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INSTITUTE FOR ALTERNATIVE FUTURES

INNOVATION AND REGULATION; MODELS FOR REENGINEERING

November 10, 1994

(12:05 p.m.)

MR. PECK: Good afternoon, and welcome to our Foresight Seminar on Innovation and Regulation: Models for Reengineering.

I'm Jonathan Peck of the Institute for Alternative Futures. I'll be moderating today's discussion, and trying to set some of the ground work in advance, just in terms of establishing what we're talking about, how we're going to hold this dialogue and what some of the roles will be.

For the many of you that know the Institute, you can anticipate that this will be a highly interactive discussion. That's what we're seeking. Our role is to help Congress look forward and think about how things are going

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to be changing and what are the ways in which you, as policymakers, can best shape the future we want to live in.

We've had a number of foresight seminars that have led up to today's conversation, beginning with the seminar looking at regulation in the 21st century.

We had people from the FDA, we had Lou Lasagna, whom I like to think of as the godfather of today's regulatory system, with the 1962 amendments.

And then we looked at cost effectiveness, specifically where there are clear regulatory issues and gray zones in terms of how the FDA regulates information about pharmaceuticals.

Then we went on to look at innovation and what are the characteristics of the most innovative organizations and a very telling point made by a Harvard professor who studied innovation is that because there's so much innovation in the marketplace today, there's going to be very great pressure to have innovation in regulation.

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Foresight Seminars on Health and Innovation

And his final word was that the most important thing for policymakers is to focus in on innovation and regulation. That will be critical in the years ahead.

We then went on to look at our last foresight seminar, specifically at a form of innovation in the marketplace in disease management systems.

That sets up our look today at innovation and regulation models for reengineering.

Just as a little commercial for our next foresight seminar, where we're going to look very specifically at some of the challenges of biotechnology and specially the new knowledge on the human genome are going to bring in innovation and regulation, we'll be doing that on December 2nd over on the House side, so you can look for an invitation there.

On today's topic, what we are seeking to do is introduce a different model for regulation. We're very fortunate to have Douglas Michael, who has come from the

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Foresight Seminars on Health and Innovation

University of Kentucky School of Law, where he's an associate professor.

He has studied a model of audited self-regulation and he can talk about where that model worked, what are the characteristics of where that model is very appropriate.

We're also fortunate to have Peter Bewley, who is Senior Vice President and General Counsel for NovaCare, which is a leading rehabilitation management services company. He has the experience of what's going on in the marketplace. He also has valuable experience as former associate counsel for Johnson & Johnson with the regulatory model that's currently in place for pharmaceuticals and devices.

So we have an ability to use this panel in a dialogue about different models of regulation.

I'd like to encourage you all to see this as an exploration, an exploration for all of us to take to look at different potential models and their applicability.

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My role as a futurist is going to be to encourage all of us to look at the appropriateness of different models for regulation for, not today's environment, but for the clear changes that are coming, so we're looking at the late 1990s and beyond because it's quite clear that in 1962, when much of the current model was put in place, it was a very different world.

There were independent providers. Physicians were independent. They are increasingly networked. Many are under managed care and use information systems that allow decision-making to take place in a very different environment.

Those are the kinds of changes that I'm going to play a role in trying to encourage you to all think about as we look at these different models for regulation.

I'm going to encourage all of you to take the perspective of this as an exploration. We're not here to

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attack any one model. We're here to really explore what are the appropriate models for reengineering.

One of the experiences I've had as a consultant to many companies that are into the total quality improvement and the process reengineering world is that they have to ask themselves, if you were starting all over to do this today, would you create the same processes.

So those are the kinds of questions of reengineering.

One of the things that we want to be asking today is, if we were going to start all over again on a regulatory model, would we start with the same kind of model or would we begin to say, let's explore another model?

Fortunately, we have Douglas Michael, whose expertise is not in pharmaceuticals but in another model, to help guide us through that.

So if I can invite you to come up first.

Then we'll go on to Peter Bewley.

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Questions can come up. We just ask that people here are off the record. Any people in the press, they are off the record unless we give permission to quote from them.

Thank you.

MR. MICHAEL: Thank you, Jonathan. I'm glad to be here. I'm flattered to be called an expert.

What I'm really going to share with you is my last two and a half years of research in regulatory reform. I think it's appropriate even now. I think this is really a fixture in what's otherwise a shifting -- maybe shifting is too kind a word to give it -- political landscape.

Every president and every Congress wants to reduce the deficit and reform the bureaucracy, so I think it's an enduring topic. It seems to have passed to the Vice Presidents, George Bush, Dan Quayle and recently Vice President Gore, who was given the modest task of reinventing the Federal Government.

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My work began with the Administrative Conference of the United States with a research grant a couple of years ago, to look at what they have called "audited self-regulation."

I was interested in that, with my experience, having been on the staff of the Securities and Exchange Commission, and being familiar with a couple of models of industry self-regulation in stock exchange and corporate dealer regulation.

As I began to work on my research, I worked with the Administrative Conference Committee, I really found two different types of programs; those with some intermediate self-regulatory organizations composed of regulated entities or people associated with them, who stood in between the department or agency and the actual regulated entities; and another model in which there was no such intermediary, where there was significant work done by each regulated entity to determine its own compliance and compliance method.

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The conference really separated the two, hence, the distinction in my little hand out here between what I call audited self-regulation, which involves an intermediate SRO, or self-regulatory organization, and self-enforcement, which really doesn't.

The first product of audited self-regulation was first presented to the Administrative Conference about a year ago. They sent it back to the committee for further work, and approved a set of recommendations in June.

I haven't seen them yet but I know they're out. Jeff, I'm sure, can get some for you. You can talk to the Administrative Conference, they have copies of my study and the Conference's recommendations.

The second project on self-enforcement I'm still working on. I'll have my first meeting at the Administrative Conference Committee in a week. That portion of my handout, therefore, is more preliminary. It's my study at this point. They haven't had their say in it.

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Foresight Seminars on Health and Innovation

As you noticed, there's a disclaimer on the cover. I don't pretend that any of this necessarily represents the Administrative Conference's opinion.

I think both of these may or may not be models that will work. They are certainly appropriate to consider in the areas you're talking about today.

As Jonathan said, I'm going to let Peter discuss the specifics. I can focus more on the general model.

