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THE BURDEN OF HEALTH SERVICES REGULATION

HEARING

BEFORE THE

JOINT ECONOMIC COMMITTEE
CONGRESS OF THE UNITED STATES

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THE BURDEN OF HEALTH SERVICES REGULATION

THURSDAY, May 13, 2004

UNITED STATES CONGRESS,
JOINT ECONOMIC COMMITTEE,
Washington, DC

The Committee met, pursuant to notice, at 10:05 a.m., in room SD-628 of the Dirksen Senate Office Building, the Honorable Robert F. Bennett, Chairman of the Committee, presiding.

Senators present: Senator Bennett.

Representatives present: Representative Stark.

Staff present: Tom Miller, Donald Marron, Colleen J. Healy, Mike Ashton, Nancy Marano, Wendell Primus, John McInerney, and Deborah Veres.

OPENING STATEMENT OF SENATOR ROBERT F. BENNETT, CHAIRMAN

Senator Bennett. The hearing will come to order.

We want to welcome you all to today's hearing where we will explore how regulation of health care services affects their cost, quality and availability.

Health care is the most intensively regulated sector of our economy. It's also one of the largest, accounting for more than 15 percent of GDP. Significant attention has been paid to the relative costs and benefits of regulation in other industries, as well as for the economy as a whole. But the costs and benefits of health care regulation have often been overlooked. We need to learn more about the impact of the complex web of rules and regulations that govern how we spend and use more than $1.7 trillion annually.

Health care is certainly a vital item in all our lives, and regulations can improve its quality and reduce its costs. However, there's a significant risk that the promised benefits of health service regulations will fall well short of their costs.

One challenge is that some proponents of regulation are often not the ones who bear its ultimate burden. This disconnect can lead to excessive regulation. A related challenge is that many regulatory costs are less visible than spending outlays and higher taxes. As a result, the political calculus may tilt toward using less visible regulatory means to accomplish objectives that would lack sufficient support if they required a more transparent commitment of public funds.

There's often another disconnect in which people do not appreciate how the burdens of regulation are ultimately borne. Many consumers believe that insurers or employers pay the extra costs

that result from tighter regulations, required expansions in covered services, et cetera, when in reality, those costs eventually come out of their own pockets in one form or another.

Today, we plan to examine whether health services regulations are delivering sufficient benefits to justify their costs. This is a new and developing area of research with important policy implications. Patients, consumers and taxpayers are the ones who bear their ultimate costs of unnecessary regulation. Excessive regulatory burdens can also harm our most vulnerable individuals, such as the uninsured and lower-income health care customers.

I have some personal experience on that, as I will undoubtedly be moved to relate as the hearing goes forward, based on some members of my family who have been caught up in some excessive regulations.

Now much health care regulation is premised on the judgment that most health care consumers don't know, don't want to know, and cannot know enough to make important decisions for themselves.

I don't know if that's true often enough to justify the level of health regulations that we have, but we hope to find that out today because we have a panel filled with people who all have their own experience examining the costs and benefits of health services regulation and how our regulatory system works.

I will introduce the panel one by one after we've heard from the Ranking Member, Mr. Stark.

[The prepared statement of Senator Bennett appears in the Submissions for the Record on page 31.]

OPENING STATEMENT OF REPRESENTATIVE PETE STARK, RANKING MINORITY MEMBER

Representative Stark. Mr. Chairman, thank you. I must, as I don't often do, take issue with the premise of today's hearing—The Burden of Health Services Regulation—because it assumes that regulations are simply useless impediments to economic efficiency and prevent the lowering of health care costs.

Many regulations are created or borne from the abuse of human beings and the degradation of their fundamental rights. Simply put, many regulations protect people's lives. So there can be no rational debate, it seems to me, about doing away with health care regulations writ large for the sake of efficiency and thrift.

We've seen, unhappily, the prisoner abuse scandal in Iraq and what happens when regulations break down—in this case, military regulations. But the human toll that followed that breakdown was unacceptable.

Countless examples of regulations that curb abuses in health services exist. In the good old days, hospitals routinely turned away poor women in labor until Congress intervened and enacted MCOLA, which prohibited this practice and guaranteed access to emergency care to all people, regardless of their ability to pay.

Ms. Gottlich will give us her account of how nursing home regulations have reduced patient neglect and mistreatment that was widespread before consumer protections were put in place.

Right now, CMS claims it's heavily regulating the Medicare prescription drug discount cards because there are already instances across the country of seniors being defrauded.

Regulations at the FDA ensure that the drugs that are sold and the devices we use are safe and efficacious. Should we roll back those and should we let whatever that new pill is be sold without any regulation?

There's a bit of concern there.

So I'd like to challenge our witnesses to pinpoint a group of regulations that would save a great deal of money without unleashing disastrous consequences.

We'll hear a lot about reigning in Medicare malpractice costs, a popular example this year—talking about untold savings in health care. But the Congressional Budget Office has found that malpractice insurance and legal fees have a negligible effect on overall health care costs.

In fact, CBO estimates savings of less than one-half of 1 percent if liability limits were enacted and the President's budget shows no savings from such caps.

Now, ironically, Dr. Conover shares this vision and advocates regulating the malpractice tort system. So I guess that regulation is okay. It's just other regulations we don't like.

I'm troubled that we're having this hearing focusing on some very complex and preliminary calculations of costs and benefits, where no detailed documentation supporting of various analyses exists.

These studies aren't widely accepted or recognized among a broad range of health economists. And even more disturbing is that in some instances, zero benefits have been assigned to important sets of regulations where, clearly, the benefits are not zero.

Eliminating regulations will do nothing to increase access and affordability of health care, as some witnesses have argued. There's no guarantee that money ostensibly saved from less regulation would be put towards covering the uninsured.

The likely result would be that insurance companies, doctors, hospitals and pharmaceutical companies would merely pocket any savings.

So I think that the premise of rolling back regulations is foolish. It won't lower costs. It won't increase access or affordability. And it may very well kill some innocent people, which is the bottom line of what we ought to be careful about in what we're hearing today.

But I look forward to hearing the witnesses and being able to challenge these assumptions.

[The prepared statement of Representative Stark appears in the Submissions for the Record on page 32.]

Senator Bennett. Thank you very much. I think you've highlighted the issues in the debate and maybe that's the reason we're having the hearing, to find out exactly where it comes on.

I don't come into it with any pre-conceptions one way the other, except, as I say, some anecdotal information. And each of us is the prisoner of his own experience. And the hearing, maybe, can help us break out of that particular prison.

Professor Christopher Conover of Duke University has worked for several years to develop an initial set of estimates of the net

burden of health services regulation as a whole, as well as that of its primary components. If there's a regulatory elephant in the room that's increasing the cost of care and reducing its quality and availability, Dr. Conover may be able to provide us with some initial measurement of its size and scope.

Professor David Hyman of the University of Maryland has written extensively about health care regulation, most notably in the areas of managed care, emergency room treatment, and mandated benefits. He's also coordinated recently 2 years of hearings on health care competition conducted jointly by the Federal Trade Commission and the Department of Justice.

Dan Mulholland is a senior partner at Horty, Springer & Mattern. He is one of the nation's leading health care attorneys and serves as chair of the credentialing and peer review practice group of the American Health Lawyers Association.

And Vicki Gottlich, who is an attorney in Washington as well, she's in the Washington, DC office of the Center For Medicare Advocacy, where she provides legal assistance, research, consultation, and litigation support regarding Medicare and employer-sponsored health benefits.

We appreciate all of your willingness to be here with us and we will hear from you in the order in which I've introduced you.

So Dr. Conover, if you would go first.

STATEMENT OF CHRISTOPHER J. CONOVER, PH.D., ASSISTANT RESEARCH PROFESSOR OF PUBLIC POLICY STUDIES, TERRY SANFORD INSTITUTE OF PUBLIC POLICY, DUKE UNIVERSITY, DURHAM, NC

Dr. Conover. Mr. Chairman, and Members of the Committee, it is a great privilege to testify today.

How much of the phenomenally high level of health costs in the U.S. can be attributed to health services regulation and how many uninsured might be covered were we to reduce this sizable regulatory burden? My remarks today will provide some tentative answers to both questions based upon the preliminary results of more than 2 years of research conducted in part under contract to the Department of Health and Human Services. My comments this morning are my own and not intended to represent the views either of the department, my university, Coach K or the Duke Blue Devils.

[Laughter.]

We used two approaches to determine the net impact of regulation. The first was a top-down approach that relied on extrapolations from other industries. If we take the percent of costs due to regulation in other industries such as airlines, telecommunications and the like, and apply these to health services, we find that health regulation could have imposed an annual cost of at least $28 billion, but it may have been as high as $657 billion.

The sizable difference between our lower and upper bounds illustrates neatly the limitations of this approach. Moreover, it is easily possible that the regulatory burden in health care is even higher than a simple extrapolation from other industries would suggest. That is why it is worth investing effort in our second, much more fine-grained, bottoms-up approach.

We examined the literature for nearly 50 different kinds of federal and state health services regulation, including regulation of health facilities, health professionals, health insurance, pharmaceuticals and medical devices and the medical tort system. These cover the gamut from mandated health benefits to state certificate of need requirements for hospitals and nursing homes.

We systematically tallied both the benefits and costs associated with these regulations and found that the expected costs of regulation and health care amounted to $340 billion in 2002 alone. As shown in the bottom of my first chart, our estimate of the benefits from this was $212 billion, leaving a net cost of $128 billion.

Three areas account for the lion's share of this net burden. The medical tort system, including litigation costs, court expenses, and defense of medicine, totals $81 billion. FDA regulation adds another $42 billion. And health facilities regulation adds $29 billion.

This suggests that the states and Federal Government both have important roles to play in finding ways to trim regulatory excess.

If we could get the next chart.

The $32 billion in net benefits from health insurance regulation arises from one simple fact. It includes $46 billion in savings due to ERISA. Recall that ERISA protects self-insured plans from having to comply with state benefits mandates, premium taxes, and other insurance regulations. If we left ERISA out of our analysis, the net cost of regulation would rise to $174 billion, as shown in my second chart.

It was not the purpose of our study to make recommendations on specific regulatory reforms to be pursued, either in medical torts or any other domain. Instead, we were trying to provide something that has never been achieved previously—a big-picture view of the overall impact of health services regulation with the intent of identifying broad areas where regulation may be excessive, while sizable health care regulatory costs should be put into context.

For example, our analysis has ignored entirely tax policy as it relates to health care. Yet, federal and state tax subsidies for employer-provided health care in 2004 will exceed $210 billion.

Thus, there are areas apart from health regulation where Americans could get much more bang for the buck.

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. The estimates in our synthesis, as uncertain and incomplete as they may be, have been assembled with the same motivation.

How do all these numbers relate to the uninsured?

Our bottoms-up look found that the net cost of regulation imposed directly on the health industry itself is 6.4 percent, meaning that health expenditures and health insurance premiums are at least that much higher than they would be absent regulation.

Based on consensus estimate about the impact of higher prices on how many would be likely to drop health insurance, this increased cost implies a 2.2 percent reduction in the demand for coverage. This translates into 4 million uninsured whose plight argu-

ably could be attributed to excess regulatory costs, or roughly one in 11 of the average daily uninsured.

In these calculations, we have simply assumed that all regulatory costs are spread relatively evenly across all payers in the system, but some forms of regulation such as state insurance regulation, tend to be more narrowly focused on individuals and small groups.

So were we to more finely calibrate our estimates of net impact and look at the impact on small firms, for example, we would find that it would be greater than the 6.4 percent average effect. But, of course, there's a different way to look at this burden as well.

Admittedly, our estimates are still preliminary and we are now engaged in a process of careful review of all of them. But it seems unlikely that the adjustments yet to come would alter this central conclusion.

The net burden of health services regulation likely exceeds the $48 billion annual cost of covering all 44 million uninsured by a considerable margin. So a legitimate policy question is whether the benefits of excess regulation outweigh the benefits of coverage for all Americans?

With 18,000 uninsured dying every year due to lack of coverage, is maintaining our current regime of excess health regulation worth letting that continue?

This is a question worthy of serious consideration, especially during "Cover The Uninsured Week."

Thank you for your time.

[The prepared statement of Dr. Conover appears in the Submissions for the Record on page 33.]

Senator Bennett. Thank you very much.

Mr. Mulholland we'll do you next. We're not capable of moving around. We have to go in linear fashion up here.

So, even though I introduced Dr. Hyman before you, let's just go down in the order in which you're sitting.

STATEMENT OF DAN MULHOLLAND, J.D., HORTY, SPRINGER & MATTERN, PITTSBURGH, PA

Mr. Mulholland. Thank you, Mr. Chairman. I'm not Dr. Hyman, but I play him on TV.

Senator Bennett. Yes, that's right.

[Laughter.]

Mr. Mulholland. Mr. Chairman, Representative Stark, thank you very much for the opportunity to speak to the Committee today.

My name is Dan Mulholland. I'm an attorney with the law firm of Horty, Springer & Mattern in Pittsburgh, Pennsylvania. Our firm practices exclusively in the area of health care law. We provide legal representation as well as educational opportunities to hospitals, their boards, management and physician leadership across the country. I've been with the firm since 1976.

Our firm and the nature of our practice put us in a unique position—to directly observe both the effects and the workings of the health care regulatory system in this country.

And I'm here today to tell you that it's not pretty.

There are a number of disturbing practical effects that come from over-regulation of health care. Patient care sometimes takes a backseat to paperwork. The ability of people in health care to simply make decisions based on common sense is often trumped by bureaucratic rules and fiat.

But most disturbing is the fact that some of the major federal, as well as state, regulatory initiatives in the past 20 years that were designed to address legitimate problems and to come up with workable solutions for those problems have had a lot of unintended negative consequences and in some cases, have actually worked to destroy the trust and the teamwork that's necessary in health care to deliver quality services to patients. All of us are affected by that.

Professor Conover described the quantitative effects of this regulatory structure on health care. But I'd like to address this effect from a qualitative standpoint.

A lot of times when hospitals and doctors are faced with regulations, the level of complexity has grown to the point where they really don't understand or fully comprehend how those regulations can affect them. And this has one of three effects.

In most cases, hospitals, doctors, nurses, others in health care do the best they can to try to comply with these health care regulations. But because they are so complicated, because these regulations continue to proliferate and because sensible laws sometimes are implemented in a less-than-sensible fashion with complicated regulations, the people who are involved on the front lines of health care often don't know that they're violating a particular law until after the fact.

This can be compounded by the fact that almost every decision that a hospital board makes, that a physician makes, that hospitals and physicians make together, can be second-guessed at one level or another, either by a whistle-blower, by a plaintiff's attorney, or by a regulatory agency.

And the way in which these laws are implemented, the way in which the laws are applied, is anything but even. That's caused a lot of people to simply adopt a cynical attitude towards government in general and towards the regulatory system in particular.

It's caused some people to try to look for ways around the law and not only spend a lot of unneeded resources in terms of consultant and legal fees, which from my perspective, isn't that bad of a thing, but from the perspective of society, is not a good thing at all.

It also allows unscrupulous individuals to come up with schemes to not only avoid the regulatory structures that apply to them, but actually engage in conduct that any reasonable person would think to be improper.

Finally, you have a situation where a lot of people, good volunteers on hospital boards, non-profit community hospitals, physicians who have long served their communities as practicing clinicians, nurses, and other people involved in providing health care, have simply thrown up their hands and said, it's time for me to cash in my chips and leave.

In the case of the volunteers, they have no chips to cash in. They simply get worn down by having to deal with one new regulatory problem after another, and the best and the brightest in health care, who we all rely on for our daily health care needs and in

some cases, place our lives in their hands, are deserting the health care industry.

Again, these costs cannot be quantified. But they are very real. We see them every day, day in and day out in our practice when we represent hospitals, their boards and their physician leadership.

And what we would urge the Committee to consider is that any new regulatory initiative should be carefully vetted to make sure that it will not have these unintended consequences and would be absolutely necessary, rather than reacting to a particular problem that gets a lot of media attention and then coming up with a solution that causes more problems than it solves.

I'd be happy to answer questions after the other witnesses have given their statements.

Thank you very much for your time.

[The prepared statement of Mr. Mulholland appears in the Submissions for the Record on page 59.]

Senator Bennett. Thank you, sir, for your comments.

Dr. Hyman.

STATEMENT OF DAVID A. HYMAN, M.D., J.D., UNIVERSITY OF MARYLAND SCHOOL OF LAW, BALTIMORE, MD

Dr. Hyman. Mr. Chairman, and Representative Stark, thank you for inviting me to testify before you today.

The last time I testified before the Senate was just over 10 years ago in front of the Senate Finance Committee, when Daniel Patrick Moynihan was presiding.

It took me 10 years to recover. I'm hoping it won't be as long between my next appearance.

[Laughter.]

I'm currently a Professor at the University of Maryland School of Law. I'm also currently serving as special counsel to the Federal Trade Commission. I'm here only in my academic capacity. None of my remarks, whether written or oral, should be imputed to the commission or any of the individual commissioners. Much of what I'm going to say today is drawn from a series of articles I've written over the last decade on the regulation of health care.

Generally speaking, although I have submitted extensive written testimony, my remarks are drawn from regulatory theory and things that I've written about mandates, including the Patient Bill of Rights.

First, I want to commend the Committee for considering these issues. The impact of regulation of health care is a matter of vital importance because it affects the cost, quality and availability of medical services. Regulation has both benefits and costs. And we're focusing today on costs, but it's important to appreciate that benefits matter as well. You can't have a system to deliver services that doesn't have regulation constraining and addressing misconduct by a whole range of participants.

For obvious reasons, we tend to focus on the benefits of regulation. But regulation has costs as well and you have to carefully factor in those costs when deciding whether you're making things better or making things worse.

Excess regulation, as the two previous speakers have noted, makes health care more expensive and at the margins, makes

health care coverage unaffordable, leading to an increase in the uninsured.

It's economically inefficient to adopt regulations whose costs exceed their benefits. And it's a difficult challenge to quantify both sides of the equation, but there is plenty of evidence to suggest that we routinely do exactly that in health care.

Such regulation is often popular. But that doesn't change the fact that it wastes our scarce resources and worsens the straits of the poorest and least powerful among us—those who the regulations are often sold as protecting.

The problem has been studied at considerable length by lots of scholars. Just to briefly summarize some of the difficulties, when you're enacting legislation, it's difficult to have both the time and the training to weigh the conflicting evidence on costs and benefits. Evidence on cost is often unavailable. Estimates are subject to considerable uncertainty. The timeframe for regulating is days, weeks and months. The timeframe for studying the problem as academics need to arrive at a broad-based assessment of costs and benefits, is more on the order of months, years, and so on. When one enacts regulation, it's important to recognize that it comes on top of a whole series of prior attempts to regulate the field. And every time you go back, you look at the lowest-hanging fruit and try and address that problem. And obviously, at some point, all the low-hanging fruit is gone and you have to climb higher in the tree. To strain the metaphor unnecessarily, the risks of falling out of the tree start to go up the higher you have to climb.

There's also a real problem with the drafting of legislation because providers have their own interests at heart and lobby heavily for solutions that reflect their interests rather than those of beneficiaries or the general public. When you couple all of those things with the emotional overlay of health care issues, the off-budget feature of lots of the regulations and the extensive scope of pre-existing regulation, it shouldn't come as a big surprise that health care is particularly prone to regulatory over-reach.

The consequences for the nation's health are quite significant. Higher prices make it more difficult for Americans to obtain health insurance and needed care. Lots of small employers don't offer health insurance at all. When employers do offer health insurance, price increases that can result from regulation such as mandates result in limitations on coverage, employees refusing to sign up, and employers dropping coverage. There are a range of estimates of the elasticity of health insurance purchasing decisions, but I don't think anybody believes that increasing prices above their current level is going to result in more people purchasing insurance. And there are a number of studies—there are volumes of studies establishing the adverse consequences that result from not having health insurance.

Stated more broadly, non-costworthy regulation is likely to have a systemic adverse effect on the quality of care actually provided to the population as a whole. A policy of quality above all else can price the standard of care beyond the budget of many Americans. And we should not place the poor and less fortunate in a position of choosing between nothing but the best and nothing when it

comes to health care coverage. But excessive regulation will do exactly that.

This concludes my prepared remarks.

[The prepared statement of Dr. Hyman appears in the Submissions for the Record on page 70.]

Senator Bennett. Thank you very much.

Ms. Gottlich.

STATEMENT OF VICKI GOTTLICH, J.D., L.L.M., CENTER FOR MEDICARE ADVOCACY, INC., WASHINGTON, DC

Ms. Gottlich. Good morning. I'm Vicki Gottlich, an attorney with the Center for Medicare Advocacy. I'm presenting the testimony along with my colleague, Toby Edelman, who got the better end of the deal and is giving a speech in Florida this morning to nursing home ombudsmen.

[Laughter.]

We thank you for the invitation to testify before the Committee on behalf of health care consumers and their advocates.

From our perspective, representing the rights and interests of older people and people with disabilities for more than 25 years, we do not think that health care regulations are the cause of high health care costs. And we do not think that reducing regulations will, per se, reduce savings.

Without laws and regulations mandating specific conduct, health care providers may not provide adequate care or a safe environment. Laws and regulations are frequently enacted to correct problems and bad outcomes that have already occurred after they have occurred. And when fully and effectively implemented, laws and regulations can both improve care and reduce costs.

We use examples related to nursing home residents in our testimony today because, by definition, nursing home residents are among the most vulnerable populations and the benefits to them from standards and regulations are well documented.

Recent experiences with fires in nursing homes show that, too often, facilities will not provide a safe environment for residents if the rules allow them to do otherwise.

While sprinklers are recognized as the best mechanism to avoid deaths from fire, the rules grandfather in older facilities and allow them to use less effective measures with predictable results.

Last September, a fire broke out in a Tennessee facility. Eight residents were killed in the fire. More died later. And 80 residents were sent to the hospital. After the fire, the nursing home corporation committed itself to installing sprinklers in 16 of its facilities that did not have any, at an estimated cost of $10 million, approximately $625,000 per facility. The state began considering legislation to require sprinklers and the National Fire Protection Association called for all nursing homes nationwide to be equipped with sprinklers. Regulations followed disaster. They tried to correct problems that have already happened.

For this nursing home corporation, the costs of installing the sprinklers after the fact were much greater than the costs would have been had they installed sprinklers originally.

There have been lots of hearings in the Senate about the cost of poor care. Nearly 13 years ago, the Subcommittee on Aging of the

then-Labor and Human Resources Committee, issued a report describing the high cost of poor care in nursing homes. Avoidable incontinence, avoidable pressure sores, and avoidable restraints were all found to cost the health care system billions of dollars, as it tried to undo avoidable damage to residents.

The Nursing Home Reform Law of 1987 and its implementing rules are a prime example of laws that improve the quality of care for residents in important respects, while being cost-effective in savings billions of dollars. When the reform law was enacted, nursing practice and the nursing home industry generally believed that restraints would protect residents from injuries and falls. As a result, in the late 1980s, an estimated 41 percent of all residents were physically restrained. The law and its regulations changed that paradigm.

In 2003, 8.79 percent of residents were physically restrained, a dramatic reduction in a relatively few years. The Institute of Medicine report on long-term care quality in 2001 called the reduction in restraints the greatest improvement in nursing home care and credited what were then HCFA's regulations in oversight.

Being restraint-free is clearly better for residents, both physically and psychologically, and cheaper for government payers as well. The other example involves the minimum data set which was developed by HCFA through an intensive public process that involved all sectors of long-term care.

An evaluation in 1996 found that the MDS resulted in more positive outcomes. More residents had hearing aids and were involved in activities and fewer negative outcomes. Fewer residents had catheters. Hospitalizations were reduced by 26 percent, reflecting an annual estimated savings to the Medicare program of $2 billion in hospital costs in 1992 alone.

As we describe in our written testimony, clinical staff and administrators continue to resist using the MDS, even as they acknowledge that it gave them better information about residents and helped them to provide better care.

Unfortunately, as we describe in our testimony, and as the GAO and IOM have documented, the government is often too timid in exercising its rule-making authority and overly deferential to health care providers.

However, strong Congressional oversight and the Clinton Administration's nursing home initiative in 1998, helped redirect CMS's—what was then HCFA's—approach, making the enforcement system more consistent with federal law and more likely to achieve its goal of assuring prompt correction of deficiencies and sustained compliance by facilities.

Nevertheless, many beneficiaries have been hurt by what the GAO described as the lax and overly tolerant enforcement system that the federal agency at first created in deference to the nursing home industry.

I know I'm over time, but I'd like to end with one current example of the misunderstanding about the burden of regulations.

Currently, CMS in January implemented a new fast-track appeals process for HMO appeals when care is terminated from home health agencies and other agencies.

The home health agencies complain that the notice requirements in this new process are overly burdensome because they have to give notice two days in advance before home health services are terminated. The real issue in this situation is not the notices, but the HMOs themselves are only approving one or two home health visits at a time, rather than the 60-day care plan required in the traditional Medicare program. As a result, the home health agencies are having to give a notice at every single visit.

What we've really discovered in this instance, and the home health agencies agree, is that the Medicare beneficiaries are not getting the home health services to which they're entitled.

We also know, based on a lot of litigation that we've done, when individuals don't get notice of their appeal rights, they don't appeal and they don't get care to which they're entitled.

We further know that when our clients don't get the home health care services to which they're entitled, their conditions deteriorate, they often get placed in nursing homes, and we have unfortunately seen too many of our clients die in this situation.

From our perspective, the regulations that are issued really are issued to protect the beneficiaries. The regulatory process, as found through what happened in the nursing home reform law, reflects the practices of the industry itself. And when regulations reflect the best practices of the industry, they are not burdensome. They are instead implementing good quality of care.

Thank you for holding the hearing and thank you for inviting me to testify.

[The prepared statement of Ms. Gottlich appears in the Submissions for the Record on page 94.]

