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Health Care Regulation
A $169 Billion Hidden Tax

by Christopher J. Conover

Executive Summary

Students of regulation have known for decades that the burden of regulation on the U.S. economy is sizable, with the latest figures suggesting this cost may approach $1 trillion in 2004. Surprisingly, given that the health industry is often viewed as among the most heavily regulated sectors of the U.S. economy, previous estimates generally have ignored the cost of regulating health care services.

Using a "top-down" approach, one can arrive at a "back-of-the-envelope" estimate that health services regulation imposes an annual cost of $256 billion per year (with a range of $28 billion to $657 billion), suggesting that health services regulations could increase estimates of overall regulatory costs by more than 25 percent.

A far more accurate "bottom-up" approach suggests that the total cost of health services regulation exceeds $339.2 billion. This figure takes into account regulation of health facilities, health professionals, health insurance, drugs and medical devices, and the medical tort system, including the costs of defensive medicine. Moreover, this approach allows for a calculation of some important tangible benefits of regulation. Yet even after subtracting $170.1 billion in benefits, the net burden of health services regulation is considerable, amounting to $169.1 billion annually. In other words, the costs of health services regulation outweigh benefits by two-to-one and cost the average household over $1,500 per year.

The high cost of health services regulation is responsible for more than seven million Americans lacking health insurance, or one in six of the average daily uninsured. Moreover, 4,000 more Americans die every year from costs associated with health services regulation (22,000) than from lack of health insurance (18,000). The annual net cost of health services regulation dwarfs other costs imposed by government intervention in the health care sector. This cost exceeds annual consumer expenditures on gasoline and oil in the United States and is twice the size of the annual output of the motion picture and sound recording industries.

Finding ways to reduce or eliminate this excess cost should be an urgent priority for policymakers. It would appear from this preliminary assessment that medical tort reform offers the most promising target for regulatory cost savings, followed by FDA reform, selected access-oriented health insurance regulations (e.g., mandated health benefits), and quality-oriented health facilities regulations (e.g., accreditation and licensure).

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No one before has even attempted to compile a comprehensive estimate of the overall benefits and costs of health services regulation.

Introduction

There is a significant amount of literature on the benefits and costs of regulation in the U.S. economy, with the first efforts to estimate the overall impact dating back to the mid-1970s.[1] From this work it is known that regulations impose a considerable burden on U.S. businesses and consumers: the impact of regulation on the overall economy will approach $1 trillion in 2004.[2] In contrast, however, no one before has even attempted to compile a comprehensive estimate of the overall benefits and costs of health services regulation. With health expenditures projected to absorb one-sixth of the economy in less than a decade,[3] it makes sense to focus on this void in our understanding of the impact of regulation. Therefore, researchers at Duke University have spent two years developing a preliminary synthesis of the literature on the benefits and costs of health services regulations, and are continuing today to refine those early estimates as well as fill in the gaps in what is now known.[4]

My colleagues and I have had as our central goal to develop a tentative estimate of the net cost of health services regulation in 2002 and to compare that to important benchmarks such as overall personal health care expenditures (PHCE) and gross domestic product (GDP). More specifically, we address the following central questions: What is the net burden of health services regulation in the United States? What fraction of U.S. GDP and health spending is attributable to regulation? Ideally, we would want to know whether the benefits of such regulations exceed their costs. Likewise, it would help policymakers understand the opportunity cost of regulation in terms of alternative uses to which these same resources might be put or in terms of the number of lives that could be saved each year by trimming "excess" regulations that fail a cost-benefit test.

Economic regulations such as restrictions on business entry, pricing, or output (ostensibly to protect consumers from high prices charged by natural monopolies or from being victimized by "fly-by-night" operators) generally are viewed as providing negligible benefits. The chief exceptions relate to regulation of natural monopolies and antitrust, where, in theory, regulation may enhance efficiency rather than reduce it.[5] In contrast, social regulations designed to control the harmful or unintended consequences of market transactions (such as air pollution, occupationally induced illness, or automobile accidents) generally are viewed as having the potential to confer sizable benefits in addition to whatever costs they impose. Whether such regulations result in a net benefit depends on their success in addressing various types of market failures, including externalities in both production and consumption. Given that various markets in health services fall short of conditions required for perfect competition, the possibility that health regulation may produce benefits in excess of costs cannot be rejected a priori.[6]

There are disparate views on the merits of measuring regulatory costs without taking into account the benefits of regulation. Although there is not complete agreement on how to measure regulatory costs, benefits estimation "is as much an art as a science due to imperfect methodology and insufficient data."[7] Despite these limitations, some argue that "while estimating the benefits of environmental, health, and safety regulation is not straightforward, it is not informative to exclude them from a discussion of regulatory costs and benefits."[8] Similarly, the Office of Management and Budget itself has stated, "presenting costs without benefits is not very informative and potentially misleading."[9] Others, however, take the position that while the benefits corresponding to federal budget expenditures are recognized by policymakers, "an overall understanding of expenditures or budgetary costs is essential for reasoned decisionmaking" and "there are considerable gains from understanding the cost side alone."[10] Despite some of the foregoing limitations in measuring them, we opted to include health benefits in this study.

To the extent that researchers have tried to quantify the benefits side of regulation in dol-

lar terms, especially in the case of regulations intended to be market perfecting, estimates are included here. As a practical matter, however, the lion's share of research on health services regulation has been on the cost side, just as it has been in the previous work on regulation generally.[11] But even in cases where solid benefits estimates do not exist, there is value, for reasons detailed elsewhere,[12] in attaining a good understanding of the cost side of regulation: (1) to help educate citizens, businesses, and taxpayers about the macro costs of health services regulation on the economy; (2) to permit comparisons with other estimates to better understand the relative burdens imposed by various types of regulation, thereby potentially improving resource allocation; and (3) to improve the evaluation of different approaches to regulation in hopes of making the regulatory process more efficient.

As a general matter, social regulation has expanded significantly over the past two decades, at the same time that economic regulation has been declining. The same general pattern is visible in health care: regulations of the health industry that were motivated by the hope that regulation could stem rising health costs generally have declined, as all but one state has shed hospital rate setting and a number have dropped or weakened their certificate-of-need regulations. At the same time, however, there has been increasing concern about using regulation to improve quality of care or access to services. Hence it is difficult to say, on balance, whether health services regulation is relatively more or less burdensome today than it was 20 or 30 years ago.

This study discusses how regulatory costs in health care can be measured, and then provides individual sections in which preliminary findings are provided on the costs and benefits related to health facilities regulation, health professionals regulation, health insurance regulation, pharmaceutical and medical device regulation, and the medical tort system. At the end, summary estimates are included for health services regulation in general, and the opportunity costs of such regulations are discussed.

Measuring Health Services Regulation Costs

Two approaches were used in determining the net impact of regulation. The first was a "top-down" approach that relied on extrapolations from other industries. The second was a "bottom-up" approach that systematically examined the available literature in detail for evidence regarding the costs and benefits of a broad variety of health services regulations.

"Top-Down" Approach

The "top-down" approach looked at the costs of regulation in other industries such as airlines, railroads, telecommunications, and other sectors that have long been studied by economists, and calculated the percent of gross economic activity in those industries that various studies have attributed to regulatory costs. For industries that have seen considerable deregulation since 1988, figures may be somewhat dated. Nevertheless, unless one believes that the health industry has undergone a similar form of deregulation, the figures represent plausible impacts for a "typical" regulated industry. By applying these percentages to the health sector, we arrive at very rough back-of-the-envelope estimates of upper and lower bounds on the plausible magnitude of the regulatory burden. As shown in Table 1, this so-called "top-down" approach suggests that in 2002, health regulation could have imposed an annual cost of $256 billion, with a range from $28 billion to $657 billion.

The large difference between the minimum and maximum cost estimate illustrates neatly the limitations of this approach, which inevitably leaves us with a great deal of uncertainty about where the truth lies. But a further limitation is that it is easily possible that the regulatory burden in health care is even higher than a simple extrapolation from other industries might suggest. After all, according to University of Rochester health economist Charles Phelps, "the U.S. health care system, while among the most 'market

Health care is the most regulated sector of the U.S. economy.

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Table 1
"Top-Down" Estimates of Cost of Health Services Regulation (billions of 2002 dollars)

Industry	Source	Year of Estimate	Type of Cost		If Applied to Health		
			Efficiency	Transfer	Efficiency	Transfer	Combined
Airline	Hahn and Hird 1991	1988	8.9%	18.0%	137.7	279.1	416.8
Barge	Hahn and Hird 1991	1988	3.3%	9.9%	51.0	153.1	204.1
Manufacturing	Crain and Hopkins 2001	2000	2.4%	1.0%	37.1	15.5	52.6
Rail	Hahn and Hird 1991	1988	10.0%	29.4%	154.1	455.6	609.7
Services	Crain and Hopkins 2001	2000	1.0%	1.5%	15.5	23.2	38.7
Telecommunications	Hahn and Hird 1991	1988	10.6%	31.9%	164.3	492.9	657.3
Trade	Crain and Hopkins 2001	2000	0.8%	1.0%	12.4	15.5	27.9
U.S. Total	Crain and Hopkins 2001	2000	1.5%	1.0%	23.2	15.5	38.7
Summary							
Mean			4.8%	11.7%	74.4	181.3	255.7
Minimum			0.8%	1.0%	12.4	15.5	27.9
Maximum			10.6%	31.9%	164.3	492.9	657.3

Note: Figures may not add to totals due to rounding.

oriented' in the industrialized world, remains the most intensively regulated sector of the U.S. economy."[13] That is why it is worth investing effort in the much more fine-grained "bottom-up" approach entailed by our literature synthesis.

"Bottom-Up" Approach

The literature synthesis in this study includes a broad range of health-related regulations, covering the gamut from health facilities regulation, health professionals regulation, health insurance regulation, Food and Drug Administration regulation, and the medical tort system. I am confident that no major domain of health services regulation has been excluded from this review.[14] However, domains of regulation that cut across all industries, such as employment regulations (worker health and safety, employment discrimination restrictions, etc.) were excluded, even though these too might have the effect of elevating health expenditures. The argument against the inclusion of antitrust regulation was that, despite its particular influence on the health care industry, antitrust is broadly applicable across other types of industries, and thus would not qualify as a unique "health service" regulation.

Moreover, one could not include costs without also somehow including benefits that may be difficult to measure. Although antitrust regulation of facilities, professionals, or insurance were not included, we did include state statutes exempting health facilities from antitrust laws (e.g., when a hospital merger is said to be in the public interest) on grounds that equivalent exemptions do not exist in other industries and these exemptions may result in identifiable costs. Moreover, it is worth noting that the cost estimates herein do not include the costs imposed on health providers by continual changes in public payment policies. In that regard, the estimates here could be viewed as a conservative assessment of the size of the regulatory cost burden in health care.

From an economist's viewpoint, all costs are opportunity costs, representing the maximum value to society of opportunities foregone in obtaining a good or service. From this standpoint, "the cost of regulation is equal to 'the change in consumer and producer surpluses associated with the regulation and with any price and/or income changes that may result.'"[15] But calculation of lost consumer and producer surpluses requires the estimation of supply and demand curves, necessitating infor-

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mation often not at hand. Since measuring opportunity costs can be difficult, as a practical matter, most cost studies instead typically measure compliance costs incurred by the regulated industry. Failure to account for lost consumer surplus has been criticized since ignoring it will underestimate the loss to society of products consumers can no longer buy; conversely, calculating compliance expenditures based on preregulation output runs the risk of overstating regulatory costs because as soon as regulated firms raise their prices, consumers will shift to other products, thereby mitigating the welfare loss.[16] In light of the difficulties of measuring lost consumer and producer surplus, direct compliance costs at the postregulation level of output have generally been viewed as providing a lower bound on the social value of opportunity costs.

Indeed, it is known from other applications that inclusion of compliance costs alone would substantially underestimate the true costs of regulation. For example, in environmental regulation, general equilibrium models have shown that gross social welfare losses (i.e., all direct and indirect costs combined) equal roughly twice the measured costs for direct compliance.[17] Therefore, this study has made every effort to estimate the *total* social cost of health services regulations; that is, "the value of the goods and services lost by society resulting from the use of resources to comply with and implement the regulation, and from reductions in output."[18] Costs have been reported in four major categories so that those who disagree with the inclusion of a particular category or how such costs have been calculated may easily set them aside and still find these results useful.[19]

Under *government regulatory costs*, monitoring and enforcement activities are included, with federal and state costs separated where possible. Also included in this category are the expenditures of for-profit or not-for-profit organizations that undertake such activities through contract or delegation by the government. There is a parallel set of *compliance costs* incurred by the health care industry or consumers (e.g., time losses). While the latter could

be estimated only for a handful of regulations, virtually all regulations entailed some sort of industry compliance costs, encompassing both private- and public-sector losses (e.g., federal regulations regarding hospital quality may impose costs on state and local hospitals). Note that legal costs (including enforcement penalties) may only be borne by a subset of entities deemed as not in compliance and that enforcement penalties effectively are transfers (i.e., are included on both the cost and benefit sides of the ledger). Summing compliance costs across all health services regulations allows for a determination of what fraction of health expenditures is attributable to regulation.

