

CATO INSTITUTE

POLICY FORUM

THE NEW MEDICAL PRIVACY REGULATIONS:
WILL THEY PROTECT OUR MOST PERSONAL INFORMATION?

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Moderator:

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With:

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and Tom Miller, Cato Institute

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P R O C E E D I N G S

MR. HUDGINS: Good afternoon. I'm Edward Hudgins, Director of Regulatory Studies here at the Cato Institute. And I want to welcome you all to our F.A. Hayek Auditorium for today's policy forum on "The New Medical Privacy Regulations: Will They Protect Our Most Personal Information?"

In, I believe, November 1999, the Clinton administration issued its proposed regulations to protect the privacy of medical records. Around that time we had a policy forum at the Cato Institute to examine the matter. Among the issues raised at that event were the following:

Do those regulations, in fact, limit too much the ability of private parties, such as businesses, to use patients' information with a patient's consent?

Do law enforcement officials have too much access to records without search warrants or a proper respect for due process?

Do the regulations in fact give Federal Government bureaucrats even greater license to use an individual's medical records without first acquiring the consent of the individual?

Are the regulations simply part of Clinton care implemented on the installment plan?

Today we will examine the final regulations, which are scheduled to go into effect on February 26th, 2001.

Now, over the past decade people have grown much more concerned about their own privacy and the privacy of their records and information. Last year, for example, the census provoked strong outcries from the public about invasions of privacy by the Federal Government. What was interesting was that the 2000 census was little changed from the 1990 census. Why, then, was there such a strong reaction in 2000 but very little in 1990?

Well, over the past decade the Internet especially has sensitized people to privacy issues. Most people now appreciate that their most intimate personal information can find its way online and be viewed by millions of unwanted eyes, including, for example, things like social security numbers and even, heaven forbid, credit card numbers.

But government invasions of privacy also have sensitized citizens to the issue. We have seen cases with the IRS looking at the personal tax records of individuals, not because they're auditing them but just because they're curious about how much money particular movie stars or celebrities might be making. Some 1,000 FBI files on opponents of the Clinton administration somehow found their way into the White House. Banking regulators have been pushing for two years to be able to

more closely monitor where individuals obtain money that they're depositing in accounts and what they plan to do with money that they take out of accounts.

Now, proponents of the medical privacy regulations say that they are needed to protect citizens as the government works to make the processing of medical claims even more efficient. Both privacy and efficiency are worthy goals but I think we need to ask whether the two can be realized when the government is so heavily involved.

Now, today we're going to have three speakers to evaluate the new regulations. I want to note, by the way, from the start that we did invite a speaker from HHS, and one individual agreed to do it, but unfortunately she was out this week and it was very difficult to get anyone else. Interestingly enough, at HHS they said that they now have a little speaker's bureau, so if you want someone to come and speak on this issue, you have to fill out some forms and turn them in, and they will evaluate them and decide whether to send someone over and who to send over. Now, if this presages how efficient they're going to be processing medical records, I would be a little bit concerned, but we can talk about that later.

Our first speaker will be Ron Weich. Ron is a partner at the law firm of Zuckerman & Spaeder and has served as legislative consultant for the American Civil Liberties Union.

He received an undergraduate degree at Columbia University in 1980 and a law degree at Yale in 1983. Part of his legal career was as Assistant District Attorney for New York County.

From 1989 to 1997, he served in the U.S. Senate, notably as General Counsel to the Committee on Labor and Human Resources. And he was also chief counsel to Senator Kennedy on the Judiciary Committee. He spoke at our last forum, about a year ago, so now we'll get to hear whether the regulations have changed for the better in the year in between.

So, Ron, take it away.

RONALD WEICH,

ZUCKERMAN SPAEDER, LLP

MR. WEICH: Thank you, Ed. I would like to commend Ed personally, and the Cato institute impersonally, for convening this panel today and for showing the continuing work of the Cato Institute in monitoring these issues. I mean, there are all sorts of organizations that would have one panel on the subject, but I think Cato deserves our thanks and commendation for continuing to follow this issue through the years, through the different stages of the legislative and regulatory process, so that interested citizens can understand how this issue is evolving over time and for the better or the worse.

I note that when we held the previous forum I was seated on the left side of the panel -- of course, the audience is right side -- and now I'm on the right side of the panel, which is your left side, which only goes to show that when it comes to privacy issues there's really no difference or it doesn't matter between left and right what is left or right when it comes to privacy. And I think that we are heading to a very interesting time in the privacy debates.

The ascension of George W. Bush to the presidency creates interesting opportunities for privacy advocates and for libertarians, generally. Obviously, the Republican Party bills itself as the party of limited government and therefore should be concerned about privacy and keeping government out of our records.

At the same time, I think there's no denying that Republicans are generally "cozier," if you will, with corporate and business interests. And, in many respects, it is those interests, although not exclusively those interests, that have an interest in obtaining, as Ed says, personal, intimate information for commercial purposes. So, that tension will play itself out over the course of the next couple of years. And I think in particular on medical privacy, it will be very interesting to watch and it's important for people to be involved.

As Ed said, I'm both a partner in a law firm and a legislative consultant to the ACLU on this and related privacy issues. So, I have followed the medical privacy debate, now, for some time and the ACLU has been in a somewhat evolving mode on this issue. Several years ago we were deeply distressed, and indeed we condemned Secretary Shalala's proposed regulation, which was sort of a model privacy regulation. This was in 1997.

Among other things, we were distressed at her implementation of a congressional directive regarding unique health identifiers, something that I'm sure many in this room -- and certainly Sue and Tom, my co-panelists -- are very familiar with, which was an effort to really track people through the health care system in a very frightening, big-brother kind of way. And many in this room, I think, contributed to the outcry that caused that proposal to be shelved, and there remains a bar on the expenditure of any Federal funds for that activity.

But, since 1997, due to a lot of public pressure, we think that the Department of Health and Human Services came to a somewhat better place. And the proposed regulation that was published -- I guess, it was sort of in three stages -- there was the model regulation in 1997; there was a proposed regulation published last year; and now it's in final form, although not yet fully effective.

That sort of middle stage we were more positive toward than we were in 1997, but we remained skeptical about key aspects of it, especially law enforcement access to records; the question of whether patients would be required to consent before their records were used, even for such basic purposes as treatment, payment, and health care operations; and the exception that existed in the regulation at that time for the use of medical information in government data systems. And that was just a red light for the ACLU, because we know about data creep.

We know that well-meaning government bureaucrats collect information for one purpose -- in this case, perhaps health promotion, public health, or some such thing -- but it ends up being used for other, less noble purposes, and that's a great danger to the citizenry. So, we expressed those concerns, but we were also pleased to see a process move forward. Because we believe at the ACLU that government does need to act to protect privacy.

There is a very respectable point of view -- and I believe it was expressed at the previous forum -- that this is a matter for markets. Let patients negotiate with their health care providers and determine whether privacy is worth a certain expenditure or something else. I don't dismiss that point of view lightly, but the ACLU in this instance has concluded that the market is not a suitable mechanism. Individual patients do

not have adequate bargaining power as against their doctor or certainly their HMO, and therefore we think the government needs to step in with privacy protective laws or regulations.

So, that's where we were last year. Now the question is posed: How have the final regulations come out? Are we still supportive of the efforts or do we think that the train has gone off the tracks? It's a closed question. This is not, I think, clear for anybody. People who have studied the issue for a long time are anguished by the question of whether this is a step forward or a step backward.

