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PROCEEDINGS

MR. PECK: Good afternoon, everyone. Thank you for coming. I'm Jonathan Peck of the Institute for Alternative Futures. We're here today for a discussion of health reform and the future of innovation.

Clearly, over the years, of all the foresight seminars we've done, we're at a year where it's never been as important to help Congress establish foresight. In this context, the ability of Congress to give us a future that's better than what we have presents a tremendous opportunity. And I feel so fortunate that, as we look at innovation and decide how Congress can help give us what we would like, we've been able to attract speakers of such tremendous caliber and great knowledge.

They did make me promise to not say that they're two of the smartest people I've spoken with in the last two years, so I'm not going to say that.

(Laughter.)

MR. PECK: But, Rebecca Henderson, who is Associate Professor of Strategic

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**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

**PROCEEDINGS**

Management at the MIT Sloan School, has done a marvelous job of understanding innovation inside the pharmaceutical industry. In some ways, Rebecca knows failure like Bo Jackson knows baseball. She's really studied who's failed and who has succeeded across different industries.

So she will give us some of the lessons learned through her access to a volume of data about the history of innovation among leading pharmaceutical companies in this country. She'll be followed by Professor Steven Wheelwright, who is Professor of Management at the Graduate School of Business Administration at Harvard University, across the river.

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

Dr. Wheelwright has studied innovation across different industries, so he can talk from A, autos, to Z. I don't know what the Z is in this case, but he's also done a good deal of work in the medical devices field. He's looked at biotechnology and he's consulted with a variety of companies, so his expertise spans not only pharmaceuticals, but innovation throughout health and other industries.

We have two of the people who may be the smartest two people I've spoken with in the last few years who have studied innovation deeply across industries and have discovered some lessons that they think are important for you, as you set policy.

So those in Congress who make policy that affects innovation, through oversight or legislation, I hope you'll listen well. I know I will be taking lots of notes!

We will begin with Rebecca Henderson. Rebecca?

PROFESSOR HENDERSON: Thank you very much, Jonathan. I'm delighted to be here. This is the first time I've addressed an audience in Washington ..no, forgive me, it's the second time, but I'm more used to addressing MBA students, so I will try to be more modulated. I tend

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

to bounce up and down and run around the room with MBA students.

As Jonathan said, I am obsessed with failure. I am, as perhaps you can tell from my accent, British. And when I graduated from college, I joined MacKenzie's Manufacturing practice in London. That meant closing plants in Northern England.

I worked in a wide variety of industries, nearly all of whom were characterized by firms that had once been great and were so no longer. And I became very intrigued at how firms that were seemingly well-run, with people that were not stupid or foolish, could miss seemingly obvious changes in their environment and preside over a slow slide into the sea.

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

When I finished my Ph.D., I took up that interest, and I've been studying large, failing firms for the last ten years now. (Laughter.)

PROFESSOR HENDERSON: I've done work in semiconductors, a little bit in automobiles, in machine tools, in aerospace instrumentation, and some consumer goods industries. About three years ago, I started working in pharmaceuticals. Now, why pharmaceuticals? Some of the industry people I met were distinctly nervous, as if I was a vulture that had moved in.

I wanted to look at pharmaceuticals because it's one of the few high tech industries in this country that has managed to survive a major scientific revolution. The most successful firms in the pharmaceutical industry, as you know, have pretty much made the transition from randomly injecting compounds into depressed rats to much more science-driven, much more rational methods of drug discovery.

I was very interested in how firms could do this. What was it about how they were managed or the industry in which they were located that let them survive--that let them not be General Motors. So Jonathan's asked me to compress the subsequent three years of research into

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

**PROCEEDINGS**

ten minutes. So here it goes.

I set off on a research project where I was able to collect internal firm data from ten major European and American companies. Between these ten large companies, there are about 30 percent of all the research conducted in the world. I was able to get data at the research program level--right down inside the firms--on every area they'd invested in, both in research and in clinical development for up to the last 30 years. I have, on average, 20 years of data from these *firms*.

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Foresight Seminars on Health and Innovation**

PROCEEDINGS

On top of that, I conducted a program of qualitative interviews. Thinking that the numbers will tell you something but not the whole story, I went inside these firms and tried to really understand the history of cardiovascular drug development. I focused on cardiovascular because it's one of the biggest, there's been a lot of change, and it's pretty much indicative of how these firms have been managed.

So for these ten firms, I went inside and I interviewed everyone I could about the history of cardiovascular drug development. Instead of saying something like, "How did you guys stay innovative" or "What on earth went wrong"--and get answers like "We used teams" or "We had a visionary CEO"--I asked questions like, "Why didn't you have beta blockers" or "What led to your decision to invest in anti-arrhythmic technology?"

I interviewed over a hundred people. This is three year's work. As you can tell, it's taken a long time, but we've just finished the preliminary analyses. That's what I'd like to show you today.

It seems that the answer to my question going in--how did some of the firms in this industry manage to survive this major scientific revolution?--is quite complex and has a number

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

of dimensions. It seems that the successful firms actively managed the flow of information across the boundaries of the firm and within the firm. That is, these companies are part of a very productive, very high velocity scientific community that's evolved in this country but has its roots in much earlier periods.

One of the things that makes the pharmaceutical industry different from some of the other firms I've studied is the strength and vitality of the public sector and the publiclyfunded research. The need to stay connected to the public sector--the need to ride the

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

scientific wave--has prevented them from getting as fragmented and as stultified as some of the other firms I've studied.

Let me back off and tell you a little bit about what I saw go wrong in other industries and then come back to these results again. What I've seen in the other industries is that successful firms split up the problem into pieces. So suppose I've been designing a car for ten to 20 years. After a while, I do door handles and you do doors. You work in the engine group. I learn what I need to know about what everybody else is doing, so that one develops a set of information filters and communication channels that act to make the structure of the organization reflect the way they do things.

So think about your own lives. As I talk, you're carefully filtering what I say to pick out two or three things that matter for you. And the other half of your mind is thinking about which of the 15 telephone calls that are on your desk when you get back you're going to return. You've learned what you need to know about what everybody else is doing. The world is far too complicated to know much about what's going on beyond your own local problem domain.

Now when a company is first started, or when the science is changing really rapidly, we

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

**PROCEEDINGS**

meet in groups all the time. I have a very open mind about what innovation looks like, about where it's going to come from. Over time, as the industry becomes more stable and as the pattern of innovation becomes more regular, I focus more and more on my little local piece and pay less and less attention to what the rest of the organization or to what the rest of the industry is doing.

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

Now I've seen the phenomenon in firms as big as General Motors and in groups as small as 20 people. It seems to be a natural tendency. A way to make the world less complicated is to focus on what I know and push the rest away.

What I find extremely interesting about pharmaceuticals is, in the best performing firms-- we really have to be careful here because there are firms in the industry that are not high performing, that did not make the transition to more science-driven research--an early focus on science, perhaps because there was a CEO who was a leading scientist or perhaps because they had one successful drug that was based on understanding the science, got translated into a focus outwards to the scientific environment and, within the firm, to a refusal to be satisfied with splitting the program up into little pieces.

I see in the quantitative data, when I run the statistics, that successful firms are very diversified. That is, they have research in a variety of areas and that the productive firms are productive because they're productive in all sectors.

Technically, I'm more likely to be productive if the guys across the corridor are doing well and if my competitors are doing well, and if the science is doing well. So how well I'm

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

doing is a function of how well the community in which I'm embedded is doing, not any part of the rest of the firm, but in the larger industry and academic community.

That result comes screaming out of the statistics: that successful firms manage their diversity and are large enough to take advantage of what's going on outside the firm. When you look at the organizational mechanisms they're using, they are not satisfied with any one organizational structure. They constantly are experimenting with organizing by scientific discipline, organizing by disease, etc. When they allocate resources, they constantly refer

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

back to the science. The management of research in these successful companies is part of a deeply productive community.

