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CONSUMER-DIRECTED DOCTORING: THE DOCTOR IS IN, EVEN IF INSURANCE IS OUT

HEARING

BEFORE THE

JOINT ECONOMIC COMMITTEE
CONGRESS OF THE UNITED STATES

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SECOND SESSION

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CONSUMER-DIRECTED DOCTORING: THE DOCTOR IS IN, EVEN IF INSURANCE IS OUT

WEDNESDAY, APRIL 28, 2004

UNITED STATES CONGRESS,
JOINT ECONOMIC COMMITTEE,
Washington, DC.

The Committee met at 10:03 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: Donald B. Marron, Tom Miller, Leah Uhlmann, Colleen J. Healy, Mike Ashton, Wendell Primus, Deborah Veres.

OPENING STATEMENT OF SENATOR ROBERT F. BENNETT, CHAIRMAN

Chairman Bennett. The hearing will come to order.

I understand that Dr. Berry is in the building and will be with us shortly.

We very much appreciate our witnesses being here this morning. We're here to explore how some doctors are finding alternatives to the traditional third-party payer health care system, and at the same time providing better care for their patients.

Many doctors are frustrated by the state of our current health care system, and their patients are, too. Doctors are continually faced with third-party entities interfering in their practice, pushing them towards a system that focuses on arcane regulations rather than patient care.

Low reimbursement rates require physicians to increase the number of patients they see, while shortening the length of office visits. And they must also shoulder the burdens of increased practice costs, time-consuming paperwork and rising medical liability premiums.

Many patients, particularly those with lower incomes, find it difficult to obtain affordable care and to receive it in a timely manner. They often feel rushed through brief office appointments without having adequate time to address their questions and concerns, or adequate help to navigate the complex medical system.

Today's hearing will examine the experiences of innovative and entrepreneurial doctors who are responding to gaps in the current system by returning to an older style of medical practice—a patient-focused approach that used to be the norm. By adopting these approaches, doctors are finding ways to spend more time with their patients and provide a better quality of care.

We will examine the potential reach of these early trends among innovative physicians who deal more directly with their patients than do physicians relying predominantly on third-party insurance mechanisms.

Now, I recognize that insurance-free medical care may not work for everyone. But early evidence of consumer-directed doctoring suggests that some physicians and patients are reacting favorably to this way of providing care, and in some cases, it has produced lower costs.

In other cases, it has offered a more enhanced level of personal medical service. And on occasion, it has delivered both. In any case, it means providing better value.

By studying how these entrepreneurial physicians are building their practices, we can learn about the strengths and weaknesses of our current health care system and how better to address them. By understanding alternatives to the system, we may be able to improve medical price transparency, help relieve medical liability pressures, and retain highly-trained physicians who are increasingly frustrated by the present system.

We'd like to welcome our panelists today, all of whom have experience delivering health care through innovative or entrepreneurial means, or who have studied the issue in an effort to understand the implications of this emerging trend.

I will wait until after we've heard from Mr. Stark to introduce each of the witnesses. But again, we thank you for being here and look forward to your testimony.

Mr. Stark.

[The prepared statement of Senator Robert F. Bennett appears in the Submissions for the Record on page 37.]

OPENING STATEMENT OF REPRESENTATIVE PETE STARK, RANKING MINORITY MEMBER

Representative Stark. Thank you, Mr. Chairman. Excuse me, but I certainly am in need of treatment today. If I could afford the services of our witnesses, I would probably be better off for it.

This hearing appears to be an installment in your side of the aisle's move towards replacing traditional health insurance with high-deductible health plans and health savings accounts and that sort of thing.

This time the rationale is that doctors provide cheaper health care to patients if we do away with the insurance companies and their pesky paperwork.

Now I'd state right off that I'm certainly not a poster child of insurance companies in this world. But I'm not sure that they don't provide a service to many of us.

The frustrations in dealing with insurers have led some doctors to accept only cash payments. And the doctors claim that they can offer lower prices for office visits and other simple procedures because they reduce overhead from all the paperwork and the insurance reimbursement and so forth.

"Concierge care"—as it's been dubbed—is kind of a new country club for us rich folks. And we pay a big premium just to belong, and then we're guaranteed access. We don't have to sit around with

the riff-raff. But we still have to pay for each service that we receive.

I guess the danger is that if a large number of the doctors open these types of practices, the health care system will move much more quickly into a dual system, with the wealthy paying for exclusive access and the poor taking what's left over—public charity care, whatever.

Having access isn't quite the same as having health insurance. A growing body of literature shows that people without health insurance forego even necessary care and don't have their care properly managed. They incur the risk of serious complications and lower overall quality.

And I'm particularly amused by the concept of "empowering" consumers to make more choices about their health care. The need for health care is unanticipated. We rely on our doctors' expertise, not our own, to guide our decision-making.

As I often say, we may ask questions of our doctor, but we never question our doctor. And the policy of consumer-directed doctoring says, basically, "patient—heal thy self."

I guess I've spent the last 20 years of my congressional career in the health care policy and I've never known so-called "consumer-driven" or "consumer-directed" health care to perform well. It seems to shift costs to consumers who pay more. Then we get to the HSAs and some of these other programs, the high-deductible plans. All I can see is that that's another tax shelter, again, for the rich, and it doesn't do much to help us select.

Now I have a personal disclaimer here.

A number of years ago, I went to Johns Hopkins with prostate problems. And probably one of the leading surgeons in the world was there and he just looked at me and said, "I don't take insurance, fella. If you want me, it's $5,000 up front."

And I said, okay, I wanted him, because as many of you may recognize, this was delicate surgery and I wanted to come out of there with all my moving parts in working order. So I paid it.

Now, I'm not sure that there are a lot of people who could. And I found out why he doesn't take insurance. Blue Cross kicked in $1,300. That's what they would have paid him. And he wanted $5,000.

So there are people—I guess if you want the best and the brightest, you have to pay up for it. Maybe he occasionally did it free, but I'm just suggesting that this does go on. I'm not sure it should, but it does.

So I'll be interested in hearing from our panel today and see what light they can shed on how to help us all, every American resident, receive first-class medical care more equitably.

Thank you.

[The prepared statement of Representative Pete Stark appears in the Submissions for the Record on page 39.]

Chairman Bennett. Thank you very much. I normally do not comment on other Members' comments. But I do feel moved to make this one disclaimer. And maybe it's the fact that I'm in the Senate and Mr. Stark is in the House.

But I can assure you, Mr. Stark, that there is no conspiracy on our side of the aisle to try to undermine the present system.

There is certainly none on my part.

Representative Stark. I'm glad, because I don't like any conspiracy that I'm not a part of, Mr. Chairman.

Chairman Bennett. I see. Okay.

[Laughter.]

Chairman Bennett. These hearings, and we are doing a series of them, are structured simply in an effort to take a fresh look at the entire health care system, a simple desire to say that nothing is beyond examination. At least from my point of view, there are no sacred cows that cannot be looked at.

It stems from my conviction that the present system, however satisfactory it is in many ways, is inadequate, is falling short in a large number of ways. And I want to take a clean sheet of paper look at every aspect in the health care area to see what is working and what isn't, to see if, in the end, we can't make a recommendation to the legislative committees, on which you sit and I don't—maybe that gives me some degree of objectivity, that I'm not on the Finance Committee or the HELP Committee. So I have absolutely no responsibility.

Representative Stark. If you were going to become a Democrat, you wouldn't, either. Okay.

[Laughter.]

Chairman Bennett. That's a step I'm not planning to take.

[Laughter.]

Chairman Bennett. As I think I may have said when I became Chairman of this Committee, Alan Greenspan once said to me: "When Hubert Humphrey was Chairman of the Joint Economic Committee, he made it look as if no other Committee in Congress mattered, because he said, 'you have no legislative mandate. Therefore, you can look at everything.'"

And I corrected him. I said, "No, Alan, we do have a legislative mandate." And he said, "Oh, what is it?"

And I said, "We're required to offer a comment on the annual report of the President's Council of Economic Advisers."

And he said, "As I said, since you have no legislative mandate, you can look at everything."

I don't think that there is anything that is affecting our economy more than rising health care costs. I hear it from corporate executives as their number-one cost problem over and over again, one that they cannot seem to contain.

So I think it appropriate that we look at every conceivable aspect of the system to try to understand it better. And at the end of the day, I hope that we can make some recommendations to the legislative committee.

But may I assuage my Ranking Member's fears that this is not the part of a long-term conspiracy on behalf of the Republicans to try to undermine anything or promote anything other than, I hope, solutions that can be embraced in a bipartisan fashion.

I'm not naive enough to expect that that will really happen, but at least it's a consummation that we can work towards.

If you need an additional rebuttal, I'll be happy to allow you that.

Representative Stark. [Nods in the negative.]

Chairman Bennett. Okay. With that, let us turn to our witnesses, whom I will introduce in the order in which I think we should hear from them.

Dr. Bernard Kaminetsky, from Boca Raton, Florida, operates a practice that specializes in concierge care, or retainer medicine, where patients primarily seek preventive care, get involved with wellness plans and individualized attention and 24-hour access to a personal physician.

And then we'd like to go to Dr. Robert S. Berry, who is here from the PATMOS EmergiClinic in Greeneville, Tennessee. Dr. Berry will talk about his experience building a pay-as-you-go practice. His office fully discloses its prices up front, receives payment at the time of services, and generally does not accept any third-party insurance reimbursements.

Dr. Alieta Eck, a Physician from Piscataway, New Jersey, runs a—did I pronounce that city correctly?

Dr. Eck. "Pis-cat-away."

Chairman Bennett. Piscataway. Okay, I apologize to the Piscatawayans who may be offended.

She runs a charitable care clinic that combines community resources with more efficient methods of health care delivery, to meet the urgent medical needs of the poor and the uninsured.

And then batting clean-up, we will hear from Dr. Robert Berenson, who is an experienced physician, now a Senior Fellow from the Urban Institute here in Washington, DC. He has focused on health care policy, particularly Medicare.

We look forward to each of you.

Dr. Kaminetsky, we will start with you.

STATEMENT OF DR. BERNARD KAMINETSKY, M.D., F.A.C.P., COLTON AND KAMINETSKY, BOCA RATON, FL

Dr. Kaminetsky. Thank you, Mr. Chairman, Mr. Stark.

I am a 51-year-old, board-certified internist presently practicing as an MDVIP-affiliated physician in Boca Raton, Florida. I affiliated with MDVIP because of the inability of the current health care environment to accommodate the necessary emphasis on wellness and prevention that is essential to perform comprehensive preventive care. Instead, current practice, because of time constraints, focuses predominantly on acute care. I am honored to be able to discuss my career, and my decision to provide my patients with the choice to obtain the preventive care and early detection services that they have requested and deserve.

I had always aspired to be a doctor, even from the age of six, as my mother could tell you. I attended Albert Einstein College of Medicine in New York, where I was elected to membership in Alpha Omega Alpha, the national medical honor society. I completed my training at New York University-Bellevue Hospital Center, where I served as chief resident in medicine and was responsible for the continuing medical education of the house staff. My Bellevue experience was certainly unique. I cared for addicted single mothers, Park Avenue matrons, the homeless and suburban entrepreneurs. Following training, I stayed on as a faculty member at the New York University School of Medicine.

During my career, perhaps the greatest change in primary care has resulted from the rapid growth of managed care, especially in the realm of Medicare HMOs. Reimbursement, as we all know, became lower than traditional fee-for-service Medicare, but doctors essentially had no choice.

Capitation—in other words, accepting fixed payment per-patient per-month—held the potential to be very remunerative, because whatever was not spent on the patient accrued to the doctor.

However, such an arrangement was never acceptable to myself or my partners because of the obvious inherent conflict of interest. In that setting, a doctor is incentivized to order as few tests and as little medication as possible in order to improve the bottom line.

Moreover, that approach to care emphasized treatment of acute problems with diminished emphasis on prevention.

Concomitant with declining reimbursement, we faced an increase in our overhead on a continual basis. The health care costs for our employees continually rose. Malpractice insurance has skyrocketed, especially in crisis states such as Florida.

We attempted to cut staff, but that caused untenable delays. And we became more and more constrained in our efforts to be pro-active with regard to health care and became more and more reactive.

It seemed there was only one way a practice could promote prevention and still maintain its financial viability, and that was by seeing more patients. But the reasoning was clearly circular—more patients would mean less time for prevention, while a solution mandated more time, not less.

As a profession, we all had great ideas, but we were lacking in the ability to implement any meaningful change. I was very seriously contemplating leaving clinical medicine.

Last June, the *New England Journal of Medicine* documented that only 55 percent of recommended preventive care is administered. Only 52 percent of recommended screening is performed.

It's been estimated that a doctor with a typical patient load of 2,500 patients, if he were to comply with the recommendations of the U.S. Preventive Services Task Force, he would spend 7.4 hours of each day on prevention only—obviously, only a tiny fraction of the day would then be devoted to acute care.

In a similar vein, if one planned on performing comprehensive preventive exams of even an hour in length for each of the 2,500 patients in a typical practice, that would be 2,500 hours, or one entire year solely for annual exams, with no time whatsoever for acute care.

In contrast, if a practice is limited to 600 patients, such as my current practice, then 12 hours a week, or even 18 hours, is devoted to annual preventive exams with ample time available for routine and urgent care.

Hence, my decision to join MDVIP, a program which is focused on annual preventive care, physical exams, individualized wellness planning tailored specifically to a patient's needs.

I make prevention the foundation of my practice rather than a set of often ignored recommendations. My practice style allows me to dwell on exercise, nutrition, weight loss, smoking cessation, curtailment of alcohol use. I provide detailed analyses for the patients

of their medical and family history, nutritional, psychological and fitness screenings, cardiograms, comprehensive labs, imaging studies.

And all of this is supported with electronic documentation that is given to the patient to carry on a CD in their wallet.

My practice is limited to 600 patients by necessity. In order to offset the decline in revenue associated with the far smaller practice size, the patients pay an annual fee to receive these preventive care services which are not covered by Medicare or commercial insurance.

Early analysis suggests that the scope of care that is delivered in a practice such as mine results in enhanced patient outcomes. Preliminary studies using a modified HEDIS survey of MDVIP-affiliated practices in Florida have yielded results that far exceed the national quality of care averages.

Moreover, these same practices have experienced approximately 30 percent fewer hospitalizations relative to national averages, a highly significant difference.

Who are my patients?

The demographic make-up of my current practice very closely mirrors that of my former practice. My patients range in age from 18 to 101, and come from all socio-economic backgrounds, including patients on fixed incomes and those whose incomes qualify them as upper middle class.

Those patients who chose not to avail themselves of the benefits of the MDVIP prevention program remained in my former practice and a new internist was hired to join the group, take my place, and ensure continuity of care for all patients.

For myself, for my patients, the clock has truly been turned back. The practice environment of the past is like it used to be. I really feel like I'm a doctor again, a confidant, an advisor.

I'm in a position to incorporate the newest recommendations regarding prevention. It's a win for the patients. It's a win for the doctors. It's a win for the insurers because of the reduced hospitalizations.

I can't imagine anything could be better. Thank you.

[The prepared statement of Dr. Kaminetsky appears in Submissions for the Record on page 41.]

Chairman Bennett. Thank you very much. We appreciate that. Dr. Berry.

STATEMENT OF DR. ROBERT S. BERRY, M.D., PATMOS EMERGICLINIC, INC., GREENEVILLE, TN

Dr. Berry. Mr. Chairman, Mr. Stark, thank you for inviting me to testify before this Committee today.

I am grateful that our leaders want to know what is happening at the grassroots level and you are willing to consider a perspective of an ordinary primary care physician like me when deliberating health care policy.

I'm Dr. Robert Berry. My background is primary care internal medicine and emergency medicine. As a physician in a private practice that does not take any insurance, I believe I might be able to offer you fresh insights on some of the seemingly insurmountable problems we face in health care today.

Over three years ago, I left ER medicine to start a clinic primarily for the uninsured in my community. I thought I might be able to help them avoid unnecessary expensive visits to the ER.

My motivation was simply to try and flesh out in my own life an answer to the age-old question—"who is my neighbor?" Of course, I don't refuse other patients willing to do payment at the moment of service. In fact, because this seemed to be the unifying theme of our practice, I chose its acronym—PATMOS—as the name for the clinic.

PATMOS is similar to charity clinics such as Dr. Eck's in that it serves many patients falling through the cracks of our broken health care system, except that we don't receive any taxpayers' funds, either directly as subsidies or indirectly as a tax-exempt organization.

It is similar to boutique clinics such as Dr. Kaminetsky's in that it contracts directly with its patients, except that most of our patients don't have insurance.

The prices for medical services at our clinic are quite reasonable—$35 for a sore throat, $95 for a simple laceration.

I can keep my fees this low and, thus, affordable to the uninsured and patients with high deductibles, because I avoid the crushing overhead and hassles of processing relatively small medical claims, a service from which they clearly do not benefit.

Mine is only one of many non-boutiques, cash-only clinics in this country. There is a growing movement of physicians like me who offer affordable quality medical care by refusing to sign insurance contracts.

We are no longer willing to tolerate anyone intruding into the once-sacred doctor/patient relationship. And the mainstream media is catching on.

Last November, *The Wall Street Journal* featured our clinic on the center of its front page in an article entitled, "Pay As You Go MDs—The Doctor Is In, But Insurance Is Out."

Just several weeks ago, the AP News ran a story on Simple Care, a network of cash-only clinics, which was picked up by CNN and many local media throughout the country.

National news programs have highlighted other cash-only clinics as well. The media is tapping into a rich vein of frustration and fear, frustration with costs escalating and no end in sight, while medical care is becoming less accessible and less personal.

Fear that we might end up with a single-payer system where delays for treatment can be inhumane.

Clinics like ours offer hope that there are doctors out there today who care, and who don't cost an arm and a leg.

In Canada, the median time from a mammogram to a mastectomy is 14 weeks. Personally, I don't think I could look a woman in the eye, inform her that her mammogram was suspicious for cancer, and then have to tell her that the cancer might have spread before she can receive treatment.

Of course, in Canada, I wouldn't be put to that test, because clinics such as mine are currently illegal there.

The issue before you now, it appears, is very simple—who will control health care dollars?

The government? No. Medical decisions are much too complex and personal to entrust to distant bureaucrats, many of whom lack basic medical knowledge.

How about the patients, then?

In my opinion, the most cost effective and humane solution to many of our health care problems is to allow ordinary Americans to manage their own routine medical care by giving them control over health care dollars. They can do this now with pre-taxed, tax-deferred personal and family medical accounts within consumer-driven health plans and spend them at clinics like ours.

It is, after all, their money and their health. They should control both.

Ronald Reagan once again said, "There are no easy solutions—just simple ones." All that is required is being a neighbor.

[The prepared statement of Dr. Berry appears in Submissions for the Record on page 57.]

Chairman Bennett. Thank you very much.

Dr. Eck.

STATEMENT OF DR. ALIETA ECK, M.D., DRS. ECK, APELIAN AND MATHEWS, PISCATAWAY, NJ; ZAREPHATH HEALTH CENTER, ZAREPHATH, NJ

Dr. Eck. Good morning. Thank you for the opportunity to speak before this Committee and share some of my experiences as a private practicing physician, in the trenches, so to speak.

I have prepared a written testimony, which you have. So I'm just going to try to summarize.

Chairman Bennett. It will be part of the record.

Dr. Eck. I was a registered pharmacist before I became a physician. I graduated from St. Louis University School of Medicine, did a residency in internal medicine at Robert Wood Johnson University Hospital in New Jersey. I'm board-certified in internal medicine.

I live and practice in New Jersey, but I participate in a health benefits reform message board. Experts from across the country—we've been discussing the different problems related to health insurance. New Jersey is considered the poster child with what can go wrong with how government can mess things up so badly.

In 1992, they created an individual health coverage program to ensure that people that didn't have private insurance or government-sponsored insurance could purchase insurance. So they standardized plans.

The state was attempting to make it easier for people to understand the plans and comparison shop. But the net effect was a staggering increase in premiums and an equally staggering increase in the number of people who are uninsured.

So New Jersey is really ripe for change.

There were 220,000 individual policies in 1996; 90,000 now, and they're going down quickly.

As you'll look up on the web site, you'll find that an individual policy for $1,000 deductible, 30 percent co-pay, is now about $4,000 a month.

They actually publish these rates in New Jersey.

The reasons are many. But it's government. The government has told people that the insurance companies have to have a community rating. They have guaranteed issue. They have a $300 mandated amount that they have to pay for check-ups. All kinds of government mandates in each insurance policy. They limit the level of the deductible. And there's intense political pressure to avoid change.

I've outlined all of the reasons for this in my prepared comments.

I even asked our Senator, Jon Corzine, I said, please, let us buy health insurance across state lines. But that's not legal in New Jersey, or I don't know if anywhere else. It certainly wouldn't be against the commerce clause of the Constitution and it would allow a lot less people to be uninsured.

Anyway, I have two practices. I have a private practice with four physicians. And there, we have cut things way down so that we have two full-time employees, about six part-time employees. Very efficient. We don't do any HMOs. We don't do any private insurance.

And this keeps our costs way down and our prices are very reasonable there. We earn a living there.

We participated in one non-capitated HMO. But they looked at our charts and decided that we had charged a higher level than we should have. And therefore, they wanted a claw back. They wanted to take back some of the money that they had given us for services that we had rendered.

We got out in a hurry. And that was the last HMO that we were in.

We found that, in a hospital conference, they gave us a graph and they showed us a horizontal line was where how long people stayed in a hospital. And the vertical line was how much we spent.

And they told us if we were in the upper right-hand corner, we were bad doctors. Lower left-hand corner, we were good doctors.

In other words, our whole training was being compromised by how much we spent, and that was really the most important thing, as Dr. Kaminetsky had noted.

Well, there is a problem of access for the poor. So although our prices are reasonable, we also want to help people who are struggling and have nothing.

We have fascinating stories of people that we have helped in the other practice that we have, called the Zarephath Health Center. We've been in existence for 6 months now and we've been able to take care of people in a very personal way. Not a bureaucratic way, not a one-size-fits-all way.

But you get to know these people and you say, well, how can I help? And how can I make a difference?

There's a little building that was given on our church property for us to use. Our overhead is about $500 a month. We have all volunteers taking care of people. And they come in. And I want to tell you about a couple of these people that we've been able to take care of.

A 28-year-old woman came. Her father had died from a long illness. She had been the primary caretaker and became very depressed. She lost her apartment. She had no job and needed $230 worth of medicine.

She went to the local social service agency and they looked at their lines and they filled in what she needed. She said, "You know, the way you could get help is to just get pregnant."

Well, she was smart enough to realize that wouldn't really help her. So she wound up coming to us. We helped her access a pharmaceutical program where she could get $230 worth of this medicine, a three-month supply. And after that, they wouldn't repeat it until she got a letter from the social services agency that said why they had turned her down. They wouldn't write it.