While the focus of most analysis of regulatory costs is on direct costs that are reasonably straightforward to measure, there are hidden costs that some researchers have made efforts to quantify for selected regulations. *Indirect costs* are far harder to measure as they include second-order effects of price and quantity changes stemming from regulation; nevertheless, the lost consumer and producer surpluses resulting from these regulatory distortions are very real. For example, there may be general equilibrium effects that result from productivity losses, reductions in quality, product substitution, discouraged investment, or a slower rate of innovation. Such effects have been the focus of some criticism of FDA regulation, for example. A related impact of particular importance in health services regulation, but one that may not be captured in traditional general equilibrium models, would be any morbidity or mortality losses that are the inadvertent result of regulations. While the question of whether or how to convert health losses into dollar terms may be controversial, it would potentially give a biased and incomplete picture of the costs of health services regulation not to take into account these impacts. Likewise, in cases where the impact (positive or negative) of regulation on uninsured risk has been measured, I have included both the external cost of being uninsured (i.e., including all costs borne by taxpayers or private patients) as well as the monetized value of the increased mortality risk faced by the unin-

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sured due to failure to get timely and adequate diagnostic and treatment services.

Finally, *social welfare costs* arise whenever regulatory costs result in higher taxes and/or when compliance costs result in higher prices. This category includes the lost consumer and producer surpluses resulting from these taxes and/or compliance costs (also called efficiency or deadweight losses) as well as any companion collection and compliance costs associated with whatever method of taxation is used to finance government regulatory costs.

Health Facilities Regulation

There is an enormous variety of health facilities in the U.S. health system, all subject to varying degrees of health services regulation. Facilities include *inpatient hospital facili-*

ties, such as short-term general hospitals, specialty psychiatric facilities (short-term and long-term), and substance abuse treatment facilities (including detoxification facilities); *ambulatory care facilities*, such as hospital outpatient departments, medical offices/clinics, ambulatory surgical centers (ASCs), birthing centers, diagnostic imaging centers (DICs), outpatient laboratories, and pharmacies; and *post-acute care facilities*, such as home health and hospice services, renal dialysis centers, skilled nursing facilities (SNFs), and intermediate care facilities (ICFs, including those for the mentally retarded).

I have adopted a consistent style of presenting results, starting first with the standard distinction between access, cost, and quality. First, it is a bit more manageable to compare and contrast the sheer number of regulations when sorted in this fashion. Second, and relat-

Table 2
Cost of Health Facilities Regulation (millions of 2002 dollars)

Type of Regulation	Costs			Benefits			Net Cost	Percent
	Expected	Minimum	Maximum	Expected	Minimum	Maximum		
Access	**11,764**	**2,192**	**29,676**	**3,805**	**701**	**8,236**	**7,959**	**31.7%**
EMTALA	4,436	1,261	10,965	2,146	421	4,930	2,291	9.1%
Hospital uncompensated care pools	6,678	698	16,591	1,524	233	3,601	5,154	20.6%
Hospital community service requirements	317	123	961	135	46	397	182	0.7%
Hospital conversion regulations	9	8	132	-	-	-	9	0.0%
Limited English proficiency requirements	324	102	1,027	-	-	-	324	1.3%
Costs	**14,128**	**11,949**	**190,378**	**14,840**	**20,745**	**27,095**	**(712)**	**-2.8%**
Health care fraud and abuse	3,209	2,224	9,945	2,154	1,808	2,912	1,054	4.2%
Facility medical records (includes privacy)	1,068	696	9,217	1,222	993	1,450	(154)	-0.6%
Organ transplant regulation	1,815	1,653	1,785	1,807	280	4,644	8	0.0%
Certificate of need	110	26	157,859	-	5,067	-	110	0.4%
Hospital rate setting	69	57	3,023	51	4,421	-	18	0.1%
Pharmaceutical price regulation	7,626	7,163	8,149	9,606	8,176	18,088	(1,980)	-7.9%
Other cost-related facilities regulations	233	129	400	-	-	-	233	0.9%
Quality	**21,799**	**9,596**	**57,592**	**3,973**	**3,973**	**3,973**	**17,827**	**71.1%**
Hospital accreditation/licensure	8,640	833	31,885	-	-	-	8,640	34.5%
Nursing home accreditation/licensure	3,581	1,963	6,821	3,973	3,973	3,973	(392)	-1.6%
Other facilities accreditation/licensure	2,078	465	7,447	-	-	-	2,078	8.3%
Peer Review	2,063	1,314	5,481	-	-	-	2,063	8.2%
Clinical Laboratory Improvement Act (CLIA)	3,236	3,065	3,466	-	-	-	3,236	12.9%
Other quality-related facilities regulations	2,200	1,955	2,492	-	-	-	2,200	8.8%
Grand Total	**47,692**	**23,737**	**277,645**	**22,617**	**25,418**	**39,303**	**25,074**	**100.0%**

Note: Figures may not add up to totals due to rounding.

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ed, if it is found that a particular type of regulation imposes undesirably high costs, or conversely appears to be markedly less costly, the question naturally arises whether there is a logical substitute for it (or in the latter case, whether it should logically displace other less efficient forms of regulation aimed at the same purpose). Having in one location the results for a particular class of regulations facilitates these kinds of comparisons. The findings regarding facilities regulation are summarized in Table 2.[20]

Access-Related Facilities Regulations

Under *access related* are included (1) the Emergency Medical Treatment and Active Labor Act; (2) hospital community service requirements (which include uncompensated care obligations imposed on facilities that receive federal Hill-Burton grants or loans to build or expand hospitals, state community service requirements, and state statutes mandating that county hospitals provide indigent care)[21]; (3) hospital uncompensated care pools that tax hospitals and redistribute the revenues to facilities providing higher-than-average uncompensated care loads;[22] (4) hospital conversion regulations that impose state oversight on the process of converting public or nonprofit facilities to for-profit status; and (5) limited English proficiency requirements that require hospitals and other health facilities to hire translators to assist patients who cannot communicate in English. Although the mandatory provision of transplant-related data by hospitals admittedly was intended to increase access to transplant services, it is included later under cost regulation as part of organ transplant regulation and therefore excluded here to avoid double counting. All told, these access-related facilities regulations as a group cost $11.8 billion but provide benefits of only $3.8 billion. Hospital uncompensated care pools (net cost $5.2 billion) and EMTALA (net cost $2.3 billion) account for the lion's share of this net cost.

In theory, uncompensated care pools should be beneficial on net; that is, they

should induce facilities to provide more uncompensated services to uninsured patients than they might otherwise in a less level competitive market. At worst, such pools arguably would be relatively benign, simply transferring resources from one set of hospitals to another. However, at least 10 different studies have found conflicting evidence about whether such pools actually increase the overall provision of uncompensated care. More worrisome, two different studies have found that the existence of such pools was associated with a dramatic increase in the risk of being uninsured among those with low incomes (e.g., 14.4 percentage points for those below poverty).[23] Since being uninsured is associated with a sizable increase in one's reliance on publicly subsidized care (approximately $554 per capita uninsured in 2002)[24] as well as an elevated risk of death,[25] both result in significant social costs attributable to this regulation.[26] Even if the uninsured receive care as a result of such programs, most of the adverse health effects of being uninsured stem from delays in seeking primary and preventive care as well as a lack of continuity of care,[27] which are unlikely to be affected by uncompensated care pools.[28] In addition, the billions of dollars in uncompensated care provided through pools cannot be viewed as pure transfers. Evidence from the RAND Health Insurance Experiment, which measured changes in utilization and expenditures of patients exposed to different levels of cost sharing in insurance plans, shows that among patients given free care, 31 percent of the care they consume is wasted—that is, the value the patients attached to the care was 31 percent lower than its average cost.[29] Hence even without any adverse effect of pools on the uninsured rate, the benefits of such pools would be lower than their costs. EMTALA poses a similar problem in terms of reducing the incentive to remain insured and of providing care that has a value that may be less than the cost of its provision.

Cost-Related Facilities Regulations

Under *cost related*, fraud and abuse regulations are included—a large umbrella that

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includes state laws as well as a raft of federal restrictions such as the False Claims Act of 1863, Medicare and Medicaid antifraud statutes, the Civil Monetary Penalties Law, federal self-referral prohibitions (also known as Stark I and II), and fraud and abuse provisions included in the Health Insurance Portability and Accountability Act of 1996 and the 1997 Balanced Budget Act. Also included is medical records regulation (including the recently issued HIPAA privacy regulations as these relate to health facilities as well as parallel privacy policies adopted by states). The categorization of the privacy regulations as cost related may seem arbitrary but is justified on grounds that these regulations seek to minimize the tangible and intangible costs associated with privacy violations. Pharmaceutical price regulation (which in turn includes federal average wholesale price restrictions for Medicaid and state pharmaceutical regulations), organ transplant regulation, certificate of need (CON) regulations, and hospital rate setting are also included. Finally, other cost-related health facilities regulations include the Patient Self-Determination Act of 1990[30] and hospital discharge data systems, the principal use of which relates to better informing the public about costs, but which also have an important quality purpose. As a group, these cost-related facilities regulations cost Americans $14.1 billion, and provide benefits of $14.8 billion. Health care fraud and abuse (net cost $1.1 billion) and CON regulations (net cost $110 million) provide the greatest net cost, while pharmaceutical price regulations provide the greatest surplus of benefits over costs ($2.0 billion; see below).

Even though the government collects $2.1 billion in enforcement penalties (treated here as a transfer), the gross cost of health care fraud and abuse regulation is estimated to be $3.2 billion, inclusive of government regulatory costs, industry compliance costs, and efficiency losses from tax collection and regulatory costs. All industry compliance costs (including enforcement penalties) are treated as roughly equivalent to an excise tax (i.e., raising prices and reducing demand/output for

facility services accordingly). Based on the most authoritative calculations of efficiency losses associated with the lower output attributable to output taxes[31]—also known as the marginal excess burden (MEB) of output taxes—these compliance costs are multiplied by 20.9 percent to estimate the hidden social welfare losses they impose. So again, even if enforcement penalties are treated as a raw transfer, the result is that costs exceed benefits for an activity that is widely viewed as self-financing.

Aside from hospital rate setting, certificate of need (CON) regulation is perhaps the single most widely studied area of health services regulation in terms of the sheer number of empirical estimates available from which to derive a composite impact assessment.[32] CON regulations require facilities to obtain state approval (i.e., a certificate of need) prior to constructing new hospitals, nursing homes, or other health facilities. The scope of CON regulation varies by state, but many states now regulate the introduction of new equipment and services such as magnetic resonance imaging units, "air ambulances" (typically helicopters), or other expensive equipment. This research provides very mixed results. In the best case, CON regulations save money and lives by regionalizing facilities and conferring upon the "winners" higher surgical volumes, which traditionally are associated with lower mortality rates. In the worst case, they increase costs and lead to worse health outcomes. The most recent studies that use the most credible statistical methods and most recent data find no impact of CON regulation on health spending (and concomitantly no increase in health spending among states that have elected to drop CON regulation), so zero was used as the expected value. In light of mixed evidence regarding CON regulation's effect on health outcomes, no effect was an expected value, with sizable increases in mortality in the worst case and more modest decreases in mortality in the best case.

Pharmaceutical price regulation is a good example of why caution must be applied to these findings. Since 1990 drug manufactur-

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ers have been required as a condition of Medicaid coverage to provide rebates of at least 15.1 percent (or their "best" price offered to any other purchaser, whichever is lower) to state Medicaid programs for outpatient drugs. Another condition, imposed in 1992, requires manufacturers to list their brand name drugs on the Federal Supply Schedule, thereby extending these Medicaid discounts to other major federal purchasers of pharmaceuticals, including the Department of Veterans Affairs and the Department of Defense. However, a careful study of the impact of the Medicaid Drug Rebate Program found that these "most-favored-nation" provisions had no detectable effect on the rate of inflation for prescription drugs, implying that any savings enjoyed by Medicaid and other public payers effectively was being shifted to other payers, leaving average prices unaffected.[33] Thus, for the most part, any benefits enjoyed by the public sector apparently are offset by equivalent increases in costs in the private sector. However, these regulations are expected to result in a net benefit to society solely due to the efficiency gains—or more precisely, the reduced efficiency losses—that result from financing a small share of overall pharmaceutical consumption through hidden taxes on industry rather than income taxes. These efficiency gains should disappear were the scope of these regulations to widen.