When I turned my attention to development, that is, to the management of clinical testing, the results look a little different. There, the preliminary data suggests some evidence that there is a “General Motors problem,” although I hesitate to pick on GM.

In the science-driven areas, firms are very flexible and responsive. But in clinical development and their approach to the market, years of experience with a very long--quite structured--process had let people sort of back off. I do my little piece and you do your little piece, but we don't revisit the entire system in the same way.

That's starting to change dramatically. The high performing firms that I can see in my data are starting to revisit how they manage clinical testing and how they manage their relationship to the marketplace in a very aggressive way. That is, they're starting to take the same qualities of looking outwards--of revisiting what they're doing--and applying it to the rest of their value-added chain.

**Institute for Alternative Futures**  
**Foresight Seminars on Health and Innovation**

PROCEEDINGS

While I'm coming to the end of my ten minutes, Jonathan asked me to wrap up with some of the public policy implications of my findings. I think one of the reasons the industry has been so successful has been because of the public policy regime, the nature of publicly funded science, the history of how education in this country has driven a very productive research sector. But as we think about moving forward, the challenge is to take that innovative capability and extend it to other aspects of the pharmaceutical product, to pharmaceutical testing and use. I think that's a major challenge facing the industry and I think that public policy will be a huge part of making sure that challenge is met well.

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

**PROCEEDINGS**

Thank you very much.

MR. PECK: Thank you, Rebecca.

You're all mad at me for only giving her ten minutes, right?

You're going to forgive me when you hear Steve, and then when we open this up so that they're both available to explore together the knowledge of innovation and policy implications.

Steve?

PROFESSOR WHEELWRIGHT: Thanks, Jonathan.

As Jonathan mentioned, while I spent a lot of time with medical devices, some pharmaceuticals, much more of my background is innovation and products development across a wide variety of technology intensive industries.

What I'd like to do is frame for you my perspective on health care innovation, where I

**Institute for Alternative Futures**  
**Foresight Seminars on Health and Innovation**

PROCEEDINGS

think some of the opportunities lie, and what that implies about public policy. As consumers, we all run into lots of new products, some of which we like, some of which we don't like. Let me just mention four characteristics that drive the way that other industries think about innovation and product development that I think are just starting to be recognized in health care innovation and product development. So I want to use examples from nonhealth care, and then I'll come back and focus on what does this mean in the health care area broadly defined.

The first trend that I see is that markets increasingly desire customization but they want it with high reliability. Some of you may have read books, like ones with titles like "Mass Customization", "Market Fragmentation," things like that. The idea is that all of us,

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

as consumers, we don't want the standard five million widgets that are all identical. And I think in health care, this has long been the case. We want customized health care.

However, none of us these days tend to be very patient about mistakes, problems, or defects in the products we normally see. And one of the challenges to an organization is how to develop a new, next-generation product so that it can be customized to individual subsegments of the market, but also have the robustness, the quality, the durability, the reliability that you've come to expect.

If you take a car, for a moment. Those of us who are a little older can remember cars were not nearly as good ten years ago as they are today. There is absolutely no comparison between even a first year model today and ten or fifteen years ago. And there are lots of statistics in this. So one of the trends that I think is really pervading our consumer markets is this desire for customization, but impatience with defects, problems, and bad experiences.

The second trend with regard to innovation and product development is that competitive forces are driving things to shorter life cycles. Now it takes three characteristics to get a shorter life cycle into a marketplace. One is that you have to have something new that adds value so that

**Institute for Alternative Futures**  
**Foresight Seminars on Health and Innovation**

PROCEEDINGS

the new product is more desired by the customer than the old product. The second thing is that you must have a way for the market to digest this value added. It has to make sense to your customer. Just because there's a brand new car every year doesn't mean that all of us go out and buy a brand new car every year.

Most of us get in certain habits. I happen to have a father-in-law who waits every three years. I happen to be on the longer-term cycle of every five or six years. But

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

different people have different abilities and different desires to accommodate a rate of change. So that affects how those competitive forces are shortening the cycle.

The third trend is that as industries mature, the focus on innovation tends to shift from component innovation--such as in an auto industry getting the best braking system and the best windshield wiper system, and so on--toward the best system solution.

Now the difference between innovation in a systems solution and innovation at the component level is night and day, because, typically, a single organization doesn't deliver the entire system. Think about health care. It might be a combination of the hospital, the doctor, the drug company, and the medical device company. You could have all of those involved in a single system, say, a hernia operation.

The same is true in lots of other areas.

What you see happening in other areas is that, as markets mature, the whole community of participants in that industry shifts its focus from innovation in components to innovation in the system. As I say, I think that's happened much more in most industries than in the health care

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

industry.

And finally, the fourth trend is that there's the pervasive role of information technology in product innovation. In fact, I view information technology as the facilitator. It's the means by which you're able to customize things, shorten design cycles and design lives, and integrate very diverse components into a new system.

For example, it's not unusual today for a medical device company to have a room set up where they prototype the environment that their product's going to get used in. So let's suppose you're trying to create a next generation pacemaker that happens to be smaller, more

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

programmable, more unique to who you are, and everything else. They would actually have a room where the doctor installs the pacemaker, and it's got an adjacent room where the pacemaker gets programmed so that it becomes "your pacemaker," unique to what your body needs.

Now let me just look at three things that I think are major implications for health care. You might not normally think about it this way, but I think they are part of the challenge of what you do with policies to make health care better and better on multiple dimensions, as opposed to just sticking with the status quo or tightening the thumbscrews on the status quo.

The first is one of the things that happens because of these trends is that there are multiple dimensions of innovation. Innovation in health care has largely been thought of as an invention of new molecules or an entirely new device that is opening up an area where nothing existed. It's kind of the breakthrough view of innovation.

I think one of the things that is undoubtedly going to happen in health care is innovation is going to come in cost, it's going to come in quality, it's going to come in timeliness, as well as some of these performance areas. But the performance areas are going to get harder to achieve.

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

**PROCEEDINGS**

In fact, that's what generally shifts a lot of the focus from component innovation to system innovation, because you can make great strides in the system without a whole lot of breakthroughs, if you figure out how to bring the pieces together better.

The second thing is you need a broader perspective on what is it we're trying to innovate. Are we trying to innovate drugs, medical devices, or products? Or, are we trying

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

to innovate the system? The procedures surrounding the system could be everything from the payment part of the system to the identification of who needs what part of the system. And finally, it requires new tools and a reorganization of work, as Rebecca was describing. It is very challenging, however. Let's suppose you buy the scenario that we need to think more of systems innovation. Well, how do you recreate the system, if you're only a piece of it that's used to working in a fairly narrow perspective? That's a major challenge.

As I look at innovation and some of the trends I've just been describing, I think most of us have some misconceptions, in part because we're all consumers and so much of our view of health care is biased by our personal experience. Let me just mention three of these.

If you think of quality in health care, well, it turns out people have done lots of studies about that, about what is quality, what do you think of? It turns out that if you generally go and ask a group of doctors, they think about it as breakthrough inventions. If you think about quality, though, in terms of an HMO. it's probably outcomes relative to the disease state. You can then ask the question, what actually drives quality? This is an interesting question because the data are actually very clear and very consistent, and that's not normally the case. If you look at quality, it's driven, in terms of outcomes, by how many times the people doing the procedure have done it

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

**PROCEEDINGS**

before. That's all that counts.

So, if you're getting a cornea transplant, you only need to ask one question. Ask the doctor, his staff, the hospital, whoever's involved, how many times have you done this procedure. If the answer is a thousand, you're in pretty good shape. If the answer is ten, you'd better look further into it.

**Institute for Alternative Futures**  
**Foresight Seminars on Health and Innovation**

PROCEEDINGS

One of the things that suggests is that there's a big difference between breakthrough innovation and innovation that's looking for best practice, which is really what those people who have done a thousand procedures have discovered. They've discovered best practice. That's how they get good outcomes.