So we just called around. We found out how much the medicine cost, wrote her a check and bought her her medicine.

It's a tax-deductible gift that people had given to us to help take care of the poor. We helped her. Now she's getting a job. She's not going to need us any more. That's the kind of person we're helping.

Another, a 52-year-old woman is taking care of her 54-year-old sister dying of breast cancer. She has no insurance. Her family has no insurance. She went to the local hospital where she thought she could get reasonable care. They charged her $495 for a physical and blood work. They then gave her a prescription for a mammogram.

Now she has no money, no anything. She came to us. We said, wow, we could have done that for a whole lot less. But we gave her the money for a mammogram. And she got it and thankfully, she's okay.

Interestingly, her sister was just told that she can get on to Medicaid as of July 1st. And she'll be dead by then. So she has really no help. We'll help her, too.

The bureaucratic systems just don't really help, when you really get down to the bottom to where people are struggling.

Just to summarize. I love being a physician. It's the most rewarding of professions. But we're struggling because a lot of government mandates—the malpractice situation is extremely difficult. That makes it harder and harder for us to provide reasonably-priced care.

There are 15,000 retired doctors in New Jersey who can't even help in our clinic because they can't buy the mandated health insurance. Or aren't interested in paying a lot for health insurance.

Those doctors——

Chairman Bennett. You mean malpractice insurance, don't you?

Dr. Eck. I'm sorry. Malpractice insurance, yes. That's an army of people who could serve the poor in our very personalized way if they were just freed up from that kind of a liability.

Anyway, we have to hurry because there are a lot of Americans that are being hurt. The obstetricians and neurosurgeons aren't able to do what they do best because of the malpractice situation.

To summarize, that's basically it. We just need less government pressure on us and more freedom to practice the way we were trained.

Thank you.

[The prepared statement of Dr. Eck appears in Submissions for the Record on page 80.]

Chairman Bennett. Thank you very much.

Dr. Berenson.

STATEMENT OF DR. ROBERT A. BERENSON, M.D., SENIOR FELLOW, THE URBAN INSTITUTE, WASHINGTON, DC.

Dr. Berenson. Thank you, Mr. Chairman, Mr. Stark, and the other witnesses. I appreciate the opportunity to speak here today.

I've provided testimony or a statement for the record. I'm going to divert from that because yesterday evening, I had an opportunity to read the testimony of the other witnesses and found it very interesting and wanted to comment briefly on some of what I read and heard this morning.

Chairman Bennett. Your full statement will be included in the record, as is the case with all of the witnesses.

Dr. Berenson. Thank you very much. And I actually found I had a lot to agree with in the testimony and the statements of the other witnesses.

I think, in composite, they are painting a picture of an increasingly dysfunctional health care system, where primary care physicians, in particular—and I guess we're all, I'm an internist, also, a board-certified internist. I think in particular feel that the system is not working very well for ourselves or for our patients.

I certainly think in aggregate, the other witnesses presented a good picture of the symptoms of our current system and I fully understand their responses, how they've tried to cope with the problems in their own way.

I was actually in a similar situation about a decade ago to Dr. Kaminetsky, where I was working harder trying to just stay afloat.

I think the best year I ever had practicing internal medicine was making about $35 an hour on a full-time basis, making $75,000.

I took time with my patients. Insurance didn't reward me for taking time with my patients. And I wound up, instead of doing what Dr. Kaminetsky did, moving on to more of the policy side of health care to try to see what we could do about improving the system.

So I'm quite sympathetic to what they have described.

However, I think I disagree with some of the proposed approaches, or at least where the physicians suggest the solutions lie.

Dr. Berry made some very compelling comments about how a patient has a choice between going to a busy, crowded emergency room, spending hours, getting a huge bill and not terrific service. And he was providing an alternative to that.

And indeed, all of the physicians described sort of the growing impersonality and bureaucracy that characterizes medicine.

Let me briefly tell you a story of my wife, who a few years ago was traveling in a city where she didn't know any physicians. She was on a trip, developed a fever of 103, felt terrible at about 6:30 at night, and decided she needed to get some medical attention.

She went across the street to a pharmacy that was open. Got the name of a physician to call. Called, a man answered. She said, "Can I speak to the physician?" He said, "I'm the physician." She had expected to be going through a whole array of people, actually expected to be talking to an answering service.

Described her problem. The physician said, "I'll be right over."

In half an hour, had seen her, diagnosed her, given her a prescription, and billed her for $40, which she paid on the spot.

That's the way medicine should be practiced.

That was in France. That was not the United States. That was in a social health insurance system. In Belgium, physicians make as many home visits as they do office visits. In other words, just the fact that there is social health insurance does not mean that we have to have a bureaucratic, impersonal, costly health care system.

There are clearly examples of problems. The UK is under-funded. There are long waits. Canada is having a problem. Other systems have problems. But to equate bureaucracy with government, I think, is a mistake.

In my opinion, the kinds of problems that we have don't call for moving towards high deductible plans that put even greater financial burdens on individuals to seek care, but actually should be addressed by dealing with the problems of uninsurance and under-insurance, by the huge waste and inefficiency that we have because of, in particular, the individual and small group insurance market, which does not work very well and extracts 40 cents on every dollar. These dollars are not going to patient care and this insurance market creates some of the confusion that physicians and patients experience.

And I think we have a continuing problem that has not been adequately addressed by the Medicare Resource-Based Relative Value Scale or by private insurance, which tends to follow the RBRBS, in which we over-reward procedures and tests and doing things to patients and under-reward the activities that physicians are trained to do, but are not compensated for doing.

So I think there are lessons in what these doctors have described for changes in public and private insurance companies. But doing away with front-end insurance coverage, I do not think is the solution.

Specifically, on the issue of health savings accounts, I think they actually exacerbate some of the problems. The healthy and wealthy would be able to do reasonably well with high-deductible plans. But those with chronic diseases, which are an increasing percentage of the population, who would immediately go through their deductible and be in the catastrophic part of the insurance, would be worse off because of adverse selection.

And so the premiums would go up more and more for those with illnesses, and those who are healthy and wealthy would be able to essentially opt out of the insurance pool.

Similarly, I would argue that the costs in health care which are driving government budgets and private premiums through the roof, are associated with a small percentage of patients who generate a huge percentage of costs.

Virtually anywhere that you look, whether it's in Medicare or in private insurance plans, about 5 percent of patients generate about 50 percent of the costs.

In Medicare, patients with four or more chronic diseases represent about 79 percent of spending in the Medicare program.

To provide some incentives for people to use their own money to shop more carefully might feel good. It might reduce some marginal, discretionary services. It would not make a dent in what's driving our health care spending, which is really spending for the very sick.

And then the thing that would bother me the most, and picking up on some of the remarks that Dr. Kaminetsky made, is that people with high-deductible plans who are not affluent would be making choices about whether they should forego early prevention and early diagnosis and treatment, which should forestall health problems down the road and reduce spending down the road.

I don't think we have any evidence base to suggest that people, basically being asked to be their own doctor, know how to make those kinds of choices.

I certainly would not go there based on what we know right now.

So let me conclude by saying I look forward to our discussion. I think the physicians are on to something when they describe the problems in the health care system.

I just don't think that moving more towards a market solution is the way we want to go.

Thank you very much.

[The prepared statement of Dr. Berenson appears in Submissions for the Record on page 91.]

Chairman Bennett. Thank you very much. I look forward to discussion with all of you.

If I might, Dr. Berenson, picking up on your example of your wife. If I understood Dr. Eck correctly, the physician in France that you talk about would not be permitted to do that in the State of New Jersey. Is that correct?

Dr. Eck. I don't think he'd be permitted to do that in Canada. But in New Jersey, they could do that. Cash practices are okay in New Jersey.

It's just that if you wanted to have health insurance, the mandates are all in the health insurance policies, which makes the price of the insurance policies go up. But, yes, cash payments are okay in New Jersey.

Dr. Berenson. I'm not aware specifically of New Jersey, but there have been developments of physicians starting activities to do home visits.

I actually think it's sort of a mechanical thing. In some countries, patients pay at the point of service and then get reimbursed from the social security system. In other places, they send the insurance through up front.

I don't think that—we do not have to have all of the overhead associated with the current practice of U.S. medicine in a well-insured health care system, is the point that I want to make.

Chairman Bennett. Yes. And I find agreement there between what you're saying and the experience that's being demonstrated here.

Now, Dr. Kaminetsky, respond to Dr. Berenson. By the way, I never mentioned health savings accounts in establishing this hearing.

It's interesting that that's where the conversation goes because that's where the conversation has been.

As I said in my response to Congressman Stark, I'm not carrying water at this point for any particular solution. We just want to find out what will work to make physicians, as these physicians have indicated, get excited about practicing medicine again.

Increasingly, I hear that physicians want to get out of it, that the bureaucracy, whether it be private or government, is intolerable.

Among physicians, I don't get any division between the bureaucratic heavy hand of an insurance company or the bureaucratic heavy hand of the government. It isn't an anti-government kind of thing.

It's a revolt against the idea that a third party, whoever it may be, is constantly injected into the equation.

So let's go back to understanding where we are.

Now, Dr. Kaminetsky, will you respond to Dr. Berenson and talk about what——

Dr. Kaminetsky. When you raised the point, which is, of course, on the principal reasons we're here, discussing physician dissatisfaction and why doctors have chosen to make changes in the nature of their practice.

The premise underlying the question or the criticism of what I do is the assumption that were I not doing what I'm doing, I would just be back on the treadmill the way I was, seeing 30 people a day, dealing with acute care, but paying little, if any, emphasis to prevention.

That's a flawed premise, because I was certainly on the verge of leaving the practice. I had done enough investigation to actually be very seriously contemplating signing a contract with a pharmaceutical company. And of course, many physicians have, unfortunately, left the profession because of the frustrations involved. And sadly, their skills are being lost.

Concerns—Dr. Berenson touched on many different aspects. What I do is a solution. It's certainly a niche product. To quote from the AMA's report of the Council on Medical Services—"The phenomenon of retainer medicine is inherently self-limiting. The more physicians charge for their services, the smaller the demand for their services. These economic realities limit any potential for widespread adoption of retainer practice."

In terms of access, I also want to emphasize that affording oneself of the opportunity to concentrate on preventive services and, as a patient in a smaller practice, reap the de facto benefits of being a patient in a smaller practice, is a matter of choice.

Certainly, for those patients, of my former patients who were not capable of making the choice because they truly would find that $1,500 prohibitive, those patients are still my patients.

We call them scholarship patients. There's absolutely no differentiation between the preventive services they receive and any other patients.

So, I do not believe that access is limited by the nature of an MDVIP affiliated practice because of it being a niche product, and because those patients who truly are not capable of making the choice are accommodated, nonetheless.

Chairman Bennett. Any other comment before I turn it over to Mr. Stark on this?

[No response.]

Chairman Bennett. Okay. What I'd like to do, Mr. Stark, if it's all right with you, is for you to take a round and then I would hope that the six of us could have a roundtable kind of conversation rather than the traditional your turn, my turn, my time, your time.

Let's interrupt each other and interact with each other, if that's acceptable to you.

Representative Stark. It certainly is. Thank you. That's generous of you, Mr. Chairman.

Like Dr. Berenson, I haven't heard anything this morning that gets me terribly upset. I have to look at the Stark family.

I like the idea of what we call the "boutique." I'm just enough of a snob that I'd just as soon be able to call the doctor at home and do a whole lot of things that—now, the Senator and I have available to us, courtesy of the United States Navy, a whole clinic full of doctors who are available 24/7. And we don't wait. I mean, we really don't. And they're high-class physicians.

And it is a form of medical care delivery that this country could not afford.

But we know what the boutique of the boutiques is like. And it's pretty nice. And I have some of my colleagues who have retired who get out into the real world and miss that very much. They could afford and would go to a physician.

We changed with our three little children pediatricians. Same reason. We just got sick of being shuffled. They ran maybe three offices and had 15 physicians. And that got to be just more than we could deal with until we found a physician who would deal with the children and we could contact her. So I think that's instinctive.

The trouble with it, I suspect, is if everybody went that way, we would get into much more of a two-class system than we have.

Let's assume that the 40 million uninsured are one class and those who enjoy medical payment systems are in another class.

So I have no quarrel there.

Dr. Eck, first of all, you're to be commended for formalizing your commitment to treating people without charge. I have often suspected that when I hear physicians, and I hear a lot of physicians every year, complaining about how poorly Medicare pays them and how much time they spend on pro-bono services, that the only time I think they really mention pro-bono services is when I see them in my office.

But that's a skepticism that you certainly disprove.

As for cash only, I have this experience. Near Annapolis, where we live, there's a doc-in-the-box person who doesn't require an appointment and is near our home. And often, either our nanny or my wife or I will go there when we're pretty sure what we need. We're pretty sure it's an ear infection and we need an antibiotic, or whatever.

And she's very accommodating. She takes cash, but we can send her bill on to Blue Cross. And sometimes they'll pay us some and sometimes they won't, depending on what she writes down that she's done to us. This physician serves a real purpose in our community.

There's a nighttime pediatrics that now takes adults as well. It's a community organization mostly of pediatricians and a couple of family practice physicians. And they're open 6:00 till midnight and Saturday afternoons and some Sundays for the time that children mostly seem to get sick. And they will take adults.

So I had an experience there, and this is what troubles me.

I was waiting to register my son to go in, probably with an earache. A woman was next to me and they were saying how much she had to give them her insurance card or her credit card. They did not take her insurance. She had a young child with her and the child was quite obviously in some pain. They wanted $65.

She had driven, for those of you who know the area, from Kent Island all the way to Annapolis. So this wasn't just in the neighborhood. They made some effort to bring this child some distance. And she couldn't afford the $65.

So she left with the child and hopefully went to the Annapolis Medical Center and waited around the emergency room for a while.

And there are people—and it's hard for many of us who are more comfortable to understand where $65 is a real barrier to getting the kind of attention that we think, as patients, that we'd like at the time. And that's a problem I have.

I wanted to ask because I want to talk about the free market in a minute.

In each of your practices, for the primary care patients—and I don't know how many of you provide other services than primary observation and referral. But give me what you think would be the median dollar amount that your patients spend. Not including your fee.

But what does a patient on your books spending a couple of thousand, three thousand, two thousand, one thousand, what's the median of people who you see?

But before you get to that, my concern is, and I think in your testimony, Dr. Berenson, you presented this to some extent.

I don't think that we as lay people—and the Senator may be better at this than I am—I don't think that we're able to shop for medical care or services.

I can go out and shop, with the help of *Consumer Reports*, for automobiles and tell you how to get the best deal on a Camry or a Lexus or whatever you're looking for, and we know about that.

And my wife can tell you where to go to get the best produce, whether it's best at Fresh Fields or Giant and what days the fish is fresher, where.

But we are absolutely clueless as to what it costs or what kinds of things to go shopping for in terms of medical services.

And I had my staff, just for the heck of it, shop in your hometowns earlier this week. It took four of them about 3 hours apiece. And I would just ask—and it was two things—a head CAT scan and a colonoscopy.

And I don't know if you found a bargain colonoscopy, if you'd like to run out and get one right away. But let me just ask Dr. Berry.

In Greeneville, Tennessee, do you know what the range of colonoscopy charges—now they all said about $2,500 for anesthesiology and the facility fee.

Dr. Berry. Do you want to know the doctor's fee or the hospital's fee?

Representative Stark. What would you guess the range is?

Dr. Berry. The doctor's charges versus what he's reimbursed—the doctor's charges I think run between $600 and $800. The hospital charge to the uninsured——

Representative Stark. We said that we were uninsured.

Dr. Berry. Uninsured.

Representative Stark. The ranges we got were $900 to $1,500.

Dr. Berry. Okay.

Representative Stark. Dr. Eck, what do you think——

Dr. Berry. The hospital, by the way, sir, would be about $1,500 for the uninsured.

I know that because I have a copy of a bill from someone who came in.

Representative Stark. That's okay. I'm just trying to——

Dr. Berry. And his wife's insurance was——

Representative Stark. What do you think they are in Piscataway?

Dr. Eck. Piscataway. It's an Indian name.

Representative Stark. Just the doctor's fee. What do you guess?

Dr. Eck. I'd say about $1,200 to $2,000.

Representative Stark. You'd pay too much. $600 to $1,200 is what we got.

Dr. Kaminetsky, do you want to take my test? What would you guess?

Dr. Kaminetsky. I would hazard a guess of about $800 for the doctor's fee.

Representative Stark. Well, we got $500, $900, $650 and $1,100 in Boca Raton where we called.

So, I guess the only reason I say this is that it took us forever and a day. And if you need a head CAT scan, you're probably not in shape to be spending a couple of hours calling around to get the best price. We don't shop for that. You tell us to take a test. We take it and hope we pass. And we go where you send us.

Dr. Eck. If you're going to save several hundred dollars, you would shop around. That's not that hard.

Representative Stark. Well, Doc, I want to tell you that there are times when various malfunctions hit you and you're in no mood to shop around.

Dr. Eck. Well, that's different.

Representative Stark. And my sense is that——

Dr. Eck. Then what you need is a general contractor who knows the system who can help you out.

Representative Stark. I'd just point out that it's difficult for us——

Dr. Berry. I've done the shopping, Mr. Stark, and I've gotten discounts from hospitals and from other—not for colonoscopies. I've tried. I haven't been able to do that. But for an MRI, for example, cash payment to our clinic would be $530, and that includes the interpretation. If they want to put it on their credit card, $550.

Representative Stark. But you're doing that.

Dr. Berry. I've done that for a lot of tests.

Representative Stark. What I'm suggesting is that that's fine, and that's as it should be.

But we as patients——

Dr. Berry. That's why you come to me.

Representative Stark. Precisely.

Dr. Berry. Because I've done that work.

Representative Stark. And what I'm trying to suggest is that that's what's wrong with these high co-payments—we as patients don't know how to do that. We don't know what we're looking for.

Dr. Berry. Well, what happens out in the real world is that patients talk among themselves and they find out which doctors they can trust.

Chairman Bennett. Right.

Dr. Berry. And that's why more and more patients are coming to me.

Chairman Bennett. Yes. If I can intrude my personal experience in this.

I don't shop for dollars, but I shop for doctors. And if I can give you a somewhat parallel example. You talk about automobiles.

I am as clueless when it comes to car repair as I am medical repair. I have no idea whether I'm getting ripped off by a——

Representative Stark. You are.

Chairman Bennett. Okay.

[Laughter.]

Representative Stark. Go into the repair shop with that in mind and you'll be right.

[Laughter.]

Chairman Bennett. I have found in my lifetime repairmen, auto repairmen who are willing to talk to me. And you spend some time talking to them, they'll tell you who in the community gives you good service and good prices and who doesn't.

And usually, I take the coward's way out and simply take the car back to the dealer, which may or may not be the right thing to do.

But when I'm worried about money and I've got an old car that I've got to deal with, I'll talk to a mechanic who will tell me who the other mechanics are.

Now, do the same thing with doctors. And doctors break the code of silence if you get to know them and they'll say, "the question is, all right, doctor, if you had a problem, where would you go?"

And inevitably, in one area, and I won't identify it, because I don't want anybody listening to this to start to go down the trail. But in one area in my family, we've had a particular problem that has occurred in several members of the family.

We have asked doctors—"Okay, if you had this problem, where would you go?" And the same name has come up every time.

And by careful activity, every member of our family that has had that particular problem has gotten in to see that doctor.

I don't think it's just because I'm a Senator that I can make a phone call and say, "Will you see my grand-daughter?" And have him say "yes."

The network is out there. One of the great frustrations with managed care is that you can't do that. Indeed, when I was CEO of my company picking plans for my employees, I picked the plan that made the most economic sense, which is what the incentive is.

And then when I looked at the particulars, I said, "Wait a minute. I don't want this plan," because the doctor with whom I had a relationship was not on the list of doctors.

I got around it by going to a doctor who was on the list whom I knew and said, "Will you please accept the assignment of my pri-

mary physician and immediately refer me to the doctor that I want?"

And he knew the doctor that I wanted. He agreed with me that it was a very good choice and said, "sure."

So we gamed the system by my signing up with this plan and worked it around so that I never ever saw the doctor who was on the list as my primary care physician.

Dr. Eck. You know, it's interesting. The very best specialists you won't find on any plan because they can name their price.

Chairman Bennett. That was the case with the doctor that I wanted.

Dr. Eck. They can name their price, they're so good. Who do you want to go to when you need that neurosurgery? I'd rather go to the best and pay more than go to the doctor on my plan. That's why I'm not in any plan.

Representative Stark. I just wonder if I could get the numbers real quick and then I'll yield.

Have you guys thought about what the median patient spends for primary care in your practice each year?

Dr. Berry?

Dr. Berry. At my clinic?

Representative Stark. Yes.

Dr. Berry. I know what they spend per visit.

Representative Stark. No. Well, what would you guess they spend in a year?

Dr. Berry. I don't know that, sir, because I don't keep those kinds of records.

But they spend $51 per visit, which includes the professional fee, the labs, whatever tests that I order and whatever medicines I provide there or dispense from the clinic. That's the total visit.

Representative Stark. Any idea, Dr. Eck?

Dr. Eck. The average person? Again, I don't have those kinds of records, either. I'm just imagining.

Some of them like to come a lot. They feel better when they see me a lot. So they might pay $500 or $600 a year, if they're not very, very sick.

Representative Stark. All right.

Dr. Kaminetsky, other than the fee, what's your average?

Dr. Kaminetsky. As Dr. Eck said, a lot of patients like to come a lot. And one of the old complaints about Medicare, of course, is that there's no disincentive for a patient to come for a very trivial complaint.

But I'd say the vast majority of my patients are either paying for their Medicare supplement, which is several thousand dollars a year, plus medications, depending on what their needs may be in terms of relative health.

My non-Medicare patients, their main expense would be the cost of their health insurance, which would vary. I think single with children—for my family of five, I pay $1,300 a month.

Representative Stark. Most of your patients have insurance. And that covers most of what you would bill them for, your procedures.

Dr. Kaminetsky. The vast majority, yes.

Representative Stark. Okay. Thank you.

Dr. Kaminetsky. Can I take the opportunity?

Chairman Bennett. Sure.

Dr. Kaminetsky. I just want to respond to Mr. Stark's anecdote about changing to the pediatrician. And of course, you change because you are frustrated by the lack of access.

Chairman Bennett. You shopped.

Dr. Kaminetsky. The prevention program, the emphasis is truly prevention.

For example, numerous studies have shown that what is most effective in getting patients to stop smoking is doctor-patient intervention. Not Nicorette gum, not nicotine patches, not Welbutrin, but doctor-patient intervention.

When I have a smoker and I'm trying to get him to stop, it's almost like a game. But he knows that a designated day of the week, every week, he's going to get a phone call.

That's prevention.