Senator Bennett. Thank you very much. I appreciate your comments. And you do give me the opening to talk about the anecdote that I hope is not controlling my approach here, but that I think is perhaps instructive, and it occurred in a nursing home.

I have a daughter of whom I'm very proud—I'm proud of all of my children. But this one in particular that I'm talking about got her master's degree in speech therapy from George Washington University, and her first job was in a nursing home.

You have to know this daughter to understand that she is not very patient. She gets quite passionate about things. She had been there, I think, about a week before we got a phone call late one night and she said, "Dad, you're a Senator. You've got to fix Medicare. Medicare is a disaster." I said, "Now calm down, Heather. Tell me about it."

This was the example that occurred to her. She was called in—here's a woman in a nursing home who is having swallowing problems. The doctor said, get the speech therapist. She's the expert in these kinds of things.

And so, Heather shows up all excited. Examines the woman, makes a diagnosis—this is what you need to do. And says that she needs this kind of treatment.

The woman's family says, "Not on your life. You're not touching our grandmother until we find out whether or not this is covered by Medicare, because we won't pay for it. If it's covered by Medicare, you can go ahead and do the treatment. But if it's not, we won't pay for it."

Well, Heather says, "Fine." And she naively says, "Is this covered by Medicare?" I think it was 3 days later, the woman in the nursing home whose assignment it is to cull through the Medicare regulations to determine what is covered and what is not, came up with an answer.

And back to my daughter, she says, "Dad, do you know who the highest-paid person in this nursing home is? It's the woman who handles the Medicare regulations. That skill is in such small supply that we pay her more than we pay the administrator of the hospital or any of the doctors or any of the nurses, and she controls the nursing home. Because until she says yes or no, nothing can happen."

And unfortunately, for an impressionable, idealistic young woman fresh out of college, she had some patients die as she was waiting to get the word from this woman who handled the Medicare regulations as to whether or not she could, in fact, provide the treatment.

She said, "I can't tell any of my coworkers here at the nursing home that my father is a Senator because they're all so mad about Medicare and how it gets in the way of our providing treatment with the labyrinthine regulations."

And then came the final one, which I probably shouldn't say in public, but will anyway, removing any names.

A doctor said to her, "Heather, go ahead and do it. I will prescribe a procedure that is covered by Medicare so that we can be paid. And just don't tell anybody that you're not performing that procedure. You are, in fact, performing the procedure that the patient needs." Highly illegal, and the potential for abuse is enormous.

I resonate with what Mr. Mulholland said when he said these impenetrable regulations run the risk—and indeed, if I heard you correctly, produce the result of disrespect and disregard for the law as people on the firing line see them getting in the way of providing treatment.

Now with all due respect to Dr. Conover, whose research I think is tremendously valuable, I'm with Mr. Stark on this issue. I'm less concerned with the dollars than I am with the treatment.

I'm less concerned with an economic analysis that says it costs us this many dollars and yes, we could use those dollars elsewhere and so on.

If the case can be made, however, that you're getting better treatment and it's impossible to put a dollar value on what that treatment might be, I'm willing to accept higher costs.

But the driving experience here is that the regulations produced worse care. And I think I heard Mr. Mulholland say the same kind of thing from his experience as a lawyer handling cases connected with this, that the regulatory burden, costs aside—and really, Dr. Conover, I'm not trying to put down your research because I think it's very valuable and I appreciate your sharing it with us. But costs aside, there is a care problem here.

I accept your analysis of the restraints and obviously, the sprinkler thing—that's easy. That's very clear. Anybody can say, putting sprinklers in outmoded facilities is the right thing to do. And a mandate that that be done clearly makes some sense.

Ms. Gottlich. Senator, can I——

Senator Bennett. Yes. The experience at least in this one nursing home, if my daughter is telling me accurately, everybody in the nursing home, except perhaps the woman in the corner office who is making the decisions as to who can do what, is thoroughly frustrated in their ability to provide care by the complexity of the regulations.

Now, yes, I'd like to have your response.

Ms. Gottlich. Actually, I have had similar experiences in a variety of different payment systems. So what I wanted to share with you was a situation in a self-insured plan where an individual was trying to get coverage for a child who had been severely injured in a car accident and needed continued therapy.

He couldn't get the information from his self-insured plan, which is not subject to regulation. And it took so long. And it was clear that if the child didn't get the therapy, his condition was going to deteriorate. So what the family ended up doing was applying for Medicaid for that child.

I was really troubled by that situation because the care decision affected, quite frankly, not only the child, but it affected me because the child suddenly became somebody on Medicaid.

I think a lot of these issues are not necessarily determined based on regulations, but they're cost mechanisms because the way our health care system is devised, it's better for the health payer, regardless if it's Medicare, Medicaid, or private ERISA plan, if they don't pay for health care.

I think a lot of the regulations are designed to actually limit rather than provide the care that the doctor in your daughter's situation felt was medically necessary.

I think that it's a bad situation. There are lots of issues going on with Medicare in terms of some of the complexity.

But I think that it happens in other payment systems as well.

Senator Bennett. I don't dispute that for a minute, that Medicare is not by any means the only culprit.

Mr. Stark, I think as we've done in the past, you take your question period here, and then the six of us will simply have a roundtable and go back and forth.

Representative Stark. I apologize to the witnesses. Pollen seems to be not well-regulated and my ears are stuffed up as a result. So I don't know whether I'm shouting or whispering and I apologize for that.

Let me ask a couple of questions. First of all, the principal regulations—somebody did a chart between federal and state.

If you take Medicare off the table, you haven't got much beef with the Federal Government other than HCFA, right?

We don't regulate torts. We regulate pharmaceuticals. I would love to have you there when we argue with my constituents who want to bring their pharmaceuticals in from Canada.

Would any of you object to allowing that without regulation? It would save a lot of money. Does anybody find that a regulation that we ought to keep?

Ms. Gottlich. Well, of course, you know that we would support the importation of drugs from Canada.

Representative Stark. I wonder if the other three witnesses would, too.

Mr. Mulholland. Representative Stark, I think you can argue on both sides of that.

But I think your observation earlier was correct that, in large part, the regulatory problems that have been caused as a result of federal regulations are ultimately tied to the Medicare program, which again gets tied to the costs.

Representative Stark. Okay.

Mr. Mulholland. And that creates——

Representative Stark. But Conover here is talking about $600 billion or some figure. We only spend approximately $300 billion on Medicare. How are you going to save—if you take that off the table and you guys are in the wrong forum? You ought to go back to the states—Maryland or North Carolina.

[Laughter.]

States are the ones who—they regulate doctors. They regulate lawyers, right?

Should we do away with the bar exam?

Mr. Mulholland. I've already passed, so it wouldn't matter to me.

Representative Stark. That's right.

[Laughter.]

Then NOLO would take over the legal profession.

At some point, we spend your money, the taxpayers' money. We have some obligation to make sure that it's spent fairly.

Now the Defense Department doesn't care. They'll give Boeing whatever they need, as long as they get kickbacks. But that's not what we try to do in Medicare. We spend—we have, admittedly, 14 percent of Medicare money is spent incorrectly. About half of that is fraud and about half of that is just mistakes.

I'll bet you that Blue Cross doesn't do any better. Because as a matter of fact, it's Blue Cross who administers Medicare under contract, so I suspect for the private market—and then if you walk around and you're under 65, like the witnesses are, you can do anything you want.

The doctors can treat you. The doctors aren't under any—there are the privacy regulations, but, again, that has nothing to do with Medicare. That has to do with the whole general issue of privacy in this country. And there are people who are concerned about that and civil libertarians are concerned—I hope. Scalia and Thomas and Ashcroft, the great civil libertarians of all time. But you're beating a dead horse here.

You want to go home. Talk to your state legislators about this.

California, we've already passed tort reform. So don't talk to us. Let the rest of the states pass it if they think it's the right thing to do. Has Maryland got tort reform?

Dr. Hyman. That would be for me. Yes. And my friends who are plaintiffs' lawyers complain bitterly about it.

Representative Stark. Yes, but they have it, right? So you don't care whether we have federal or not. Correct?

Dr. Hyman. I actually was talking earlier about insurance mandates, which are both federal and state level.

Representative Stark. Where?

Dr. Hyman. It's also important——

Representative Stark. Whoa.

Dr. Hyman. The Pregnancy Discrimination Act of 1976, the Newborns and Mothers Protection Act. I can list a number of the mental health parity requirements that are found in HPPA. There are federal mandates. The disproportionate percentages are at the state level.

Representative Stark. But you like ERISA.

Dr. Hyman. I think ERISA serves its function quite effectively. Actually, when I started, I said that——

Representative Stark. I get the sense that you guys are picking and choosing here the regulations that——

Dr. Conover. But the reason that ERISA saves money is because it exempts plans from——

Representative Stark. But it's a regulation, though, isn't it? It's a regulation that keeps lawyers like these other guys——

Dr. Conover. It's a very funny regulation in that regard.

Representative Stark. Wait a minute. It's a regulation, right?

Dr. Conover. It's a regulation that exempts——

Representative Stark. You like it, don't you?

Dr. Conover [continuing]. Exempts plans from a lot of other regulation, yes.

Dr. Hyman. Representative Stark, I don't think—I didn't hear anyone at the panel to say that all regulations are bad.

I thought the point of the testimony was that regulations can be good, except to the extent that their costs exceed their benefits.

Representative Stark. But Dr. Conover over here doesn't have any benefit in any of his analysis, right? You've got zip for benefits.

Dr. Conover. No, that's not right at all.

Representative Stark. Wait a minute. You told me—you don't show any benefits in your analysis.

Dr. Conover. If you look at that chart, you can see we're showing $207 billion worth of benefits.

Representative Stark. In nursing homes, it's zero. Right?

Dr. Conover. In that particular one, we didn't find literature that showed——

Representative Stark. You've got to find literature.

Dr. Conover. That showed a cost.

Representative Stark. You can talk to lawyers here and they'll tell you that there's some kind of a system for determining the value of life. I don't know how you guys figure that, but I'm sure that you'll find some literature that will tell you that life has some value. Do you believe that?

Dr. Conover. I do believe that life has some value, yes. Absolutely.

Representative Stark. Okay. Can you quantify it?

Dr. Conover. Well, in our estimates, we were using a value of life of $4.4 million.

Representative Stark. Okay. And you can't find any cost benefit in regulating nursing homes?

Dr. Conover. In the evidence that we went through, we did not.

Representative Stark. Ever been in a nursing home?

Dr. Conover. Well, yes. I've visited people in a nursing home.

Representative Stark. Ever had a relative in one?

Dr. Conover. My granny was in one for a while.

Representative Stark. As I say, I find this highly selective. You think that reimportation shouldn't be regulated, right? Or not. I'm not getting an answer.

Mr. Mulholland. I really haven't formed an opinion on that, Representative Stark. But I think your point about Medicare being responsible for a lot of the regulations to some extent underscores what Professor Conover was talking about because Medicare is the largest payer by far in the country for health care——

Representative Stark. Whoa, whoa, whoa. We paid $300 billion out of about $1.4 trillion spent on health care services in this country. Now, c'mon. Do your math. If you've got your shoes and socks off, you can do that math.

Mr. Mulholland. I'm not saying it's the majority of payment, but it's the largest payer. There's no other payer that's as big as Medicare in terms of being a single source of payment.

Representative Stark. Okay.

Mr. Mulholland. If Professor Conover's figures are right, $128 billion net cost of regulations, that would mean that Medicare is bearing approximately a third of that based on the numbers that you had just given, Representative, which mean that the regulatory system, the Federal Government has imposed on the system, on the health care system, actually is costing the Federal Government more money.

So it becomes a self-fulfilling prophecy. More payment, more regulation, more cost.

Representative Stark. That's the wackiest thing I've ever heard, I'll tell you.

Okay, guys. As I say, libertarianism is alive and well in the world. And the Cato Institute and the American Enterprise and the Club For Growth, God help us if they were ever to provide medical care to our indigent.

Mr. Chairman, they're all yours.

[Laughter.]

Senator Bennett. Well, let me make the same point that I think was trying to be made.

I certainly do not believe that all regulations should be repealed. Nor do I believe that the regulatory scheme, the careful regulatory scheme is not absolutely essential.

I think everybody will agree that we have a responsibility at both federal and state level to provide a sensible scheme of regulation. Having conceded that, I would trust that you would concede that such a scheme of regulation should be reviewed from time to time to see if there are some regulations that don't make sense, that do in fact end up costing the system more than the benefits, and, in the exchange that Ms. Gottlich and I had, actually reduce the level of the quality of care, that the regulations get in the way of providing intelligent care.

I'm satisfied that Medicare has reached that point, that it has become so labyrinthine to try to find your way through the Medicare regulations and come up with an understanding of what Medicare really does require and does not require, has reached the point where it's appropriate for the Federal Government, particularly

those of us who pass the laws, to say it's time to take a long, hard look at this. It's getting in the way of providing quality care.

But I will certainly join with you that regulation is essential. And I don't think there's anybody on the panel that would disagree with that.

Representative Stark. Let me——

Senator Bennett. Yes.

Representative Stark. My name was taken in vain in some of this testimony, but it was taken in vain long before that by whichever administration was in when we wrote what are called, obscenely, I think, the Stark Laws.

It's important—I think Dr. Hyman raised the issue of the Stark Laws, right?

Mr. Mulholland. I believe I did.

Representative Stark. You did. Okay. The Stark Laws were written at the behest of a Republican administration, okay, initially over my objection. I said, what the hell. These guys ought to be able to go make money any way they can. Well, they finally showed me, some place in Florida and the AMA finally came around, that there was very excessive utilization because of kickbacks, basically.

But the initial law—and I'm not a lawyer, but I have to paraphrase it, about a paragraph. And it says, and correct me if I'm wrong, Mr. Mulholland, but the original federal law said, whomsoever will taketh or receiveth or generate a kickback, a spiff, a commission, in cash or in kind for referring a service to another under Medicare or Medicaid, will do 5 years or $50,000. That was it. That's all it was.

I was told that the prosecutors wanted a clear line to prove intent. What did I know? I'm just a politician. I don't know law. I am not a lawyer. But I said, all right. We'll have a line. And we wrote the bill and then the regulations came. And you know what? Those regulations just became a set of instructions for you, Mr. Mulholland, to draw loopholes, to say, now to my clients, aha, here are the clear lines. And you can get around them by this and this and this.

So when they came back, we had to have Stark 2. The more the lawyers dreamed up loopholes, the more we had to have regulations to close the loopholes.

I would go back to the original bill. That's just one paragraph, if I had my way, and then you'd have to tell all these docs, you'd better be careful, doc, because they could come after you for criminal activity. But I don't know. And being able to say I don't know to the doc would probably have as good an effect as this big stack of regulations.

So I'll make a deal with you. Let's go back to that original. But then let's put a few docs—you've got some guys who are good criminal guys in your law firm? Let's put one or two in jail for doing what we probably both agree is wrong, and you wouldn't need all the regulations.

But it's just like the tax law. We write laws to close the loopholes that you guys get paid big money to get them through. So the lawyers, Mr. Chairman, share equally in this blame for regulation. Right?

Mr. Mulholland. Representative Stark, I'm prepared to shake on that deal right now.

[Laughter.]

Representative Stark. Okay.

Mr. Mulholland. And that was exactly the point I was trying to make in my written remarks. That original law, the anti-kick-back law, is still on the books and the reasoning behind the first "Stark Law" is let's make it a little bit simpler, draw a little bright line.

I don't quibble at all with that. But it's the complexity of the regulations. Once you start thinking, well, what about this, what about that—you've gotten to the point now where hospitals are worried that if they serve a meal that costs $25.25 to their doctors, that a whistle-blower can come after both of them and recover literally millions of dollars in false claims actions.

So there is some question about proportionality. But I'd love to have that.

Representative Stark. We got our limit up to $50 in Congress. So you could buy us a meal. I think $50 is the limit.

Mr. Mulholland. We once had——

Senator Bennett. It's $50 in the Senate. I don't know what it is in the House.

[Laughter.]

Mr. Mulholland. We once had the Chief Counsel for the Office of Inspector General visiting the health lawyers in Pittsburgh and we wanted to give him something. But he said, I'm subject to this, too.

So we got him a $100,000 Bar and said, here, take this home to your kids. But that's the level of complexity that's happened. When an otherwise legitimate statute has grown out of control, it's metastasized—and you're right. It's almost not sporting to blame lawyers. Lawyers are responsible for some of this, too.

On the other hand, this has served like a millstone around doctors and hospitals.

Actually, we represent a lot of people in this. We give a lot of educational programs. In fact, we're giving a series of audio conferences on the new Stark regulations. You'd be more than welcome to join if you want to be a guest star on it, Representative.

But this is something that——

Representative Stark. It's out of control. It's like a virus.

Mr. Mulholland. My partner and I were giving a little talk on this about two weeks ago and we started explaining it. And we suddenly had a very frightening revelation.

We understood those regulations. And we thought about seeking some mental health counseling as a result.

[Laughter.]

So if there's anything you can do to simplify the regulations or get back to the basics, I think that would be welcomed with open arms because then, only the truly unscrupulous would have something to worry about.

Now the people who want to follow the law are burdened down with worries about compliance, and there are still crooks who are bilking the Medicare system for billions.

Representative Stark. At least what I see is that there are areas in which those of us who are powerless need some protection, which laws can turn out to be regulations, the complexity of which will drive you nuts.

I concur in that. I am subject to it, as the Chairman is. Apply for a building permit in Maryland, just once, I urge you. I'm now in my third year of the same permit. So I'm sympathetic.

And then I realize that I'm probably the person who caused those problems, or my colleagues, in the first place. But it is frustrating.

Senator Bennett. We'll be glad to blame you specifically.

[Laughter.]

Representative Stark. I can't quite accept the quantification as a way to say, we're going to pay for—I would agree with you that we should review our regulations. Our oversight functions should be more thorough. We should listen to Mr. Mulholland and get the advice of experts, who agree with us.

It's a problem that ought to be resolved. How do we do it? I'm with you. But the idea that a regulation, as a systemic problem in the world, if it's any different with medical care than it with pharmaceuticals or flying an airplane and running an airline, or running a bank.

These are there and generally not—because the Chairman and I sit back here and say, what kind of a regulation could we dream up today to make Dr. Conover's research exciting and make Dr. Hyman's life awful.

We don't do that. We hear from people that had something bad happen to them. And we say, well—and then we find out that maybe more bad things are happening to people and we, somehow in our enthusiasm, try to put a stop to it.

Does that often become burdensome? Yes. Does it save lives? Many times.

So I don't know how we can get to a happy medium.

Senator Bennett. Well, I do think it's useful for us to have some kind of economic analysis of cost. I agree that the cost should not be the controlling factor in the decision we make.

But it's one thing for Ms. Gottlich and me to exchange anecdotes—and I can prove that Medicare, Medicare regulations and their complexity, has caused delivery of health care problems in a particular nursing home, and arguably, contributed to some deaths. But I have no idea in the universe how expensive that is.

I can intuit that there's an expense connected with it, but I can't come up with anything.

So in defense of Dr. Conover, I think these kinds of studies are helpful and useful because they give us a guideline as to how big the problem is.

I don't think we're ever going to get to the point where all of the regulations are understandable or all of the regulations are easily enforced. Human nature is such that you don't get there.

But I think that we ought to recognize that there is a lot of money tied up in this and therefore, a lot of opportunity to, Ms. Gottlich, improve care and improve safety, and Dr. Conover, save some money at the same time. And that strikes me as a win/win.

Dr. Conover. Right. I wanted to talk about the 48-hour maternity stay mandate because that's a good example of regulation that

came about because of a concern about a problem. And we crafted a solution and it imposes a cost on the system.

And yet, when you look at the clinical evidence about whether that saves lives, there really isn't any. So it's an example where there was this impulse to put regulation on the books, and we didn't have any evidence about—there was just a supposition that, well, gee, if women get discharged too quickly, that's going to be a problem for quality.

And so, we put this regulation on the books and, retrospectively, we've now done the clinical studies to look at whether it made a difference or not. In terms of outcomes, it appears not to have. But once it's on the books, it's sort of there forever.

So we're continuing to incur the annual cost of that. But we're really not getting a health benefit that would be commensurate with that cost. And that's problematic. And that's an example of how regulation sort of accretes onto the system.

Ms. Gottlich. But I'd like to address that, as the only person in this discussion to whom that applies.

There's a quality of life issue. From personal experience, having gone through this twice, there are definitely people who want to go home immediately and there are definitely people for whom 48 hours is not going to save their lives. But it means that they're going to be better able to cope.

And so, the other things that we have to look at are post-partum depression, how they're able to deal with their kids, what systems do they have in place.

So it's more than the really adverse outcomes. Benefits sometimes are just not measurable.

What does it mean for a nursing home resident to be able to have her breakfast at 9:00, as opposed to 6:00 in the morning? That's certainly a burden on a nursing home that improves the quality of life of the resident. I could tell you my extra day in the hospital after my second child was born really did a lot for my second child and me because I didn't have to deal with my first child. That's an anecdote.

Representative Stark. My most recent two children were twins who were born within the past 3 years. And I want to tell you, I wanted to stay the extra day at the hospital with my wife and the twins, regardless of what she might have wanted.

[Laughter.]

May I?

Senator Bennett. Yes. For the record, our last children were twins as well. And when the nurse asked my wife, "Do you have any more children at home?", and she said, "there are four." "Oh, you poor thing. You poor thing," the nurse kept repeating over and over again.

But that's just one of the things that bonds us—you have twins and so do I. Go ahead.

Representative Stark. Dr. Conover, I gather you feel that the zero benefit for nursing homes may change.

Dr. Conover. They may change, right. That's why we're going through all of these, yes.

Representative Stark. In the acute care area, you have a zero benefit for—is that just for the accreditation?

Dr. Conover. For hospital accreditation and licensure.

Representative Stark. Now I'll let you and Dr. Hyman get into this. I'll just start an argument and stand back and watch you guys.

[Laughter.]

Representative Stark. I would say that, and this is an area of pure economics, that in some states—the best state in the country, I might add, is the State of Maryland in terms of regulating hospitals.

They have one of the best hospitals in the world. They come in by law at 10 percent below the national average for Medicare rates. They've never had a hospital go broke because they won't let them.

But we've recently come up with this issue of, if you don't control the market, are you apt to cause the demise of a hospital? And is that something to be regulated?

In this case, I don't have an opinion. But in every state except the State of Maryland, we're seeing boutique hospitals appear in an effort for doctors to make some extra money because they participate through a loophole in the Stark Law, in the profits of those boutique hospitals.

And again, I don't get morally indignant about that, but it's tending to cause some real problems with community or broader acute care hospitals, who find profit centers being taken away by the cardiologists or the eye surgeons or whatever, and leaving our community hospitals with just the expensive stuff that doesn't have much profit.

That's not an area really that I see us regulating unless the hospital industry decides that maybe there's a reason like accreditation to decide whether we need hospitals on an economic basis.

Now do you think that's something that the state should get into or not?

I don't know as we will—I don't want to unless the hospital association comes almost unanimously and says, look, this ought to be controlled or you're going to cannibalize the structure under which hospitals have grown over the last 50 years in this country.

And if we suddenly take that apart, we may have some fiscal problems that we'll get called on to solve. Is that an area that we should regulate?

Dr. Conover. Well, when you talk about accreditation, I think of that as quality regulation. And I guess I'm not aware that the specialty hospitals are creating——

Representative Stark. Well, there's also the certificate of need.

Dr. Conover. The certificate of need.

Representative Stark. Which is accreditation.

Dr. Conover. Okay. But certificate of need is something that I've studied a fair amount. And when you look at the evidence about certificate of need, we generally find that it doesn't do what it was intended to do, which is to save costs. And almost half the states have gotten rid of certificate of need because of that.

Representative Stark. Yes.

Dr. Conover. But the states that continue with certificate of need defend it on either access or quality grounds.

And on the access issue, I think any community would have to ask the question, if you basically reduce competition, and we know

that if you reduce competition, you're going to end up with higher prices in an area——

Representative Stark. What about accreditation just then on federal standards? Don't you think that there is a benefit to having some minimal standards under which you, say, put a stamp of approval on this thing and say, this qualifies as a hospital?

In other words, you and I could go out and buy a Motel 6, paint a red cross on the side and say, ha, we've got a hospital, and up our rates from $39 a night to $500 a night.

Dr. Conover. Well, accreditation historically has been a state responsibility.

Representative Stark. Yes.

Dr. Conover. I'm not sure I would be in a position to argue why the Federal Government could do that better than state governments could.

Representative Stark. Well, the only reason we do—I don't know if we do it better—is that Medicare pays hospitals in all 50 states.

So that if we are going to say, you meet our standard for collecting from Uncle Sam, you've got to meet these standards. And there's no reason that we should go easy on California and be tough—Maryland gets a waiver because they're good guys.

So that's the reason, possibly we should leave it to the states. We leave it to the states with regard to doctors.

Dr. Conover. Right.

Senator Bennett. Is "good guys" a term of legal art?

Representative Stark. Yes.

[Laughter.]

Senator Bennett. Yes. Okay.

Dr. Conover. So what you're describing is the very reason that Medicare gets involved in all of this. And that's why I wasn't sure I understood——

Representative Stark. Well, I'm just saying, is there a cost—you say there's zero benefit to it. And I've got to think there's some benefit, whether it's a state regulation that gives them the seal of approval or federal.

Dr. Conover. The issue is what would happen otherwise absent regulation. Would a hospital go into business and provide shoddy care and start killing people?

Representative Stark. Try Tenet. Try Tenet in Redwood, California, where they killed 167 people through outrageous cardiological practices that were giving people heart transplants when they were healthy. And hopefully, some of the Tenet officials go to jail because of this.

Yes. The answer is, yes, indeed, there are scalawags in any area. There are even some of our colleagues who have gone to jail on occasion.