On the positive side, let me note the following: There are principles of privacy enshrined in this regulation that do not exist in Federal law today. There are no Federal medical privacy protections except in the limited area of substance abuse, and therefore anything that is privacy protective in Federal law is by definition a step forward. I know that that's a definitional question, whether it actually is protective, but certainly there are aspects of this regulation that empower consumers and citizens with rights that they did not previously have.

There is, for example, a right of access to your own medical records in this regulation. You might say, "Well, don't I have that already?" No, you don't. Not under Federal law. Some States have acted, but there is not now a Federal law or

regulation that says you have the right to inspect your own medical record.

There is a right, albeit limited, to amend your own medical record if there is something in the record that you believe is incorrect. There is a right, a principle, enshrined in this regulation, subject to all kinds of exceptions, which I and the other two panelists will talk about, to limit the dissemination of your medical information. That's just a basic thing that you'd think should be there because you own your medical information. And yet it's not there in Federal law today. And with all the exceptions, this regulation puts that basic principle in law and provides a foundation upon which people can build, both in the regulatory process, perhaps the legislative process, and perhaps through litigation. So, those are things that are good.

There are improvements, some of which were suggested by the ACLU and other privacy groups, from the 1999 version. I guess this is "HHS 3.0," if you will. There are three iterations down the road -- actually, many more iterations, not all of them public. For example, that government data system exception that we complained about has been eliminated in its entirety. It is just not there as a separate exception. It works its way in, in other ways, but that sort of sweeping blanket exception any time the government wanted your information is not there.

They've improved, for example, the provisions regarding use of medical records in civil litigation. They've improved the protection of the privacy of the deceased. It had been a two-year period after you die in which your records would be protected; now it's in perpetuity, subject to some exceptions.

Indeed, one of the significant improvements is that there is now a requirement of patient authorization for all purposes, not just outside of the doctor's office, but even within the doctor's office, for treatment, payment, and health care operations. It is a very limited kind of authorization that is required. It is, in fact, what I think could be fairly called coerced consent, because the doctor can refuse to treat you if you don't consent to the use of your information for treatment.

HHS had originally proposed a different version of that. And I was talking just recently with Bob Gellman, who some of you may know, a very respected and longstanding privacy advocate and expert, especially in the medical privacy area. He worked on the Hill on these issues for many years. Bob says he was actually in favor of the initial version, in which patient authorization was not required for those purposes because he thought it's always a fraud. You go in there now, and it's one of those papers that you more or less have to sign to get to see a doctor, and he thinks it creates a false sense of security.

But, from our perspective, we thought it was important for there to at least be that moment when patients realize that there were rights that they are relinquishing; there should be some opportunity for negotiation between patient and doctor. So, we thought that that was an improvement, that in this latest version there is a requirement of authorization.

So, those are some of the strengths. Enough said about that, because we only have a limited time and there are so many weaknesses. Let me address the weaknesses in two categories, and then I'm sure the other panelists will supplement my remarks.

First of all, there are statutory weaknesses, where HHS didn't have the authority to promulgate a stronger regulation because Congress didn't delegate that authority. And then there are what I would call discretionary or regulatory weaknesses, they had the authority and they just didn't use it in the right way.

The statutory weaknesses, I think there are two. One, the coverage of the regulation, because of the coverage of the statute, is limited. That is, only certain entities are required to abide by the privacy protections, the nondisclosure protections in this regulation: health care providers, health care clearing houses, essentially, the plans, your doctors and the plans and their agents, are the people who are directly covered by the regulation.

But there is a whole list of entities that come into contact with medical information that have no obligation to be respectful of your privacy: life insurance companies, employers, banks, and police agencies are just some of the entities that will, in the course of their business, come across your records, and they're not covered by these regulations. HHS made an attempt to rope them in by creating this concept of business partners, so that, for example, an insurance company that is a business partner with a doctor has to abide by the regulations under the contract. But it's a very tenuous kind of coverage and not clear that it's enforceable.

And that brings me to a second statutory weakness beyond coverage. There really is no meaningful enforcement mechanism in these regulations. You cannot sue if your privacy rights are violated. You can try to claim a breach of contract, if there were these contracts between doctors and others, but it's untested at this point. What we had hoped for was that there would be a private right of action in the statute to make it clear that if my rights are violated I can go to court or a class of us similarly aggrieved could band together to go to court to extract some remedy, and perhaps prospective remedy, to force compliance. And that's something that Congress needs to address. There are civil penalties that HHS can assess under this regulation but they're not very meaningful.

So, let me move then from statutory weaknesses to discretionary weaknesses. And, here again, I want to just talk about two big ones, because they're the ones we focused on. And they are the exceptions for law enforcement access and then the exception for marketing.

Law enforcement, and I spoke at length on last time. Some of you were here, so I'm not going to go over all of it. But you know what the issue here. The question is whether the cops, in the course of their investigations, somehow have some special right of access to your records.

Now, some people would say cops should just be like anybody else and shouldn't get records without your consent. I think, frankly, that is not a realistic perspective, certainly not in this political environment and probably, speaking as a former prosecutor, I don't think that's the right policy. I think that there have to be circumstances in which, in the course of an investigation, the police can obtain information about a suspect without that suspect's consent. Otherwise, they wouldn't get the information.

The question is, how do they go about getting it? The principle that the ACLU argued for was that before the police can obtain medical information, sensitive as it is, they should be required to present their argument for why they need it and why it outweighs the privacy interest of the patient to a neutral

magistrate -- a judge or a magistrate or some judicial officer -- not somebody engaged in what Justice Cardozo called the competitive enterprise of ferreting out crime -- not a district attorney, not a police supervisor, but a judge of some kind, a judge who can neutrally weigh privacy versus law enforcement interests. And then that review should occur under a meaningful probable cause standard.

The Fourth Amendment strikes a pretty good balance. It doesn't say that the police never get information; it says they have to have probable cause to believe that a crime has been committed and so forth. And there's a balancing test build into the Fourth Amendment that judges utilize all the time that we think should be used here. Indeed, it's especially important that it be used here. Unfortunately, that is not the system that HHS proposed last year, and they have not significantly improved the scenario this year. Therefore, the final regulation will not meaningfully limit law enforcement access to medical records.

Just to summarize why that's the case, first of all, there is not a requirement of judicial review. The police are allowed to obtain information by use of an administrative subpoena or what's known as a civil investigative demand. These are not like warrants or court orders, because they don't go through a judge. They're issued either by a cop or by a prosecutor.

And I've done this as a former prosecutor. You reach into your desk, you pull out this stack of summonses. And it's just a Xeroxed piece of paper. You fill out the name and the address, you sign it, and you send the cop on his way, and he gets the information by virtue of that process. It's not adequate. It is not protective. It's not the Fourth Amendment. Therefore, we oppose that provision.

There is also, and separately, a very broad identification exception in these regulations, where the cops don't even have to use that minimal written process that I just described if they are searching for a suspect. But it's not limited to somebody who committed a crime 30 minutes ago; this is just if they're in search of a suspect or a material witness. They're allowed to go to a hospital emergency room, for example, and demand information. There are some limits on what they can demand, but it's not very limited.