My general research design in both of these was to first survey the literature of people who purport to be experts generally in regulatory reform in government regulation, and to see what they said would be the characteristics of a good system of self-regulation or self-enforcement. To cull from that, characteristics of the agency or the industry or the regulatory program itself that they said would be key to an effective program. And then to go out and look and survey the government departments and agencies and see if there are any such programs. And then a

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simple matter of matching up the two to see if the successful programs compared with the models.

In both instances, I think we've come up with a fairly robust set of characteristics that describe effective programs and try to separate them from the ineffective ones.

I usually expect people I talk to to take notes. I've taken the notes for you. So if you didn't get one of these, please do. There will be a short quiz at the end of the seminar.

On the first page of this handout is a distillation of my study on audited self-regulation which, as you'll recall, where there's an intermediate or self-regulatory organization between the government agency doing the regulating and the regulated entities who are expected to comply.

The people who write generically on this suggested almost overwhelming advantages to this kind of approach where it can work as indicated here. The people in

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the SRO often have more technical expertise than their counterparts in the agency or department. They can be more flexible in their implementation. They and their constituents' regulated entities will have more of an incentive to comply with rules and policies of the SRO than of the government agency.

There could be cost savings certainly, at least to the government and perhaps even overall costs of compliance may be lower.

Most importantly, the researchers said this kind of regulation was better suited to the newer social regulation, newer being than of the sixties and seventies, which tended to apply across industry groups, as opposed to regulations before then, which were more industry specific.

You had new comprehensive programs of environmental protection work place safety or consumer protection which cut across industries through the entire economy.

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The most obvious, I guess, disadvantage is what I would call the fox-in-the-hen-house argument. This was a great concern when we took the proposal to the Administrative Conference, that self-regulation is deregulation in sheep's clothing.

It really isn't. It's regulatory reform and it can work as well, depending on how confident you are of the agency or department to do its job in the first place.

If they would be good direct traditional command and control regulators, they'd be good delegating the authority to others and supervising it and making sure it's effectively used.

As far as the audited self-regulation goes, the bottom of the first page here, this summarizes pretty well, I think, what the Administrative Conference's recommendation says.

The regulatory program, if it's susceptible to this audited self-regulation model, should be one that

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requires decentralized decisionmaking. It requires decisions to be made that would vary across the industry.

For example, those prototype areas. You want to say, "the workplace." Well, that's going to differ dramatically among the five million or so work places that are subject to OSHA rules, for example. The industry would have to be one that's made a meaningful investment in a self-regulatory organization.

Typically, they're composed of the regulated entities themselves, but not always, one example being in certification of medicare and medicaid providers. The use of the Joint Commission and like agencies, the agency itself has to be able to be a reviewer of regulations, not a regulator itself, so their role is more to say, is the Joint Commission, is the New York Stock Exchange doing its job in regulating those people or in certifying the hospitals to be medicare providers.

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And how do I, in the agency, oversee that, rather than directly do it myself.

And as lawyers and administrative procedure experts, we came up with a group of procedural protections that we would feel that the self-regulatory organization itself would have to follow to have a fair process.

We were assured, from the foregoing, that it would be efficient. We were concerned with some modicum of due process, if you would call it that, both of their adjudication in individual cases, and what they would do that compares to rulemaking that government agencies do.

Now I had put on the shelf, off to one side, while we were working on this, the whole other group of regulatory programs I had found where there really wasn't any intermediate interest group that was doing the implementation of the regulations. That's on the second page where I've talked about just self-enforcement generically.

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This one, I want to caution you again, is still just my research. The Conference hasn't met or talked about it at all, and you may never hear about it or see it again, depending on what they have to say, but here it is.

That's why I've done it second, because it's very similar. It's like audited self-regulation but without an intermediate self-regulatory organization relying more on the individual entities, subject to the law and the rules, to figure out themselves how to comply, with the agency left in the secondary role of supervision, monitoring, and occasional direct enforcement.

The theory is that this is a way to assure compliance by encouraging compliance rather than by punishing non-compliance.

The regulations that would be suitable are like the ones that I've described before; where they're complex, where there's required to be different judgments made by each regulated entity as to how best to comply, and in fact,

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successful compliance will require different responses from each of the regulateds in the population.

Those regulated entities are mostly large or complex organizations where there's a great deal of delegation going on already. So in order to make the thing run, you have a lot of managers who are delegating substantial decision-making authority already and that model simply lies on top of it.

It's also more important, said the theorists, when you're dealing with why is the regulation there in the first place, is it preventing something that is so horrible that it needs to be prevented, rather than simply finding those people who happened not to comply.

If it is, it seems paradoxical, but it would be more suited, say, to people who study regulatory reform.

For this decentralized kind of individualized decision-making, it would be better to work with the regulated entities to prevent the violations than it would

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simply be to wait and find a few that occur, find them, if the consequences of that violation can't be repaired or redressed by any kind of fine or prosecution. Very well.

The key component of a self-enforcement system would be regular self-reporting by those who are complying and careful monitoring of those reports by the overseeing agency or department, and the agency or department being willing to take an educational role, occasionally to step in, and not start from ground zero to build a compliance program in any entity, but to help educate them a little bit as to how best to do it.

That expertise, of course, has to be at the agency level too. And there always has to be some residual program of good old fashioned traditional surveillance and a direct enforcement to deal with the people for whom that method of encouragement to comply works the best. There will always be a few of those people.

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The rest of them may realize that they have an inherent economic self-interest in compliance, not only by themselves, but by their competitors, as well. And there may be larger, moral reasons for wanting to comply with the law generally.

I will finish where I started out in this second study, which is a quote from Chester Bowles, who was the price administrator in World War II, and he made the rough and ready estimate that 20 percent of the regulated population will comply with any regulation simply because it's the law of the land. Five percent will attempt to evade it, and the other 75 percent will comply so long as they think that the five percent will be caught and punished.

That's basically the theory. He didn't have any statistics to back that up.

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What I've generated in terms of statistics is in the following six pages, which I'll leave for you to read at your leisure.

The first three are examples of programs of audited self-regulation where there's an intermediate SRO. The last three pages are examples of self-enforcement programs where the agency has left to the regulated entity how best to determine how to comply.