But what I'm suggesting is that, yes. It's worse in the nursing homes where we can have 6-packs and mom and pop can decide to take six people in like Jim Jones did in Guyana. Yes, there are people who will prey on those who are susceptible.

Dr. Conover. Regulation is a continuum. There's zero regulation and then there's what we've got now. I'm not arguing to go back to zero, okay?

Representative Stark. Okay.

Dr. Conover. What I'm saying is, let's look at the areas where it looks like regulations' costs are disproportionate to any benefits and dial back to that level.

Representative Stark. No quarrel.

Dr. Conover. In most domains, it doesn't mean it's going to be zero regulation. But I think we've heard lots of testimony today about the extent to which regulation has gone beyond the point of being—where the benefits are now less than the costs that are being imposed on the system. We need to look at that.

Representative Stark. What about, Dr. Hyman—do you like Maryland's hospital system, the all-payer system?

Dr. Hyman. No.

Representative Stark. You don't?

Dr. Hyman. No.

Representative Stark. Why? The hospitals do.

Dr. Hyman. Well, it's not an accident that the hospitals do, which is alone a reason to be skeptical about it as a taxpayer.

Representative Stark. They fought it when it went in.

Dr. Hyman. I know. But then it turned out, like lots of these things, to reward them. It's not an accident, as you observe, that there's only one state left in the union that has rate-setting. And that's because the history of rate-setting, like the history of certificate of need, does not bear close examination.

It does—rate-setting, like certificate of need, can be used to maintain safety-net institutions. Sometimes those institutions should be maintained. Often direct, overt subsidies are a better way of doing that than embedding it in the price and pretending that there isn't a cost associated with it.

But sometimes hospitals shouldn't be kept open. And the rate-setting system, which takes as its mandate—keep every hospital open forever—doesn't discipline that process.

Representative Stark. I think that's unfair with Maryland.

What they have done is to—yes, they do set rates. But so does everybody. I don't know that there's a hospital around that gets the sticker price, unless you just walk in with cash.

Blue Cross sets rates. Aetna sets rates. Medicaid sets rates in various states. That's not uncommon.

It's just that the net effect in Maryland was to set the rates on a hospital-specific basis. They recognized, for example, that Johns Hopkins, as a teaching institution, perhaps had a need for a different rate structure than a smaller rural hospital.

But that smaller rural hospital also had some needs because of a lower population and having fewer services. But what they cut out was the discounting and the uncompensated care. So that, basically, every patient who came through the door paid the rate, the same rate, including Medicare and Medicaid.

So the issue of not wanting to take Medicaid patients because they pay less, in California, was off the table. And then if a hospital was going broke, rather than just keep it alive, they might have paid a neighboring hospital a little extra to take that hospital under its wing and provide the services.

As an observer from far away, I've always felt that the Maryland system was one that states should look at because, in terms of price and quality, it's come out with a pretty good mix.

Dr. Hyman. Again, I think this is one of these things that, if you have perfect information and good incentives, rate-setting, if it were done by angels, it would probably work well. It's not.

And again, it's no accident that a whole series of states experimented with rate-setting and then, with the exception of Maryland, everyone else has walked away from it.

Like certificate of need, there are problems with information and incentives that mean, in the real world, it doesn't work as expected to in the journals written by academics.

Representative Stark. Would you suggest that we shouldn't rate-set in Medicare?

Dr. Hyman. Well, let me just be clear. There's a difference between rate-setting and payers saying, here's what we'll pay and vendors saying, here's what we'll take.

Rate-setting is everybody pays sticker price and nobody can discount. And it has a series of distributional consequences.

The question that you should ask yourself is, if it's good for hospitals, why shouldn't it be good for Wal-Mart and hardware stores and everything else? The state ought to say, the right number——

Representative Stark. There's a very good reason, Doctor.

Dr. Hyman. Well——

Representative Stark. You and I—I'd challenge the panel to take the test. The Chairman's taken it with me and we've both failed.

We don't know what it is we're purchasing as consumers. We can't spell it. We hurt. Often we're not in a mental state, because of pain, to make a reasonable decision.

We take the advice of a professional. And we take that advise—we swallow the bait whole.

Now with the Internet, we may get a little bit more information. But, basically, it isn't like shopping for a digital camera where we can't go to *Consumer Reports*. You can go to *U.S. News & World Report* and figure it's a good hospital.

But I've often challenged my witnesses to say that I have this special arrangement with Georgetown Hospital because I'm such a good guy, they love me. And I can arrange for all four of you this afternoon—I'll give you my business card and I'll write your name on the back and you can go over and get a proctoscopic examination or a pap smear at half price if you go there today between 2:00 and 3:00.

Now I've never had anyone take me up on that. This isn't what we buy. It isn't like going to Wal-Mart and shopping. That's a long argument with the people who say, let the market—let people decide how to buy medical care. They can't. It's not like buying a Chevrolet or a Ford.

Dr. Hyman. Representative Stark, if you view the problem as an informational deficit, then the sensible strategy is to try and get more information out and have people be more effective agents for patients.

But rate-setting is not going to be the strategy you're going to employ to address that problem.

I certainly agree with you. Lots of patients have difficulty knowing what's going on. Although, people who have chronic illnesses, not surprisingly, are much better at this than patients with an acute attack of something that happens once and never again.

But regardless of your views on how severe or minimal that problem is, you wouldn't use rate-setting to fix that problem. It doesn't synchronize with the problem that I think you've accurately identified.

Mr. Mulholland. If I could just turn to two things that you talked about.

That's an example of regulations that are fairly benign. They're not as complex as a lot of state hospital licensing regulation.

For the most part, they make sense. They say that you have to have a board, you have to have a medical staff, and you have to have nurses—common sense. The problem there is how they're enforced. And again, it's because various regulations have accreted over the years that drive the enforcers in a manner that they have no control over.

I'll give you an example.

Most complaints about violations of conditions of participation fall in one of two areas for hospitals. One is restraints and I think that some of the more forward-thinking restraint regulation reforms that Ms. Gottlich talked about are good. People shouldn't be tied up in strait-jackets.

But sometimes people need to be restrained for their own good. There can be a difference of opinion. Somebody complains to the government. That's all well and good. That's everybody's right.

At that point, they respond to what could be a fairly easily resolvable situation—talking to the doctor, the nurses, the patient, family—and turn it into a huge federal case because they're required to do a complete resurvey of the hospital—not just with restraints, not with respect to this issue, but with respect to everything.

Not only that, the government is then required by their own regulations to put a notice in the paper that unless the hospital corrects everything within 60 or 90 days, that they're going to be excluded from the Medicare program.

That happened once in New Orleans a couple of years ago where a very well respected institution was being subjected to an investigation. This notice got out. And senior citizens went berserk. They were very frightened that their hospital was not going to be open for them. And it's still taken well over a year to settle down the public relations nightmare that that hospital faced. But more importantly, the kind of consternation it forced on all of those senior citizens.

So even common sense regulations can be applied in a way that create a lot of unintended results and a lot of negative results.

Also, once that happens, the hospital is then going to be resurveyed by the joint commission, the private accreditation body that Medicare relies on——

Representative Stark. Questionable——

Mr. Mulholland. One could raise questions about any of these agencies. But that's the second one.

Then the office of inspector general will come in and see what the joint commission did to make sure that it's fulfilling its deem status responsibility.

So what would be a relatively easy to resolve situation results in three separate major investigations that completely ties up the nursing administration.

Using an anecdote, Senator, similar to yours, my cousin runs a nursing home in New Jersey. She right now, because of all the assessment requirements that came with the prospective payment system for skilled nursing care, has a situation where if someone is in the nursing home for 6 months, they're going to get at least eight separate, federally-mandated assessments.

Now the concept of looking at a patient's needs again makes sense. But these are multi-page forms that are very complicated, take a lot of time to resolve. And she has to pull her best nurses off of clinical duties to do this.

Her nurse administrators do nothing but handle paperwork. And that's one of the things contributing to the nursing shortage.

The other thing you mentioned, Representative Stark, was specialty hospitals.

There was the moratorium imposed last year which was an amendment to one of the exceptions in the so-called "Stark Law." CMS is studying this issue.

But one of the problems hospitals have is that they're dealing with this in a competitive marketplace with one hand tied behind their back. One of the things that the doctor-owners who are threatening the viability of a lot of community hospitals by pulling out well-paying cases into these specialty hospitals, and then dumping, if you will, Medicaid and indigent patients on the hospital, one of the things that they're concerned about is, well, maybe the hospitals say, we don't want you around here at all any more.

It would be like me going to my law firm and saying, hey guys, I want an office. I want secretarial help. I want a computer. But I'm going to be working for the law firm down the street, and there's nothing you can do about it because if you did, that would be called economic credentialing.

So I think that the market could deal with that problem just as effectively, if not more so, than regulation if hospitals and doctors were able to compete on an even playing field, and the hospital saying to the doctor, you have a conflict of interest. Now you have to leave.

Representative Stark. Several hospitals have, haven't they?

Mr. Mulholland. They have done so and several courts have upheld it.

But there is this strange case in Little Rock, Arkansas about 2 months ago where the court said that if a patient wants to be treated by any particular doctor in any hospital, regardless of the circumstances, the hospital has to let the doctor in.

And that would apply theoretically even if the doctor was proven to be incompetent or disruptive.

I think that, to the extent that Congress can resist the impulse that now is being applied to several state legislators, to outlaw this so-called economic credentialing, which is nothing more than protecting physicians who have these ownership interests, I think that

would be a big plus as well. Simply letting the market operate in some areas can provide more efficient solutions. Certainly not in every solution.

And I'm not suggesting that all regulations should be destroyed. But Congress and state legislators need to consider carefully the unintended consequences of addressing one problem and creating five more.

And they also need to see how the enforcement agencies apply the laws that might make sense, but in a way that wouldn't make sense.

Representative Stark. Let me follow—may I?

Senator Bennett. Sure.

Representative Stark. There is a question about JCAHO and their ability to regulate, particularly because they're paid by the guys they regulate, which may create some odd incentives.

I am a strong believer in regulating by the spirit of the law rather than by the letter of the law.

But I believe that when you regulate with the spirit of the law, you need some well-trained, highly-qualified regulators.

The reason that you go by the letter of the law is you've got guys who really may not understand all the details of how to operate a nursing home or whether a lawyer has been unethical or not. So they just go down a checklist. That's easier than the person who has to reason it through and then say, well, maybe we should have done it a little bit this way and not so much that way, which takes some reasoning ability.

Savings and Loans in California are regulated by the letter of the law and it may have led to our disaster some years ago.

National banks, however, are pretty much by the spirit of the law. Bank regulators who come in have wide latitude to make changes in the bank, suggest that board members are changed, get rid of executives. And their enforcement is just to stay there until the bank goes along.

And I find it better and we've had a better record in regulating. I would like to see that type of regulation in the hospital area. I would like to see people come in and rather than having to go through each medical record, fly speck at a time, be able to look at the hospital administrator and say, look, you're 3 weeks or you're 3 months behind in getting these forms filled out, without even talking about how well they're filled out, and say, I'm going to come back in two weeks and if they're not done, you're not going to take any more patients for a while.

But I'd feel more comfortable with that type of situation. That's hard to legislate, Mr. Mulholland.

Mr. Mulholland. Absolutely.

Representative Stark. To legislate kindness and sympathy and all those things, it's difficult to get into words.

Mr. Mulholland. But the more you micro-manage through regulations that proscribe every single thing, the more you invite exactly what you're trying to avoid.

Representative Stark. We don't. With the exception of the Internal Revenue Code, which I spend a lot of time with, our laws are generally quite general.

It is the regulation process and the ability for people to review those and complain, and the bureaucracy, for better or for worse, that leads to this.

Now it's our job to change it, perhaps, and review it. But as all of you who have either studied or been involved with it, these regulations don't come out of what we see on the floor.

Thank you.

Senator Bennett. Yes. The time is going by. When the Ranking Member said, no quarrel, I was ready to end the hearing instantly because we very seldom come to that point.

But I think, Mr. Stark, you've put your finger on the issue. I don't know how this shows up in the record, but we pass laws like this [indicating].

They go to the regulators, who write regulations like this [indicating bigger].

And then, all too often, the people in the field administer them like this [indicating bigger still], as if they have all the power in the world and things happen that Congress does not intend.

But we come back again to the item that is intriguing me in this whole thing.

If the total burden in dollars that comes as a result of this excessive regulation, and we will stipulate it is not our fault—we've managed to do that. If the total burden that is put on the system of this regulation absorbs something like the dollars that Dr. Conover has laid out, those are dollars that could in fact be going to the less visible victims, the ones who do not get into the nursing home because they do not have any kind of insurance.

Well, okay, they get in there if it's Medicare if they're old enough.

But if they have other kinds of problems, they don't get what they need because the system is paying too much for this over-regulation.

I will stipulate, Dr. Conover, that your numbers are wrong. But I don't know whether they're wrong on the high side or the low side. And I think you provided a service to us by indicating that whatever they are, they're significant in size.

And this is something that all of us ought to be concerned about and see if we can find some remedy for.

With that, let me thank you all for your participation. We appreciate the effort that went into your preparing your testimony.

If you have written testimony, it will of course be included in the record in full.

The hearing is adjourned.

[Whereupon, at 11:40 a.m., the hearing was adjourned.]

Submissions for the Record

PREPARED STATEMENT OF SENATOR ROBERT F. BENNETT, CHAIRMAN

Good morning and welcome to today's hearing where we will explore how regulation of health care services affects their cost, quality, and availability.

Health care is the most intensively regulated sector of our economy. It is also one of the largest, accounting for more than 15% of GDP. Significant attention has been paid to the relative costs and benefits of regulation in other industries, as well as for the economy as a whole, but the costs and benefits of health care regulation have often been overlooked. We need to learn more about the impact of the complex web of rules and regulations that govern how we spend and use more than $1.7 trillion annually.

Health care is certainly a vital item in all our lives, and some regulations can improve its quality and even reduce its cost. However, there is a significant risk that the promised benefits of health services regulations will fall well short of their costs.

One challenge is that proponents of regulation are often not the ones who bear its ultimate burden. This disconnect can lead to excessive regulation. A related challenge is that many regulatory costs are less visible than spending outlays and higher taxes. As a result, the political calculus may tilt toward using less visible regulatory means to accomplish objectives that would lack sufficient support if they required more transparent commitments of public funds.

There is often another disconnect in which people do not appreciate how the burdens of regulation are ultimately borne. Many consumers believe that insurers or employers pay the extra costs that result from tighter regulations, required expansions in covered services, etc., when in reality those costs eventually come out of their own pockets in one form or another.

Today, we plan to examine whether health services regulations are delivering sufficient benefits to justify their costs. This is a new and developing area of research, with important policy implications. Patients, consumers, and taxpayers are the ones who bear their ultimate costs of unnecessary regulation. Excessive regulatory burdens can also harm our most vulnerable individuals, such as the uninsured and lower-income health care consumers.

Much health regulation is premised on the judgment that most health care consumers don't know, don't want to know, and cannot know enough to make important decisions for themselves. I don't know if that's true often enough to justify the level of health regulation we have, but we hope to find that out today.

Today we have a panel filled with people who all have their own experience examining the costs and benefits of health services regulation, and how our regulatory system works.

Professor Christopher Conover of Duke University has worked for several years to develop an initial set of estimates of the net burden of health services regulation as a whole, as well as that of its primary components. If there's a regulatory elephant in the room that is increasing the cost of care and reducing its quality and availability, he may be able to provide us with some initial measurements of its size and scope.

Professor David Hyman of the University of Maryland has written extensively about health care regulation, most notably in the areas of managed care, emergency room treatment, and mandated benefits. He also recently coordinated 2 years of hearings on health care competition, conducted jointly by the Federal Trade Commission and the Department of Justice.

Dan Mulholland is a senior partner in Horty, Springer & Mattern. He is one of the nation's leading health care attorneys and serves as Chair of the Credentialing and Peer Review Practice Group of the American Health Lawyers Association.

We'll also hear from Vicki Gottlich, an attorney in the Washington, DC office of the Center for Medicare Advocacy, Inc. where she provides legal assistance, re-

search, consultation, and litigation support regarding Medicare and employer-sponsored health benefits.

We welcome you here today and look forward to your testimony.

PREPARED STATEMENT OF REPRESENTATIVE PETE STARK, RANKING MINORITY MEMBER

Thank you, Chairman Bennett. I have to take issue with the premise of today's hearing—"The Burden of Health Services Regulation"—because it implicitly assumes that regulations are simply useless impediments to economic efficiency and lowering health care costs.

In fact, many health care regulations are borne of the abuse of human beings and the degradation of their fundamental rights. Simply put, these regulations protect people's lives. So there can be no rational debate about doing away with health care regulations writ large for the sake of efficiency and thrift.

We've seen with the prisoner abuse scandal in Iraq that when regulations break down—in this case military regulations—the human toll that follows is simply unacceptable.

Countless examples of regulations that curb abuses in health services exist. Hospitals routinely turned away poor women in labor until Congress intervened and enacted the Emergency Medical Treatment and Active Labor Act (EMTALA) which prohibited this practice and guaranteed access to emergency care to all people, regardless of their ability to pay. Ms. Gottlich will give us her account of how nursing home regulations have reduced patient neglect and mistreatment that was widespread before consumer protections were put in place.

Right now, the Centers for Medicare and Medicaid Services claims it is heavily regulating the Medicare prescription drug discount cards, because there are already instances across the country of seniors being defrauded. The Bush Administration has admitted that they have to keep a close eye on the private companies that are providing drug cards, in order to prevent seniors from being fleeced. Not withstanding these regulations, I still doubt that these cards will be able to provide much value to the elderly—but these concerns stem from loopholes in the underlying statute.

Regulations at the Food and Drug Administration ensure that the drugs we are sold and devices we use are safe and efficacious. Do we want to roll back those protections? I support re-importation from selected countries as a method to lower prescription drug costs and think we can do so in a manner that preserves important safety measures, but in this case many on the other side of the aisle oppose doing so precisely because they claim it might undermine our regulatory structure.

I think our witnesses will be hard pressed to pinpoint a group of regulations that would save a great deal of money without unleashing disastrous consequences. Reining in medical malpractice costs is the popular example of untold savings in health care, but the Congressional Budget Office has found that malpractice insurance and legal fees have only a negligible effect on overall health care costs. In fact, C$O estimated savings of less than one-half of 1 percent if strict liability limits were enacted, and the President's budget shows no savings from such caps.

Ironically, Dr. Conover shares this vision and also advocates regulating the malpractice tort system by limiting damages patients and consumers can collect from providers and companies—so apparently regulation isn't all bad.

I am also troubled that we are having this hearing focusing on some very complex and preliminary calculations of the costs and benefits of health services regulations. There is no detailed documentation supporting the analysis by Dr. Conover. The study is not widely recognized or accepted among a broad range of health economists. But even more disturbing is that in some instances zero benefits have been assigned to important set of regulations where clearly the benefits are not zero.

Let's be clear. Eliminating regulations will do nothing to increase access and affordability to health care, as some of our witnesses have argued. There is no guarantee that money "saved" from less regulation would be put toward covering the uninsured. Indeed, the likely result would be insurance companies, hospitals, doctors, and pharmaceutical companies pocketing the savings.

Rolling back regulations is foolish because it won't lower costs, and it won't increase access or affordability to health care. More importantly, it's just too dangerous to our health.

Testimony of

Christopher J. Conover, Ph.D.
Assistant Research Professor of Public Policy Studies
Terry Sanford Institute of Public Policy, Duke University

Before the Joint Economic Committee
United States Congress
Hearing on *Health Care Costs and the Uninsured*
10:00 a.m., May 13, 2004

Mr. Chairman and Members of the Committee:

How much of the phenomenally high level of health costs in the U.S. can be attributed to health services regulation? And how many uninsured might be covered were we to reduce this sizable regulatory burden? My remarks today will provide some tentative answers to both questions based on the preliminary results of more than two years of research conducted in part under contract to the Department of Health and Human Services. My comments this morning are my own and not intended to represent the views of either the Department or Duke University.

Research on the Benefits and Costs of Health Services Regulation

Overview

I have conducted previous empirical work on a number of domains of health services regulation, including certificate-of-need, hospital conversions, hospital community service requirements (e..g., Hill-Burton), professional credentialing, Blue Cross and Blue Shield plan conversions, state health insurance reforms, managed care regulation and medical tort reform. But my remarks today are based principally on research conducted under contract to the Agency for Healthcare Research and Quality with funding from the Assistant Secretary of Planning and Evaluation, Office of Disability, Aging, and Long-Term Care Policy. This work began in the spring of 2002 and has continued through the present. A second phase of this

work is expected to begin shortly and would entail further empirical work, collection of additional data and publication of a large literature synthesis.

There is a sizable 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-1970's.[1] From this work we know that regulations impose a considerable burden on U.S. business and that the impact of regulation on the overall economy may be approaching 1 trillion dollars a year. In contrast, however, no one before had 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,[2] it made sense to focus on this void in our understanding of the impact of regulation. Therefore, the objective of the first phase of our research was to develop a preliminary synthesis of the literature on the benefits and costs

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[1] Previous efforts to synthesize the overall burden of regulation in the U.S. include Weidenbaum, M., and R. DeFina. 1978. "The cost of federal regulation of economic activity." American Enterprise Institute, Washington, DC.; Litan, R., and W. Nordhaus. 1983. Reforming federal regulation. New Haven: Yale University Press; Hahn, Robert W., and John A. Hird. 1990. The Costs and Benefits of Regulation: Review and Synthesis. *Yale Journal on Reguation* 8: 233-278; Hopkins, Thomas D. 1992. Costs of Federal Regulation. *Journal of Regulation and Social Costs* 2, no. 1: 5-31; Hopkins, Thomas D. 1995. *Profiles of Regulatory Costs*, Rochester Institute of Technology, Rochester, NY.; Hopkins, Thomas D. 1996. *Regulatory Costs in Profile*, Policy Study No. 132. Center for the Study of American Business, Rochester, NY; Crain, Mark W., and Thomas D. Hopkins. *The impact of regulatory costs on small firms*, RFP No. SBAHQ-00-R-0027. The Office of Advocacy, U.S. Small Business Administration. http://aspe.hhs.gov/health/reports/hipabase/toc.htm; and Dudley, Susan, and Melinda Warren. 2002. *Regulatory Response: An Analysis of the Shifting Priorities of the U.S. Budget for Fiscal Years 2002 and 2003*, Regulatory Budge Report 24. Mercatus Center, George Mason University and Murray Weidenbaum Center on the Economy, Government, and Public Policy, Arlington, VA, and St. Louis, MO., the latter representing the 24th in a series of annual reports issued by the Weidenbaum Center on the Economy, Government, and Public Policy (formerly the Center for the Study of Business) at Washington University in St. Louis (this latest report is a joint effort with the Mercatus Center at George Mason University). Most of these syntheses focus on federal regulation, as does an annual report required of Office of Management and Budget since 1997 that outlines the costs and benefits of all federal regulations. See OMB, Office of Information and Regulatory Affairs. 1997. *Report to Congress on the costs and benefits of federal regulations*; OMB. 1999. *Report to Congress on the costs and benefits of federal regulations*; OMB. 2000. *Report to Congress on the costs and benefits of federal regulations*. OMB. *Making sense of regulation: 2001 report to Congress on the costs and benefits of regulations and unfunded mandates on state, local and tribal entities*; OMB. 2002. Draft Report to Congress on the Costs and Benfitrs of Federal Regulations; Notice. *Federal Register* 67, no. 60: 15014-45. A comprehensive review and synthesis of the cost of workplace regulations whose scope and style are the inspiration for our synthesis is provided by). Johnson, Joseph M. 2001. A Review and Synthesis of the Cost of Workplace Regulations. Mercatus Center, George Mason University.

[2] Heffler, Stephen, Sheila Smith, Sean Keehan, M. Kent Clemens, Greg Won, and Mark Zezza. 2003. 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 Exculsive: 54-65.

of health services regulations, culminating in a research plan to do further work to help fill important gaps in our current knowledge identified in the first phase.

Expert Panel

This work was completed by researchers at the Center for Health Policy, Law and Management with expert guidance from an advisory panel of 20 knowledgeable experts whose collective expertise included health facilities regulation, health professionals regulation, health insurance regulation and the medical tort system. Apart from providing guidance on the scope and content of this literature synthesis, and feedback throughout the process, most of these experts convened for a 1-day conference at Duke in February 2003. These experts included noted legal scholars such as:

- Clark Havighurst, JD, the William Neal Reynolds Professor Emeritus of Law at Duke University;
- Mark A. Hall, JD, Professor of Law and Public Health at Wake Forest University School of Law and School of Medicine; and
- David Hyman, who also is testifying today.

We also included experienced health economists such as:

- Joseph Antos, PhD, a Resident Scholar at the American Enterprise Institute;
- H.E. Frech III, PhD, Professor at the University of California, Santa Barbara;
- Robert B. Helms, PhD, a resident scholar and director of Health Policy Studies at the American Enterprise Institute;
- Michael Morrisey, PhD, a professor in the Department of Health Care Organization and Policy at the University of Alabama at Birmingham (UAB) and Director of the Lister Hill Center for Health Policy at UAB;
- Mark V. Pauly, PhD, the Bendheim Professor of Health Care Systems, Business and Public Policy, Insurance and Risk Management, and Economics as well as Chairperson of Health Care Systems Department at the Wharton School, University of Pennsylvania; and

- Frank Sloan, the J. Alex McMahon Professor of Health Policy and Management and Director, Center for Health Policy, Law and Management, and a professor of economics at Duke University.

We also included several individuals with expertise dealing with health regulations "in the trenches" so to speak, including:

- Dan Mulholland, who also is testifying today;
- Christy Gudaitis, JD, Assistant University Counsel for Duke University and Duke University Health System, and
- Duncan Yaggy, PhD is Adjunct Professor of Public Policy Studies and Director and Chief Planning Officer, Duke University Health Systems.

