

Programme OPERA – ENTRETIENS

Entretien – santé n°8

Pour citer cet entretien : Beaussier, Anne-Laure, Entretien santé n°8, Programme OPERA (*Operationalizing Programmatic Elite Research in America*), dirigé par W. Genieys (ANR-08-BLAN-0032) (*insérer hyperlien*).

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Interviewer: Okay. Maybe my first question will be about your current position here and maybe how you arrived here.

Responder: Okay. My current position is, I am the Vice President for Health Policy within the Government Affairs and Policy Department here at Johnson and Johnson, and it is a global responsibility, so not just the US, but other countries. Our focus in my group is being proactive in interacting with government around different changes that we anticipate or that we are, you know, already engaged in and we know are going to happen.

So, we have a special expertise in the area of reimbursement.

Okay, reimbursement.

And also in Medicare and Medicaid, because a number of us came from working in the US government.

Okay. Okay. And maybe how-- why did you choose to come here?

Oh, how did I get here? I was in touch with my former colleagues from government who-- some of whom were here, at Johnson and Johnson, and when I decided to leave government, they asked me to come and speak to them about a position here, so I was first, you know, a good part of my career was spent in Medicare and Medicaid, then I went to the Congressional Budget Office, which is a Congressional agency, and worked on the Medicare drug benefit, which was a new benefit which was being introduced in Congress, and then passed, and then, as I say, I was in conversations with former colleagues who were working here, and they asked if I'd be interested in a position here, so that's how I ended up here.

Okay, thank you. I would-- if you agree to describe to me your former position, maybe in the healthcare financing administration, I have seen that you have been the Director for Policy Development and then Associate Director for Policy, so what was your role in that period, and what reforms were you specifically involved in?

Okay, so, as the Director of Policy Development, my responsibilities were in the reimbursement area, in the coverage of new benefits, under Medicare. Also, in what are known as the waiver programs, these are programs that allow the states or, in particular, the states-- these are state waivers, to experiment beyond what the statute or the law would permit. So, an example would be providing home-based care to people who otherwise would be in nursing homes or long-term care facilities.

Or, providing managed care options through HMOs, rather than the traditional delivery system. So, those are examples of-- these were Medicaid waivers. Medicare coverage was, for example, "should Medicare cover heart transplants, should Medicare cover some new technology." Those were the kinds of coverage decisions we dealt with, and then reimbursement was the DRG systems, the Medicare physician fee schedule, and we also had responsibility over the health and safety standards for hospitals, nursing homes and other facilities.

So, that was the Director of Policy Development, so the Bureau of Policy Development had a very broad scope, and then when I became Associate Administrator for Policy, that position reported directly to the head of the agency, HCFA, and it had responsibility for the Bureau of Policy Development that I just described, but also the research and development functions of HCFA, and those were both research on the Medicare side and research on the Medicaid side.

And the Office of the Actuary, the chief actuary, is the person who makes the long-range forecasts for the Medicare program, 75-year, how long will it take before the trust fund goes-- requires-- goes into deficit, that kind of thing. So, again, that had three units in it, of which one was the Bureau of Policy Development, another was research and development, demonstrations, and the third was the actuary's office.

Okay. And you were Director of Political Development in the early '90s?

Yes, policy development, yes.

And around 1970--

1997? Yes.

Okay.

I can send you-- or give you my resume, my CV with all the dates on it, because I don't remember the exact dates, but during the '90s, you may remember that that was when the Hillary Clinton health reform was going on, 1993, '94, and I was involved in that, and I co-chaired a working group that was in charge of short-term cost controls.

Working?

Group on short-term cost controls, with David Cutler, he's a professor at Harvard right now, and he was an advisor to President Obama during the campaign. So, he's an economist. He was the outside person, I was the inside person. Every working group had a government person and an academic, or an outside advisor, and he was the outside advisor.

Was it part of the task force, the (inaudible)

Yes, we were all part of the task force. The task force had several working groups, I think it was five or six, and we were with one, and I belonged to another one, which was on the global budget, and that was chaired by Larry Levin, I think his name was, L-e-v-i-n, and Sherry Glied, G-l-i-e-d, co-chaired that one. So, there were a number of different working groups.

Okay, Sherry Glied.

Glied. They're both economists. Larry Levin and Sherry Glied.

Economists, okay. So, what was your activities in this working group, and how did you participate? What different ideas was discussed?

We were in charge of trying to figure out, well, the way the health reform legislation was designed, it would be a delay of two years before the new system would go into effect.