Most of the rest are examples of programs that are effective and operational now. There are a few at the end of both tables of programs that were never tried or tried and discontinued.

MR. PECK: Thank you.

What we will now do is ask Peter to come up as an expert in the current regulatory process, and also as a knowledgeable person about delivery systems, to reflect on that.

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I did give Peter enough warning so that he did get a chance to read Doug's papers in advance, so if you would now come up.

MR. BEWLEY: Thank you, Jonathan.

I even made some notes while I was reading.

One of the things that struck me as I was reading Doug's papers and as I was listening to him, was that what he's talking about is not new to FDA regulation and enforcement.

Much of what he talks about, although he doesn't make reference to it in his papers, has been incorporated, to a greater or lesser extent, in some FDA activities.

The problem is that it's been haphazard, probably hasn't been thought through as to its applicability across the board, and hasn't really been thought through systematically in the way that Doug has laid it out.

Let me give you a couple of examples of the kinds of things that I'm talking about and how they fit into both

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the audited self-regulation model, although perhaps not perfectly, and into the self-enforcement model in fact probably more perfectly.

Let's talk about audited self-regulation first.

We have someone here from the USP. That is probably one of the earliest examples of audited self-regulation because what the Food, Drug and Cosmetic Act says is that you violate the Act if you pretend to be a USP product and you're not, but you comply with the Act if you are a USP product and comply with the monograph.

Many of the things that Doug has talked about, in terms of having an intermediary exist with the USP. USP actually creates the standards, creates the test methods, and then people apply those standards and test methods to their own products.

Then the FDA comes in and audits you to determine whether you conform with those standards, and in fact will find you in violation of the Act if you don't comply with

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those standards, a perfect example, I think, of audited self-regulation.

One of the questions that we ought to be asking ourselves is whether that model can be expanded. It is today used only with old drugs. That is not to say that the monographs just don't apply to new drugs; they do. But for most drugs today, you must have affirmative FDA approval in order to market the product.

Why couldn't we, I'll talk a little bit about this later, once we have obtained approval of the first product in an appropriate manner, and have given that product its appropriate patent life, and taken care of the issues of exclusivity, why couldn't we make the USP the guardian of further entrance into the marketplace and remove -- here I'm talking about removing the entire generic drugs division from the FDA, remove that from the FDA and in terms of savings costs and head count, a major contribution to that from an FDA perspective.

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Let me flip over to the second kind of enforcement that Doug talks about. And that is self-enforcement.

If you look at the Radiation Control For Safety Act, it is a perfect model of self-enforcement. The agency sets the standards and then each manufacturer self-certifies its products as meeting those standards, and each manufacturer is obligated to tell the agency when its products fail to meet those standards.

It fits right in with what Doug is talking about. There are severe penalties for failure to meet standards, and if you read Doug's writings, he talks about the issues of criminal sanctions when people self-report in the context of self-enforcement. And those issues are right there in the Radiation Control For Safety Act.

This is not unique to the United States in the medical device area. The European Community has just gone through the process of taking an unregulated medical device

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environment -- essentially unregulated -- and turned it into something between audited self-regulation and self-enforcement.

It has done this by authorizing notified bodies, organizations that you might equate with Underwriters Laboratories, to certify manufacturers' quality systems which, under the European system, go from the design of products, the design stage, all the way through manufacturing.

You have your system certified, and then, for most products, you simply market the products that are the result of the system, and there is no government intervention whatsoever for some products.

You also have to establish for the notified body that you've done the necessary testing for the product to assure its safety.

But, again, this model seems to work, or at least seems to be attractive in the medical device area.

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The one area where I have some difficulty in seeing either of these models extended is to the first approval of a new drug product. I say I have difficulty. I don't think it's impossible. I think it's something that probably deserves some serious attention and serious thought.

Let me give you some other ideas about things that we could do that fit within Doug's model.

Let's talk about new uses for already-approved drug products. The agency spends an awful lot of time today working on approval of new uses.

Jonathan has said, in this new environment, in this managed care environment, what are the trends we see?

Well, one of the trends we see is that the managed care organizations want to use products based on the latest scientific information. They want to use them most cost-effectively, and they want information from the

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manufacturers of these products about how the products can be used most effectively.

Can we reduce the doses? Can we shorten the treatment period? Can we use one cancer drug on another kind of cancer?

Companies today can't answer those questions without getting FDA approval. That's an overstatement but it's close to the truth.

Why shouldn't we have audited self-regulation through peer review journals, for example?

Why can't we say that new uses for approved products can be approved externally by the peer review journals or by the USP through USP dispensing information, the AMA drug evaluations, something like that, and take the load off the FDA to approve these new uses for already approved drugs.

Good manufacturing practices. Does the agency have to be involved, on a day to day basis, in inspecting

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and enforcing the good manufacturing practices for drugs and devices?

Can we use the EC notion of having an underwriter's laboratories certify on an on-going basis compliance with good manufacturing practices?

One of the benefits of approaching it that way is that you divorce the product approval process from the good manufacturing practice enforcement process.

One of the things that the agency does today is hold over manufacturers' heads, compliance with its views of what good manufacturing practices are against the threat of non-approval of its products.

If you divorce those and have Underwriters Laboratories responsible for on-going review of good manufacturing practices, we take that kind of what I believe to be an inappropriate regulatory hammer out of the hands of the agency.

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Outcomes measurement. Again, in the environment we have today, as Jonathan talks about in managed care, one of the critical issues for managed care organizations is what are the outcomes from treatment, and how do I measure those outcomes? How do I measure the cost of the outcome against the quality of life improvement in the patient against the reduction in morbidity or mortality?

Nobody knows the answers to those questions today. Those are some of the toughest questions we're dealing with today.

Yet, the FDA today, because it directly regulates advertising and promotion of both pharmaceutical products and medical devices, is hindering the dissemination of information about outcomes.

Why can't we use the same peer review process that I talked about earlier?

Or why can't we rely on the managed care organizations themselves, who are not, as the FDA believed,

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unsophisticated sole practitioners, but who are staffed with Pharm.Ds and expert pharmacologist physicians?

Why can't we rely on the purchaser in this context to make decisions about the quality of our outcomes research and make purchasing decisions based on their evaluation of that information?