As suggested above, the $6.3 billion benefit to the public sector also imposes a $6.3 billion cost on the private sector. Yet because the gross public savings are $6.3 billion annually, society saves the marginal cost of collecting that $6.3 billion in taxes. Those would-be marginal costs are estimated to be 52.5 percent of revenues collected. This includes administrative costs (0.5 percent), taxpayer compliance costs (12.0 percent), and the MEB of the input taxes (e.g., income taxes) that likely would finance this would-be expenditure (40.0 percent).[34] Thus the further benefit of not having to collect the $6.3 billion in taxes is roughly $3.3 billion. However, when estimating the costs of these regulations, we likewise must account for the efficiency losses

that result from imposing this $6.3 billion hidden tax on the private sector. We treat this cost shift as the equivalent of an excise tax since such costs effectively raise the pharmaceutical industry's cost of doing business and would have the same theoretical impact as an excise tax, including lower output. The MEB was, therefore, employed for *output* taxes (such as excise or sales taxes), which is 20.9 percent.[35] Thus the further cost of imposing this $6.3 billion hidden tax on the pharmaceutical industry is roughly $1.3 billion. The different MEB figures applied to the benefits realized by the public sector and the costs borne by the private sector produces the entire $2.0 billion net benefit of these pharmaceutical price regulations. These regulations, then, produce a net benefit that is wholly due to the reduced level of economic inefficiency that results from the reallocation of a small tax burden—not a reduction in average prices for pharmaceuticals.

Moreover, it is important to recognize that the federal rebates are relatively small in the overall scheme of things; $6.3 billion in public savings for Medicaid, VA, and DOD combined is less than 4 percent of the $162.4 billion spent on pharmaceuticals in 2002.[36] At such small volumes, these discounts are roughly equivalent to the limited number of deeply discounted seats available on an airline. Were *all* seats subject to such a discount, the plane could not fly, as its average revenue would not exceed the costs of getting the plane to its destination. In the same fashion, cross-national comparisons suggest that if the entire U.S. market was to enjoy comparable discounts, that might result in a predictable decline in research, development, and innovation.[37] Thus a regulation that is apparently beneficial on a small scale might become quite costly on a larger scale.

Quality-Related Facilities Regulations

Quality related includes hospital accreditation and licensure, which includes Medicare conditions of participation (COPs, which have many purposes, but quality is arguably the central one) and state accreditation and licen-

A regulation that is apparently beneficial on a small scale might become quite costly on a larger scale.

sure; nursing home accreditation and licensure (including COPs, the Nursing Home Reform Act of 1987, and state regulations); and licensure for all other health facilities. Also included is peer review, encompassing Quality Improvement Organizations and the Health Care Quality Improvement Act of 1986; the Clinical Laboratory Improvement Act of 1967 as amended; and other quality-related facilities regulations such as FDA regulation of blood banks, blood-borne pathogen requirements imposed by the Occupational Safety and Health Administration, and health outcomes reporting systems mandated by states. (Note that medical malpractice is discussed as a completely separate category on grounds that it affects facilities, professionals, and even insurance plans to some extent.) Collectively, these quality-related facilities regulations imposed a cost of $21.8 billion and provided benefits amounting to $4.0 billion. Hospital accreditation/licensure (net cost $8.6 billion), the Clinical Laboratory Improvement Act (net cost $3.2 billion), and peer review (net cost $2.1 billion) are the three largest contributors to this cost.

Medicare and the majority of state health departments that license or certify hospitals rely on the Joint Commission on Accreditation of Healthcare Organizations to certify quality. Yet a recent assessment concluded, "it is apparent that the JCAHO is not associated with improving the quality of care."[38] There have been relatively few studies of the impact of state nursing home regulation, in part because virtually all such facilities are regulated, and hence the absence of a plausible comparison or control group limits such studies to examining whether changes in regulation have been associated with changes in quality over time. It too often is not possible to unravel whether observed differences really reflect differences in actual quality or merely differences in the quality of reporting.[39] For example, an apparent decrease in quality postregulation may not really mean that care has gotten worse, but instead that more of what was happening preregulation is now being reported. There have been more concerted efforts to measure the impact of federal nursing home regulation, but again, it is difficult in these studies to isolate the pure effect of regulatory changes from other factors that were changing during the same time period. The available evidence suggests a historical decline in the inappropriate use of physical and chemical restraints, along with declines in rates of urinary incontinence, catheterization, and hospitalization, at least some of which can be attributed to the Nursing Home Reform Act of 1987.[40] These effects are difficult to translate into dollar terms. In my analysis, based on a single study,[41] I have credited these regulations with producing hospital savings that effectively offset the significant costs associated with regulating nursing homes ($22,000 per nursing home). However, it is worth noting these same regulations also have been shown to reduce access to care for those on Medicaid,[42] an adverse impact I had no good way of monetizing. Thus whether on balance these nursing home regulations have produced any net benefit depends on the weight that is attached to quality improvements relative to lowered access.

CLIA is another good example of well-intentioned regulations that impose sizable costs resulting in an inherent trade-off between any potential gains from the standards themselves and health losses associated with patients who elect not to be tested due to higher prices. One simulation found the benefits of improved cancer screening were completely offset by the reduction in the number of people screened as a result of higher prices that resulted from CLIA.[43]

Health Professionals Regulation

There is even more variety among health professionals, most of whom are subject to varying degrees of health services regulation. Health professionals include *physicians/dentists*, such as professionals with a doctoral degree, including doctors of medicine (MDs), doctors of osteopathy (DOs), and doctors of dental science or dental surgery (DDSs); *mid-level*

providers include physician assistants (PAs), optometrists, podiatrists, and advance practice nurses (such as nurse practitioners, nurse midwives, and nurse anesthetists), all of whom have a more limited scope of practice than physicians and are subject to varying supervision requirements depending on the state in which they practice. Also included are *mental health providers* such as psychiatrists (MDs), psychologists (PhDs), psychological associates, social workers (MSWs and PhDs), and others; *other allied health providers* such as dental hygienists, licensed practical nurses, pharmacists, registered nurses (RNs), radiology technicians, therapists (e.g., physical, occupational, speech, and their assistants), and others; and *alternative medicine providers* such as chiropractors, naturopaths, acupuncturists, and others.

Although some aspects of facilities regulation are directed at changing the behavior of health professionals (e.g., surgical outcomes reporting systems), I have included these under facilities since the burden of compliance typically is borne by the facility rather than health professionals directly. Thus, in terms of sheer numbers, there are fewer regulations included on the health professionals side, even though in reality health professionals as a group are prob-ably regulated just as heavily as facilities are. Findings regarding health professionals regulation are summarized in Table 3.[44]

Access-Related Professionals Regulations

Under *access related*, only Medicare physician payment rules are included, as these were explicitly designed to expand access for Medicare beneficiaries by prohibiting physicians from billing Medicare patients for the difference between their standard charges and the amount Medicare would recognize as allowable (i.e., balance billing), and placing restrictions on the ability of physicians and Medicare beneficiaries to contract for Medicare-covered services outside the Medicare program (i.e., private contracting). While the ban on balance billing effectively transfers income from physicians to patients (which patients presumably would view as beneficial), they also encourage higher demand (and hence additional waste) relative to the situation that prevailed before the ban was imposed. Taking all of these effects into account, these rules impose a net cost of $1.2 billion.

Cost-Related Professionals Regulations

Cost related include federal and state regulations related to fraud and abuse; federal

Medicare physician payment rules impose a net cost of $1.2 billion.

Table 3
Cost of Regulation of Health Professionals (millions of 2002 dollars)

Type of Regulation	Costs			Benefits			Net Cost	Percent
	Expected	Minimum	Maximum	Expected	Minimum	Maximum		
Access	**6,771**	**5,082**	**7,972**	**5,614**	**4,481**	**6,172**	**1,157**	**16.2%**
Medicare assignment rules	6,771	5,082	7,972	5,614	4,481	6,172	1,157	16.2%
Costs	**15,092**	**12,131**	**34,722**	**11,069**	**10,257**	**11,991**	**4,023**	**56.4%**
Fraud and abuse	1,502	1,186	2,166	1,567	1,401	1,843	(65)	-0.9%
Professional medical records (includes privacy)	1,024	731	7,846	1,260	1,056	1,464	(236)	-3.3%
Medicare GME cap	12,566	10,214	24,711	8,242	7,800	8,684	4,324	60.6%
Quality	**7,686**	**3,522**	**22,239**	**5,734**	**2,085**	**18,199**	**1,952**	**27.4%**
Professional accreditation/licensure	6,549	3,414	15,754	4,740	1,981	12,981	1,809	25.4%
National Practitioner Databank	44	39	66	98	49	392	(54)	-0.8%
Commercial limits on practice of medicine	988	18	6,004	817	16	4,694	171	2.4%
Limitations on medical resident working hours	106	50	416	80	39	131	27	0.4%
Grand Total	**29,549**	**20,735**	**64,933**	**22,417**	**16,823**	**36,361**	**7,133**	**100.0%**

Note: Figures may not add up to totals due to rounding.

and state regulation of medical records as they relate to offices/clinics for physicians, dentists, and other health professionals; and Medicare graduate medical education (GME) payments. These regulations result in $15.1 billion in costs and $11.1 billion in benefits. Medicare GME payments account for all of the $4.0 billion in net costs. These payments impose a net cost of $4.3 billion, taking into account gross federal payments of $8.2 billion (which are assumed to be transfers, i.e., benefits to recipient hospitals and costs to taxpayers) and then accounting for the efficiency losses associated with tax collection.

Quality-Related Professionals Regulations

Quality related includes professional accreditation and licensure (e.g., state medical practice acts and Medicare COPs as they relate to physician offices, the National Practitioner Databank, commercial limits on the practice of medicine (including corporate practice of medicine regulations and advertising restrictions imposed by the Federal Trade Commission and states), and limitations on hours worked by medical residents. These regulations cost Americans $7.7 billion annually, with corresponding benefits of $5.7 billion. As on the facilities side, the single largest net cost is attributable to professional accreditation/licensure (net cost $1.8 billion), even after accounting for $4.7 billion in benefits in the form of higher earnings for selected health professionals attributable to the restriction in supply arising from such regulations.

Table 4
Cost of Health Insurance Regulation (millions of 2002 dollars)

Type of Regulation	Costs			Benefits			Net Cost	Percent
	Expected	Minimum	Maximum	Expected	Minimum	Maximum		
Access	**81,412**	**58,119**	**124,159**	**72,281**	**40,939**	**144,940**	**9,131**	**-29.0%**
HMO Act of 1973	-	-	8,330	-	-	8,037	-	0.0%
Anti-discrimination restrictions	214	14	7,414	114	6	4,424	100	-0.3%
Mandated health coverage	74,928	55,059	92,089	68,283	38,188	123,726	6,645	-21.1%
Employer mandates	-	-	39	-	-	73	-	0.0%
Continuation of coverage	44,321	40,597	48,545	29,294	18,488	41,957	15,027	-47.8%
Benefit mandates	30,606	14,461	43,505	17,125	10,943	45,211	13,482	-42.8%
Health provider mandates	-	-	-	12,156	8,757	15,950	(12,156)	38.6%
Person mandates	-	-	-	9,707	-	20,535	(9,707)	30.9%
Insurance Market Reforms	5,386	2,297	15,241	3,066	2,121	7,458	2,321	-7.4%
Health plan conversion regulations	44	21	96	-	-	264	44	-0.1%
High-risk pools	840	728	990	818	623	1,031	22	-0.1%
Costs (w/o ERISA)	**10,707**	**7,393**	**23,933**	**8,960**	**6,779**	**24,873**	**1,746**	**140.1%**
ERISA	793	180	4,043	46,636	26,527	75,973	(45,842)	N/A
HIPAA administrative simplification	846	602	1,119	3,289	2,340	4,349	(2,443)	7.8%
Insurance privacy regulations	2,032	1,445	12,009	3,265	2,323	4,317	(1,233)	3.9%
Medicare as secondary payer	3,220	2,978	3,490	1,936	1,663	3,613	1,283	-4.1%
Medigap minimum standards	1,017	119	2,900	-	-	-	1,017	-3.2%
General Insurance/HMO Regulation	3,592	2,249	4,415	470	453	12,594	3,122	-9.9%
Quality	**7,184**	**2,692**	**24,597**	**3,684**	**2,008**	**11,072**	**3,500**	**-11.1%**
Medicare + Choice COPs	245	148	631	-	-	-	245	-0.8%
Professional rights	-	-	-	-	-	-	-	0.0%
Patient protections	6,939	2,544	23,967	3,684	2,008	11,072	3,255	-10.3%
Grand Total (w/o ERISA)	**99,303**	**68,205**	**172,689**	**84,925**	**49,726**	**180,885**	**14,377**	**100.0%**

Note: Figures may not add up to totals due to rounding.