Finally, we included individuals with general expertise in the area of measurement of regulatory costs or experts with unique training or perspectives on the issues being discussed such as:

- Lesley Curtis, PhD, Assistant Research Professor, General Internal Medicine, Duke University Medical Center
- Walton J. Francis, independent health consultant;
- Randall Lutter, PhD, Resident Scholar with AEI;
- Kevin Schulman, MD, MBA, Professor, Department of Medicine, Duke University Medical Center and Faculty Director, Health Sector Management Program, Fuqua School of Business at Duke University.

Scope of Regulations Reviewed

All told, our literature synthesis included a broad range of health-related regulations, covering the gamut from health facilities regulation, health professionals regulation, health insurance regulation, FDA regulation and the medical tort system. We are confident that no major domain of health services regulation was excluded from this review. We purposely excluded domains of regulation that cut across all industries, such as employment regulations (e.g., worker health and safety, employment discrimination restrictions) even though these too might have the effect of elevating health expenditures. We considered whether to include

antitrust regulation. The argument against inclusion was that, despite its particular influence on the healthcare 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. We ultimately decided *not* to include general antitrust regulation of facilities, professionals or insurance, but did elect to include state action statutes that provide exemptions from antitrust laws on grounds that equivalent exemptions are not provided in other industries and these exemptions may result in identifiable costs." Moreover, it is worth noting that our cost estimates do not include the costs imposed on health providers from continual changes in public payment policies. In that regard, our estimates should be viewed as a conservative assessment of the size of the regulatory cost burden in health care.

Table 1 shows all the topics included in the area of health facilities regulation, broken down by whether these regulations principally were aimed at improving access, cost or quality of care. We recognize that some of these categorizations might be viewed as arbitrary. Certificate of need laws, for example, were originally justified predominantly on the basis of controlling costs, but in recent years, as questions have been raised about the efficacy of such programs in controlling costs, the justifications have tended to focus more on CON's purported ability to improve access and/or quality. Some of the most important areas of facilities regulation in terms of net costs (i.e., benefits minus costs) include accreditation and licensure for hospitals and nursing homes, hospital uncompensated care pools and regulation of clinical laboratories.

Table 1
Health Facilities Regulation

Regulation	Locus
Access	
EMTALA	F
Hospital uncompensated care pools	S
Hospital community service requirements	
Hill-Burton	F
State community service requirements	S
State indigent care mandates	S
Hospital conversion regulations	S
Limited English Proficiency requirements	F
Costs	
Fraud and abuse	
False Claims Act of 1863	F
MedicareMedicaid fraud and abuse statute	F
Civil Monetary Penalties Law (CMPL)	F
Self-referral prohibitions (Stark I and II)	F
HIPAA fraud and abuse provisions (1996)	F
BBA fraud and abuse provisions (1997)	F
State fraud and abuse requirements	S
Medical records (includes privacy)	
HIPAA Privacy Rule	S
State privacy regulations	F
Organ transplant regulation	F
Hospital provision of transplant-related data	F
Organ transplant sales ban	F
Certificate of need	S
Hospital rate-setting	S
Pharmaceutical price regulation	
Medicaid Average Wholesale Price	F
State pharmaceutical price regulation	S
Other cost-related facilities regulations	S
Hospital discharge data systems	S
Patient Self-Determination Act of 1990	F
Quality	
Hospital accreditation and licensure	
Medicare conditions of participation	F
State accreditation and licensure	S
Nursing home accreditation and licensure	F
Medicare conditions of participation	F
Nursing Home Reform Act (OBRA '97)	F
State accreditation and licensure	
Other facilities accreditation and licensure	F
Medicare conditions of participation	F
Ambulatory Surgical Centers	F
Diagnostic Imaging Centers	F
Home Health Agencies	F
Renal Dialysis Centers	F
Pharmacies	F
Ambulances	F
State accreditation and licensure	S
Peer Review	
Quality Improvement Organizations (QIOs)	F
Health Care Quality Improvement Act (1986)	F
Clinical Laboratory Improvement Act of 1967	F
Other quality-related facilities regulations	
Regulation of blood banks (FDA)	F
Blood-borne pathogen requirements (OSHA)	F
Health outcomes reporting systems	S

Table 2 shows topics included in the area of health professionals regulation, most of which are focused on either costs or quality. Again, in terms of overall net cost impact, the most important areas of health professionals regulation include Medicare GME payments, professional accreditation and licensure and Medicare assignment rules.

Table 2
Health Professionals Regulation

Regulation	Locus
Access	
Medicare assignment rules	F
Costs	
Fraud and abuse	
False Claims Act	F
MedicareMedicaid fraud and abuse statute	F
Self-referral prohibitions (Stark I and II)	F
HIPAA fraud and abuse provisions (1996)	F
BBA fraud and abuse provisions (1997)	F
State fraud and abuse	S
Medical records (includes privacy)	
HIPAA Privacy Rule	F
State privacy regulations	S
Medicare GME payments	F
Quality	
Medicare conditions of participation	F
National Practitioner Databank	F
Professional accreditation/licensure	S
Commercial limits on practice of medicine	
Corporate practice of medicine	S
Advertising restrictions	
FTC	F
State advertising restrictions	S
Resident duty hours limitations	S

Table 3 shows the many different federal and state regulations affecting health insurance that were included in our analysis. The areas having the largest net cost impact include mandated health coverage, managed care patient protections and general health insurance/HMO regulation.

Table 3
Health Insurance Regulation

Regulation	Locus	Health Insurance			Managed Care			Integrated Delivery Systems		
		Blue Cross/ Blue Shield	Com-mercial Insurance Companies	Self-insured Health Plans	HMOs	IPAs	PPOs	PHOs	MSOs	PSOs
Access										
HMO Act of 1973	F				x	x				
Anti-discrimination restrictions	F									
Rehabilitation Act of 1973	F	x	x	x	x	x	x			
Pregnancy Discrimination Act of 1978	F	x	x	x	x	x	x			
Americans with Disabilities Act	F	x	x	x	x	x	x			
Child Abuse Prevention and Treatment Act	F	x	x	x	x	x	x			
Mandated health coverage										
Employer mandates	S	x	x	x	x	x	x			
Continuation of coverage										
State requirements	S									
COBRA (1985)	F	x	x	x	x	x	x			
Mandated health benefits										
Mandated standards of care	S				x	x	x			
Other mandated health benefits	S	x	x		x	x	x			
Mental Health Parity Act (1996)	F	x	x	x	x	x	x			
Newborns' and Mothers' Protection Health Act	F	x	x	x	x	x	x			
Women's Health and Cancer Rights Act (1998)	F	x	x	x	x	x	x			
Mandated providers	S	x	x		x	x	x			
Person mandates	S	x	x		x	x	x			
Insurance Market Reforms										
Small-group insurance reforms	S	x	x		x	x	x			
Individual market insurance reforms	S	x	x		x	x	x			
Community rating	S	x	x		x	x	x			
Health alliances (voluntary & mandatory)	S	x	x		x	x	x			
HIPAA (1996)	F	x	x		x	x	x			
Health plan conversion regulations	S	x			x					
High risk pools	S	x	x		x	x	x			
Costs										
ERISA (1974)	F			x						
HIPAA (1996) administrative simplification	F	x	x	x	x	x	x	x	x	x
Privacy regulation										
State requirements	S	x	x	x	x	x	x	x	x	x
HIPAA (1996)	F	x	x	x	x	x	x	x	x	x
Medicare as secondary payer (1980)	F	x	x	x	x	x	x			
Medigap minimum standards (1990)	F	x	x		x	x	x			
General Insurance/HMO Regulation										
General insurance regulation (solvency/rates)	S	x	x							
General HMO regulation (solvency/rates)	S				x	x	x			
Premium taxes	S	x	x		x	x	x			
Quality										
Medicare + Choice conditions of participation	F	x	x	x	x	x	x	x	x	x
Managed care regulation										
Professional rights										
All products statutes	S				x	x	x			
Anti-gag rules	S				x	x	x			
Due process protections	S				x	x	x			
Prompt payments statutes	S				x	x	x			
Patient protections										
Any-willing-provider statutes	S				x	x	x			
Continuity-of-care requirements	S				x	x	x			
External review statutes	S				x	x	x			
Drug formularies	S				x	x	x			
Limits on financial incentives	S				x	x	x			
Patient bill of rights	S				x	x	x			
Bipartisan Patient Protection Act (2001)	F				x	x				

The Burden of Health Services Regulation in the U.S.

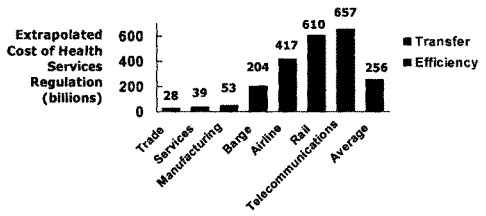
We used two approaches to determining the net impact of regulation. The first was a "top down" approach that relied on extrapolations from other industries. The second was a "bottoms up" approach that systematically examined the evidence.

In the "top down" approach, we 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. Some of these figures, dating to 1988, admittedly are somewhat dated cost estimates for industries that in some cases subsequently have seen considerable deregulation; 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. Moreover, these industry figures may be underestimates insofar as ex post estimates of the savings that resulted from deregulation of the airlines, railroads and trucking industries have tended to be significantly greater than ex ante estimates (Hahn and Hird 1990).

Thus, one may either view these 1988 estimates as being similarly flawed or as having benefited from the lessons learned from ex post calculations. 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 burden. As shown in Fig. 1, this so-called "top-down" approach suggests that in 2002, health regulation could have imposed an annual cost of at least $28 billion to as much as $657 billion. (See Figure 1).[3]

[3] See Appendix A for details of these calculations.

Fig. 1. "Top Down" Estimate of Health Regulation Costs, 2002 (billions)



The sizable 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 oriented" in the industrialized world, remains the most intensively regulated sector of the U.S. economy."[4]

This is why it was worth investing effort in the much more fine-grained "bottoms up" approach. As noted above, we examined the literature for nearly 50 different kinds of federal and state health services regulations, including regulation of health facilities, health professionals, health insurance, pharmaceuticals and medical devices and the medical tort system. These various regulations covered the gamut from mandated health benefits to state certificate of need requirements for hospitals and nursing homes. We systematically tallied both the benefits and costs associated with such regulations[5] and found that the expected costs

[4] Charles E. Phelps. *Health Economics*, 2nd edition. Addison-Wesley Publishing Co. 1997: 539.

[5] In many cases, the national dollar impact of a particular form of regulation never has been estimated per se, e.g., state certificate of need regulation of hospitals and nursing homes. In these cases, we synthesized the literature on the percent change in health costs associated with that form of regulated and then calculated the aggregate national impact by applying these estimated effects to aggregate health expenditure estimates for the states that still maintain such regulations. In some cases, our estimates also included mortality gains and losses reported in the literature. In these cases, we monetized such losses using conventional assumptions about the willingness-to-pay value of a human life. We used a standard value of a statistical life that amounted to $4.4

of regulation in health care amounted to $340 billion in 2002. As shown at the bottom of Fig. 2, our estimate of benefits was $212 billion, leaving a net cost of $128 billion. Three areas account for the lion's share of this net burden: the medical tort system, including litigation costs, court expenses and defensive medicine, totals $81 billion, FDA regulation adds another $42 billion, and health facilities regulation adds $29 billion. This suggests that the states and federal government both have important roles to play in findings way to trim regulatory excess.

Fig. 2. "Bottoms Up" Estimate of Health Regulation Costs, 2002 (billions)

Type of Regulation	Benefits	Costs	Net
Facilities	18.3	47.7	29.4
Professionals	22.4	29.5	7.1
Insurance	131.6	100.1	(31.5)
Pharmacy/Devices	7.1	49.0	41.9
Medical Tort System*	32.5	113.7	81.2
TOTAL	212.0	340.0	128.1

*Includes costs of medical professional liability insurance, courts and defensive medicine. Claimants' costs not compensated through awards are excluded.

With the caveat that our findings are still preliminary, to date we have found that in the domain of health facilities regulation, of the 16 separate areas of regulation we studied, only 2 produced benefits that exceeded costs. Similarly, benefits exceeded costs for only 3 of 8 health professional regulations we studied and 7 of 19 areas of health insurance regulation. This is not equivalent to saying that we believe 31 areas of health regulation 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 of this. 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 this be through caps on damages, alternative dispute resolution—this would be an improvement over the status quo.

million for our average estimates, with $1.6 million and $6.6 million as lower and upper bounds. See Mrozek, James R. and Laura O. Taylor. "What Determines the Value of Life? A Meta-Analysis." *Journal of Policy Analysis and Management* 21, No. 2 (Spring 2002): 253-270 for a detailed justification of these values.

In the context of seeing that most domains of health regulation cost more than the benefits they produce, it may be surprising to see that the reverse apparently is true for health insurance regulation, where benefits exceed costs by $31.5 billion a year. But it is important to note that this arises predominantly due to ERISA which alone provides a net savings of $46 billion. Recall that the benefits of ERISA are the protection it affords self-insured plans from otherwise having to comply with state benefit mandates, premium taxes and other insurance regulation costs. Given that ERISA plans cover 124 million Americans,[6] the cumulative savings from avoiding these regulatory costs is sizable. Thus, without ERISA, the total cost of insurance regulation would be more than 40 percent larger than we have estimated here and the total benefits would be one quarter larger. In that case, costs would exceed benefits by more than $14 billion. In short, ERISA is a peculiar form of regulation whose benefits arise chiefly by exempting certain health plans from even more onerous regulation. Had we left it out, our estimate of the net cost of regulation would have risen by more than one third to nearly $175 billion (Figure 3).

Fig. 3. "Bottoms Up" Estimate of Health Regulation Costs (w/o ERISA), 2002 (billions)

Type of Regulation	Benefits	Costs	Net
Facilities	18.3	47.7	29.4
Professionals	22.4	29.5	7.1
Insurance (w/o ERISA)	84.9	99.3	14.4
Pharmacy/Devices	7.1	49.0	41.9
Medical Tort System*	32.5	113.7	81.2
TOTAL	165.3	339.2	173.9

*Includes costs of medical professional liability insurance, courts and defensive medicine. Claimants' costs not compensated through awards are excluded.

[6] Copeland, Craig, and Bill Pierron. 1998. *Implications of ERISA for health benefits and the number of self-funded ERISA plans.*

It was not the purpose of our study to make recommendations on specific regulatory reforms to be pursued, either in medical torts or any other domain of health regulation. Instead, we were trying to provide something that has never been achieved previously: a "big picture" view of the overall impact of health services regulation with the intent of identifying areas where regulation might be excessive. For each of the areas so identified, one would have to rely on further study or experts in that domain to sort through the best approach to reform. In all likelihood, only in some of these cases would experts judge that we should dispense entirely with regulation.

While sizable, health care regulatory costs should be put into context. For example, this analysis has ignored entirely tax policy as it relates to health care. Yet, federal and state tax subsidies for employer health benefit contributions in 2004 will amount to $209.9 billion[7]—an amount that would effectively more than double our estimate of the cost of health services regulation 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 billion in 2002) is wasted, i.e., "appears to provide no benefit in terms of survival, nor is it likely that this extra spending improves the quality of life.[8]" Thus there are areas apart from health services regulatory costs where Americans could get more bang for the buck.

Finally, 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."[9] The estimates in our synthesis, as uncertain and incomplete as they may be, have been assembled with the same motivation.

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[7] Sheils, John, and Randall Haught. 2004. The cost of tax-exempt health benefits in 2004. *Health Affairs* Web Exclusive, no. W4: W4-106-W4-112.

[8] Skinner, Jonathan, Elliott S. Fisher, and John E. Wennberg. 2001. The efficiency of Medicare. NBER Working Paper Series #8395Cambridge, MA: National Bureau of Economic Research.

[9] Hahn, Robert W., and John A. Hird. 1990. The Costs and Benefits of Regulation: Review and Synthesis. *Yale Journal on Reguation* 8: 259.

Net Regulatory Costs and the Uninsured

Increases in the Number of Uninsured

How do all these figures relate to the uninsured? Our "bottoms up" look allowed us to determine that the net cost of regulation imposed directly on the health industry itself is 6.4 percent, meaning that health expenditures (and 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 2.2 percent reduction in the demand for coverage. **This translates into 4 million uninsured whose plight might be attributed to excess regulatory costs, or roughly 1 in 11 of the average daily uninsured.**

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.[10] Assuming an average overhead cost no higher than 15 percent, a 6.4 percent increase in health spending (i.e., health benefits) attributable to health industry compliance costs would be associated with a 5.4% increase in overall health insurance premiums (i.e., 6.4% x 85%=5.4%), so applying the lower bound elasticity estimate yields a 2.2% reduction in demand for coverage. There are 185 million adults and children currently covered by private health insurance[11] A 2.2 percent reduction in demand translates into 4.0 million uninsured. Using upper bound estimates of the net impact of health regulation (9.8%) and price elasticity (-.6) would imply that 9.2 million could be uninsured due to health regulation.

Our figures imply that for each 1% increase in private health insurance premiums, there would be a 0.4% reduction in demand for private coverage, which at current levels of private coverage implies 740,000 newly uninsured. There is another widespread rule of thumb based on a Lewin study estimate that each 1 percent increase in health insurance premiums results in 300,000 uninsured. The genesis of this figure and its limitations have been discussed

[10] 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

[11] Mills, Robert, and Shailesh Bhandari. 2003. *Health Insurance Coverage in the United States: 2002*, U.S. Census Bureau. U.S. Government Printing Office, Washington, DC

elsewhere,[12] but it is worth noting that it applied only to employer-based coverage and assumes that one third of those losing coverage would be able to obtain alternative group coverage through other family members, purchase less comprehensive individual coverage or qualify for public coverage such as Medicaid. A one-third reduction obviously would affect our own estimates, but from the standpoint of public policy, it is as important to know whether a newly uninsured individual is absorbed by Medicaid as whether they remain uninsured. Moreover, the Lewin estimates are based on the estimated relationship between employee contributions and decisions to retain coverage. But the typical small employer covers about half of all premium costs for group coverage, so a 1 percent premium cost could translate into anywhere from a 0 percent to 2 percent increase in the employee premium contribution depending on how much of the increase is passed through by the employer.

There also are several differences between our estimates and those used in recent cost estimates by CBO that are worth noting:

- Our estimates of the impact of health services regulation affect medical expenditures (and hence health insurance premiums) across the board; in contrast, federal mental health parity and PBOR proposals would apply only to group health plans (leaving out 16 million non-elderly with individual coverage) and in some cases exempt small employers (20 or fewer in some bills, 50 or fewer in others), exclusions that may leave out as much as 30 percent of private sector employer-based coverage; see Jennifer Bowen, Jeanne De Sa and Stuart Hagen memorandum "Estimate of S. 543, the Mental Health Equitable Treatment Act" July 12, 2002). Moreover, CBO always takes into account states that may have already enacted similar mandates or protections as their purpose is to calculate the net effect of a change in federal law. For all these reasons, the base of persons having coverage from which demand reductions are calculated is generally smaller in the CBO estimates than in ours.

[12] GAO. 1998. *Private Health Insurance: Impact of Premium Increases on the Number of Covered Individuals Is Uncertain*, GAO/HEHS-98-203R. United Sates General Accounting Office, Washington, DC.

- CBO assumes that 40 percent of premium increases would be effectively absorbed by employers and passed back to employees in the form of lower compensation; they assume the remaining 60 percent would be offset by changes in profits, by purchasers switching to less expensive plans, by cutting back on benefits or dropping coverage (see CBO, *Congressional Budget Office Cost Estimate: S. 1052 Bipartisan Patients' Bill of Rights Act* (as passed by the Senate on June 29, 2001), July 20, 2001). For all these reasons, the net amount of each 1 percent premium increase that is actually left over to influence demand for coverage is much smaller than ours (i.e., we take into account the full 1%).

The CBO approach makes sense when analyzing mandates that provide some sort of benefit at an additional cost since employees (and their employers who are presumed to reflect their preferences) presumably are willing to pay *something* for an additional benefit even if it is not the full cost. However, in our case, we had already netted out any benefits from regulation, so the residual $128 billion in costs should more appropriately be viewed as the equivalent of an excise tax. As CBO Director Douglas Holtz-Eakin has testified recently: "Clearly, an increase in premiums having nothing to do with the quality of the insurance benefit (a tax on premiums, for example) would lead to a reduction in the number of people with health insurance since the price increase would lead some people to drop their coverage."[13] In short, any differences between CBO estimates and ours are more apparent than real.

One final complicating factor is that there are huge variations in the estimated elasticity of employer offers of health insurance coverage, ranging from -.6 to –1.8 for small firms and 0 to -.2 for large firms. [14] Demand elasticity estimates for individuals show a similar range. Thus, the ultimate outcome of whether an individual becomes uninsured is a combination of a) employer decisions whether to continue offering coverage; b) employer decisions about how much of a cost to pass through to employees (and in what form); c) employee decisions whether to retain coverage; and d) alternative coverage options for employees and their

[13] Statement of Douglas Holtz-Eakin, Director of Congressional Budget Office, The Uninsured and Rising Health Insurance Premiums before the Subcommittee on Health Committee on Ways and Means U.S. House of Representatives March 9, 2004

[14] 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

dependents who drop coverage (or are dropped from coverage). Given these uncertainties, we believe our estimate is a reasonable one, but that the true figure might be lower or higher than we have estimated.

It is worth noting that for purposes of calculation today, we have simply assumed that all regulatory costs are 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 on selected groups, e.g., small groups and individuals. Were we to more finely calibrate our estimates to determine the percent cost increase facing small firms, for example, we undoubtedly would find that the impact was greater than the 6.4 percent average effect. This matters not only in terms 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.

Affordability of Universal Coverage

But of course, there's a different way to look at this burden as well. In light of the $35 billion in subsidized care already being provided to uninsured patients,[15] researchers have recently estimated that it would cost only $34 to $69 billion in added health spending to cover the all of the nation's uninsured.16 In light of these figures, the potential opportunity costs of this regulatory burden become very clear: the average estimates from both our "top down" and "bottoms up" look at this problem suggests we could cover this cost several times over. Admittedly, our estimates are still preliminary and we now are engaged in a process of careful review of them. But it seems unlikely that the adjustments yet to come would alter this central conclusion: **the net burden of health services regulation likely exceeds the annual cost of covering all 44 million uninsured by a considerable margin**. So a legitimate policy question is whether the benefits of regulation outweigh the benefits of coverage for all

[15] Jack Hadley and John Holahan. "How Much Medical Care Do the Uninsured Use and Who Pays for It?" *Health Affairs Web Exclusives*, January-June 2003. February 12, 2003: W3-66.
[16] Jack Hadley and John Holahan. "Covering the Uninsured: How Much Would it Cost?" *Health Affairs Web Exclusives*, January-June 2003. June 4, 2003: W3-250-265.

Americans. For example, in the context of the IOM finding that 18,000 uninsured die every year due to lack of coverage, is maintaining our current regime of health regulation worth letting that continue?

This is a question worthy of serious consideration especially during Cover the Uninsured week. Thank you for your time.

Appendix A

Fig. 1 Supporting Documentation. "Top-Down" Estimates of Cost of Health Services Regulation (billions of 2002 dollars)

Industry	Source	Year of Estimate	Type of Cost: Efficiency	Type of Cost: Transfer	If Applied to Health: Efficiency	If Applied to Health: Transfer	If Applied to Health: Combined
			Percent		Billions		
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: For estimates obtained from Hahn and Hird [S1], all percentages are calculated based on estimated regulatory costs reported by authors divided by GDP for each respective industry in the year shown. The industry categories used for the GDP estimates were a) transportation by air; b) water transportation; c) railroad transportation; and d) communications (which includes telephone/telegraph and radio/TV). These percentages were applied to estimated National Health Expenditures for 2002. Crain and Hopkins [S3] report regulatory costs as a percent of receipts, so these percentages were applied directly to NHE.

Parameters	Year	Efficiency	Transfer	GDP
Airline [S1]	1988	3.8	7.7	42.7
Barge [S1]	1988	0.3	0.9	9.1
Rail [S1]	1988	2.3	6.8	23.1
Telecommunications [S1]	1988	14.1	42.3	132.8
National health expenditures, US, 2002 [S:	1,547.6			

Sources

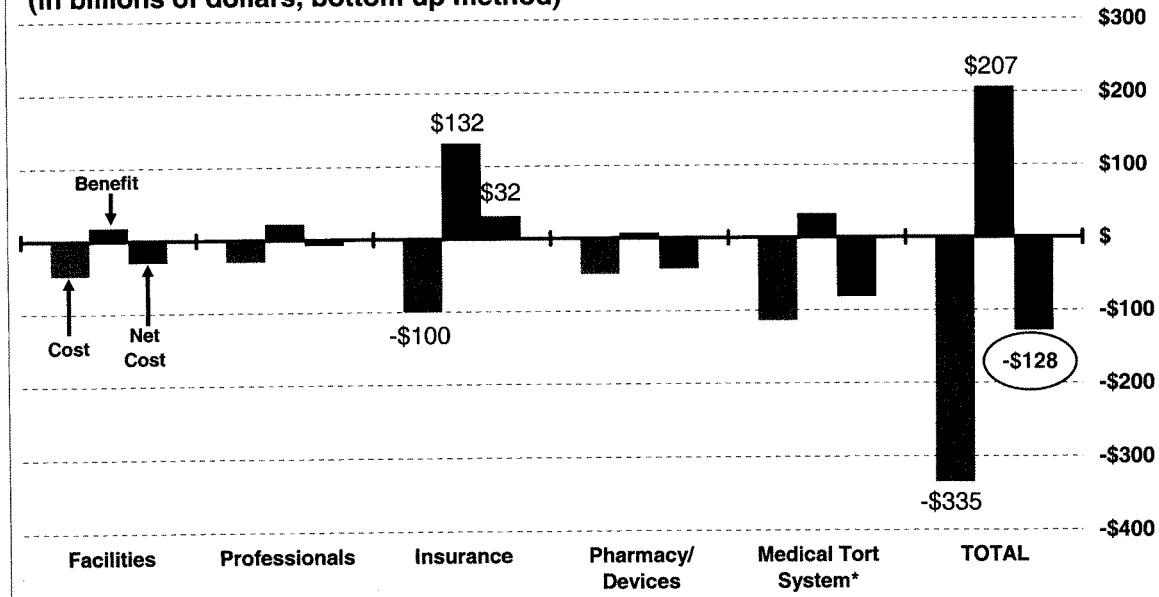
[S1] Hahn, Robert W., and John A. Hird. 1990. The costs and benefits of regulation: review and synthesis. *Yale Journal on Regulation* 8: 233.