With 2,500 patients, I couldn't possibly do it. Now it is true, again, a de facto benefit of being in a smaller practice, as when you're competing with 600 people for an appointment versus competing with 2,500. It's different. But the emphasis in the program is prevention.

And as far as the concern about creating tiers, well, medicine is tiers. We've got HMOs. We've got PPOs. A Medicaid patient can't see a doctor who is not a participant in Medicaid. And a Medicare HMO patient cannot see a doctor who is not a participant in that HMO.

This is another product in a very pluralistic market which offers many different options for patients. And the AMA's Council on Ethical and Judicial Affairs, specifically referring to retainer practices, has endorsed the concept that, "the patient has the freedom to select their health care on the basis of what appears to them to be an acceptable trade-off between quality and cost."

Representative Stark. I have no quarrel with it at all. I am a little uncertain as to how it deals with extra billing relative to Medicare. But that's a very technical problem for another day. But other than that——

Dr. Berry. To answer your question, though, all you have to do is multiply, say, the patient sees me 4 times a year for hypertension. That would be about $200.

Representative Stark. One of the problems we have, and then I'll get out of this, what I was leading up to is that, on average, and averages are bad. We spend $7,000 a year on a Medicare patient.

Now, most of that is spent on those beneficiaries who are very much older than I am. But nonetheless——

Chairman Bennett. And in the last 30 days, isn't it?

Representative Stark. Yes. But I think even if you took the 20 percent at the right hand of the curve and lopped it off, we'd still be at $2,000 or $3,000, anyway that would be spent, again, on average, by these 40 million Medicare beneficiaries.

And I don't know that they could get insurance, absent community rating and forced across the country and a whole lot of other things that they could afford if we didn't have it.

Now you may not like it as the best system, but many of us think it's pretty efficient. And prior to 1965, I was active in finding insurance for my grandparents and my parents and it was impossible.

So for those people who remember back that far, it was a great burden that was removed from the worries of seniors as to what they were going to do about paying for health care.

And in those days, it wasn't as expensive. There weren't as many sophisticated techniques and tests and things to pay for. But it was still a concern for people.

Dr. Eck. Do you remember what the cost of a hospital bed was per day back in 1965?

Chairman Bennett. It's under a $100.

Representative Stark. I'm going to guess, in the neighborhood of $100 and change.

Dr. Eck. In New Jersey, it was $39. But once all those dollars came infusing in, that was part of the reason for the medical inflation that has occurred.

Representative Stark. You could buy a Mercedes for $2,000 in 1965, too.

Chairman Bennett. A Mustang, maybe.

Representative Stark. A Mercedes.

[Laughter.]

Representative Stark. A Mustang was $900.

Dr. Eck. Medical inflation is higher than Mercedes inflation.

Chairman Bennett. Yes.

Dr. Berenson, get into this.

Is there any evidence that concierge care or insurance-free medicine of the kind that we're talking about here which Mr. Stark has endorsed as something he'd like to see survive—the Canadian system clearly says, no, we will not allow this to survive.

Is there any evidence that this has contributed significantly to the escalating health care costs? Hasn't the orthodox insurance and medical practice been able to escalate entirely on its own without any help or upward pressure from this kind of thing?

Or is, in fact, this a threat to the now more traditional kind of financing?

Dr. Berenson. I guess a couple of responses.

First, we're combining to some extent apples and oranges here, because as I understand what Dr. Kaminetsky is doing is he's got a separate subscription for a certain kind of additional service.

Chairman Bennett. We deliberately tried to get three different kinds of examples instead of the same one all 3 times.

Dr. Berenson. So, in a sense, I think people are paying extra out of their pocket, without tax-subsidization for this special attention. And it probably marginally increases overall costs. But it's so small, that I don't think it's anything to worry about.

And it might actually have benefits, as he points out, in promoting early diagnosis and treatment.

Again, these other approaches, whether it's having special, cash-only emergi-clinics or physicians who are starting home visit services and getting paid, that's not where the money is in the health care system. And so——

Chairman Bennett. When you say the money, you mean the costs.

Dr. Berenson. The costs. I mean, that's not what's driving health care costs.

So, again, as sort of niche activities, certainly a free clinic is a worthwhile activity that's taking care of uninsured. So I don't think what we're talking about today as sort of niche activities is a threat or driving up health care costs.

What I get concerned about is seeing this become part of a philosophy of moving away from the important social role of insurance pooling risk. To think that we can take these few examples and build it into something bigger is what bothers me.

Chairman Bennett. Well, let's pursue that. Let's not talk about philosophy. Let's just talk about the market.

Suppose this catches on and a lot of people decide they want to do it. You consider—in other words, there's a threshold, if I understand what you're saying—as long as they remain small and scattered and not very many, you're not going to worry about it.

But is there a threshold at which point the Dr. Berrys and the Dr. Ecks and the Dr. Kaminetskies multiply where you say, "Wait a minute, this does become a threat." And at that point, you're going to come to the Congress and say, "You've got to take action to stop it."

Dr. Berenson. I guess my concern is, if we develop—if at some point we're developing specialized services that attract the healthy and the affluent into a separate sort of risk pool that they benefit from, we just drive up the risks for those who have no choice but to have comprehensive insurance.

And so, we may save a few dollars on some reduced discretionary services—if somebody doesn't need an MRI because they're a weekend tennis player and they're going to have to pay out of pocket and they make a decision not to have it, that might reduce some expenses, if it's purely discretionary and it's something that somebody doesn't want to pay for out of pocket.

But the problems created for those who are in the basic comprehensive insurance pool, I think, are not worth that sort of marginal savings.

Chairman Bennett. So there is a point at which you would draw the line and say, by government fiat, we're going to say "no more?"

Dr. Berenson. I'm not sure that I know where that line is, because these are very diverse kinds of activities.

Chairman Bennett. Well, I'm not looking for the line. But philosophically——

Dr. Berenson. Philosophically, I think that's right. I think we don't want to go too far down this road.

Chairman Bennett. Okay.

Dr. Eck, do you serve the wealthy and draw people away from insurance?

Dr. Eck. No, I believe in insurance. I just believe that the insurance model has to be correct.

I believe in high deductible insurance. I don't want people trying to run through their deductibles so that they can get into insurance where everything is covered and then over-spend.

So that's why I like the idea of high deductible and then paying for their services via health savings accounts for the lower things.

Representative Stark. Can I add to that?

Chairman Bennett. Sure.

Representative Stark. I would assume that all four of you feel that whatever the plan, at some amount, $2,000 or $3,000, there ought to be a catastrophic benefit for people who need surgery or severe—do all of you feel like that?

Dr. Berry. I have that kind of insurance.

Representative Stark. Yes.

Chairman Bennett. And I agree with that, too.

Representative Stark. Just the first thousand or two. And beyond that, whoever they are, they ought to have some coverage.

Dr. Eck. It just has to be properly designed. My family, since 1997, has not had health insurance, and I'll tell you why.

Because we live in New Jersey, it was way too expensive and it's not worth the money.

But we were able to get into a Faith Christian group where they could put restrictions on our behavior that would lower the cost of health care for all. And therefore, we pay $215 a month to be covered for catastrophic events that exceed $900. And it's extremely reasonable, and it works, and it's covered. It's not insurance. Therefore, it doesn't get under the department's banking and insurance.

Representative Stark. Do they provide that for warlocks? Have you ever heard?

[Laughter.]

Dr. Eck. They'd have to have their own.

[Laughter.]

Representative Stark. I can't find any. That's why I ask.

[Laughter.]

Dr. Berry. That's because their behavior is so high risk.

[Laughter.]

Dr. Kaminetsky. My practice is entirely compatible with insurance. It does not supplant insurance in any way. And certainly, my patients are far from being cherry-picked as being healthy and wealthy.

It's because of the nature that many of them have chronic illnesses and they would like to forestall getting more seriously ill, that they put the emphasis on our preventive products.

So, certainly, if anything, though it's a small sample, our preliminary data, as I said, shows a 30 percent reduction in hospitalization rate. I am convinced that we are saving insurance companies money.

Chairman Bennett. But your comment there seems to be counter to what Dr. Berenson says, because you say that you're getting the sicker rather than—that is, people who have chronic problems that they want to deal with.

Dr. Kaminetsky. No, I have an entire spectrum.

Chairman Bennett. Okay.

Dr. Kaminetsky. The point I was trying to make is that it's not just getting young, affluent, healthy people who want to live longer than 50.

Chairman Bennett. Okay. In other words, there is no adverse selection.

Dr. Kaminetsky. Absolutely.

Chairman Bennett. All right.

Dr. Berenson, you want to say something?

Dr. Berenson. Well, simply that they have their full insurance coverage. And in addition, they are purchasing some additional services. I think we should actually do the study that's implied here.

A lot of the best physicians I know in Washington where I practiced for many years, and from what I understand from around the country, practice a different style, which is spending lots more time with their patients—these are primary care physicians, often internists. And because they are doing that, they believe that they are reducing unnecessary referrals to other specialists. They think they are reducing tests and procedures and saving money.

This should be subjected to some real testing, and if it demonstrates, in fact, that that's what the effect is, I don't know why insurance companies within their insurance products are not rewarding Dr. Kaminetsky for doing exactly that kind of thing.

I don't know why we have to have this to be extra insurance, I guess is what I'm saying. Why shouldn't Medicare, as I've suggested, and other payers, actually pay additional fees for the coordination activity that primary care physicians should be doing, but don't have time to do for their patients who may have seven doctors and take 35 medications in a year. They're not paying for any of that kind of coordination. And so important care falls through the cracks.

So I guess what I'm saying is I haven't heard anything here today that's not compatible with insurance products, whether public or private. I think there have been some misguided decisions by insurance companies, public and private, about what they're paying for.

Chairman Bennett. Okay. That's getting——

Dr. Berry. May I say something here?

Chairman Bennett. Sure.

Dr. Berry. I think that actually the low co-pay, low deductible so-called "insurance," which is not really insurance at all, is, in fact, increasing the cost of care for a number of reasons. And I don't think that the government should encourage that with their tax policy, because right now, it's open-ended. A company can write as an expense $10,000, $20,000. And the rest of the country is paying for that, including the uninsured.

They're effectively subsidizing these low co-pay, low-deductible insurance policies.

What I'm for is payment at time of service for routine health care. And he says that it's not going to reduce costs much. I don't know. But there are about a half billion patient-doctor interactions or encounters per year in primary care.

Now you change the mindset of people. Instead of their asking, "Doc, don't you think I need that MRI or some blood work on this?"—they will be asking, "Doc, do you really think I need to have that test done?"

Let me tell you, that changes the whole equation. And I suspect that once you translate that cost savings per encounter, you would see significant cost savings. I don't know what the numbers are. Policy people can probably churn those out. But you don't get visits

at $51, including all that I provide, without doing some penny-pinching.

Chairman Bennett. Dr. Eck.

Dr. Eck. In May, we're going to have "Cover The Uninsured Week." That's a big publicity event where I think what we're saying is that people who have no money, somehow we have to come and cover them. And by covering them, we have to buy them health insurance.

I would disagree with that, because the whole idea of health insurance is not necessarily health care and it's phenomenally expensive.

There's a little center in New Jersey that is a lot like ours, only it is 4 years old. It sees 6,000 people a year who have no money, and it's all volunteers. It's a lot like what we do, volunteer doctors and physicians. Their budget is $500,000 a year for 6,000 people. That translates to $83 a year per person.

Now these people get health care. So do they have coverage? No. But they get health care. They get referred. The hospital takes care of them if there's a problem. The community that's working that's getting health care to people.

Everybody's happy. Patients love it. They get personal care. The doctors feel good. They're volunteering their time. It's not a big, expensive, bureaucratic—actually, it was covered on "20/20," and I think it's a real solution to take care of the poor.

Is it a two-tiered system? I suppose. They're not paying. But it's getting the job done. And I think that we should look into that as a way to get health care to the poor rather than the big government programs.

Chairman Bennett. Mr. Stark.

Representative Stark. Well, I think we're—let me just try this. We don't think boutique medicine is inherently bad. All of us——

Chairman Bennett. Say that again. I didn't hear you.

Representative Stark. We do not think——

Chairman Bennett. You do not think. Okay.

Representative Stark. We don't think it's inherently bad.

Chairman Bennett. You said it quickly enough that I heard, "we all think."

Representative Stark. Now all of us want better access. But not everyone has the type of access that we are able, either as professionals or politicians or wealthy people—we're in a class distinct from, say, the family of four with $25,000 of income or less, they don't have the advantage.

Chairman Bennett. Unless they live in Dr. Eck's neighborhood, and then they do.

Representative Stark. They may. But they don't as a matter of practice. So, obviously, there are perverse incentives in the fee-for-service area to do more to get paid more. That's an incentive that we've had to deal with a lot, and I'm sure the physicians recognize.

But there's also the reverse of that incentive, is when you don't have any insurance. There's a big of an incentive to postpone perhaps getting treatment because your tolerance for pain may go up as your pocketbook gets thinner.

And I think if we could figure out somewhere in between, Mr. Chairman, how we can be sure that the person who has to come up out of pocket—now in Dr. Eck's area, there are non-governmental organizations that provide. There aren't in a lot of areas. I mean, your neighborhood—and your neighbors are to be commended—but that doesn't exist universally.

So if we could be sure that the people at the lowest income scale, let's just suggest, had access as any of you would suggest they need for either primary care, for preventive care, to do all the things that you'd recommend, and also then, for those of us at the other end, are somehow prevented from abusing the system by over-indulging our whims to chat with you nice professionals whenever we get the urge or sneeze, that's the middle ground that perhaps we're all pushing towards. I don't know what the answer is. There may be different approaches.

Dr. Berry. I think part of the answer is doing payment at the time of service for routine health care.

Representative Stark. What if you don't have any money?

Dr. Berry. The administrative overhead for doing——

Representative Stark. What if you're homeless and don't have any money? How do you pay at the time of service?

Dr. Berry. That's a separate and small issue, I will admit. There's no question about that.

But let me say this, that when I was working in the ER, 80 percent of TennCare patients who came, adult TennCare patients, smoked cigarettes.

Assuming $1,000 a year, that would be 20 office visits at my clinic. They need to be made accountable as well. They need to be acting neighborly as well. And they don't need to be driving Toyota Sequoias. They don't need to own vast tracts of land. Some of the people's net worth on TennCare is much higher than mine will ever be. So there's something wrong with that.

Representative Stark. I think you're quite right. I just think that we don't have a system—I noticed in Colorado recently, it was in the press yesterday or the day before, the emergency rooms are, many of them, trying to triage now to keep the burden of unnecessary visits——

Dr. Berry. They could come to our clinic.

Representative Stark. I beg your pardon?

Dr. Berry. Our clinic is ideal for that. And they're not willing to forego a $1,000-a-year cigarette habit——

Representative Stark. If they have any money.

Dr. Berry. Their problem is with priority, not with my price.

Dr. Eck. There are 32 volunteers in medicine clinics across the country.

Representative Stark. You have a clinic that can handle it.

Dr. Eck. There are 32. And they just need to be encouraged. And I think that army of retired physicians that I was speaking about, if we could relieve them of the malpractice burden so that if they donate their time, they're not liable for anything that might have a bad outcome, we can make a big difference.

Representative Stark. You're getting close, Doc. If we relieve them of the malpractice burden and maybe the tax burden, we're really paying you. And I have no quarrel——

In other words——

Dr. Eck. They're not getting paid. These doctors aren't getting paid. They wouldn't be getting paid. They would be giving free service. You take care of the poor. Just relieve them of the malpractice burden so that they're free to do this.

Representative Stark. What do we do in areas where there aren't any nice guys like that?

Dr. Eck. They're all over the country. There are 15,000 in New Jersey.

Representative Stark. Send everybody who can't afford to New Jersey.

[Laughter.]

Chairman Bennett. No, let's not send them to New Jersey.

[Laughter.]

Dr. Eck. So there must be a lot in other states. That's what I'm extrapolating.

Chairman Bennett. One of the issues that this panel has highlighted that gets ignored a great deal in the discussion of health care is the number of doctors who are voting with their feet and walking away from medicine.

And that has to say to us that there's something wrong with the current system if it is driving away its most qualified practitioners.

At the risk of opening another area, and I'll shut it off very quickly if indeed this does inflame a lot of comment:

When I got involved in looking at education, I discovered a very interesting thing. Education is the only area where people will accept a lower price for the privilege of not teaching in public schools.

Private schools pay lower salaries than public schools and teachers will voluntarily walk out of the public school for the privilege of teaching in an environment that they consider more conducive to education.

Now I'll quickly shut that door, having opened it.

But it does represent a signal that there's something wrong that has to be dealt with. And we find some of the best teachers refuse to go into public education, and they go elsewhere.

I know that because I used to run a company that was basically an education company and we had wonderful teachers, none of whom would have any interest in teaching in public schools, and the public schools were the poorer for that.

So if we are in fact seeing "hamster health care," which is the phrase I use with physicians on the treadmill all the time; and therefore, physician satisfaction going down, and as I've talked to physicians and I think what you're saying here, it's not financial. It's not because they're not earning enough money that they decide that they have to get out of medicine because they can make more money someplace else.

It's what you have said here, they are feeling that they cannot perform what they were trained to do, and so they're leaving health care.

Dr. Eck. A lot of them are leaving the HMOs and that frees them up.

Chairman Bennett. Okay.

Dr. Eck. That frees them up tremendously. And I think most of us sitting here enjoy practicing medicine.

Dr. Kaminetsky. But the problem you just touched on is a very serious one. I don't know if anyone might have seen, not this past Sunday, but the week before, *The New York Times Sunday Magazine,* Lisa Sanders at Yale, a primary care professor talking about the declining applications every year to primary care.

We're all primary care-givers. And the national residency match program, every year there's been a decline in internal medicine and family practice.

So with the numbers of primary care-givers going down, at the same time that the population is getting older and demographically, the need for internists is going up. Furthermore, there are more reasons to see a doctor now.

For instance, as an example, someone who might have had congestive heart failure 10 or 15 years ago would have been treated with just Digoxin and a diuretic.

Now there are many other modalities of therapy. There are many new drugs. There are inhibitors, ARBs, and so forth. There's more reason to see the doctor. There's an older population and there are fewer primary care-givers.

Now part of the problem realistically is not because—you're right. I agree with you. It's about being a doctor and giving care.

However, when you graduate with $175,000 of debt, you're not immune to a respected mentor saying, "You know what? Don't go into medicine."

So one of the potential solutions is maybe there needs to be more government intervention and subsidizing private medical school education in return for encouraging people to go into primary care subsequently.

Dr. Berry. I'm not so sure about that. But it seems that society doesn't value the services of a physician today quite so much.

Had I graduated from the University of North Carolina business school in 1992 instead of graduating from the medical school in 1989, I would be making more than I would be if I were still practicing emergency medicine, a considerable sum.

So that shows—if you're a senior or junior college student and trying to decide what you're going to do with your life, why would you go into medicine? You're going to get paid less. You have long hours. You've got incredible risk. People's lives are in your hands. Why do it? I think that that's a legitimate question to be asking.

Dr. Berenson. I'd like to add, I think we sometimes lump all docs together. And what's I think the serious problem right now is the lack of training in the primary care fields. In the same article that Dr. Sanders wrote in *The Times,* there was a reference to Alan Goroll, who is a professor at Harvard who is a friend of mine. I was in his class at college.

He told me that last year's graduating class at Harvard Medical School, of about 160 graduates, 20 were going into internal medicine. But of those 20, 15 were going into cardiology and gastroenterology and perhaps 5 were becoming the kinds of doctors that you call at 2:00 in the morning.

That's something we haven't talked about, everybody getting a doctor with whom we can have a relationship as the way to get their basic primary care.

There was another article I saw in *The Times* surveying graduates of some medical school. 40 percent of them wanted to go into dermatology because the pay was better, the hours were better, there was no night call. I don't think they're so unhappy, frankly, the dermatologists of the world. I do think that practicing primary care right now is very difficult. And a lot of doctors I know are giving up HMOs. They're giving up Medicare.

Medicare patients are complicated. They have four, five or six problems and many medications and it's hard work. And we're not rewarding them and compensating them appropriately or giving them sort of the kind of nonrenumerative support that I think they need.

And I would offer a policy opinion on this one. Because in the Medicare statute, we have control over expenditures for physicians, the Congress, CMS, Medpac, don't look at where we're spending that money because we control expenses.

So the fact that we are sending huge signals about what specialties to go into, and those signals are don't go into primary care, is not anything that has gotten policy-makers' attention. I think it needs to be focused there.

Representative Stark. Are you familiar with the German system? Do you like it?

The only people on fee-for-service in Germany are the primary care docs. You go to the hospital and it's a flat-rate per day, whether you've got a plantar wart to be removed or a heart transplant, the same amount. And all hospital-based physicians, which are all surgeons, are paid a salary, except if you're the chairman of a department at a university. Then you can charge a fee on top. And it just turns our system on its head.

In other words, you maybe get three pfennings for a Xerox, but you get a long Chinese menu of things that you can charge as a primary care doc. And they do much better than their counterparts, unless they happen to head a department.

Dr. Berry. Well, I think I would be doing much better if I could see, instead of three patients an hour, four patients an hour. I would be almost making as much as that MBA from Carolina.

The problem is that, besides the government subsidizing low copay, low-deductible insurance, they make it very difficult for doctors to do this kind of practice. They require basically doctors to opt out of Medicare. If I did not opt-out of Medicare, I would have to refuse Medicare beneficiaries showing up at my clinic asking to be seen, willing to pay me $35 out of pocket. Quite frankly, I'm not willing to discriminate against Medicare beneficiaries in my community.

So that is one policy that you could look at, is to roll back this crazy opt-out clause, because I can't find physician coverage for my clinic. I had to shut down the clinic today. Nobody's going to work at my clinic because everybody still takes Medicare. I've opted out.

Chairman Bennett. Any other comment on that?

[No response.]

Chairman Bennett. Well, let's wrap this up. This has been enormously helpful, and I'm very grateful to the four of you.

Dr. Eck. Can I just say one more topic we haven't touched on? And that is the plight of the uninsured.

In New Jersey, I know, they get charged 300 percent of what Medicare pays for a hospital visit. If a hospital visit costs $10,000, the uninsured get charged $30,000. Tremendous. And these are the people who presumably really can't afford it. And so then liens get put on their house and the whole thing.

What we have found out is that if you go to a little island in the Caribbean that is not the United States, there are little hospitals there that can take out a gall bladder and they would charge $1,000.

Compare that with $30,000 in New Jersey, $1,000 in the Caribbean.

And so we're looking into that. And we're just saying, what would happen if Americans came down and had an operation done there? Maybe we could even bring our surgeons down. And they're very positive. The surgeons are saying, "Hey, we would do that. We would do it for free if you gave us a week in the Caribbean." So we're looking into it and I'll keep you posted.