And, really, this raises the specter of medical records being used as a vast law enforcement database. And I must say I immediately drew the connection in my mind between that scenario and what we saw at the Super Bowl. We all know here at the CATO Institute -- and I'm sure it was front-page news -- when the police scanned the faces of everybody walking into the Tampa Stadium and immediately compared it, using technology, to a

database of known felons, terrorists, and con artists. I love that, what's a con artist?

And, sure enough, they found a ticket scalper. He escaped somehow, but that's what they came up with, a ticket scalper. And no libertarians.

(Laughter.)

MR. WEICH: And no ACLU consultants.

It's scary stuff. It really is just George Orwell come to life. And you could just see this happening in the medical records context, because all of the records are collated; they're computerized; it's a push of a button. And back to first principles here, if people believe that their records are subject to that kind of use and scrutiny, they will be less likely to seek medical treatment. They will be less likely to be candid with their doctor about sensitive medical conditions, reproductive rights, mental health, substance abuse.

This is a public health issue. This isn't just abstract privacy; we're talking public health here. So, that identification exception is really awful. There is no balancing test. There is no requirement of notice. There is no exclusionary rule. It's just bad.

My time is going to run out in a minute, so I'll just touch on marketing, knowing that my co-panelists are well prepared to talk about the marketing exception here.

Essentially, we got into this business of trying to protect medical records, in large part, because we've all had the very unsettling experience of receiving a solicitation in the mail from your health plan saying, "Oh, you're pregnant. Why not try Unfamile formula?" Or "We've heard that you have diabetes. Here's something that you should consider to treat your diabetes."

It's just very violative of privacy. You thought you had a confidential conversation with your doctor a week ago, and suddenly the postman and your family members or your roommate, people who are reading this know that you are receiving this information, not to mention the marketers themselves, and you just don't want that to happen. That should flatly be prohibited.

HHS has, and this was not in the proposed regulation that showed up at the 11th hour, there is a very broad and really disturbing marketing exception that permits the covered entities, the health plan and so forth, to use, in effect, an opt-out system. That is, they can solicit you through the mail -- it doesn't have to be face to face, except under certain circumstances -- for these medical services. They have to make a threshold finding that the product they're hawking to you would be beneficial, but that's just their determination. And they have to give you a chance to opt out.

Well, we will know what's wrong with opt-out. The burden should not be on the consumer; the burden should be on the marketer to obtain consent in advance. There should be an opt-in. Look, I'm all for people being able to consent to the use of their medical information. Maybe you want to receive that solicitation in the mail, you want to find out more about possible treatments, drugs, clinics, whatever. But if you want that, you should have an opportunity to ask for it. It shouldn't be foisted upon you and the burden placed upon you to opt out.

So, having said all of that, this is pretty bad. How bad is it? Not so bad that the ACLU opposes the regulation outright. Indeed, we have said publicly, and I say today, and we will say tomorrow, and we'll say at a late February date for when final effectiveness comes upon us, we think these regulations are, on balance, despite their weaknesses, a step forward for privacy, because there's nothing in Federal law that meaningfully protects medical privacy.

The regulation does not, for the most part, not in any real way, preempt State efforts. For example, there was nothing in this regulation that would prevent a State from passing a stricter prohibition on health care marketing in a way that the State law would trump this Federal marketing exception. And we're going to be encouraging States to do that. I think the battle now shifts to State capitols.

And then there's the legislative process where, despite Congress' inaction in this area for several years, we hope that Congress is now prepared to step in to finally redress some of the statutory weaknesses and fix some of the mistakes that HHS made here. It's a tough call. I do not begrudge or criticize or fault anybody who would say that on balance the regulation is weak.

I think in part you can look at -- I think they used to say something about Franklin Roosevelt, that he was proud of his enemies or some such thing -- but you could say that this regulation should be judged by its enemies, in part, because, as you can see, the health care industry, the marketers, the hospitals, the insurance companies, are lining up against it. I think that tells you something about whether they see this as being, on balance, a pro-privacy regulation. And I think they do, and they don't like it and they want to block it.

We think this regulation should go into effect and that then States, Congress, and advocates should work to improve the areas that I have mentioned. Because notwithstanding that we are in the Cato Institute, an island of ideological purity in this great city of rampant pragmatism, I think we do have to be somewhat pragmatic about the political situation. There is not a better product, a better pro-privacy regulation, or legislation, that has emerged in the last couple of years. And those of us

who have been working on these issues for a couple of years would like to establish a beachhead, a foundation upon which advocates can build, to ensure that eventually we have what we seek: comprehensive Federal medical privacy protections.

(Applause.)

MR. HUDGINS: Thanks a lot, Ron. That was a very good presentation of the pros and cons.

By the way, on the issue of marketing, I might mention that a number of us here at Cato are looking into various other aspects of privacy; for example, a market for privacy, where it kicks in, who has consent or doesn't have consent, et cetera. So, for those of you interested in the broader issue, you'll be seeing more coming out of me, Adam Thierer, Wayne Crews, and others here at the Cato Institute.

Our second speaker is Sue Blevins, who is the founder and President of the Institute for Health Freedom, which is a nonpartisan, nonprofit group here in Washington that believes in patients' rights and patients' choice. Before founding the Institute, Ms. Blevins was a nonresident Fellow at the Institute for Humane Studies, which is out at George Mason University.

She also served as a consultant and primary author of a report for Governor Weld of Massachusetts for his Task Force on the Health Care Industry. She has a master's in public health from Harvard University. And it's interesting because last year

Sue was one of the people who actually read through every single phrase, sentence, and word of the regulations.

In fact, I remember her pointing out to me, saying, "Ed, look at this. The Federal Government can give your medical records to undergraduates to do research without your permission." Isn't that interesting -- kind of squirreled away somewhere on page 439 of the regulations. Well, Sue has read through the entire regulation yet again, the new regulations, every word, et cetera. Since we're talking about medical issues, I was going to ask her the health care issue, about how her eyes are after all of that.

By the way, indeed, one of the problems I think with these regulations is that they're very difficult to understand. Last time we had Gary Claxton of HHS, who I thought did a very good job of explaining what the regulations said and what they didn't say and so forth, but that's one of the problems -- just figuring out what the regulations say. Well, since Sue has actually read through the first version and the new version, we're going to hear from her, and she's going to tell us what's the difference, if any.

So, without further ado, Sue.

SUE BLEVINS,
INSTITUTE FOR HEALTH FREEDOM

MS. BLEVINS: Well, thank you, Ed. And, I, too, would like to thank the Cato Institute for hosting this timely forum on the new medical privacy rule.

If you've been following this privacy debate, your head is probably spinning from reading the many conflicting opinions regarding the rule. During the past few months, the former Clinton administration and some advocacy groups -- and I should say some coming from the more communitarian perspective -- have been claiming that the rule offers an impressive new right to medical privacy. On the other hand, industry stakeholders -- and, in particular, insurers, hospitals, pharmaceutical companies, and researchers -- have voiced deep concerns about the projected costs and other compliance issues associated with the rule.

Well, the conflicting opinions are leaving consumers wondering, But how does the rule affect me as an individual? And does the rule really give me the right to maintain the privacy of my health information, especially as medical records are increasingly becoming stored and transferred in electronic format?