[S2] Heffler, Stephen, Sheila Smith, Sean Keehan, M. Kent Clemesn, Greg Won, and Mark Zezza. 2003. Health Spending Projections for 2002-20012. *Health Affairs Web Exclusive* W 3: 54-65.

[S3] Crain, Mark W., and Hopkins, Thomas D. 2001. *The impact of regulatory costs on small firms*. Office of Advocacy, Small Business Administration.

Health Regulation Costs Outweigh Benefits by $128 Billion in 2002

(in billions of dollars, bottom up method)

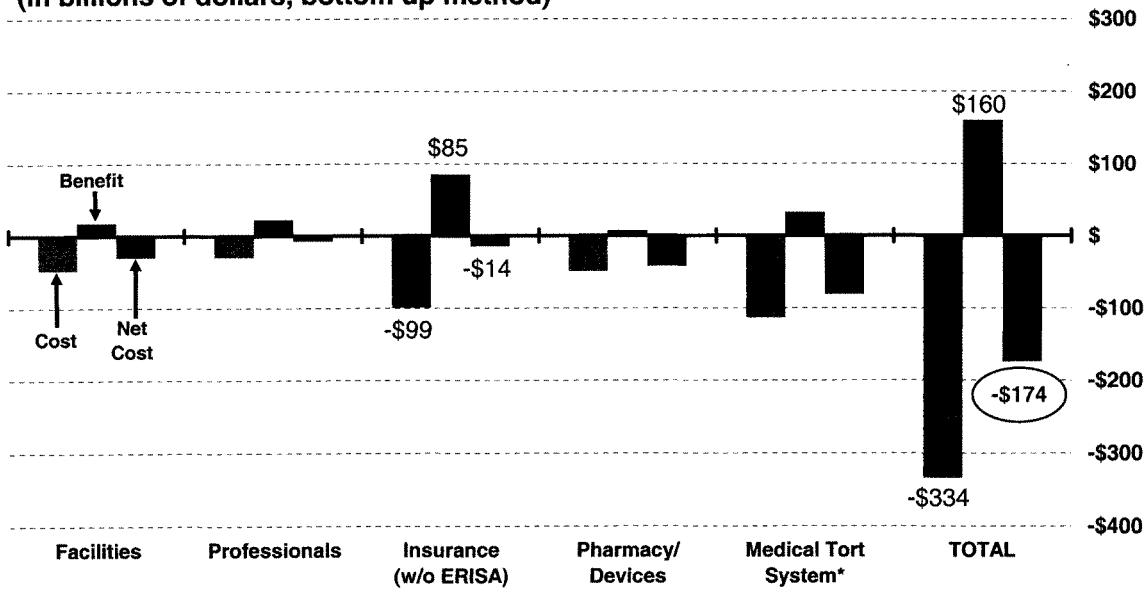


*Includes costs of medical professional liability insurance, courts and defensive medicine. Claimants' costs not compensated through awards are excluded.

Source: Christopher J. Conover, Center for Health Policy, Law and Management, Duke University

Health Regulation Costs, Without ERISA Benefits, Outweigh Benefits by $174 Billion in 2002

(in billions of dollars, bottom up method)



Source: Christopher J. Conover, Center for Health Policy, Law and Management, Duke University

*Includes costs of medical professional liability insurance, courts and defensive medicine. Claimants' costs not compensated through awards are excluded.

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May 19, 2004

Christopher Conover
Assistant Research Professor
Duke University
Center for Health Policy, Law and Management
Box 90253
Durham, NC 27708

Dear Dr. Conover:

Thank you for testifying before the Joint Economic Committee on May 13, 2004 at the hearing on the Burden of Health Services Regulation. I appreciate you taking the time to share your expertise with Congress on this important issue. I am writing with additional questions as a follow-up to the hearing. These questions and your answers will be included in the record of the hearing's proceedings.

- Are mandated benefits and other mandates for insurance coverage a significant cost driver? Are most mandates similar, or do certain ones tend to impose the greatest burdens on health care costs, insurance premiums, and insurance coverage levels?

- Why should we consider the costs and burdens of the medical tort system as part of the overall burden of health services regulation?

- Is one person's regulatory burden another person's regulatory benefit? Or is there a net loss behind various regulatory transfers?

- What other estimates of the net burden of health services regulation are available, and how do they compare with yours? Do they use different methods? What else do we need to know as we attempt to measure and analyze the costs, benefits, and burdens of health services regulation in the future?

Should you have any questions about these inquiries, please do not hesitate to contact me or Tom Miller, of my Joint Economic Committee staff, at (202) 224-5171.

Sincerely,

Robert F. Bennett
United States Senator

TERRY
SANFORD INSTITUTE
OF PUBLIC POLICY
D U K E

Center for Health Policy, Law and Management

June 4, 2004

The Honorable Robert F. Bennett
Chairman
Joint Economic Committee
Congress of the United States
Washington, DC 20510-6602

Dear Senator Bennett:

I am writing in response to your letter of May 19 regarding my testimony on May 13.

Question 1: *Are mandated benefits and other mandates for health insurance coverage a significant cost driver? Are most mandates similar, or do certain ones tend to impose the greatest burdens on health care costs, insurance premiums, and insurance coverage levels?*

According to our estimates, mandates are the single greatest contributor to the net cost of health insurance regulation. Continuation of coverage mandates have a net cost in excess of $15 billion and other benefits mandates (such as mental health parity, 48-hour maternity stays and similar mandates) result in a net cost in excess of $13 billion. The lion's share of these benefits mandates are imposed by states rather than the federal government, which is one of the reasons ERISA produces such sizable cost savings by preempting these state regulations from covering even more health plans than they already do. It also underlies the reason that Maryland is now undertaking a very serious effort to deregulate health insurance, a development you may have read about last week: http://www.nationalreview.com/comment/gratzer200405270842.asp. As part of our follow-on research for this project, we will be examining this issue of mandated benefits in further detail and hope to have even more complete and reliable estimates in a year or so based on an analysis that fully accounts for all major sources of health insurance regulation and using more authoritative data sources. We will be happy to provide these improved estimates to the Committee once they are available.

Question 2: *Why should we consider the costs and burdens of the medical tort system as part of the burden of health services regulation?*

This is an excellent question, for 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 important 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

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third parties, the result is that consumers effectively are being required to purchase a form of disability 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 (see Clark C. Havighurst, James F. Blumstein and Troyen Brennan, Health Care Law and Policy, 2nd ed. New York: Foundation Press, 1998: pp. 924-925 for further discussion on this point). Likewise, the entire convention of contingency fees adopted in the U.S. rather than "loser pay" 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, damage caps etc. 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" in the first place. Leaving aside the question of whether we ever could or should, certainly there is no question that the "system" is in theory amenable to change through various identifiable policy changes.

Question 3: *Is one person's regulatory burden another person's regulatory benefit? Or is there a net loss behind various regulatory transfers?*

There is no question that there are identifiable beneficiaries of regulation. If states impose commercial limits on the practice of medicine, the result will be higher prices and hence higher incomes for selected types of providers, i.e., a transfer from consumers to suppliers. Certificate of need restrictions has been expressly justified on "taxation by regulation" grounds to create franchises that permit hospitals to cross-subsidize merit goods such as indigent care, teaching, or research. While it may appear that transfers per se impose no net costs on society (since every loss by one party is counterbalanced by a gain by another), the reality is that such transfers do create market distortions or encourage rent-seeking behavior by those wishing to become "winners." Hopkins argues that the existence of transfers can result in real costs that theoretically could fully equal the transfer amount as interest groups, lobbyists, lawyers and other experts all vie to direct the flow of transfers to particular groups.[1] Others argue that rent-seeking behavior causes transfers rather than the opposite: hence the cost of such behavior should be viewed as a cost of a democratic political system.[2] But even if the costs of rent-seeking behavior are set aside on such grounds or found to be trivial, social costs arise indirectly from these transfers since they must be financed through mechanisms--for example, income and payroll taxes or higher medical prices--that impose deadweight losses or otherwise affect the use of real resources.[3]

Question 4: *What other estimates of the net burden of health services regulation are available, and how do they compare to yours? Do they use different methods? What else do we need to know as we attempt to measure and analyze the costs, benefits, and burdens of health services regulation in the future?*

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[1] Hopkins, Thomas D. 1992. Costs of Federal Regulation. *Journal of Regulation and Social Costs* 2, no. 1: 5-31.

[2] Office of Management and Budget, Office of Information and Regulatory Affairs. 1997. *Report to Congress on the costs and benefits of federal regulations*, Office of Management and Budget, Office of Information and Regulatory Affairs.

[3] As an example, for the federal income tax, compliance costs alone may be as high as 20.4 percent according to one estimate (J. Scott Moody, "The Cost of Complying with the Federal Income Tax" Special Report No. 114, Washington, D.C.: Tax Foundation: July 2002).

There are no comparable estimates that we have been able to locate. Previous efforts to synthesize the overall burden of regulation in the U.S. include Weidenbaum and DeFina (1978);[4] Litan and Nordhaus (1983);[5] Hahn and Hird (1990);[6] Hopkins (1992, 1995, 1996);[7] Crain and Hopkins (2001);[8] Crews (1996; 1998; 1999; 2000; 2001; 2002; 2003);[9] and Dudley and Warren (2002),[10] the latter representing the 24th in a series of annual reports issued by the Weidenbaum Center on the Economy, Government, and Public Policy (formerly the Center for the Study of Business) at Washington University in St. Louis (this latest report is a joint effort with the Mercatus Center at George Mason University). Most of these syntheses focus on federal regulation, as does an annual report required of OMB since 1997 that outlines the costs and benefits of all federal regulations (OMB 1997; 1999; 2000; 2001: 2002).[11] Johnson (2001)[12]

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[4]Weidenbaum, M., and R. DeFina. 1978. "The cost of federal regulation of economic activity." American Enterprise Institute, Washington, DC.

[5] Litan, R., and W. Nordhaus. 1983. Reforming federal regulation. New Haven: Yale University Press.

[6] Hahn, Robert W., and John A. Hird. 1990. The Costs and Benefits of Regulation: Review and Synthesis. *Yale Journal on Reguation* 8: 233.

[7] Hopkins, Thomas D. 1992. Costs of Federal Regulation. *Journal of Regulation and Social Costs* 2, no. 1: 5-31. Hopkins, Thomas D. 1995. *Profiles of Regulatory Costs*, Rochester Institute of Technology, Rochester, NY. Hopkins, Thomas D. 1996. *Regulatory Costs in Profile*, Policy Study No. 132. Center for the Study of American Business, Rochester, NY.

[8] Crain, Mark W., and Thomas D. Hopkins. *The impact of regulatory costs on small firms*, RFP No. SBAHQ-00-R-0027. The Office of Advocacy, U.S. Small Business Administration. http://aspe.hhs.gov/health/reports/hipabase/toc.htm

[9] Crews Jr., Clyde Wayne. 1996. *Ten Thousand Commandments: An Annual Policymaker's Snapshot of the Federal Regulatory State*, Competitive Enterprise Institute, Washington, DC . http://www.cei.org/gencon/025,01430.cfm; ———. 1998. *Ten Thousand Commandments: An Annual Policymaker's Snapshot of the Federal Regulatory State*, Competitive Enterprise Institute, Washington, DC . http://www.cei.org/pdf/1194.pdf; ———. 1999. *Ten Thousand Commandments: An Annual Policymaker's Snapshot of the Federal Regulatory State*, Competitive Enterprise Institute, Washington, DC . http://www.cei.org/pdf/1611.pdf; ———. 2000. *Ten Thousand Commandments: An Annual Policymaker's Snapshot of the Federal Regulatory State*, Competitive Enterprise Institute, Washington, DC . http://www.cei.org/pdfs/tenthou2000.pdf; ———. 2001. *Ten Thousand Commandments: An Annual Policymaker's Snapshot of the Federal Regulatory State*, CATO Institute, Washington, DC . http://www.cato.org/tech/pubs/10kc_2001.pdf; ———. 2002. *Ten Thousand Commandments: An Annual Snapshot of the Federal Regulatory State*, CATO Institute, Washington, DC . http://www.cato.org/tech/pubs/10kc_2002.pdf; ———. 2003. *Ten Thousand Commandments: An Annual Snapshot of the Federal Regulatory State*, CATO Institute, Washington, DC . http://www.cato.org/tech/pubs/10kc_2003.pdf;

[10] Dudley, Susan, and Melinda Warren. 2003. *Regulatory Spending Soars: An Analysis of the U.S. Budget for Fiscal Years 2003 and 2004*, Regulatory Budge Report 25. Mercatus Center, George Mason University and Murray Weidenbaum Center on the Economy, Government, and Public Policy, Arlington, VA, and St. Louis, MO.

[11] Office of Management and Budget, Office of Information and Regulatory Affairs. 1997. *Report to Congress on the costs and benefits of federal regulations*, Office of Management and Budget, Office of Information and Regulatory Affairs; ———. 1999. *Report to Congress on the costs and benefits of federal regulations*, Office of Management and Budget, Office of Information and Regulatory Affairs.

———. 2000. *Report to Congress on the costs and benefits of federal regulations*, Office of Management and Budget, Office of Information and Regulatory Affairs; ———. 2001. *Making sense of regulation: 2001 report to Congress on the costs and benefits of regulations and unfunded mandates on state, local and tribal entities*, Office of Management and Budget, Office of Information and Regulatory Affairs; ———. 2002. *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benfitrs of Regulations and Unfunded Mandates on State, Local and Tribal Entities*, Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC. http://www.whitehouse.gov/omb/inforeg/2002_report_to_congress.pdf; ———. 2003. *Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benfitrs of Regulations and Unfunded Mandates on State, Local and Tribal Entities*, Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC. http://www.whitehouse.gov/omb/inforeg/2003_cost-ben_final_rpt.pdf; ———. 2004. *Informing Regulatory Decisions: 2004 Draft Report to Congress on the Costs and Benfitrs of Regulations and*

provides a comprehensive review and synthesis of the cost of workplace regulations whose scope and style are the inspiration for our own synthesis. These previously works have largely steered clear of health services regulation: to the excess they consider health regulation at all, the focus is on health and safety regulation (e.g., OSHA, Consumer Product Safety Commission) rather than regulation of health services.

While the scope of what we have done differs from these other syntheses, the methodology is very similar, namely deciding on which specific aspects of regulation fall under the umbrella of health services regulation, systematically surveying the literature to find evidence about benefits and costs and reconciling the competing estimates to arrive at an expected figure in each domain. Relative to these other efforts, we have had to do more "patching and filling" to arrive at our final figures. For example, while there are dozens of studies that have looked at the impact of certificate of need regulation on total or hospital costs, no one previously had attempted to quantify the aggregate national impact of having such laws in place. This required us to take the best scientific evidence regarding CON's effects on costs and applying these figures to estimates of health spending in the particular states that still retain this form of regulation. In contrast, applying these estimates to the entire amount spent on health care in the U.S. would have overestimated CON's impact. Hence, we believe it was worth the effort to arrive at a more accurate estimate, but this was not as simple as just lifting an aggregate national cost impact figure from a previously conducted study.

I would like to thank you again for the opportunity to testify and the chance to provide this further information for the record. If you have any further questions, please feel free to contact me (919) 684-8026 or e-mail conoverc@hpolicy.duke.edu.

Best wishes,

Christopher J. Conover, PhD
Assistant Research Professor of Public Policy Studies
Terry Sanford Institute of Public Policy
Director, Health Policy Certificate Program and
Senior Fellow, Health Inequalities Program

Unfunded Mandates on State, Local,and Tribal Entities, Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC. http://www.whitehouse.gov/omb/inforeg/draft_2004_cbreport.pdf

[12] Johnson, Joseph M. 2001. A Review and Synthesis of the Cost of Workplace Regulations. Mercatus Center, George Mason University.

TESTIMONY OF DAN MULHOLLAND[1]
BEFORE THE JOINT ECONOMIC COMMITTEE
MAY 13, 2004

Health care can mean the difference between life and death. Doctors, hospitals, nurses and other health care providers do their best day in and day out to save lives, help the sick and injured, and comfort the dying. There is no way their contributions to society can be measured, in dollars or otherwise. But the cost of governmental regulation of the health care field can be quantified – objectively and subjectively. Either way, it's far too high. It is especially ironic that the Federal government – which is the largest single payer for health care – is also its biggest cost-driver by virtue of the volumes of confusing and often self-contradictory rules that have been imposed on health care providers over the years.

The health care regulatory system has reached the point where no one – no doctor, no hospital, no lawyer, no government agency – can even begin to fully understand it, let alone comply with it. This hampers the ability of caregivers to provide vitally needed services in an environment where virtually everything they do can be second-guessed by lawyers, whistleblowers or government agents. The costs imposed by such unnecessary and burdensome rules are ultimately borne by consumers and taxpayers. Even more troubling is the fact that the regulatory system has sewn the seeds of distrust among health care providers, who must work as a team to furnish quality health care services. Unless meaningful regulatory reform is pursued, our health care system will continue to deteriorate.

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The statutes and regulations that apply to health care providers are too numerous to mention. However, certain federal laws bear particular attention, because they have had the opposite effect of what they were intended to accomplish. Rather than improve the quality of health care services or enhance access to care, these laws have driven a wedge between health care providers, fostered disruptive conflicts, and actually reduced the availability of needed health care services, while driving up costs. Examples of such well-meaning but counter-productive regulatory schemes that will be highlighted in this testimony include the Emergency Medical Treatment and Active Labor Act ("EMTALA"),[2] the Privacy Regulations adopted under Health Insurance Portability and Protection Act ("HIPAA"),[3] Medicare prohibitions on "physician self-referral" (the so-called "Stark Law"),[4] and the National Practitioner Data Bank.[5]

1. EMTALA

The EMTALA statute was passed in 1985 in response to concerns that patients were being denied needed emergency medical treatment because they could not afford to pay. The law requires all hospitals to provide a medical screening examination as well as stabilizing treatment to any patient presenting to the hospital's emergency department prior to admitting, discharging or transferring the patient. This seems fairly straightforward and, on its face, unobjectionable. However, like so many other laws, the devil is in the details. One of the provisions of EMTALA[6] requires hospitals to maintain a roster of physicians who are "on call" to provide specialized treatment. If a patient needs the services of a specialist, that physician must respond

to the call from the emergency room or face sanctions along with the hospital for violations of EMTALA.

Prior to EMTALA, hospitals had informal relationships with on-call physicians. With the exception of a handful of highly publicized cases where patients were turned away from emergency rooms, this system worked well. However, once EMTALA was enacted, and on-call procedures became more rigid and formalized, the fear of sanctions for failing to properly respond to a call from the emergency department has caused doctors to be less willing to voluntarily provide emergency room call coverage. The EMTALA on-call requirement coupled with the potential for greater exposure to malpractice liability resulting from treating patients in an emergency room setting, has led many doctors to demand payment for providing call coverage. This has created a serious strain on fragile hospital finances and driven up the cost of care.

In some markets, physicians have refused to provide call altogether or retired from active practice because of the demands placed on them by the formalized EMTALA on-call rules. In one community, Lake Charles, Louisiana, there used to be five neurosurgeons who were available to provide call coverage at the two tertiary hospitals in that city. Now there are only two. According to health care executives in that community, this was a direct result of the increased burden placed on the neurosurgeons as a result of EMTALA call coverage requirements.

As a result, emergency room call coverage for neurosurgery can only be provided in that community two out of every three weeks. During the week when there is no neurosurgery coverage, patients with serious head or spinal trauma must be transferred to other communities, which can seriously jeopardize their health or even their lives. A similar situation occurred in Las Vegas, Nevada last year, which received national attention. Trauma centers had to close because of the lack of neurosurgery coverage. Similar problems have been reported across the country, in communities large and small. Access to vital emergency services is threatened as a result of a law originally designed to enhance access to those services.

2. HIPAA Privacy Regulations

The HIPAA privacy regulations are another example of good intentions having less than favorable results. No one can argue that patients have a reasonable expectation that their medical information will be maintained in a confidential manner. This was a universally accepted principle observed by health care providers for years. However, the regulations issued by HHS to implement the privacy provisions of the HIPAA statute attempt to micro-manage virtually every conceivable communication involving health information and have snarled health care providers in red tape. Hospitals, physician offices and other health care providers have spent substantial amounts trying to comply with these rules. With the advent of the HIPAA security regulations scheduled to go into effect next year, even more costs will be imposed. These costs and the disruptions associated with changing basic practices to comply with these complex rules not only demoralize health care providers. They also breed distrust between patients and

providers when informal confidentiality rules that have been respected for centuries are now replaced by diktat which simply serve as a trap for the unwary.

3. The Stark Regulations

The regulations issued on March 26, 2004[7] interpreting the prohibitions against physician referral of "designated health services" to hospitals and other entities under Section 1877 of the Social Security Act (commonly called the "Stark Law" after its sponsor Rep. Pete Stark, the ranking minority member of this Committee) are even more mind-numbingly complex. The law that these regulations implement started from the reasonable premise that physicians who owned clinical laboratories would have an economic incentive to order more tests, some of which may not be medically necessary. However, now that that statute has been amended to cover a wide variety of "designated health services" (including all inpatient and outpatient hospital services), <u>any</u> financial relationship between a hospital and a physician, no matter how small or inconsequential, is presumptively illegal. The regulations implementing this law define the concept of "financial relationships" so broadly that even seemingly innocuous things such as free meals at the hospital's cafeteria, quality-enhancing continuing medical education, or time-honored customs such as professional courtesy can be challenged if they do not fit within the narrow confines of the rules. Hospitals are now saddled with onerous record-keeping requirements having to account for every benefit (both monetary and non-monetary) realized by physicians who practice at the hospital. This will lead to substantial additional compliance costs

and legal fees. It will also further erode the relationship between hospitals and physicians, who may fear that any kind of economic relationship could be suspect.

The concern about these regulations is heightened by the fact that anyone can, pursuant to the whistleblower provisions under the False Claims Act,[8] secretly charge a hospital or physician with violations of the Stark law and stand to recover a huge windfall completely disproportionate to any impact that the hospital-physician relationship might have on the Medicare program. For example, under the new regulations, if a hospital provided a dinner for members of its medical staff which cost more than $25 per doctor, the dinner would constitute an "incidental benefit" that would technically exceed the regulatory threshold and taint the entire relationship between the hospital and each physician. As a result, every referral by those doctors to the hospital could be found to violate the Stark law and give rise to False Claims Act penalties of $11,000 per referral plus three times the amount paid to the hospital by Medicare. The whistleblower could receive up to 30% of this penalty. It is hard to believe that this was ever contemplated when this law was enacted.

These rules are creating a state of paranoia among providers. They will likely create an atmosphere where providers will avoid otherwise beneficial relationships for fear that violating these rigid rules will result in ruinous liability. Once again, patients will ultimately suffer if the professionals and institutions who serve them forgo the benefits of closer integration due to fear of government sanctions.

4. National Practitioner Data Bank

Finally, the National Practitioner Data Bank has created an extremely adversarial relationship between doctors and hospitals. To some extent, it actually threatens the future of voluntary medical peer review. The Data Bank was enacted as part of the Health Care Quality Improvement Act of 1986[9] as a mechanism of enabling health care entities and licensure boards to find out if doctors had been subject to licensure sanctions, professional review actions or malpractice payments. Among other things, any final professional review action by a hospital, as well as any resignation by a doctor while under investigation or in return for not conducting one, needs to be reported to the Data Bank. This has led to a situation where even minor hospital peer review inquiries are fought tooth and nail by physicians who fear that they may ultimately lead to a Data Bank report. Hospitals have also been sued by physicians alleging that reports to that Data Bank were defamatory, sometimes because the hospital simply used reporting codes mandated by the Health Resources Services Administration.[10]

As a result, every peer review action is now likely to be contested because it could lead to what is perceived to be a career damaging report to the Data Bank. Doctors on peer review committees are therefore less likely to aggressively pursue bad medicine for fear of being embroiled in nasty litigation. Thus, the peer review system, which is the only meaningful mechanism to assure the ongoing quality of medical services, has been threatened by a well-intentioned attempt to track physicians who have had competence or behavioral problems.

These are just a few examples of the many rules and regulations that impact the relationships of health care providers. These regulations impede rather than facilitate the delivery of quality and affordable care. This situation is compounded by the byzantine Medicare reimbursement rules, the failure to enact meaningful tort reform, and often conflicting federal and state regulatory schemes which impose additional burdens. Health care providers should be free to care for patients, not saddled with rules that impede their ability to do so. We would therefore respectfully suggest that this Committee, as well as all policymakers in both the Legislative and Executive branches of government, carefully assess the regulatory burden on the health care system and take into account the costs and practical effects of any future regulatory initiatives.