But that's not where innovation has historically been focused. Much more the innovation has been focused on the breakthrough. The reality is that if you're interested in outcomes, you want to discover what's the best way. That is the type of innovation that has tremendous payoff and is equally important as the breakthrough kind, most industries have found. So part of this broadening of perspective is: how do we encourage innovation of that type that is the best practice repeatedly applied, as opposed to innovation of the breakthrough type?

A second thing that can be learned from other industries and applied to health care is, looking from a system perspective as opposed to a component perspective you actually get a quite different path for a solution. Let's take, for example, an area that we've spent a little bit of time on but you probably don't all know equally well, and that's a hernia operation.

It turns out the way hernia operations used to be done is you make an incision, kind of

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

**PROCEEDINGS**

weave together the layers, fix the weakness, and sew things up. In a week or two, the patient would be ready to go back to work. Well, this is one of those areas that is probably amenable to less invasive surgery techniques. Basically, you go in through the side, come in around behind, and you actually put some kind of a screen or mesh against the outer layers to provide strength.

**Institute for Alternative Futures**  
**Foresight Seminars on Health and Innovation**

PROCEEDINGS

It turns out you can do that in the doctor's office. You don't have to have a hospital to make that work. It's interesting, however, that it now costs about two to three times to get the less invasive version than it does to get the traditional version. Yet, when you think about it, that doesn't seem right. It should be cheaper because it's faster, it's easier, it's more reliable, and it's higher quality.

Part of the problem is that it is approached in a component fashion, instead of in a systems fashion. Let's suppose there's somebody who makes the device, that is, this mesh screen. If you are the company that invented that, that's all you're worried about, and you convince doctors to try it.

From a health systems point of view, what you'd like to do is get a new system developed and designed concurrently. That is, you might need to have a drug that's going to help in some of the recovery process. You might need to have more than one device. That is, there might actually be some surgical tools, as well as some other things needed. You obviously need to have a procedure that is fast, trouble-free, and reliable--a kind of best practice, if you will.

But rather than thinking of those as independent things that emerge on their own when

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

people get around to it, this is what it means to opportunistically look at the system and really innovate in the system, not just in a single component or in a bunch of components serially, which I think is the more traditional view in health care.

Finally, the third one I'd add is that the opportunities to improve cost, quality, and timeliness using information technology. I view this as phenomenal in the health care industry. And they come in a variety of forms.

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

One of them is the form that Rebecca's been studying, in the exploration and discovery of new molecules. It turns out that one of Cray supercomputers' biggest customers is the pharmaceutical industry, because it's a whole lot cheaper to explore alternative molecules and drug possibilities by simulating and testing in a computer than it is to run through the lab animals and all sorts of things that would be the alternative.

But then it goes way beyond that. It gets into clinicals. How do you actually structure, gather, and analyze the data so that you're systematically folding the data together and efficiently analyzing it?

You could think about best practice. One of the fascinating things I heard the other day in a hospital was that they have developed what they call Kizan events. It's not unusual to go into a medical facility, or any business for that matter, and find if you had a clean slate you would probably do some things differently. We'd put a door in that wall, or we'd have Fred sit there, or we'd have Sally sit here, or we'd change the process.

The whole notion of a Kizan event is to spend thirty days getting ready to change the way you do a particular process, whether it's billing, admitting, or a surgical support area in the

**Institute for Alternative Futures**  
**Foresight Seminars on Health and Innovation**

PROCEEDINGS

operating room. And then, at the end of thirty days, you actually change it in one day. Then you have to go back and make sure that you “backfill,” if you will, and make this a part of the routine so that everybody thinks of it as the new way of doing it, as opposed to an exception. But you get tremendous leverage from doing that and you get it quickly. But you need data to do it, and that’s the point. The information technology is the way to deal with that. Well, those are just some of the possibilities.

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

I think the real challenge, from a policy perspective is to learn the lessons from other industries about system innovation as opposed to just component innovation: lessons about the role of information technology: lessons about mass customization with high reliability, the best practice notion. There are many opportunities to craft how a very strong industry will evolve over time, as opposed to letting it paint itself into a corner or even inadvertently painting it into that corner, at least in some dimensions.

Let me stop at that point.

And Jonathan, I think, is going to field questions for us.

MR. PECK: Thank you, Steve.

Many of us are about to participate in Kizaning health care. There's two things that strike me. Rebecca has given us this notion of innovation coming out of community, and Steve has pointed to this future where innovation has this systems dimension that we have to look at. To some extent, all of us are both part of the community of innovation and stand some place in the system. Congress is part of the system. Each of us in some way is in it. We stand there. How

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

do we change this in a way that gives us more innovation so that each of us on the consumer side gets what we want?

I think we've got some characteristics of that, but that's just my observation. And this is really for you. So what I'd like to do is have you direct questions wherever you'd like. I ask that you identify yourself. For members of the press, the speakers are on the record and others are off the record, unless you secure permission. So with that, we'll go to question and answer, and we can do that for approximately an hour. Let's see what strikes you, particularly those of you who have to try to make the policy relevance of this clear.

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

MR. SUNDWALL: David Sundwall, Medical Director and Vice President of American Health Care Systems.

It has been rumored for some time that health reform is going to slow down biomedical research extraordinarily. What we're famous for in this country's going to come to a grinding halt. I apologize to Dr. Henderson if I missed your comments earlier. You may have gotten to this, but I would really welcome the perspective of these folks if in fact that will happen, or if there'll simply be incentives for different sorts of biomedical research or technologies.

PROFESSOR WHEELWRIGHT: I'll take a shot.

That is probably the singlemost common complaint you hear if you're out studying product development in health care, product developers, medical devices, pharmaceuticals, that kind of thing.

It seems to me there are two scenarios that are very different as to how this might actually unfold. One scenario says that we are going to take the way we've organized the world now, the way FDA now does things, and we are going to add more detail, locking in everything

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

else. If that's the scenario that happens, it will absolutely take longer and cost more money.

The other scenario is that we have a chance to redesign using this systems view--to think about the FDA as part of the system, not something outside the system. So if you thought about how to get parallel paths going on in our early development that the FDA already in principle understands and agrees to, then we're in a much better position. And I can imagine actually getting much faster at product approvals of the right products.

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

I mean, you still have to go through the validation and everything, but that would require redefining the relationship between those doing the product development, the FDA and other government agencies, stepping back from the way we've split it up so far, saying, no, what we really need to do is to look at this much more broadly and bring all the relevant parties in. And in fact, the challenge that I will often give to companies is they ought to be proactive. They know a lot about their products, about the technologies. They ought to be out seeking how do they bring the FDA in earlier.

Their natural reaction to that is: "The last people I want in here earlier is the FDA." But I think the reality is that is what must happen if you want to get faster approval.

MR. SUNDWALL: Just to clarify the question a little bit, I appreciate that and I think we could use system design for the FDA, but the concern I keep hearing is that under a capitated system or whatever kind of limits you're going to put on health care expenditure, there's just simply not the opportunity', there's not the venture capital.

And quite honestly, I hear conflicting views. Has venture capital dried up or not. Is in fact the fear of reform or cost containment at the national level so great that we're really going to

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

stifle the innovators, the creators, before they ever get to the approval process?

PROFESSOR HENDERSON: Let me try one cut at that. It's certainly the case that fear of reform has changed behaviors; that is, that firms are concerned and are thinking much more precisely about what they're doing. I think in it's best sense, it's accelerated trends that were already there. That is, the firms I'm working with are very concerned to introduce therapies that have significant therapeutic benefit. They are thinking about them in terms of a life cycle cost-effectiveness perspective. Those changes are to the good.

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

In my view, any kind of reform that links pharmaceuticals much more tightly to their end health outcomes, which allow prices to reflect value in use--what they do, what people are willing to pay for them--is likely to encourage innovation and drive innovation.

And certainly this is something you probably hear a lot. But when you're actually talking to the scientists, they're on fire with the possibilities for the science and what could be done to make progress and to address conditions that have not been addressed before. And that drive is still there and still very much in place.

