



EDWARD M. KENNEDY ORAL HISTORY PROJECT

**INTERVIEW WITH DAVID KESSLER**

March 9, 2008  
San Francisco, California

**Interviewer**

Janet Heininger

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TRANSCRIPT

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**Heininger:** This is an interview with David Kessler on March 9, 2008, in San Francisco. Why don't we start at the very beginning? When did you meet him, which is all part of how did you come to work for [Orrin] Hatch?

**Kessler:** I think it goes back—

**Heininger:** Before that?

**Kessler:** It goes back a significant way.

**Heininger:** Oh, good. That's good to hear.

**Kessler:** I went to school in western Massachusetts.

**Heininger:** At Amherst, right?

**Kessler:** I was always interested in medicine and the sciences, but in the broader aspects, in the social aspects of medicine and science. I went down to the basement and I pulled out—from 1972 when I went to the bookstore and ordered it, my college— What was the price?—\$6.95 for the book. This was 1972 it was published, so it's 35 years ago. There are eight questions: Should good healthcare cost an American everything he owns? Should good healthcare mortgage a family's future? Should Americans be denied good healthcare because they cannot pay? Should health insurance be big business? Senator Kennedy was—it would be a decade later that I met him.

You know, when you're a kid, certain people are bigger than life. I grew up with Senator Kennedy being bigger than life. Back 35 years ago, he had defined the moral imperative on healthcare. I always wanted to go work on the Hill, but I was a kid in college in western Massachusetts. I had no idea how to do that and I didn't know anybody who had done that, and didn't know about how you even— At college, I wrote and said, "Can I come do an internship?" and didn't hear anything back. That was about 1972.

I went on to medical school, to an internship in Baltimore, and I again tried to get some experience on the Hill. I went to Senator Kennedy's staff and I still to this day remember my interview with Larry Horowitz. At this time I had not met Senator Kennedy. Larry was the—you can't even say Larry was the senior staffer; he was almost the junior Senator. I was in my

residency at Hopkins, I had gone to law school, and I was one of a dime a dozen. Larry had seen all of us and there was no room. I didn't get anywhere with Larry, particularly, and at that point, over the next couple of months, the Senate changed hands.

**Heininger:** So this had to have been 1980.

**Kessler:** Right. My résumé must have still been in the pile—this was when it was called Labor and Human Resources—because when the Senate changed hands, I got a phone call from one of Hatch's folks.

**Heininger:** So they solicited you?

**Kessler:** Again, I may have—my résumé was there, but I remember getting a phone call from one of Hatch's health staffers saying, "We need help. There's no one here," because they were gearing up. They had never been in the majority before. "We would love you to come down. We need help."

Kennedy has always had—and I think this is very important—he's always had very senior, seasoned, professional, smart staff. If anything, my sense was Kennedy at some point got to view staff as almost a liability. Staffers—sometimes they'd get him into trouble, but he always had the seasoned staff.

I started volunteering. I was low man on the totem pole. Low man on the totem pole is probably an overstatement of my position. I now appear in—I guess it was the old Senate Arms building. They gave me a phone at first and no desk, and then I moved over to Senate Arms before it was torn down. That's early 1980s. I still don't think I had met Senator Kennedy. I may not even have met Senator Hatch. I understood how it worked. I was a volunteer staffer. I was coming down from Baltimore. But those years, certainly for me, were both very formative and informative, because there was always a history of a staff member or two, someone who was comfortable going between the staffs. If you put Hatch's staff and Kennedy's staff in the room together in 1980, chances are their backs would get up. But that wasn't the members—Be careful, that wasn't Senator Kennedy.

**Heininger:** Yes, the staff.

**Kessler:** The staff was beginning to be somewhat of a—There were ideological divides, but there was a strong history of at least one of us who had no barriers. Our friends were on both staffs. At that time, Larry's the senior staffer, but JoAnne Glisson and Jim Steinberg were on Senator Kennedy's staff, and on Senator Hatch's staff—these were the health staffs—were Ron Docksai and Steve Grossman. I was able to go back and forth between those, and that taught me more about how to negotiate and how the Senate worked. Those were very formative.

Glisson and Steinberg were real pros. They were seasoned, very smart, and appropriately cynical. You couldn't pull any wool over their eyes. Most people don't recognize, especially when you're in the role that Senator Kennedy and Senator Hatch have been in, as chair of the committee—When you're chair of a major committee, you really are responsible for the workings of the United States Government. Yes, there are big issues. Yes, there are major

political issues and battles. But much of the day-to-day work that takes up 95 percent—it's keeping the United States Government running.

There were a whole host of issues, everything from NIH [National Institutes of Health] to FDA [Food and Drug Administration], to the other public health agencies, that didn't command national attention or even much of a Senator's time, but that was our job. The majority of those issues, staff would be able to handle. Five percent of issues were member-only issues, and the rest were staff issues. But it was in going back and forth between staffs that you got a sense of how the Senate worked and, for me, that was critical.

Because I worked for Senator Hatch, I had the privilege—not a lot, but there were those few times when you're in the office, when the door is closed, when a Senator is really allowed to talk candidly. Their feet are up on the table and they're comfortable. What was very clear and defining, and I don't know how much it occurred before Hatch, but there was an extreme personal fondness and an extreme degree of caring. This was personal. They liked each other. They cared.