Health Insurance Regulation

With 185 million Americans covered by private health insurance, health insurance regulation represents an arena of enormous activity at both the federal and state level. Such regulations cover the gamut, regulating Blue Cross and Blue Shield carriers (which, if not-for-profit, are often regulated somewhat differently than their commercial counterparts), commercial insurance companies, self-insured plans, and various flavors of managed care, including health maintenance organizations (HMOs) and preferred provider organizations (PPOs). These entities write group coverage for employers, associations or similar groups, as well as individual coverage. Findings regarding health insurance regulation are summarized in Table 4.[45]

Access-Related Insurance Regulations

Access related includes the Health Maintenance Organization Act of 1973, anti-discrimination restrictions (including the Rehabilitation Act of 1973, Pregnancy Discrimination Act of 1978, Americans with Disabilities Act of 1990, and Child Abuse Prevention and Treatment Act Amendments of 1984), and several types of mandated health coverage. These include the employer mandate enacted in Hawaii in 1974; continuation of coverage requirements (including the Consolidated Omnibus Reconciliation Act of 1986 and state rules); mandated health benefits (including mandated standards of care such as bone marrow transplants, and three federally mandated health insurance benefits: the Mental Health Parity Act of 1996, Newborns' and Mothers' Protection Health Act of 1996, and Women's Health and Cancer Rights Act of 1998).[46] Also included are mandated provider laws (e.g., those applying to coverage for services of podiatrists, optometrists, psychologists, chiropractors, physical therapists, and nurse practitioners among others), and so-called person mandates that require carriers to cover adopted children, for example. Also included are a variety of federal and state insurance market reforms including small-group insurance reforms, individual market reforms, community rating, health alliances (both voluntary and mandatory), and insurance reforms contained in HIPAA. Both voluntary and mandatory alliances are included, on grounds that the former still rely on the power of the state and result in an allocation of resources somewhat different than if the state had left the market alone. Finally, health plan conversion regulations and high-risk pools are included.[47]

Collectively, access-related insurance regulations cost $81.4 billion and provide benefits of $72.3 billion. Continuation-of-coverage mandates (predominantly stemming from federal regulations) have a net cost of $15.0 billion, while benefit mandates have a net cost of $13.5 billion. Although the latter include a handful of selected mandates imposed by the federal government, including minimum length of stay requirements for newborns and mothers, the vast majority of these mandates are imposed by states.

Cost-Related Insurance Regulations

Cost related includes the Employee Retirement Income Security Act of 1974, two key provisions of HIPAA (administrative simplification and privacy regulation)[48], Medicare-as-secondary-payer rules passed in 1980, Medigap minimum standards enacted in 1990, and general health insurance/HMO regulation (which focuses on solvency regulation and rate justification since managed care regulations addressing quality concerns are handled in the quality section). Also included are premium taxes, on grounds that states have used these not purely for revenue generation, but also to alter the structure of the industry to some extent (e.g., favoring domestic over out-of-state corporations and sometimes favoring Blue Cross/ Blue Shield plans over commercial insurers). These same objectives might also have been obtained through more conventional regulation, but states have effectively substituted tax policy for regulation in this instance.

All told, cost-related insurance regulations provide a net cost of $10.7 billion. It

Continuation-of-coverage mandates have a net cost of $15.0 billion, while benefit mandates have a net cost of $13.5 billion.

should be noted that to represent the burden of health services regulation accurately, the Employee Retirement Income Security Act is excluded. ERISA's $46 billion net benefit arises from blocking the costs that state regulations (state benefit mandates, premium taxes, etc.) would otherwise impose on self-funded employer health plans that cover 124 million Americans.[49] Since those would-be costs are not entered on the cost side of our ledger, to include the benefits ERISA provides by blocking them effectively would credit ERISA with creating $46 billion in benefits, when in fact the law merely returns these health plans to a preregulation status quo ante. As such, ERISA's $46 billion net benefit would make the burden of health services regulation seem lighter than it is by hiding costs currently being borne, such as the entire net cost of FDA regulation (see below).

Quality-Related Insurance Regulations

Quality related includes Medicare Plus Choice COPs and a variety of managed care regulations; some of these might be as appropriately conceptualized as access initiatives, but they are included here on grounds that they are said to be motivated by concerns about patient quality. While all arguably are intended to improve patient quality, those focused on professional rights (including anti-gag rules, due process protections, and prompt payment statutes) are distinguished from those focused on patient protection (including any-willing-provider regulations, continuity-of-care requirements, external review regulations, regulation of drug formularies, limits on use of financial incentives, and "patients' bill of rights" regulation), on grounds that the former are aimed at countering the market power of managed care organizations vis-à-vis individual providers, while the latter are more focused on patients. Since a federal "patients' bill of rights" statute has not been enacted, costs are based only on state statutes currently in effect. These quality-related insurance regulations cost $7.2 billion but provide benefits of only $3.7 billion, mainly because of the $3.3 bil-

lion net cost imposed by patient protection regulations.

FDA Regulation of Pharmaceuticals and Medical Devices

Regulation of pharmaceuticals has been in place for nearly a century, starting with the Pure Food and Drugs Act of 1906 (which gave the government control over the labeling of drugs); such regulation of pharmaceuticals was initially motivated by concerns over adulterated patent medicines and a desire to protect the public against false claims made for them. By the 1930s, concern had broadened to protect the public from unsafe, potentially harmful drugs, culminating in the Food, Drug and Cosmetic Act in 1938, which extended control over advertising and labeling and required proof that drugs were safe. Finally, by the early 1960s, concerns that Americans were being sold drugs of questionable efficacy at very high prices led to the 1962 Amendments to the FDC Act, which added proof of efficacy to proof of safety as a criterion for drug approvals. Medical devices came under FDA control in 1976 with the passage of Medical Device Amendments.[50]

The FDA approval process, while streamlined in recent years, still requires many years of rigorous testing before a drug or medical device can receive approval. There has been a decades-long debate over whether the FDA approval process achieves the appropriate balance between minimizing the risks associated with early introduction of potentially hazardous pharmaceuticals and giving patients ready access to needed pharmaceuticals. Critics of the FDA approval process argue that even with recent reforms, the process is far too expensive and lengthy, leading to concerns that it may be either inhibiting innovation or at least delaying life-saving medications from getting quickly to market. In this view, the principal costs of the process relate to the amount industry must pay to get through the

These quality-related insurance regulations cost $7.2 billion but provide benefits of only $3.7 billion, mainly because of the $3.3 billion net cost imposed by patient protection regulations.

Table 5
"Bottom-Up" Estimates of the Cost and Benefits of Health Services Regulation (millions of 2002 dollars)

Type of Regulation	Costs			Benefits			Net Cost
	Expected	Minimum	Maximum	Expected	Minimum	Maximum	
Health Facilities	47,692	23,737	277,645	22,617	25,418	39,303	25,074
Health Professionals	29,549	20,735	64,933	22,417	16,823	36,361	7,133
Health Insurance (w/o ERISA)	99,303	68,205	172,689	84,925	49,726	180,885	14,377
Food and Drug Administration	48,995	20,259	210,037	7,132	1,867	21,387	41,863
Medical Tort System	113,693	40,729	195,351	33,047	8,363	295,815	80,646
Grand Total	339,231	173,664	920,655	170,137	102,196	573,752	169,094

Note: Figures may not add up to totals due to rounding.

process and the avoidable mortality and morbidity that result from lags in the approval process. The theoretical benefits of FDA regulation lie in protecting the public from potentially hazardous drugs and from squandering resources in purchasing drugs that either do not work, are unsafe, and/or do not represent good value for the money.

The most thorough empirical analysis I was able to locate was by Dale H. Gieringer, who systematically calculated both the number of lives lost due to FDA-imposed delays and the estimated annual number of lives saved due to keeping unsafe drugs such as Thalidomide off the market.[51] In a typical decade, he estimated the average cost of FDA delays at between 21,000 and 120,000 lives and the average benefits of FDA regulation (relative to the approval process in foreign countries) at between 5,000 and 10,000 lives per decade. Over a 30-year period, the ratio of drug-related disabling injuries to deaths was 18,000 to 5,100. Using these figures as a starting point and then making reasonable adjustments to reflect subsequent improvements in the process that have led to shorter delays, the lost lives were multiplied by $4.4 million apiece; this reflects the value of a statistical life based on numerous labor market studies showing that workers collectively demand this amount in higher compensation in order to accept jobs whose risk collectively results in one extra death.[52] The value

of each drug-related disabling injury is assumed to be equal to 10 percent of the loss attributable to each death. Combining these estimates, I conclude that FDA regulation imposes an annual cost on society of $49.0 billion and annual benefits of $7.1 billion (see Table 5). The lion's share of this cost represents the value society places on the net number of lives that are lost while waiting for better pharmaceuticals to be approved (after subtracting the number of lives saved by FDA safety regulation).

Medical Tort System

The medical tort system is unlike some other components of health services regulation in that it arises out of common law rather than an explicit identifiable statute or body of regulations. However, there are some important features of the medical tort system that warrant its inclusion under the broader umbrella of health regulation. First, there are many features of the medical tort system that are affected or distorted by policy. For example, many states impose mandatory requirements on professionals and/or facilities to purchase liability coverage. When coupled with the fact that most health spending is paid for by third parties, the result is that consumers effectively are being required to purchase a form of disability

FDA regulation imposes an annual cost on society of $49.0 billion and annual benefits of $7.1 billion. The lion's share of this cost represents the value society places on the lives that are lost while waiting for better pharmaceuticals to be approved.

insurance against the risk of some injuries arising out of medical treatment, with providers often being financially insulated from the consequences of a medical error.[53] Likewise, the convention of contingency fees adopted in the U.S. rather than "loser pays" conventions seen in other countries contributes importantly to the ultimate size and impact of the medical tort system. Third, there certainly are alternative policy arrangements that have been proposed (and in some states adopted) for better achieving the same objectives as the medical tort system, such as no-fault liability insurance, damage caps, and so forth. Thus, whether by omission or commission, the current medical tort system could be viewed as the result of policy even if one cannot point to a single statute or policy that created this "system." Leaving aside the question of whether we ever could or should alter it, certainly there is no question that this "system" is in theory amenable to reform.

The medical tort system serves both as a compensation mechanism as well as a potential deterrent to medical injury. Clinicians are expected to be more likely to change their behavior if the odds that errors will be discovered and/or the financial consequences of negligence increase. Historically, the states, rather than the federal government, have been responsible for establishing and enforcing rules governing tort liability in medical care and other settings. A number of states have adopted major reforms such as caps on noneconomic damages or caps on attorneys' fees. However, the focus in this section is on measuring the overall cost of the current "system" rather than the potential gains from reforming it.

In the current system, both facilities and health professionals may be involved in decisions to purchase professional liability insurance. Since it is up to individual patients to decide whether to sue in a given case, a surprisingly high fraction (98 percent) of actual victims of negligence opt not to sue. Conversely, less than one in five malpractice claims appear to involve actual negligence.[54]

Critics of the medical tort system argue that it is neither fair nor efficient, too often seeming to be a random lottery in which a lucky few are overcompensated and the majority of victims are undercompensated. There is substantial controversy over whether the current system results in any appreciable degree of defensive medicine, defined as medical services not expected to benefit the patient but which are undertaken to minimize the risk of a subsequent lawsuit. The problem with defensive medicine and its measurement is that "some so-called defensive medicine may be motivated less by liability concerns than by the income it generates for physicians or by the positive (albeit small) benefits to patients."[55] Yet at the same time, there are widespread reports by medical professionals of its presence.[56] In theory, negligent behavior will be deterred if the negligent party has to bear the costs of acting negligently. So, in principle, the malpractice system may improve patient safety as well as compensate those who are injured. The two most controversial and difficult-to-measure aspects of the medical tort system relate to defensive medicine and deterrence.