PROFESSOR WHEELWRIGHT: One other side comment on this is that in terms of the funding, venture capital typically funds the creation of new organizations, not the extension of product lines or the addition of new product lines to an existing organization.

My sense is that most of that funding comes through the organization's credibility in more traditional financial markets. That is, can they guarantee a stream of cash flow that would allow them to pay back the money they need to borrow? Are they generating enough cash to invest in these additional new products and things like that?

**Institute for Alternative Futures  
Foresight Seminars on Health and Innovation**

PROCEEDINGS

Building on what Rebecca said, I think there's such enthusiasm out there for the possibilities. I'm thinking particularly of, say, the medical device industry, where in the less invasive surgery, the number of possibilities is mind-boggling.

So I don't see a scenario where it's going to be hard to get money. It may be hard to create new firms, so you may have to do it through existing businesses who say, oh, we're going to have another division that is in that business. So you take a J&J or whoever it happens to be, and they add some other division. That's much more likely, I think, than creating new firms.

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PROCEEDINGS

MR. LEVIN: Peter Levin from Senator Mack's office.

We always hear, in working with young scientists, they are always full of enthusiasm about the next stage. And the drug companies have always liked to hype this. But we have just seen drug companies buy up one another and spend billions of dollars buying retail networks.

I'd like to ask both of you, from your experience in other industries, what happens to companies who decide, instead of putting their money into major innovation, they're going to spend billions buying dealer networks?

PROFESSOR HENDERSON: I'll start and Steve will go on.

It depends entirely how these networks are used. That is, the firms that I know well that have made this kind of acquisition are very concerned that they should use it, not simply because "now we own another business, like I am Burger King and go out and buy a chicken joint," but that the future of pharmaceuticals is in understanding how they're used and how they impact on patient health over the life time.

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PROCEEDINGS

And the scientists I've talked to are talking about how do we use that data to guide our research to understand what kind of drugs make a difference inside the firm? So it need not be a diversion. It depends entirely on how it's used.

I'm hopeful because in the companies--and I can't talk about who's in my sample for reasons of confidentiality--they hope to take the cross disciplinary skills they've learned in research and integrate the network into that cross disciplinary conversation. I'm sure we can tell horror stories. Steve will perhaps mention some of them.

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PROCEEDINGS

It need not work that way. I don't think there's any guarantee but there's no, from me, no per se assumption that it's a bad idea. It's not immediately clear it's a diversion. It may be very, very productive.

PROFESSOR WHEELWRIGHT: I think the real test on this issue of whether it's productive or not really has to do with will they change that thing they acquire and its value to society. If what they plan to do is not change it, then absolutely they overpaid for the asset and it's an old asset.

If, however, they take the perspective of, boy, here's a piece of the system that we've never participated in but if you took that piece--as well as the piece we are in--and you recombine them, you could get more efficient and responsive much faster. That is, there are significant benefits. This actually is the kind of classic issue in corporate strategy, which is, do you want to buy related, integratable businesses, or do you buy separable, autonomous ones.

MS. BOSCO: Lynn Bosco, the Agency for Health Care Policy Research.

A huge amount of innovation has gone on in biotechnology firms but the culture of

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PROCEEDINGS

biotechnology firms has to be different from a large pharmaceutical house. How do you perceive the future of the biotechnology firm?

PROFESSOR HENDERSON: That's a great question, and one that I was extremely interested in when I began my study. My initial hypothesis, going into the pharmaceutical industry, was that these firms had let biotech pass them by, and it was yet another example of hierarchical firms not responding to the environment.

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PROCEEDINGS

That changed. I came to believe that some of the firms in the industry--and I stress some, by no means all--had in fact reacted to biotechnology by incorporating the techniques of biochemistry and molecular genetics as tools for looking for new drugs.

So if one thinks about the fact that they were looking for small molecule drugs, they incorporated the knowledge which spawned the biotechnology industry into their organizations to look for commercial drugs. In the best managed firms in the industry, that has been done quite successfully.

What is much more difficult, I think, is the transition to looking for large molecule drugs themselves. That is, looking for biotechnology products as a drug. I think the jury is still out on whether the large firms can make that transition effectively. It calls on skills that they have not developed to date.

I think so far--and I want to hand it over to Steve because he's been doing a lot about this--it's not clear that main line pharmaceutical firms made a mistake in not aggressively pursuing large molecule drugs, for a couple of reasons. The first is that it's not clear that anyone has made any money in biotech.

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**PROCEEDINGS**

MR. PECK: Excuse me. First, could you differentiate small and large molecule drugs?

PROFESSOR HENDERSON: I'm sorry. Small molecules are non-biological product molecules. They're not very fragile, you can beat them up. You can swallow them and they're still okay when they arrive in your liver.

Big molecules are what the biotechnology companies make. They're usually the proteins that the body makes or variations on body proteins. They're much, much longer

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PROCEEDINGS

and they're much more fragile. They're much harder to make. You can't just swallow them usually, they're harder to find, and they're harder to develop.

Think about it this way. If you're looking for conventional molecules, you want to understand all the complex biochemistry. And if you're looking for small molecules, you want to find a small molecule that'll go in and just break the big molecule apart. That's what you're looking for. If you're a biotech company, you might be looking for a whole other big molecule that will come in and work in the body in a different way. I'm bastardizing the science.

(Laughter.)

PROFESSOR HENDERSON: So it's not clear that conventional pharmaceutical firms have sort of made a mistake here. If you look at money into biotech and money out, it's not clear that we've gotten a lot more money out than has been put in.

Secondly, a lot of the small biotech firms were set up for incentive reasons. That is, the large firms had problems paying the star scientists from academia the money they thought they were worth. Most star scientists wanted to get a return for their inventions, so it was more effective to set up small firms and exploit those individuals' insights.

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**PROCEEDINGS**

As the industry transitions to where this technology is much more routine and stars have less of an impact and it's much more business as usual, the question is still open.

Steve?

PROFESSOR WHEELWRIGHT: Actually, one of the studies we've been doing--with my colleague, Jerry Bassano--has been looking at development projects in eight different major pharmaceutical companies and a dozen biotech companies and what's different in terms of how they do it.

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PROCEEDINGS

I guess my view is exactly what Rebecca's is. I don't think we can conclude at all that the big firms should have done anything differently? than they have. Typically what they've done is they've funded a lot of the small biotech firms. Then they become the licensee in terms of manufacturing, distribution, and some of those kinds of things, which leverages their assets, makes it so the biotech firm doesn't have to duplicate those same assets, and makes tremendous sense from a societal efficiency point of view.

The other two things, though, that I think are characteristic of biotech, at least in our study is, one, that most of those organizations are still young enough to still have a lot of momentum from the university and non-business setting they came from. You take a firm like Tyron--where I've had some students doing a study, and we've written a case or two on them-- basically they still look a whole lot like the San Francisco State research lab that they started at.

And as they transition, then it may make sense for some of the pharmaceutical companies, who are larger and more traditional, to say, oh, we could acquire that company and bring something of value to them that they can't do right now. The other thing that's clear is that they behave like small companies, and they take chances with regard to FDA and other kinds of things that a big company would never take.

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**PROCEEDINGS**

That may be exactly what, as a society, we want them to do because it's such a new area, so many things have yet to be defined in terms of standards and things like that. But it's probably much more efficient to let little firms do that and put at risk their firm than it is to expect big firms to do it and put at risk all those other things they're doing.

MR. PECK: Thank you.

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PROCEEDINGS

MR. SIEGFRIED: John Siegfried.

I'm with what used to be Pharmaceutical Manufacturers' Association, and Pharmaceutical Research and Manufacturers of America. I have two questions.

One is that it's widely ballyhooed in the trade press that by the year 2000 or 2005, what we may well be seeing is a replication of the auto industry with two or three large manufacturers, a sort of General Motors, Ford, Chrysler type of situation, existing in the pharmaceutical industry.