Right.

We were asked to come up with an approach that would restrain growth and costs for those two years, because if you think about it, the belief was that unless there was some constraint, that all of the stakeholders, all of the hospitals, the doctors, the manufacturers of drugs and medical devices, etc, would raise their prices in that two-year period, because they would anticipate the new system would put more pressure on pricing.

So, the concern was that costs would go up very fast over the next two years until the new system came in. Our job was to come up with various approaches for putting constraint on those costs, and the approach that we used was, we really discussed a number of different approaches. What had been historically, like wage and price freezes. We looked at other possible ways to constrain costs, like putting a limit on premium increases in healthcare finance, and we also looked at imposing government rates on private sector providers for their care in order to keep down prices.

So, those were sort of the approaches we looked at. In the end, we talked about, and it was based on a series of presentations to the-- there was a group of senior advisors at the level of the President's cabinet, and we would present these various options and get questions, and further work was done and so on and so forth. In the end, we moved in the direction of putting a-- some sort of restraint on healthcare premiums, but we didn't actually build that into the legislation.

It was a consideration, but in the end, I don't believe it made it into the final legislation. It's very-- as you can imagine, it's very controversial to cap increases in premiums. So, but that was our job.

Okay. Would you remember who supported these various options, or what kind of group of people or--

We didn't have the same-- in fact, one of the criticisms of the Clinton approach was there wasn't enough conversation with the stakeholders, for example, consumers, insurance companies. The insurance companies mounted a campaign to defeat the healthcare bill, so there wasn't much interest in collaborating with them. So, I think one of the criticisms was, not enough input was taken from those who were affected.

It was more of a discussion about what was practical and what could be done, and I think the thinking was that as soon as the legislation was introduced, there would be lots of interaction with interest groups before the legislation was ever passed. So, I think that's the way they approached it, I think the Obama Administration concluded that was a mistake, that they should have brought people in earlier to the discussion in framing the legislation, and that's, in fact, what was done in this set of efforts, bills that were developed.

Okay. So, you talked with experts?

We talked with experts, we got input from people within our agencies, as well as-- we relied a lot on the literature as to what different techniques would work, and that sort of thing.

Okay. I'm sorry-- I have a bit of a problem. I think I get somewhat--

Let me see if I have a-- we might have something. Try these.

Thank you so much. Okay. So, experts within the administration, the--

And some outside experts, because obviously, there were a lot of outside experts who were participating in this task force.

From think tanks or foundations--

Academics, as in, David Cutler was on-- was there from Harvard University, I think, they had, you know-- Paul Starr from Princeton University, there are a number of people who are-- who were associated with children's programs and so on. It was just a number of outside people who were involved.

Okay. Would you say that the Harvard University people was-- were very involved?

I wouldn't-- I mean, I can't remember. It was 14-- 16 years ago. You could probably go to the public record and figure out who was-- there were 500 people named, and it's-- the lists were out, so you could figure it out.

500? For sure.

Yeah, so they were from a lot of different places.

And-- because I have tried to find these task-- working groups on the public record, but I had a lot of trouble to find--

I don't know if the working groups were ever published. Mostly, the working groups were-- I'm trying to remember who was on our group. It was a mixture of agency people and some

outside experts and that kind of thing. Yeah. So, I think if you looked at the list of 500, most of the working groups were made up of the people on that list. Precisely who was on which group, I couldn't tell you.

Maybe would you remember just who were-- what were the other groups?

Oh, gosh. I don't think I can. There was a global budget group, I remember. There was one on, I think, the workforce, so, healthcare workforce, that kind of thing. But, you know, I just don't remember. I think-- you could try Googling this, because it's hard to believe they wouldn't have some record. There was actually a lawsuit. You might be able to get the records from the litigation. The task force was sued for violating-- I don't know if it was the Federal Advisory Committee Act, or something, where these kinds of groups should be made more transparent in their proceedings and so on and so forth.

So, if you look in-- there was a lawsuit, and I believe there were a lot of documents that were provided in that discussion.

Sure, I will, I will work on it. And after the Clinton healthcare-- after the debate, were you involved in other reform, for instance, the SCHIP, Balanced Budget Act?

I was involved in the Balanced Budget Act, but not SCHIP, per se. The Balanced Budget Act, a lot of that had to do with reimbursement changes, and so for that reason, a lot of that fell into my organization's, you know, responsibility, and so, if you'll recall, I was the Associate Administrator at that time, so the direct responsibility for a lot of those changes were in the Bureau of Policy Development.