Take that all out of the hands of the FDA and reduce the staff in drug marketing, advertising, and communications division by three-quarters?

Keep that division there for the purpose of auditing what's going on out in the marketplace and make sure that there aren't any really big lies being told, but let the purchasers evaluate the information.

These are sort of random thoughts, as I was reading Doug's paper.

One other area of self-enforcement and self-reporting that already exists is in adverse drug reactions. Today, manufacturers are required to report those to the

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FDA. The FDA evaluates them when it wants to, doesn't evaluate them when it doesn't want to. But the manufacturers themselves have to worry most about them because of tort liability.

So the real enforcement from an adverse drug reaction product defect standpoint today comes from manufacturers themselves who are worried about being sued for the product problems, and who are worried about the ultimate liability down the road with the FDA, if they fail to report.

But in fact the Agency is not the primary enforcer with respect to product defects today.

Let me go back to good manufacturing practices. You may think that it's beyond the pale that the FDA would give up the right, routinely, to enforce good manufacturing practice obligations but, in fact, they're doing that today in the context of consent orders for companies that have been found to have seriously violated the GMPs.

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One of the things that's included in consent orders on a fairly routine basis is that the company engage an independent, outside GMP auditor who will report to the company and to the FDA if serious problems arise.

This is a case of an intermediary being created. And, in fact, Doug's point is you need intermediaries to exist, or you have to create them. In the FDA area, there are a number of intermediaries, either like a USP or like GMP consultants or like underwriters' laboratories that already exist that we're going to be looking at as models for going forward on self-regulation.

I think with that, I'll sit down.

MR. PECK: Thank you.

I think we've got some provocative ideas here for us to look at, as having some relevance to reengineering the FDA.

With that, let me ask for questions.

Please identify yourself when you ask a question.

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MR. WEST: Bob West, Food, Drug, Chemical Services.

Some of your ideas in relationship to standards of manufacturing and controls made some sense.

I think where we get into real problems is whenever there's a proof of efficacy or proof of safety involved, which is still an integral part of an alternative or new use for an old drug.

I don't think it would be in the interest of the FDA, nor would it be in the public interest at the moment, to give that up. Unfortunately, the US FDA, in contrast to the Europeans', are even reluctant, at the present time, to turn over to peer reviews, the idea of an IND. The first stage of an IND being reviewed by the institutional peer review group, and that being adequate.

That's done all the time in Europe today. You can go to phase two in Europe without talking to any regulatory people at all.

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We're not there, and I think one of the major problems we have, and I've talked to a number of world class investigators who are terribly afraid that some of the innovative first study work and new technology is not being done in this country, and will not be done in this country with our current regulatory climate.

They may even be done in the third world, rather than being done here.

We have gotten ourselves in a regulatory box which we can't get out of.

MR. BEWLEY: Bob, the fact that the Agency is not ready to give up authority in a particular area doesn't bother me at all. I'm quite happy to tell the FDA that it has to give up that authority, if I can convince Congress that that's the only way to go.

When you talk about new uses for approved drugs, the Agency does not add value, because those uses are in use today.

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Foresight Seminars on Health and Innovation

In cancer chemotherapy, in particular, over 50 percent of the use of products is off label, based on publications or based on word of mouth, or based on other sources of information, not FDA approval.

It seems to me that where the FDA does add value, as it doesn't in that particular case, we ought to get rid of them.

MR. PECK: Peter, let me just ask, even in that regard, because you're talking about today looking forward to more integrated service networks of providers, is that going to be more so?

MR. BEWLEY: Absolutely, because those integrated service networks are going to have even better capabilities to evaluate the claims and the research for those products than do individual practitioners.

When 90 percent of care in the United States is managed care, and you have organizations like Kaiser

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evaluating products based on the published research and in fact doing their own research, absolutely.

MR. PECK: Other questions?

MR. VALENTINO: Joe Valentino from the USP.

USP's always been very careful and limited its activities to standard setting. And it has distinguished enforcement of the standards from the standard setting.

And some of the things that you proposed would cross the line for USP and would involve us in not only standard setting, but perhaps in certification or some sort of a licensing thing.

I'm just wondering, first of all, if that's a distinction you want to make.

Also, do you see any problem with a private organization having both roles, the ability to set the standard and then enforce the standard?

Are we getting very close to the line of what would constitute a governmental body?

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MR. BEWLEY: Actually, Doug has talked about that in his research.

MR. MICHAEL: I was interested when Peter brought that up, because standard-setting is sort of like a self-regulatory organization, if you will, because one of the key things that makes regulation regulation is the ability to affect conduct.

Technically, standard-setting organizations don't have that. The USP is one of many. The government relies on its regulations with Underwriters Laboratories on building codes and all kinds of things, and those entities just set the standards. Technically, they don't enforce.

Now you have a hard time convincing the Federal Trade Commission or the Justice Department, for example, that the people who subscribe to those standards don't also enforce them too, but it's clear that the standard-setting entity itself does not.

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That was a long previous topic of the Administrative Conference. They had someone else do a lot of research and they had recommendations on appropriate procedures in standard-setting organizations.

But you're right, it's very different to take that additional step and say, we're going to make the standards and/or either enforce them or certify them if they don't.

MR. PECK: Are there examples where that certification is done by a standard-setting body in relationship to the self-regulation?

MR. MICHAEL: The ones that I've cited here are not standard-setting bodies but they all have independent implementation.

MR. VALENTINO: We did it once, many, many years ago with liver preparations when there was a problem with how to standardize liver preparations. And had manufacturers submit the results of their clinical testing

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to a USP committee which then assigned a potency to it that allowed the product to be labeled and thus marketed.

It was a forerunner of the new current drug application procedure, but was done entirely in the private community.

MR. MICHAEL: In response to the previous question, I would imagine that one of the other things that impacts whether or not you can do this is simply the political realities.

There are lots of situations, the point being that the FDA isn't going to give that up probably because they don't see that there's a way that it would work over here. There are lots of things that you could do, it would be prudent to say.

First it would be possible to say, if banks could do their own safety and soundness certifications, they'd probably know better than the people from the comptroller's office that are going to come in. That's not going to

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happen. It's going to have to be years because bank failure is going to have to fade from memory.