The real answer is they cared about each other. Perhaps they knew the kind of life they led, what it was like to be in public view all the time, the kind of pounding, the kind of beating up that they take, the kind of pressure that they take. If you've experienced it and you're there and you have those kind of pounding pressures—always being criticized by someone, battling sometimes your friends even more than people from the other side—it almost took somebody who was a senior Senator to be able to understand another Senator. Their personal relationship mattered more than anything else. It wasn't policy, it wasn't politics. It was the antithesis of staff. Staff would get their backs up in the room—for some reason they thought that was their job—but not Senator Hatch, certainly, with Senator Kennedy.

I think that—I don't remember specifically—there were some more challenging moments in Senator Kennedy's personal life, even in the early 1980s, when Hatch cared. The details are fuzzy. I wasn't there when the two of them were together, but I was there watching Hatch talk about Senator Kennedy with a fondness that transcended anything that I had seen.

**Heininger:** Eventually, they each attended the other's mother's funeral.

**Kessler:** Of course. That's a given, if they could. People didn't understand the closeness because, ideologically, on the political spectrum, not only are they apart, but Massachusetts and Utah—Senator Hatch—I guess he grew up in Utah and also lived, if I'm correct, in Pennsylvania. But they grew up in different parts of the country.

They had very different backgrounds. They had very different family upbringings and very different roots. Orrin was always a very disciplined formal dresser, no hair out of place. You could track Senator Kennedy's political career and his weight. Very different personality styles—Orrin always much more controlled, Senator Kennedy much more outgoing—and you could see that inherent in how they were built, how they responded to the outside world. Their personalities are very different. It was not out of political expediency that they not only warmed—they saw each other's foibles. They were not blind.

And so I'm watching that, and I'm a kid. I had been at a hearing maybe once or twice—I mean, when I saw Senator Kennedy, it was when I was behind Senator Hatch at a hearing. I was very junior staff, but that's what I saw in the 1980s. If you fast forward to 1990, I had left for a decade.

**Heininger:** How many years were you there in the Senate, under Hatch? Were you there for two years, or more?

**Kessler:** I was there for two years. Again, I'm a volunteer. I'm doing my residency, so I'm going back and forth BW [Baltimore-Washington] Parkway night and day. Even when I went to New York, where I met Fritz [Reuter] at Montefiore in 1982, I was still going back and forth, still doing some hearings on certain subjects. So it was about two years, but a very intense two years. Staff, especially at my level, does not spend a lot of time with their members.

**Heininger:** Right.

**Kessler:** There are staff to whom that's important. You know, that's how they see themselves. To me it was a privilege just working with their staffs and getting to know their staffs and their values, and understanding how the Senate works. People don't understand how much work there is. There was a lot of work for Senator Kennedy and Senator Hatch to do, because they were chairs. The reauthorizations, I mean, the government would stop functioning unless they got things done.

So for me growing up as a kid, first knowing what Kennedy stood for as far as being probably one of the very first to make healthcare a moral issue, and then watching him in his relationship with Senator Hatch become very personal, non-ideological, and in some ways very practical. It's striking how somebody could, on the one hand, hold to, believe, stand for, value, such an important core principle: healthcare for all. And yet in the day-to-day there were practical compromises that moved us maybe an inch, a step ahead, two steps back, a step ahead. It became clear, certainly to me over that decade between the '80s and '90s, that Kennedy had become a master of the Senate, if not *the* master of the Senator, not to use a cliché. I saw it personally. The next time I would see this it was very personal because I was nominated by the first President [George H.W.] Bush in the fall of 1990, and from the moment—

**Heininger:** I think November.

**Kessler:** Well, November of 1990. There were eight days left. My nomination got sent up to the Hill eight days before the Senate was going to adjourn, and Senator Kennedy and Senator Hatch had decided—I got a phone call from White House personnel that said, “Look, we’re going to send your name up. Don’t worry, they’re going to adjourn, and it will be after the first of the year when they come back that we’ll really do your confirmation.”

I was the first FDA [Federal Drug Administration] Commissioner to require confirmation. A couple of hours later, I got a call from White House personnel. You think they’re going to say, “Oh, never mind, we’ve changed our minds,” and they said, “We just talked to Senator Kennedy and Hatch”—and Kennedy is now chair—“and we’re going to get your confirmation done before they adjourn.”

**Heininger:** Now, mind you, given how junior a staff member you had been, and a volunteer, I assume your presumption was that you hadn't risen, necessarily, to the level that these guys would then go out of their way to accelerate your confirmation process.

**Kessler:** Accelerate it?

**Heininger:** That they knew you well enough that they would even think—

**Kessler:** Are you talking about—?

**Heininger:** It is, shall we say, unusual for them to do a confirmation in the last eight days of the session? Yes.

**Kessler:** Right. Not only that—this was, *We're going to do a full-field FBI [Federal Bureau of Investigation]* —

**Heininger:** In eight days?

**Kessler:** In eight days. I said, "When are you going to do the hearing?" And the word came back, "We're going to do the hearing after we confirm you."