Okay.

But, somewhere around 1997, and I can't remember exactly when the BBA was, but our agency was reorganized, and our-- we did away with the Associate Administrator, across the board, those were eliminated, those positions, and then created centers, or divisions, that were different, they were more of a matrix. So, under the old system, most Medicare policy fell-- Medicare policy in the fee-for-service area fell under the Bureau of Policy Development. A lot of that was preserved, but we changed it, and we merged the Bureau of Policy Development functions with the Office of Managed Care.

So, the Medicare health plans joined with the Medicare fee-for-service changes, and we renamed it the Center for Health Plans and Providers, so it was called CHPP, and Bob Berenson was the Director, and I was the Deputy Director of that, and we had a-- remember I mentioned the benefits, or medical coverage was in our organization and the Bureau of Policy Development. That got moved, in the reorganization, to the Office of Clinical Standards and Quality.

So, now, you moved Medicare coverage out, and Medicare payment was in a different place, so they split those two. The thinking there was, they didn't want to leave the impression that concern about payments would drive our decisions about what, clinically, should be covered by Medicare. So, they wanted to separate those two, and they wanted to bring managed care and fee-for-service closer together, because the organization was-- we had better resources, if you will, in the fee-for-service side, so we had more people, and the thought was, if we

wanted to give them equal consideration, we needed to have them together in the same organization.

Equal-- that's an important change, because that's an important change in the course of Medicare, of the program.

Yeah, and the concern that drove that was a concern by our Administrator, Bruce Vladeck, who worried that if we left the Office of Managed Care on its own, that there was criticism, by Republicans, in particular, that we were not resourcing the Managed Care Office enough, and the reason was that it was viewed by them as privatizing Medicare.

So, the reason it's the Office of Managed Care is that, instead of directly paying for services through vendors, we pay private insurance companies to provide a-- more of an HMO-like package, and Republicans tend to like that, and Democrats tend to be concerned about that, because they feel like it breaks the bond with Medicare directly, okay?

So, Bruce felt, by bringing them together, we were signaling that it was an important part of the program, and that we were going to resource it appropriately. When Clinton left office, the Republicans came in, George W. Bush, and the head of the agency actually-- Tom Scully, was his name, decided to break managed care off from fee-for-service, to go the other direction, and to create its own office, its own unit that was strong.

So, he decided to strengthen it, but to break it away from the traditional Medicare. He did that because-- for a similar reason that Bruce brought them together, and that was that there was somebody in the Assistant Secretary's Office at HHS, who is now Governor of Louisiana, Bobby Jindal.

Bobby Jindal?

J-i-n-d-a-l. Bobby wanted to create a separate agency for the private part of Medicare. He didn't trust the government-run organization. He wanted to create more like a private-sector entity to run the private part of Medicare. So, Tom, who did not agree with that position, felt the way to combat that view was to set up a separate center and strengthen it, and add resources to it, and he called it the Center for Beneficiary Services, CBS. I think that's right. Center for-- I think it was Center for Beneficiary Choice, CBC, is what it was called.

That way, he made it co-equal to the fee-for-service part, but he made it a stronger organization than just-- than it had been before it was merged in with the fee-for-service part. It's a little hard to follow, but--

No, it isn't, it's so interesting.

They-- it really goes to philosophy, and whether you treat managed care and the private part of Medicare equally or not, whether-- and there's been a feeling on the part of Republicans that it hasn't gotten equal treatment over the years, and now, of course, in the most recent health reform, the additional payments that went to the private side, to Medicare-advantage, those have been substantially cut in health reform and used to help fund the expansion of coverage for everybody.

So, right now, under Republicans and George W. Bush, there were increases provided to those private plans that made them more generous than the traditional Medicare program, and they could offer things like eyeglasses and hearing aids and physical fitness programs and things like that, wellness programs, that made them very attractive to Medicare beneficiaries, especially the younger elderly.

Okay.

So, the Obama Administration has again decided they, again, the Democrats have always been less excited about this private side of Medicare, so they have done-- taken a major cut in the payments to those plans. Now, a major cut only makes them sort of equal to the equivalent fee-for-service. So, when they were first established, they were paid at 95% of the average, per capita amount that was spent on Medicare beneficiaries in their area.

Under the enhanced payment, they went as high as 110%, 115% of the average amount paid under Medicare fee-for-service in their area. They are now back down to 100% or so, or they're going to be. So, that just gives you an idea. They went from less-well paid to better-paid to now, they're kind of on parity, but they view it as a big cut, because they have had to take real reductions in their payments.