The Food Safety and Inspection Service in Agriculture has tried unsuccessfully many times to streamline the inspection processes in meat packing and processing and poultry packing and processing plants, simply because Congress won't have it. They had to adhere to an outdated law which, as you probably know, requires physical inspection of every carcass. It doesn't do any good at all, but they won't change it.

MR. BERGER: Ed Berger of the Institute for Health Policy Analysis.

If I may further that last point, there seem to be two parts of the political issue that are important, having to do with the Congress.

One is there's certainly a feeling abroad in some parts of the land that has gone in the direction of a trend that's quite different from the one you've suggested.

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That is, traditionally over decades, we've separated regulation from promotion in government agencies in order to make it purer. And in fact, another step has just been taken this last week.

The public trend in this country has been to in fact push more and more activities on government regulation and make it purer by separating it from promotion in the FDA, the Department of Agriculture, the Nuclear Regulatory Commission, the AEC and so forth. And I'm just not familiar, with a very few exceptions in the last few years, with any suggestion that that trend is liable to be reversed; that the Upton Sinclair phenomenon of many years ago isn't going to rise again in some fashion that will put a scare tactic in the face of the public.

The second is that the Congress itself will give up jurisdiction if they in fact turn over regulation to a private body, and it would be seem to be antithetical to their own desires to have that happen.

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But having said that, what do you both think?

MR. MICHAEL: It depends how badly they want it to work. I would say the prime example of where that's happening, despite suspicions, is in air pollution regulation. Maybe I'm being a little unfair to the EPA, but it's bogged down, it's broken down. They simply can't do what the law has required them to do.

OSHA has the same problem. There are five or six million work sites in the country that they can't get into directly if at all, and the EPA can't directly permit or through the state-certified programs, get permits or permission in every area where there needs to be certification done as the law requires.

MR. BERGER: There are lots of examples where Congress has placed obligation with regulatory agencies that they know full well cannot be fulfilled, however many resources are put into those places.

Notwithstanding, that hasn't stopped that trend.

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MR. BEWLEY: I think one of the things that you're missing is the first word of Doug's approach which is audited. You don't give up the authority in the agency ultimately to regulate. In fact, it is a key to audited self-regulation that the agency be able to enforce. What you give up is the day to day regulation, the day to day involvement of the federal officials in the running of the business.

Is that fair?

MR. MICHAEL: Okay.

MR. PECK: I think Ed's raised an interesting point. It has to do with public outrage when something goes wrong. And one could see, on this political trend, if we want somebody to blame something went wrong, does that make this approach unfeasible or is what you're saying, no, we can still go after what is wrong and show that, and it would be I think what you called the residual enforcement for those, yet it may be politically possible or also satisfying

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to Congress and the public that this kind of system will prevent some proportion of what's going so that there will be actually fewer instances to be outraged.

Have I mischaracterized?

MR. MICHAEL: I think you need both Congressional faith in the agency, like I said before. Do they take their mission seriously or don't they?

If Congress isn't satisfied they take their mission seriously, they won't be willing to pass off any of their responsibilities.

MR. SCHULKE: David Schulke from Congressman Wyden's office.

I think that a couple of the ideas that each of you has shared is very interesting. My bosses like the idea, for example, of having sort of a supervised industry dissemination of new data about off-label uses, prior to the whole protracted period of peer review and publication which

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some people in FDA have asked legitimate questions about, but we're trying to figure out a way to make it work.

One of the things that gives me pause, however, in this approach, either for off-label use or any other regulatory apparatus, is the experience within the JCAHO.

If you look down at the sort of nuts and bolts of it, the JCAHO is exactly what you depict, a state-audited, self-regulatory organization; health care financing through contracts with the state government to conduct Health Care Finance Administration surveys, behind the JCAHO a certain amount of time, of the health care providers that are certified by them.

But if you look at the bulk of these providers, when it's time for JCAHO to come in, they know they're coming and they work their tails off for weeks to get up to snuff to be ready.

I've seen people like this going through unbelievable amounts of work to get ready so they'll look

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okay, so that they can go back to sleep for three years and wait until the next time to be good.

What alarms me about it is there's no lasting impact of that. I know providers have lived through cycles like this, I've lived through cycles like this with them, and by golly, you know, it's the same every time. They have to work their butts off to get ready, and I'm thinking, where is the lasting impact, not just the stage set, you know, for the inspection.

It worries me that that would be true. It's true of direct federal regulation and direct federal inspection, as much as it is for self-regulatory organizations.

It seems to me it would be a much more fundamental dynamic we'd have to worry about. If you're going to have an entity which is not an enforcer and doesn't have that frame of mind where they're going to come in less often, and they're going to try to conserve government resources, like JCHO, you have this problem in spades.

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You can't legitimately claim the trust of people on the hill or anywhere else with this model, as long as that underlying problem is not resolved.

I believe that the federal effort does not solve it. But at least if it's more often, and the people who do it are regulators and they understand that role, and we have some feeling that they're a little closer to direct responsibility than you are with this couple of arm's length removed process.

Any suggestions for how to make that work?

MR. MICHAEL: It can't work unless you've identified underlying incentives for people to comply with the law. The economist's best example is, if it's in your economic interests, it's good business to comply because that's the reason for the regulation to be there.

If you don't perceive that there's a reason that affects your business, you won't be motivated to comply with it.

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Manufacturing and pharmaceuticals is a good example, and meat and poultry processing, and stockbrokering. You have a vested interest in making sure that your shop is clean and everyone else's is too. Because the public won't buy your product if they think it's an adulterated, fraudulent product.

Whether or not you can convince policymakers of that, or whether or not it's true on a grander scale, I don't know.

In areas where you can't identify that self-interest, it can be created by the agency with leniency, something very comparable to what you talked about.

OSHA has a very small but fairly successful program of voluntary participation in work site health and safety inspection. And the carrot they have is we will inspect you tri-annually instead of annually, if you pass our standards, and you certify yourselves and work with the

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employees at your work place, you won't see us for three years. Otherwise, you can count on seeing us every year.

The main reason that the program is so small is that in fact you can't count on seeing OSHA every year. You'll be lucky if you see them once every 15 or 20 years, so the carrot isn't as big as they'd like it.

But maybe that's an example where, if the self-interest isn't there, you can create it by maybe turning it around in the issuing of government permits or grants, or being left alone.