**Heininger:** You obviously made quite an impression on them.

**Kessler:** I don't think that's fair. It wasn't that I spent a lot of time—I spent a lot of time with their staffs; their staffs knew me—but they were very loyal. Both Senator Hatch and Senator Kennedy were very loyal and so this is—

**Heininger:** But what their staffs know gets filtered back up to them.

**Kessler:** Oh absolutely. But in the end, I mean, there's no busier time than the end of the session. Again, if you talk about the simple mastery—How do you get this done in eight days? I wasn't there, but it was reported to me that Senator Kennedy called a markup on my nomination in the cloakroom the day they were going to adjourn. He got everyone, and the markup was—I wasn't there, but there was some jibe at Senator Hatch that, "He worked for you." "He's a good guy." "He worked for you, Orrin, but it's OK." It was one of those. But it was that mastery. They tell you it takes—if you ask somebody today to confirm, they would tell you it's six months to confirm somebody.

**Heininger:** Or more.

**Kessler:** If you want to do something and you know how to do it—and he knew how to do it.

**Heininger:** But it's also extraordinary that they did it. They chose to do it for you.

**Kessler:** No, they didn't choose to do it for me. They chose to do it, I believe, because—and again, one of the true values that I saw in Senator Kennedy was that he cared deeply about protecting good government. He cared deeply about protecting the public, and in order to protect the public's health and safety—

There was a period of time when the agency wasn't working. It was coming off after crisis, the generic drug scandals. The agency was viewed as not up to the task. There was a daunting set of responsibilities, and it wasn't good government; it wasn't good for anybody to leave the agency leaderless. That's what they understood. It wasn't good for the industries that the agency regulated, it wasn't good for the morale of the agency, and it wasn't good for the health and safety of the American public to leave the agency without a head. That's what mattered. That's what drove this.

It was more important that they found somebody in whom they had confidence, yes, someone their staffs told them they could have confidence in. They told the White House they were going to do this. Senator Kennedy told the White House that he's going to do this in eight days. He also had, again, very professional staff.

He had, without a doubt, probably one of the greatest Senate investigators, in Walter Sheridan. In a world where very few people understand the Senate investigative role, let alone mindset, Walter Sheridan was probably the role model of what a Senate investigator should be and could be, in a range of individuals who sometimes varied. You talk about some people being mad dog, the degree of focus you would have to require, and unrelenting in what it takes. Walter Sheridan was at the senior point of his career. He was the Senate investigator. He was in charge of vetting everyone. He had a young junior investigator, Mark Childress, a Senate aide, and they did the confirmation.

**Heininger:** Now, was this the time when Nick Littlefield was there? Or was David Nexon there?

**Kessler:** Nick Littlefield was there, and Larry was never far.

**Heininger:** No, he wasn't.

**Kessler:** Even when Larry wasn't there, he was there. Larry was always, for decades, certainly in the health arena, Senator Kennedy's alter-ego. You almost had a sense, and I don't know this, I don't know the dynamics. I never really saw the internal dynamics, but it almost appeared that Larry was an adopted son.

**Heininger:** So how did your confirmation hearing go, after you were confirmed?

**Kessler:** The problem was, in those eight days, that Senator [Albert] Gore wasn't on the Labor and Human Resources Committee. He wasn't a member of that committee, and Gore showed a very strong interest in science and health. He was the ultimate policy wonk. The Hatch/Kennedy duo left Senator Gore out, and so Gore put a hold on my nomination. But they made a deal with Senator Gore that they would allow him to come to the hearing and he could ask me questions at the confirmation hearing. It was probably right after I got there, after the first of the year, and it was at the end of the month, if I remember it. It's always nice to have the votes, to have been sworn in, and then having a confirmation hearing.

**Heininger:** I can't say I've known of any other case where that's happened.

**Kessler:** And it will not happen again.

**Heininger:** No, I don't think so. *[laughs]*

**Kessler:** See, that's what I'm saying. Gore had pushed for the FDA Commissioner to be confirmed.

**Heininger:** Right.

**Kessler:** And Senator Kennedy and Senator Hatch make a deal: *We're going to do this and we're not even going to hold a hearing until after we confirm him.* Gore had passed the legislation. He had pushed for the legislation.

Senator Kennedy was most gracious at the hearing. There were the appropriate questions. Understand that at the time, 1990, there was only one AIDS drug on the market, and it didn't work very well. It was a very mediocre drug. People were dying. I think that was where Senator Kennedy's questions were focused. It was taking the FDA a long time to approve drugs, way too long, 30 months on the average.

Senator Kennedy's questions went well. Senator Hatch's questions went well. The hardest questions were from Senator Gore. It was really the first time that I had gotten to know, to see—I don't remember my courtesy call from Senator Kennedy, but it was at the hearing that he really got to see me. So here he's gone to bat, he's confirmed me in eight days. If I had spent time with him, maybe it had been 15 minutes.

I had one leg up, besides having worked for Senator Hatch and having gotten to know Senator Kennedy's staff very well—I'd almost felt like I was working for both of them. You didn't say that, but that was the role you were playing. During the 1980s, after I left the Hill as staff and came back as Commissioner, I taught at Columbia Law School. I taught food and drug law there. I remember the first day of class one year: I'm co-teaching it, and it's one of those moments—you're going around the class of about 20 students, everyone's introducing themselves. We were going around and doing names, and a woman says, "My name is Caroline Kennedy."