And when exactly did this 115% (inaudible)?

That was-- when was it put into effect. It was-- I want to say sometime after the year 2000, or around that time. So, after-- let's see. Clinton-- Bush was elected in 2000, right? So, it was somewhere after Bush was elected, around 2000, 2001, probably, that period.

Okay, because it was not really visible, it was not visible (inaudible), like the Medicare Modernization Act. It was more-- I wouldn't say discreet, but this-- I think this was--

Yeah, the Medicare Modernization was 2003, right? It might have been as late as that, but anyway, it was part-- if you remember, that period, Republicans were the majority party in the House and the Senate. They got the Medicare drug benefit passed, and I think they may have also increased payments to managed care at that time. I'm not sure exactly, but it's in that time period.

Sure. And so that tells us a lot about the priority of the Administration and the political-- that's very interesting.

Yeah, but at the end of the day, neither Democrats nor Republicans act very differently when it comes to Medicare. The one big difference is the one we just talked about, whether you believe that the government directly should pay for services, or whether you believe that the government should work with the private sector to provide services.

Right.

Once you get beyond that, when you get into cost-containment issues, there's remarkable similarity.

Okay. For instance?

If we-- every time there is a President's budget, Medicare is targeted for reductions, and the reductions are remarkably similar, whether they're coming from a Democratic administration or a Republican. Very similar.

How would you explain that? Are the people working-- experts on Medicare the same working for both--

Well, yeah. They're the same people, you know, regardless of who comes in, the people that really understand the programs and who have spent their careers in the government are the ones who generate these ideas. So, that's part of the reason. But the other reason is, in order to get savings that-- we call it-- that you can score, that you can actually count, that will be counted by the Congressional Budget Office and by the Office of Management and Budget, there are only so many things you can do.

You can cut rates, you can raise co-insurance, you can do things of that sort, but there are only so many things you can do to reduce the rate of growth and costs in Medicare. Because it's such a big program, and because fundamental change in a delivery system is so hard to accomplish, and not enough is known. The so-called low-hanging fruit, things that are easy to do, are pretty well known.

Low-hanging fruit?

That's a term that we use here. The things that are easy to do, easy to pick, are sort of the same things. Cut rates, you know, increase co-insurance, etc. That kind of thing.

Actually, I think that's not that different with what we can do in France.

Yeah, I'm sure. It's-- I mean, any policymaker has to-- if you're trying to convince the legislature that-- or the-- whoever you have to convince about the budget, that you're actually cutting the budget, or you're cutting the future budget, you have to have things that can be counted, and that's really what it comes down to.

Many other things that we think are important, like, managing chronic disease, very hard to say what do you do to change-- to bend the curve on those costs.

Okay. Maybe would you agree to talk about your experience in the CBO?

Sure. My experience there was only one year, and I was asked to come and help them with their modeling.

Okay.

CBO, in order to estimate the cost or the savings of a new benefit has to build a model to say, "Okay, all these things are inter-connected. If you change something over here, what might happen over there, what impact will it have, and so on," and my-- the part they wanted me to contribute to was really related to, operationally, what would happen, how long would it take Medicare to make this change, what would happen if no private plans decided to offer the Medicare drug benefit?

Because, at the time it was being debated, there were no Medicare drug benefit plans available. They had to be created. And so the question they had was, well, what happens if we don't have one in an area? How can we account for that? How can we make sure that people get the coverage they need.

So, I was there to provide sort of an operational view of what could happen, and so that was my contribution, and so to the extent that there were budget proposals to change, again, to figure out how to save money in Medicare, I contributed to that work as well, so, again, I was only there one year, so it wasn't a very lengthy experience.

Okay, but you were there during the debate of the prescription drug benefits?

Right, right.

And so, again, what was the idea-- the different ideas that you viewed from the CBO that you worked on?

What was the--

The idea, or the different provisions?

Oh. Well, what CBO does is, it builds a model, tries to figure out what are all the elements that could be affected by legislation, and then it has to work with the Congress, the-- so it's an agency of the Congress. Congress comes forward and says, "We're thinking about this model," or "We're thinking about that model, tell us what it's going to cost or save."

So, it's a more reactive position, if you will. Occasionally, and during that time, CBO would put out papers on various topics to help Congress understand the economic dimensions of, say, whether there's good competition or not-good competition amongst plans offering the prescription drug benefit, and how would these plans interact with employer plans, and things of that sort.