MR. BEWLEY: I guess another way to create that self-interest is with some sort of unannounced spot check on both the provider, the hospital, and the JCHO, so the provider never knows that he's free for the next three years.

What he knows is there's a ten percent chance that HCFA will show up at the door twelve months after his

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survey to make sure he's still doing the things that he said in the survey.

MR. SCHULKE: You'll permit me one sentence?

I think that then you have to bear in mind that the very diminished regulatory presence of all the agencies that we're talking about already suggests that you aren't going to get a lot of savings by paring that back.

Because HCFA and FDA have a very thin field presence. And a lot of the presence is so slender and infrequent, I think, that I'm not sure it has the effect that you're saying it should have. Logically, it should, but the chances of getting hit by HCFA inspection to seek contradictory JCAHO accreditation is infinitesimally small.

And I suspect the same is true for FDA in a lot of its activities, like marketing, since that takes place in such a widely disseminated way. That's my concern about it. And the motivation for doing this is likely to be cutting

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back on government expenditures which will make the auditing function less credible.

MR. PECK: Other questions?

MR. VALENTINO: I was just going to make a comment.

I think with some of the employee protection statutes, I consider USP to be a hundred percent audited all the time by OSHA. If anything goes wrong in our place, OSHA's going to know about it in five minutes, because I'm sure one of our employees will make that call.

MR. MICHAEL: That's the main protection for this voluntary program. There's inspection of every reported accident or incident and the employees are ever willing to report what their employers are doing.

One thing that makes it worthwhile is an informed adversary on the other side. The counterpart is, I think, missing when you go to consumer regulation.

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Can you be an informed consumer of pharmaceuticals? You can see an accident or an injury.

MR. BEWLEY: You can be an informed consumer of pharmaceuticals if you're Kaiser or one of the other major managed care organizations. That's what's changing.

MR. BERGER: On the other side of my argument, there are two examples, relatively minor, in your camp, I would say, in recent times.

One is a very small program, formerly within the EPA, which had to do with the regulation of flocculents used in water treatment plants which the EPA in fact voluntarily gave away to a certified organization.

The other is in the realm of cosmetics where about 20 years ago, I guess, 14 years ago, a fairly elaborate system, based very much on the Administrative Procedures Act, in fact was set up privately to review the list of ingredients in cosmetics.

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That continues to the present day over the kicking and screaming of FDA. But in fact it has, I think, worked quite well.

MR. BEWLEY: Actually, the cosmetic industry is an excellent example of a bunch of the principles that Doug is talking about.

The way you get onto the market with a cosmetic is simply to make a determination for yourself that it is safe, and then go to market. Your risk of exposure is if the FDA should come to you and say, show me the proof that this is safe, and you don't have it.

In addition, from a risk standpoint, there is a completely voluntary program to notify the FDA of adverse reactions to cosmetics. Some companies participate in the voluntary program and some companies don't.

The third example, the cosmetic ingredient review that's run by the CTFA, is another example. The cosmetic

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industry is probably the best example of an FDA-regulated industry that in fact tries to operate on Doug's model.

MS. CHERTOF: Susan Chertof from Arnold and Porter.

I have two questions. They're not really related.

One is, someone said that the economics of the situation are such that the industry has an incentive to keep itself clean or consumers will stay away from the whole industry.

The example I think you used was the stocks and bond industry.

But it seems to me, for that incentive to exist, it has to be a product that people can take or leave. You know, people can put their money in the bank if they don't trust stocks.

But I wonder with health care devices that are used during surgery, or drugs, or cancer treatments or

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whatever where the individual person is not in a position to evaluate and really doesn't have any choices available to them, if that kind of incentive can even exist.

MR. MICHAEL: I think you're right. I think it breaks down at a certain point where you don't have a choice. You have a choice with meat and poultry. You can ignore it completely. You have less control with prescription drugs, and almost no choice at all.

MS. CHERTOF: What would make self-regulation work?

MR. MICHAEL: I never tried to shop it as a cure all.

MR. BEWLEY: But I will.

(Laughter.)

MR. BEWLEY: Doug's basic premise is that you need an incentive. One incentive can be that you need the industry, as a whole, to look clean, but another incentive, there are a whole bunch of incentives.

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Another incentive is the tort law system where, if you market a defective product, you end up paying substantial damages.

Another incentive is the threat of regulatory action if it's a credible threat. And I agree with you, David, it has to be a credible threat.

So there are a number of different incentives that one could either acknowledge or create that would make audited self-regulation work in the food, drug, and device industry.

MR. PECK: Also, just a point is that in your example, a machine used during surgery, the decisionmaker there typically would be the hospital or managed care organization, as opposed to the consumer, at that point.

And actually I think that's true probably of pharmaceutical selection too. It's a formulary decision. A drug decision about a prescription is likely to have come through some organization as opposed to an individual

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consumer or physician, where there are different levels of information.

So I would just like to point that out so that we're thinking about the future situation, rather than the past.

MS. CHERTOF: That's kind of a good segue to the second question I want to ask from NovaCare.

You seem to be suggesting that managed care organizations could sort of function as a proxy for consumers in having the expertise and the incentives to evaluate things and keep bad stuff off the market and good stuff on.

It seems to me that their motivations are going to be different. I mean, this is just as sort of an individual health care consumer. I'm not sure a company that is looking at its bottom line is looking at the same thing that I want to look at.

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And I'm not sure I feel comfortable having them be the watchdog.

MR. BEWLEY: One of the key issues in health care reform is how to get quality of care into the evaluation of managed care organizations. There are a lot of discussions going on about report cards.

At the end of the day, if this is all going to work, you're going to have some way of evaluating HMO 1 against HMO 2 against HMO 3, such that a consumer can say, I'm much more comfortable with HMO 1 because they really score high when it comes to cancer outcomes.

So I'm going to pay a little bit more. I'm going to contribute something. My employer gives me \$5,000 a year. I'm willing to add \$2,000 to that to belong to this HMO because they have better outcomes.

We need to have information available so that consumers can evaluate the quality of care provided by the managed care organizations. Then it will work.

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MS. CHERTOF: Who's going to do that?

Are you back to some sort of regulatory organization?

MR. BEWLEY: You know, having come from the providers' side and the manufacturers' side, I haven't given a lot of thought to how we create the quality of care measures for the managed care organizations.