I'd be interested, from your background and experience, whether that's a realistic anticipation and if it is, whether it's good or bad. The other thing that I just wanted to raise--as we look at innovation and it's something that concerns me greatly--is that, even without a health care plan in action or legislative action, the research spending, at least within the American pharmaceutical sector, for the first time in 20 years has dropped to less than ten percent. That, to me, is a great concern. I wonder what your feeling about that is in the total perspective?

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PROCEEDINGS

PROFESSOR HENDERSON: Let's take the first question first. My quantitative statistical results suggest that there are economies of scale in doing pharmaceutical research, but that they are not huge. So that any of the firms in the top twenty worldwide are easily above critical threshold.

So my results do suggest that the firms that are smaller than that are operating at suboptimal scale. That's particularly marked in the more recent data because the complexity and the sophistication of the science that's required to develop new drugs now means that you have to have peptide chemists and molecular kineticists and all these specialists.

it's now the

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PROCEEDINGS

It's really much more efficient to spread over a larger research organization. The big mergers we're seeing are operating at a scale beyond the critical mass research. And I'm going to turn it over to Steve to talk about what they might be driven by and whether they'll continue.

PROFESSOR WHEELWRIGHT: Two things.

One is the case of the auto industry. One interesting statistic is that even back 20 years ago, the number of viable worldwide participants in the auto industry was five. Today, it's 20 plus. So there are actually more firms.

Now there aren't more firms, period, if you think of whose nameplate you see today. You don't see as many U.S. nameplates as you used to. There used to be an American Motors, there used to be Studebaker. You used to have these other firms.

If you actually think about it, though, from a competitive interaction point of view, and who's viable in the long haul, the auto industry is actually much more competitive now than it was at any time in the past 20 or 30 years.

And I think one of the things that's likely to happen in the pharmaceutical and health care

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PROCEEDINGS

field is you are likely to get more viable players above this critical mass. Now one of the things that's a problem and a worry--and I will certainly add this as a perspective--is that a lot of the mergers aren't mergers because of scale, they're mergers because it's easier to solve a problem by merging than it is to solve it some other way.

Take the pharmaceutical industry, for example. There were a couple of studies done in the late eighties that basically said that every pharmaceutical in the world, every major company had twice as many plants as they needed and twice as much capacity. Now clearly

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PROCEEDINGS

that means you've got to shut a whole bunch of plants and you've got to reduce the capacity, or if you shut enough plants. you can leave the rest the size they've been.

In that case, a lot of the mergers--if you'll look at a Bristol-Meyers Squibb and what actually happened afterwards, for example--it was how do you solve the excess capacity/excess plant problem. It's much easier to do it after an acquisition and say, "Oh, we now have two plants in Germany and two in France. We only need one." So you just decide which is the better of the two.

So you've got a more efficient structure as a result of that merger but you didn't necessarily solve some of the other things that we normally think of as a merger helping. You've basically solved the plant problem, but you could have solved it other ways.

PROFESSOR HENDERSON: The second question is harder.

I think anytime an industry goes into a period of uncertainty, one would expect to cut back on innovation. And the question for me is, "Is the slowdown or the drop in the rate of growth more a response to the uncertainty--in other words, what is going to happen--than it is to

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PROCEEDINGS

a particular fear about any particular outcome?”

I'd really like to keep with Steve on this. I think one can write scenarios in which health care reform does have bad impacts for innovation. I don't think that's something to concentrate on, because something good could happen here for the industry. And I don't think anyone's talking about dramatic reductions in public funding for biomedical research, for example. And that's a classic input into research.

I think the fundamentals are there, the science is there, and the need for the therapy is there. As we think about the health care budget and where one could fundamentally make

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PROCEEDINGS

progress, innovation--doing things in a new way--is where it's going to be. But this is stuff you all must be familiar with.

PROFESSOR WHEELWRIGHT: I would actually add to that the notion that if you think of the pharmaceutical companies as having been spending--let's suppose it's eleven percent or whatever that number happens to be--the vast majority of research funds on discovery of new molecules, testing and then getting those to market approved. If you take the hypothesis I've put forward--which is that the industry needs to shift more towards system solutions--a lot of what a systems solution is not hard, it's not discovery.

One way to read what may be going on is we're making this transition and the industry hasn't learned yet how to count the stuff that is system-innovation focused. Because typically it's very clear in most major pharmaceutical companies that R means a very specific thing in the R&D equation, means certain kinds of people, means specific kinds of physical settings and doing certain kinds of things.

But if you accept the possibility that some of these other forms of innovation may actually have higher payback than concentrating it all back on the traditional R, then either

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PROCEEDINGS

you've got to redefine what you're measuring, or you're going to watch the R decline and D will pop up somewhere else, in the development of these more innovative delivery systems and all of that. But we may not be able to measure them, at least not in the near term. Over time, people will figure out how to do it, and as you look at mature industries, you can really see that.

PROFESSOR HENDERSON: Can I just add to that on the measurement issue? I have the R&D figures split between discovery and development and research spending--that

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PROCEEDINGS

is. looking for new compounds--has more than tripled in real terms in the last 30 years. Spending on clinical testing has more than quintupled in real terms in the last 30 years. So, I would be nervous about taking the aggregate figure and saying research is down and not knowing how it was being spent. Because, if what's happened is some of the late-stage phase three trials for drugs--that perhaps now are viewed to offer not such a significant benefit--have been canceled, that's very different from the discovery budget that is right back at the beginning, where new science is cut. So I think we really ought to know that split.

MR. COOK-DEEGAN: Bob Cook-Deegan.

I'm trying to understand, when you classify something as a high performance firm, it sounded like, maybe I've over-interpreting, but it sounded like there was a very tight coupling between that judgment and high success in new drug discovery.

If you took those two budgets apart, the D part and the R part, is there a tighter correlation between the R part and the drug discovery on the one hand, that is budget levels, or is that a management thing of how you spend those R dollars? Or are you saying that there's also been innovation in the D component?

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PROCEEDINGS

I just wanted to tease those apart because, for policy purposes, NIH is at the front end of the R process. FDA is linked to the D process and I'm trying to find out which thing is more important.

PROFESSOR HENDERSON: You're asking a number of questions here which I think are all excellent, so let me try and step through them one by one.

First, when I talk about high performing firms, I'm talking about--because of the state to which my analysis has got--high performing in discovery. So this is the high performing

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PROCEEDINGS

front end. Now there are firms out there that are high performing in the stock market sense, but have done it through other means, perhaps through end licensing compounds or through running development very effectively or excellent marketing. So there's not a one-to-one match between high performance and discovery and high performance in the stock market. I think that increasingly there'll be a tighter and tighter link so that it's high performing at the front end.

The second question is whether high performing in the front end is associated with many more research dollars, or is it an organizational thing. Let me tell you a story here. The story goes something like this. Thirty-five years ago, you could find drugs by having tanks of rats down one side of the room and just going down and sticking compounds into them. Now that's a caricature, but it's not too far off.

Twenty to 25 years ago, people start to learn much more about how the body works. And instead of simply putting things into a hypertensive rat and hoping blood pressure goes down, we can now say, well, "We understand the chain of chemical reactions that leads to hypertension, and we can look for a compound that breaks that chain." So instead of having tanks of rats, we have test tubes and we put the compounds in the test tubes and we look for

it.

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Foresight Seminars on Health and Innovation**

**PROCEEDINGS**

Some firms made that transition much faster than others. And firms that were starting to make that transition in the seventies are, by now, really up and running on that. And they're doing, I would submit, science which is, in some ways, as interesting as science that's going on in the public sector. Indeed, it's become necessary to do fundamental science in the firms to understand what the people in the public sector are doing. So that the high

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PROCEEDINGS

performing firms are running seminars, they're having placement programs, they're hiring the best Ph.D.'s--it's very, very tight linkage.

There's a fringe out there that's still sticking things into rats because that was the way to find stuff and it worked very well and we found a lot of good drugs. And it's taken a little while to say, okay, it's not working so well anymore so we'd better do things differently. So what do we do? There's a kind of wrenching adjustment process that some of those firms aren't going through well. That's one group.