**Heininger:** Oh, oh.

**Kessler:** So Caroline was—I had taught her food and drug law, which is always a bit of a risk. This was a lot of reading, hundreds of pages of reading, but she was a great student and focused. I think she probably saw me as sort of in the professoriate role, I mean, she saw me as a teacher, and I don't think that hurt.

**Heininger:** I'm sure it didn't.

**Kessler:** If you asked me whether she did all the reading, that would be a different story. No one does.

**Heininger:** True for any student.

**Kessler:** So there was that connection, but it was really at the hearing where he got to—and he pays attention during hearings. The percentage of hearings that really result in something



different happening coming out of the hearing than going into the hearing is probably a very small percentage, but when you're chair, you've got to be there. Senator Kennedy cared.

At the end of the hearing, one of my friends overheard Kennedy say something to Hatch. I wasn't there, but again, it was related to me and it was something like, "Hey, he's pretty good." So here he had gone to bat. Then I'm sitting there and Gore's firing questions at me. Senator Kennedy's questions were all, you know, they were—but Gore and I were going at it. We would become very close friends over the next 15 years, Senator Gore and I, but that was our first encounter. It wasn't a cakewalk, that hearing. That was my arrival—very different this time—not as very junior staff, but coming back as an agency head, coming back as principal.

**Heininger:** Well, in ten years that's quite a shift.

**Kessler:** But we were well trained, and I give Senator Kennedy's staff, the Joanne Glissons and the Jim Steinbergs, and the Larry Horowitzes, and Senator Hatch's staff—we were trained to do these things. I think that's a part of government, mentoring. People don't understand, you can't go back. You could go into these jobs, but having served on the Hill under Senator Hatch, and working with Senator Kennedy, and with their staffs on the day-to-day issues that involved the public health service agencies, and understanding what the dynamics were—but for that, I don't think they would have trusted me. They wouldn't have seen me. But they also had an opportunity to train me. I was the one responsible. No doubt I gave Senator Hatch more heartburn than Senator Kennedy.

**Heininger:** Later, but did he know it at the time?

**Kessler:** No.

**Heininger:** Right.

**Kessler:** But did *I* know it at the time? You don't tend to see United States Senators as mentors of who they train and who works for them. It's not the mentor as professor. It's not the mentor you spend a lot of time with. I maybe spent ten minutes with Senator Hatch and five minutes with Senator Kennedy over two years, but their presence, the way they're running things, you know what's going on. You don't know what's really going on, but there are things that you learn in those experiences that prepared us to do what we were being asked to do.

**Heininger:** Well, if every agency had spent some time in Congress, relations between the Executive and Congressional branches would be much better, because there would be a lot more understanding of why the process works the way it does.

**Kessler:** I think that's absolutely key.

**Heininger:** It's a foreign country to most people who become agency heads, because it's not a comprehensible process from the outside. It's a very frustrating process.

**Kessler:** Right, absolutely. The bigger lessons for me were in the role that Senator Kennedy played and the contributions that he made in shaping American healthcare policy. There's a broader role. We may yawn at these hearings. Staffs and Senators may view them as somewhat

theater, where little work gets done at the hearing itself, but we underestimate the extent to which those hearings shape, in the end, the view of the American public.

What agency heads don't understand is that the way you're perceived by Congress—Congress is just an intermediate forum for the way you're perceived by the American public. What happens in that hearing room is the megaphone, or the large screen, even though it's a small screen while you're in that room, and if it's not reported on, or if it's not televised, or if it's not on the evening news, what happened in the room probably may not make—you know, it's the trees falling in the forest; it doesn't make a difference. But in the end, how do you shape the view and the values of the country?

Over the next seven years, there was another major change with Senator Kennedy. In the '80s, when I was Senate staff, Senator Kennedy was viewed very differently than he's viewed certainly in the '90s, or currently, or how history will record. In the early '80s, when they said, "The liberal Senator from Massachusetts," it was said with a degree of—it came to mean something very different over the next 20 years. The one thing that to me was most striking was the level of respect that Senator Kennedy gained over the next 20 years, from the '80s to the present, because everybody knew what his principles were.

He was authentic. You knew what he believed in and he stuck to those beliefs, and that became the greater value. People on the other side—there's very few people you can say that about, who are consistently true to their principles. So back in the early '80s when people would say, "The most liberal Senator from Massachusetts," or, "The most liberal Senator in the Senate," it was said with some degree of controversy and some degree of—

**Heininger:** Dismissiveness.

**Kessler:** Dismissiveness. Over the next—people who were even on the opposite end of the political extreme viewed somebody as being that true to their values, and that true to their principles—it's that steadiness, that conviction that you see coming through when he wrote this book that I read when I was a kid in college in 1972, *In Critical Condition*. Those values stayed unwavering and changed the moral—I mean, really did move the country in a significant way.

We still haven't figured out how to do healthcare, and that probably is the greatest frustration, personally, and it may never be accomplished in the ideal form. The notion that you would have drugs available that treated people and people couldn't have access to them—that it was only in the very late stages of illness, when it would be too late, that they'd end up getting medical care. Or where people could not get the basics of prevention and primary care—they didn't have access to that. Viewing that today and as a boy, and the country viewing that, I think something's wrong with a country that doesn't do this. And that's the view of the country.