Defensive Medicine

Over the past two decades, a number of studies have sought to measure empirically the nature and extent of defensive medicine. The most definitive studies to date were conducted by Daniel P. Kessler and Mark B. McClellan. The first of these found that states with any of four restrictions (caps on noneconomic or total damages, prohibitions on punitive damages, no automatic addition of prejudgment interest, and offsets for collateral-source benefits) decreased long-run hospital expenditures for patients with acute myocardial infarction (AMI) by 5.8 percent. For patients with ischemic heart disease, the reduction resulting from reforms was 8.9 percent.[57] Because there were no significant changes in patient outcomes, it is presumed that these spending differences reflect a measure of defensive medicine—expenditures that could be safely eliminated without apparent harm to patients. If these estimates were applied to total health spending, the

There are important features of the medical tort system that warrant its inclusion under the broader umbrella of health regulation.

savings would amount to $69 billion to $124 billion in 2001.[58]

To respond to concerns that states with aggressive managed care were more likely to adopt reforms (and hence their findings were attributable to managed care rather than defensive medicine), the authors did a follow-up study that explicitly controlled for managed care penetration, finding smaller but still significant effects. Specifically, they found that direct reforms decreased long-run hospital expenditures for AMI patients by approximately 4.2 percent and ischemic heart disease patients by 4.4 percent.[59] The authors estimate from their latest findings that "at least for elderly heart disease patients, an untried reform that reduced the legal-defense burden on physicians and hospitals by one-quarter—which is within the range of policy possibilities—could be expected to reduce medical treatment intensity by approximately 6.2 percent, but not to increase the incidence of adverse health effects."[60]

The Congressional Budget Office has applied the Kessler-McClellan method to a broader set of medical conditions, but found no parallel evidence that restrictions on tort liability reduce medical spending. When the same method was applied to a different dataset, there were no statistically significant differences in per capita health care spending between states with and without limits on malpractice torts. The Congressional Budget Office regards the question of whether such limits reduce medical spending an open one and is continuing to examine it using alternative approaches.[61]

There are two issues with the most recent Kessler-McClellan estimates. First, unlike earlier estimates, they do not purport to measure the full extent of defensive medicine. Instead, they focus on a much narrower question, which is whether tort reforms might be expected to yield reductions in defensive medicine. However, their data may be used to estimate the overall level of defensive medicine. A recent analysis of state data from 1985–2001 found that the "earned premiums" per physician—that is, the portion of malpractice insurance premiums that applies to the portion of the policy period that has already expired (i.e., the period for which the insurer is no longer at risk)—were 12.7 percent lower in states that capped noneconomic or economic damages compared to states without such reforms.[62] Assuming that the proclivity to practice defensive medicine is roughly correlated with the final risk associated with professional liability suits, one could arguably multiply the Kessler and McClellan figures by a factor of eight in order to approximate the overall amount of defensive medicine that would be eliminated were the current level of financial risk removed entirely. That is, the Kessler-McClellan figures represent the response of physicians to tort reforms that on average reduced the economic pressure to practice defensive medicine by roughly one-eighth. Presumably, the response to removing such pressures entirely would be much greater.

This relates to the second issue. Kessler and McClellan selected two procedures for which they could measure both spending impacts and also make definitive statements about patient outcomes. Their dataset by its nature was restricted to Medicare patients. A conservative approach would limit the estimate of defensive medicine to hospital costs associated with those two procedures for Medicare-eligible patients. But that would tacitly ignore the widespread evidence of potential defensive medicine in other procedures such as caesarean sections and diagnostic testing.[63] The most extreme approach would be to use the Congressional Budget Office estimates of no measurable defensive medicine as a lower bound on grounds that they examined a broader set of conditions. But if the real motivation for defensive medicine is to avoid being sued at all (as opposed to lowering the payout in cases where a suit is won), then reducing premiums by a modest amount (e.g., by capping damages) should not be expected to produce any evidence of a reduction in defensive medicine even if the practice of defensive medicine is widespread. While there are legitimate concerns over

Critics of the medical tort system argue that it is neither fair nor efficient.

whether older methods of estimation may overstate the extent of defensive medicine, the weight of the evidence overall could not support a claim that there was zero defensive medicine, even as a lower bound. Such claims are contradicted by the findings of the best empirical study to date[64]—even if the results of that study are *not* extrapolated to all Medicare spending or all health expenditures.

Deterrence

Trying to measure the deterrent value of the medical tort system is even more problematic. In the current system, it is now widely accepted that tens of thousands of patients die annually because of medical negligence.[65] Patricia Danzon's recent literature synthesis states, "the only credible study of deterrence of medical negligence is from Weiler et al. (1993)."[66] In New York, a multivariate analysis showed that the medical malpractice system reportedly deters 28.8 percent of all malpractice, but this estimate was not statistically significant, possibly due to small sample size.[67] The ratio of negligent injuries to negligent deaths was 2.9:1 in New York,[68] but was 10.4:1 in a study of Colorado and Utah.[69]

Combining the most plausible estimates,

we conclude that the medical tort system imposes costs of $113.7 billion (of which roughly $70 billion represents defensive medicine) but provides benefits amounting to $33.0 billion (most of which is attributable to mortality/disability averted due to deterrence, but which also accounts for the compensation paid to injured patients).

Total Cost of Health Services Regulation

When estimates across all five major categories of regulation are combined, the expected costs of regulation in health care amounted to $339.2 billion in 2002. As shown in Table 5, benefits are estimated to be $170.1 billion, leaving a net cost of $169.1 billion. Three areas account for the lion's share of this net burden (see also Figure 1). The cost of the medical tort system, including litigation costs, court expenses, and defensive medicine, totals $80.6 billion. FDA regulation adds another $41.9 billion, and health facilities regulation adds $25.1 billion. That suggests that the states and federal government both have important roles to play in finding ways to trim regulatory excess.

> The medical tort system imposes costs of $113.7 billion but provides benefits amounting to $33.0 billion.

Figure 1
Health Regulation Costs Outweigh Benefits by $169 Billion (2002)
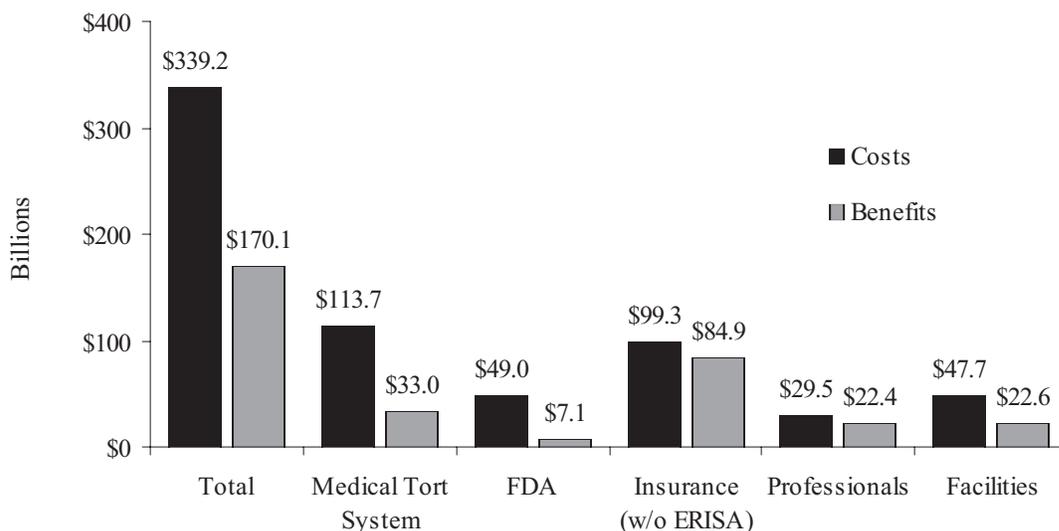
Uncertainty in Regulatory Costs

The uncertainties in these figures are considerable, reflecting a combination of gaps in knowledge as well as large methodological differences across studies in terms of how to measure costs and benefits. These uncertainties will presumably narrow as more researchers focus their attention on what we have shown to be a sizable yet little-explored domain of regulatory burden. Thus, the conclusions we can draw at this juncture are of necessity somewhat limited. Nevertheless, it is instructive to consider some of the implications assuming that our expected net cost estimate is found to be a reasonable approximation of reality even after the myriad figures comprising this aggregate are poked and prodded by experts in the years to come.

Uncertainty has been a sine qua non of previous efforts to estimate regulatory costs. Although the first effort to compile an aggregate cost of federal regulation produced only a point estimate of $66.1 billion (in 1976 dollars),[70] most subsequent efforts have produced ranges in which the upper bound typically is at least three times as high as the lower bound. For example, Robert E. Litan and William D. Nordhaus's pioneering study estimated the aggregate annual cost of federal regulation at $34.7 billion to $90.6 billion (in 1977 dollars).[71] The first comprehensive effort to measure the costs and benefits of federal regulations found that the net effect of economic and social regulations could range from a net cost of $111.7 billion to a net benefit of $58.2 billion, leading the authors to conclude that "existing tools for estimating regulatory impacts are extremely imprecise, and that most estimates more properly are viewed as 'guesstimates.'"[72]

The uncertainty in estimates for individual industries is even higher. Studies of the cost savings resulting from trucking deregulation vary by an order of magnitude, and studies of the cost of railroad regulation differ by two orders of magnitude.[73] In this context, some of the variation observed across individual studies of health services seems quite tame and a three-fold difference between the upper- and lower-bound estimates of overall health services regulatory costs might be viewed as reasonably respectable. That said, the 30-fold difference between our high and low estimates of cost-related regulations for health facilities shows that there is substantial room for narrowing the range.

With the caveat that these findings are still preliminary, to date I have found that in the domain of health facilities regulation, of the 18 separate areas of regulation studied, only three produced benefits that exceeded costs. Similarly, benefits exceeded costs for only 3 of 8 health professional regulations studied and 5 of 19 areas of health insurance regulation (one of these was ERISA, effectively a deregulatory measure). This is not to say that the 36 areas of health regulation where costs appear to exceed benefits should be discarded entirely, since in at least some cases it is possible that regulatory reform could produce a better alignment of benefits with costs. The medical tort system is a good example. This system clearly produces some benefits, including compensation to patients and deterrence of medical errors. However, if there were a way to achieve the same or greater benefits less expensively—whether through caps on damages, alternative dispute resolution, loser pays, contractual limitations on liability, and so forth—that would be an improvement over the status quo.

Benchmarks of Comparison

Health care regulatory costs should be put into context. In terms of GDP, $169 billion represents 1.8 percent—roughly the relative size of the Medicare program in 1989 and more than the federal share of the Medicaid program ($148 billion), as well as total corporate tax collections ($148 billion), and the budget deficit ($158 billion) in 2002.[74] This is comparable to the gross state products of seven states: Alaska, Idaho, Montana, North Dakota, South Dakota, Vermont, and Wyoming (combined gross state products: $174 billion in 2001).[75] It also represents more than U.S. consumers spend on gasoline and oil ($165.8 billion in 2002)[76] and double the out-

In 2002 the cost of health care regulations exceeded the budget deficit.

put of the motion picture and sound recording industries ($81.8 billion in 2002).[77] Spread across all households, health services regulation cost the average household an estimated $1,546 in 2002.[78] Assuming the net annual cost of health services regulation remains constant, it will exceed by a factor of three the $534 billion that will be required to fund the new Medicare prescription drug benefit over the next 10 years, and will exceed the revenue necessary to eradicate Medicare's financial imbalances over the next 75 years.[79]

Health services regulation adds to—and often dwarfs—other costs imposed by government intervention in the health care sector. For example, this analysis has ignored tax policy as it relates to health care. Yet federal and state tax subsidies for health insurance in 2002 amounted to an estimated $177 billion[80] and generated roughly $106 billion in efficiency losses[81]—an amount that would increase the estimate of the cost of health services regulation by three-fifths had it been included. On a smaller scale, a recent study of Medicare found that $26 billion of Medicare expenditures in 1996 (equivalent to $34 bil-

lion in 2002) is wasted ("appears to provide no benefit in terms of survival, nor is it likely that this extra spending improves the quality of life").[82] This does not even count the presumably much greater amount of care that may confer some medical benefit, but which has a value to patients is less than the cost of its provision.[83] Nor does it count the amount of such waste in Medicaid, the State Children's Health Insurance Program, or other government health programs. Thus, there are clearly areas apart from health services regulatory costs where Americans could get more bang for the buck (Figure 2).