Well, I'm going to share with you a brief analysis, especially given our time here, on the final medical privacy rule from the individual's perspective. I know that a lot of lobbyists have read the rule from their industry's perspective, but I want to share with you -- I read it with the following questions in mind. As I read it, I thought to myself, under this rule, when I go to a doctor for treatment, am I guaranteed the right to enter into a private contract with a doctor? Period. That's what I want to know. And is the contract allowed to say that I do not give my consent to share my medical records for any purposes unless, of course, there is a law enforcement purpose, such as I've been convicted of a crime or I'm a suspect and the law enforcement official obtains a warrant or subpoena?

In other words, under the rule, am I able to truly maintain a confidential patient/doctor relationship? That's what I wanted to know. And the answer I should share with you is an unequivocal no, Americans do not have the right to privacy under this rule. In fact, the rule actually requires that every doctor and every other health care practitioner in this country must share their patients' records with the Federal Government; specifically, the U.S. Department of Health and Human Services.

Consumers' records are going to be shared without their permission. And under the new rule, the government even has the authority to access an individual's psychotherapy notes in order

to monitor compliance with the new rule. So, in effect, what the government is doing here is saying, We're giving you this new rule, that Ron has talked about, in order to protect your privacy. And in order to make sure that all the doctors and other providers are maintaining your privacy, we're going to come in and invade it and monitor that. That's what we're looking at here, folks.

And the compliance section of this new massive rule hasn't been written yet. That is still to come. So, we don't know, for example, is every doctor going to have to submit a report, saying here's how many patients I have, here's how many patients' records I'm keeping confidential. We don't know that yet. But what we do know is that you do not have a right to privacy.

What right do you have under this rule? And I would sum it by you do have one right. And that is the right to complain. That's it. The right to complain. Under this rule, if you think your privacy has been breached, you can complain to your doctor or hospital. They call them "covered entities," groups that the rule applies to. All they have to do is document that you complained.

You also have the right -- now, I'm actually insulted by this new right to complain because I thought we always had the First Amendment, and we were always free to complain -- but,

anyway, HHS is saying you have this new right to complain to the Secretary of Health and Human Services. And when you complain, the Secretary "may" investigate -- not "shall" investigate -- "may" investigate your complaint.

Now, last February, I sent a letter to HHS with some concerns about the rule and had questions about the unique health identifier. I actually hand-delivered the letter, got a signature at HHS, from the Humphrey Building, making sure that I had proof that the letter was indeed delivered. I never got a response.

Sure, I could go through the Freedom of Information Act and hire lawyers and handle it another way but, quite frankly, I'm not convinced that HHS is going to respond to complaints. But you do have that right to complain. And if HHS decides it will investigate the complaint, and it finds a breach of privacy, then HHS gets to impose fines and collect money from the guilty party. You, the consumer, whose privacy was breached, get nothing.

And, as Ron has mentioned, under the rule you have no private right of action, so you can't sue if your privacy is breached. Thus, I think it's misleading to tell Americans that they have a new right to privacy and that this rule is going to offer them great protections. I wholeheartedly disagree with these statements.

Now, probably one of the most important issues that people were concerned about was the issue of consent. And HHS actually acknowledges that during the public comment period, in which they received over 52,000 comments, the issue that drew the most comments was the issue of consent. Now, initially HHS was going to prohibit doctors from getting your consent for health care treatment, payment, or health care operations. It's a very broad term. It doesn't have to do with having an operation; it has to do with the functioning of the health care system.

People were very concerned about that. The public was actually outraged. There were a number of comments in response to that. And HHS did change the rule, but actually I think it's a terrible trick. They basically now say your doctor has to get your consent for the doctor to be able to use your information for health care treatment, payment, or operations -- the same terms. But the doctor can condition treatment on whether or not you give that consent. And the government is actually laying out the terms for your contract. A consent that doesn't include those provisions is not considered a valid consent form under this provision.

I have a real problem with that. I want to be able to go into a doctor and have an individual, private contract, and have it say what I want it to say, not that I'm going to have to release my information in order to get care.

One other thing that I think is really important. When you talk about releasing your information for treatment, I think, clearly, most people would think, well, that's common sense. If you're going to the doctor and you want to get the treatment, the doctor has to know your information. They have to know your allergies. There's a lot of information, quite frankly, that if I were a doctor, I wouldn't be willing to treat you without you sharing that information that I need to know. But when you sign away and you give permission for treatment, what you don't realize is that you are actually giving permission for any doctor to use your records to treat any patient. Go figure.

That really means that your doctor can use your records to treat your neighbor, or your neighbor's doctor can use your records to treat your neighbor. Basically, that term "treatment" is a very, very, very broad definition. It doesn't mean just to treat you. It really opens the door to many, many people having access to your records. I think, again, that's very misleading of HHS to put out information saying that patients have a new right to privacy when in fact they don't.

One last issue here. And I could go on and on and on with many points. I really look forward to the question-and-answer section, because of time I'm going to be cut off here. But, Ron, you brought up the issue of government health data systems. And in the proposed rule HHS -- and in this

rule there's a whole list, and I handed out a paper that is a summary of myths and facts surrounding this rule -- in the proposed rule, there was a whole list of people that have access to your records without your consent: law enforcement officials, researchers, public health officials, it can be used for judicial administrative proceedings. The list goes on and on and on.

One of the them in the proposed rule was government health data systems, and also banks. In the final rule, they removed the term "government health data system" and they removed the term "bank." So, you think, well, no more government health data system. No, that's not the case. There is absolutely nothing in this rule that would prevent the Federal Government, State governments, or private parties from compiling your personal health information and storing it in large databases without your consent.

Now, you're probably thinking, well, wait a minute. I'm going to get this new copy of my medical records and I'm going to get this accounting of how my information is used, so surely I can go to these agencies and find out whether my medical records are stored in these databases. But you can't. Let me cite one page. And this is just an example of how things were written. On page 82-554, HHS writes -- and follow me here for a minute, it's a little long -- and I quote here:

"Individuals have a right of access to any protected health information that is used in whole or part to make decisions about individuals. This information includes, for example, information used to make health care decisions or information used to determine whether an insurance claim will be paid. Covered entities often incorporate the same protected health information into a variety of different data systems, not all of which will be utilized to make decisions about individuals.

"For example, information systems that are used for quality control or peer review analyses may not be used to make decisions about individuals. In that case, the information systems would not," I repeat, "would not fall within the definition of designated record set. We do not require entities to grant an individual access to protected health information maintained in these types of information systems."

So, basically, there is nothing, Ron, in this rule that prevents the Federal Government -- or, really, State governments will most likely be the ones collecting the data and linking it through a nexus of systems with the Federal Government.

And due to the time, let me go ahead and just wrap this up. Just so summarize, I'd like to stress that in the next few years, because of the Health Insurance Portability and Accountability Act that was passed in 1996, nearly everyone's

records are going to become electronic. It's too complicated to go into. And Ron can probably explain this. But there's actually a mandate on insurers to process claims electronically. So, whether you like it or not, unless you're totally paying cash, your records are going to become electronic.

With just a click of the mouse, it's going to be much easier for your doctor to share records with many, many third parties. This final rule permits, and actually makes it easy, for many third parties to have access to your records without your consent. So, I think Congress and the new administration should take a close look at the Health Insurance Portability and Accountability Act of 1996, look at this final rule, and try to fill in the gaps where Americans truly don't have medical privacy.

Thank you.

(Applause.)

MR. HUDGINS: Thanks a lot, Sue.