Thirty-five years ago that was Senator Kennedy's view, and that was held by only a very few people. Legislation and regulation are important but in the end it's how our country views a problem. Our perception and our values are more important than any one piece of legislation. That's not true when it comes to Social Security and Medicare. There are probably certain things that are as important, but you've got to put up there how we perceive a problem and what we think the solutions are. The question becomes, *how* are you going to get everyone insured today?

**Heininger:** Not *whether*.

**Kessler:** Right. That probably has been my sense of Senator Kennedy's biggest legacy, you know, that you move a country, certainly in healthcare. There are other areas—you will talk to others of other very significant contributions, but that to me is the greatest contribution—being able to get us to see the problem that way and still, on a day-to-day basis, to do the deals, to lead the deals, to get the work of the Senate done, to advance it step-by-step—Children's Health Insurance—

Certainly in the FDA, no one has stood for the public's interest more than Senator Kennedy. It must have been in the mid-1990s, where Senator Kennedy had achieved a level of comfort and mastery of the Senate that very few others in the history of the Senate have ever come close to. Everybody has good days and bad days. Everyone's on at certain times and not on at certain times, but when he is on—and there were more days where you started seeing when he was on, rather than off—not only was he remarkably effective, but there were moments where—There are not a lot of times in Washington when you can say you're having fun. We had tried to—and when you think about it, this shouldn't be a very controversial issue. We said to the pharmaceutical industry, “We want you, over the next decade, to be able to get information to patients about the drugs that they take.”

**Heininger:** Package inserts.

**Kessler:** Right. We called them “med guides.” They were advertising on TV, in the advertisement concept, but just giving basic information: What's the dose? What are the side effects? What's this for? How to take the medicine. We had come out with a regulation that said that a certain percentage of prescriptions should have these med guides in place, and if the industry had voluntarily done this and met those timeframes—75 percent of prescriptions by 2000, something like that—if they had these med guides, the regulations would go into force.

Again, it's the incentive. There was a big push, and I forget who was on the other side of this, but there was an amendment on the floor to stop this. One of my colleagues at the agency had gone over— You know, these are the times when you really do want friends. He was a great friend to the agency. He believed in the agency and the agency doing its work. It was giving information in a straightforward fashion to patients so that they can use the information if they wanted to. It was certainly something he believed in.

He went to the floor and he held up a bottle of pills and he held up a can of dog food, and he said, “There's more information on this can of dog food, about what's in it and how you use it, than there is on this bottle of pills.” That was one of the moments where you could tell he was having fun. He had achieved an ability—he was in good form. Whatever personal stuff, whatever stuff that got in the way in earlier years, nobody could pull off something like that the way he pulled it off. That just stopped the other side.

**Heininger:** Did it make it onto the evening news? I mean, that's a perfect 30-second sound bite.

**Kessler:** But at that point, I don't think he—I never got a sense that he cared. What he cared about was: What was good public health policy? What was good public health? What was good

for the agency to be able to do its job? What was good legislation? Whether it got on the evening news—

**Heininger:** Except, when you talk about the issue of shaping public perceptions, the image of holding up—“There’s more information on this can of dog food than there is in this prescription of pills” is the perfect way, in fact, to make people understand that they don’t have that information.

**Kessler:** But there are a lot of people who focus on the public relation strategy. *How is this going to play on the evening news?*

**Heininger:** True.

**Kessler:** That was not part of his calculus. I could be wrong. Yes, there are people on staff who are in charge of that, and there are members, to this day, who would only care about, *Where’s that camera? Where is that reporter? Get this on the evening news.* He did it because it was the right thing, and if it got on the evening news, it got on the evening news. He wasn’t playing for the cameras. I never got a sense he was playing for the cameras.

**Heininger:** That’s an interesting comment about him.

**Kessler:** Maybe it’s because his life was always on camera that he didn’t have to—

**Heininger:** He didn’t have to seek it out.

**Kessler:** Right. I’ve dealt with other people who have had the opportunity, who always think in those terms. I would be in his office and we would be talking very substantively, with a level of focus of what would be good public health policy. It wasn’t whether this would play well here or there. There was a commitment certainly over the 35 years that I’ve watched his career, since my adult years—I don’t think anybody could have defined a set of values and have stuck with them.

A few basic principles have guided most of his actions, certainly in healthcare. What is good? How do you protect those who can’t protect themselves? How do you make the lives of the public a little bit safer, a little more secure? Those values, where those came from—He developed them very early on. He took it beyond ideology; it wasn’t ideological. I remember going up to Worcester with him. It was at UMass, Worcester. There was a conference on biotech.

**Heininger:** Was that the OraVax?

**Kessler:** I forget, but we spent a day together. He understood the role and he was comfortable with the role. Massachusetts had grown to become a big biotech center. It was very important for the state and it was certainly increasingly important for Cambridge and Harvard and MIT [Massachusetts Institute of Technology]. Worcester was trying to build—A lot of cities were betting their future on this. He’d draw the line at letting them control the FDA. He knew different roles. And it wasn’t where there were a lot of companies and they were local companies, and he felt—

Again, he just stayed very true to his core beliefs. He understood that these companies were doing important research trying to get drugs that worked. He had problems with inappropriate promotion, inappropriate marketing. He saw companies that crossed the line, and certainly held some hearings on marketing and promotional activities that were improper. He had beliefs and values, and I guess some say he became a little more to the center. I never saw it. To me, it wasn't where he was. He had basic core values and he stuck with them and knew how to get things done. They worked very hard. I don't think people understand how hard, the amount of work that goes in if you're in the leadership.