One final benchmark concerns overall personal health care expenditures (PHCE), which includes spending on medical services such as hospital care or physician services but excludes program administration of public programs such as Medicare and Medicaid, private insurance company administrative costs, government public health activities, and investments in medical research and health-related construction. Because the bottom-up analysis allows one to isolate health industry compliance costs from other costs (such as general-

Figure 2
Benchmarks of Comparison
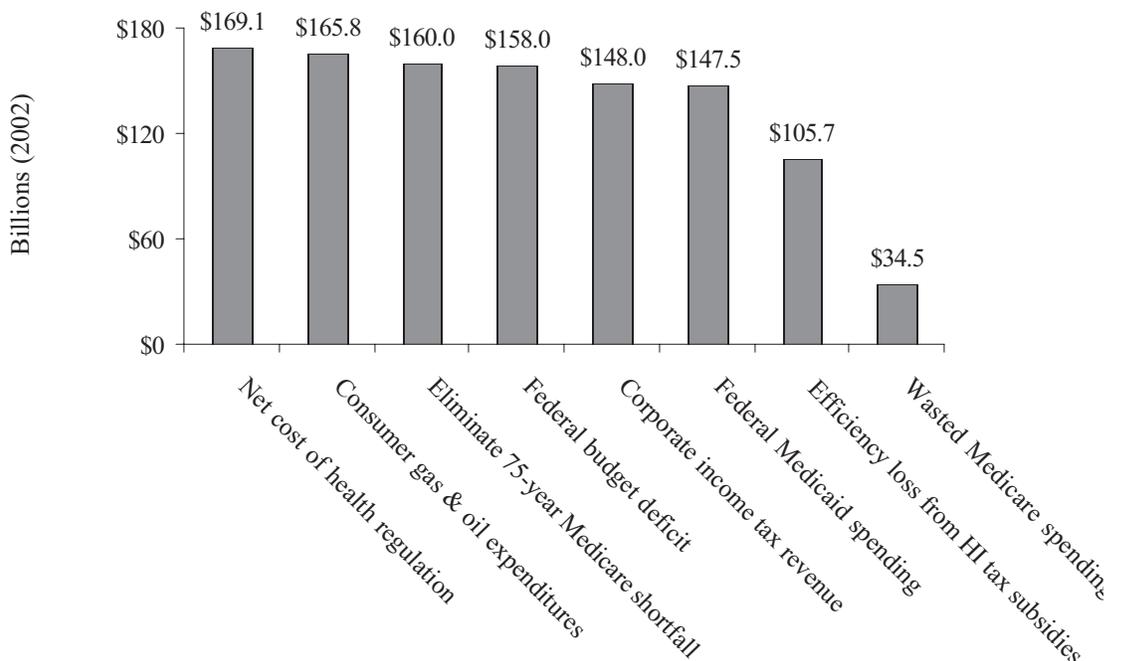
ized unemployment effects), we can estimate the share of overall PHCE that can be attributed to regulation. Looking at costs alone, a total of 14.5 percent of PHCE can be chalked up to regulatory costs. However, benefits (i.e., various sorts of cost savings or increased income via transfers) to the health industry are 5.6 percent, leaving a net burden of 8.9 percent, and suggesting that regulatory costs add an average 8.9 percent to the cost of all personal medical expenditures.

Trends in Regulatory Costs

How has the burden of health services regulation changed over time? W. Mark Crain and Thomas D. Hopkins have shown that between 1970 and 2000, federal regulatory agency budgets grew by 203 percent in real (inflation-adjusted) terms, or 3.7 percent annually.[84] FDA expenditures during this same period grew nearly ten-fold in current dollars, or 3.3 percent annually in real terms.[85] Real PHCE grew 5.4 percent annually during this same period.[86] Thus it seems likely that the cost of health services regulation grew at least as fast if not faster than federal regulatory costs in general. In fact, if the costs of health services regulation had grown only as fast as general regulatory costs rather than PHCE, this would imply that net regulatory costs amounted to 14.4 percent of personal health care expenditures 30 years ago, compared to 8.9 percent today. While it is plausible that regulatory burdens in health care have lightened to some extent during this period, it seems unlikely that the net burden of health services regulation has declined nearly 40 percent in relative terms over three decades, lending further plausibility to the alternative presumption that the regulatory burden in health care has grown in rough tandem with PHCE itself. If so, health services regulation likely constitutes a growing share of the net burden of regulation overall, and failure to include this component in conventional estimates of the costs of regulation in general will produce a flawed picture whose distortion will only magnify over time.[87]

Opportunity Costs of Health Services Regulation

Health services regulation and the uninsured. How do all these figures relate to the uninsured? If the annual net cost of regulation imposed directly on the health industry itself is 8.9 percent, this implies that health expenditures (and prices for medical items, including health insurance premiums) are at least that much higher than they would be absent regulation. Based on consensus estimates about the impact of higher prices on how many would likely drop health insurance, this increased cost implies a 3.8 percent reduction in the demand for coverage. This translates into 6.8 million uninsured whose plight arguably might be attributed to excess regulatory costs, or roughly one in six of the average daily uninsured.[88]

The foregoing figures are derived as follows: Most recent estimates of the price elasticity of demand for health insurance lie in the -.4 to -.6 range.[89] Assuming an average overhead cost no higher than 15 percent, the 8.9 percent increase in health spending (i.e., health benefits) attributable to health industry compliance costs would be associated with a 7.6 percent increase in overall health insurance premiums (i.e., 8.9 percent x 85 percent = 7.6 percent), so applying a mid-range elasticity estimate yields a 3.8 percent reduction in demand for coverage. There are 185 million adults and children currently covered by private health insurance.[90] A 3.8 percent reduction in demand translates into 6.8 million uninsured. Using upper-bound estimates of the net impact of health regulation (17.5 percent) and price elasticity (-.6) would imply that 15.9 million Americans, or 38.6 percent of the average daily uninsured, could be uninsured due to health regulation (Figure 3).

It is worth noting that for purposes of calculation, all regulatory costs are assumed to be spread relatively evenly across all payers in the system. For many forms of regulation, such as professional licensure and credentialing, this is a plausible assumption. But some forms of regulation, such as state insurance regulation, tend to be more narrowly focused

There are 6.8 million uninsured whose plight arguably might be attributed to excess regulatory costs, or roughly one in six of the average daily uninsured.

Figure 3
Percentage of Average Daily Uninsured without Coverage Due to Net Cost of Health Services Regulation

As income rises, mortality falls because people are able to purchase more health and safety.
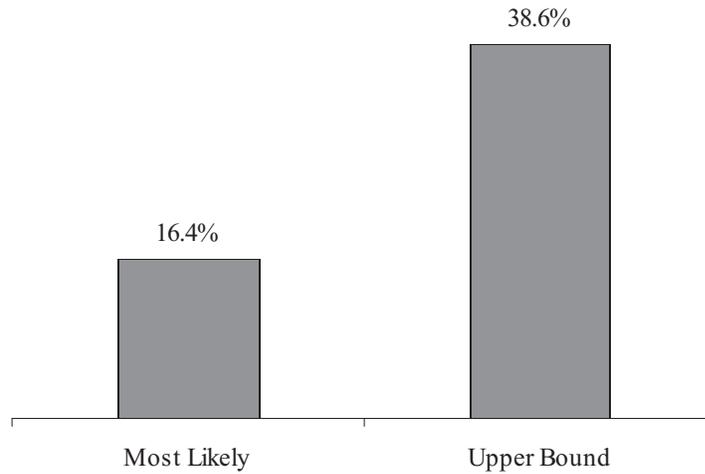
on selected groups—for instance, small group and individual purchasers. Had it been possible to calibrate these estimates more finely to determine the percentage cost increase facing small firms, for example, we undoubtedly would find that the impact was greater than the 8.9 percent average effect. This matters not only because of equity considerations but because the groups disproportionately impacted tend to be much more price sensitive than others. Hence, the uninsured are more likely to come from small groups and those relying on the individual market than among those covered by large employers.

Health services regulation and increased mortality. There is another way to evaluate the opportunity cost associated with health services regulation. A variety of studies have established a trade-off between income and mortality: as income rises, mortality falls because people are able to purchase more health and safety. The best of these studies

Figure 4
Health Services Regulation and Mortality

22
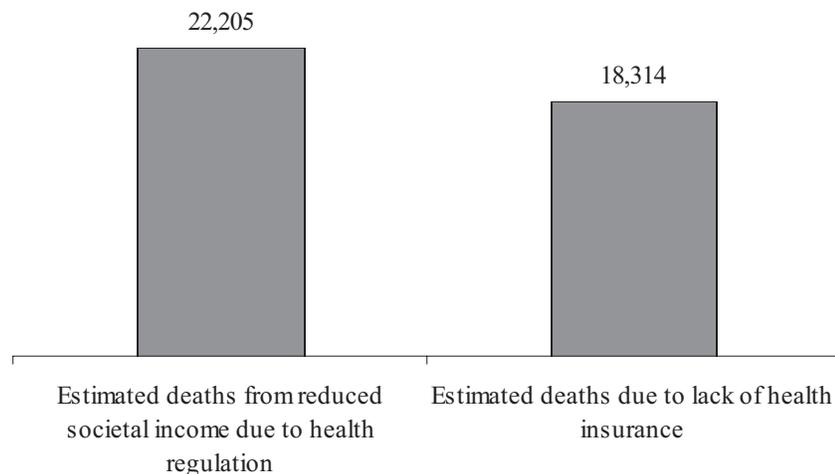
control for prior health status. The median estimate from four such studies shows one statistical death for every $7.6 million reduction in societal income (in 2002 dollars).[91] This implies that $169 billion in health services regulation costs could itself induce upwards of 22,200 deaths a year. Unless these regulatory expenditures achieve benefits at least equal to this number of deaths, Americans would be better off taking their chances on less regulation and instead saving 22,200 lives for certain by keeping this income in the hands of consumers, thereby enabling them to purchase safer products (cars, homes, etc.) or to make other investments to improve their health. Moreover, the Institute of Medicine has estimated that 18,000 uninsured Americans die every year due to lack of coverage.[92] In other words, over 4,000 more Americans die every year from health services regulation than die due to a lack of health insurance (Figure 4).

Conclusion

The pressures to regulate are unrelenting. For example, after failure of the Senate and House to agree on conflicting versions of a "patients' bill of rights" passed by each chamber in 2001, the issue has been dormant. However, the recent unanimous Supreme Court decision in *Aetna v. Davila*, that patients covered by ERISA plans cannot sue their managed care companies for damages in state court,[93] has now put the issue back on the front burner.

More than a decade ago, some pioneers in estimating regulatory costs stated, "We believe that improving and disseminating better information is likely to induce decision-makers to scrutinize the costs and benefits of regulation more carefully. We hope that this increased care will lead to more efficient decisions."[94] The estimates in this report, as uncertain and incomplete as they may be, have been assembled with the same motivation.

In terms of priorities, it would appear from this preliminary assessment that med-ical tort reform offers the most promising target for regulatory cost savings, followed by FDA reform, selected access-oriented health insurance regulations (e.g., mandated health benefits), and quality-oriented health facilities regulations (e.g., accreditation and licensure). Conversely, tinkering with ERISA would appear to be something that should be approached with a great deal of caution and careful consideration. What should be clear from even this rough picture of the health services regulatory landscape is that the potential savings from regulatory reform in health services are far too great to be ignored.

Notes

1. Previous efforts to synthesize the overall burden of regulation in the United States include M. Weidenbaum and R. DeFina, "The Cost of Federal Regulation of Economic Activity," American Enterprise Institute, 1978; Robert E. Litan and William D. Nordhaus, *Reforming Federal Regulation* (New Haven, CT: Yale University Press, 1983); Robert W. Hahn and John A. Hird, "The Costs and Benefits of Regulation: Review and Synthesis," *Yale Journal on Regulation* 8 (1990): 233–78; Thomas D. Hopkins, "Costs of Federal Regulation," *Journal of Regulation and Social Costs* 2, no. 1 (1992): 5–31; Thomas D. Hopkins, "Profiles of Regulatory Costs," Report to the U.S. Small Business Administration, 1995; Thomas D. Hopkins, "Regulatory Costs in Profile," Policy Study no. 132, Center for the Study of American Business, 1996; W. Mark Crain and Thomas D. Hopkins, "The Impact of Regulatory Costs on Small Firms," RFP No. SBAHQ-00-R-0027, Office of Advocacy, U.S. Small Business Administration, http://aspe.hhs.gov/health/reports/hipbase/toc.htm; Susan Dudley and Melinda Warren, "Regulatory Response: An Analysis of the Shifting Priorities of the U.S. Budget for Fiscal Years 2002 and 2003," Mercatus Center at George Mason University, 2002, http://mercatus.org/regulatory studies/article.php/41.html; and Susan Dudley and Melinda Warren, "Regulatory Spending Soars: An Analysis of the U.S. Budget for Fiscal Years 2003 and 2004," Mercatus Center at George Mason University, 2003, http://mercatus.org/regulatorystudies/article.php/425.html. See also Office of Management and Budget, "Report to Congress on the Costs and Benefits of Federal Regulations," 1997, 1999, and 2000; Office of Management and Budget, "Making Sense of Regulation: 2001 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities," 2001; Office of Management and Budget,

Americans would be better off taking their chances on less regulation and instead saving 22,200 lives for certain by keeping this income in the hands of consumers.