There's another group that worked out that science was good. It didn't work out how you had to link the science into getting drugs, so you basically got great universities inside the firms, and there was wonderful science going on but no drugs.

So the very high performance firms are linking the science to the downstream to the system, so they are talking to the people in clinical development, they're talking to people in marketing--they have tight, interfunctional linkages. So the secret to the high performance seems to be, one, linking to academia and public science, and, two, linking inside the firm and the whole chain.

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**PROCEEDINGS**

And that's only intermittently correlated with spending a lot of money. There are firms out there that spend a lot of money. They've got great science and they may have generated a lot of public good in fact. For example, my statistical results suggest that there are very substantial spillovers across firms, so that even if I do not find many drugs, my research may directly benefit my competitors. Of course, in such a case I still might not deliver much for the stock market--but I would have created a fair amount of public value.

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PROCEEDINGS

So there is a linkage. All other things equal, you'd rather spend more money than less, and there are returns to scale. But managing it well is absolutely key and makes, in my data, as much as 50 percent of the difference between firms. So the organizational variables are as much as 40 to 50 percent of what's going on.

PROFESSOR WHEELWRIGHT: It's interesting. If you take another sector and look at something like medical devices, there's practically no R going on, it's all D. And basically they are great mechanical engineers who have figured out there's a whole side to health care that has nothing to do with drugs and chemistry, that has to do with mechanics. If you look in those firms, they're doing a tremendous amount of development, testing new products, trying new things. And basically they rely on--if they need a new adhesive or they need a new Teflon coating or they need a way to make a finer grade catheter, or whatever--they rely on somebody else to do that. All they do is they just make systems out of these mechanics.

So you can find a lot of different variations but the same thing would be true, that Rebecca said. It's management and kind of focusing on where can we add value. How do we add that value. And then being efficient and effective at it that makes the difference.

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PROCEEDINGS

MR. PECK: I'm going to take this gentleman's question, but I just want to take the prerogative of asking that we come back to Bob's question, because when you think of it from a policy perspective, you've got NIH and you've got FDA. And I'll just ask you to comment on both the community perspective of Congress, FDA, NIH, industry and the community and the systems perspective in a way that might help each of these people who create policy reflect on what they might do.

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PROCEEDINGS

With that, I'll give you the first question.

MR. FEIN: My name is Oliver Fein. I'm with Senator Mitchell's office. I was interested particularly in your sense of a public community in science. It is very unusual, it seems to me, in this country, that we talk about innovation coming out of the public sector, or in any way being associated with the public sector. Everyone tries to take things from the public sector and put it into the private sector, so that one can be more innovative.

Could you talk more about what I think is in fact a very good and real dynamic that we should learn from and perhaps extend beyond just the issue of biomedical science?

PROFESSOR HENDERSON: When I first started working in pharmaceuticals, I was amazed at, in the higher performing firms, the willingness of individuals to look outside their organization and across scientific disciplines. It was quite different from any other industries I've been in.

And I said, what's driving this? It seems to me clear that there are two things that are driving it. One is that we don't know enough about the human body and medicine to be able to

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Foresight Seminars on Health and Innovation**

PROCEEDINGS

split it up into pieces yet. That is, we can have door handle engineers because we pretty much understand building doors, but if I'm looking for an antidepressant, I know that anything I put into the body is going to have effects elsewhere.

And so my problem, as it were, is constantly reinforcing. I need to reach out across what I know. I can't be satisfied. The second reason, it seems to me, was the embedding of the industry in the public context. This takes two forms. The first was the fact that a lot of people working in the industry have a long history of lives as academic scientists and many of them evaluate themselves and their success on the basis of their standing in the academic

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Foresight Seminars on Health and Innovation**

PROCEEDINGS

or larger public community. That gives them incentives to publish, it gives them incentives to communicate what they learn, and to reach out away from their boundaries.

I've been in firms where they say, you know, "We are Joe Blogg's pharmaceutical company. Joe Blogg's first and foremost. I don't publish, I don't want to tell them about what I do." But the high performing firms, they say, "I am a molecular biologist specializing in Y, and let me show you my academic appointments and the publications." That's a source of pride. So the individuals have an ethic that reinforces not focusing just on the local area. And I don't want to miss that benefit, because I think a very strong public sector provides and reinforces those people.

The second thing is the creation of science. I think it's easy to fall into caricatures of the relationship between public and private science. One caricature is that all the great discoveries were made in the public sector. The pharmaceutical guys come along and they just take the molecule and make a ton of money and there's nothing really to it.

The other caricature, and I've heard both of these, is that the public sector guys, they have no clue about reality. They showed a reaction once but they don't understand what it's like

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Foresight Seminars on Health and Innovation**

PROCEEDINGS

to really make a drug that works in someone. They're just clueless and they think they're doing great science but we just follow after them and we do the real stuff.

I really think the reality lies somewhere in between and that the moving back and forth between public and private is enormously fruitful. I'd caricature myself here, but in the public sector, we've got a lot of fundamental investigation of the basic biochemical mechanisms inside the body. Why do I get depressed? Why do I feel anxious? Not to speak to the current moment.  
(Laughter.)

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Foresight Seminars on Health and Innovation**

PROCEEDINGS

PROFESSOR HENDERSON: Why do I feel anxious? What is the biochemical reaction? The academic scientists have the freedom to look and to understand, and they are trying to find, in a sense, those chemical reactions that we can then try and find ways of interfering with. Now a lot of that work is also going on inside the firms. So, as I said, they understand what the public guys are doing. But they are trying to translate that scientific knowledge into entities that can then have therapeutic effects, and that's not trivial at all. There's a lot of very sophisticated science in finding a compound that will interfere with this chemical reaction that will survive its transmission through my body and that won't create other side effects.

And there's a movement, to and fro. As I was doing case studies of drugs, I would come across scientists that would talk to their colleagues who would publish and go to conferences and the flow of information was very much two ways. I think that's one of the very outstanding successes of the U.S. economy and that's a strong statement to make. But coming from an economy where so many of the large firms are sliding into the sea, and finding all this dynamism rooted as much in the public sector as anything else, it's just tremendous. And, as you can tell, I'm excited about it.

PROFESSOR WHEELWRIGHT: Let me, if I might, just pick up on one of the things

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Foresight Seminars on Health and Innovation**

**PROCEEDINGS**

Rebecca was saying and add to it. That's just art versus science.

I think there's been a misnomer often times in the health care field that university researchers and others always want to be "a scientist." I mean, the goal is you don't want to be called an artist. What kind of recognition is that if you're a faculty member and everything else.

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PROCEEDINGS

But the reality is that health care is so complex, as Rebecca was describing, and there are so many parts that we don't understand, that it really is an art. What it means is that the best researchers may have great scientific discipline but they're also great artists. They get connected. They understand how things come together and how things begin to interact. They may not have a clear picture of it, but they've got a better picture than you or I might have. That's really where the leverage is.

Maybe 20 years from now, we'll have segments of it that are enough science that we'll start to draw lines. I would hope that actually won't be the case because the other thing that I think has happened in the industry--in the community, if you will--is that often times people specialize around the things that they're best at.

The university is best at doing certain kinds of things, NIH is best at doing certain kinds of things, firms are best at doing other kinds of things. And it doesn't tend to be R in most cases. Now where you have so much art and so much interaction, you need a much more collaborative approach to it. I actually think that the model that we seem to be headed towards is continued collaboration. We'll actually see other industries pick up more of that because it really does make much more efficient use of resources.

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Foresight Seminars on Health and Innovation**

PROCEEDINGS

MR. PECK: If you put the Congressional staff and Government agencies and FDA and NIH into this collaborative model, are there implications for public policy in terms of thinking about systems knowledge and how to approach this?