**Heininger:** Do you attribute it principally to longevity, and steadfastness to these principles, or was it affected in part by his abandonment of his Presidential aspirations?

**Kessler:** I saw him become increasingly comfortable, increasingly effective, increasingly at ease and increasingly masterful over the last 25 years. When did he get married?

**Heininger:** Ninety-one-'92 was when he met Vicki [Reggie Kennedy] and married her.

**Kessler:** That was seen as a very big plus—among staff. Whether it's the realization that you're not going to be President—and again, I don't have the insight, I'm not the shrink here, I'm not privy to that. But there was a general sense, if my memory serves me right, that more than anything else that gave him a steadiness and a comfort, and he became increasingly effective.

I guess he didn't have to do it. He wasn't auditioning for anything. But then you've seen others who have not had to audition for anything else, and they've not continued their own level of effectiveness. They've not increased. When he was on the floor with that can of dog food and pushing what was good for the public health, he was fully in command. He was doing what he wanted, what he believed in doing, and he was very effective. No one could have been more effective than he was.

And there wasn't a lot of—you get a sense in a lot of Senators that there's a lot of internal calculus to every decision: *Here are the plusses. There are the minuses. Do I do this? Is this going to advance this?* That was never my sense. He knew. Where he learned it, where he got it, I can't tell you, but certain core principles, certain core values, shaped him, and he did what he did. When the personal stuff became more under control, there was more of a steadiness that allowed him to be at ease, and he excelled. He did it like no one else could do it.

I don't think the values changed. I think the values had always been there, but he became—to me, he was wise. He had the life experience. He had the set of values. He understood where things fit in the broader context. He wasn't auditioning for anything. And he cared. I was fortunate, because he cared about health. That was very important to him, that set of issues. And he's willing to stick with things. You talked about—how you phrased your question: "He's got longevity...."

**Heininger:** What would you attribute it to? Longevity and—

**Kessler:** Longevity gives you something. Longevity is useful but not sufficient. We will probably get tobacco legislation this year, after ten years of trying. That doesn't happen because of longevity alone. That happens because there are a few individuals who are willing to persist

and stick with an issue, day in and day out, when the cameras are on or when the cameras are not on. That's what longevity gives you. If you're only there for a certain number of years, you can't accomplish that.

In this country, the way we do policy—Sometimes there are stimulating events that drive policy, but in the end, the vast majority of policy is made because— Something in the beginning has all the elements of sound policy but it's still viewed as controversial. Over time, you can change how the issue is viewed, so it's no longer viewed as controversial.

**Heininger:** I liken it to issues ripening, so that they reach a point where, as you say, they've sunk in and now the timing is right.

**Kessler:** Because what was controversial is no longer controversial. Tobacco was once very controversial. What was really controversial about it? I mean, it was no different than it is decades later, but now it's viewed as OK, it's time to get it done. That's the advantage of being there and persisting and knowing, but it's knowing how to get it done. Senator Kennedy passed, last year, in the drug safety legislation, probably the most fundamental change in the drug safety laws in 40 years. It doesn't get a lot of fanfare. No one has fully understood the implications of everything that's in that statute.

**Heininger:** What was in it from last year that's important?

**Kessler:** For the last 30 years, since the '62 [Estes] Kefauver-[Oren] Harris amendments, the law was always written so that, up until the day the agency approves a drug, the drug is unsafe. The FDA approves the drug and then, from that day on forward, the drug is on the market and it's viewed as safe.

That's obviously not the reality. Data will come in over a period of a time. Not all data is in hand before a drug gets approved. Most people don't realize that if you're going to use a drug in even 10,000 patients and the risk of death is one in 12,000 from that drug, you may not see that death until after that drug has been on the market. The legislation that was passed last year by Senator Kennedy changes how you view drug safety, so that over the life history of the drug you have to have risk management plans to be able to deal with the drug, and plans to be able to look for and deal effectively with risks after a drug comes on the market. Few have even fully come to grips with the significance of what that means and how that will be implemented, but it gives the agency and the pharmaceutical industry—it's almost a paradigm shift in how you look at the life history of a drug.

**Heininger:** Did it require—as in the recent cases of things like Vioxx, where, as more data became available after they were on the market, more questions are asked about the drug safety? We weren't seeing that earlier on?

**Kessler:** Yes.

**Heininger:** Is that what caused the issue to come to the forefront, or make the time right to be able to pass that?

**Kessler:** Well, it really does. He was chair of—what years was he chair of Labor and Human Resources, and then Health?

**Heininger:** He took it back in '87, had it until '95, and took it back in 2001 when [James] Jeffords switched.

**Kessler:** That is instructive and important. We don't pay enough attention to the pendulum swings. If you look at the pendulum swings in FDA policy and health policy, and the changes in both the Senate—who's chair and who's ranking member—you could almost plot FDA history in terms of who's chair of what was Labor and Human Resources and now is called the Health Committee. So, look at the pendulums. In the late '80s and early '90s, you had the HIV epidemic, and we knew it was taking the FDA too long to approve, by any standards. We put in certain things with Senator Kennedy. We did the prescription drug user fee; he enacted that.