So, papers to inform the discussion and to inform the people who were writing the legislation, but mainly, what CBO does is, they have to take proposed legislation and estimate what would be the impact. So, it's a more reactive role.

Right, okay. You had worked for Democratic administration, and then for the CBO during a Republican Congress, but the CBO is non-partisan?

Right, and I was working-- let's see, I started-- I worked for the US government for 30 years, so I've worked for Republicans, Democrats, Republicans, Democrats. I mean, it has been a number of different administrations, so when I was at the Medicare and Medicaid agency, that was under Ronald Reagan, and then George Herbert Walker Bush and Bill Clinton, and then George W. Bush.

So, those Presidents, just during the time, so there were Republicans and Democrats involved. And then, as I was leaving, the Obama Administration. Well, actually, the Obama Administration didn't come until later, but it was a series of different kinds of people.

That's very interesting, because we are talking this day about polarization, but your trajectory and your background is really bipartisan. How would you explain your trajectory? Is it really unusual, or--

Not in the-- we have a distinction between political appointees and career officials, and I was in the career force, or the career group, and the career staff work with people in both parties, and-- also, the executive branch, that actually administers the laws and regulations, and writes the regulations, is different than the legislative branch.

The legislative branch, which is Congress, is much more politicized. There's definitely, you know, in any administration, they've got a political agenda that has to do with the underlying philosophy of the party, but your day-to-day operations are just running the government and getting the job done, which is mainly not a political job, it's mainly getting the job done, right?

So, in our case, as new technologies come along, we have to assess them, evaluate them, decide if Medicare will cover them. We have to put out yearly regulations, setting the rates for hospitals and physicians. This is not mainly a political process, it's a process of keeping the program current with what was going on in healthcare.

Okay.

And then a lot of what you do at the agency, probably to a greater extent, even, it's similar to Congress but different, is that you work with a lot of people in the system, so on a daily basis, you're meeting with hospital groups, physician groups, medical device manufacturers, pharmaceutical companies, consumer groups, states, the heads of Medicaid agencies. You're meeting with all those people because they're-- the decisions that are made by the agency have an impact on them.

So, they come in and they see you, and as an administrative agency, you basically have an open door to try to hear different perspectives as you make these rules. A lot of what you do is, you put out rules for public comment, taking public comment, you consider it, you change rules, you finalize them, etc. So, all of that is a big process, and I would say there's always politics, but it's not mainly what you do. Mainly what you do is run the programs, it's very operational.

Sure. And as the agency-- as specific, the HHS or the CMS, has a specific point of view on what is a good policy or, I mean, is the CMS supporting some options?

I-- that's the interesting thing is, when you say a specific point of view, I think-- there are principals that guide the people there, okay? So, one principal would be, you want to do what's best for the beneficiary, for the patient. Another principal would be, you don't want to waste the taxpayer's money, and it doesn't matter whether you're a Republican or a Democrat, those two principals guide a lot of what you do.

Within that, a lot of these decisions about how you run the program, there is no one right answer. So, let's say you're trying to make a payment change, I'll think of one in particular, we were putting in place a physician fee schedule for the first time, it's called the RBRVS,

and we had to decide probably the central decision was how much does the government want to convene advisory groups to set the different weights in the fee schedule, or how much do we want to have physician groups do that and bring their recommendations to us?

And we decided that we'd just as soon they do it and bring their recommendations. We could turn them down, or we could modify them, but we were fearful that if the government tried to do everything, we would be criticized, you know, everything we did would be criticized.

If we let the medical groups get together and come up with a consensus position, then we could-- the only thing we need to worry about is what we call the conversion factor. You set the weights, you decide whether, you know, heart transplant is worth 50 points, an appendectomy is worth 1 point, and then the only issue is, it's 50 times what? So, what's the conversion factor? What's the multiplier?

And that was the government's role, because we were controlling the overall amount of money. So, that was the role we reserved for ourselves and then we, of course, also reserved the right to modify some of the weights that were presented, but generally we thought it would be better for them to do it, because the different groups would balance each other out, the family physicians, the primary care, the surgeons, you know, etc, would be able to really work that out amongst themselves and present them back to us.

So, we went with that decision, but there are many-- you know, we could have gone the other way and said, "Let's set up committees, and let's-- we'll oversee the whole process." So, there's no wrong decision, if you know what I mean, you have different choices as to how you approach something, and as to a philosophy, again, the philosophy was basic fairness that would provide access to the beneficiaries, but not be foolish about, you know, encouraging inflation costs.