Dr. Berry. Well, the front page of *The Wall Street Journal* shows a Canadian citizen going to India to pay for a hip replacement that costs about $5,000. He would have had to have waited a year-and-a-half for it in Canada. And the $5,000 is about a quarter of what he would have been charged in the United States.

Dr. Berenson. If I could, I think, though, that Dr. Eck's comment is something that I wanted to address about sort of this alternative approach of low-cost, often what has been called "charity" care. I worked in a free clinic. I also saw patients who didn't have insurance. I'm sure all of these physicians provide uncompensated care.

But I remember an experience I had. I had a patient I was seeing for nothing who needed a chest x-ray. So I called the head of my hospital where I admitted and said, "Can I get a free chest x-ray?" And the guy said, "I'd love to help you out, but I don't have anything to do with the x-ray department. That's owned by somebody else, a separate radiologist company."

The point is that medicine, health care is a very complex—there are many people who have to provide services. So the physicians providing cut-rate and good services perhaps, but the hospital is then charging 3 times more for that same patient or the radiology group is not discounting their MRI rates or might actually be price. discriminating more against the person who has poor insurance or no insurance. And so, I commend approaches to fill gaps and to provide some services in a lower cost way.

But I think it's pretty clear from the studies that are being done by—some by my colleagues at the Urban Institute—that people do better with insurance. It does drive up costs some, but their health care is better. And there are some cost offsets.

And an alternative of non-insurance, second-class, "we do the best we can for you," I don't think is something that we as the United States should be looking to as the major way we provide health care to the uninsured.

Chairman Bennett. I haven't heard anybody here say this morning that we should get rid of insurance.

My concern is that insurance ought to be insurance. Now I've used this before and it's an imperfect analogy, like every analogy is, but I use it again to make the case.

I have homeowner's insurance. I would be foolish not to have homeowner's insurance. It's a wonderful policy. If the house burns down, they not only replace the house. They replace the paintings on the wall. They replace the carpets on the floor. They replace the silverware in the drawer in the kitchen and the clothes in the closet. Everything.

It's just terrific.

But try as I might and read the fine print as often as I can, I can't find anything in the insurance policy that will reimburse me for mowing the lawn or painting the front door when the dog scratches it, which the dog does quite often. Or used to when we had a dog.

Insurance is for the issues that I cannot handle in the every day experience. And I pay to have the lawn mowed. I pay because I'm in Washington and can't be there, the guy who mows the lawn, also takes care of the garden. And that's just part of the expense of having to maintain two homes.

I guess when we live there, we'll plant our own tulips. But at the moment, my wife likes to go home to see tulips and I pay for that. I cannot file an insurance claim to pay for the tulips.

Dr. Kaminetsky. By way of analogy, if the branch falls on your roof and it's damaged and the adjuster comes and says, "Well, we're going to fix this area over here," you're not in a position to say, "Well, you know, that's really not going to look nice. I want the whole roof."

By way of analogy, there is no reason why an adult child can't say with regard to their 92-year-old mother with metastatic carcinoma, "I want her in the ICU, doctor."

I'm not proposing more bureaucratic oversight of Medicare. But these are types of real-life issues that come up every day where, as we all know, half the Medicare dollars are spent in the last 6 months of life, and there's essentially no oversight about appropriateness of care and whether the dollars should perhaps be reapportioned, which is obviously a very weighty issue with a lot of ethical and moral considerations, but one which has been too long ignored.

Chairman Bennett. Thank you for that addition. I'll use it from now on.

[Laughter.]

Chairman Bennett. This is the point. If we can, in fact, make insurance truly insurance by incentivizing people to be in the businesses that these three are in, I think it's absolutely inevitable that the cost of insurance will come down and come down quite dramatically. Particularly if they practice the kind of medicine that Dr. Kaminetsky focuses on, and I assume the other two do as well, which is the way to keep costs down is to keep people healthy.

There is no incentive in a pure insurance program to keep anybody healthy. It's all focused on acute care and not focused on prevention.

And there have been fairly significant studies, case studies of folks who spent a whole lot more time on prevention, having pro-

duced the enviable result of having lower costs and higher satisfaction on the part of the people that are in the insurance pool. We've had testimony on that in previous hearings.

So the problem with the poor is a clear problem. But, quite frankly, the insurance system, whether it's government or private, is part of the problem.

And I now repeat to you a conversation I had with a woman in Utah who heard me give a brilliant luncheon speech on this subject and came up afterwards and said, Senator, you haven't the slightest idea what you're talking about.

And I said, Okay. Teach me.

And she's a woman who spends almost all of her time dealing with the homeless and the poor. And she said, the primary problem with the homeless and the poor is not that they don't have any money. And it's not that they don't have access.

They cannot navigate the system.

The rules are so overwhelming, the bureaucracy is so daunting, that they can't navigate the system. And she said, you should be spending more time on community health centers—and I've been to the community health center in Salt Lake, where, when you walk in, the first thing that happens to you is somebody approaches you and becomes your navigator and says, Okay, this is where you can go. This is where you can go.

Medicaid, charitable activity, the Shriners Hospital, whatever it might be, there is a mentor or navigator that knows about those things, which the person on the street who is homeless has no clue. Even though in the law he may have access to or eligibility for, in his own capability, he can't navigate the system.

So I want to encourage community health centers of that kind that will help the poor and the homeless with their real problems rather than their perceived problems as we sit behind this dais and make judgments about them.

We are spending as a society plenty of money on health care. But, in the language of the west, we are not seeing the water get to the end of the ditch.

There's plenty of water in the irrigation reservoir. But when we pull up the gates, the water is not getting to the end of the ditch. And we've got to do something to see to it that the percentage of GDP that we are spending on health in this country produces the kind of result that that money could, in fact, buy.

Dr. Berenson, I'm not sure that there is a level where I would cut off what these people are doing. I would hope that we could devise some kind of a system, and the government's got to do it, because the tax code drives the health care system. The tax code drives what employers do. And then the government steps in with Medicare and Medicaid and that's, what, 40 percent of the dollars.

I end with the way I began. I'm hoping that we can find a clean sheet of paper solution that takes the very best of these entrepreneurial activities that are producing at least in the populations that they serve better health care at a lower price with, if Dr. Kaminetsky is correct, an impact on the insurance system because it makes fewer demands on the hospital structure and other things that the insurance system is using.

This is not an either/or. This is not "we want to kill the insurance system by a purely market system." But at the same time, we don't want to kill the market entrepreneur system by the Canadian model that says, you've got to do it our way or you can't practice medicine.

Okay. That's the end of my oration.

Representative Stark. I'm just curious. In thinking about the problems of primary care, do any of the three of you have a code—Medicare doesn't quite cover it yet—for what I would call disease management?

You come close, Dr. Kaminetsky, in your practice. But let's say that a diabetic comes in. Would you charge them $100 a month or $50 a month and say, "I'll send you out for the tests?" Do any of you have that?

Dr. Berry. Well, if somebody wants, say, 30 minutes of my time, that would probably cost $100, if they really wanted to sit down——

Representative Stark. No. But would you proactively say, "I'll call you. I'll be after you." You talk about it in maybe stopping people from smoking. One of you mentioned that.

But we're looking at disease management as a procedure, if you will, for primary care docs to be the interlocutory between a variety of providers and the patient. And I just wondered if any of you were doing that in your practices now?

Dr. Eck. Diabetes a great example. It's very education-intensive. People just have to understand their disease and be reminded and don't do this and do this and check your sugars. It's very complicated.

You try to make them make a little list of their sugars and what they ate and that type of thing. I like to see diabetics once a month. But some of them are very, very smart and very good at it and they don't need to be seen that often.

It depends on the person. It's not a one-size-fits-all type of management.

I don't do insurance. So if it's a long visit and if they're high-maintenance, they get charged more.

Representative Stark. But you don't set up an annual program where you would get after them.

Dr. Eck. I don't tell them. Every year you check their——

Dr. Berry. They've got to see an ophthalmologist.

Dr. Eck. Yes.

Representative Stark. Pardon?

Dr. Berry. They've got to see an ophthalmologist every year, make sure you're looking at their feet.

Dr. Eck. There are certain things that you make them do routinely—check their eyes, check their micro-albumin, the urine. See if they're developing that. A good foot exam.

Those type of things, we just do without telling them. But this is part of their program.

Representative Stark. Thank you, Mr. Chairman.

Chairman Bennett. The kind of thing that the Capitol physician does for you and me.

Representative Stark. Gets after us.

[Laughter.]

Chairman Bennett. And we pay for it.

Representative Stark. Yes, we do.

Chairman Bennett. Anybody else have a last burning comment you want to make before we leave? We've held you here all morning.

Representative Stark. Thank you.

Dr. Berry. Let insurance manage risk and patients manage care.

Chairman Bennett. That's a pretty good bumper sticker.

[Laughter.]

Dr. Eck. There you go. The real answer is to allow individuals to deduct the health insurance just as the employers do.

And therefore, the employers should be relieved of having to buy the health insurance policy. Just like the employers don't buy our car insurance policy, our homeowners insurance.

That would make a phenomenal difference.

And then I think if people were spending their own money, they wouldn't pay for HMOs, and that would be the end.

Chairman Bennett. Well, if they were, the HMOs would change dramatically.

Dr. Eck. Absolutely. If people had to buy their own insurance, they'd really buy it in value.

Chairman Bennett. Again, I'm sorry. But my market orientation comes in here. If I go to an HMO and I get treated badly, I get disrespected, I get shuffled off, I have to wait a lot, and I control the money that's paying for that HMO, and I can say, "Look, if I don't see the doctor in another 5 minutes, I am out of here and my money is out of here with me. I'm going down the road to another HMO that's run by Dr. Eck." The HMO concept is not a bad concept, except as it is run for the economic and financial benefit of the people who own it because their customer is the third party who doesn't care how I get treated.

Dr. Eck. That's right.

Chairman Bennett. But if the person who is running the HMO is dependent upon my patronage, just the way that the person who is running any other business is dependent on my patronage, why, the waiting times will go down, all kinds of marvelous things will happen.

I don't want to leave it just that we trash HMOs and we want to eliminate HMOs. But if we give the customer the economic power to determine what's going to happen in the HMOs, I think the three of you, and maybe if you can lure Dr. Berenson back into the practice of medicine, the four of you, might some day open an HMO based on the concepts that you're practicing here.

Thank you very much. The hearing is adjourned.

[Whereupon, at 11:55 a.m., the hearing was adjourned.]

Submissions for the Record

JOINT ECONOMIC COMMITTEE
ROBERT F. BENNETT, CHAIRMAN

For Immediate Release:
April 28, 2004

Contact: Rebecca Wilder (202) 224-0379

Chairman's Opening Statement
Senator Robert F. Bennett

Hearing of the Joint Economic Committee
"Consumer-Directed Doctoring: The Doctor Is In, Even If Insurance Is Out"
April 28, 2004

Good morning and welcome to today's hearing. Today we're here to explore how some doctors are finding alternatives to the traditional third-party payer health care system, and at the same time providing better care for their patients.

Many doctors are frustrated by the state of our current health care system, and their patients are too. Doctors are continually faced with third-party entities interfering in their practice, pushing them toward a system that focuses on arcane regulations, not on patient care. Low reimbursement rates require physicians to increase the number of patients they see and shorten the length of office visits. They must also shoulder the burdens of increased practice costs, time-consuming paperwork, and rising medical liability premiums.

Many patients, particularly those with lower incomes, find it difficult to obtain affordable care and to receive it in a timely manner. They often feel rushed through brief office appointments, without having adequate time to address their questions and concerns or adequate help to navigate the complex medical system.

Today's hearing will examine the experiences of innovative and entrepreneurial doctors who are responding to gaps in the current system by returning to an older style of medical practice, a patient-focused approach that used to be the norm. By adopting these approaches, doctors are finding ways to spend more time with their patients, and to provide a better quality of care. We will examine the potential reach of these early trends among innovative physicians, who deal more directly with their patients than physicians relying predominantly on third-party insurance payment mechanisms.

While insurance-free medical care may not work for everyone, early evidence of consumer-directed doctoring suggests that some physicians and patients are reacting favorably to this way of providing care. In some cases, it has produced lower costs. In others, it has offered a more enhanced level of personal medical services. On occasion, it has delivered both. In any case, it means providing better value.

By studying how these entrepreneurial physicians are building their practices, we can learn about the strengths and weaknesses of our current health care system and how better to address them. By understanding alternatives to the system, we may also be able to improve medical price transparency, help relieve medical liability pressures, and retain highly-trained physicians who are increasingly frustrated by the current system.

We'd like to welcome our panelists today who all have their own experience delivering health care through innovative and entrepreneurial means.

Dr. Robert S. Berry is here from the PATMOS EmergiClinic in Greenville, Tennessee. Dr. Berry will talk about his experience building a pay-as-you-go practice. His office fully discloses its prices up front, receives payment at the time of service, and generally does not accept any third-party insurance reimbursements.

Dr. Bernard Kaminetsky from Boca Raton, Florida operates a practice that specializes in "concierge care" or "retainer medicine," where patients primarily seek preventive care, wellness plans, individualized attention, and 24-hour access to a personal physician.

Dr. Alieta Eck, a physician from Piscataway, New Jersey runs a charitable care clinic that combines community resources with more efficient methods of health care delivery to meet the urgent medical needs of the poor and the uninsured.

We'll also hear from Dr. Robert Berenson, an experienced physician, who is now a Senior Fellow from The Urban Institute here in Washington, DC. His work focuses on health care policy, particularly Medicare.

We look forward to hearing them describe their unique approaches to build a medical practice without the bureaucracy of the health insurance system.

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REP. BARON P. HILL (IN)
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Opening Statement
Representative Pete Stark
Joint Economic Committee Hearing
April 28, 2004

Thank you, Chairman Bennett. Today's hearing appears to be the next installment in the Republicans' push toward replacing traditional health insurance with high-deductible health plans, also known as Health Savings Accounts (HSAs). This time the rationale for HSAs is that doctors can provide cheaper health care to patients if we do away with the insurance companies and their pesky paperwork.

Frustrations dealing with insurers have led some doctors to accept only cash payments from patients. Physicians claim that they can offer lower prices for office visits and other simple medical procedures, because they can reduce the overhead from filing paperwork and obtaining insurance reimbursement.

"Concierge care" – as it has been dubbed – is like a new country club for the rich, since members pay a hefty premium just to join. But in this case the only thing that club membership guarantees is access – the opportunity to call on a doctor – since members are still required to pay for each medical service they receive.

The danger is that if a large number of doctors choose to open up these types of practices, the health care system will become even more inequitable than it is today. The wealthy will pay for exclusive access to quality care, and everyone else will continue to have inferior access to primary care physicians, specialists, and basic medical advice.

Having access to a physician is not the same as having health insurance. A growing body of literature shows that people without health insurance forego even necessary care and do not have their care properly managed, thereby increasing the risk of serious complications and lowering the quality of overall care.

The concept of "empowering" consumers to make more responsible choices about their health care decisions is misleading rhetoric. Health care needs are often unanticipated and patients rely on their doctors' expertise – not their own – to guide medical decision-making. A policy of consumer-directed doctoring says, "patient – heal thy self."

Having spent much of my Congressional career in health care policy, I have never known so-called "consumer-driven" or "consumer-directed" health care to perform well or to have much potential. These high-deductible plans are not consumer-driven, nor do they offer much choice. Instead, they simply shift costs to so-called "consumers" who pay more and

more out-of-pocket, making it difficult for patients to get the care they need. Furthermore, high-deductible plans would likely undermine coverage that people receive through their jobs, as employers looking to cut their costs look more and more to HSAs.

HSAs are yet another tax shelter for the rich, who have no trouble affording insurance or quality health care. The President has now proposed to spend $41 billion on HSAs and high deductible plans, which will at best extend health insurance to a tiny fraction of the 44 million who don't have coverage today. The Administration's policies are not directed toward insuring the uninsured. Instead, their policies attempt to insert more "cost consciousness" into the system to reduce consumption, but fail to meet even that objective.

High-deductible plans are unlikely to alter the overall level of spending on health, but would undoubtedly shift more costs to people who can barely afford their current obligations. In all likelihood, these plans could have the perverse effect of increasing overall spending as people delay care until their treatment is even more costly than it would have been if treated early.

If Republicans were really interested in controlling costs, they would have given the Secretary of Health and Human Services authority to negotiate prescription drug discounts in the Medicare program, but that's a topic for another hearing.

High-deductible plans don't reduce costs or increase health coverage, they simply discourage people from using health care services.

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Testimony of Bernard Kaminetsky, M.D., F.A.C.P.

Joint Economic Committee

United States Congress

April 28, 2004

I. Introduction

I am a 51-year-old board certified internist, presently practicing as an MDVIP affiliated physician in Boca Raton, Florida. I affiliated with MDVIP in order to provide my patients with comprehensive preventive care services that unfortunately can no longer be offered in a traditional primary care setting. This decision was prompted by the inability of the current healthcare environment to accommodate the necessary emphasis on wellness and prevention that I believe is essential for comprehensive preventive care. Instead, current practice, because of time constraints, focuses predominantly on acute care. I am honored to be able to discuss my career, and my decision to provide my patients with the attention to prevention and early detection that they have requested and deserve.

II. My Background

Choosing a career was a simple choice, inasmuch as I'd always aspired to be a doctor, even from the age of six. I attended Albert Einstein College of Medicine in New York, where I was elected to membership in Alpha Omega Alpha, the national medical honor society. Following graduation, I completed my training at New York University-Bellevue Hospital Center, where I served as chief resident in medicine and was responsible for the continuing medical education of the medical staff. My experience as

intern and resident was fulfilling, enlightening, and, because of the nature of medicine, with its unforeseen outcomes and complications, humbling. I believed that my intensive training, at one of the country's biggest and busiest urban medical centers, prepared me to be a consummate physician. I was trained to be academically proficient, empathetic and socially conscious. My Bellevue experience was unique. I cared for Park Avenue matrons and addicted single mothers, suburban entrepreneurs and the homeless. At the conclusion of my residency, I believed I was ready for the real world.

Following training, I stayed on as a junior faculty member at New York University School of Medicine. My position combined teaching with practice, an arrangement I considered optimal. Practicing in an academic environment allowed me to stay current and to apply what I learned to my practice.

About eight years into practice, in 1992, I encountered a situation that was new to me. A patient called and asked if I was on the panel of the insurance company that her employer was switching to. Until then, a patient's insurance carrier had never been a concern. If the patient had Medicare, I accepted assignment. When the patient was younger, insurance typically paid eighty percent of my fee, and the patient paid the balance. If the patient didn't have insurance, we made other arrangements. I now discovered that whether a patient saw me was no longer dependent on his preference, or trust in my skill, but rather on whether I was on his plan. At first, I considered this an isolated phenomenon, but it soon became clear that, unless I too joined the panels, my practice was at risk of becoming financially unsustainable.

Coincident with these changes, academia also began to change. The practicing faculty began to feel more pressured by declining reimbursement. With less time

available, it became increasingly difficult to volunteer uncompensated hours for teaching. Formerly, the attending staff had very generously donated their time.

Bowing to legislative constraints, residents in New York State changed from an every third to an every fourth night schedule. In addition, residents were no longer on call all night. They went home at midnight, without regard to whether a patient was stable or decompensating. This was implemented to mitigate the effects of stress and sleep deprivation. An unintended consequence of this change was the adoption of a more time clock oriented approach to healthcare. An intern no longer went home when his or her work was done. They went home when the "shift" was over. Faculty members were criticized for being "overly academic," and teaching rounds were sometimes perceived as keeping staff from getting their work done. Moreover, the spectrum of pathology previously seen at Bellevue had narrowed. In the years prior to the advent of highly active antiretroviral therapy, most admissions were due to HIV related disease, and the residents became less interested in an atmosphere that was increasingly oriented toward less time with patients. The gratification from teaching is understandably diminished in such a setting.

At that time, South Florida had a reputation as possessing a burgeoning population and an inadequate number of rigorously trained physicians. Some of my New York patients, who wintered in Florida, suggested that I would do well there. I made the move.

Perhaps it was naive to think that the changes in medicine wouldn't become universal. What I had not anticipated was the rapidity with which managed care, particularly in the realm of Medicare HMO's, would take hold. Because of the generous

pharmacy benefit which was then offered, these plans held great attraction for patients. Of course, the reimbursement was lower than traditional fee for service Medicare but doctors had no choice. The alternative Medicare HMO model, called "capitation", i.e. accepting a fixed payment per patient per month, held the potential to be very remunerative. Whatever was not spent on the patient accrued to the doctor. However, such an arrangement was never acceptable to myself and my partners because of the obvious inherent conflict of interest. The doctor is incentivized to order as few tests, and as little medication, as possible in order to improve his or her bottom line. Such an arrangement was not suitable to us. Moreover, the approach to care emphasized treatment of acute problems with diminished emphasis on prevention. Quantitatively, the time for preventive care was simply not there.

Concomitant with declining reimbursement, overhead continued to increase. Healthcare costs for employees rose. Malpractice insurance skyrocketed, especially in crisis states such as Florida. We attempted to cut staff but untenable delays occurred. We became more and more constrained in our efforts to be *pro*active with regard to healthcare, and were far more *re*active. It was apparent that there was only one way a practice could promote prevention and still maintain its financial viability: by seeing more patients! But the reasoning was circular. More patients meant less time, so how could a physician implement prevention? A solution would necessitate ***more*** time, not less.

III. My Decision to Fundamentally Re-orient My Practice to Emphasize Preventive Care

The need for primary care is growing. Changing demographics, characterized by growth of the elderly as a percentage of the population, is not a problem confined to Social Security planning and Medicare budgeting. As the population ages, the number of primary care providers must expand accordingly. However, what is happening economically to practitioners of internal medicine is not lost on today's medical students. Average debt upon graduation is currently $110,000. I've spoken to a student who has incurred $175,000 of debt. Respected teachers, who were once role models, now advise students to consider seriously dermatology or the more lucrative surgical subspecialties. Each year the national residency-matching program documents a decline in applications for internal medicine and family practice programs. The American College of Physicians has been forced to launch an initiative program to try to attract students to primary care. I have been present at gatherings of internists where the question has been posited, "Who would encourage their child to go into internal medicine?" Not a hand goes up. Doctors are concerned that their children will not be able to attain the professional gratification that makes practicing medicine a joyful pursuit.

Declining reimbursement and more elderly patients equals more visits. But, is that a viable or sustainable model? The Annals of Internal Medicine has pointed out that as newer technologies are developed, physicians are less and less able to find the time to incorporate these changes into their practice. ("General Internal Medicine at the Crossroads of Prosperity and Despair: Caring for Patients with Chronic Diseases in an

Aging Society," *Ann Intern Med* 2001; 134: 997-1000). Whereas before, a patient with congestive heart failure may have been treated with just diuretics and digoxin, now one must consider ACE inhibitors, beta-blockers and aldosterone antagonists. How many additional visits will this entail? Where does one find the time for them? Patient education is, and should be, time consuming. The days of the paternalistic physician, who freely prescribes without offering an explanation, are long gone. Suppose a diabetic patient is well controlled. Her blood tests document that the standard of care is being met. But a newer insulin might work just as well and may be given only once per day instead of three times. It might not be an advantage medically, but it will improve the patient's lifestyle tremendously. Of course, the patient will need to come in frequently during the transition. It is horrific that a physician must even consider such matters.