ENDNOTES

1. Mr. Mulholland is a senior partner in the health care law firm of Horty, Springer & Mattern, P.C. in Pittsburgh, Pennsylvania. The firm represents and advises hospitals and health systems throughout the country. In providing testimony to the Committee, Mr. Mulholland is not acting on behalf of any client.
2. 42 U.S.C. §1395dd
3. 45 C.F.R. Parts 160 and 164
4. 42 U.S.C. §1395nn
5. 42 U.S.C. §11131 et seq.
6. 42 U.S.C. §1395cc(a)(1)(I)
7. 69 Fed. Reg. 16054
8. 31 U.S.C. §3729
9. 42 U.S.C. §11101 et. seq.
10. E.g., Wheeler v. Methodist Hospital, 95 S.W.3d 628 (Tex. App. 2002), Stephan v. Baylor Med. Ctr., 20 S.W. 3d 880 (Tex. App. 2000); Simpkins v. Shalala, 999 F. Supp 106 (D.D.C. 1998).

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May 19, 2004

Dan Mulholland
Horty, Springer & Mattern
4614 Fifth Avenue
Pittsburgh, PA 15213

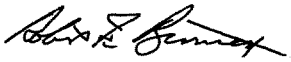
Dear Mr. Mulholland:

Thank you for testifying before the Joint Economic Committee on May 13, 2004 at the hearing on the Burden of Health Services Regulation. I appreciate you taking the time to share your expertise with Congress on this important issue. I am writing with an additional question as a follow-up to the hearing. This question and your answer will be included in the record of the hearing's proceedings.

- In your testimony you say that no hospital, doctor, lawyer or government agency, can understand the complexities of the system. Are we punishing doctors and administrators for violations of federal regulations of which they are unaware?

Should you have any questions about this inquiry, please do not hesitate to contact me or Tom Miller, of my Joint Economic Committee staff, at (202) 224-5171.

Sincerely,



Robert F. Bennett
United States Senator

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May 27, 2004

Senator Robert F. Bennett
c/o Joint Economic Committee
Congress of the United States
Washington, DC 20510-6602

Re: Hearing on Burden of Health Services Regulation
May 13, 2004 – Follow-Up Question

Dear Senator Bennett:

Thank you for your letter dated May 19, 2004. Your letter posed the following question:

> In your testimony you say that no hospital, doctor, lawyer or government agency, can understand the complexities of the system. Are we punishing doctors and administrators for violations of federal regulations of which they are unaware?

My response is as follows:

> We frequently encounter situations in our law practice where health care providers are genuinely surprised to find out the common practices may violate some federal or state statute or regulation. Providers frequently have only a vague understanding that some federal or state law might apply to a particular transaction, but they rarely fully understand what rules apply or how the regulations work.
>
> An example would be the way in which medical groups compensate their physician employees. The recently enacted physician self-referral regulations establish very complicated rules for when and under what circumstances physicians can be compensated for revenue generated by in-office lab tests, x-rays or other "designated health services." These rules are not intuitive, and often run counter to normal physician compensation practices. How the physician can be paid varies based on whether the physician is a hospital employee, a solo practitioner, or a member of a group practice.

There have also been occasions when hospitals have been forced to pay civil money penalties for billing errors that were the result of confusing, vague or inconsistently applied regulatory rules or guidance. This happened on a large scale several years ago when hospitals were called to task for "unbundling" clinical lab tests that were performed for patients for the purposes of Medicare reimbursement. Hospitals that were erroneously paid by Medicare were forced not only to repay this money to Medicare, but also paid substantial amounts over and above the repayment and were forced to sign complicated, costly and onerous "corporate integrity agreements" with HHS.

The rules that govern health care have evolved to the point where they either serve as a trap for the unwary or a road map for individuals and organizations who wish to take advantage of every loop hole and penalize the government and thereby the taxpayers. The conscientious providers who do their best to follow the rules are saddled with significant legal and consulting fees and compliance costs. Once again, we would urge that Congress carefully consider the ramifications of any broad ranging statute that might impose more regulations on health care organizations.

I hope that this response is helpful to you. If you have any other questions, or if I can ever be of any other assistance to the Committee, please don't hesitate to contact me.

Sincerely,

Daniel M. Mulholland III

DMM/djm

cc: Tom Miller

136980.1

Testimony of

Professor David A. Hyman, M.D., J.D.

University of Maryland School of Law

Before the Joint Economic Committee

United States Congress

Hearing on Health Services Regulatory Costs and the Uninsured

10:00 a.m., May 13, 2004

Mr. Chairman and Members of the Committee:

Thank you for inviting me to testify before you today. I am currently a professor at the University of Maryland School of Law. As of July 1st, 2004, I will be a Professor of Law and Medicine at the University of Illinois. I am also currently serving as Special Counsel to the Federal Trade Commission. I am here only in my academic capacity; none of my remarks, whether written or oral, should be imputed to the Commission or to any of the individual Commissioners. Much of what I will say today is drawn from a series of articles I have written on the regulation of health care.[1]

I commend the Committee for considering these issues. The impact of regulation on health care is a matter of vital importance, because it affects the cost, quality, and availability of medical services. Regulation has both benefits and costs. For obvious reasons, there is a tendency to focus on the benefits of regulation – and those benefits can be quite considerable. The difficulty is that regulation has costs as well – and those costs must be carefully considered, to avoid doing more harm than good. In the context of our discussion today, excess regulation makes health care more expensive and can make health care coverage unaffordable – leading to an increase in the uninsured. It is economically inefficient to adopt regulations whose costs exceed their

[1] *See, e.g.*, David A. Hyman, "Why Competition Law Matters to Health Care Quality," 22 Health Affairs 31-44 (March/April, 2003) (with William Sage and Warren Greenberg); David A. Hyman, "What Lessons Should We Learn From Drive-Through Deliveries?" 107 Pediatrics 406-8 (2001); David A. Hyman, "Do Good Stories Make For Good Policy?" 25 J. Health, Politics, Pol'y & L. 1149-1155 (2000); David A. Hyman, "Regulating Managed Care: What's Wrong With A Patient Bill of Rights," 73 S. Cal. L. Rev. 221-275 (2000); David A. Hyman, "Accountable Managed Care: Should We Be Careful What We Wish For?," 33 U. Mich. J. L. Ref. 785-811 (1999); David A. Hyman, "Managed Care at the Millennium: Scenes From A Maul," 24 J. Health, Politics, Pol'y & L. 1061-1070 (1999); David A. Hyman, "Drive-Through Deliveries: Is Consumer Protection Just What the Doctor Ordered?," 78 N.C. L. Rev. 5-99 (1999); David A. Hyman, "Consumer Protection and Managed Care: With Friends Like These. . .," 1998 Health L. Handbook 283-305 (1998); David A. Hyman, "Consumer Protection in a Managed Care World: Should Consumers Call 911?," 43 Vill. L. Rev. 409-466 (1998); David A. Hyman, "Lies, Damned Lies, and Narrative," 73 Indiana L. J. 797-865 (1998); David A. Hyman, "Patient Dumping and EMTALA: Past

benefits – and there is plenty of evidence to suggest that we routinely do exactly that in health care. Such regulation may be popular – but that does not change the fact that it wastes our scarce resources and worsens the straits of the poorest and least powerful among us.

The problem has been studied at length by law professors, economists, and political scientists. The basic difficulties can be summarized in a few paragraphs. Few legislators and regulators have the necessary training or time to weigh the (often conflicting) evidence on the benefits of any given legislative initiative. Evidence on the cost of a particular intervention is frequently unavailable, and estimates are subject to considerable uncertainty. The time-frame for doing empirical research on the matter under consideration is counted in months and years, while the time-frame for legislation and regulation is counted in days and weeks. Because the "lowest-hanging fruit" is targeted first, incremental regulatory efforts are more likely to be non-cost-justified. The drafting of legislation is also readily hijacked by entrenched providers, who have their own interests at heart. When these factors are coupled with the emotional overlay accompanying health care issues, the off-budget feature of many of the reforms, and the extensive scope of pre-existing regulation, it should come as no surprise that health care is particularly prone to non-cost-justified regulation and legislation.

The consequences for the nation's health are significant. Higher prices make it more difficult for many Americans to obtain health insurance and needed care. Many small employers do not offer health insurance at all because it is too expensive.[2] When employers offer health insurance, price increases can result in limitations on coverage, employees refusing to sign up for insurance,

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Imperfect/Future Shock," 8 Health Matrix 29-56 (1998).

[2] David A. Hyman & Mark Hall, *Two Cheers for Employment-Based Health Insurance*, 2 Yale J. Health Pol'y, L. & Ethics 23, 26 (2001). See also Kaiser Family Foundation/Health Research and Educational Trust Employer Health Benefits 2003 Annual Survey, http://www.kff.org/insurance/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=21185, at Chart 12; Feldman, R., Dowd, B., Leitz, S. & Blewett, L., "The Effect of Premiums on the Small Firm's Decision to Offer Health Insurance" Journal of Human Resources, 32(4):635-58 (1997) (estimating a fairly high firm-level demand elasticity for health insurance (-3.91 for single coverage, -5.82 for family coverage), and calculating that if monthly premiums to firms increased by $1, the proportion of firms offering health insurance to employees would decline by almost 2 percentage points.)

and employers dropping coverage.[3] Estimates of the price elasticity of health insurance vary, but no one believes that increasing prices above their current levels result in more people purchasing insurance.[4] Numerous studies establish that the lack of health insurance has deleterious consequences, including increased mortality – 18,000 deaths per year by one estimate.[5] The Institute of Medicine recently concluded that the uninsured receive too little medical care and receive it too late; are sicker and die sooner; and receive poorer care when they are in the hospital even for acute situations like a motor vehicle crash.[6]

Stated differently, non-cost-worthy regulation is likely to have a systemic adverse effect on the quality of care actually provided to the population as a whole. People may die or suffer adverse outcomes if their insurance does not cover "everything," but they will also die or suffer adverse outcomes if they are unable to afford health insurance. A policy of "quality above all else" can price the standard of care beyond the budget of many Americans, and undermine the quality of care actually received. Stated differently, setting an inefficiently high level of health care quality as the mandatory minimum ignores both the short-term consequences for price and access and the long-term consequences of increased price and decreased access on quality. Conversely, lower prices can actually contribute to higher quality. As an article I co-authored last year in Health Affairs noted, "when costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions."[7]

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[3] *See* http://www.kff.org/insurance/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=21185 , at Chart 27-28.

[4] Sherry Glied, Dahlia K. Remler & Joshua Graff Zivin, *Inside the Sausage Factory: Improving Estimates of the Effect of Health Insurance Expansion,* 80 Milbank Q. 603 (2002).

[5] *See* Institute of Medicine, Insuring America's Health: Principles and Recommendations (January, 2004) http://www.iom.edu/includes/DBFile.asp?id=17736

[6] *See* Institute of Medicine, Care Without Coverage: Too Little, Too Late (May, 2002) http://www.iom.edu/includes/DBFile.asp?id=4160.

[7] Sage, W., Hyman, D., & Greenburg, W., "Why Competition Law Matters to Health Care Quality" Health Affairs, 22:2 at 35 (March/April 2003).

We should not place the poor and less fortunate in the position of choosing between "nothing but the best and nothing" when it comes to health care coverage – but excessive regulation will do exactly that.[8]

Health Care Regulation: The Case of Mandates

Health care regulation comes in a wide variety of forms. For our purposes today, I will focus on state and federal mandates of health insurance benefits. Mandated benefits fall into three general categories: (1) *provider mandates,* which require health insurers to cover services provided by certain providers or categories of providers (*e.g.*, any-willing provider laws and laws mandating coverage of services provided by a select group of providers (*e.g.,* massage therapists or naturopaths)); (2) *coverage mandates,* which require health insurers to cover particular classes of individual patients and conditions (*e.g.*, mental health parity); and (3) *benefit mandates,* which require health insurers to provide a specified minimum level of benefits (*e.g.*, 48 hour postpartum hospitalization, direct access to specialists). Some states mandate few benefits, while others do so as a matter or routine. The federal government mandates a small number of benefits.[9]

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[8] David A. Hyman, *Accountable Managed Care, supra* note 1, at 802-803 ("Perhaps that result accords with our ethical sensibilities, but it is cold comfort to those who must now choose between nothing but the best and nothing.") *See also* Uwe E. Reinhardt, Uncompensated Hospital Care, in Uncompensated Hospital Care: Rights and Responsibilities 1, 11 (Frank A. Sloan et al. eds., 1986) ("The champions of the poor, and the poor themselves must recognize that, in the political and budgetary climate of the 1980s [and 1990s], pursuit of the maxim 'for the poor, nothing but the best' may leave the poor with nothing.").

Similar difficulties have been noted in the impact of tort law on access to medical care. *See* John A. Siliciano, Wealth, Equity, and the Unitary Malpractice Standard, 77 Va. L. Rev. 439, 486-87 (1991) ("Tort law instructs health care providers to treat the poor the same as the rich, but then blithely ignores the fundamental impact that resource scarcity and the provider's freedom to refuse care to the poor have on the efficacy of its command... By embracing the chimera of equality between the rich the poor, [tort law] effectively disables health care providers from offering reasonable, low-cost care to large numbers of the medically indigent. Thus, through its adherence to the unitary ideal, tort law may end up killing the poor with an unthinking and misguided kindness.")

[9] Federal mandates include the 1978 Pregnancy Discrimination Act, the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), the 1996 Health Insurance Portability and Accountability Act (HIPAA), the 1996 Mental Health Parity Act, the 1996 Newborns' and Mothers' Health Protection Act, and the Women's Health and Cancer Rights Act of 1998.

Proponents offer a number of reasons for supporting mandates.[10] Some proponents view health care as a "merit good" and suggest that mandates are a way of preventing discrimination against particular conditions. Others believe mandates provide access to benefits valued by beneficiaries but withheld by employers or insurers. Some proponents argue that mandates can correct for informational asymmetries, bounded rationality, and adverse selection in the insurance market. If employees have more information about whether they will face high medical bills than employers do, employers that provide generous fringe benefits may end up attracting employees who are disproportionately likely to make expensive claims. This dynamic might discourage employers from offering comprehensive benefits to employees. Additionally, many insurers and employers might be reluctant to offer a benefit that attracts high cost employees or beneficiaries.

Opponents of mandated benefits argue that forced inclusion of insurance benefits raises premium costs, and may lead employers to opt out of providing health insurance, and employees to drop their coverage.[11] Opponents generally argue that the free market is likely to do a more efficient job allocating resources between health insurance and other consumer goods (and arriving at coverage terms for the amounts spent on health insurance) than the state or federal government. Mandating benefits takes away the option of the lower priced insurance and forces consumers to pay for insurance they may not want or to go without coverage at all. Compliance with mandates is difficult for employers and insurers operating in multiple states – unless the employer opts for a self-funded employee benefit plan, which is not subject to such mandates.[12] Thus, state mandates can actually decrease the number of covered lives in state-regulated insurance plans – and the more aggressive the state, the greater the impact. The burden of mandates is not uniformly shared. When mandates are group-specific, there is evidence that the cost of those

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[10] Russell Korobkin, *The Efficiency of Managed Care "Patient Protection" Laws: Incomplete Contracts, Bounded Rationality, and Market Failure*, 85 CORNELL L. REV. 1, 8 (Nov. 1999). *See also* Lawrence H. Summers, *Some Simple Economics of Mandated Benefits*, AM. ECON. REV., 79:2 (May, 1989) 177-183, at 178 (suggesting that individuals may "irrationally underestimate the probability of catastrophic health expenses, or of a child's illness that would require a sustained leave.")

[11] *See* David A. Hyman, *Consumer Protection in a Managed Care World: Should Consumers Call 911?*, 43 VILL. L. REV. 409, 437 (1998) ("Policy sellers must weigh whether broadening coverages . . . [is] worth doing if [it] price[s] the policy out of the market – or result[s] in a shift in the nature of coverage from that which is most appealing to the covered pool as a whole."); Mark A. Hall, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS AND ECONOMICS OF RATIONING MECHANISMS at 22, 24 (1997) (identifying mandates as an important source of inefficiency, and observing that "[e]conomists explain that it usually makes no sense to mandate or encourage insurance that many consumers are unwilling to buy.")

[12] It is no accident that Professor Conover found that the cost of regulation would have been substantially larger absent ERISA preemption.

mandates are regressively shifted to the targeted group.[13] Mandates can also encourage overuse of the covered services.[14]

The need for many mandates is also questionable; health insurers have obvious economic incentives to offer the benefits that consumers desire and are willing to pay for. In order for mandates to improve the efficiency of the health insurance market, state and federal legislators must be able to identify services the insurance market is not currently covering for which consumers are willing to pay marginal cost. This task is challenging under the best of circumstances -- and benefits are not mandated under the best of circumstances. As noted previously, providers of the mandated benefit are usually the most vigorous proponents of the mandate. This fact makes it more likely that the mandated benefit constitutes "provider protection" and not "consumer protection."

Mandates are likely to limit consumer choice, eliminate product diversity, and raise the cost of health insurance. The result is to increase the number of uninsured Americans, as employers and employees opt out of the market. Those who do have health insurance are forced to pay more for it than they otherwise would – limiting the amounts they have available for other needs and wants.

Regulatory Theory: Comparative Institutional Imperfection

It is elementary health economics that there are a variety of imperfections in the markets for health care coverage and delivery. These imperfections affect virtually every aspect of the relationships between providers, payors, and consumers. A non-exhaustive list of these imperfections would include the reality that physicians are at best imperfect agents for patients in providing diagnostic services and treatment options, and employers are at best imperfect agents for employees in selecting health plans and coverage terms. ERISA compounds these problems, by insulating some decisions from effective review. In addition, information is costly, and it is frequently inefficient for any given patient to invest the necessary effort to learn about such

[13] Jonathan Gruber, *The Incidence of Mandated Maternity Benefits*, AMERICAN ECON. REV., 84:3 (Jun., 1994) 622, 639.

[14] Gruber, AMERICAN ECON. REV. at 640. For example, the number of cesarean births per 1,000 population doubled from 1975 to 1981 after maternity coverage was mandated

matters in advance. Quality is difficult to assess, let alone value -- and employers and employees are likely to differ on the appropriate mix of cost, quality, and access, even before illness strikes. Many employers provide few (or no) health plan alternatives to their employees. Because plans are a "bundled" product aimed at a diverse workforce, the alternatives which any given employer offers frequently do not include desired and desirable features from the perspective of any given employee.

Additional difficulties are created by the bounded rationality of consumers. Even if consumers behave rationally when it comes to health care coverage and delivery (itself a contested assumption), there may be circumstances in which it is rational not to pay much attention to one's health insurance contract. The chronically ill may care a great deal about whether their physician is covered by their new insurance plan, but those who are well are understandably less concerned with such matters. Life is short, and reading the fine print in one's insurance contract is not high on most peoples' list of favorite weekend activities -- particularly when they do not perceive that their efforts will have any effect on the terms of the contract. Even if one is prepared to read the insurance contract, it does not follow that one will pay attention to the specific terms which, after-the-fact, turn out to be important. Against this backdrop, "bounded rationality" constrains the operation of market forces which would normally ensure the optimal mix of quality and price.

In the view of many commentators, the government can correct these imperfections with judicious regulation. The argument is quite straightforward. The government has the information, resources, and expertise to develop optimal managed care contract terms. Indeed, if such terms are a public good, no one will be willing to invest the necessary effort to develop such terms. Because the terms will be universal, the distorting effects of adverse selection are also greatly attenuated. The government also has the credibility to resolve these matters impartially, because it has no economic interest in the outcome. Finally, the whole point of living in a representative democracy is to provide a legislative forum for addressing such matters, and to protect those who cannot protect themselves.

Although these arguments might seem appealing, there are significant reasons to be skeptical about the likely merits of government intervention into these markets. It is easier to identify

agency conflicts and bounded rationality than it is to solve such problems.[15] A regulatory solution will not necessarily solve these problems, and it may well make them worse. The internal plan trade-offs must be made, no matter whether it is an employer or the government doing so -- and there are no guarantees that the government can do it better than anyone else, particularly in light of the heterogeneity of employee preferences, and the reality that quality and value are difficult for both employers and government to assess. Government is also subject to symbolic blackmail on behalf of sympathetic identifiable patients, and interest group lobbying.[16]

Similarly, claims of bounded rationality are subject to severe hindsight bias. After illness strikes, everyone involved has an understandable incentive to exaggerate how their behavior would have been different "had they only known" -- including their willingness to have paid higher premiums to secure coverage. *Ex ante*, willingness to pay is not nearly so apparent. These facts significantly undermine the validity of bounded rationality as a basis for regulation.

Even if bounded rationality is a significant problem, the bounded rationality of any given individual is compensated for by the presence of knowledgeable repeat-player agents in the employee benefits department, who negotiate on behalf of their employees. Of course, it does not follow that employers are the only entity that could provide these services, and the use of employers as agents has certain disadvantages. Finally, if bounded rationality is actually a serious problem in the health insurance market, it is hard to explain the far-better documented phenomenon of adverse selection.[17] Regardless, it is important to note that markets can function even in the presence of bounded rationality, since it only takes a few knowledgeable purchasers to drive the market.

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[15] *See* Christine Jolls, Cass R. Sunstein & Richard Thaler, *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471, 1485 (1998) ("Any suggestion that the government should intervene in response to people's mistakes raises the question whether the government will be able to avoid such errors.")

[16] *See* John P. Dwyer, *The Pathology of Symbolic Legislation*, 17 ECOLOGY L. Q. 233, 287 (1990) ("Once Congress has taken the position that public health must be protected at any cost, it is difficult for the legislature to adopt a more moderate position. Position-taking by other legislators and charges of trading lives for dollars will deter many legislators from supporting such amendments.")

[17] *See* MARK HALL, MAKING MEDICAL SPENDING DECISIONS 53(1996) (outlining cases where severe adverse selection has been documented). Stated more concretely, adverse selection can only occur if consumers understand the terms of their insurance contracts and act accordingly, while bounded rationality can only exist if consumers do not understand the terms of their insurance contracts. It is difficult to see how these circumstances could exist simultaneously, unless, of course, only some consumers are boundedly rational. The issue is therefore an empirical one as to which effect is larger -- and that issue can not be resolved on theoretical grounds.

The legislative/regulatory process also has its own set of distortions -- a fact which regulatory enthusiasts are prone to overlook. Legislators and regulators tend to identify "necessary reforms" on the basis of bad anecdotes and popular appeal, but that strategy is hardly a recipe for sensible public policies. Legislators and regulators also tend to discount the trade-offs and costs that result from their reforms. In a voluntary insurance market, cost-increasing consumer protections will predictably price some people out of the market -- and it is hardly self-evident where the cost/quality/access equilibrium should be set, let alone whether there should be a single standard for all coverage. The drafting of consumer protections is also readily hijacked by entrenched providers, who have their own interests at heart. Finally, the emotional implications of these issues ensure that legislators will be reluctant to embrace the necessary trade-offs.

These issues are complicated by the way in which the costs of regulation have been presented. Costs are typically expressed in terms of the increased premium per subscriber per month or in terms of the annual percentage increase in premium costs. However, the use of individual costs elides the aggregate cost/benefit issue, which must be considered in weighing the merits of the regulation.[18] The point may be more apparent if one compares this costing strategy to that employed in a typical design defect case against a car manufacturer. The plaintiff invariably argues that the manufacturer could have prevented some horrific accident by spending a nominal amount per car to make a particular improvement. If the jury only considers the cost per car in deciding whether the automobile manufacturer was negligent, the failure of the automotive manufacturer to incur these nominal costs virtually ensures a whopping verdict. However, if the jury must multiply the cost per car by the number of cars sold, and then evaluate how many lives would be saved and lost by incurring that expense, the trade-offs look vastly different. In like fashion, the relevant inquiry for assessing the merits of a proposed regulation is whether it will improve the mix of health care with regard to cost, quality, and access, and by how much, and at what aggregate cost. A debate which focuses on the cost per subscriber per month provides no useful information about the desirability or lack thereof of a patient bill of rights.[19]

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[18] Stated in terms of the Hand formula, an investment in a particular consumer protection is worth doing only if the cost of the initiative (B) is less than the probability of an adverse outcome (p) multiplied by the resulting costs and damages (L). *See* United States v. Carroll Towing, 159 F.2d 169, 173 (2d Cir. 1947).

[19] The argument sometimes made that the cost of a particular treatment was so *de minimus* that the MCO had

These considerations demonstrate that the merits of regulation can not be resolved on the basis of platitudes about "market failure" and "unaccountability." Enthusiasm is not a sufficient precondition to ensure that legislation and regulation will improve on the status quo. The critical institutional competence questions are whether legislators/regulators have the necessary information, preferences, and incentives to beat the alternatives in setting the terms of trade. In economic terms, the issue is which agency relationship (consumer/employer-insurer or constituent/state-federal legislature) is less imperfect across the relevant dimensions of cost, quality, and access. As Richard Epstein has pointedly noted, "it would be easy to assume that collective responses are preferred when markets are corrupt and governments virtuous. It is far harder to reach that conclusion when self-interest and corruption creates difficulties from both quarters."[20]

Health Insurance: An Overview of the Trade-Offs

Although health care contributes to health, not all services are equally beneficial. Fraud aside, there is considerable controversy about how and whether expenses that make a variable contribution to health should be constrained.[21] There is general agreement that it is appropriate for private insurance to provide coverage for services so long as benefits exceed costs. There is equally general agreement that it is appropriate to exclude coverage for services which provide no benefit. However, there is a considerable amount of controversy about the exclusion of services which provide a positive benefit, but one which is less than its social cost (cost-benefit-no-man's-land).[22] Indeed, the prevalence of third-party insurance encourages patients to demand

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no real economic interest in denying coverage is meritless for precisely the same reason.

[20] Richard A. Epstein, *Why is Health Care Special?*, 40 KANS. L. REV. 307, 311 (1992).

[21] Health policy scholars are essentially unanimous that cost-benefit tradeoffs are inevitable. *See, e.g.*, Henry Aaron & William B. Schwartz, *Rationing Health Care: The Choice Before Us*, 247 SCIENCE 418, 419 (1990); David M. Eddy, *Health System Reform: Will Controlling Costs Require Rationing Services?*, 272 JAMA 324, 326 (1994); VICTOR R. FUCHS, WHO SHALL LIVE?: HEALTH, ECONOMICS, AND SOCIAL CHOICE 29 ("We must recognize that we can't have everything"); Lester C. Thurow, *Learning to Say "No,"* 311 NEW ENG. J. MED. 1569, 1569 (1984) ("Instead of stopping treatments when all benefits cease to exist, physicians must stop treatments when marginal benefits are equal to marginal costs.")