But I don't see why self-regulation can't work in that environment as well.

MR. PECK: Just a couple of references because it's an important question you've raised.

We have dealt with this in two former Foresight Seminars, and there is, certainly for the managed care groups that are doing quality evaluation. HDIS standard setting is one example, but another is, and David, I remember you in our Cost Effectiveness Foresight Seminar, last year.

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Your point is so important and it was driven home by a person who was saying, make sure, whenever you hear cost effectiveness, you're asking the question, from whose perspective. Because the managed care organization that has an annual profit part of that will have a different perspective than you and I might have because we don't think about our health in annual terms. We may be thinking about the life course.

And so how you measure cost effectiveness, even over what time period you take to measure it, is very much a function of what perspective you're taking.

So I think your question is a very significant one.

Yes, sir?

MR. ING: Tom Ing. I'm a health fellow from Senator Simon's office.

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As an epidemiologist, I think there are certain applications, certain products or industries where self-regulation may work.

I wonder, though, if we've got to keep in the back of our minds the difference between making the regulation process regulations more efficient in the first place, versus do we want a whole new model.

But let me just come back.

One of the things I worry about in the self-regulation model for industry or the high risk products for industries is the sense that industry can be relied upon as being objective in their analysis and evaluation of the research.

I've personally been involved in some analysis of studies done by companies, private companies and industries that basically had their conclusions before they started their study.

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One of the industries I can think of basically is the tobacco industry. That's a pretty clearcut example, I think, of this problem.

I wonder if you had some thoughts about, do we really need another model for a high risk industry or product versus a lower risk industry or product.

MR. MICHAEL: This is supposed to be a good one in the sense that the regulator is supposed to be there as a consultant. Do you mean the risk of the product?

MR. ING: How does that play with the type of regulation model that you would want to apply to that industry?

Do you think the risk of a product or the risk of an adverse outcome as a result of that product, given no regulation or deregulation, should play a role in deciding what kind of model to use for your industry?

MR. MICHAEL: Yes, but it may be opposite.

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I'm not sure I have good real world examples but I think the theory makes sense. If the event you want to prevent is an accident at a nuclear power plant, which is kind of irreversible, it's better to work with NRC and with INPO and with the utility to prevent it, rather than to say, here are the standards and we'll watch you.

If there's a meltdown, you're going to have to pay a big fine. That doesn't work too well.

Congress was willing to permit the trading -- I shouldn't call them rights -- permits to emit sulfur dioxide and cause acid rain. You can trade and permit those.

I don't think they permit the same kind of trafficking in adulterated meat and unsafe drugs or anything like that. So, yes. The more severe the harm that the regulation's directed at, the better it is to work with the regulated entities to prevent it, which is encouraging compliance, rather than punishing non-compliance.

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I mean, it's easy to say that. It sounds good but how do you do it? If you start with that philosophy, you ask different questions.

MS. VOGT: Donna Vogt, CRS.

I'm not sure I understand completely but it seems like just a little down the road, you have a lot of barriers to entry of new people into industries that are self-regulated because this, "self-regulated group" could sort of put up barriers so that you wouldn't have new entries, new people coming in, more competition. You'd in fact have more and more of a monopoly situation.

Can you respond to that?

MR. BEWLEY: I'm not sure I understand why that would be if you met the standards.

Take the Radiation Control For Safety Act, which is the second piece of Doug's model or Doug's second model, where the standards are set, either by the agency or it could be by USP or somebody like that.

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And then the company, itself, tests its product to see whether it meets those standards, and then certifies, puts a label on the product and says, this product meets the standards and markets the product.

Anybody can do that. There is no limitation on participation in the standard-setting organization or in going to market. So I don't think there's anything in Doug's model that inherently restricts entry to the market.

MR. MICHAEL: I think your concern is legitimate and many people have it.

What we're talking about is concerted conduct by the regulated entities to not restrict competition because we want to get a good product. That's restricting competition regardless.

As the gentleman from USP probably knows, standard-setters are favorite anti-trust defendants because if you standard set plus a little bit, you'll be in trouble.

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If you've studied that across the law, you don't get good answers but you get lots of cases.

ASME is a good example. You have to be careful when you're a standard-setting organization or even a self-regulatory organization process, and courts typically follow process-oriented remedies in looking at open proceedings, fair proceedings. Not packing the hall, when the standards are set, with your people setting the standards.

They look more at process protections and it seems like perhaps a peculiar union to say we want open hearings, we want notice, we want good procedures; otherwise, we'll be suspicious of your anti-competitive motivations, but that seems to have been the answer.

It arises much more frequently with the audited self-regulation model because the self-regulatory organization has inherently the power to affect conduct. The standard-setters aren't supposed to, but they do.

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MR. VALENTINO: I'd have to agree with everything you've said. We're always very conscious of someone presenting to us a lockout specification which would prohibit someone from coming to market, and we do have the procedures. We have publication and notice and open meetings and things like that.

But one thing that's a little different in our decisionmaking process is that we're not an industry consensus body, which most standard-setting organizations are. Our standards are set by elected experts who come from the industry, the government, and academia, as well as private practice.

So what you do is, you have a blend of interests looking at a product or the standards for that, and that sort of eliminates a lot of what might occur to have lockouts.

MR. PECK: So the process protections are vital.

MR. VALENTINO: Very much so.

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MS. CLAYTON: Eleanor Clayton, General Accounting Office.

This is, if you'll forgive me, straying a little away from the FDA and pharmaceutical aspects into the service side. I'd like to take advantage of Mr. Bewley's presence.

Do you see any application of either of these models in your own industry or similar service, rather than to a device-oriented industry?

MR. BEWLEY: Frankly, I don't.

One of the things that Doug points out in his paper is that there are certain areas where, for public policy reasons, we stay away from regulation.

I think the practice of medicine was one of those areas.

Of if we don't stay away from it, we're very, very careful about how we do it.

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I think the same thing applies with respect to how hospitals treat people, how physical therapists treat people. I think we want to stay away from telling individual providers exactly how they have to do this.

We can establish practice guidelines that tell people generally what the outcomes are that they ought to be looking for, and when they ought to intervene. I'd be much more careful about regulating the actual delivery of care.