**Heininger:** Was that principally for resource purposes, because the FDA needed more resources to be able to test these drugs?

**Kessler:** I'll get to that. Sure. It was, *How do you not change the standards?*

**Heininger:** But get them out faster.

**Kessler:** Well, not get them out faster, but get them evaluated faster—maybe get them out, or maybe not get them out.

**Heininger:** Well, true, to evaluate faster.

**Kessler:** Get a decision. How do you get a decision done? Senator Kennedy trusted us on that. I went to the senior reviewers of the agency and I said, "Look, it's 30 months. It's too long to evaluate a drug." And the answer was, "Do you want it fast, or do you want it right?" I said, "How do you get both?" We worked out a deal that if we had additional reviewers, we didn't have to change the equation. You weren't going to get onto the market if you didn't deserve to get on the market, but if we had more reviewers and you deserved to get on the market, or you didn't deserve to, that decision would be made within a certain period of time.

**Heininger:** But he wasn't on the same side with you, initially, on using outside contractors, was he?

**Kessler:** We never agreed to outside contractors. We opposed outside contractors. That was Bush I and the [J. Danforth] Quayle competitive discounts. I don't think we ever really—I mean, we agreed to, at most, a pilot project. We kept that at bay.

But on prescription drug user fees, where the reality was we were not going to get more appropriations, and where 30 months was too long to evaluate a drug—If a company is paying a user fee—if you apply to a college, if you pay them \$25 for your application fee, it doesn't mean you're going to get in. We designed the program with the industry, and Senator Kennedy and Congressman [John] Dingell and Congressman [Henry] Waxman supported us. They went along.

If you look through the early 1990s, we did accelerated approval. We started off with one HIV drug, and we ended up with a good dozen by the mid-1990s. But you saw, also, when the Senate changed hands in '94 and he's not chair, that the pendulum starts swinging. Senator [Nancy] Kassebaum is a true gem, but the momentum for accelerated approval or the FDA going even further—there was a further push on that pendulum.

**Heininger:** A private-sector push?

**Kessler:** Oh absolutely.

**Heininger:** And at the same time, you have a [Newton] Gingrich revolution in the House, which is pushing for massive cuts in healthcare—

**Kessler:** This was not a good time to be a regulator. Had Senator Kennedy been there, it would have been a lot different. We lost on dietary supplements, big time.

**Heininger:** Which is a very interesting issue, in and of itself.

**Kessler:** Right. So, we lost big time on dietary supplements. FDAMA, the Food and Drug Modernization Act of '97. Again, all this ended up being moderated, so it didn't do any real harm in the end. But if you look at the push toward, *Is the FDA going to push to do stuff faster or do stuff safer?* Senator Kennedy was with us certainly in the early '90s, when we had the HIV, but that pendulum— My sense is if he had stayed as chair, had the Democrats still been in control—You know, he had appropriately divided loyalties with Judiciary, in what he would chair, but you can plot the legislative history of, *Are you trying to get the agency to do things faster or are you trying to get it slowly*, by who's chair of the committee.

So you talk about longevity, but you still have these breaks in control of the Senate. In the end, the system is set up so that you can't do a lot of damage in majority versus minority. There are always the appropriate checks, in the end.

**Heininger:** But you can do enough.

**Kessler:** Well there are certainly shifts. Look at dietary supplements. You asked me this last round how much of this was Vioxx, and how much of this led to the last drug safety. You could wonder what would have happened had he been chair continuously. A lot of the pendulum swinging back and forth in FDA regulation; FDAMA on the air of getting it out sooner in '97, drug safety a decade later, being safer—It makes a difference who's chair of the major committees.

**Heininger:** Does it basically come down to which party is more receptive to pressures from private enterprise?

**Kessler:** That's an oversimplification. Yes, you're right. Everyone has constituencies, and they think they have more influence than they probably have. I think Senator Kennedy cared, appropriately, about the companies in Worcester and in Boston that are trying to do important things, and he's appropriately proud and feels comfortable and doesn't see them on the other



side. Certain Senators are willing to carry water more for certain constituencies, no question, and no one could ever say he carried the water for the pharmaceutical industry, at all.

**Heininger:** No. But philosophically, when there is a party shift, and particularly with the '94 shift, with the Gingrich revolution, I would assume that the pressures from private enterprise would be accelerating on all committees, in whatever form.

**Kessler:** It was a view of government's role. It went to the heart of what was the rationale for government. Look, people recognize—during those shifts, they understand these things, that there are temporal limits, that things are going to change. They go, "All right, well, this is my turn, so I've got to get everything done during my turn." And there's a big push. So why was there legislation on FDA in 1997 to speed up the approval, and in 2007 there was legislation focused on drug safety? They focused on very different philosophical things. There were very different chairs of the committee.

**Heininger:** With one person remaining constant as either chair or ranking minority—because the chairs have changed, not just changed, but whereas it was initially Hatch and Kennedy, it became Kennedy and Kassebaum, and it has shifted again. It's [Michael] Enzi in there now. There have been these shifts, but there's been one constant. It's always been Kennedy on one side or the other.