Our final speaker is Tom Miller, who is the Director of Health Policy Studies here at the Cato Institute. He has not been with us too long but certainly comes with an impressive background. He worked for 14 years at the Competitive Enterprise Institute, as the Director of Economic Policy Studies. And we like to say that we steal the best from the Competitive Enterprise Institute, and Tom is one of them who was writing

papers that we would publish over here, and so I guess he finally just decided he might as well join us. And we're happy that he is here.

He has a bachelor's in political science from NYU and a law degree from Duke University. And we'll wrap it up with Tom's evaluation of the new regulations.

Tom.

TOM MILLER,
CATO INSTITUTE

MR. MILLER: Thank you, Ed.

I'm currently self-medicating for a bad cold, so I hope I get through this talk without operating any heavy machinery and resorting to street mime. And I should mention also that I think I'm suffering from severe depression from last night's last-second victory by the Virginia Cavaliers over my Duke Blue Devils in basketball.

(Laughter.)

MR. MILLER: Well, that's my story on my medical situation. I'm sticking to it. Those of you who are currently downloading my files on the Internet can find out what the true diagnosis is.

(Laughter.)

MR. MILLER: It's kind of ironic that the HIPAA privacy regulations can have folks criticizing them for disclosing too much and protecting too little. It really takes a Federal Government regulation to accomplish both extremes at the same time, burn up a lot of money, a lot of nuisance, and ultimately just simply taste bad and be less filling. But let's start by reviewing how we got to the stage of HHS issuing a final set of medical privacy regulations.

The 1996 legislation was sold politically on the basis of its portability reforms. It promised to protect the medically insured middle-class with job protection against -- for those who had jobs -- protection against preexisting condition restrictions, premium increases, and loss of coverage when they change jobs. Now, one way to offset the costs of that accompanying regulatory burden was to promise new savings in health care costs through administrative standardization of electronic data gathering and sharing.

That naturally gave rise to fears about privacy abuses from centralized databases, electronic health information networks, and easy rapid access to personal medical information. So, a few lines in the HIPAA legislation required Congress to legislate privacy protections by a certain date or else HHS was to provide regulations in this area.

Not surprisingly, Congress couldn't reach a political consensus on privacy rules. It didn't offend more voters and interest groups than it pleased, but the politicians got the next best position. They get to leave HHS to take the blame for the final rules, keep their own hands clean, and then even intervene as white knights down the road to selectively respond to constituent concerns and complaints.

So, the political market for privacy has found a temporary equilibrium. Politicians can claim that they are protecting voters' broad demand for medical privacy. The costs are off budget as an unfunded mandate on the private sector. And officeholders can periodically find fault with those HHS regulators for going too far.

Now, at the heart at this political charade is the fact that there will be no stable sustainable political consensus position on the more difficult pressure points and tradeoffs for medical privacy practices and preferences. But it does provide an ideal platform for regulatory mischief and broader political agendas. We should be very suspicious of regulatory offers that begin, "Hi, I'm from the government and I'm here to protect your privacy."

Let me step back for a moment and fill in some gaps in the previous speakers' fine presentations regarding some problems in the latest HHS regulations themselves, not that I believe they

can be fixed or one should simply aspire to make the regulatory trains run more efficiently to the wrong station. But after that, I'd like to suggest an alternative contractual approach to medical privacy protection, to be followed by a broader look at the more fundamental reasons why we're faced with more medical privacy protection issues in our health care system than we need to be.

Now, take a look at the latest HHS regulations before your eyes glaze over. There are a few improvements, but I don't have time to discuss them.

(Laughter.)

MR. MILLER: Well, I actually probably do have time to discuss them, but I won't spend time on it. Among the long list of remaining problems -- and I'll mostly list them in only brief discussion -- I'll start with the costs.

It's ultimately going to be paid by the public through higher health insurance premiums, higher taxes or lost benefits, including the innovative uses of information that might be chilled by regulatory overkill and uncertainty. And don't take the lowball HHS number for costs, which also presumes mythical offsetting benefits through the administrative standardization procedures, and that there will be earlier and more effective medical treatment. These are overstated and they're unlikely to materialize.

We can be sure that the cost of centralized rules will be disproportional to the real value they deliver. We face a number of uncertainties and complexities in this latest set of rules. The minimum necessary standard is likely to trigger fears of liability for inadvertent violations and the need for case-specific examination of each element of each disclosure. And how real and effective will that prior written consent be?

As Ron was pointing out, and calling it coerced consent, doctors can insist on consent as a preliminary to treatment, but in the extreme, aren't we just going to be back to sign this boilerplate release form, and a reprise of the old Jack Benny dilemma? You remember, "Your money or life." And he'd pause and say, "I'm thinking, I'm thinking." In this case it would be, "Your privacy or your health care."

Will de-identification of personal health information really work? There are going to be particular problems with this in the retrospective medical research area, particularly when covered entities simply decide to lock down their medical archive rather than expose themselves to gratuitous costs, risks, and liabilities. Now, there's the business associates contract rule. That, in effect, shifts the burden of law enforcement on to health plans and medical providers. They used to be called business partners. I guess now you have to work for seven years and bill a lot of hours in order qualify as a partner.

The expensive medical privacy rules are going to work to the competitive advantage of the large incumbents in the health care/health information field. And that's going to create additional barriers to entry and discourage innovative use of information and new delivery systems.

Now, not surprisingly, as Sue was pointing out, the government users of medical information will be at the top of the information food chain, with greater access. Public health is privileged as well as disclosures authorized by law in support of policy, planning, regulation, or management functions. As Mel Brooks once said in *The History of the World, Part I*, "It's good to be the king."

What about preemption? It's biased toward more restrictive privacy regulation. I'm reminded of the old Paul Simon song, "One Man's Ceiling is Another Man's Floor." Most of the business community would prefer one bad uniform set of Federal regulations to multiple State regulations, some better, some worse. But it's likely that we're going to get the worst of both worlds.

Litigation, I disagree with Ron here. I think that's where the real bonanza opportunity is for some folks. Despite no explicit Federal cause of action in the HIPAA regulations, resourceful plaintiffs' attorneys should be able to use the underlying promises in the Federal regulations to craft State

causes of action, perhaps claiming reliance on published information practice notices, or perhaps even claiming third-party beneficiary status in suits based on breaches of business associate contracts.

Ron, I know ACLU attorneys. You guys can do better than that.

(Laughter.)

MR. MILLER: And the only worthwhile lawsuit in this area would probably be one claiming unconstitutional delegation of authority, from the legislative to the executive branch of government, in the original HIPAA legislation that set the HHS default privacy rulemaking in motion.

We've already seen a lot of privacy mission creep in the various stages of these HHS regulations. Now they apply not just to electronic health information that's individually identifiable but non-electronic paper records and oral communications, as well. And this is only the beginning of multiple rounds of uncertainty, complexity, reinterpretation, and litigation. Having established a medical privacy regulatory platform within the Federal Government, you can be sure that the scope of future regulation will grow and grow and grow.

Well, how do we get off this runaway train?

Let's go back to the basics. Consumers certainly value medical records confidentiality very highly. They expect to have

it protected, and they expect no disclosure to third parties without their consent. But is confidentiality all inclusive? What do consumers really care about most in what they want to be kept private? What sort of tradeoffs are they willing to make in sharing medical information with other parties for other kinds of benefits? And what mechanisms will ensure that individual consumers get to make those choices and benefit from taking greater personal responsibility in determining and exercising their privacy preferences?

