its advocates is that it will reduce the incentive to practice "defensive medicine" – decisions to treat that are based on avoiding malpractice liability rather than potential medical benefit.

Whereas the logic of this argument is qualitatively compelling, the best evidence thus far pertains to specific examples. Attempts to find a large, systemic effect of malpractice rules on costs have been inconclusive. The potential costs of a system that is more favorable to physicians are that the malpractice system will be less able to identify and to weed out poorly performing physicians, that genuine victims of malpractice will not be compensated, and that institutions such as hospitals, clinics and insurers will have less of an incentive to monitor physician quality and take measures to assure the quality of care. The empirical evidence on these issues also is inconclusive. Because the empirical evidence is weak, I do not believe it is possible to offer a definitive conclusion about whether the benefits of a regulatory approach to medical malpractice would be superior to the use of litigation – not because litigation is so wonderful, but because both litigation and regulation are highly imperfect institutions for improving economic efficiency.

The second potential focus of regulation, which is regulating payment and coverage decisions by third-party payers, is more plausible than using regulation to set and to enforce more efficient standards of care. In addition to the issues surrounding the definition of the

standards of care, the behavior of insurers in making decisions about payments (traditional insurance) or treatment (integrated HMOs) has the added dimension of contract enforcement. Unlike medical malpractice, existing laws have prevented the judicial system from developing and enforcing a standard system of adjudicating the validity of coverage denials. One could approach the problem in two ways: by eliminating restrictions against suing HMOs and private insurance plans, or by creating a regulatory system that would perform the same function as the courts would perform in the absence of these restraints.

As in the case of malpractice reviews, a regulatory system is likely to favor insurers more than a system of litigation. But either is likely to hold insurers to a more rigorous standard than is currently the case. Again, there is no definitive empirical evidence on this matter, but one factor seems to me to tip the balance in favor of the regulatory solution. If health care reform includes increasing consumer choice over health plans, then the problem of denial of coverage is likely to be less severe (although not non-existent, as explained above). If so, a more modest exposure of insurers to review of coverage decisions may be all (or more) than is necessary to improve the performance of the industry.

RELATIONSHIP TO THE NATURE OF SYSTEM-WIDE REFORM

The final issue that I address is how the case for regulation of any kind depends on the nature of the system reform that accompanies it. I consider the range of options to be single-payer (“Medicare for all”), the two-prong employer mandate (insure or be taxed), an individual mandate with a tax credit or deduction for non-employer based insurance, and direct subsidies of insurance (health care vouchers or an insurance tax credit with the elimination of employer-

based insurance).

Obviously, if the reform is a single payer system, decisions about provider qualifications and reimbursement rates stop being regulatory issues and become procurement issues. Both legally and politically, it is unlikely that the government can or will prohibit all forms of private payment, just as Medicare does not pay for everything, allows recipients to join HMOs, and has parallel supplemental insurance coverage. Hence, a single-payer proposal would have a regulatory component to the extent that it sought to regulate private payments. But this outcome seems extremely unlikely, and not worth taking seriously.

Beyond this, there is no natural reason why single payer (as long as it preserves an HMO option and the option for private insurance) would force any further change in most of the existing system of provider regulation. The main uncertainty arises because single payer would eliminate employer-based insurance, and so would eliminate the ERISA exemption of insurance that is an employee benefit from litigation over coverage decisions. Thus, a plausible companion to single payer is a regulatory agency to set and enforce standards for denial of payment (insurers) or treatment (HMOs).

At the same time, Medicare for all could co-exist with a great deal of regulation that currently exists and that generally serves to protect providers. Because providers, whether rightly or wrongly, are likely to perceive Medicare for all as a serious threat, a disadvantage of single-payer is that it probably reduces the likelihood of simultaneously reducing the existing array of regulations affecting health care.

A less radical version of Medicare for all is a two-prong employer mandate: employers must either offer health insurance to employees or pay a tax to finance participation of their

employees in either a version of Medicare for the non-retired or the federal employees medical program. Focusing exclusively on the regulatory implications, this proposal is not procurement, and will give rise to a system of regulation for defining the scope of minimum mandatory coverage and determining compliance with the program. The part that enrolls new customers in either Medicare or the federal employee health plan will be a procurement process, and so will resemble the existing system.

How the regulatory component develops will depend on the way the statute sets up the process for determining mandatory coverage by employers to enable them to escape the tax. My expectation is that small business will be accorded significant influence on this matter. If so, the procedures will make self-provision of insurance a cheaper option for nearly all companies, implying some combination of less coverage and lower quality than for the existing federal benefit program.

This proposal has an even less disruptive effect on the current system, so carries no necessary requirement that it come to grips with the existing regulatory system for care and insurance. Again, attempting to reform this system against the wishes of providers while taking an action that substantially increases coverage and imposes significant costs on small business does not seem politically attractive, so my expectation that there is no serious short-term chance for significant reform of existing regulation as part of this reform.

The third reform candidate is an individual mandate with a tax credit or deduction for insurance premiums, with employer-provided insurance satisfying the mandate. An essential ingredient of this proposal is a regulatory mechanism for determining the minimum requirements under the mandate and, perhaps, the qualifications for insurers to participate in the program (that

is, to qualify for the tax benefit). The insurance industry possesses most of the relevant information about the cost of various forms of coverage and the potential demand for plans among the uninsured. Consequently, the procedures for setting these standards are likely to accord great weight to the desires of the insurance industry – probably favoring more over less.

This proposal is the least disruptive of the present system, and so is not closely related to whether reforms of other regulations can be a part of it. Thus, reform of existing regulations seems not significantly less likely under this proposal than if no health care reform were being proposed.

An individual mandate that replaces employer-based insurance shares with Medicare for all has the feature that it does not necessarily disrupt the institutions of the sector other than that it eliminates the ERISA protection of most existing private insurance. Thus, it, too, is likely to give rise to a regulatory solution to payment and treatment decisions, which inevitably will cause both more expenditures on care and more expenditures on resolving disputes. The significance of these changes is difficult to guess, but if one believes that medical malpractice is a significant source of costs in the provision of care, one should also be inclined to think that the end of ERISA protection will lead to similar cost increases through its effects on insurers.

Because this system is not procurement – the transaction is between citizens and the government regarding their insurance – the mechanisms for determining minimum qualifying plans are regulatory, and as such are likely to be heavily influenced by health care providers and insurers. This feature does not bode well for reducing per capita expenditures on health care.

The final important feature of this proposal is that, like Medicare for all, it gives consumers substantial opportunities for choice. Hopefully this feature of the proposal will

reduce the demand for regulation of the quality of care, and pave the way for eliminating much of existing state regulation. But there is no necessary reason why this would happen unless providers perceive that the benefits they derive from establishing a mechanism for regulating payments by insurers and the minimum standard of coverage offset the loss arising from more choice (and hence competition). I lack sufficient information to know how providers will come down on this assessment, but I am skeptical that they will see this proposal as sufficiently beneficial to them that they would willingly give up existing anticompetitive regulations. If so, the net effect of this proposal is more regulation and higher per capita costs. This does not make the proposal undesirable – I actually prefer this to the others. But as a mechanism for reducing inefficient regulation and health care costs per unit of treatment, I am doubtful that it will have much of an effect.