PROFESSOR WHEELWRIGHT: I would see two things that are very obvious. These are narrow and it has to do with my experience as to why I mention these two. One is in the approval process. It seems to me it makes great sense to think about approving the

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PROCEEDINGS

system as well as the specific component--not just approving the component and then letting these people use that component in that system and these people in that system, and guess what? It's twice as effective over there as over there.

I think there's an opportunity in terms of public policy to actually encourage best practice and the transfer of best practice by looking at both the system that the component's in, as well as the component. I think we're still going to get most companies to focus on the components.

The other thing that I think is a possibility is--if you look at how most industries have tended to restructure over time, transitioning from a component focus to a system focus--the system they ended up with was very different than the traditional system. It tends to not be the result of having one smart group of people think through what's the right system and then just execute it. It's much more a trial and error kind of thing. If you actually look at an industry, you'll see some people trying to redefine the system that way, some that way, some another way.

I actually think we're going to have to allow that to get to the right system. That is, we're going to have to let the right system emerge because it's too complex for any one group of people to predict what is absolutely the right system. Take something like a hernia operation and

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**PROCEEDINGS**

all the pieces--you have to let some people go down one path and some go down another. Now you want to have some limits and controls but you also want to encourage that.

MR. PECK: I was thinking of a forum, not a hernia operation, but perhaps the lessons would cross over.

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PROCEEDINGS

Questions?

MR. HELMS: I guess I would want to ask Professor Wheelwright. I liked your statement that people need to look at systems and there emerging in marketplaces. In other words, what you're saying is that the market really determines what's effective and so on.

PROFESSOR WHEELWRIGHT: And the best way for them to interact.

MR. HELMS: But suppose I take this, Jonathan's notion about what public policy has to do with this. Suppose I interpret this as some people are discussing now, that instead of the FDA concentrating on components, they get into the business of regulating cost-effectiveness studies. And suppose they do this under the guise that they're going to look at approving the system? And they turn out to act like the bureaucrats that we all criticize over there because they've always had a narrow viewpoint and their incentive structures within the FDA is sort of, you know, don't take the chance. If there's any doubt, wait, or don't approve it.

I guess what I'm wondering, I can see the FDA deciding to go with the systems approach and backfiring, and what you'd really get is much more foot dragging.

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**PROCEEDINGS**

PROFESSOR WHEELWRIGHT: In fact, I can imagine a scenario where, if you said we're going to take a systems approach and we're only going to look at refining existing systems and getting everybody to use current best practice, you'd actually head towards this dead end. Eventually, you wouldn't get any improvement and you'd need a whole step change to get the next right system.

So, for example, if you take the traditional hernia operation, you could have so controlled that as FDA in terms of that system that nobody could try a less invasive type of

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PROCEEDINGS

solution system. I think what you need to do, though, is you need to say, look, there are different objectives and we'd better have a different process for accomplishing this objective than that one.

I don't think you can get to best practice using the same exact set of standards and procedures as an FDA organization. You can't get the best practice the same way you'd get to exploratory discovery of a new thing. So you may well need two systems and you may well need to make it possible for people to say, well, "What we're trying to do is X. It's on this innovation side. Let's have a set of rules that do in fact make sure that it's thoroughly tested and everything else." That allows them the ability to get all the elements right and kind of create a new path to go in.

That's a very different set of procedures than "Okay, you want to do an enhancement to an existing process by tweaking this or tweaking that." Then we need a different process to control that, to make sure that it's validated before we go ahead and put it into the public.

So I think you're going to end up with needing multiple systems as opposed to one-size-fits-all. It's not going to work if you try the one-size-fits-all.

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PROCEEDINGS

MS. BOSCO: It seems to me that during the past few years, a major question--why, in the strategic planning and all that the industry does, did the pharmaceutical industry not, were they not able to catch this current, the flattening increase; no longer a ten percent increase per year?

It took them a while. Why would you think that they didn't think of that?

PROFESSOR HENDERSON: Three years ago, I was at a conference actually hosted by what was then the Pharmaceutical Manufacturers Association. I was the second speaker.

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PROCEEDINGS

The first speaker was the public relations consultant who defended the oil companies during the oil crisis. He stood up and he said, you guys are the oil companies of the nineties. This is going to get rough. You know, you haven't gotten your story across. People see your prices are too high, and everyone looked at them and said, "Oh, yes, really?"

I think it's hard to perceive sea changes in the environment in advance. And there were individuals within firms who clearly saw how things were going to shift. But it takes time to refocus the organization.

PROFESSOR WHEELWRIGHT: A similar conclusion, but another way of thinking about this is that any organization has multiple forces acting on it. Some of those forces have to do with quarterly earnings or investment analysts' reports. There are a whole bunch, you know, of quarter to quarter improvements.

Not to pick on pharmaceuticals, but in that industry there were a whole set of forces that, for a long time, they paid the most attention to, which had nothing to do with, "Well, wait a minute, what does this look like on an inflation scale, you know? And how does it compare with real inflation and things like that?" What's happened is those other forces had to get a loud

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PROCEEDINGS

enough voice that the industry said, “Oh, you’re right.” In fact, I heard a CEO of one of the companies try to convey to some managers about the reality of pricing in the industry, and he says, “Look, the test you want to use is to take our new drug, whatever it happens to be, and I want you to go home and sell it to your grandmother or grandfather or your parent, who is 20 to 25 years older than you are, on why they ought to pay this price.

He says, “If you can’t do it, then we need to make some major adjustments. He says, “Now if you can do it, we may still need to pitch the message a little differently, but

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PROCEEDINGS

that's different. You know, I think there are some realities that are now coming into sharper focus. And one of the things that the industry needs to do is make sure it's being responsive and amplifying the driving forces that are really going to shape the future. It hasn't always done that in the past.

MR. MCDONOUGH: Bob McDonough from Upjohn.

If I could just comment on that as well. I have done my own little project within the industry over the past few years, and this goes to what both the speakers have talked about, the systems and some of the disconnects.

We thought we had a very well-connected company and I think most people did too. But I've gone around asking people at Upjohn and asking people from other companies, what's the daily cost of your product? Of this product in your own company? Most people didn't have any idea. I mean, I know that sounds incredible but it's actually true.

The other side of it is, for most of our products, the most expensive one, other than a fairly sophisticated antibiotic that you'd only take for a few days, costs \$2.25 a day. So it's a

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PROCEEDINGS

percentage increase. You're still talking about pennies a day and that's not something that's necessarily going to translate and get any triggers any place, even if you're looking at it.

I mean, if you're looking at the whole system, you say, well, it's 25 million people spending two cents a day. That's a lot of money, but that isn't how the process works. That is not how the distribution system works. So you can do real funny things with percentages and increases in sales that don't necessarily translate into what the reality is often.

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Foresight Seminars on Health and Innovation**

PROCEEDINGS

MR. SIEGFRIED: You're all being much kinder to the industry than I would have been and I'll talk about it afterwards. I wanted to go back to a comment earlier and raise the question: in this whole process of innovation and where we are, how you would see the effect of the current trend to write practice guidelines, which in fact may well be stultifying to innovation. We're really saying this is the way and if you deviate from this way, we won't pay for it. In fact, newer drugs, therapies or treatments aren't going to fit into that until somehow they have been proven cost effective. And the opportunity for that may be very limited because of the whole health care system we're now operating in.

Could you comment on that, please?

PROFESSOR WHEELWRIGHT: I guess picking up on a comment I made a few minutes ago, it seems to me that refining an existing practice in order to get better practice is a very different animal than creating a whole new reference point, a **new** system solution that you're then going to have to do that series of refinements to. And we need to have a perspective that says we need both. If we put everything under one set of procedures that simply refines the existing system, we're painting ourselves into a corner and you'll end up with, well, "We're very good at this but, you know, five years ago, if we'd gone with this other system for how you

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Foresight Seminars on Health and Innovation**

PROCEEDINGS

accomplish the same end, we'd be far better off than sticking with this older one." So I think what it really requires is that we think of multiple procedures for how do you get something approved and what is it you're trying to approve.