So, you're always balancing those things.

Okay. And you may be more protected from the politics in the agency than--

Somewhat, because the political appointees generally have to deal with the politicians, but we, very often, directly were targeted for write-in campaigns, letter-writing campaigns. We were often asked to go up and testify-- I testified before Congress a number of times, asking us to explain why we were doing one thing versus another.

I remember, particularly, one hearing that I went to where the members of Congress did not understand why a given person, who would be eligible for Medicare because they were over 65, but also eligible for Medicaid because they were poor-- they were getting funding from both places, why that funding was not better-coordinated so that in fact there were times when we duplicated-- Medicaid would pay for something and Medicare would also pay for something.

So, you know, they didn't understand the fact that the states actually operate Medicaid and the federal government operates Medicare, and the fact that sometimes the states do not share as much data on the same people, made it difficult. But, you know, to a member of Congress, that made no sense. They're both federal programs, as far as they're concerned, even though they're both run by the states.

So, that's the kind of thing, even though it's operational, it can become political, because then - especially if a particular party wants to make the administration look bad, they'll say, "See, they're letting fraud and abuse happen, they're not watching out for this, there's waste going on, and the Obama Administration, or the Clinton Administration is not paying enough attention to this, or the Bush Administration is letting this go." So, that's where politics gets in.

And the legislative oversight?

Right, and they do sometimes legislate things to deal with issues where we would disagree that the issue-- the way they've legislated it will actually help, but it doesn't matter, it's now legislated and you've got to deal with it. So, politics is always there.

Since you have been in these different places like White House, HHS, and the Congress, and the CBO, how would you see the evolution of the interaction of these three parts of the government? Like, for instance, the HHS and its role in reform, is it more important or less important than it was in healthcare reform?

You mean in the Clinton?

Yeah. I have also seen the Medicare Catastrophic Coverage Act, and the role of the Secretary was very important, and what about now, and other-- maybe a long-term?

Okay, so, I don't-- here's the thing is, the role of the Secretary is very much dependent on the President. So, for instance, some Presidents like strong Cabinet Secretaries, and some Presidents prefer to run more of the policy out of the White House. I would say that President Obama likes to have a strong White House.

He also has good secretaries, but I think it remains to be seen, I think healthcare reform legislation was run through the White House, the effort, the strategy, with maybe some of the content provided by HHS. I think it remains to be seen what's going to happen in the implementation. There, you would think, now, the agencies would get much more involved, it's much more of an operational role, but I understand that the White House is staffing up to do more oversight and involvement from the White House.

So, it's not so much there's an evolution. It could change, depending on the President. President Bush, and I can't even generalize too much, but I would say that from what I can tell, my limited experience, Republican presidents tend to be more comfortable delegating to the cabinet secretaries and having them run things. Democrats tend to be-- to like a stronger White House.

And it may just be that Democrats generally like a more centralized approach, and Republicans generally like a more decentralized approach, if you think about the whole issue of how much flexibility states are given in healthcare, it is stronger under-- generally under Republican presidents who believe in a less-strong central government and letting the states do more, and they sort of approach their cabinet the same way. They let more power happen at the Cabinet level.

The exception would be somebody like Bill Clinton who was a governor, and so he tends to want-- he tended to want to give the states more flexibility because he was a governor, and he thought they should always have more flexibility. He was more state-sensitive, but he ran a strong White House. So, I don't think it's an evolution, I think it's very dependent on the personality of the President whether they want a strong HHS or not, for instance.

That's very interesting.

There's a book, if you have time, it's very short, written by Richard Neustadt, N-e-u-s-t-a-d-t, and it's called-- I think it's called "Presidential Power," and he-- each chapter is a story about a different President and the different styles they had, sometimes more hands-off, sometimes more hands-on, and it gives you a sense of the different ways in which they approach problems.

Sure. Maybe, back in just recent days, have you been involved in the healthcare reform process?

Yes, we have, very much so.

So, would you like to describe how?

Sure. So, first we began about two years ago, actually, four years ago, we began working on the issue of comparative effectiveness research, and we decided that this was going to be a significant issue for our industry and for healthcare reform, and that we wanted it to have a-- we wanted to support an entity that would be much more of a public/private entity, with openness, transparency and inclusion of industry along with other stakeholders. So, we began working on that four years ago, and we published an article in Health Affairs, the Journal of Health Affairs, on that issue, and if you want to, I can send you the link for the article, if you're interested.