MR. MICHAEL: I don't know if it's one of the biggest examples of managed care, but medicare and medicaid have basically contracts with one agency in each state which is an insurance company by a different name, but they have the same problems.

You make sure that cost containment doesn't turn into quality containment as well. It's anathema to have the government tell doctors how to practice medicine.

You may or may not believe that, but that's what they say in Congress. So they want that contracted out to

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people who presumably know the business better and aren't directly responsible to government to have contracting review over those decisions.

MR. SCHULKE: I'd like to follow up the question of Dr. Clayton.

Mr. Bewley, this is about applying the audited self-regulatory model to the service side.

In this never-ending Congress, there was a bunch of proposals, you know, to try and reach into this area, as opposed to paring back the regulatory presence as opposed to FDA which is the context that this is usually brought up in.

There was an attempt to use this kind of model to get closer to accountability for services. The idea was to require quality improvement activities by health plans which would require the insurers of providers, which were members of the networks, that there would be an auditing entity, probably a foundation or somebody who would be looking over the shoulder of those entities to be sure that they were

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really profiling the outcomes, observing how much variation there was, and trying to reduce the variation towards the best practice, and if they didn't find that was going on, to nudge them to do it.

Is that a faulty application of the model, or does that seem to you to make sense?

It's not the same thing as saying what the standards were for an M.D. but instead looking at the outcomes, and attempting to get their own practitioners to move toward best practices.

MR. BEWLEY: Where I personally come out on that, and I have to say I don't speak for my company in this regard, is that it makes much more sense, first, to try to create the measures, the quality measures and see what happens as managed care organizations begin to try to compete with each other on those outcome measures, rather than create an organization to start forcing people to adopt practices.

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That's where I come out.

MR. PECK: If I could make just a couple of observations. At our last Foresight Seminar on Disease Management Systems, where best practices were among -- we were saying, we can see best practices for people, for example, who are very sick with diabetes or some of these rare life-defining conditions.

That question of incentives, that they adopt those, where they rely on managed care.

It seems to me, David, you're raising that from a different vantage point, but that issue is alive and is significant to address from a policy perspective.

And second, really you mentioned before, there are consultants who can play that role, and so there are companies that now do the evaluation of best practices.

Med Qual would be one example where they look at hospital data and do comparative analyses to say what's the

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best practice, and then how can you get all the hospitals in the system up to the best practice of the standards.

That seems to me, as a dynamic in the marketplace, these things are there.

MR. WEST: That thinking, though, assumes there's equal professional competence in each one of the institutions. Plenty of the data suggests, for example, whether it be angioplasty or bypass surgery, if you don't do it often, your results are not going to be as good as the guy that does.

You may prescribe the quality but there's no hands-on experience.

MR. BEWLEY: That's why availability of information on the outcomes is critical.

MR. PECK: And to consumers, as choice makers.
Yes, sir?

MR. WHITE: Tom White from PHARMA, the Pharmaceutical Research and Manufacturers of America.

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I was interested in Peter's treatment of the GMP as really a good candidate for affecting change that would serve both the patient, the industry, and I think the regulator.

There are several aspects of Part 211. I don't know how many people here understand Part 211. It's certainly the rigorous regulation for good manufacturing practices for finished pharmaceuticals.

The basic underlying concept of Part 211, when it was developed in the mid-seventies, was to provide a quality assurance program for drug manufacturers to assure that products released to the market were safe, effective, and of good quality.

It originally was what was required but the regulatory creep, you might call it, changed from what was required to how that assurance was maintained.

So Part 211 now represents a barrier to improved drug manufacturing. It represents a barrier to

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technological advancements that are now available for drug manufacturing.

I'll give you one example right now.

The agency has, out for review and comment, a proposed rule on electronic signatures and electronic batch records. It's called the electronic signature proposed rule.

The genesis of the proposal came from industry's concern that a provision of Part 211, a specific provision that required a handwritten signature on a batch record, and the industry was increasingly, as you might expect, going to electronic systems for managing the drug manufacturing process and controls for those processes.

MR. PECK: May I interrupt for a second, Tom?

Would that mean, just for example, an electronic continuous monitoring, as opposed to physically dipping in and sampling.

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MR. WHITE: That's part of the context, but this is a specific provision in Part 211 that says there must be a handwritten signature signed by a human being. So the electronic counterpart to that is a system that is either a sign off or coded or whatever that accomplishes the same thing.

But right now, in the Federal Register, is a proposed rule to fix this. But it fixes it with an unusual and overly burdensome validation of an electronic system that far exceeds what a human signature requires.

In other words, there's almost an incentive for a drug manufacturer to say, forget it, we'll stick to the handwritten signature. We won't implement this electronic batch reg system.

It provides that sort of barrier to implementation of improvements to the drug manufacturing process.

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I'm convinced that an electronic system, when you remove the human element, actually assures you greater quality, greater control over the system because you can build an audit trail electronically, you can call up the record. The record is usually date-stamped. You know when the action occurred. You know who was involved. And in the GMP, it's a closed system. So the record is almost immutable.

But what's being set up is an unrealistic threshold for the electronic system to somehow surpass the authenticity, the credibility, putting the handwritten signature on a pedestal it doesn't deserve.

MR. BEWLEY: I'd go farther, as you might expect, and say that the big problem with the GMP is its regulatory gloss. One could easily interpret signature to be an electronic signature. The problem is agency inspectors who increase the requirements or freeze the requirements of the

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GMPs on their own without the sense of where industry is going.

And it's a perfect place for audited self-regulation, absolutely.

MR. PECK: So right now, regulation is a barrier to innovation and improvement in manufacturing process; that is, there's lower incentive because of the regulatory system that's still trying to tie it to an old signature as opposed to computerized electronics.

MR. MICHAEL: It happens out of frustration or inertia. I think that's a perfect example of what you all know is regulating the input as opposed to regulating the output. If FDA had stepped back and said, "Why did we have the signature requirement?", like you said, and then just say to the manufacturers, have a system that does this. You know what it is, go do it, and show us that it works.

MR. PECK: Are there other questions or comments?

(No response.)

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MR. PECK: In that case, I'd like to thank all of
you for coming and thank our panel.

(Applause.)

(Whereupon, at 1:30 p.m., Thursday, November 10,
1994, the Conference was concluded.)