Are you trying to create a new system that you want to get good enough but it's reasonable to have the public start making use of it, and everything else. Or are you trying to refine an existing system in which you may have done this procedure millions of times?

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PROCEEDINGS

And so you have to think about both of those, but you have to think about them separately. And in fact, companies who are most effective at incremental innovation do it quite differently than the breakthrough kind of innovation. So it's a matter of recognizing those differences and supporting the possibility of which is it. Is it this or is it that, and having some guidelines for what goes where.

MS. TESKE: Judi Teske from Amgen.

I guess I'd like to go back to the first question that David asked on the impact of health care reform. Not just health care reform in terms of what might come out of the Congress this year and next year, but the health care reform that's going on as we speak. Managed care focuses--contrary to what you're talking about--a systems approach where a lot of people are looking very definitely at the pharmaceutical bottom lines or at the cost of pharmaceuticals.

Compared to what? Compared to the rest of the system costs and how you might be helping in fact to decrease hospitalizations, that kind of thing. I've heard a lot of wonderful information in here about studies and so on but I really haven't yet felt that we're at the corner of understanding what the impact of all these things is going to have in the future. Because I come

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**PROCEEDINGS**

from an industry that is unlike the large companies that you've been studying or a smaller biotech company. We're a large biotech company so we're kind of an interface in a strange place. But nevertheless, we started out as nothing 14 years ago, and we are among the success stories.

What I'm worried about is the companies that are right now still at that bubbling up stage. Great scientists, great science, wonderful things--but they don't have a product to sell

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PROCEEDINGS

yet. And they are--and I know some of you are here from the Biotech Trade Association--having tremendous problems attracting the kind of financial resources that they need to continue.

So they are right now dropping back into research in some of these areas that your paper talked about. And so I think this is something we should all be very concerned about. I know there's a lot of different competing interests here. All of us have an interest in finding out how to do things more conservatively in terms of cost and so on, but compared to what is the question.

I don't want to save money at the expense of saving lives. I certainly know that's what we're dedicated to, and I assume all of us in the room care about that. So there's a lot of tensions here that we haven't yet teased out of this discussion about the impact of health care reform in the broadest sense of the word on innovation on where the rubber hits the road--where we've got people that have the resources to take those uncharted paths, not the best practice but the uncharted paths, which I think we want, at least certainly that's what I want.

PROFESSOR HENDERSON: You raise some very difficult issues, several of which I

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**PROCEEDINGS**

don't know how to address. Let me start with the easiest one. By the very nature of research, it creates a problem in the marketplace, as it were.

Imagine that I'm trying to find batteries that don't pollute the environment. I do a huge amount of research. I introduce it to the market. My competitor next door tomorrow takes my design, makes the same thing, and then we beat it out.

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PROCEEDINGS

That's what patents were originally designed to protect, designed to give you a limited control over your ideas, so you can get a return from them. One of the issues in pharmaceuticals is that some products are quite easy to copy. Someone can do all the basic science and I can come along and say, "Well, that's a nice idea, why don't I make this small change and I'll introduce a drug." Not all me-toos are like that. Some so-called me-too drugs are the result of both of us working hard on the science and getting to the same place at about the same time.

But sometimes it is possible to make modifications to the first compound and introduce a secondary compound. If what we get--and let's call it health care reform in the broad sense--is a firm like Kaiser saying, "I'm not going to give you more than the manufacturing costs for this drug, period." That will, by definition, crucify innovation. It must.

Now, clearly that's a very extreme position. I'm less pessimistic than you are in that I think there is a concern with getting people healthier and having drugs in the long term. I think as long as we're giving some return to innovation, there will be innovation. Now we're right over the borderline though into very difficult questions, which is what is the value of the treatment. I don't know how to answer that.

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**PROCEEDINGS**

I think that we haven't yet had a political debate about that. But I was trained as a neo-classical economist, which is a branding that I haven't quite shaken free of. But if we can get a price for drugs which reflects their value to people, then we have no problem in funding innovation. How we say what is the value to people is a huge debate that I don't know how to address.

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PROCEEDINGS

PROFESSOR WHEELWRIGHT: In fact, if you think of the traditional kind of supply and demand curve kind of theory, generally you've relied on the markets in most industries to set a price where sure enough the industry manufacturing and having done the developments says, "Yes, I can sell enough at that price to make a good return on the investment I've already made." And in the market there are enough people who say "It's worth more than that price to me. I'll buy it."

Of course, there are some people that say, "You know, if you'd lower the price by ten or 20 percent, then I'd buy it too, but I'm not going to buy it if you're going to keep the price up." I think part of the challenge in the health care discussion is who's going to set that price. And are you going to allow variable pricing?

Because in every other industry you look at, there's lots of variable pricing. In fact, that's what allows many industries to expand dramatically, by saying, "We're going to marginal price down here for these people, then we're going to do this other kind of pricing up here."

And sure enough, the ones who buy it down here are trying discriminate in the marketplace to those who value it highly and those who don't. But they want to sell it to both.

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PROCEEDINGS

One of the major challenges in the health care debate, which I certainly don't have an answer to, is: are you going to have a single price? Because, if you do, now you've changed the whole basic economics of the company because if you set it low, they say I'm not going to innovate, it doesn't pay. If you set it high, they won't have enough volume, even though they're making a very high margin, to get a return on the \$200 million or whatever the number is they spent to develop that new drug.

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PROCEEDINGS

If you allow discriminatory pricing, then you've got a whole fairness issue, especially if the market's not setting it. Now we live with discriminatory pricing all the time. Any time you get on an airline, if you compare what you paid for your seat and what I paid for mine. You know, that's kind of a classic issue right there, but I think health care is a much more complicated one in terms of who's going to decide whether or not we have discriminatory pricing and who's going to decide whose value sets the price level, if we have a single price level.

MR. SUNDWALL: I can't resist making a comment on that because it's so relevant to the debate going on right now, because in fact retail pharmaceuticals and drug store chains have an amendment. They have a position in the Clinton bill that would in fact guarantee them discounts we give through our purchasing groups. This seems a little antithetical to the market based way it's being sold, but it's fascinating that they're just trying to just get away from that discriminatory pricing.

MR. HELMS: Just to continue with this, economists call profit maximizing--be it via multi-pan pricing or price discrimination--being able to sell at different prices along the demand curve. I would contend that is going on to a certain extent in the international market in the sense that the big, relatively free U.S. market drives the incentives to innovate by the big companies.

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PROCEEDINGS

Most of them are all international and it seems to me it's logical for them to approach a country like Spain, France or Portugal and say, "Well, the margin, as long as I can negotiate a price--even if I'm doing it in the regulatory scheme--covers my manufacturing and distribution costs. It allows me to make more money. But if you then anticipate that the U.S. market is now going to be price-regulated, it seems to me you

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Foresight Seminars on Health and Innovation**

PROCEEDINGS

certainly changed--I guess in Rebecca's terms, you know, if you put that kind of regulation on, it would certainly kill innovation.

PROFESSOR WHEELWRIGHT: In the U.K. now, the government basically pays the lowest price available in the market for that drug. Now that means if I'm a pharmaceutical company, and I allow my Greek subsidiary to sell into the U.K. market, the U.K. government can decide to pay me on all my product what the Greek subsidiary is charging for it, which then changes the whole market dynamic. That's basically what I think Dave was talking about in terms of if we give the same discount to everybody, you've changed the whole equation and the world looks very different.

MR. PECK: So we've got a global system. That's probably a good topic for another day. I think at this point, we've come to the end of our time. I'd like to ask each of you to be thinking about the systems concept, the community concept and the nature of innovation and what we hope for, because people in this room have a lot to do with what we create.

I'd also like you to leave with great thanks to what I think is a wonderful panel, definitely two of the smartest people I've talked to.

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**PROCEEDINGS**

(Applause.)

(Whereupon, at 2:00 p.m., Thursday, June 9, 1994, the seminar was concluded.)