We need to move beyond the false choice of centrally planned government action and simply doing nothing. We need some contractual solutions that would give individuals the power to choose more privacy or less privacy without requiring full privacy for everybody or for nobody. Private contracts are superior to rules that are dictated by politicians, bureaucrats, or judges. They're more sensitive, much more sensitive, to the wide range of individual preferences that people have with regard to privacy.

Now, often we say we value privacy -- and medical privacy more so, but other kinds of privacy -- yet we act differently in practice when faced with real choices and tradeoffs. There are double standards. We often want maximum personal privacy, but we want to know everything in the world about someone else.

So, in the final analysis, the baseline setting for medical privacy expectations is going to be much stronger than for other types of other information sharing. And the rules that we set down for privacy are going to be broader than just for medical privacy. And keep that in mind, because they need to be consistent with the overall structure of information sharing that we're going to have for a very information-intensive economy in the decades ahead.

So, some preliminary considerations, or screens, in evaluating what we do in privacy policy would include taking a look at our commitment of our society to open information flows. Those open information flows are consistent with our core First Amendment values and a fundamental underpinning idea of an open democratic society in a market-based economy in which individual choices are exercised.

What do we really mean by "private"? The law should protect as private only information that someone actually and reasonably believes is private. There are limits to what is private. What's a reasonable expectation of privacy in terms of sharing information? Too much privacy may facilitate the dissemination of false information, protect the withholding of true information, and interfere with necessary information collection, organization, and storage that businesses and individuals need to make informed decisions.

Let's not overlook the concept of harm. We restrict information flows so as to protect privacy only when a specific harm is actually being threatened. In choosing how best to protect our privacy, do we really want to rely on the government, or do we want to rely on other types of private self-help mechanisms? Traditionally in the United States we have historically focused on government as representing the greatest threat to privacy and wanting to restrict its access to information. Should we now ask the government to enter private areas of our lives in order to protect our information?

In the alternative, there are various means of individual and collective private action, which can, through a combination of technologies, markets, industry self-regulation, competitive behavior, and individual judgment, protect our privacy much more effectively than through government means.

Competitive businesses will respond to market demands for privacy. Businesses lose their customers when they don't meet the expectation of those customers. The government throws them in jail, brings out the guns, seizes their property, sees how they can get through the next election.

Is health privacy different than other types of privacy?

Well, it certainly is true that other users of health care information can no longer afford to ignore the initial core

preferences of individual health care consumers. There has been a lot of free, unpriced information that has been used for many possibly valuable purposes. But it's going to be up for renegotiation now in light of what's been a clear signal from the public in terms of what they value as their medical privacy. The question is, is that going to be determined through political means or through other voluntary market means?

Now, the complexities of trying to legislate medical privacy are endless. When a political consensus is not clear, achievable, or perhaps even desirable, we ordinarily do return to voluntary choices and market-based mechanisms, particularly in this case where we should be quite skeptical about placing our trust in the Federal Government to protect individual privacy interests. In the search for an alternative to top-down political regulation of medical privacy, we need to recognize the wide variation of privacy preferences that people need to determine on their own.

Privacy is subjective. It changes from person to person. It's certainly not encompassed in a single consensus standard. The right to privacy can conflict with others' right to know the truth and the right to benefit from the information economy. Rather than have the government decide for everyone what tradeoffs are worth making for privacy, we need a different type of mechanism based upon contractual approaches, and those

approaches that can price information and more efficiently allocate medical data than a centrally planned solution would.

Pricing, unlike central planning, respects consumer preferences. It takes into account individual needs, values, and tradeoffs before allocating resources to their most valued uses. One mechanism that goes beyond and moves beyond political regulation involves determination of the false standards, primarily set through standardized form contracts for different ranges of information in various industries and business settings.

Certainly in the area of medical privacy, the initial default standard is going to be set much closer toward the no-disclosure and maximum-privacy end of the spectrum. But then you talk about moving from that, into either an opt-out or opt-in from that standard, in which people in the margin begin to determine whether there's something to be gained by disclosing more medical information as opposed to retaining it.

Perhaps it's through an inducement from a private company saying, "We'll give you a benefit, and here's what's so attractive about it." Or when you buy a contractual arrangement with a no-disclosure policy, it might be priced more expensively, whether that's health insurance or a particular type of medical service. That's how we begin to kind of, in effect, customize the preferences for privacy.

Now, there are some considerations for that default rule. What are the relative transaction costs in setting that default rule? You might need to set the rule to that which most parties want their setting. Fewer parties then are forced to contract around the rule.

Is a privacy default rule then less expensive than a disclosure rule? There is not a single answer in every case. We do know that the cost of invading others' medical privacy, though, has fallen as the advances in technology have risen. So, privacy is more valued and people will be willing to pay for it and bargain for it.

Now, in these promised benefits, the pricing mechanism operating through private contracts I think is going to be more sensitive to variations in the valuation of privacy. It can enable information to be collected in voluntary transactions instead of either commanding its disclosure through political coercion or making voluntary information-sharing prohibitively difficult.

Let's get outside the box for just a moment, because that's kind of saying, "Well, we're going to have to do in this way because it's the system we have." But we'd have fewer privacy problems if we had a different kind of health insurance system. If we leveled the tax treatment of our health purchases and moved in the direction of defined contribution plans, all of

a sudden you wouldn't be worrying about what your employer knows about your health information. They wouldn't be as involved in purchasing your health insurance and possibly receiving information about you.

If we purchased less comprehensive health insurance, such as that with a high deductible, coupled with a medical savings account, for cash spending on discretionary private matters, we would, again, have less of a third-party health information trail. In the same way, if not as much of health care dollar was flowing through third-party insurers, they wouldn't be tracking how you spent that money, whether it went for the right things or was appropriate or was fraudulent.

If individuals were initially more in control of their health insurance choices, they would also be likely to seek longer-term contractual relationships with insurers or insurance brokers. They would provide more effective protection against changes in their personal health status and insurability.

So, in conclusion, I opt out of HHS-style privacy regulation and politics as usual. Let's reform the health care system to make that more possible.

Thank you.

(Applause.)

MR. HUDGINS: Thanks a lot, Tom.

A couple of things I just wanted to highlight. I'm impressed by the argument that we're at the beginning of multiple rounds of uncertainty, reinterpretation, et cetera. One of the interesting things about these regulations is that the word "except" is used a considerable number of times, that to try to figure out what it means -- you have so many "except" for this case and "except" for that case -- it really does open it up to interpretation.

A second thing I'll note is that Ron began by saying that the ACLU had determined that markets, at least at this point, are not adequate to protect privacy. What Tom has suggested is that perhaps what we're now seeing is the emergence of markets for different levels of privacy. So, maybe today it's not the case; perhaps tomorrow it will be.

I like to give the example and I usually hold up my little Giant Food card here. Suddenly all of the grocery stores are literally paying you to allow them to track your purchases. That's why you have this little card. And I can't get a discount at my local grocery store unless they scan this in. Why is this? Are they just trying to harass me?

Well, no. It's because they want certain information from me and they are willing to pay for it by giving me a discount. So, you actually are seeing this emergence of a market for certain levels of privacy and certain levels of protection,

which goes beyond the medical privacy issue, though it certainly encompasses it. Now, as I say, that's one of the issues we're very concerned about here and interested in at Cato, so you'll see a lot more coming out on that.