"Draft Report to Congress on the Costs and Benefits of Federal Regulations"; and *Federal Register* 67, no. 60, pp. 15014–45. A comprehensive review and synthesis of the cost of workplace regulations is provided by Joseph M. Johnson, "A Review and Synthesis of the Cost of Workplace Regulations," Mercatus Center at George Mason University, 2001.

2. This figure extrapolates from a year 2000 estimate of the total cost of regulation ($843 billion) reported by Crain and Hopkins, inflated to 2004 on the basis of the annualized increase in regulatory costs per household from 1995 to 2000 (1.2 percent: reported in the same source) and annualized increase in households from 2000 to 2002 (2.2 percent: U.S. Census Bureau figures reported in *Statistical Abstract of the United States* 2003, Table 65), yielding a 2004 estimate of $871 billion. To this is added $25 billion in federal regulatory costs in 2002 reported by Dudley and Warren, "Regulatory Spending Soars."

3. Stephen Heffler, Sheila Smith, Sean Keehan, M. Kent Clemens, Greg Won, and Mark Zezza, "Health Spending Projections for 2002–2012: Spending on Hospital Services and Prescription Drugs Continues to Drive Health Care's Share of the Economy Upward," *Health Affairs Web Exclusive* 2003, pp. 54–65, http://www.allhealth.org/recent/audio_03-17-03/HealthSpendingProjections.pdf.

4. Draft working papers for each of 47 specific components of health services regulation assessed for this study are available at http://www.hpolicy.duke.edu/cyberexchange/Regulate/CHSR/CHSR.html. These papers are in the process of review and will be updated as improved estimates become available. For a discussion of the project's advisory panel, see Christopher J. Conover, "Research on the Benefits and Costs of Health Services Regulation," Testimony to the Joint Economic Committee, May 13, 2004, pp. 3–4, http://jec.senate.gov/_files/ConoverTestimony051304.pdf.

5. Hahn and Hird.

6. The issue of the degree to which health care is "different" from other economic commodities has a long history, stemming from Kenneth J. Arrow's seminal work on the topic: "Uncertainty and the Welfare Economics of Medical Care," *American Economic Review* 53 (December 1963): 941–73. An excellent discussion of the extent to which medical care deviates from the competitive model may be found in a special issue of *Journal of Health Politics, Policy and Law* 26, no. 5 (October 2001) on the subject of "Kenneth Arrow and the Changing Economics of Health Care." It is generally agreed that widespread third-party payment, the pervasive amount of uncertainty, the large information asymmetry between the patient and caregiver, and the presence of externalities (in which individual behavior, such as getting a vaccination, confers benefits on others) all continue to make health care somewhat different from most other markets (see Charles E. Phelps, *Health Economics*, 3rd ed. [Boston: Addison-Wesley, 2003] or other standard health economics texts for further explanation).

7. Hahn and Hird., p. 254.

8. Ibid., p. 248.

9. Office of Management and Budget, 1997, p. 15.

10. Johnson, p. 5.

11. Hahn and Hird represents one of the first efforts to quantify both the costs and benefits of various regulations, but few other studies have followed suit. The annual mandatory Office of Management and Budget reports to Congress on the costs and benefits of federal regulation, which build on the Hahn and Hird estimates by adding to them the costs of new major federal regulations, are another exception.

12. Johnson.

13. Charles E. Phelps, *Health Economics*, 2nd ed. (Boston: Addison-Wesley, 1997), p. 539.

14. See http://www.hpolicy.duke.edu/cyberexchange/Regulate/CHSR/CHSR.html.

15. Maureen L. Cropper and Wallace E. Oates, "Environmental Economics: A Survey," *Journal of Economic Literature* 30, no. 2 (1992): 721.

16. Office of Management and Budget, 1997.

17. Office of Management and Budget, 1999.

18. Environmental Protection Agency, "Guidelines for Preparing Economic Analyses," 2000, p. 113.

19. For purposes of discussion and subsequent analysis of costs and benefits, I have slightly modified the five basic cost components used in the Environmental Protection Agency's *Guidelines for Preparing Economic Analyses*, splitting their compliance cost category into two separate pieces, one focused on health industry compliance costs and the other focused on compliance costs incurred by consumers.

20. See http://www.hpolicy.duke.edu/cyberexchange/Regulate/CHSR/CHSR.html.

21. I recognize these are obligations placed on *localities* rather than *facilities*, but included them

since they may have implications for cost of care in locally owned facilities.

22. Although some states partially fund hospital uncompensated care pools from revenue sources other than interhospital transfers, our calculations indicate these other sources contribute less than 10 percent of revenue to uncompensated care pools nationwide.

23. The first such study used data from the 1986 National Health Interview Survey. See K. J. Rask and K. N. Rask, "Evidence that Uncompensated Care Funds and Medicaid Influence the Purchase of Private Insurance," Discussion Paper no. 94-09, Colgate University, Department of Economics, 1995. Similar findings were reported when the same approach was applied to 1989 and 1992 NHIS data in K. N. Rask and K. J. Rask, "Public Insurance Substituting for Private Insurance: New Evidence Regarding Public Hospitals, Uncompensated Care Funds, and Medicaid," *Journal of Health Economics* 19, no. 1 (2000): 1–31.

24. Jack Hadley and John Holahan, "How Much Medical Care Do the Uninsured Use and Who Pays for It?" *Health Affairs Web Exclusive*, January–June 2003, February 12, 2003, W3-66.

25. Among adults, being uninsured is associated with a 25 percent increase in the annual risk of death, resulting in 18,000 excess deaths each year, according to Institute of Medicine, *Care without Coverage: Too Little, Too Late* (Washington: National Academy Press, 2002).

26. Both here and for other regulations found to increase the number of uninsured, I estimated increased social costs by multiplying the estimated increase in the number of uninsured by $554 (calculated from Hadley and Holahan) and the estimated increase in annual deaths among this group by $2.9 million, the estimated value of a statistical life for the uninsured. This estimate varies from the estimated value of a statistical life for the entire population by taking into account the relative age and income of the uninsured, since the value of a statistical life has been shown to increase with age and income. Per-Olov Johansson, "The Value of a Statistical Life: Theoretical and Empirical Evidence," *Applied Health Economics and Public Policy*, Special Issue, 2003, pp. 25–33.

27. The Institute of Medicine (*Care without Coverage*, p. 99) concludes that the principal beneficial effect of insurance is ensuring a regular source of care and continuity of coverage. The report further states: "having health insurance coverage that does not afford access to a regular source of care for any reason (e.g., geographical scarcity, restricted provider pools, inadequate provider participation) may result in outcomes for insured adults that differ little from those for uninsured adults."

28. Nonetheless, one gap in our knowledge relates to the health benefits that result from uncompensated care pools. This is an area that merits further research. Thus our estimate of the extent to which hospital uncompensated care pools increase mortality by reducing insurance coverage could be viewed as an upper-bound measurement.

29. The 31 percent is calculated from figures reported in Table 5.7 of Emmet B. Keeler, Joan L. Buchanan, John E. Rolph, Janet M. Hanley, and David M. Reboussin, *The Demand for Episodes of Medical Treatment in the Health Insurance Experiment*, Rand Corporation, R-3454-HHS, March 1988. It should be noted that hospital uncompensated care pools are not unique in encouraging the consumption of care that is worth less to the patient than its cost at the margin; both public and private insurance have the same effect. As a result, the marginal effect of uncompensated care pools will be to increase wasteful consumption to the extent they encourage individuals to consume more wasteful care than they would have with the help of either public or private health insurance. Though it can safely be assumed that some patients who receive care as a result of uncompensated care pools would receive some care financed through public or private insurance in the absence of such pools, there is no good way of determining (1) how much care these patients would consume in this counterfactual world or (2) how that care would be financed. It is my hope that this knowledge gap can be filled in the future. Without a reliable measure of these variables, my estimates assume such patients would have no coverage, and thus should be viewed with caution.

30. I include PSDA as a cost-related regulation since it imposes education and documentation requirements on various health facilities; its central purpose is to reduce unnecessary end-of-life care so long as this does not reduce quality of life, so it more logically belongs under cost than either access or quality regulation.

31. C. L. Ballard, J. B. Shoven, and J. Whalley, "General Equilibrium Computations of the Marginal Welfare Costs of Taxes in the United States," *American Economic Review* 75, no. 1 (1985): 123–38.

32. C. J. Conover and F. A. Sloan, "Evaluation of Certificate of Need in Michigan. Volume I: Final Report," Duke University, Center for Health Policy, Law and Management, April 2003, http://www.hpolicy.duke.edu/cyberexchange/issues/regulation/index.htm.

33. C. Daniel Mullins, "Most-Favored-Customer Protection and Medicaid Rebates under OBRA 1990," *Journal of Research in Pharmaceutical Economics* 7, no. 3 (1996): 49–63.

34. Ballard, Shoven, and Whalley, pp. 123–38.

35. Ibid., pp. 123–38.

36. Katharine R. Levit, Cynthia Smith, Cathy Cowan, Art Sensenig, Aaron Catlin, and the Health Accounts Team, "Health Spending Rebound Continues in 2002," *Health Affairs* 23, no. 1 (2004): 172–81.

37. Patricia M. Danzon and Michael F. Furukawa, "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries," *Health Affairs Web Exclusive*, October 29, 2003, W3-521–536.

38. Troyen A. Brennan, "The Role of Regulation in Quality Improvement," *Milbank Quarterly* 76, no. 4 (1998): 714.

39. Kieran Walshe, "Regulating US Nursing Homes: Are We Learning from Experience?" *Health Affairs* 20, no. 6 (2001): 131.

40. Institute of Medicine, *Improving the Quality of Care in Nursing Homes* (Washington: National Academy Press, 2001).

41. Catherine Hawes, "The History and Impact of Federal Standards in OBRA-87," The Commonwealth Fund, December 1996.

42. Virender Kumar, "Nursing Home Quality of Care: OBRA 1987, Competition and Demand" (PhD diss., University of North Carolina, 2001).

43. M. Helfand, G. T. O'Connor, M. Zimmer-Gembeck, and J. R. Beck, "Effect of the Clinical Laboratory Improvement Amendments of 1988 on the Incidence of Invasive Cervical Cancer," *Medical Care* 30, no. 12 (1992): 1067–82.

44. See http://www.hpolicy.duke.edu/cyberex change/Regulate/CHSR/CHSR.html.

45. Ibid.

46. Note that all three of the latter were HIPAA amendments, but to avoid any confusion, I use the actual statute names (although the Newborns' Act is often referred to as 48-hour maternity stay).

47. I include high-risk pools but not, for example, Medicaid, since most states with pools require either mandatory participation by carriers and/or mandatory contributions to cover pool losses; hence their operation is more "regulatory" in style than a pure subsidy program. Moreover, due to ERISA, these mandatory participation and contribution rules result in a somewhat uneven playing field and further aggravate incentives for large employers to self-insure and escape state insurance regulations.

48. Regulations for these two major provisions were issued separately, each with its own cost estimate. Therefore, it made more sense to treat them separately rather than focus on HIPAA as a single regulation.

49. Craig Copeland and Bill Pierron, "Implications of ERISA for Health Benefits and the Number of Self-Funded ERISA Plans," EBRI Issue Brief 193, Employee Benefits Research Institute, 1998.

50. Paul J. Feldstein, ed., *Health Care Economics*, 3rd ed. (Hoboken, NJ: John Wiley & Sons, 1988), pp. 455–56.

51. Dale H. Gieringer, "The Safety and Efficacy of New Drug Approval," *Cato Journal* 5, no. 1 (Spring 1985-Summer 1985): 177–201.

52. Based on a recent meta-analysis of the dozens of available value-of-life studies, I used a standard value of a statistical life that amounted to $4.4 million for our average estimates, with $1.6 million and $6.6 million as lower and upper bounds. See James R. Mrozek and Laura O. Taylor, "What Determines the Value of Life? A Meta-Analysis," *Journal of Policy Analysis and Management* 21, no. 2 (Spring 2002): 253–70, for a detailed justification of these values.