Last June, the New England Journal of Medicine documented that only 55% of recommended preventive care is administered, and only 52% of recommended screening is performed. It has been estimated that if a doctor, with a typical patient load of 2500 patients, complied with the recommendations of the U.S. Preventive Services Task Force, he would spend 7.4 hours a day on prevention. Only a tiny fraction of the day could then be devoted to acute care.

The above scenario describes what my day had become. I was on a treadmill, running at an ever-accelerating pace, desperately trying to do the best for patients with a limited resource, i.e. time. I was essentially putting out the fires of acute problems and was frustrated by my inability to place appropriate emphasis on prevention and wellness. I was disappointed professionally and missed the gratification that had always been inherent in physician-patient interaction. Patients, too, were becoming increasingly

unhappy. While they were sympathetic to the time constraints I labored under, they read about, and wanted, more preventive care. Patient dissatisfaction was particularly irksome and frightening, since studies have demonstrated that malpractice is often not the product of malfeasance, but, rather, is due to poor communication between doctors and patients. Yet, how can that dynamic be altered when numerous surveys report that patients routinely feel that they are not getting enough face time with their physician?

In early 2001, it became apparent that I was no longer the physician I had trained to be. I was always frenetic. I treated heart disease while desperately trying to devote attention to nutrition and exercise. I treated emphysema but lacked the time to consistently call each patient regularly and encourage him or her not to smoke. Sometimes that's what it takes - direct engagement rather than technologically based intervention.

What was I looking for? A way to make prevention the foundation of my practice rather than an often ignored recommendation. A practice style that would allow me to dwell on exercise and nutrition, weight loss, smoking cessation and curtailment of alcohol use. A method to provide patients with electronic tools that would guarantee timely transfer of clinical data between providers. Planners have been talking for years about the need for a dramatic change in the delivery of primary care, but I knew of no feasible solution. Similarly, in regard to technology, smart cards, containing digitized patient data, had been regularly touted. I'd yet to see one. As a profession, we were awash in well-intentioned ideas, but lacking in the ability to implement meaningful change. I was ready to abandon clinical medicine. It was a most propitious confluence of

events that MDVIP came on the scene just as I was on the verge of leaving clinical medicine.

In a typical practice of 2,500 patients, if one worked 50 weeks a year and planned on performing a comprehensive preventive exam of even an hour in length for each patient, then 50 hours a week would be devoted to annual physical exams. Of course, that leaves no time whatsoever for acute care. In contrast, if a practice is limited to 600 patients, such as in my current practice, then 12 hours a week, or even 18 hours, can be devoted to annual preventive exams, with adequate time still available for routine and urgent care.

Hence my decision to join MDVIP, a program focused on an annual preventive care physical examination and related wellness planning, individually tailored to a patient's needs. This includes detailed analysis of medical and family history, nutritional, psychological and fitness screenings, EKG's, and comprehensive lab and imaging studies. In order to offset the decline in revenue associated with the far smaller practice size, patients pay an annual fee to receive these preventive care services. MDVIP provides me, and other physicians located in eight states, with the operational, technological, and administrative support required to effectively establish a preventive care based practice.

What does it mean to patients who are members of a practice limited to 600 patients? It means they know that when I talk about diet and exercise I really mean it. I will urge them repeatedly, and be able to assist them throughout the year, to be more compliant with proactive preventive care initiatives. It means they will travel with a pocket CD which contains a comprehensive summary of their history, physical exam,

medications, allergies, EKG tracing, x-ray findings and digitized images. I could offer you many anecdotes, but here's just one. A patient had her CD with her when she was hospitalized in Beijing, and it made an incalculable difference in her care. Her physician called me from Beijing, late at night, to discuss the information on her CD, which was essential to his treatment decisions. With a practice limited to 600 patients, I was able to recall details even when at home, and without access to the chart, and actively participate and assist in the care of my patient in another part of the world. How could I ever commit to memory the details of 2,500 patients, or have the ability to offer this level of involvement consistently to each of 2,500 patients? Logistically, it could not be possible.

My patients are thrilled. I've rediscovered the intimacy that traditionally had been part of the doctor patient relationship. Soon after starting my new practice, I realized that patients would share with me stories that they had never told me before. For instance, one woman tearfully related that she had never told me that she had been an abused wife and was seriously injured. I asked her why she had never shared that with me. As similar stories have surfaced, I have come to realize that the reason I now knew was because of the changing dynamic of our relationship. I have become a friend, a confidant—a real doctor, just like Sinclair Lewis' Dr. Arrowsmith. It is gratifying beyond description.

The emphasis on prevention mandates that the practice be kept small. Otherwise, there wouldn't be enough time to perform a comprehensive exam and implement wellness plans for each patient. The *de facto* benefit of being a patient in a smaller practice is that the ambiance of the office is less harried; the tenor of the office staff is calmer. Patients exhibit relaxed body language. Calls are returned promptly. Patents reach me by e-mail. No phone tag. Again, these are *de facto* benefits of being in a smaller

practice. They are simply reflections of how I run my practice. When a patient calls and tells my assistant that his oncologist hasn't gotten back to him about his CAT scan results and he is nervous, we assuage the concern by obtaining the results, even though we haven't ordered the test. When a patient asks me to tell her a little about her *sister's* rare illness (and her sister is not a patient!), I am able to oblige. When I reassure my patients, when I address their fears, I'm being a doctor again. Would a busy physician taking care of 2500 to 3000 patients reasonably be able to research a matter totally devoid of any relevance to their patient's care? Despite the best of intentions, it would be very difficult.

I've frequently been asked how an MDVIP practice is received by the specialists I work with. Actually, specialists enjoy seeing my patients. Quite often, a patient will appear for a consultation without the reason for the consultation being clearly documented. This can be frustrating to the specialist who asks the patient, "why are you here?", and gets a blank look in response. In contrast, before my patient sees the consultant all pertinent records, x-rays, labs, etc., will have already been faxed. Furthermore, the software tracking that MDVIP has provided advises me that the patient has seen a specialist and prompts me to speak with the specialist regarding the visit. If a patient comes in and advises me that they had an appointment with a consultant that was arranged through other auspices, my office makes sure to get a record of the visit. Since elderly patients will often see several consultants, the only way to prevent potentially harmful drug interactions is to make a determined effort to keep abreast of any medication changes instituted by a physician other than myself.

MDVIP has assisted me in establishing benchmarks for preventive services. Our patient satisfaction scores are extraordinary, and the membership renewal rate exceeds

95%. Not surprisingly, our hospital admission rates are unusually low. Because our practice is small, a patient with swelling of the ankles or shortness of breath is invariably seen the same day. The patient is therefore treated when his or her congestive heart failure is incipient, and presentation to the emergency room in the middle of the night is avoided.

Our attentiveness to an old fashioned style of care, with emphasis on prevention, results in significant savings to insurance providers. I listen to patients -- literally. Much has been written about the increasing reliance of practitioners on technology, to the exclusion of a careful physical exam. My utilization is lower because I rely less on expensive imaging studies and more on careful scrutiny of physical findings. I *listen* to the heart and lungs carefully, as I was taught in medical school. I'm judicious with my use of tests. Sometimes, careful auscultation with a stethoscope obviates the need for an expensive echocardiogram.

My relationship with my patients is special. I am their "doctor". I am not a provider chosen from an insurance company roster. My patients trust me. Many physicians typically must order an excessive number of tests to protect themselves from the threat of malpractice. Because of the time I now have for preventive care, and the trust engendered, I am not subject to that fear. My patients and I recognize that whatever the outcome, I gave them my best.

Who are my patients? The demographic makeup of my current practice very closely mirrors that of my former practice. My patients range in age from 18 to 101, and come from all socioeconomic backgrounds, including patients on fixed incomes, and those whose incomes qualify them as upper middle class. Those patients who ***chose*** not

to avail themselves of the benefits of the MDVIP prevention program remained in my former practice and a new internist joined the group to take my place and ***insure continuity of care for all such patients***. I use the word "chose" advisedly. For the vast majority of patients, joining my new practice was a matter of choice. The financial foundation for this dramatically smaller practice setting is largely based upon an annual fee of $1,500. Such an amount is certainly significant. However, $125 per month to maintain one's health is certainly no less important than a cell phone and cable bill, which cost more.

Nonetheless, for those patients for whom it was not a choice, for those who truly could not afford the membership fee, the fee was waived. Those patients are full members and reap the benefits of the prevention program. Absolutely no distinction is made between the paying and the "scholarship" patients.

IV. The Role of Preventive Care Based Programs Such as MDVIP

In order to fully understand my practice, it is essential to recognize that the preventive services I provide to patients are not covered by Medicare or by commercial insurance. Perhaps the most striking, and least understood, aspect of the Medicare program, from the perspective of patients, is that Medicare is designed to cover only a portion of the healthcare expenses of seniors. Indeed, annual preventive care physical examinations are specifically excluded from coverage under Medicare.[1] Similarly, these services are beyond the scope of care that is covered under commercial insurance. Accordingly, patients who desire such services must obtain them using personal funds.

[1] The recent Medicare Modernization Act of 2003 established a limited one-time preventive care examination available only during the first six months of Medicare eligibility

Clearly, I am not suggesting that my practice is an option for all patients, as there cannot be a single healthcare alternative for all segments of society. I firmly believe, however, that my practice offers a compelling and viable choice for many patients who seek services that are not available in traditional primary care practices.

The national media has described my MDVIP practice, and other efforts by physicians who incorporate annual fees in their practices, as "retainer" or "concierge" based medicine. Although initially the subject of some controversy, this approach, when properly implemented, is now acknowledged by both the Federal government and the American Medical Association as an appropriate and innovative option for patients.

Charges in excess of the Medicare fee schedule for covered services are, of course, contrary to law. However, in a May 1, 2002 letter to Rep. Henry Waxman, Secretary of Health and Human Services Tommy Thompson specifically confirmed that as long as a charge, such as the fee associated with my practice, is solely for non-covered services, such fee is consistent with Medicare law. The HHS Office of the Inspector General recently reaffirmed this determination in an alert dated March 31, 2004. As stated in the OIG Alert, "Medicare participating providers can charge Medicare beneficiaries extra for items that are not covered by Medicare."

The American Medical Association has considered retainer medicine and supports such practices. In its Report of the Council on Medical Services issued in June 2002, the AMA found that

> ". . . retainer practices ***are consistent with long standing AMA policy*** in support of pluralism in the delivery and financing of health care. . .The success of retainer practices in the market ***is the best evidence that these practices fill a market need.*** There are several factors that explain the successful proliferation

> of this model to date . . . first, these practices fill otherwise unmet market demand . . second, retainer practices may lead to market driven improvement in quality . . . third, the practices have great appeal to physicians and their patients. ***Instead of spending a few minutes with each patient, physicians are at liberty to spend as much time as needed with each patient, which may result in higher patient satisfaction, higher physician satisfaction, and better outcomes for the patient. (emphasis added)"***[2]

The suggestion that such practices will deny access to care is misplaced. As found by the AMA, retainer practices are:

> "a growing but small-scale market phenomenon that seem to have sparked a disproportionate share of media attention . . . The phenomenon of retainer medicine is inherently self-limiting. The more physicians charge for their services, the smaller the demand for their services . . . ***These economic realities limit any potential for widespread adoption of retainer practice and any potential growth in retainer practice to adversely impact patient access to care. . . The Council currently finds no evidence that special retainer agreements adversely impact the quality of patients' care or the access of any group of patients to care. (emphasis added)"***

Although there is no factual basis to suggest that MDVIP, or similar programs, would diminish availability of physicians, MDVIP nonetheless requires all affiliated physicians to provide for continuity of care for ***all*** patients that elect not to become MDVIP members. This is done to insure that patient care is not interrupted when a patient chooses to not remain with a physician who begins an MDVIP affiliated practice, and this policy formed the basis for the establishment of my practice.

MDVIP provides a niche service. It meets the needs of patients who desire these services but would not otherwise receive them because they are not covered by insurance, and therefore are not provided. In parallel fashion, it meets the needs of those physicians who seek to employ a methodology that emphasizes prevention and wellness. The sentiment has been expressed that patients should not be allowed to receive these services

[2] The AMA Council on Ethical and Judicial Affairs also determined in June 2003 that "retainer" practices are consistent with ethical guidelines and recommended policies to ensure appropriate transition to, and operation of, such practices.

at a time when tens of millions are uninsured. However, that notion is flawed because the presence or absence of preventive services has no discernible impact on the plight of the uninsured. Those who may believe that physicians should not run MDVIP affiliated practices assume that, were I not doing what I am presently doing, I would still be on the treadmill, seeing 30 patients a day. That assumption is incorrect. As I related earlier, I was on the verge of leaving clinical medicine and would have done so if not for MDVIP. In fact, many fine physicians, frustrated and overburdened by a system that does not place the physician-patient relationship at the forefront, have left the profession, and, sadly, their skills are being wasted. In any case, even if I were still in my old practice, would that ameliorate the plight of the uninsured? From a purely logical standpoint, causality cannot be inferred.

It appears that the quality of care that I am able to provide may be enhanced as well, as suggested by the AMA position statement of June 2002. Preliminary analysis, using a modified HEDIS survey of MDVIP affiliated practices located in Florida, yielded results that far exceeded national averages.[3] These same practices were also surveyed to

[3] In 1990 the National Committee for Quality Assurance (NCQA) was founded. NCQA is a private not-for-profit organization that measures the quality performance of over 90% of all health plans. NCQA developed a series of measurements known as HEDIS, the Health Plan Employer Data Information Set. HEDIS is a tool that uses more than 60 different measures to evaluate the care and service performed by health plans. HEDIS makes it possible for consumers and employers to compare the performance of health care plans on an "apples-to-apples" basis, something not previously possible. The HEDIS criteria include the evaluation of preventive measures, such as the percentage of female patients receiving mammograms. It also includes treatment data, such as the successful management of high blood pressure and elevated cholesterol. These are just some of the treatment aspects evaluated by HEDIS. Although MDVIP practices are not health plans, the use of HEDIS data allowed for a preliminary assessment of the care provided to MDVIP patients. The MDVIP physicians surveyed had superlative HEDIS scores, which cumulatively approached an average of 90% compliance against a sample of HEDIS criteria. While each individual HEDIS evaluation has its own numerical score, the range of national compliance generally runs from 40% on the low side to 77% or 80% as a high score on some measures. Most health plans achieve compliance in the 60% to 70% range when all HEDIS scores are averaged. These numbers have real life significance. For example, raising the compliance numbers for blood pressure treatment from 40% to 68% could potentially save an estimated 28,000 lives in a population of 100,000.

determine the average number of patients admitted to hospitals throughout the year. This is not only of importance in regard to patient health, but also in the context of the dramatic expense associated with hospitalization. Significantly, the results showed approximately 30% fewer hospitalizations relative to national averages compiled by Milliman and Robertson, a leading national actuarial consulting firm. This applied across all age ranges, even though MDVIP participation is skewed to an older patient base. Admittedly, these results are preliminary since they are derived from a small number of practices and in one locale. It is noteworthy, however, that the locale is an area known to have one of the highest hospitalization rates in the nation. Early analysis nonetheless suggests that the scope of care that can be delivered in an MDVIP affiliated practice such as mine can result in enhanced patient outcomes.

V. Conclusion

I was quite idealistic when I started practicing medicine. The bond of trust that I had with my patients was of paramount importance to me. For a while I loved being a doctor. Then, the dynamic began to change and gradually eroded. My "customer," if you will, was no longer the patient. It was the insurance company. The patient paid the insurance company, and the insurance company, in turn, paid me. There was no transaction utility between the patient and me. Now, with great appreciation for the fortunate position I find myself in, I can proudly say I'm a doctor again. I treat people, not clients. I am their healer, their friend, their confidant. This is how it was when I was a child in the early 60's. For myself and my patients, the clock has been turned back, and the practice environment of yore has been restored. Doctors are now in a position to incorporate into their practices the newest recommendations regarding prevention. It's a win for patients, a win for doctors and a win for insurers who save money. What could be better?

Joint Economic Committee of Congress

Testimony of

Robert S. Berry, M.D.
President & CEO of PATMOS EmergiClinic, Inc.
Greeneville, TN

April 28, 2004

Good morning. Thank you for inviting me to speak with you today.

My name is Dr. Robert Berry. I graduated from the University of North Carolina Medical School in 1989 and did my residency in Primary Care Internal Medicine at the University of Alabama Hospitals in Birmingham. I became board certified in Internal Medicine in 1992, scoring at the 99th percentile on the exam's "core component" – a measure of competency in General Internal Medicine. Up until I started this clinic over three years ago, I practiced Internal Medicine for six months and Emergency Medicine for the balance. I became boarded in Emergency Medicine in 2003.

I represent a growing movement in cash only practices and the patients who use them. Yet our clinic is a little different in that we center medical services around the unique needs of the uninsured. They are the most cost effective healthcare consumers, and we all could learn something from them.

Our clinic is similar to charity clinics in that it serves patients falling through the cracks of our broken healthcare system - except we don't receive any taxpayers' funds either directly as subsidies or indirectly as a tax-exempt 501c3 corporation. It is similar to boutique clinics in that it contracts directly with its patients - except that most of our patients don't have insurance.

How and why I started an insurance-free medical clinic

In January 2001 I left ER medicine to start a clinic primarily for the uninsured of my community as an attempt to flesh out in my own life an answer to the age-old question, "Who is my neighbor?" Of course, I don't refuse other patients willing to do "Payment At The Moment Of Service." In fact, because this seemed to be the unifying theme of our practice, I chose its acronym PATMOS as the name for the clinic.

As an ER physician, I knew the people the charts classified as "self-pays." In a small community such as ours, I purchase goods and services from many of them. They are all in a real sense my neighbors – too poor for $10 co-pay insurance and too rich for Medicaid. Like the political prisoners Rome used to banish to Patmos Island, they are effectively political exiles within our healthcare system.

Most doctors refuse to see them. In fact, one of our uninsured patients mentioned at the beginning of a front and center article in the Wall Street Journal last November that he had been refused care by every primary care doctor he called in a nearby town before coming to us. For practices set up for insurance, the uninsured tend to disrupt patient flow. Many cannot pay for tests and procedures sometimes needed to exclude potentially litigable misdiagnoses. The uninsured simply take too much time with too much risk for uncertain payment. No wonder physicians turn them away and refer them to the ER.

But the ER, as we all know, isn't an appropriate place for these patients either. Charges are higher, work-ups much more expensive, and few physicians are willing to see them in follow-up. Although one Princeton healthcare expert referred to them in *Newsweek* as "expendable people – mostly low-income, hard-working stiffs, socially and politically marginal," I had learned from my work in the ER that they are neither destitute nor derelict. In our community they are farmers, construction workers, stone masons, Hispanics, Mennonite families, beauticians, cleaning ladies, small business owners and their employees – hard working folk who pay their bills. They told me they didn't have the time to wait at government clinics and did not like the quality of care they received there.

They urged me to start a practice and promised that they would come see me if I did. I thought that maybe over time this clinic might replace my income from the ER with the hope that I could jettison increasingly wasteful, irrational, and dehumanizing bureaucracies as much as possible from my practice and from my life.

Because of the charitable nature of the clinic, I had considered making it a non-profit to take advantage of tax breaks and to raise money for my own salary. After several discussions with my attorney, I had pretty much decided against it. He pointed out that dealing with a board would probably be about as frustrating as every other bureaucracy I had encountered since my residency. In addition, even though I would be the one building the patient base, the board could dismiss me whenever it wished, and the years I would have invested might well end in futility and bitterness. Since the sick and injured we will always have with us, I reasoned that it was more prudent in the long run to depend on them for my income rather than on fickle donors and ever-changing tax laws. The long-term risks did not appear to be worth the short-term financial security a non-profit might offer.

The idea of making the clinic non-profit became academic very quickly as my plans to make the clinic full time were realized sooner than I had expected. For various reasons, the president of the hospital where I worked had my ER contract terminated abruptly. I simply did not have time to start a practice and raise money too. Had I pursued the non-profit option, the idea of this clinic might still be in committee. At that point, I had to make a decision – either obtain ER work at another hospital or start the clinic full time. For better or worse I stepped out in faith and decided on the latter. The clinic was up and running within two weeks of my dismissal.

A visit to the clinic

In general we are a walk-in clinic for routine minor illnesses and injuries – I would characterize us as a high capability urgent care. We are open every morning Monday through Saturday for walk-ins and some afternoons by

appointment. Sometimes I treat established patients over the phone and charge their credit card.

So let's suppose that you are a patient coming to the clinic for the first time – what would you see and experience?

As you walk up to the clinic, you will see a large sign that has information about the cost for various medical problems. Poison ivy - $25. Sore throat - $35. Simple lacerations - $95. A doctor who actually enjoys practicing medicine today – priceless (and we do take Mastercard). These fees, which are about 50% of the Medicare Allowable, are listed on the brochure I brought with me and should be available to you.

The only way that I can keep my prices so low is by avoiding the crushing overhead and hassles that other physicians allow third party payers to impose on their practices. I even don't take Medicare, a potential source of a great number of patients, because doing so would force the uninsured to pay for the cost of processing other patients' medical claims – a service from which they clearly do not benefit. Forcing me to hire more staff to bill on behalf of Medicare beneficiaries would defeat the purpose of my clinic. From day one, the clinic has centered care around the uninsured and patients with high deductibles, even if it meant seeing fewer patients and thus receiving a lower income.

Contracting with a third party payer obligates a physician to some extent to the one paying the bills. This would force me into a conflict of interest I am not willing to accept. I recoil at the thought of being anything less than completely transparent, putting before each patient my best recommendations and their estimated costs. This is exactly how I would like to be treated if I were in their shoes. This engenders a trust not currently present when a bureaucrat is allowed to intrude into the doctor-patient relationship – one that many Americans today still consider second in importance only to family.

Advertising my fees and qualifications, by the way, initially ran counter to my ideas of medical professionalism. I realized I had to overcome this professional arrogance if my core clientele – the uninsured and people with high

deductibles – were to learn about the cost breaks of a clinic not taking insurance. Such advertising is permitted within the by-laws of our state medical board.

We have worked out discounts with various other providers in the area so that a cholesterol panel is $20 to the patient; a complete chemistry is $25; X-ray's with a radiologist's interpretation at Takoma Adventist Hospital are $70. Some patients choose to pay one of the chiropractors near the clinic $35 for an extremity X-ray and bring the film back to me for an interpretation and treatment. Costs to the patient here are about 60% those of other physicians' offices, 40% of the local urgent care, and 10 to 20% of the local ER's.