I thought I'd give Ron a quick chance to maybe comment, since we've kind of come full circle on the market point, and then we can open up to questions.

MR. WEICH: I appreciate your giving me a moment here. And I won't take long because I think the questions should be enlightening.

I think the discussion today and, really, the excellent presentations of my co-panelists, bring into sharp relief the basic question of how to approach this privacy issue and related privacy issues. When you start thinking about medical privacy, you hit a fork in the road, right at the outset. Do you want the government to set some rules here, some basic boundaries for what medical providers, health care providers, and corporate interests that deal with medical information can do, or do you want to leave it to individual contractual arrangements? I think that is a very healthy debate to have.

I know that the Cato Institute resolves that question in a number of different areas on the contractual side. But I can just say, speaking for the ACLU, that we, a long time ago in this area, went down the other road. We have consistently argued

for government protection here. And you see a parallel discussion in the area of civil rights. I know there are very respectable voices saying that civil rights should not be enshrined in law, that it should be a matter for individuals to negotiate. We think that's an area where government intervention is appropriate, necessary, and we want stronger laws. We want laws, and we want them to be stronger.

I can assure everyone, as you know, that the ACLU spends, and my colleague, Greg Nojeim, could put a number on this, but I venture to say upwards 80 percent of our time opposing legislation. But there are areas -- privacy and civil rights are the two that immediately come to mind -- where we think there needs to be government rules to protect individuals, because individuals are not well situated to negotiate on their own. I thought that Tom's arguments were cogent; I did not ultimately find them persuasive.

So, once you're past that fork in the road, if you're down the path of trying to get government regulations, then there's an argument about whether these regulations are strong enough, whether they sufficiently protect privacy, whether there are too many exceptions. But I think you have to recognize that, at the outset, you're deciding whether the government should get into this area. And we resolve that question in favor of government action.

MR. HUDGINS: Thank you.

Okay, let's have a few questions from the audience. A microphone will be brought around to you. If you could please give us your name and identify where you're at, so we'll know who we're speaking to. Why don't we start right up here. The microphone is coming down.

DR. MARSHAL: Yes, my name is Dr. Joseph Marshal. I'm a gynecologist here in Washington, D.C. I'm an old-fashioned physician in that I'm still fee-for-service and I have no associations with any managed care or HMO's.

MR. HUDGINS: Congratulations.

(Laughter.)

DR. MARSHAL: Well, it's tough, but it's very rewarding.

The panelists touched on some aspect of these two scenarios that I'd like to present, and then if you could comment on it, because we physicians are subjected to this all the time. I will get phone calls or written information from my patients' health insurers, wishing information about the patient because they want to process their claim.

Now, I've already gotten paid from the patient, but this is payment for the patient. So, they want to know, for instance, certain aspects of the care that I gave them. Well, I comply, and I'll send them the information that they request.

The second scenario is that I will get calls from other physicians, who are seeing either my patient or other patients, and they're saying, well, you did some laboratory tests. We would like to have them in the patient's chart. So, I will fax laboratory tests to the physicians, and, conversely, I will get information back from the physicians. So, the fax machines are going back and forth.

So, my question really is, then, will these new rules affect adversely this free flow of information that I give to other physicians and health insurers without having the patient's consent? And it's truly for the patient's benefit, number one, that she'll be able to be compensated; and, number two, that if another physician is caring for her, any information I have about her might benefit him. So, if you could comment I'd appreciate it.

MR. HUDGINS: Okay, anyone want to start?

MS. BLEVINS: Sure. Actually, what's very interesting about this rule is when HHS goes to defend its costs savings overall, there is a section of this rule that the public probably doesn't get to read because they're not going to read back far enough. In the regulatory flexibility analysis section, if you just look at that section of the rule, way in the back, basically every time HHS goes to say, "Well, is this going to cost more

money?" it says, "No, because that's currently how things are being handled today."

So, HHS, and I'm actually going to cite this one page for you, on page 82-783, it says, "Because providers are already obtaining such consent, this requirement represents a minimal burden." So, basically, HHS is saying currently you or the insurance company or an employer or someone is already getting consent from a patient when the patient is signing up for the insurance plan. So, there is no new "burden" is what HHS is saying.

And, if anything, I think, again, my position is it gives too many people access to your records, and it allows information to flow much faster, not just over fax lines but now over the Internet.

MR. HUDGINS: Ron?

MR. WEICH: Here's how I think that's an area that will play out under the new regulations. I think that the status quo will not dramatically change for the following reason. These regulations require a kind of patient consent for that information to be disseminated in the way that you described that closely tracks current practice. I don't know about your office in particular, but many doctors, at the outset of the formation of the patient/provider relationship, ask patients to sign a

piece of paper that essentially you do not. Okay. Many doctors do.

If you do not, you would now be required to give patients the opportunity to consent or not consent for the dissemination of their medical information for treatment, payment, and health care operations. If they don't want to consent to that, you don't have to treat them. I think that Tom's theories about whether patients will seek out privacy or not, as they wish, based on market and value, will be tested, because the regulations set up a situation where some providers may decide to offer more privacy and patients can avoid less private practitioners.

But in the situation you've described, a consent would be required at the outset before you could disseminate the information either to the insurance company or to another provider. It's the kind of consent that is within treatment, payment and health care operations. The first of the two scenarios you described is clearly payment, and the second one, it sounds to me like health care operations -- if it's sort of doctors working in some sense on the same issue for a patient.

So, consent is required, but treatment can be conditioned on consent. And then the patient would have a right to know that that dissemination occurred. There would be a right of access to the records; doctors would be required to maintain

an audit trail; there would be a minimization requirement, so you couldn't just send the whole record. There are special limitations on the dissemination of psychotherapy notes, for example.

There is not a special protection for reproductive health, and you've mentioned that you are in obstetrics and gynecology. There's no special protection there. It sounds like your practice is unusual in this regard, but I think that most people would find that the world has not changed dramatically under these regulations, that there would be a formal Federal requirement that that initial consent occur, that there be a right of access and a right to know when the dissemination of information happens.

MR. MILLER: Ed, I would put a couple of caveats on that. We know what would happen today. Now let's project ahead as to what happens with these types of rules. Sure, this is the routine, ordinary thing, and we assume that you can have any type of consent agreement you want as a physician.

This is the first stage of Federal control of health information. Don't you think we're going to get other layers of requirements for what are fair information practices in the health care marketplace? What is the proper disclosure? Things you can do and can't do? That's not in the first round. That comes later on.

Secondly, there is a myriad number of "gotcha" opportunities. If someone slips up and doesn't do it exactly the right way, just the uncertainty, the chilling effect of kind of, "Well, this is a lot of problems," is going to change behavior just because of the fact that we're dealing with kind of a multi-layered set of regulations. I think I'll stop there.

MR. HUDGINS: I think we have one right back here.

By the way, I'll note that, for someone in a small practice, we had a real good piece by Jonathan Emord, called "Murder by Medicare" in Regulation Magazine. I believe it was Volume 21, Number 3, which looks at just the costs of the paperwork. So, you might find that particularly interesting.

Yes, go ahead. Next question?

MS. HALL: Hi, I'm Christine Hall, from CNS News, and my question is really for all the panelists.

I'm wondering whether you all draw a distinction between, on the one hand, what you might argue is the freedoms of the private sector to gather information and, on the other hand, what you might call restrictions on the Federal Government, or governments in general. Because I think there are some people who would argue big government, big corporations, the same thing, and then there are others I think that would certainly argue that there really is a difference between the two.