So, just to give you a sense, we started a long time ago identifying issues that we thought were going to be important in health reform, and then getting actively engaged. That was one. There was another issue that came up in health reform, we didn't know was going to come up in health reform, but we have been active on for some time, and it's the area of a regulatory pathway for biosimilar drugs, these are like generic, biologic-- so, that's not the term I'm using.

And, again, that was probably about four years ago we started working on it with the Europeans, on developing a pathway, and then bringing that to our US discussions. About two years ago, we began developing positions on various elements of health reform, so, where do we stand on universal coverage, what is it that we stand for when it comes to private insurance, how do we feel about the employer role, individual role, etc, and we developed positions on those.

And the other thing that happened, and this was not part of our thinking, but it just came forward was, we started getting calls about Johnson and Johnson's Prevention and Wellness program for our employees. We've had a strong prevention and wellness focus for about 25 years, and we have data going back at least 10 years on reduction and risk-factors associated with wellness and prevention.

So, we started getting calls about that, our CEO was invited to meet with the President, and some other CEOs on our record of reducing costs, so that was another thing that came in. We also, really within the last year, became very active in the whole issue of what should the industry contribution be to health reform.

So, through our trade association, PhRMA, we worked on this agreement with the administration and the Senate Finance Committee to contribute about \$110 billion or so toward the cost of coverage of new people, through various concessions and additional rebates that we would offer, additional discounts, plus a tax that the industry would pay, and then in the last six or eight months, we've been working on the medical device side of our business, with our trade association AdvaMed, to devise an appropriate contribution from the device industry, and we developed the rationale for reducing the original provision from \$40 billion from the industry down to \$20 billion, so we put together the economic rationale for reducing that level.

So, we've been involved in lots of ways on the policy, from a long-term perspective, to some of the financing in, really, the last year and a half or so, and then, on the wellness and prevention side, we've been quite active, just meeting with those members of Congress interested in those provisions, which-- many of which are in the bill in the legislation.

Right. So, you're (inaudible) with the Senate Finance Committee and the members involved--

Very much so, though we've also worked on the House side, with the House Ways and Means Committee, and some of the members of the Energy and Commerce Committee, and, again, on a lot of our issues, we worked through the trade associations, but on some of them, we are leading the trade associations, so our positions on comparative effectiveness and biosimilars are, J&J is the lead organization-- company that has taken the lead on those in devising the industry position, and then on the taxes and fees from the industries, we've really worked-- the device fee, I'd say, we were the lead company on that, but on the pharmaceutical company, we were part of the larger organization in putting that solution together.

Okay. This is interesting. And, when you talk about the Congressional committees, what about the Congress leadership? Who takes a very important role in the reform?

Well, in our case we-- it was Senator Baucus, with the Senate Finance Bill, was where a lot of the focus of the White House was, so we knew that the bill that he devised was going to be an important bill. The bill that he had had more of the elements that we supported, like the comparative effectiveness entity that he put forward was a public/private entity, of the sort that we had been advocating.

On the House side, it was more of a government authority, which we didn't support as much, and then other elements, you know, that we felt were stronger in his bill, a greater degree of support for a truly public/private coverage of people as opposed to the government public plan, for instance, which, we were concerned, would lead to price controls.

The House side had many more price controls embedded in the bill that we were not in favor of, so we did work more with the Senate side and the White House.

Okay. This is really interesting. Maybe would you have time for one or two more questions?

Sure, yeah, and then I have to go.

I don't want to bother you, because I could ask questions forever, so just tell me-- sorry.

Yeah.

Maybe your personal engagement and the evolution of your ideas during your career about what is a good public policy in healthcare reform, do you have changed your ideas, and--

Not really. I think my experience in the public sector has made me aware of the strengths of the things that government does well, but also some of the things the government doesn't do as well, and so where-- I guess my thinking has always been, even when I was in government, recognizing the limitations. So, the example I gave you of-- we made a decision to let the medical groups decide on the weights. That was a decision that was based on my belief that there are some things the government would do poorly, and probably not successfully, where the private sector is better at it, and that goes back a long way.

So, that philosophy is what, in a way, guides me, and I feel that there are important things for government, and there are important things for the private sector, and we need the right balance.

Right balance. I see. And maybe why did you-- maybe about your professional background, and what is your professional background? You could talk to me about this (inaudible) position more, and why did you choose to specialize in healthcare, in this sector?