Upon entering the clinic, you see to your immediate right my board certification diplomas in Internal Medicine and Emergency Medicine, my Internal Medicine residency certificate from the University of Alabama Hospitals, my medical school diploma, and state license. You decide, perhaps, that I'm not some sort of quack after all and proceed to sign in at the desk where my fee schedule is posted. Everything is up front and honest.

My office assistant realizes that you have not been here before. She offers you a patient information sheet that usually takes less than 5 minutes to fill out. Since we fit under the Country Doctor exemption, there are no long HIPAA confidentiality agreements to pore over and sign. In fact, I have had some insured patients who have transferred their care to my clinic because they refused to sign these incomprehensible forms at their former physician's office.

The intake sheet explains a little about our clinic – that we don't take insurance and expect payment at the time of service. It also says that if you do have commercial insurance we can forward the claim to a billing service for a $10 surcharge, but there is no guarantee that you will be reimbursed.

Since the majority of our patients don't have insurance, they are delighted to learn about our service. Some bemoan that they had wished they had known about us before they incurred their $1000 bill at the ER. It is personally very gratifying to be appreciated by the lower middle class folk who form the economic backbone of this country and whom I have the privilege of calling my friends and neighbors.

Being in this type of practice gives me, I believe, a unique perspective on the mindset of Americans who are used to low co-pay, low deductible insurance. Every day presents me with new lessons in human behavior. It can be quite amusing, for example, to observe their responses to my intake sheet – they're kind of like Pavlov's dogs – except rather than salivating in anticipation of a delicious meal they are conditioned to expect healthcare on the cheap (if not entirely free). You can see the wheels churning as they try to process this new thing confronting them.

For example, after reading our intake sheet one Sunday afternoon, one very wealthy, prominent member of our community developed a puzzled look and in all sincerity asked me if my clinic were legal. I responded, "For now, but if we adopt single payer healthcare like Canada's, it won't. Then you will have to wait in the ER all afternoon."

Others have walked out in disgust announcing to everyone in the waiting room that they were off to see a real doctor. One teenage boy ran into the clinic to ask how much it would cost to treat him for a sore throat. "Thirty-five dollars," my assistant replied. He ran back to the front seat passenger side of his family's Lexus and informed his mother. She shook her head in disgust and peeled off.

With some it seems I'm the last stop in their desperate attempt to find a doctor without having to resort to the ER. After trying their regular doctor (2 weeks for the next appointment - sorry), and the local urgent care where waits can be on the order of hours not minutes, they rush in here delighted to find they will be seen quickly. Their countenance changes when they find out we don't take third party payment.

They can be heard agonizing, "But I have good insurance – just a $10 co-pay - see it says so right here on my card." I examine the card and, well, the information on it is all very interesting but I have to tell them that it has no currency at our clinic. I simply state the obvious - that health insurance does not equal health care (as many patients are quickly coming to realize).

Sometimes I'll press the point and ask if they have insurance for routine car maintenance to which, of course, they reply no. Then I ask, "If you don't

have insurance for routine car maintenance, they why have it for routine medical care since fees at our clinic run anywhere between an oil change and a brake job." A lot of time this comparison gets through to them. If still not convinced, I just tell them they have a decision to make about the value of their time and health.

It's obvious that we have a lot of re-educating to do of the commercially insured population. But mark my word, as their co-pays and deductibles are increasing, you wouldn't believe how quickly they are learning. One company just raised its co-pay to $35, and I am seeing many more of its employees at the clinic. Price when not adulterated by government subsidies can be a wonderful educator of value.

Getting back to the patient: While you are filling out your intake sheet you happen to overhear typical conversations my office assistant has with people calling on the phone. "No, we don't take insurance. The average fee is between $35 and $50." It seems if they were so discriminating when it came to spending their insurer's money, we wouldn't have a healthcare crisis on our hands.

Anyway, you filled out your sheet and are brought back by my office assistant to an exam room. She serves as a combination receptionist / lab tech / and nursing assistant. She takes your vitals and pulse ox with one of those machines you see in ER's while jotting down your chief complaint. She carries the phone with her, and if it rings will answer, "Can you hold, please?" until she finishes with the patient, or if she's real busy I will take the call. The patients in the clinic get first priority. When the clinic is busy, I will take the vital signs myself with the machine and usually by the time it has finished I have pretty well completed the history as well.

Let's say you have the stomach bug of the month, and I determine you aren't dehydrated and are able to keep pills down. I dispense 12 Promethazine 25mg pills prepackaged from our little dispensary for your nausea so you don't have to stop by a pharmacy on the way home. I show you the instructions on the label, write them on the discharge instructions, and give you our handout sheet on clear liquid diets, and you are out the door for $40.

If you are dehydrated, I'll recommend an IV, and if you agree, I will administer 2 liters of IV fluids over about an hour, give Promethazine IV if you have a driver, and before you leave dispense Promethazine gel with instructions about how to apply it on the inside of your forearm. You go from feeling like a withered plant to bursting with life again – all for only $130. In the ER this can run over $1,000.

Do the prices seem a little low to you? They probably are. However, I would much prefer a modest income and the freedom to take care of appreciative patients than being rich and forced by government mandate to take care of patients who feel they are somehow entitled to my services.

Clinic Results

PATMOS is located in a village of 16,000, in a county of 60,000, in a state where only 10% are without insurance (one of the least in the nation) and 25% have Medicaid (one of the highest in the nation). In addition, there is a government run clinic in town, two others within 15 miles of town, and a charity clinic in a town 25 miles away. No large company in our community to my knowledge has yet to adopt a consumer driven health plan such as an HRA or an HSA where employees are motivated to find low-cost healthcare. I compete daily against 10 to 20 dollar co-pays.

Given a market so stacked against us, how have we been able to survive these last three years? By providing value and service at fair and honest prices as any other successful small business does. We have nearly 5000 patient charts with (at last count) approximately 51% uninsured, 38% commercially insured, 8% Medicaid recipients, and 3% percent Medicare. The clinic has added 800 new patients in the last six months.

My break-even volume is about 1.2 patients an hour. My average volume over the last 6 months has been about 3 patients an hour, which makes my net income before taxes a little less than what I was making in the local ER. At 4 patients an hour, I would be making about 50% more than I was making in the

ER. The average cost per visit over the last six months including the professional fee, tests, and medicines has been $51.53 per patient.

To put this in more concrete terms, an uninsured patient came to us last week from the local urgent care after refusing to pay the $105 they required up front to be seen for a sore throat. She paid us $35 after the visit.

Other PATMOS-type clinics

I am not alone in this effort. There are many other physicians in this country currently doing low-cost, non-boutique cash-only clinics, and they are gaining increasing media exposure. They are filling real needs in this country, especially for the uninsured.

The largest such network of clinics is SimpleCare, founded in 1998 by two family physicians in Seattle, WA. According to Vern Cherewatenko, MD, there are now over 2000 healthcare providers who are members of their organization (including me). They started their cash only clinic out of financial necessity. Their managed care market was squeezing them so severely by increasing overhead and hassles while cutting their reimbursement that they actually began losing money.

They had five clinics in an IPA and were billing $10 million per year, but were losing $80,000 per month, despite doing everything to cut expenses to the bone. Their average reimbursement per patient visit was $43 while the average cost per patient visit was $50 ($20 of which was incurred in billing). The overhead was so bad that he remarks, "At one time we needed six medical records clerks...just to photocopy the records of patients who, on a monthly basis, transferred in and out of our care on these various managed care plans."

Dr. Cherewatenko is the most prominent leader in the direct payment movement. He appeared on the cover of the April 2002 issue of U.S News & World Report, on NBC news and PBS, as well as in the Wall Street Journal, USA Today, and Forbes Magazine. On April 4th, his organization received national exposure through the AP News service, which was then picked up by CNN and many local media throughout the country. Within three days, his website had

over 25,000 hits with the average time per hit being over 40 minutes. He had interviews taped last week with both the NBC Nightly News and CNN Financial News.

The co-founder of SimpleCare, David MacDonald, D.O, has gone on to start Liberty Health Group, "a medical consulting company with a special focus on the Consumer Directed Health Care Model."

California family physician Tom Lagrelius helped start INDOC – Independent Doctors of the South Bay – in 1997 and is currently listed among its directors. It "was created and serves as a nonprofit patient-oriented doctor referral network that is committed to advancing personalize, private, 'unmanaged' healthcare." The INDOC website contends that "third-party interference between patient and doctor should have no place in the practice of medicine."

CashCare America in Warrenton, VA "is building a nationwide network of physicians, dentists, pharmacies, and hospitals that have pledged to charge you the discounted rate offered to managed care insurance companies if you pay cash rather than rely on insurance reimbursement."

Several religious medical cost sharing plans offer a non-insurance alternative where members share expenses to a large deductible and the risk is reinsured beyond that. Amounts of the monthly "share" tend to run a fraction of the cost of most health insurance premiums. Brochures for two such plans, Samaritan Ministries and Medi-Share, are available in our clinic's waiting room.

Todd Coulter, MD, a black internist from Mississippi, has had a cash only practice for 2 years. He charges a flat rate of $40 per visit. Head of the AMA's young members section, he advises other physicians to "get off the Medicare plantation." His clinic has been featured on the CBS Evening News.

Mike Harris, MD, a urologist from Michigan, got rid of all his third party contracts several years ago. Herb Rubin, a gastroenterologist from California, has been doing direct payment for a number of years and decries "the coarsening and commoditization of our once noble profession" at the hands of managed care. Curtis Harris, M.D., J.D., an endocrinologist from Oklahoma, started doing cash only about 5 years ago. He is on the board of the Christian Medical & Dental

Association and recently submitted an article concerning cash only clinics to be printed in the next issue of the CMDA magazine *Today's Christian Doctor.* Lawrence Huntoon, MD, a neurologist from New York, just recently gave up his last insurance contract as a non-participating provider with Medicare.

The week after I gave a talk to a medical organization last fall, an attendee called me to say he had decided to drop all insurance contracts and start a cash-only practice. The April 23rd issue of Medical Economics contained an article entitled, "No coding, no insurers – no kidding," featuring not only SimpleCare but many other physicians throughout the country whom I had never heard of starting cash only practices on their own just as I have.

It appears that we are tapping into a wellspring of patient and physician dissatisfaction with costly, inefficient, paternalistic, and impersonal bureaucratic medicine. People today want control over their non-catastrophic medical care – and they want it right now, from someone they trust, and at fair and honest prices. With the advent of consumer-driven health plans empowering Americans with pre-tax, tax-deferred savings accounts to spend at clinics like these, we are poised, I believe, to see a grassroots revolution in the delivery of routine medical care.

Over a year ago, Tennessee Representative Zach Wamp in an editorial entitled "Is Healthcare Facing a 'Perfect Storm'?" identified many factors converging together threatening to sink our healthcare system. He warned us then that a federal government takeover of medicine might be imminent. It appears now that consumer-driven health plans together with these direct payment clinics that are spontaneously and simultaneously starting nationwide might well prove to be the twin engines propelling us out of this "perfect storm."

An op ed in the Wall Street Journal by economist Alan Enthoven once asked, "Where are Healthcare's New Honda's?" With more clinics like these offering services costing between an oil change and a brake job, my answer is that they are just arriving – and they are patient driven.

How cash only clinics reduce costs

Cash only clinics can reduce cost substantially. Operating expenses for a family physician vary from practice to practice depending on the locale, the extent of services that are offered, the equipment, etc. Some have their own lab and X-ray machines – many do not. According to the Medical Group Management Association, the average family physician's take home income is about $150,000 per year. Overhead is typically around 65% or $250,000.

One physician contemplating quitting medicine was quoted in last summer's *Time* magazine issue, "The Doctor is Out," as saying, "Our income is completely controlled by the government but we have no control on our expenses." In contrast, I rely on appreciative neighbors for my income, and by avoiding contracts with third party payers I have a handle on cost. My overhead is about one-third that of the typical family practice which in absolute dollar terms is over $150,000 per year – more than the typical family physician's take home pay.

According to MGMA, the average number of FTE's per family physician is about 4.4 and the annual personnel cost is about $150,000. Mine are 1.2 and $30,000, respectively. As I mentioned earlier but is worth repeating, the average cost per visit over the last six months including the professional fee, tests, and medicines has been $51.53 per patient.

If we could suspend political reality for a moment and imagine that all 300,000 primary care physicians did direct payment, the national cost savings would translate roughly into $50 billion savings on the doctor's end alone. This excludes the savings to the insurers.

If there were more reasonably priced clinics like ours around, the uninsured would not have to use ER's for their medical care and Medicaid programs could stop paying for routine medical care for many of their recipients. This would decrease pressure on ER's and would free them up to do what they do best – care for emergencies. It would also decrease Medicaid costs, which are busting many state budgets – including Tennessee's.

The biggest savings, I believe, would come from changing the consumer mindset. Instead of shielding consumers from the true cost of routine medical care with low co-pays and low deductibles, if average Americans had to pay everything up to a fixed, meaningful amount, they would be more cost conscious. My uninsured and high deductible patients feel the full cost of their routine healthcare decisions and find the best value for their dollar as they do with any other economic decision affecting their households. Many ask me to quote a fee before agreeing to be seen. Then they insist that I provide a thorough justification for the diagnostic strategies and treatment I recommend. In a sense, the uninsured and those who have high deductibles are the prototypes for consumer-driven healthcare. Applying the sum of all of these savings to the nearly half billion primary care doctor-patient encounters each year could significantly curb the cost of healthcare for everyone and make it more available and affordable for the uninsured.

I once saved an observation about reasons for waste in bureaucratic medicine (I have since lost the reference). Its *modus operandi* contrasts starkly with the lean operations of these new direct payment clinics.

> "The great Toyota production engineer, Taiichi Ohno, referred to any activity that adds cost but does not add value as **muda**. There are seven categories of **muda**. As applied to healthcare, they are as follow:
>
> • **Delay**: Idle time waiting for pre-certification for hospitals, consultations, tests.
>
> • **Movement**: Unnecessary physician visits for referrals and lab tests.
>
> • **Oversight**: Having one worker watch another worker as in utilization review.
>
> • **Inspection**: Having one worker inspect the work of another worker after it has been completed as in HCFA retrospective case review.
>
> • **Rework**: Performing the same task twice as in second opinions or refiling claims.

> • **Overproduction**: Requiring unnecessary products as in defensive medicine or processing unnecessary information, e.g. as required by HIPAA.
>
> • **Poor or Defective Design**: Design goods that do not meet customer needs, such as HMOs, Government or Employer-sponsored health care, and requiring RBRVS, CPT, DRG, and ICD-9 coding schemes."

One of the biggest savings might not be financial. According to the American Hospital Association's *TrendWatch*, over 120,000 nurses are currently needed to fill vacancies in our nation's hospitals. According to a JAMA study, there will be a shortage of 400,000 nurses by the year 2020. Again, suspending political realities to make a point, if all primary care physicians could reduce their staff by three employees, there would be 900,000 more healthcare workers who would be available for direct patient care rather than wasting time pushing paper.

Maybe it *is* time to change the political reality. After all, John F. Kennedy once said:

> "The problems of the world cannot be solved by the skeptics or the cynics, whose horizons are limited by the obvious realities. We need people who dream of things that never were."

Now we can talk about healthcare

On April 18th, the New York Times carried a thoughtful article by Senator Clinton entitled, "Now Can We Talk About Healthcare?" As a frontline physician, I believe she is right when she says, "We need care to focus on the patient" because "studies show that when patients have a greater stake in their own health, they make better choices." I too believe that "the present system is unsustainable."

However, I would have to disagree with her that "every other industrialized nation has...health care that's always available for every citizen." The evidence shows instead that universal health coverage does not universally guarantee timely, quality medical care. Although beautiful, egalitarian, and

noble in aspiration, universal health insurance has proved ugly, elitist, and ultimately inhumane in practice.

According to an article from London's Sunday Times, over one million Brits are awaiting elective surgery, despite its National Health Service having so many workers that it is the third largest employer in the world. There is such a backlog of surgeries that the government is subcontracting the work out to other European nations. The National Health Service, however, insists it's making improvements, stating on its website, "Already more than three out of four inpatients are admitted within *three months* (emphasis mine) of seeing their GP, dentist, or optician." Soothing words perhaps for the Brits, but with delays of this magnitude we Americans would be suing for malpractice.

The following quote (again from its own website) is even more incredible. "If you are suffering from chest pain for the first time and your GP thinks this might be due to angina, you will be assessed in a specialist chest pain clinic within two weeks." Faced with a potentially fatal medical condition, Americans would never tolerate such delays in care.

Despite many Americans' infatuation with Canada's system, it appears to be no better than Britain's. Canada's own National Post has reported median waits for a CAT scan of 5.2 weeks, for an MRI 12.4 weeks, and for an ultrasound 3.2 weeks. The average time it takes for a Canadian GP to refer a patient to an ophthalmologist is 15.8 weeks with another 10.8 weeks elapsing before the eye specialist actually initiates treatment. According to the Canadian Medical Association Journal, the median time from a mammogram to a mastectomy is about 14 weeks, long enough for a localized cancer to metastasize.

By comparison, just before Labor Day last summer an uninsured patient of mine came in with a worrisome cough. We obtained a chest X-ray that day which showed a shadow on the periphery of his right lung – potentially a curable lesion if cancerous. A diagnosis was made, and the patient was referred to a thoracic surgeon, who removed the cancer 4 ½ weeks from his visit to my clinic. I still see him periodically, and there is no evidence yet of recurrence or spread of the tumor.

Our own Tenncare system, often touted as a model in Medicaid efficiency, is about to bankrupt the state. It costs approximately $5,500 per person or $22,000 for a family of four. In a February 2004 Johnson City Press editorial, I made the following observations.

> "Many Tenncare patients tell me they choose our clinic because either their assigned providers don't have any openings for several weeks or they don't have a provider at all. Should we be surprised considering the pittance Tenncare pays physicians?
>
> To pay for all the overhead insurance and government impose on their practices, physicians have to stack their schedules with frequent visits from patients with simple chronic problems.
>
> So much is wasted in this petty political game of 'you pretend to pay us and we pretend to care,' that there is little left over to pay specialists for the really sick. One of my patients with severe rheumatoid arthritis cannot get an appointment with a rheumatologist who accepts Tenncare until August.
>
> In addition, about as many dollars are spent settling the small claims for routine office visits as the doctor receives for his time."

Several weeks later, Governor Bredesen in his State of the State address announced a fundamental shift in policy by introducing greater accountability at the point-of-care. He was quoted as saying, "the only way you manage utilization effectively is to have some economic skin in the game at the point of sale," calling on "able-bodied adults...to pay something." The consulting group McKinsey & Company has proposed increasing physician visit co-pays up to $32 for this "able-bodied" population – a little less than the average visit at PATMOS.

It seems that centralized bureaucracies simply cannot manage healthcare. Medical decisions are much too complex and personal to entrust to distant bureaucrats many of whom lack basic medical knowledge. The most efficient and humane solution is to allow ordinary Americans to manage their own care by giving them control over their healthcare dollars. It is, after all, their money and their health. They *should* control both.

Senator Clinton goes on to say, "It will...take the whole village to finance an affordable and accountable health system." The "villages" of Great Britain, Canada, and Tennessee might have the power to set prices and thus make healthcare more "affordable," but they cannot contain the costs. Markets, even in healthcare, will not be mocked, and costs will be extracted in terms of longer and potentially fatal delays and fewer innovations. Already more physicians at the height of their careers are choosing early retirement and fewer of our brightest students are selecting medicine as a vocation.

To whom would you rather entrust your care – a heart surgeon who is angry that his (or her) talents were commandeered in mid-career or one willing to acquiesce to the bureaucracy? Without caregivers, there can be no care – irrespective of village mandates. For no one - not even Representatives or Senators - can coerce talented and medically skilled citizens to care.

From my experience with Tenncare, there seems to be little accountability with government run healthcare. While working in a Tennessee ER for 4 years, I noted that over 80% of adult Tenncare patients smoke cigarettes. Given that a pack-a-day habit costs roughly $1,000 per year, these Tennesseans could pay for about 20 visits to our clinic with the money they would save from quitting. Indeed, any objections to paying for their own routine medical care at clinics such as ours could be seen more as a problem with their priorities than with the price.

One 40-year-old nurse with a heart attack I cared for opted for a higher paying job without insurance than one with insurance because he knew that if he did have a catastrophe he would immediately be placed on Tenncare. He was right. I happen to know that his family still owns 70 acres of land outright. I have observed some Tenncare recipients driving late model vehicles to my clinic such as Toyota Sequoias and Honda Accords. I have no problem with their smoking cigarettes or owning vast tracts of land or expensive vehicles – just not at taxpayer expense.

Corruption and waste seem to be endemic in villages, but not at neighborhood cash clinics such as ours that don't presume upon other taxpayers. Every day I am repeatedly and directly accountable to my patients. If they don't

value my service, they go elsewhere. In Canada, that "elsewhere" happens to be the United States.

What government can do to assist development of PATMOS-type practices

If policies promoted the development of direct payment clinics instead of hindering them, the current grassroots movement in low-cost clinics would probably spread like wildfire. I might then be able to find another physician to join me and thus extend the clinic's hours to my community. Then my patients wouldn't have to complain about getting charged $750 by the ER for repairing a laceration that I would have repaired for about $200 – or getting charged $400 by the ER to X-ray a boy's arm to tell him that a BB easily palpable near the skin was indeed located in his arm, when I removed it the next day for $100 (which included the price of the antibiotics). If physicians weren't so afraid of running afoul of arcane and capriciously enforced Medicare regulations, many more, I believe, would start similar clinics.

So what can you as Congressmen and Senators do?

First, you can change Medicare's "opt out" clause. Medicare regulations make physician coverage for my practice practically impossible. In order to care for the uninsured cost-effectively, I had to "opt out" of Medicare. Otherwise, I would have to turn away any Medicare patients willing to pay me directly for my services. No other physician in my area with skills compatible with mine has "opted out" of Medicare. Therefore, I cannot be available to my patients beyond office hours (otherwise I would be on call 24/7, 365 days a year), and I have to shut the clinic down completely when I take a vacation or attend meetings like this one.

Two weeks ago an emergency physician from Georgia spent the day at PATMOS trying to get an idea what it will take for him to get started part time in a practice similar to this. He still wants to continue practicing ER medicine until the practice can sustain his income needs. In order to do that, I advised him to turn away all Medicare beneficiaries, because according to Medicare's "opt out"

clause, he cannot both bill Medicare in the ER and contract privately with Medicare beneficiaries in his clinic.