MR. HUDGINS: Try to keep the answers a little more brief. Did you want to go first?

MR. WEICH: Yes. We think that there is a danger in non-consensual disclosure of information, to either governments or to private parties. I, for one, am just as disturbed to note -- and perhaps more disturbed to note -- that the government has sensitive, intimate information about me and that IBM does. And it might well lead me to engage in privacy protective behaviors to avoid the government having information as against a private corporation.

The initial rules did not adequately protect against government accumulation of information, although we thought they did a pretty good job of protecting against private corporate accumulation and use of medical information. This new marketing provision that wasn't in the proposed regulation last year unfortunately leaves the current regulation weak in both regards in the way that I've already described. But I think that a lot of government bureaucrats would say, "We're protecting you against the corporations, but of course if we collect the information it's not such a bad thing because we mean well." I think that's a premise that civil libertarians should not accept.

MR. HUDGINS: Do either of you want to give a quick response?

MR. MILLER: Well, as soon as the private corporations end up with their own police force, lots of guns, the ability to seize your property without going into court, I think it's a little bit of a one-sided balance. We've also got a long history of the government being a lot sloppier with its management and protection of information and less accountable, and I think the record is in on that one.

MR. HUDGINS: Another question over here.

MR. CANNON: My name is Michael Cannon. I'm with the Republican Policy Committee in the Senate, and I just had one question and a suggestion, I guess.

The first is, are any of you aware of a challenge that's being brought against these regulations on delegation grounds, that Congress didn't have the authority?

MR. MILLER: It has been talked about. I may not be aware of an actual case being brought, but I know there is speculation in the legal community to bring that lawsuit. Now, Peter Swier, who is very wise when he's out of government and back in academia, in my opinion -- and maybe he'll improve over time -- seems to think that he invented this in a way that they were going to dodge that bullet. It's pretty thin, in terms of what the actual statutory language in HIPAA says, in terms of the delegation. I think it's worth a shot in court. And certainly the Supreme Court has been open to that argument on occasions in

the past. It'll be a little uphill, but I've got to believe someone will take a run at that.

MR. CANNON: And my suggestion is, as someone who tries to make the case to a lot of Hill staff and senators, it would be very useful -- and maybe Cato has already done this -- to have a compendium of government abuses of legally obtained personal information about people, whether that be medical information, IRS employees snooping through celebrities' tax returns -- and not just by American governments but by others -- whether it be Nazi firearms laws, telling Hitler who had guns in their homes and who didn't so they could go confiscate them. That's my suggestion.

MR. HUDGINS: Guys, we're going to put this on the list for new papers, right?

MR. WEICH: It's already on.

MR. HUDGINS: It's already on the list. Talk to Adam Thierer. We're doing it. But that's a very good suggestion, because a lot of us have examples from different areas and I think bringing it together is probably a very good example.

Okay, we've got another question.

MR. CLARK: Hi, Drew Clark with National Journalist Technology Data. I have a question for Sue and for Tom.

Sue, could you just elaborate on what the rule says with regard to treatment, payment, and operations, and your

objections to it? Because it seems to me that there needs to be a sharing of information within the hospital about a client, about a patient's information, so could you just elaborate on what you see as the holes in that, Sue?

And let me just go ahead and ask my question for you, Tom. Could you just talk about any solution or suggestion you would have, short of basically, totally overhauling the health care system that we have, which, of course, creates many of these problems in the first place. What would be kind of an interim solution, short of the parallel track dilemma that Ron put us on, that you either believe the government needs to do something or it doesn't; is there anything that can be done in between those two?

MS. BLEVINS: Sure, Drew. I don't have a one-size-fits-all policy for anyone. If people want to go in and visit this doctor and not have a consent, that's fine. If I want to go in and be tested for HIV and say I want to pay cash and I don't want anyone to know about this, except, okay, fine, you have to submit an unidentified case to the CDC perhaps. But if I want to go in and pay cash, I don't want that data submitted to any databank. I don't want it used to treat my neighbor. I just don't.

So, to say that you have to consent for treatment, payment, and operations or it's not a valid consent is a real

problem. It's government dictating "These are the terms of your private contract with the provider." And I understand having an efficient system, but I think we've lost sight of who is the buyer, who is actually going in and buying the service and who is the supplier. And this rule clearly shows that. So, that's my problem with forcing me to share records with everyone else for treatment.

MR. HUDGINS: Tom, do you want to respond?

MR. MILLER: It's kind of a little follow-on to it. I'll answer quickly and then if Ron has an answer to both.

Drew, you're right, we can't get to their Nirvana, or at least some of our views of Nirvana.

Now, what I think we need to be vigilant about, though, is in whatever we end up with is a mess of HHS regulations. I would like to force the Congress to vote on it, so they're actually stuck with being accountable for it as opposed to always being able to have it both ways. But we at least need to structure a system where, regardless of what the stupid default settings are, there is no barrier to private parties contracting around it. Whether it's doctors, whether it's insurers, whether it's some other vendor of information, to say, yes, here's what kind of they start you out with but here's here what we're offering. We're going to disclose it. We're going to say, "Do

you want it?" And find out whether you can in fact differentiate the market that way.

I fear very strongly that in fact we're going to get exactly one size fits all. It's going to gravitate toward a certain plain vanilla, highly restrictive approach to it, and there's going to be no variation from that whatsoever. And, increasingly, over time, we'll see that develop. And that's well short of changing the entire health insurance system but, at a minimum, people should have the ability to say, "I want something different and I've found someone else who'll offer it to me."

MR. HUDGINS: Ron?

MR. WEICH: Just quickly, to get back to your initial question, Drew. The reason that you have to draw a line between treatment, payment and health care operations on the one hand, and other uses, is that the consent that's required for the other uses is not coerced. It's real consent. That is, they can't condition treatment on your refusal to grant that disclosure. So, it's very important. They've narrowed the definition of "health care operation."

We have not identified it as a significant flaw in the new version of the regulation, but I think it's something that we need to watch in operation to make sure that it's limited. The doctor has to be able to talk to the nurse; the surgeon has to be able to talk to the anesthesiologist. And getting consent each

step along the way is, frankly, absurd and dangerous to the patients, we would say.

MR. HUDGINS: Okay, real quick, Sue.

MS. BLEVINS: I have a quick statement to Michael. And that is I would like for Congress to pilot test this on themselves. Everyone who voted for this, let's try it out on them. We'll put their records in electronic format, put it in a database, let the teenage hackers go at it, and then, if they have an invasion of privacy, let them go the Secretary of HHS and file a complaint. That would be my proposition.

MR. HUDGINS: Well, there it is, guys.

By the way, Tom has alluded to the issue of Congress voting on it, and the issue of delegation came up earlier. And that's something we're very concerned about here at Cato also; that is, the fact that Congress delegates this broad, broad authority to essentially make the laws to the bureaucrats. They make the laws, Congress never votes on it. And so we feel very strongly that Congress should actually go back to Article I of the Constitution, which actually says, "The laws of this country shall be made by the legislature," i.e., Congress. And we favor going back to the Constitution just so we can get on record here.

I think we're just about of time. I'd like to thank you all for coming, and welcome you to a little luncheon

reception afterward. Could we end by thanking our panel for a very interesting discussion?

(Applause.)

(Whereupon, the Policy Forum concluded.)