Oh, in this sector? I actually started out in education. I went to work for a number of programs for-- we call them "disadvantaged," so, low-income students in the federal government, programs that were intended to provide support and help so they could go-- finish high school and go to college, and as part of that, got involved in, at the time, which was discrimination against minority students, and I went to work in an organization-- a commission devoted to civil rights, particularly for-- in-- so, school discrimination, so, again, it carried forward the education focus, and then one-- by just, really, a chance, my boss from that experience was asked to be-- to head up a special investigation of the Food and Drug Administration, which is our regulatory body, like EMEA, and-- with a focus on drugs, and he asked me if I would be one of the senior researchers in that group.

So, I went over-- that group was chartered under HHS, which at the time, was actually HEW, Health, Education and Welfare, and we reported on the relationships between the pharmaceutical industry and the FDA officials. There were many allegations at the time of improper decision-making, and so I got interested in healthcare through that project, and then when that commission ended, I came back to work at HEW, which is now HHS, in the healthcare area, and I was interested in FDA, Food and Drug, but there was no position in the Food and Drug area, so they had me be the person in the area of Medicare and Medicaid.

That's-- I was not that interested in financing, but that's how I got into it, and then one of the secretaries under Jimmy Carter asked me to head up the whole health section in the secretary's office, so, the Secretary of Health, Education and Welfare, Secretary Califano, and Harris, and so I took that on and I had a whole group that dealt with different agencies, and I was at HHS.

From there, I was asked to go to HCFA to head up their regulations and decision-making group, which was called Executive Operations, and that's how I ended up at HCFA. So, it was not a deliberate decision to go to healthcare, I kind of fell into it, and probably the pivotal moment was when I went to look at this commission looking at the FDA. At that point in my career, which was the end of the '70s, I thought I really should get out of civil rights. Civil rights was critical in the '60s, but not so-- there was obviously a focus in the '70s, but healthcare was a growing concern, and I got very interested in it, so that's sort of how I came into healthcare.

That's interesting. Maybe just you will have one or some recommendations about people we can meet that would help our research?

Yes. So, who else are you meeting in the Washington--

Actually, I have met with-- my PhD is about Congress and healthcare, so I have met a lot of people there already, but for this project, we are meeting with people who were in the legislative office of the White House under-- but we just begin, so we don't have a--

You haven't decided who you're seeing yet. Are you seeing both Republicans and Democrats?

Right, yeah.

One person you could talk with is, from the Bush Administration, is Gayle Wilenski. Do you know her? W-i-l-e-n-s-k-i, I think it is, or Y. Or, of course, Nancy-Ann DeParle, but she's very busy. You'll have a hard time getting to her. Bruce Vladeck, who I mentioned to you already, V-l-a-d-e-c-k. He was the first HCFA Administrator under Clinton. Judy Feder, F-e-d-e-r, she co-chaired the Clinton health reform.

I have--

You've met her? Okay, she's terrific.

She was perfect.

Also, Ken Thorpe, T-h-o-r-p-e, he's at Emory University, he was a key members of the Clinton task force. He was also very involved in this health reform. He heads up a group called the Partnership for Chronic Disease. It's a partnership to fight chronic disease, and he's at Emory University.

And--

Thorpe, T-h-o-r-p-e.

Which university?

Emory, in Atlanta, Georgia.

Emory, okay.

Let's see. I'm trying to think of somebody who was active in this reform. Jeanne Lambrew, if you can see her, she's at HHS, L-a-m-b-r-e-w, she's also an associate, a former associate of Judy Feder's, but she's still active in HHS. She was supposed to be the Deputy Head of Health Reform when Tom Daschle was supposed to be the head of health reform. As you know, he didn't make it as secretary, so she never took that position, but she's working for Secretary Sebelius.

Who else? Oh. Chip Kahn.

Yes.

Do you know him?

Yes, I've met him.

Perfect, because he was on the insurance side when I was on the hospital side. He was active in both reforms, in a different way. One-- this time supporting, last time opposing. And the other person who is very interesting is Bill Gradison.

Bill Gradison.

G-r-a-d-i-s-o-n. He's a former member of Congress, of the Ways and Means Committee. He was a Republican-- is a Republican. He heads-- he's head of a commission right now, but he was the head of the health insurance industry during health reform under the Clinton Administration, so he led the opposition to it.

Oh, that's interesting.

So, he's very interesting from that perspective. Just some things.

Sure, thank you, that's really helpful. I will try to reach this person. Thank you so much.

Yeah, you're welcome.