[22] *See* Clark Havighurst, *Contract Failure in the Market for Health Services*, 29 WAKE FOREST L. REV. 47, 51-54 (1994) (reviewing realities of the cost-benefit-no-man's land).

such services, because from their perspective, the subsidized cost is less than the benefit.[23] Attempts to constrain coverage of services in the cost-benefit no-man's land invariably triggers complaints about the evils of rationing and profit-driven health care.

Coverage which is more generous is also more expensive. Copayments and deductibles help fine-tune the coverage (and deal with the problem of moral hazard) by allowing for a mix of self-insurance and third-party coverage. Not surprisingly, a policy with a substantial copayment and deductible is substantially cheaper than one which pays for all medically necessary expenses. Similarly, a policy with generous hospitalization benefits is generally more expensive than one which encourages outpatient treatment, provides coverage at a limited number of inpatient facilities, or places strict restrictions on length-of-stay once hospitalized.

Willingness to purchase health insurance is heterogenous, and greatly affected by the premium. As the premium increases, the policy becomes less affordable for people at the margin. Those who are selling the policy must weigh whether better coverage is worth offering if it prices the policy out of the market. Those who would willingly have bought a more limited policy must self-insure (*i.e.*, become one of the approximately forty million uninsured Americans) once the cost of the minimum product exceeds their willingness to pay.

The demand for health care also varies in ways that are generally predictable along a number of parameters, including age, race, and sex. For example, individuals in their 20s and 30s require more sports medicine than those in their 50s; those in their 50s require more cardiac rehabilitation than those in their 20s; elderly men require urologists, younger women require obstetricians and family planning services; children require pediatricians; African-Americans require more treatment for hypertension and renal failure, while European Americans require

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[23] Because an individual with insurance has an out-of-pocket cost much less than the true cost, the social cost-benefit no-man's-land is far larger than the individual cost-benefit no-man's land. In the interest of simplicity, I focus on the social cost – although the growth of managed care arrangements has modified the dynamic somewhat, since individuals now face fewer financial barriers, but greater structural barriers to the consumption of health care services -- precisely the approach suggested by Professor Kenneth Arrow to deal with the moral hazard problems which result from the existence of health insurance:

> If individuals are free to spend as they will with the assurance that the insurance company will pay, the resulting resource allocation will certainly not be socially optimal. This makes perfectly reasonable the idea that an insurance company can improve the allocation of resources to all concerned by a policy which rations the amount of medical services it will support under the insurance policy.

more treatment for malignant melanoma. Because insurance only shifts and spreads risk for which the policy provides coverage, the specification of such coverage necessarily implies a series of tradeoffs within the common pool, with significant distributional implications within and across identifiable groups. For example, coverage of routine mammograms for women in their 40s may preclude coverage of bone marrow transplants for advanced breast cancer patients. Coverage of family-planning services may preclude coverage of more aggressive screening for sexually transmitted diseases. Coverage of aggressive screening for prostate cancer may result in more limited coverage for screening for uterine cancer. Mandates can reallocate resources within the common pool, but new or enhanced services are covered at the expense of something else -- or of increased premiums -- or both.

A Case Study of Regulation in Action: Drive-Through Deliveries

One can examine these dynamics in numerous legislative and regulatory contexts, including EMTALA, and the patient bill of rights. For current purposes, I focus on the campaign against drive-through deliveries. The campaign, which limited or eliminated the economic incentive for an "early" postpartum discharge was waged in state and federal legislatures during the mid-1990s.[24] Maryland was the first state to pass a law on the subject on May 25, 1995, followed by four more states by the end of 1995, and twenty-four more states by the end of 1996. Federal legislation was signed into law on September 26, 1996.

Despite this overwhelming legislative enthusiasm for a prohibition on drive-through deliveries, the case for such a law is actually extraordinarily flimsy. There is little or no evidence indicating postpartum stays of the specified length provide *any* benefit, regardless of how one defines benefit. Even if such stays provide a benefit, it does not follow that the benefit justifies the associated cost, or that same results can not be achieved in some other way at lesser cost. It is equally significant what these laws did not do. Drive-through deliveries were treated as a narrow, free-standing problem, rather than as part of the continuum of maternity care. The

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Kenneth Arrow, *The Economics of Moral Hazard: Further Comment*, 58 AM. ECON. REV. 537, 538 (1968).

[24] It is important to note the normative implications of labeling a postpartum discharge as "early" or "drive-through." *See* Eugene Declercq & Diane Simmes, *The Politics of "Drive-Through Deliveries": Putting Early Postpartum Discharge on the Legislative Agenda*, 75 MILBANK Q. 175, 184 (1997) ("The widespread adoption of the phrase "*early* discharge" was a victory in itself for advocates because it described the problem in a way that suggested mothers and babies might have been sent home prematurely.")

legislation did nothing about the availability of post-discharge services, the quality of services rendered before, during, and after the postpartum hospitalization, the distortions created by hospitals' use of per-diem pricing, and the manner in which managed care organizations ("MCOs") make coverage decisions.

The campaign against drive-through deliveries illustrates many of the problems outlined previously. The case for extended postpartum stays was based almost entirely on wrenching, but extraordinarily unrepresentative anecdotal horror stories and overheated rhetoric. The "reform" exploited social reluctance to make explicit cost/benefit tradeoffs in matters of public health and safety.[25] When even a portion of the costs was on-budget, legislative opposition to drive-through deliveries developed some exceedingly large loopholes. The health care providers who testified in favor of the proposed "consumer protection" neglected to mention that the issue was merely the opening salvo in their campaign against managed care -- and their preferred remedy was a return to the model of professional dominance whose excesses led to managed care in the first place.

As noted previously, twenty-nine states prohibited drive-through deliveries within a year of the issue appearing on the policy agenda. The most interesting feature of the state statutes was their tendency to expressly exclude certain portions of the population from their protections. Of the twenty-nine states which initially enacted such legislation, eighteen states excluded Medicaid beneficiaries. Since Medicaid pays for approximately forty percent of the births in the United States, with the percentage considerably higher in some states, the on-budget costs of such legislation was an obvious factor in the exclusion of the Medicaid population from the statutory ambit. Indeed, California considered such legislation, but deferred action for one year after it determined that the costs associated with prohibiting drive-through deliveries for its Medicaid population were too high. Similarly, nineteen states excluded state employees from the statutory ambit. As with the Medicaid population, the state government would incur on-budget costs if it had to purchase coverage for extended postpartum stays for state employees. Thus, most of the state legislatures displayed concern for the plight of women and infants victimized by a drive-

[25] *See* Clark Havighurst & James F. Blumstein, *Coping with Quality/Cost Trade-offs in Medical Care: The Role of PSROs*, 70 NW. U. L. REV. 6, 7 (1975) ("A policy in which a taboo surrounds any concession to the reality of limited resources is bound to be rich in posturing and assertion"); GUIDO CALABRESI AND PHILIP BOBBITT, TRAGIC CHOICES 26 (1978) ("evasion, disguise, temporizing [and] deception are all ways by which artfully chosen

through delivery only if the state did not have to foot the bill to fix the problem.

Numerous bills prohibiting drive-through deliveries were introduced in Congress in 1995, but Senate Bill 969 became the vehicle for consideration of the issue.[26] In August, 1995, the Senate Labor and Human Relations Committee held its only hearing on the issue. Senators from both parties issued stern warnings about the hazards of drive-through deliveries. The witness list was stacked in favor of the legislation. Although there was a substantial delay due to budgetary disputes between the 104th Congress and President Clinton, the Newborns' Act eventually passed Congress virtually unanimously, and was signed by President Clinton on September 26, 1996.[27] The Newborns' Act incorporated elements from many of the state statutes, but encompassed all insurers in the United States, including self-funded employee benefit plans.

Effective January 1, 1998, the Newborns Act required coverage of at least forty-eight hours of hospitalization following a normal vaginal delivery and ninety-six hours of hospitalization following a cesarean section.[28] An earlier discharge was possible if the physician, in consultation with the mother, decided it was appropriate. However, monetary payments, rebates or offering additional services to mothers to encourage them to accept less than the minimum benefits, or adjusting the compensation of physicians to induce them to discharge patients more rapidly were prohibited as well.

In a striking omission, the Newborns' Act excluded Medicaid recipients from its protections – an omission that was corrected a year later for states employing managed care in their Medicaid programs.[29] Although the original bill that ultimately became the Newborns' Act modestly encouraged the substitution of post-discharge care for postpartum hospitalization, the statute as enacted is silent on this issue and simply specifies that the attending provider, in consultation with the mother, makes the decision as to the time of discharge. For those states that had already

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allocation methods can avoid the appearance of failing to reconcile values in conflict.")

[26] The federal measures included H. Con. Res. 79, 105th Cong.(1995); H.R. 1936, 105th Cong.(1995); H.R. 1948, 105th Cong.(1995); H.R. 1950, 105th Cong.(1995); H.R. 1955, 105th Cong.(1995); H.R. 1970, 105th Cong.(1995); and H.R. 1948/S.969, 105th Cong.(1995).

[27] Newborn and Mothers' Health Protection Act, Pub. L. No. 104-204, 110 Stat. 2935, codified at 29 U.S.C.A. § 1185, 42 U.S.C.A. §§ 300gg-4, 300gg-51 (1996).

[28] 29 U.S.C. § 1185. The same provision restricted the ability of insurers to require physicians to obtain authorization for any particular hospitalization, so long as it was less than the mandated coverage. *See id.*

[29] *See* Balanced Budget Act of 1997, Pub. L. No. 105-33, 4001, 4704, 111 Stat. 275, 496 (1997).

passed legislation, the Newborns' Act provided that state law would govern, so long as it was at least as strict as the federal legislation. During the fourteen month delay between passage of the Newborns' Act and implementation, a number of additional states enacted such legislation.

As it happens, the appropriate postpartum length-of-stay is an exceedingly complex issue, heavily influenced by both social and economic considerations. In recent years, there has been a fairly precipitous broad-based decline in the rate and length of hospitalization for all conditions. If one looks at actual postpartum lengths of stay, it is remarkable how quickly one-day postpartum stays have become commonplace. One-day stays accounted for only 7.6% of vaginal deliveries in 1980, but by 1990, had almost tripled, to 21.2%. In the intervening five years, one-day stays more than doubled again, to almost 47% of vaginal deliveries.[30] There is substantial geographic variation in these figures; maternal postpartum lengths of stay following a vaginal delivery have long been substantially longer in the Northeast and shorter in the West than in the rest of the nation.[31] Postpartum stay following a Cesarean section demonstrates a similar pattern. Surprisingly, states that had the highest percentage of short postpartum stays were exceedingly slow to adopt legislation restricting such practices, while states that had the lowest percentage of short postpartum stays were quickest to adopt such legislation.[32] This pattern is peculiar; from a relative-risk perspective, one would have expected that states that had the highest percentage of such deliveries would face the highest risk from such practices, and thus would be most enthusiastic about such legislation – unless, of course, the legislation was the result of lobbying by providers seeking to maintain their preferred practice patterns in states with relatively low numbers of rapid postpartum discharges.

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[30] National Center for Health Statistics, *National Hospital Discharge Survey: Annual Summary, 1996,* Table 32 (1999) [hereinafter NCHS Discharge Survey]

[31] *See* NCHS Discharge Survey, *supra* at tbl.31; National Center for Health Statistics, *Utilization of Short-Stay Hospitals By Diagnosis-Related Groups: United States, 1980-1984,* tbl.33 (1986); National Center for Health Statistics, *Inpatient Utilization of Short-Stay Hospitals by Diagnosis: United States, 1980,* tbl.4 (1983).

[32] *See* Declercq & Simmes, *supra* note 24, at 192 ("It is therefore in the western region of the country, where postpartum lengths of stay are currently shortest, that legislative actions to lengthen stays are least successful"); Julie A. Gazmararian & Jeggrey P. Koplan, *Length-of-stay after delivery: Managed care versus fee-for-service*, 15 Health Affairs 74, 79 (1996) ("Interestingly, some of the states that recently have enacted legislation mandating hospital stays of forty-eight hours after normal delivery are in the Northeast (New Jersey, Massachusetts, and New York), where lengths-of-stay are the longest and do not vary by plan type and where managed care penetration is lower than

The evidence on the safety of rapid postpartum discharge is outlined in considerable detail in my article on the subject.[33] To summarize briefly, the empirical scholarship does not support the conventional wisdom that there are significant perils associated with rapid postpartum discharge. The major preventable causes of postpartum hospital readmission are jaundice, infection, and dehydration. The risk of readmission for jaundice is the same if the infant is discharged at any time earlier than seventy-two hours, the risk of infection is actually increased by a lengthier stay in the hospital, and the risk of dehydration is not really addressed by postpartum stays of forty-eight hours. Bluntly stated, a small percentage of postpartum women and newborn infants will be readmitted, and a tiny percentage of postpartum women and newborns will die, regardless of the length of their initial hospitalization -- a fact which makes clear the perils of an anecdote-driven approach to the issue. Even if rapid postpartum discharge increases the number of readmissions, in order to prevent one incremental readmission (which will last on average 2.5 days), we will have to provide extended postpartum hospitalization for at least 232 well newborns -- and perhaps as many as 866.[34]

Thus, mandated coverage of forty-eight hours of postpartum hospitalization simply misses the point. Mandated coverage of postpartum hospitalization of the specified lengths has little or no nexus with the detection and prevention of problems likely to result in a bad outcome. Given these results, it is not all that surprising that the Congressionally-mandated report on the Newborns' Act implicitly criticizes the Newborns' Act for its focus on the number of hours of postpartum hospital care, instead of the "needs of the mother and newborn and [] the content and quality of the care they receive."[35]

On the cost side of the ledger, it is no accident that early discharge laws were supported by physicians and nursing groups who provided hospital-based services, and opposed by nursing

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it is in other parts of the country.").

[33] Hyman, *Drive-Through Deliveries, supra* note 1.

[34] *See* Alvah R. Cass & Robert J. Volk, *Early Discharge of Newborns,* 278 JAMA 2065 (1997); Edmonson, *supra* note , at 2067.

[35] *See* Advisory Commission to the Secretary of the Department of Health and Human Services, *Initial Report to Congress Mandated by the Newborns' and Mothers' Health Protection Act of 1996.* The first recommendation of the report is to "broaden the focus of concern beyond the issue of length of stay to the multiple important factors affecting maternal and infant health," and the third recommendation is to "ensure the delivery of health care needed after leaving the hospital, regardless of length of stay. In like fashion, the Report implicitly criticizes the manner in which the campaign against drive-through deliveries was waged by observing that "the goal of postnatal and postpartum services should be to achieve optimal newborn and maternal health in the short-and long-term, and not

groups who provided home care services.[36] As one set of commentators dryly noted, "for those (physicians and nurses associated) with hospital based care, an extra day of hospitalization is a perfectly sensible policy, while those involved in home care see it as a waste of limited resources. As is often the case in health policy issues, self-interest and concern with patients' well-being were likely entangled."[37] Estimates of the cost of extended postpartum stays vary, but childbirth is the most common reason for hospitalization in the United States. I estimated in 1999 that extended postpartum stays impose a cost on this nation of somewhere between $900 million and $1.8 billion every year. If one expresses my estimate of $900 million to $1.8 billion as a percentage of the total cost of health care in the United States, it turns out to be a relatively modest .12 to .24%.[38] On the other hand, if the cost is so modest, it is rather striking that a majority of the states and the federal government were willing to mandate coverage for everyone except the 40% of births in the United States to mothers on Medicaid – and a majority of the states behaved the same with regard to state employees.[39]

From a distributional perspective, a prohibition on drive-through deliveries effectively compels the insurer to transfer resources from the common (insured) pool to those who take advantage of the extended postpartum hospitalization. In Maryland, those individuals were white women, between the ages of nineteen and thirty-five, with private health insurance, who delivered in rural and suburban hospitals.[40] As noted previously, similar results were obtained in another study; women who insisted on forty-eight hours of hospitalization were disproportionately married, college educated, with multiple children, and more than 35 years old.[41] It is very hard to make

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only to prevent rare occurrences such as hospital readmission or catastrophic events leading to death."

[36] *See* Declercq & Simmes, *supra* note 24, at 187 (noting that nursing groups "took positions on this legislation according to whether or not they provided hospital or home care services.")

[37] *See id.*

[38] If one excludes the cost of Medicare and the elderly and disabled Medicaid, the cost is significantly larger, but still modest, ranging from .18% to .35%. As a percentage of the amount currently spent on postpartum hospitalizations, it is a substantially greater amount. *See Nduka U.* Udom & Charles Betley, *Effects of Maternity-Stay Legislation on 'Drive-Through Deliveries,'* 17 Health Aff. 208, 211 (1998) (finding statute resulted in a 10% increase in charges for vaginal deliveries and 6.3% increase in charges for vaginal delivery).

[39] To be sure, Congress subsequently included Medicaid beneficiaries within the protections of the Newborns' Act – but only so long as beneficiaries were enrolled in a Medicaid managed care plan. Because most of the states now have this portion of the Medicaid population in a managed care program, the Balanced Budget Act effectively extended the protections of the Newborns' Act to the Medicaid population. However, because the costs of the Medicaid program are shared between the state and federal government, the latter was being virtuous at least in part at the former's expense -- and the majority of the former had already indicated their unwillingness to incur such expenses when given the option.

[40] *See* Udom & Betley, *supra* at 215.

[41] *See* Julie A. Gazmararian *et al, Maternity Experiences in a Managed Care Organization,* 16 Health Aff. 198, 200 (1997).

the case that such women are particularly in need of a governmental mandate to protect their interests -- or that they face significant risks as a result of drive-through deliveries.

The net result of the Newborns' Act is thus the worst of all worlds – a non-solution which misses the point of the real problem, and simultaneously makes it less likely the real problem will ever be addressed. From an economic perspective, the law effectively requires MCOs and insurers to spend money on hospital stays that do not appear to provide *any* clear benefit – let alone benefit in excess of the costs. The law also constrains the ability of MCOs and insurers to arrange for post-discharge care that does, in fact, provide a clear benefit well in excess of its costs. From an autonomy/liberty perspective, the law effectively prohibits the parties to an insurance contract from making the coverage arrangements they find most beneficial. From a feminist perspective, the Newborns' Act infantilizes women by allocating decision-making authority to the attending provider, and precluding any and all incremental payments from the insurer to the mother in exchange for an early discharge.

The law also does nothing to address the quality of care rendered during the postpartum hospitalization, nor does it encourage the development of better systems (or any systems for that matter) for delivering post-discharge postpartum care. Indeed, the Newborns' Act actually decreases the incentive to develop such systems, because the MCO must demonstrate that the post-discharge visit only replicates the services which would have been offered in the hospital -- even if women would prefer a different package of services, and even if a different package of services is more cost-effective. This implicit legislative bias is particularly problematic, because many physicians are unenthusiastic about the development of post-discharge services to begin with.

It is also worth noting the regulatory costs associated with such legislation. Legislative and regulatory time and attention are in short supply. It is hard to make the case that a prohibition on drive-through deliveries was the best use of these scarce resources. To be sure, Congress is under no obligation to tackle problems in any particular order -- although there are reasons to wonder about a reform strategy which ignores the overwhelming evidence of quality-based problems with most of American medicine, and focuses on an area where the evidence for quality-based problems is hardly colorable. Worse still, by embracing a "reform" based on the

sanctity of physician discretion, the Newborns' Act makes it much more difficult to address the real quality-based problems with American medicine, which, in fact, *are* attributable to the unconstrained discretion previously accorded physicians.

The only real lesson of the Newborns' Act appears to be that we want MCOs to cut costs in ways that are less visible -- hardly an ideal incentive, all things considered. Indeed, the potential for overly vigorous cost-containment by MCOs is such that it is far more sensible to encourage MCOs to cut costs in a manner that is open and obvious. Unfortunately, the Newborns' Act creates precisely the wrong incentives, because it signals that cost-cutting which is overly transparent will result in a legislative backlash -- meaning that cost-cutting which is well hidden will not be questioned. The Newborns' Act may well have stemmed the tide of short postpartum stays, but it undermines the very goal of quality managed care at an affordable price at which it is ostensibly aimed.

The anecdotes which led Congress and a majority of states to prohibit drive-through deliveries were heartbreaking, but extraordinarily unrepresentative. As such, they provide further proof (were any actually needed) that isolated observations do not provide a sound basis for legislation -- or much of anything else, for that matter. Focusing on the "bad outcomes" anecdotal numerator, without factoring in the "millions of successful deliveries at lower cost" empirical denominator, is a recipe for public policies that are either silly or symbolic -- and usually both.

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May 19, 2004

David Hyman
Professor of Law
University of Maryland School of Law
515 W. Lombard Street
Baltimore, MD 21201

Dear Dr. Hyman:

Thank you for testifying before the Joint Economic Committee on May 13, 2004 at the hearing on the Burden of Health Services Regulation. I appreciate you taking the time to share your expertise with Congress on this important issue. I am writing with additional questions as a follow-up to the hearing. These questions and your answers will be included in the record of the hearing's proceedings.

- If government regulations didn't tell consumers what they should do and need to know, what else would protect them in today's health care marketplace? How can we determine better where the floor of unnecessary regulation meets the ceiling of necessary regulation? Is there a difference in regulation by government bureaucracy and "regulation" by private sector administrators?

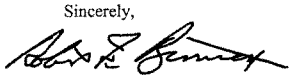
- Regulatory costs are often misunderstood and hard to quantify. What regulations are most obviously imposing excessive costs considering the benefits? Why do we still have them?

- Recently, studies have been issued that purport that the U.S. health care system ends up costing too much for the quality of health care we receive. Is it because of ill-advised regulations? Or are there other significant reasons? How much does excessive or unwise regulation count as a factor?

- Deregulation has occurred to various degrees in many other U.S. industries and business sectors over the last two to three decades? Has health care lagged behind those trends? If so, why?

Should you have any questions about these inquiries, please do not hesitate to contact me or Tom Miller, of my Joint Economic Committee staff, at (202) 224-5171.

Sincerely,



Robert F. Bennett
United States Senator

Robert. Bennett
United States Senate
Chairman, Joint Economic Committee
Dirksen Senate Office Building
Room G-01
Washington, D.C. 20510

August 19, 2004

Dear Senator Bennett:

I apologize for taking so long to respond to your letter dated May 19, 2004, seeking my views on a number of subjects relating to the regulation of health care. Your specific inquiries are reproduced below, with my responses interspersed. At the outset, I note that a report jointly issued by the Federal Trade Commission and Department of Justice on July 23, 2004, *Improving Health Care: A Dose of Competition*, addresses many of the issues identified in your letter. The FTC/DOJ report provides a comprehensive overview of the strengths and weaknesses of the health care marketplace, and in the words of the accompanying press release, "reviews the role of competition and provides recommendations to improve the balance between competition and regulation in health care."[1]

- If government regulations didn't tell consumers what they should do and need to know, what else would protect them in today's health care marketplace? How can we determine better where the floor of unnecessary regulation meets the ceiling of necessary regulation? Is there a difference in regulation by government bureaucracy and "regulation" by private sector administrators?

The premise of the first sentence in this question is inaccurate. With exceedingly few exceptions, regulation in health care does not attempt to tell consumers "what they should do and need to know." Instead, regulation generally sets standards for market entry and structure, and sometimes creates process-based minimum standards. It is difficult to see how regulation could even attempt to tell consumers "what they should do" in a fast-moving field like health care – particularly when the "proper" treatment varies,

[1] Federal Trade Commission, FTC and DOJ Issue Report on Competition and Health Care, July 23, 2004, available at http://www.ftc.gov/opa/2004/07/healthcarerpt.htm. The full report is available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf. If you want hard copies of the report, please contact Sarah Mathias at 202-326-3254.

depending on consumer preferences. That said, it is striking how little regulation in health care is directed toward supporting or encouraging informed consumer choice. Regulation that encouraged disclosure of salient, truthful, non-deceptive information has the potential to drive improvements throughout the health care system – and allow consumers to ensure that they receive the type of care they desire in a setting that accords with their preferences.

Distinguishing between "the floor of unnecessary regulation" and "the ceiling of necessary regulation" is a difficult task, and the determination will be affected by changes in technology and consumer preferences. Careful *ex ante* scrutiny of each proposed regulation, periodic *ex post* review, and a strong presumption in favor of "sun-setting" are obvious strategies for improving the quality of regulation. A complicating factor is that most of the regulation of health care occurs at the state level. At the federal level, there is little direct regulation of health care; most of the operative federal provisions are Medicare payment rules that indirectly influence the structure of the health care marketplace. Greater attention should be paid, however, to the anticompetitive consequences that can flow from Medicare's payment rules.[2]

There are a number of differences between "regulation by government bureaucracy and 'regulation' by private sector administrators." The most important differences are the rapidity of response to changing conditions, and the extent to which response is triggered by market feedback or political feedback. It can take years to finalize a regulation. Regulation tends to get ossified over time. The aggregation of these regulations also creates additional difficulties. Private sector "regulation" tends to be more dynamic, because the profit motive encourages private entities to adjust to changes in external circumstances (both market feedback and political feedback).

Government regulation is obviously not subject to direct market feedback, but it is often exquisitely responsive to political pressure. The result can be regulation that is "necessary" from a political perspective, but not from a market perspective. Such regulation may be politically appealing, but it is likely to be inefficient, and impose costs that exceed benefits.

- Regulatory costs are often misunderstood and hard to quantify. What regulations are most obviously imposing excessive costs considering the benefits? Why do we still have them?