Medicare law insists that a new patient with an "urgent" condition be turned away from the clinic. Over a year ago a Medicare beneficiary who did not have a primary care physician came to our clinic with a one-month history of weight loss and cough. Had I referred him to the ER, they would have found the mass on chest X-ray but would not have been able to evaluate it more fully. They would have given him the names of doctors with whom he could follow-up, which would have just delayed his care. As it was, the patient was diagnosed with small cell cancer and within about 2 weeks began chemotherapy. I'm not sure if Medicare would consider his condition" urgent." But how could I turn him away because of a Medicare regulation I don't understand? I had to do the neighborly thing. Otherwise, the patient might not have had a few more good months and enjoy his last Christmas with his family.

Medicare patients who want to be treated at direct payment facilities because they are unable to obtain an appointment in a timely fashion with their regular physician might either wait until their condition becomes so severe that they require costly in-patient care or resort to the emergency department earlier in their illness than is really justified. The latter option would be unnecessary for a routine problem, many times more expensive than my clinic, and inordinately time consuming for the patient.

In order to prevent treating a Medicare beneficiary by mistake and risk a fine or imprisonment, such a physician has to require all patients to sign an appropriate document stating that they are neither Medicare beneficiaries nor Medicare eligible at the time of the visit. This is an excessive burden to the clinic and inconvenience to its patients.

Quitting emergency medicine so as to "opt out" of Medicare is certainly not desirable for most emergency physicians. Even those who want to cut back on hours in the ER would like to do so slowly. We enjoy the challenges and rewards of the specialty and more would probably extend their careers substantially if it weren't for the "opt out" clause. In addition, the measure

requiring a two-year hiatus for all who dare to "opt out" is certainly a draconian disincentive to test the waters of caring for the medically uninsured.

Second, curtail the tax exemption for low co-pay, low deductible insurance. If companies want to purchase these for their employees that is fine, just not at other taxpayers' expense. Holman Jenkins of the Wall Street Journal perhaps has said it best:

> "The average family of four now pays about $1600 a year in taxes to cover the cost of a health-insurance subsidy to *itself.* No real gain to anybody occurs: We just push checks around to conceal from people the true cost of their healthcare. How bad this has become is lost on most Americans .... It is also grossly regressive: A family earning $100,000 a year gets $2357 to help pay for medical insurance; a family earning $15,000 gets only $71.... The only reform that stands a chance is one that dismantles the nutty system of tax subsidies that fuel health care inflation by commanding an unnatural urge to channel every ache, pain and prescription through a third party payment bureaucracy."

Third, allow Americans to roll over other assets such as IRA's into their Health Savings Accounts to provide immediate coverage for the high deductibles.

Fourth, promote transparency in pricing by hospitals, especially if they are non-profit. Two non-profit hospitals in Urbana recently lost their tax-exempt status because townspeople were able to demonstrate price gouging of the uninsured and draconian collection practices. The hospital nearest our clinic charged an uninsured patient of mine for a colonoscopy twice what they charged the insurance company of his wife. A patient I diagnosed with appendicitis and referred directly to the surgeon (as opposed to the ER where he would have incurred an even higher bill) was charged $5,500 by this hospital even though he went home the same day as his surgery. I suspect Medicare and Tenncare pay considerably less for the same treatment. Although this hospital is non-profit, it refused to discuss discounting rates for the uninsured at our clinic.

Extending care to all direct payers (including the uninsured)

A business sketch

There is a niche somewhere in between urgent and emergent care that is particularly attractive to emergency physicians whose careers on average cover less than a decade (due to the phenomenon many call "burnout"). It could allow us to use most of our skills and experience under less duress and without doing graveyard shifts. Originally, my clinic started this way, but financial limitations and time constraints forced me to scale back my services. Such an option would extend ER docs' careers by providing an opportunity to use most of our skills and knowledge more fully than most other options currently available.

There is probably no other group of physicians today more qualified to take care of the medically uninsured than ER docs. We provide a broader range of medical care than any other specialty. We are able to treat from the very young to the very old, from head to toe, from the chronic to the acute, from routine ailments such as ankle sprains and sore throats to emergencies such as major trauma and heart attacks. We are part anesthesiologist, part dermatologist, part gynecologist, part internist, part neurologist, part ophthalmologist, part orthopedist, part otorhinolaryngologist, part pediatrician, part psychiatrist, and part surgeon. After about a decade of practice, there are few diseases within medicine that ER physicians haven't treated and, short of major surgery and skills reserved for other specialists, few procedures that we haven't performed. Yet after the first decade of our careers, many are ready to call it quits. Most find less stressful jobs that do little justice to their unique experience and skill.

I believe that this talent could be better employed in fully equipped urgent care centers that approximate small rural ER departments in capabilities. I have worked in small, rural ER's as well as large urban ones that treat major trauma. I understand first hand the capabilities of both. In my opinion, establishing this type of facility throughout the country is an idea whose time has come, especially considering the ever-increasing cost of medical care and the 44 million uninsured. Indeed, four similar facilities (albeit hospital-associated) are already operating in New Jersey.

I predict that there would be a ready supply of physicians for facilities such as the ones that I envision. I believe that near-burned-out and burned-out emergency physicians would be willing to contribute their skill and knowledge in less stressful settings that don't require 24 hour a day, 7 day per week coverage. The burden on urban ER's would be reduced. Rural hospitals could replace much of their ER coverage with hospitalists capable of covering the whole hospital 24/7. And best of all, more urgent and semi-emergent conditions could be treated skillfully and definitively. Should true emergencies happen upon the premises (ambulances would not be allowed to transport emergency cases to such facilities), they could be adequately stabilized and sent by critical care transport to an appropriate hospital.

This presents a win-win-win situation for everyone. Seasoned emergency physicians would not waste their talent. Hospitals could use their resources more efficiently. And most importantly, patients, especially the uninsured, would be able to take advantage of the comprehensive skill of a retired or semi-retired emergency physician in a more cost-effective setting.

I have sketched out a plan for such a clinic in a market larger than Greeneville. A clinic such as ours initially requires only one trained clerical person besides the physician. At between 3 and 4 patients an hour, it becomes cost effective to hire an office assistant. It would require one other physician with a background similar to mine to alternate 12 hour days. We could also take appointments on our days off within a small space in the clinic. Neither an X-ray machine nor a lab would be necessary. In fact, there is a strip mall in a nearby town with a chiropractor willing to take X-rays for us and with a satellite draw station for a regional lab company. Only about 1600 square feet would be necessary. Much of the office equipment could be purchased second-hand at low prices as I did when I started PATMOS.

Given this, I would estimate that start-up costs would be between $150,000 and $200,000 and within 6 months the clinic would be self-sustaining. This assumes a generous amount for advertising, initial office costs, and a reasonable

income for physicians and staff. The clinic would be self-sustaining around 1.5 patients per hour.

The government would not need to foot the bill for any of this. I suspect that there are plenty of wealthy stakeholders with enough of an interest in preserving private medicine who would be willing to capitalize such a venture reasonably if not generously once they have learned of its potential. Perhaps clinics such as these are what Harvard Business School professor Clay Christensen had in mind when he coined the phrase "disruptive innovation." They are indeed a cheaper, more efficient way of providing professional services initially directed at low-end users that will likely catch on soon in the mainstream and eventually come to dominate the primary medical care market.

Direct payment primary care practices like these are pretty simple, really. But then, as President Reagan once said, "There are no easy solutions. Just simple ones."

All they require is being a neighbor.

Testimony of

Alieta Eck, MD

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"Rethinking Insurance"

Before The

Joint Economic Committee

Of The

U.S. Congress

April 28, 2004

Good morning. Thank you for this opportunity to come before this Committee to share some of my experiences as a physician in private practice. After 15 years of watching my profession go through profound changes, I would like to share some insights.

In 1965, a friend of mine was volunteering in a New Jersey hospital. She remembers that, at that time, a day in the hospital was billed at $39. 1965 was the year that government entered into the payment of medical bills, for it was the year that the two huge government programs, Medicare and Medicaid, were begun. This was also the year that medical inflation began, caused by an enormous infusion of federal dollars, resulting in today's sad statistic that a day in the hospital in New Jersey is billed anywhere between $3000 and $5000. My name is Dr. Alieta Eck. I was a registered pharmacist before going to medical school. I graduated from St. Louis University School of Medicine and then did a residency in Internal Medicine at Robert Wood Johnson University Hospital in New Brunswick, NJ. I am Board Certified in Internal Medicine and am part of a four physician multi-specialty practice.

Special Challenges in New Jersey

I live and practice in New Jersey. I participate in a Health Benefits Reform message board, and experts from all over the country shake their heads in awe at how a state government could mess things up so thoroughly. In 1992, New Jersey created the Individual Health Coverage Program to ensure that people without access to employer or government sponsored health care programs could purchase health coverage from a variety of carriers. All plans were standardized, and any attempt to alter the plans to satisfy consumer demands became illegal. Insurance companies were told exactly what had to be covered, what the maximum deductibles could be, and who would be eligible to enroll.

The state was attempting to make it easier for NJ citizens to understand the plans and comparison shop for the best rates. But the net effect was a staggering increase in premiums, and an equally staggering increase in the number of uninsured citizens. 220,000 individual state-approved health insurance policies were obtained in NJ in 1996. This number has dropped to 90,000 and the number is falling quickly. Anyone can pull up ehealthinsurance.com, type in a New Jersey zip code and view rates that are laughable. For example, the March, 2004 quote for a single person, "Plan C," with a 30% co-pay and a $1000 deductible, is an astounding $4419 per MONTH as quoted for all to see, by the Celtic Insurance Company. The *least* expensive plan, which still allows the patient to choose his own physicians, is offered by Oxford, at a rate of $912.20 per month for a single person. These astronomical rates can be explained by six NJ laws and facts that cause insurance rates to rise.

1. **COMMUNITY RATING**-- Charging the same whether one is male or female, 18 or 64. The healthy 18-year-olds are not willing to pay the rates needed by the sicker 64 year olds, so they drop out. This leads to more uninsured New Jerseyans and higher rates for those left in the system.

2. **GUARANTEED ISSUE**- People can avoid purchasing insurance until they feel they have a good reason. They can wait until they have symptoms, purchase health insurance, and, after the one year obligatory

waiting period for pre-existing conditions, be covered for everything. One can find he has contracted Hepatitis C, wait the one year period, and then be covered for some very expensive medicines. Less healthy people in the pool increases the cost of health insurance for all.

3. **$300 MANDATED ALLOWANCE FOR CHECK-UPS**- This actually costs $500 when you consider the bureaucratic paperwork to process the claims. Health insurance costs rise.

4. **GOVERNMENT MANDATES**- Every time we turn around, our legislature is satisfying another special interest group, mandating that all health insurance policies cover another service—in vitro fertilization was added last year. These mandates cause health insurance rates to rise and more people to drop out.

5. **LIMITING THE LEVEL OF THE DEDUCTIBLE**- In an effort to find lower cost insurance, people are asking for higher deductibles. This would lower the premiums and protect the assets of those who own a home. Individual policies with a deductible greater than $2500 are illegal in NJ.

6. **INTENSE POLITICAL PRESSURE TO AVOID CHANGE**- There are currently separate laws for Blue plans, commercial carriers, HMO's, small groups, large groups and individual plans. A "divide and conquer" mentality allows the legislature to write laws that satisfy special interests but do not apply to enough people to cause a massive protest. Regulation should focus on solvency and disclosure, applying to all plans across the board. The rest should be left to the marketplace.

Because of all the mandates, New Jersey is being left in the dust when it comes to the establishment of the newly enacted Health Savings Accounts. One insurance agent told me that there are 2300 open questions concerning the structure of these plans and the legalities of implementing them with the existing New Jersey laws.

At a recent conference I suggested to our own Senator Jon Corzine that there was one law that he, as a US Senator, could support, that would cut the number of uninsured in NJ in half. That would be *to allow us to purchase health insurance across state lines.* The internet provides a perfect vehicle, and Washington could help undo the extensive damage done by legislators in states like New Jersey. This would be entirely consistent with the Commerce clause in the US Constitution. His answer was completely unsatisfactory. He thought that this would result in insurance companies "cherry

picking" only healthy people. I countered, rather, that this would result in more people being insured, avoiding the risk of bankruptcy by owning affordable health insurance.

The Problem with HMOs and Government Run Health Insurance

Early on, in our practice, we avoided enrolling as physicians in the HMOs, unwilling to sign contracts that tied our hands while paying us some un-negotiated fee. We were being asked to swear our allegiance to the HMO, while pretending to care about our patients. I remember attending a hospital Grand Rounds where we were shown a graph with the horizontal axis being our patient's length of stay and the vertical axis being the amount spent on the patient's care. We were told that BAD doctors had patients in the upper right hand corner while GOOD doctors had patients who fell into the lower left hand corner. In other words, we were "good" or "bad" depending on how much money our patients cost the system. There was no mention about how sick the patient was, how much pain and suffering the patient endured, how kind we were, how complicated the diagnosis was to make, or how well we implemented treatment. The heart of our medical training was being undermined, and we were being taught to consider the bottom line above all else.

For several years we participated in one "non-capitated" HMO, but dropped out when the company representatives read some of our charts and determined that we had spent too much time with the patients. If we billed for a "level 3" visit, and they decided it should have been "level 2," they asked for a refund. We got out in a hurry. We wrote to our patients, explaining that we wanted to be their doctors, not the servants of their insurance company. In the letter, I included a quote from Atlas Shrugged, written in 1957, by Ayn Rand:

> "I quit when medicine was placed under State control, some years ago," said Dr. Hendricks. "Do you know what it takes to perform a brain operation? Do you know the kind of skill it demands, and the years of passionate, merciless, excruciating devotion that go to acquire that skill? THAT was what I would not place at the disposal of men whose sole qualification to rule me was their capacity to spout the fraudulent generalities that got them elected to the privilege of enforcing their wishes. I would not let them dictate the purpose for which my years of study had been spent, or the conditions of my work, or my choice of patients, or the amount of my reward. I observed that in all the discussion that preceded the enslavement of medicine, men discussed everything – except the desires of the doctors. I have often wondered at the smugness with which people answer

> their right to control my work, to force my will, to violate my conscience, to stifle my mind – yet what is it that they expect to depend on, when they lie on an operating table under my hands? Let them discover what kind of doctors that their system will now produce. Let them discover, in their operating rooms and hospital wards that it is not safe to place their lives in the hands of a doctor whose livelihood they have throttled. It is not safe, if he is the sort of doctor who resents it – and still less safe if he is the sort who does not."

Many patients left our practice, and went looking for a "$10 doctor" who would only charge them the co-pay, but many have returned, seeing a big difference in the care they receive. They now see us "out of network."

So now we do not participate in any insurance scheme, though we do continue to see patients in the Medicare program. We do not "participate" in Medicare and most of our patients pay the government determined "limiting fee," at the time of service. We dutifully send in the claims electronically, abiding by the Medicare laws. The patients get reimbursed. We do not know how much longer we will do this, as Medicare is becoming more and more intrusive, demanding and punitive—all while lowering its fee schedules. The only reason we remain in the program is the fact that senior citizens are not given any alternative. People over 65 cannot purchase health insurance outside of the Medicare system.

Our practice is very efficient. Our four doctors function well with one full time employee, one bookkeeper and six part time nurses and receptionists. No one needs to spend valuable time asking permission of the insurance companies to do tests. We negotiate directly with each patient, discussing the costs as well as the benefits of any tests we recommend. We have many patients who are uninsured, so we are very careful to order medications that are the most cost-effective. We are free to spend as much time as is needed for each patient and have a loyal following.

Caring for the Poor and Uninsured

Early on in our practice, we learned the folly of getting involved in any government program for the poor. Something seemed disingenuous in government officials promising *they* would provide free health care for the poor, and then expecting *us* to foot the bill. The reimbursement is so ridiculously low, and that comes six months after the

visit. Taking on many Medicaid patients would jeopardize our survival, so we choose to screen them ourselves, and treat the poor for free.

We began to study the root causes of poverty, and were heavily influenced by Marvin Olasky's book, The Tragedy of American Compassion (c. 1992 by Marvin Olasky, published by Crossway Books). The government looks on poverty as a simple lack of funds, and has a hard time categorizing the poor. Indeed, the government is criticized heavily when it attempts to distinguish between the "worthy" poor, those who are poor through no fault of their own, and the poor who should not be given money-- those who have a lack of funds due to bad choices and bad behavior. Both may need help, but the kind of help needs to be very different. Olasky teaches the "ABC's of Compassion," and recommends that successful people personally reach out to those who are poor. A brief summary of his seven principles of compassion is as follows:

- **Assertive**- Actively seeking ways to meet needs, fight social ills, and care.
- **Basic**- Look for people closest to the individual to meet the needs—first the family, then the community, and finally the local and state governments. This describes "subsidiarity," where those nearest the problem are most responsible, and are *subsidized* by the next level of caring commitment. Subsidiarity represents the most efficient way to care and is the least subject to fraud and wastefulness.
- **Challenging**- Gently pressure people to make changes, instead of pampering them. Help develop character traits that lead to more self-sufficiency and growth.
- **Diverse**- Treat each person as an individual, without a one-size-fits-all approach. Each is an individual made in the image of God.
- **Effective**- Try to avoid being bureaucratic and unchallenging. Utilize volunteers with their unique gifts and capabilities. The bottom line is changing lives, not counting the numbers of people treated.
- **Faith-Based**- Well managed Christ-centered charities are more effective at fighting poverty and changing lives than their non-religious counterparts.

- **Gradual**- Continually re-evaluate and check the results of the program. Gradual sustained results, tested at each step of the way, will make helping the poor most successful and sustained.

We were fortunate to belong to a church that had a building that was not in use. It had been devastated by Hurricane Floyd in 1999 and was sitting dormant. A lot of fundraising and volunteer work led to the complete renovation of the building and the emergence of the new Zarephath Health Center. (www.zhcenter.org.) Employing the principles laid out above, we began operation in September of 2003, and have been seeing and caring for the poor and uninsured ever since. Here are a few of the people our physicians, nurses and support volunteers have helped:

- A 28-year-old woman came to us six months after her father had died from a long illness. She had been his primary caretaker while holding down a job in a drugstore. When she became depressed, she lost her job and her apartment. When she applied for financial aid from the state, she was told by the caseworker that, in order to qualify for funds, she needed to get pregnant. She needed medicine that cost $230 per month. We helped her access a program designed by the pharmaceutical companies, allowing her to receive a three month supply for free. The program refused to give her more unless she had a letter from the state agency explaining their denial of aid. They would not write it. So we priced around several stores and bought her medicine to carry her over. She is getting back on her feet, has enrolled in a course to become a phlebotomist, and will be on her own by the end of the summer. She will not need us any more.

- A 20-year-old just graduated from college and was removed from her parents' insurance. She stayed at home for several months, caring for her sickly grandmother who was bedridden with advanced Alzheimer's disease and eventually died. With no paycheck and no insurance, we were able to take care of this young woman's simple illness at no cost to her. She is now at work and does not need us any more.

- A 52-year-old woman stays home with her 54 year old sister, who is dying of metastatic breast cancer. Her husband's paycheck can keep the household going, but no one in the house has health insurance. She herself is at high risk of getting breast cancer, but had not had a mammogram in 5 years. She went to the local, state-subsidized hospital, hoping to get low-cost medical care. The physicians there did a physical exam and blood work, charging her $495. Then they handed her a prescription for a mammogram. When she came to us, we checked around

for the best price, and the Zarephath Health Center gave her a check to pay for her mammogram. She recently told me that her dying sister was told that she will qualify for Medicaid on July 1, two and a half months from now. This very sick sister will likely not live that long.

- A 49-year-old is disabled with complicated diabetes. His disability income is $1000 and his rent is $725. While he is on Medicare and the state-run prescription plan for the poor, he cannot even afford the $5 co-pay. We set up an account in his name, at the local pharmacy, to draw down each time he fills a prescription. The local food stamp office told him that he qualified for only $10 per month in food stamps, so his church supplies him with gift certificates to the local grocery store. Many hands are helping this man maintain his dignity and get the health care and other support he needs.

- A 28-year-old man was terrified that he was dying. He could not hold down a job. He made several visits to the emergency room, and tests all came back normal. He had $30,000 credit card debt and was paralyzed with fear. We spent a lot of time with him, mostly in phone calls, three times a week for several months. Each time we saw him we reassured him of his good health and placed him on medicine that seemed to help. We never charged him, but, each time, we encouraged him to find work. He finally enrolled in a truck driving school and called on the Saturday morning he passed the driving test. He now has a good job, is convinced that he is healthy, and no longer needs us. His mother is eternally grateful.

People ask why we started the Zarephath Health Center for the poor and uninsured, and we reply by telling the story of the Good Samaritan. It is a story that Jesus told, about a man who was lying by the side of the road, injured and bleeding. A minister walked by quickly, thinking that he had to hurry to preach his sermon. Then a Bible teacher came by, and also felt that he did not have the time to stop and help. Finally, a Samaritan, a religious outcast, saw the man, stopped to help, and gave of his own time and resources to see that the man got cared for.

We have determined to live out our faith by following the example of the Good Samaritan. When we see people in need, we are not going to demand another government program, but rather we will use our own time and resources, and find others willing to help us do the same. We are looking for physicians and support people to donate four hours per month. We believe that there is a God in heaven, and that He would have us show compassion by meeting the physical, emotional, spiritual and

relational needs of people with whom we come in contact. We do not shove religion down anyone's throat, but we are ready to give an answer if anyone asks why we have an enthusiastic optimism about the future. We are free to tell them how a relationship with God provided the missing link in our lives and how it can be the same for them.

There is another non-profit health center, the Parker Health Center, in Red Bank, NJ. In its four years of existence, this Center has reached a point where the physicians cared for 6,000 people, with 20,000 visits last year. All the doctors and most of the staff are volunteers. They have a budget of $500,000, which computes to $83 per person per year. I would like to challenge the government to demonstrate any program that delivers care with more efficiency, patient and physician satisfaction, and quality.

One additional concern of ours, as champions of the uninsured, is the tremendous cost differential between what Medicare pays and what the uninsured are billed for a hospital visit. In New Jersey, the uninsured are billed 300% of the cost of their stay. If their stay costs the hospital $10,000, they are billed $30,000. The uninsured have no clout, and if they happen to own a house, a lien is placed on their property. We have done some investigating and discovered that a patient can have his gallbladder removed in a nice little clean hospital on a Caribbean island, for less than $1000. Compare that with the $30,000 bill we saw from one of our patients at a hospital in New Jersey. After travel, lodging, and paying the surgeons and anesthesiologist, plus a week recovering in paradise, the total bill for a cholecystectomy would not be greater than $5000 in that island hospital. The Zarephath Health Center is looking into facilitating such medical tourism for those who are interested.