53. See Clark C. Havighurst, James F. Blumstein, and Troyen Brennan, *Health Care Law and Policy*, 2nd ed. (New York: Foundation Press, 1998), pp. 924–25 for further discussion on this point.

54. David M. Studdert, Michelle M. Mello, and Troyen A. Brennan, "Medical Malpractice," *New England Journal of Medicine* 350, no. 3 (2004): 283–92.

55. Congressional Budget Office, "Limiting Total Liability for Medical Malpractice," 2004, p. 6. See also Patricia M. Danzon, "Liability for Medical Malpractice," in A. J. Culyer and Joseph P. Newhouse, ed., *Handbook of Health Economics* 1B (2000): 1341–401 for further discussion.

56. Roger A. Reynolds, John A. Rizzo, and Martin L. Gonzalez, "The Cost of Medical Professional Liability," *Journal of the American Medical Association* 257, no. 20 (1987): 2776–81.

57. Daniel P. Kessler and Mark B. McClellan, "Do Doctors Practice Defensive Medicine?" *Quarterly Journal of Economics*, May 1996, pp. 353–90. I ignore parallel findings regarding a different set

of tort restrictions showing spending increases of 2–3 percent as these were only observed in the short run but not in the long run.

58. U.S. Congress, Joint Economic Committee, "Liability for Medical Malpractice: Issues and Evidence: A Joint Economic Committee Study," Joint Economic Committee, 2003.

59. Daniel P. Kessler and Mark B. McClellan, *Medical Liability, Managed Care, and Defensive Medicine*, NBER Working Paper no. W7537, National Bureau of Economic Research, February 2000.

60. Daniel P. Kessler and Mark B. McClellan, *How Liability Law Affects Medical Productivity*, NBER Working Paper no. W7533, National Bureau of Economic Research, February 2000.

61. Congressional Budget Office, "Limiting Total Liability for Medical Malpractice."

62. Kenneth E. Thorpe, "The Medical Malpractice 'Crisis': Recent Trends and the Impact of State Tort Reforms," *Health Affairs Web Exclusive*, no. W4 (January 21, 2004): 20-30.

63. A. R. Localio, A. G. Lawthers, J. M. Bengtson, L. E. Hebert, S. L. Weaver, T. A. Brennan and J. R. Landis, "Relationship between Malpractice Claims and Cesarean Delivery," *Journal of the American Medical Association* 269, no. 3 (January 20, 1993): 366–73; Lisa Dubay, Robert Kaestner, and Timothy Waidmann, "The Impact of Malpractice Fears on Cesarean Section Rates," *Journal of Health Economics* 18 (August 1999): 518–19.

64. Kessler and McClellan, *Medical Liability, Managed Care, and Defensive Medicine.*

65. The most widely cited estimates are that 46,000 to 98,000 die annually due to medical negligence, according to Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (Washington: National Academy Press, 2001). This is based on extrapolation from a 1984 study of New York hospitals and 1992 study of hospitals in Colorado and Utah. These estimates have been disputed. See T. A. Brennan, "The Institute of Medicine Report on Medical Errors—Could it Do Harm?" *New England Journal of Medicine* 342 (April 13, 2000): 1123–25; Rodney A. Hayward and Timothy P. Hofer, "Estimating Hospital Deaths Due to Medical Errors: Preventability Is in the Eye of the Reviewer," *Journal of the American Medical Association* 286 (July 2001): 415–20; and Clement J. McDonald, Michael Weiner, and Siu L. Hui, "Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report," *Journal of the American Medical Association* 284 (July 2000): 93–95.

66. Danzon, p. 1370.

67. Paul C. Weiler, et al., *A Measure of Malpractice: Medical Injury, Malpractice Litigation, and Patient Compensation* (Cambridge, MA: Harvard University Press, 1993).

68. Ibid.

69. Eric J. Thomas, et al., "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado," *Medical Care* 38, no. 3 (March 2000): 261–71.

70. Weidenbaum and DeFina.

71. Litan and Nordhaus.

72. Hahn and Hird, p. 236.

73. Hahn and Hird.

74. "The Economic and Budget Outlook: Fiscal Years 2005–2014," Congressional Budget Office, 2004.

75. Bureau of Economic Analysis, "Gross State Product by Industry for 2001: U.S. Economic Slowdown was Widespread; Table 3.—Gross State Product in Current Dollars, 1995–2001," news release, May 22, 2003, http://www.bea.doc.gov/bea/newsrel/GSPNewsRelease.htm. Gross state product figures are inflated into 2002 dollars using gross domestic product chained price index in Office of Management and Budget, *Historical Tables, Budget of the United States Government, Fiscal Year 2005*, U.S. Government Printing Office (2004), p. 195, http://www.whitehouse.gov/omb/budget/fy2005/pdf/hist.pdf.

76. Bureau of Economic Analysis, "Table 2.3.5U, Personal Consumption Expenditures by Major Type of Product and Expenditure," custom table compiled at http://bea.gov/bea/dn/nipaweb/IndexP.htm#P, data revised July 30, 2004.

77. Bureau of Economic Analysis, "Gross Output by Industry in Current Dollars," June 17, 2004, http://www.bea.gov/bea/industry/gpotables/gpo_action.cfm.

78. The U.S. Census Bureau reports a total 109,297,000 family and nonfamily households in 2002. U.S. Bureau of the Census, "Table HH-1. Households, by Type: 1940 to Present," http://www.census.gov/population/socdemo/hh-fam/tabHH-1.pdf, June 12, 2003, p. 1.

79. According to the *2004 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Supplementary Medical Insurance Trust Funds*,

Medicare's long-range financial imbalance could be corrected by an immediate and permanent increase in the payroll tax from its current level of 2.9 percent to a new level of 6.012 percent, amounting to an increase of $160 billion in 2002 (calculations by author based on figures in Table I.C1, p. 3). Assuming that excess regulatory costs grew at the same rate as the economy, they would exceed the revenue generated by such a tax increase in perpetuity.

80. This figure was obtained by interpolating between (1) 1998 figures of $111 billion in federal tax subsidies (which include foregone income and payroll taxes) and $14 billion in state tax subsidies reported by John Sheils and Paul Hogan, "Cost of Tax-exempt Health Benefits in 1998," *Health Affairs* 18, no. 2, (March/April 1999): 176–81; and (2) 2004 figures of $188.5 in federal tax subsidies and $21.4 billion in state subsidies reported by John Sheils and Randall Haught, "The Cost of Tax-Exempt Health Benefits in 2004," *Health Affairs Web Exclusive*, no. W4, pp. 106–112.

81. This figure is based on work done by Martin Feldstein, as discussed in Robert Helms, "The Tax Treatment of Health Insurance," in Grace-Marie Arnett, ed., *Empowering Health Care Consumers through Tax Reform* (Ann Arbor, MI: University of Michigan Press, 1999), pp. 1–25, showing that 30 years ago welfare (deadweight) losses attributable to the tax treatment of employment-related health benefits amounted to about 30 percent of total health insurance premiums, work that has not been updated. Subsequently, it has been shown that prior estimates of the size of the subsidy provided through the tax subsidy has been overestimated by about 20 percent, implying that estimates of the welfare losses have been overstated by 36 percent (calculated from estimates provided in Table 5 of Jonathan Gruber and James Poterba, "Tax Subsidies to Employer-Provided Health Insurance," NBER Working Paper no. 5147, National Bureau of Economic Research, June 1995; see also their discussion on this point on p. 27). Total private health insurance premiums were $549.5 billion in 2002 (Levit, Smith, Cowan, Sensenig, et al.) multiplied by 30 percent x (1 – 36 percent) = $105.7 billion.

82. Jonathan Skinner, Elliott S. Fisher, and John E. Wennberg, "The Efficiency of Medicare," NBER Working Paper Series #8395, National Bureau of Economic Research, 2001.

83. As a crude illustration, the RAND Health Insurance Experiment demonstrated that patients with no deductible and 25 percent cost-sharing incurred waste from excess use equivalent to 14.3 percent (Keeler et al.). Since these individuals were paying 25 cents on the dollar, they presumably were not using any care of zero benefit to them. If this 14.3 percent were applied to the $267 billion in Medicare spending in 2002 (Levit, Smith, Cowan, Sensenig, et al.), such waste would amount to $38 billion above and beyond the zero-benefit estimate of Skinner, Fisher, and Wennberg.

84. Federal regulatory spending grew by 6.3 percent annually in real terms between 2000 and 2003, reportedly the highest growth since the 1970s. Dudley and Warren, "Regulatory Spending Soars." (These figures consist of the obligations incurred by 58 separate federal regulatory agencies, e.g., Food and Drug Administration, Federal Mine Safety and Health Review Commission, Federal Highway Administration within Department of Transportation, etc. Obligations include federal outlays and fees collected by regulatory agencies from businesses and individuals; they are viewed as the most accurate depiction of spending.) There is no good way of determining whether health services regulation costs would have followed suit.

85. This is based on reported outlays of $948,000,000 in FY2000 compared to $90,404,000 in FY1970, as reported in Office of Management and Budget, Budget of the United States Government, Fiscal Year 2003, Public Budget Database http://www.whitehouse.gov/omb/budget/fy2003 /db.html. The Office of Management and Budget's composite outlay deflator for nondefense outlays is used to convert FDA outlays into real terms.

86. Calculated from figures reported in Katharine R. Levit, Cynthia Smith, Cathy Cowan, Helen Lazenby, and Anne Martin, "Inflation Spurs Health Spending in 2000," *Health Affairs* 21, no. 1 (2002): 172–81.

87. Except for brief dips during the Reagan administration and late 1990s, staffing at federal regulatory agencies generally has grown, more than doubling between 1970 and 2003. Dudley and Warren, "Regulatory Response." I have no basis for even speculating whether health services would have seen faster or slower rates of growth in regulatory staffing compared to other sectors of the economy.

88. The most common source of estimates for the uninsured is the Current Population Survey, which reported 41.2 million uninsured in March 2002 (Robert J. Mills and Shailesh Bhandari, "Health Insurance Coverage in the United States: 2002," U.S. Census Bureau, Current Population Reports, P60-223, September 2003, http://www.census.gov /prod/2003pubs/p60-223.pdf.) The CPS nominally asks about coverage during the prior year and in theory should generate an estimate of the number of uninsured all year. But a comparison with other surveys suggests that the CPS is more comparable

to a point-in-time estimate—that is, the number of uninsured on the day of the survey, which I term "average daily uninsured." Indeed, comparisons with point-in-time estimates from the Survey of Income and Program Participation, the Medical Expenditure Panel Survey, and the National Health Interview Survey suggest the CPS estimate is very comparable to the number of uninsured at a point in time. See Congressional Budget Office, *How Many People Lack Health Insurance and for How Long?* March 2003, for further discussion.

89. Sherry Glied, Dahlia K. Remler, and Joshua Zivin, "Inside the Sausage Factory: Improving Estimates of the Effects of Health Insurance Expansion Proposals," *Milbank Quarterly* 80, no. 4 (2002): 611.

90. Mills and Bhandari.

91. Based on median estimated income to avoid one death, estimated in 1993 dollars from results reported by Harriet O. Duleep, "Measuring Socioeconomic Mortality Differentials over Time," *Demography* 26, no. 2 (1989): 345–51; Harriet O. Duleep, "Occupational Experience and Socioeconomic Variations in Mortality," Annual Meeting of the Population Association of America (1991); T. Chirikos and G. Nestel, "Occupational Differences in the Ability of Men to Delay Retirement," *Journal of Human Resources* 26, no. 1 (1991): 1–26; and Kenneth S. Chapman and Govind Hariharan, "Controlling for Casualty in the Link from Income to Mortality," *Journal of Risk and Uncertainty* 8, no. 1 (1993): 85–94, inflated to 2002 on the basis of the increase in per capita income in the United States from 1993 to 2002 (U.S. Census Bureau estimates report in *Statistical Abstract of the United States* 2003, Table 666, p. 443.)

92. Institute of Medicine, *Care without Coverage*.

93. Specifically, the Court held that the Texas Health Care Liability Act's cause of action for damages is preempted by the federal Employee Retirement Income Security Act. This ruling thus potentially affects 124 million Americans covered by ERISA plans (Copeland and Pierron 1998). The full text of the ruling can be found at http://caselaw.lp.findlaw.com/cgi-bin/getcase.pl?court=US&navby=case&vol=000&invol=02-1845.

94. Hahn and Hird, p. 259.

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