In my academic work, I have focused on the costs and benefits of regulating managed care. The consistent pattern is that these regulations impose costs that appear to exceed their benefits.[3] Why are such statutes enacted? My article in the Southern California Law Review suggests that we get economically irrational regulation (from the perspective of consumers) because such regulation results in highly concentrated

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[2] William Sage, David A. Hyman & Warren Greenberg, *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31 (March/April 2003).

[3] David A. Hyman, *Managed Care at the Millennium: Scenes From A Maul*, 24 J. Health, Politics, Pol'y & L. 1061 (1999); David A. Hyman, *Drive-Through Deliveries: Is Consumer Protection Just What the Doctor Ordered?*, 78 N.C. L. REV. 5 (1999); David A. Hyman, *Consumer Protection in a Managed Care World: Should Consumers Call 911?*, 43 VILL. L. REV. 409 (1998).

economic benefits (typically for the providers of the mandated services), and highly diffused costs (spread among all of the insured population).[4] Health care is also an area of the market where symbolic values are important. Such circumstances are ideal for the enactment and maintenance of non-public-interested legislation.

The FTC/DOJ Health Care Report raised similar concerns about certificate of need programs and insurance mandates, and recommended reconsideration of whether such regulation should be continued.[5] Finally, FTC staff also noted in a recent advocacy letter that pharmacy any-willing-provider and freedom-of-choice provisions were unlikely to serve consumer interests.[6]

- Recently, studies have been issued that purport [to show] that the U.S. health care system ends up costing too much for the quality of health care we receive. Is it because of ill-advised regulations? Or are there other significant reasons? How much does excessive or unwise regulation count as a factor?

There is considerable evidence that the quality of U.S. health care is not all it could be. Chapter 1 of the FTC/DOJ report goes through this evidence in some detail, and outlines how several of the prerequisites for fully effective competition are lacking or attenuated. Regulation bears some responsibility for this state of affairs, because it can chill or eliminate innovation and market entry. At the same time, the performance of the health care marketplace is influenced by a host of complex factors, and one should not blame regulation for all of the quality problems with American health care. Indeed, regulation helps protect consumers from unproven medical treatments and "miracle" cures. The challenge is to balance these considerations, in ways that protect the most vulnerable, while still securing the benefits of a competition.

- Deregulation has occurred to various degrees in many other U.S. industries and business sectors over the last two to three decades. Has health care lagged behind those trends? If so, why?

I have not studied this issue in any detail. There is no question that certain aspects of health care are less regulated than they once were, and we rely on competition in health care to a greater extent than all other countries. At the same time, the degree of deregulation of health care appears to lag most other industries. I can think of several reasons for this pattern. One obvious hypothesis is deregulation focused on industries that were regulated at the federal level. Since health care is primarily regulated at the state level, one would expect deregulation at the federal level to have little impact on the aggregate level of regulation. An additional complication is that to the extent there was deregulation at the federal level, it did really affect the Medicare and Medicaid programs.

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[4] David A. Hyman, *Regulating Managed Care: What's Wrong With A Patient Bill of Rights,* 73 S. CAL. L. REV. 221 (2000).
[5] FTC/DOJ Report, *supra* note 1.
[6] Letter from FTC staff to Patrick C. Lynch, Attorney General and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations, April 8, 2004, available at http://www.ftc.gov/os/2004/04/ribills.pdf.

As noted previously, the payment rules of these programs have a direct and profound effect on the structure and performance of the health care marketplace.

Conclusion:

Let me sum up briefly. The premise of the American free-market system is that open competition and consumer choice maximize consumer welfare – even when complex products and services such as health care are involved. The current regulatory framework for health care, which is primarily state-based, is founded on rather different assumptions. Regulation should be judiciously employed, to ensure that it is serving consumer interests, and not imposing costs without benefits. It is clear that there is much to be done to better balance these considerations in the health care marketplace.

I hope my untimely response will be of some assistance to you in your deliberations. Please feel free to contact me if you have any questions.

Best regards,

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"The Burden of Health Services Regulation"
Hearing of the Joint Economic Committee
May 13, 2004

Center for Medicare Advocacy, Inc.
Vicki Gottlich
Toby S. Edelman

INTRODUCTION

Good morning. I am Vicki Gottlich, an attorney with the Center for Medicare Advocacy, Inc. I am presenting the testimony with my colleague, Toby Edelman, who could not attend today's hearing because she is speaking to nursing home ombudsmen in Florida. We thank you for the invitation to testify before the Subcommittee on behalf of Medicare beneficiaries and their advocates.

This hearing asks whether health care regulations add unnecessary and burdensome costs and whether these dollars could be redirected to providing health care insurance for uninsured people. From our perspective representing the rights and interests of older people and people with disabilities for more than 25 years, the answers are no. Regulations protect and promote the health and the quality of life of all individuals. When properly implemented and enforced, the rules save billions of dollars for the Medicare program. We use examples related to nursing home residents in our testimony because, by definition, nursing home residents are among the most vulnerable populations and the benefits to them from standards and regulations are well-documented.

OVERVIEW

Rules implementing federal Medicare legislation have helped to assure that Medicare beneficiaries have access to high quality health care. In the area of nursing homes, the Nursing Home Reform Law and federal rules have improved aspects of quality of care for residents. In addition, the good care practices mandated by the reform law and rules are cost-effective and save Medicare dollars.

However, while the Centers for Medicare & Medicaid Services can and does play an important role in protecting beneficiaries' access to high quality care, too often, the agency is timid and overly deferential to the health care industries it regulates. Beneficiaries can be harmed as a consequence. When the regulatory system is ineffective in preventing avoidable bad outcomes from occurring in nursing homes, the health care system pays more to treat the bad outcomes. When residents develop avoidable pressure sores and need to be hospitalized to receive treatment, the Medicare program pays for the hospitalization.

THE PURPOSE OF THE MEDICARE PROGRAM IS TO PROVIDE HEALTH CARE SERVICES TO BENEFICIARIES, NOT PAYMENTS TO HEALTH CARE PROVIDERS.

Congress enacted the Medicare program in order to provide health care benefits to older people and people with disabilities. Courts have repeatedly recognized and stated that the program is designed for beneficiaries, not providers. *Home Health Services, Inc. v. Currie*, 531 F. Supp. 476, 479 (D.S.C. 1982), *aff'd* 706 F.2d 497 (4th Cir. 1983) ("[T]he statute was obviously not enacted primarily for the benefit of the provider of services, but rather for the recipients of medical care benefits."); *Gartman v. Secretary of the United States Department of Health and Human Services*, 633 F. Supp. 671, 679 (E.D.N.Y. 1986); *Mays v. Hospital Authority of Henry County*, 582 F. Supp. 425 (N.D. Ga. 1984).

THE ADMINISTRATIVE RULEMAKING PROCESS ENABLES BENEFICIARIES AS WELL AS HEALTH CARE PROVIDERS TO PRESENT ISSUES AND CONCERNS TO THE CENTERS FOR MEDICARE & MEDICAID SERVICES.

Due to the complexity of health care programs and the expertise needed to administer them, Congress delegates responsibility to the Department of Health and Human Services to provide the details for its legislative enactments. The Centers for Medicare & Medicaid Services is the component within the Department that has expertise and is given the authority to implement the Medicare statute. CMS meets its duty to implement federal legislation, including Medicare, through a public rulemaking process.

While the rulemaking process is lengthy and time-consuming, it is also, at its best, both open and highly democratic. The rulemaking process allows all sectors of the public to express their views and to be heard. Beneficiaries and their advocates, as well as health care providers, participate in the rulemaking process in order to bring their experiences and concerns to the attention of CMS. Through their comments on rules, they explain the impact of rules on all segments of the public and offer suggestions to improve or strengthen rules to achieve their statutory goals. When CMS publishes final rules, it is required to respond to these public comments and to explain its rationale in making regulatory decisions. CMS is publicly accountable for its decisions.

MEDICARE BENEFICIARIES AND THEIR ADVOCATES SEE RULES AND THE RULEMAKING PROCESS AS HELPING TO ASSURE BENEFICIARIES' FULL ACCESS TO HIGH QUALITY HEALTH CARE.

While providers may see various aspects of the laws and rules as burdensome and excessive, beneficiaries often view these same laws and rules quite differently. Beneficiaries see the laws and rules as establishing a system that protects their rights and interests in receiving full access to high quality health care.

NURSING HOME CARE

The nursing Home Reform Law enacted by Congress in December 1987 and its implementation by the Health Care Financing Administration, the predecessor agency to CMS, are a clear example of how law and regulation work effectively both to establish a high level of care as the federal standard of care and to help improve the actual quality of care that residents receive.

The 1987 reform law was the most comprehensive revision to federal nursing home law since the Medicare and Medicaid programs were enacted in the 1960s. Congress based the detailed legislation on a series of hearings in 1987 in the three committees with legislative responsibility for the Medicare and Medicaid programs; on the 1986 report of the Institute of Medicine, *Improving the Quality of Care in Nursing Homes*, which itself was the result of several years of exhaustive research; and on recommendations of the Campaign for Quality Care, an *ad hoc* coalition of nursing home provider associations, health care professionals working in nursing homes, and residents'

advocates, convened by the National Citizens' Coalition for Nursing Home Reform to identify areas of consensus about how best to translate the IoM's recommendations into federal law.

The nursing home reform law was based in large part on good practices that had been tried and proven effective in states. Requiring the training of nurse aides (who provide the majority of direct care to residents) and comprehensive assessment and care planning, guaranteeing residents' rights, and authorizing a broad range of intermediate sanctions that survey agencies could impose against facilities that failed to meet care standards were among the innovations of the legislation. These good practices involved both the care practices that nursing homes had developed and used with success as well as survey and enforcement practices that states had successfully used. The reform law made these good practices mandatory for all states and all facilities that chose to participate in the Medicare and Medicaid programs.

The Law and Implementing Regulations Promulgated by HCFA Have Promised Residents High Quality of Care and Have Led to Some Significant Improvements in Care.

The nursing home reform law and regulations and guidelines published by CMS' predecessor agency, the Health Care Financing Administration, to implement the law have led to demonstrable improvements in the care that residents receive. While the series of hearings held by Senators Charles Grassley and John Breaux in the Senate Special Committee on Aging, between July 1998 and September 2000, and by Senate Finance Committee in July 2003 documented that grave and unconscionable problems remain in the quality of care provided by too many nursing homes, the hearings demonstrated that these problems result primarily from the lack of strong public enforcement of the care standards, not from the statutory and regulatory standards themselves.[1]

The Reform Law Required Reduction in the Use of Physical and Chemical Restraints.

The requirement to reduce the use of physical and chemical restraints was based on good care practices in some nursing homes that had reduced or entirely eliminated restraints. At the time the law was enacted, however, a more common view in the nursing profession and the nursing home

[1] The Institute of Medicine's 2001 report *Improving the Quality of Long-Term Care* also identified "serious deficiencies" in assessment and enforcement of care standards as the cause of continuing serious care problems in nursing homes. Institute of Medicine, *Improving the Quality of Long-Term Care,* 251 (2001) [hereafter IoM, *Improving the Quality of Long-Term Care*].

industry was that restraints would protect residents from injuries and falls. As a consequence, in the late 1980s, an estimated 41% of all residents were physically restrained.[2]

[2] *Id.* 79.

The reform law adopted the best practice from the restraint-free movement (which recognized that restraints in fact caused more injuries to residents than restraint-free care), changed the paradigm of care on a national scale, and led to a reduction in restraint use for residents. The most recent national data indicate that in December 2003, 8.79% of residents nationwide were physically restrained.[3] Freeing residents from restraints was documented to be not only better from residents' perspective, but also a less costly way of providing care.

As Joani Latimer, a nursing home residents' advocate, wrote in the Journal of the American Society on Aging, "good law takes everyone to a higher standard."[4] The reform law set a new standard regarding restraints. When the New York-based Commonwealth Fund supported a project several years ago on restraint reduction in nursing homes, project staff asked facility staff why they participated in the research. Many answered that since the reform law now required reduction of restraints and facilities would be evaluated by the survey agency by this different standard of care, they were motivated to learn how to comply with the new rules most effectively. The project gave them that opportunity.

In a 2001 report, the Institute of Medicine attributed the reduction in the use of physical and

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[3] American Health Care Association, *Medical Condition, Mobility, CMS OXCAR Data Current Surveys, December 2003* http://www.ahca.org/research/oscar/rpt_MC_mobility_200312.pdf. These data are self-reported by facilities and unaudited by survey agencies.

[4] Joani Latimer, "The Essential Role of Regulation to Assure Quality in Long-Term Care," *Generations*, Vol. XXI, No. 4, 13 (Winter 1997-1998) [hereafter Latimer, "The Essential Role of Regulation"].

chemical restraints nationwide, which it called "the greatest improvement in nursing home care,"[5] to the requirements of the reform law:

> [M]any facilities have successfully reduced the inappropriate use of physical and chemical restraints. The focus of increased regulatory scrutiny on these two areas of care was a major contributing factor in reductions in both of these.[6]

Reducing the use of restraints is good care; it is also a less expensive way to provide care to residents.[7]

The Reform Law Required Standardized Resident Assessments.

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[5] IoM, *Improving the Quality of Long-Term Care*, *supra* note 1, 79.

[6] *Id.* 77.

[7] Charles D. Phillips, Hawes, C., and Fries, B., "Reducing the Use of Physical Restraints in Nursing Homes: Will It Increase Costs?" *American Journal of Public Health, Vol.* 83, 342-348 (Mar. 1993).

Another beneficial aspect of the 1987 reform law was the requirement that all facilities assess residents using a comprehensive, standardized, reproducible assessment instrument. The assessment would identify "potentially treatable or reversible causes of functional impairment" and would be used to plan each resident's care in the individualized care-planning process.[8]

The new resident assessment instrument, known as the minimum data set, or MDS, was developed through an intensive public process that involved all sectors of long-term care and included extensive testing. Although the nursing home reform law explicitly permitted states to develop their own assessment instruments, all states chose to use the assessment instrument and process that were developed by HCFA.

An evaluation of the impact of the MDS in 1996 found that the new assessment process improved care outcomes for residents. The study found, among other changes:

- "a 24 percent increase in the accuracy and comprehensiveness of information in the residents' nursing home records."
- "a 17 percent increase in the number of problems that are addressed in residents' care plans."
- "a 30 percent increase in the use of hearing aids for persons with hearing difficulty."
- "a 27 percent increase in the use of behavior management programs for residents who wander, display physical aggression, or resist nursing care."
- "Residents with bowel incontinence were almost twice as likely to receive a toileting program."
- "a 29 percent decrease in the use of indwelling urinary catheters."
- "a 28 percent decrease in the proportion of residents with little or no activity."[9]

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[8] Charles D. Phillips, Hawes, C., Mor, V., Fries, B.E., and Morris, J.N., "Geriatric Assessment in Nursing Homes in the United States: Impact of a National Program," *Generations* (Journal of the American Society on Aging), Vol. XXI, No. 4, 15, 16 (Winter 1997-1998) [hereafter Phillips, "Geriatric Assessment"].

[9] Catherine Hawes, "Assuring Nursing Home Quality: The History and Impact of Federal Standards in OBRA 1987," 6-8 (Commonwealth Fund, Dec. 1996).

The increase in positive care outcomes and decline in negative care outcomes that resulted from implementation of the MDS had a price tag – they saved Medicare dollars. Providing good care to residents and more accurately identifying and meeting residents' care needs also led to reduced instances of hospitalization. Dr. Catherine Hawes reported that introduction of the MDS led to a 26% reduction in hospitalization of residents, resulting in an annual estimated savings to the Medicare program of two billion dollars in hospital costs in 1992 alone.[10]

While use of the MDS led to an increase in positive health outcomes for residents and, at the same time, significantly reduced costs to the Medicare program, administrators and nurses who were questioned about the MDS reported mixed feelings about the new assessment tool. Dr. Charles Phillips, et al., reported that 43% of clinical staff were "resistant" to using the MDS and that 68% of administrators complained about the "excessive paperwork burden."[11]

> However, a majority of both administrators and nursing directors agreed that the RAI had positive effects on quality: some 59 percent of nursing directors reported that the RAI improved the quality of residents' clinical assessments, 69 percent that their staff's assessment of residents' functional status improved, and 75 percent acknowledged that the RAI was more useful than the assessment system used in the past. Finally, 78 percent of nurses reported that the RAI improved their ability to detect clinically meaningful changes in resident functioning.[12]

Health care providers may find fault with regulations even when they recognize the improved health care for beneficiaries (and cost savings to the Medicare program) that result.

QUALITY OF HEALTH CARE

Rules and regulatory systems also require and promote high quality of care for beneficiaries. This purpose of the regulatory system is also of critical importance to beneficiaries.

Ms. Latimer reports that regulation is necessary in the health care area, particularly in long-term care, because market forces may be unable, alone, to assure high quality of care for beneficiaries.[13] The factors that may make the marketplace work as a mechanism assuring high quality of products are largely absent in health care. Health care consumers may be inadequately informed; may have little choice among health care providers (because of insurance limitations or provider discrimination against program beneficiaries); and may be required to make decisions at a hurried, stressful time.

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[10] *Id.* 8.

[11] Phillips, "Geriatric Assessment," *supra* note 8, 16.

[12] *Id.* 16-17.

[13] Latimer, "The Essential Role of Regulation," *supra* note 4, 10.

Moreover, the consequences of their decisions often cannot be reversed. People can choose to buy a different television set if the one they buy breaks. Similar opportunities are unlikely in health care. Health care that is denied or inadequately provided may not be able to be fixed or corrected.

The Institute of Medicine's 1986 report on nursing home quality rejected reliance solely on market forces to improve the quality of long-term care:

> [H]istorical experience hardly supports an optimistic judgment about the effects on quality of care of allowing market forces to exert the primary influence over nursing home behavior. Nursing homes were essentially unregulated in most states prior to the late 1960s. Their operations were governed almost entirely by market forces, and the quality of care was appalling.[14]

As noted above, the IoM's report was the blueprint for the nursing home reform law that Congress enacted in December 1987. Fifteen years later, the Institute of Medicine reiterated its support for a regulatory model to assure quality in long-term care.[15]

The value of a regulatory system to assure quality of care for nursing home residents was also firmly recognized by the California Supreme Court. In a 1997 decision, the Court recognized that regulatory systems are intended to prevent avoidable bad outcomes for residents: "the very purpose of the statutory scheme" is "preventing injury from occurring."[16]

Public support for regulation of nursing homes to address quality continues. The *New England Journal of Medicine* reported that a strong majority of Republican voters (57%) and Democratic

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[14] Committee on Nursing Home Regulation, Institute of Medicine, *Improving the Quality of Care in Nursing Homes* 5 (Mar. 1986).

[15] IoM, *Improving the Quality of Long-Term Care*, *supra* note 1, 141.

[16] *California Association of Health Facilities v. Department of Health Services*, 16 Cal.4th 284, 940 P.2d 323, 336, 65 Cal. Rptr.2d 872, 885 (1997).

voters (68%) in 2000 supported increasing regulation of nursing home quality.[17]

THE HIGH COST OF POOR CARE

In June 1991, the Senate Committee on Labor and Human Resources' Subcommittee on Aging reported, in a staff report,

[17] "Health Policy 2001: The Implications of the 2000 Election," *The New England Journal of Medicine*, Vol. 344, No. 9, 679, 681 (Mar. 1, 2001).

> Explosively expensive care is required to redress the effects of poor nursing care for residents in nursing homes. Inadequate numbers of nursing assistants, poorly supervised by licensed nurses, lead to breaks in care or inappropriate care. Basic care, food, fluids, cleanliness, sleep, mobility and toileting, when not carried out, lead to devastating outcomes for residents and additional expense for the government.[18]

The Committee report identified billions of dollars spent trying to correct poor health care outcomes that would have been avoided if good care had been provided to residents in the first place. Lack of toileting that led to incontinence cost $3.26 billion in 1986; poor hydration, nutrition, mobility, and cleanliness that led to pressure sores cost $1.2 to $12 billion; chemical restraints leading to falls and hip fractures that led to hospital care cost $2.6 billion in 1985; etc.

RULES ARE NEEDED TO MANDATE A SAFE ENVIRONMENT

Too often, facilities will not provide a safe environment for residents if the rules allow them to do otherwise. While sprinklers are recognized as the best mechanism to avoid deaths from fire, the rules "grandfather" in older facilities and allow them to use less effective measures, with predictable results. Last September, a fire broke out in a Tennessee nursing facility. Eight resident were killed in the fire, more died later, and 80 residents were sent to the hospital. After the fire, the corporate owner of the facility established a relief fund[19] and committed itself to installing sprinklers in all its facilities.[20] The company estimated the cost of installing sprinklers in the 16 facilities that did not have sprinklers as $10,000,000[21] – approximately $625,000 per facility. The state began considering legislation to require sprinklers and the National Fire Protection Association is now calling for all nursing homes nationwide to be equipped with sprinklers.[22]

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[18] Subcommittee on Aging, Senate Committee on Labor and Human Resources, *Nursing Home Residents' Rights: Has the Administration Set a Land Mine for the Landmark OBRA 1987 Nursing Home Reform Law?* (Jun. 13, 1991).

[19] National HealthCare Corporation, "NHC's subsidiary facility damaged by fire" (Oct. 2, 2003), http://www.nhccare.com/press_releases/oct_2_2003.htm.

[20] National HealthCare Corporation, "NHC to Retrofit Nursing Homes with Sprinklers" (Oct. 7, 2003), http://www.nhccare.com/press_releases/oct_7_2003.htm.

[21] National HealthCare Corporation, "NHC Estimates Cost of Sprinklers $10 million" (Oct. 8, 2003), http://www.nhccare.com/press_releases/oct_8_2003.htm.

[22] National Fire Protection Association, "NFPA president calls for fire sprinklers in all nursing homes; Recent tragedies show more must be done to keep elderly, disabled safe" (News Release, Oct. 16, 2003), http://www.nfpa.org/PressRoom/NewsReleases/NursingHomes/nursinghomes.asp.

COMPLAINTS ABOUT REGULATORY BURDEN OFTEN MASK PROBLEMS WITH ACCESS TO OR QUALITY OF HEALTH CARE

A current problem experienced by home health agencies and enrollees in Medicare Advantage (formerly Medicare+Choice) health plans illustrates this point. In January of this year regulations went into effect to establish a "fast track" appeals process when a Medicare Advantage plan proposes to terminate home health, skilled nursing facility, or comprehensive outpatient rehabilitation facility (CORF) care.[23] The new procedure, established as part of the settlement of a law suit brought by the Center for Medicare Advocacy,[24] requires the provider to give the enrollee notice of the right to seek pre-termination review no later than two days before the proposed termination or, if the span of time between services exceeds two days, no later than the next to last visit.[25]

Home health agencies complain that the notice requirements are too burdensome, since Medicare Advantage plans only authorize one or two home health visits at a time. They say that the regulations would require them to provide notice of appeal rights at virtually every visit. The real issue is not that the notice obligations are too onerous, but that the Medicare Advantage plans are inappropriately denying their enrollees access to home health care to which they would have been entitled had they remained in traditional Medicare.[26] Further, it is the Medicare Advantage plans, and not the regulatory system, which creates the extra paperwork for the home health agencies by placing their own strict limitations on the amount of home care that is approved. The solution to this problem is not to eliminate the requirement to provide enrollees with notice of their appeal rights, but to require Medicare Advantage plans to provide their enrollees with the same benefits that are provided to individuals who remain in traditional Medicare.

But what happens to people who rely on Medicare if CMS decides to relieve home health agencies of their notice obligations, rather than to address the access to care problem? We at the Center for Medicare Advocacy know from our long experience of representing Medicare beneficiaries that people who do not get notice of appeal rights do not exercise those rights, and they often lose out on medically necessary health care to which they are entitled. We also know, first hand, that when our clients do not get the home health services to which they are entitled their condition deteriorates. They may be placed in a nursing home at a greater cost to Medicare, to Medicaid, and to their personal independence. And, unfortunately, we have seen such clients die.

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[23] 68 Fed. Reg. 16651 (April 4, 2003), adding 42 C.F.R. §§ 422.624, 422.626.

[24] *Grijalval v. Shalala*, civ. 93-711 (D.C.Az. Settlement Approved December 2000.)

[25] 42 C.F.R. § 422.424(b)(1).

[26] In traditional Medicare home health services are provided for 60 day periods of time pursuant to a plan of care signed by the treating physician. 42 C.F.R. § 424.22. There is no limit on the number of care plans that may be approved.

AT TIMES, CMS HAS BEEN TOO TIMID IN EXERCISING ITS RULEMAKING AUTHORITY AND OVERLY DEFERENTIAL TO THE HEALTH CARE PROVIDERS IT REGULATES.

Although Medicare beneficiaries and their advocates recognize CMS' ability to implement federal legislation in ways that improve access and quality of care, we are concerned that the agency at times defers excessively to the health care providers it regulates.

In the nursing home area, CMS had difficulty implementing the strong enforcement approach of the nursing home reform law in the face of fierce and aggressive opposition by the nursing home industry. The weak enforcement system initially established by HCFA's guidelines tolerated high levels of facility non-compliance with federal standards of care, leading to the care crisis that Senator Grassley's and Senator Breaux's hearings vividly documented. Strong Congressional oversight and the Administration's Nursing Home Initiative announced in July 1998 redirected the agency's approach to enforcement, making it more consistent with the law and more likely to achieve its goals of assuring correction of deficiencies and sustained compliance by facilities.

The Center for Medicare Advocacy, Inc. is a private, non-profit organization founded in 1986, that provides education, analytical research, advocacy, and legal assistance to help older people and people with disabilities obtain necessary healthcare. The Center focuses on the needs of Medicare beneficiaries, people with chronic conditions, and those in need of long-term care. The Center provides training regarding Medicare and healthcare rights throughout the country and serves as legal counsel in litigation of importance to Medicare beneficiaries nationwide.

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