We have many options—but we simply ask the government to step aside and allow the free market to lower medical expenses for all. Food, clothing, and shelter are greater necessities than health care, yet we have a largely free market in these needs, and inflation in these necessities is kept lower than in health care. As Peter Drucker said in the Wall Street Journal in December, 1991:

"The government has proved incompetent at solving social problems. Virtually every success we have scored has been achieved by nonprofits." He adds, "Increasingly, these volunteers (in non-profits) do not look upon their work as charity; they see it as a parallel career to their paid jobs and insist on being trained, on being held accountable for results and performance, and on career opportunities for advancement to professional and managerial—though still unpaid—positions in the non-profit. Above all, they see in volunteer work access to achievement, to effectiveness, to self-fulfillment, indeed to meaningful citizenship."

Our Zarephath Health Center could do much more, at no cost to the taxpayer, if there were tort reform that would allow retired physicians to volunteer without fear of being sued. New Jersey has 15,000 retired physicians many of whom would love to provide meaningful aid to those in need. The physicians working for the medical schools have caps on malpractice claims, as well as state-covered malpractice premiums. Why not have a similar arrangement for those physicians who would donate their time to clinics for the poor? This would alleviate the tremendous burden on hospital emergency rooms, lessen the burden of the welfare system, and provide more comprehensive help to those without insurance. It is time that we roll up our sleeves and tackle these problems in a more reasonable way.

The Only True Insurance

- If you get insurance through your employer, *you are really not insured.* If you get too sick to work, you will lose your job. You will not be able to afford COBRA.

- If you are self-employed and buy your own insurance, *you are really not insured.* When you get too sick to work, you might not be able to afford your premiums.

- If you work for a big company and get insurance through it, *you are really not insured.* The company can get downsized, lay you off, or go bankrupt.

- If you work for the government, *you are only insured while you are employed.* If you get too sick to work, you lose your job and your insurance.

- If you count on Medicare, be careful. It will go bankrupt in 15 or so years. The next generation might have little patience with you when you are old and infirm. You certainly will not be in a position to demand more health care.

- If you count on Medicaid, you will find that access to care is severely compromised, as the bureaucrats are paid before the caregivers.

- The only real insurance is the kindness of our families, our churches, and our communities. This is true charity, a synonym for love. We had better be setting up institutions that are very inexpensive to run. We had better be figuring out ways to lower the costs and reduce government mandates. The market works best when it is un-coerced, unregulated, and rewarded. Likewise, charity works best when it is given and accepted freely.

In 1997, my husband, our five children, and I dropped our own health insurance. We were unwilling to pay those inflated New Jersey insurance rates, and we chose to join a faith-based medical cost sharing program. It is not "insurance," but a commitment to "bear one another's burdens and thus fulfill the law of Christ," as stated in the Bible. We pay $215 per month to help others in the program, and they in turn are committed to helping us if any medical event exceeds $911. They hold us accountable for healthy behavior. We cannot smoke, cannot drink alcohol to excess, must attend church, and must avoid sex outside of marriage. This is how the monthly contributions can be kept so low.

I love being a physician. It is the most rewarding of professions. I want my son to become a doctor. But unless we give our physicians the respect and freedom they need to practice the compassionate medicine for which they were trained, we will watch the deterioration of the greatest health care delivered anywhere in the world. Give individuals the freedom to purchase the health coverage they want, opening up insurance opportunities across state lines. Allow people to choose the best physicians, not just those on the list provided by their insurance company. Enact true tort reform, where patients are compensated, but are not awarded jack-pot judgments for "pain and suffering" for bad outcomes. We need tort reform, with relief from skyrocketing medical malpractice premiums, or the best and the brightest will no longer be attracted to the healing professions. And we must hurry—before more Americans are harmed by the diminishing numbers of neurosurgeons and obstetricians who are willing to take risks and use their superb skills to save them. Thank you.

Consumer-Directed Doctoring: The Doctor Is In, Even If Insurance Is Out

Statement of

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The Urban Institute

Joint Economic Committee

April 28, 2004

Mr. Chairman, Mr. Stark, and distinguished members of the Committee: Thank you for inviting me to share my views on the growing phenomenon of physicians providing care outside of insurance. This is a timely hearing and I hope to bring a different perspective to the Committee's consideration of the crucial role of health insurance in protecting Americans' health and financial well-being. The views I express are mine alone and should not be attributed to the Urban Institute or any of its sponsors.

In the March/April 2004 issue of *Health Affairs*, colleagues from the Center for Studying Health System Change and I published an article titled "Financial Pressures Spur Physician Entrepreneurialism," which was based upon dozens of interviews we made with physicians and others in 12 metropolitan areas as part of the ongoing Community Tracking Study.[1] The study documented that physicians are experiencing pressures on their practices from a combination of factors, including reduced reimbursement rates, increased overhead costs, and higher premiums for liability insurance. It is not surprising, therefore, that physicians are looking for alternative revenue sources beyond what they earn for insured services. Unfortunately, we concluded that physicians' business practices are actually contributing to rising service use and, as a result, hindering cost containment efforts, the combination of which could exacerbate current problems with access to services for the uninsured and underinsured.

A particular problem we identified was the continued spread of physician investments in ancillary services and, as the ultimate manifestation of entrepreneurialism, the ownership of specialty facilities to which physicians refer their patients. We found that concierge care and similar approaches that permit and encourage patients to obtain services outside of insurance were not yet widespread. In the communities we researched, at most a handful of physicians were engaged in this form of boutique medicine. More recently, there has been a new development of "pay-as-you-go," cash-only medical care –

[1] Pham, Hongmai H., Kelly J. Devers, Jessica H. May, and Robert Berenson, "Financial Pressures Spur Physician Entrepreneurialism," *Health Affairs*, Vol. 23(2), 2004.

purportedly a lower cost alternative for patients without good health insurance, a possibly new approach which is being presented at this hearing

Some Physician Frustrations with Insurance Are Well-Founded

As physicians grow frustrated with the rising administrative costs and complexity of running a practice, the hassles associated with network contracting, and payment systems that have not kept up with the changing nature of medical practice, many believe that the health care system and the doctor-patient relationship would be better off if more care were provided outside of insurance, which would be reserved only for catastrophic expenses. The frustrations are real, as are the problems that produce them. Some responses, including those being discussed at this hearing, I believe, are meant to improve physicians' ability to provide care and to provide an alternative for patients who face escalating health insurance premiums and increasing cost-sharing as part of their insurance packages. These physicians understandably have an impulse to get out from under the rules and regulations associated with public and private insurance and to have more control over their own working conditions.

While these physician-initiated alternatives to the standard insurance-based systems may have some limited application, I think they represent symptoms of a system lacking universal, comprehensive health care insurance. Again, the oft-quoted H.L. Mencken line is applies, "There is always an easy solution to every human problem – neat, plausible, and wrong."

Clearly, there is a market for affluent patients and an elite tier of mostly primary care physicians supplementing the regular system of care based, necessarily, in comprehensive health insurance. However, the market receptivity of those able to afford concierge care and other, less dramatic approaches to providing "subscription services," e.g., communication via e-mail as an alternative to office visits, suggests that public and private payers can and should reform their payment approaches. Similarly, individuals and small employers, in particular, face exorbitant administrative costs that divert crucial

dollars from patient care.[2] Of course, physicians object to the gross inefficiencies and patient indignities associated with the individual and small-group insurance markets.

There are numerous lessons in these physician-sponsored initiatives that offer the possibility for major improvement in the operation of health insurance, private and public. For example, within insured products, we can be more creative in the use of tiered cost-sharing, modeled on triple-tiered pricing for prescription drugs, to try to influence patient behavior and have the patient bear more of the costs of truly extravagant choices. Similarly, those who provide concierge care maintain that having sufficient time to conscientiously attend to patients' concerns and needs forestalls expensive specialty care that time-pressured primary care physicians resort to. Based on my experience practicing general internal medicine for over twenty years, I concur that current fee-for-service reimbursement methods emphasize quick, face-to-face physician-patient encounters, while discouraging other important activities, such as reviewing records, coordinating care with other professionals, and communicating by telephone and e-mail.[3]

Yet, at its best, providing substantial health care services for much of the population outside of insurance is an elitist notion. It perhaps has a role for those affluent individuals willing to pay out of their own pocket, not subsidized by taxpayers, for special attention that a few physicians, frustrated with the rules imposed by insurance programs, want to offer. I do not criticize those who provide concierge care, although it is unfortunate that these physicians have felt the need to opt out.

Medical Care Has Unique Attributes that Do Not Conform to Normal Markets

For many reasons, these cash-based, extra-insurance models do not deserve broad application as a substitute for comprehensive health insurance. All developed countries

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[2] Blumberg, Linda J. and Len M. Nichols. 2004. "Why Are So Many Americans Uninsured?" *Health Policy and the Uninsured,* Catherine G. McLauglin, ed. Washington, DC: Urban Institute Press.
[3] Larson, Eric B., for the Society of General Internal Medicine Task Force on the Domain of General Internal Medicine. "Health Care System Chaos Should Spur Innovation: Summary of a Report of the Society of General Internal Medicine Task Force on the Domain of General Internal Medicine," *Annals of Internal Medicine,* 140(8), 2004.

besides the United States are able to provide universal, comprehensive insurance coverage to their populations at levels of a half to two-thirds of what the United States spends, whether calculated as per capita spending or as a percentage of the gross domestic product. These countries accomplish this either through social health insurance programs or national health systems that face similar theoretical problems associated with the moral hazard of third-party, insurance payment. But only in the United States do we seriously discuss endorsing an approach that would parcel out health care by the ability of patients to pay.

Forty years ago, on the eve of passage of Medicare and Medicaid, Nobel laureate Kenneth Arrow turned his attention to how medical care differs from most other sectors of the economy in a landmark article that is as relevant today as then.[4] Among the unique attributes of the medical care system, he pointed to the asymmetry of information possessed by buyers and sellers. "Because medical knowledge is so complicated, the information possessed by the physician as to the consequences and possibilities of treatment is necessarily very much greater than that of the patient, or at least so it is believed by both parties."

Arrow further explained at length that uncertainty, that is, the reality that the need for medical care is irregular and unpredictable, characterizes the nature of the service the professional is giving. The buyer-patient depends upon the seller–physician for a trusting professional relationship to help address the inherent uncertainty that underlies much medical care. The pervasiveness of uncertainty and the asymmetry of information lead to a relationship of trust and confidence, which is not present in a pure, market-based relationship. Thus, he concludes, "Purely arms-length bargaining behavior would be incompatible, not logically, but surely psychologically, with the trust relationship."

[4] Arrow, Kenneth J., "Uncertainty and the Welfare Economics of Medical Care," *The American Economic Review*, 53(5), 1963.

The Problems Presented by Health Savings Accounts

Some approaches you will hear about today actually assume the desirability of arms-length bargaining between patient and physician. To further their adoption, many now promote insurance products featuring high deductibles and only catastrophic insurance coverage, such as Health Savings Accounts (HSAs).

However, as I have followed the debate, I have found the logic of high deductible plans is usually supported by simplistic clinical examples that ignore the prevalence of uncertainty and information asymmetry that Arrow described. We often hear of the patient with a straight-forward clinical problem, such as an upper respiratory infection, who can avoid insurance, long waits and paper work by paying, say, $50 directly to a doctor in a clinic. We do not hear about the patient with an upper respiratory infection who also is a diabetic on insulin and has renal failure and hypertension. For such a patient, the $50 cash payment might become hundreds of dollars for a proper evaluation, especially if carried out by a physician who does not know the patient and does not have the patient's medical records. Perhaps this approach would be less costly than care in a hospital emergency department, but the goal should be that every American has a primary care physician responsible for providing ongoing care and coordinating the care provided by specialist physicians and other providers.

Another typical example used to promote HSAs is the middle-aged, weekend tennis player with knee pain whose sports medicine orthopedist recommends an MRI scan of the knee. With a high deductible plan, the theory goes, the patient who now has to pay out of pocket might challenge the need for the MRI and would then search out a facility with lower prices. The decision to proceed would be made as other marketplace transactions are.

Now to the real world. A friend of mine, with good insurance, recently had knee pain. Only it did not interfere with his tennis game, but rather with his occupation – he is a carpenter, and the knee pain was interfering with his ability to work. On the

recommendation of the sports medicine orthopedist, he had an MRI. And unexpectedly it showed a "hole" in one of the bones around the knee. Although it was interpreted as likely to be a cyst, his physician wanted him to see an orthopedic oncologist to evaluate the radiological finding. That physician concurred that it most likely was a benign cyst but strongly recommended a follow-up MRI scan six months later to make sure there was no change. The concern here was the slight chance that the abnormality represented cancer.

As it turned out, the abnormality proved benign. Two expensive MRIs were performed, and they were performed based on expert clinical judgment and at facilities selected by the physicians. Expecting patients to become not only marketplace consumers but, in effect, clinicians able to grapple with scientific uncertainty and to gamble with their own health, in this case, with the specter of cancer, is inappropriate and unfair. Again, there may be some role in insurance products for applying variable patient cost-sharing to try to influence patient decisions, perhaps to select higher quality and more efficient professionals and providers. But expecting patients to make important medical decisions without the fundamental financial protection provided by health insurance is not in the best interest of patients, physicians, or the public.

At a practical level, moving the system to large deductible plans with pure catastrophic coverage, the Health Savings Account model, would disrupt insurance markets and would not likely reduce health care spending enough to be worth the threat that this approach represents.

First, it is likely that relatively healthy, affluent individuals would be the group most likely to opt out of comprehensive insurance products, leading to high insurance costs for those whose health problems give them no choice but to remain in the basic health insurance pool. As healthier families and individuals opt out of traditional insurance coverage, those remaining in comprehensive health plans would be more expensive to insure. This will lead to destructive market segmentation, driving up premiums for traditional coverage even further and setting off a spiral of adverse selection. The

comprehensive health insurance option would become unaffordable precisely for those who need its protection.

Second, most of the costs that drive inflationary health care spending are associated with a small percentage of patients who have very large health expenditures. In most health insurance systems, private and public, with minor variations, about 5 percent of patients are responsible for about half of the expenditures. Because most health spending is attributable to the small share of individuals with very large medical expenses, increasing deductibles far above current levels will not result in much savings, even if care-seeking behavior for those with the deductibles changes marginally. Although some physicians might reasonably believe that high-deductible plans were changing patient desire to have certain discretionary services, for the system as a whole, the cost containing potential of HSAs would be illusory.

Third, by requiring individuals to pay for medical expenses up to the high-deductible amounts, starting at $1,000 for single and $2,000 for family policies, high-deductible insurance would surely discourage low- and moderate-income individuals and families from receiving preventive care and the early diagnosis and treatment needed to head off costly illnesses and complications. With all the progress made in medicine, medical care is still based on substantial clinical uncertainty, an asymmetry of information and the need for a physician-patient relationship rooted in trust. Patients correctly are risk-averse and unreasonable financial barriers to care will surely lead to adverse health consequences.

Health Care Markets Remain Unique

We can agree that forty years after Arrow's commentary things have changed in a number of ways. We now have the Internet, where some patients can gain information about details of diagnosis and treatment that even expert physicians do not immediately know. However, even with this information aide, medicine has become that much more

complex. Asymmetry of information between the seller and the buyer has not diminished. And in many ways the clinical stakes are higher.

Since 1963, we have accepted that patients should not be passive, merely accepting a paternalistic physician's diagnosis and treatment recommendations. Patient preferences for alternative treatment options and their personal values on matters of life and death need to be respected and, often, deferred to. In the area of chronic care management, it has been shown that patients can improve their own health and well-being by becoming better educated and motivated to take responsibility for directing important aspects of their own care. However, we should not confuse activating patients to take greater control over their own care with turning them into consumers able to engage the health care system as if they were buying an airline ticket on the Internet.

And physicians need to remember they are professionals, one of whose important precepts is that they should be acting in the best interests of their patients. In the *Health Affairs* article referenced earlier, we expressed the concern that, in the era of managed care, physicians sometimes felt they compromised their professional agency relationship with patients by becoming, in effect, "double agents," with potentially conflicting responsibilities to patients and the insurance companies with which they did business. We then wrote, "In the post-managed care era, physicians have responded to mounting financial pressures with a range and intensity of activities that evoke images of 'free agents' defending their own financial interests and challenging established professional norms."[5] Although the activities described in this hearing do respond to real problems spawned by practices of insurance companies, I remain concerned that the responses presented by the other physicians at this hearing would, if broadly implemented, threaten the important role of public and private insurance and further compromise the physician-patient relationship.

[5] Pham, *Health Affairs*.

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S. HRG. 108–605

THE BURDEN OF HEALTH SERVICES REGULATION

HEARING

BEFORE THE

JOINT ECONOMIC COMMITTEE
CONGRESS OF THE UNITED STATES

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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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-kickback 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

[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.

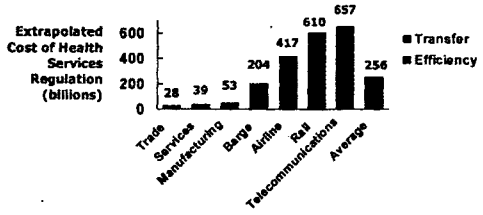
We used two approaches to determining the net impact of regulation. The first was a "top down" approach that relied on extrapolations from other industries. The second was a "bottoms up" approach that systematically examined the evidence.

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		If Applied to Health		
			Efficiency	Transfer	Efficiency	Transfer	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			4.6%	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

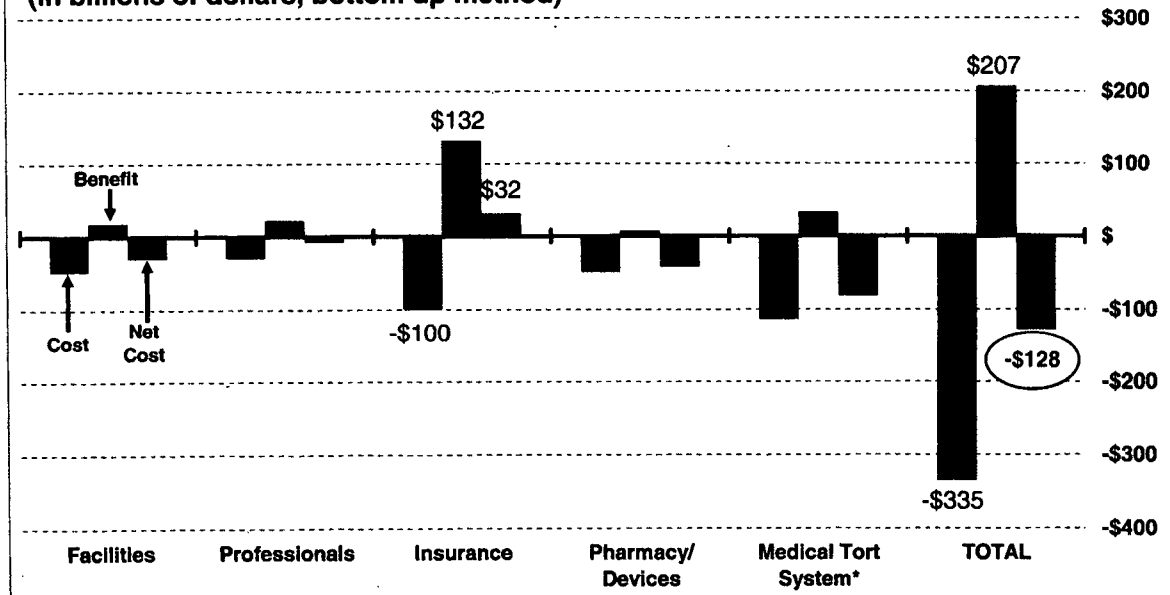
[S1] Hahn, Robert W., and John A. Hird. 1990. The costs and benefits of regulation: review and synthesis. *Yale Journal on Regulation* 8: 233.

[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)

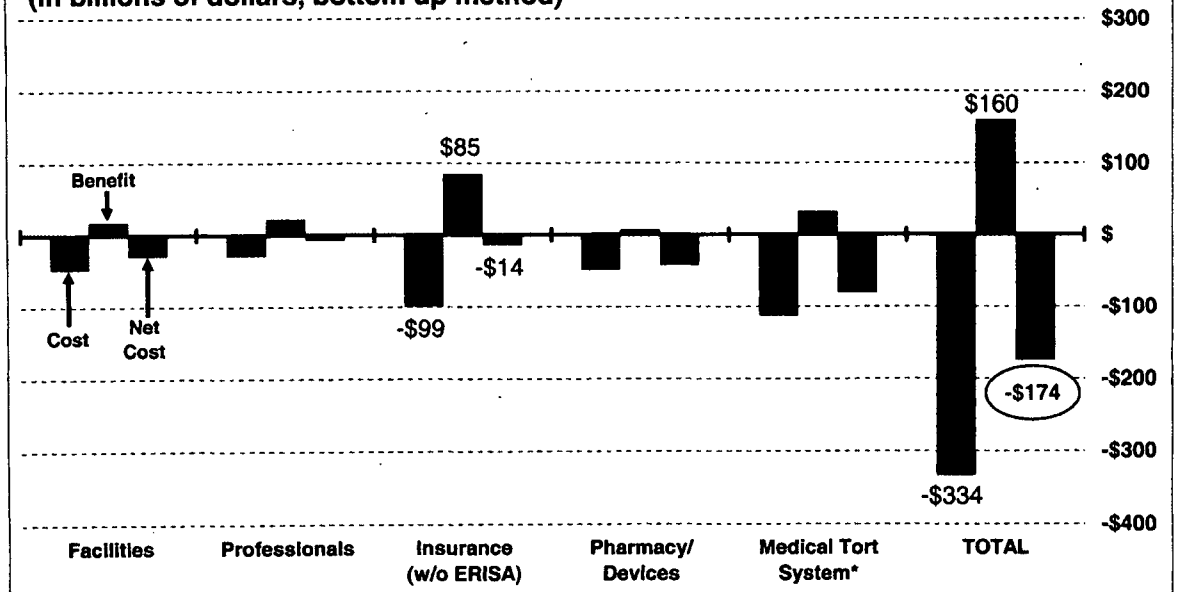


*Includes costs of medical professional liability insurance, courts and defensive medicine. Claimants' costs not compensated through awards are excluded.

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.

Congress of the United States

JOINT ECONOMIC COMMITTEE
(CREATED PURSUANT TO SEC. 5(a) OF PUBLIC LAW 304, 79TH CONGRESS)

Washington, DC 20510–6602

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
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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 Regulation* 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), any 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).

Congress of the United States

JOINT ECONOMIC COMMITTEE

(CREATED PURSUANT TO SEC. 5(a) OF PUBLIC LAW 304, 79TH CONGRESS)

Washington, DC 20510–6602

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

HORTYSPRINGER

THE FIRST HEALTH LAW FIRM

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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

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[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-

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[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.

Congress of the United States
JOINT ECONOMIC COMMITTEE
(CREATED PURSUANT TO SEC. 5(a) OF PUBLIC LAW 304, 79TH CONGRESS)
Washington, DC 20510–6602

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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