**Kessler:** There's a very big difference whether you're a chair or you're a minority.

**Heininger:** What differences did you see in how he operated?

**Kessler:** It's not how he operates. It was the agenda for the committee. The minority has influence, but a chair has an agenda-setting ability, and the years when he was not chair, I think, left the agency and left the public health more vulnerable.

**Heininger:** And this reminds you of Republican chairs that he's had very good relationships with, too.

**Kessler:** I am very close with Senator Kassebaum. She cares as much about the public health, but it's also the pressure from her side of the aisle on her that has a lot to do with it.

**Heininger:** Where did you disagree with Kennedy? There must have been issues that you were not on the same side.

**Kessler:** Well, it was very interesting. On the set of issues that I worked with, as far as values and underlying principles, I don't think there was any difference. Everything could get worked out, and that was from the very beginning. When I was working for Senator Hatch, Ron Docksai came back and handed—Ron Docksai was Senator Hatch's—I will tell you, because it was my baptism by fire. Docksai gives me this long piece. He walks back around and he says, "Who knows something about food and drug?" This is 1980. I was the volunteer and I raised my hand and I said, "Well, I did a law review article." And he said, "Well, you're now the expert."

**Heininger:** Welcome to Congress.

**Kessler:** The food industry had drafted this bill on food safety that they wanted introduced, which Senator Hatch introduced, and I was staffing it. Today, by most standards, it would be considered probably a moderate bill. Back then it was viewed as way too industry-prone. What was dramatic was that I worked it out with JoAnne; I mean, we had a joint bill. We had worked out even the most contentious—the anti-cancer clauses. Now they look extremely moderate, but we worked it out.

So, even between Senator Hatch and Senator Kennedy, on issues of science and health policy, those sets of issues, everything could be worked out. The constituencies would not necessarily be happy. They didn't get everything that they wanted. But being able to move the ball—Those weren't the five percent of issues for which there were ideological—There wasn't anything ideological. The question was: What was good health policy? What was good science policy? What was in the public interest?

Would there be issues that I had wished Senator Kennedy had put his body on the line more for, at certain times that we needed help? You can't ask him to do everything, and there aren't a lot of people you could turn around and ask, but he was there 99 percent of the time. By all standards he was there 100 percent of the time when we needed him. You can't ask somebody to go up the hill every day. No one has a sense of the demands, I mean, getting up to speed, understanding this stuff, being able to grasp this stuff. And you get three minutes to understand these complex issues before they've got to go to the floor.

**Heininger:** I'd say three minutes is a lot. It was more like, "Here's your 30 seconds."

**Kessler:** But this was always substantive.

**Heininger:** As Commissioner, did you deal principally with him directly, or did you or your office deal a lot with his staff?

**Kessler:** Both. I always felt very comfortable. He still is larger than life. The voice on the phone, "Dave?" It's very personable. To be able to hear one of the greats, and yet, you're able to talk to him. If there was an issue, of course you talked to him. The two most personal moments for me with him were with my kids: one time in Washington and one time in Boston. I had my son, he must have been five or six, and Senator Kennedy took him in his office and took him around that office and showed him the memorabilia in a way that nothing was more important in life. Is there a patio outside the office?

**Heininger:** There may have a terrace out there.

**Kessler:** Terrace, I meant a terrace.

**Heininger:** Outside of the window, yes.

**Kessler:** I mean, showing the pictures with his brothers to my son. Then, we were in Boston—I think it was 2000. It was with then-Vice President Gore. We were doing an event, I was there, Senator Kennedy and Vice President Gore. For some reason we met at the Kennedy Library, and

I had my daughter with me. My daughter in 2000 was on her way to college. He took her through that Library as if he was a kid. There was nothing more important.

To him, it was the desk. It was ten minutes, but it was a world. You can't underestimate the role that—even after 40 years how that has to shape him, because you could watch him when he's talking to a kid. It was very personal. It was very important to him. This wasn't just some show, this was part of his being, this was part of his makeup, that history and that legacy. Being able to be there with kids and sharing that legacy was something that was very important to him.

**Heininger:** Think what would have happened if you'd brought a dog. We actually have tapes of interviews with him where you read in the transcript, "Down, Splash!"

**Kessler:** It's not that I spent a lot of time with him, but I've spent a long time with him. I've had the privilege—from growing up as a kid, from afar, in western Massachusetts, to watching him in his early years, then watching him later.

The level of respect that he has earned from his colleagues—Sure, Orrin and he were close, and still it's not all that friendly. He's earned a degree of respect. A lot of it comes from just, I mean, there's been a lot of hard work that's gone into that. He didn't have to dedicate his life to this, but he really dedicated his life to the Senate.

**Heininger:** You know, there's a whole lot of legislation that I could ask you about, but this is far more important. These are very thoughtful reflections on him.

**Kessler:** If you said, "What were the influences on him? How did he pull it all together?" He did it in a way that you have to—For me, the most interesting thing of late is the joy of watching him with the endorsement of Senator [Barack] Obama.

**Heininger:** He loves to campaign.

**Kessler:** I'm on the other side working for Mrs. [Hillary] Clinton, but you could see and you could understand, when you look at his career, why he did what he did. And I only watched it on television.

**Heininger:** And don't underestimate the effect of Caroline Kennedy's decision to support Obama on him.

**Kessler:** It's the aspirational quality. As he was taking my kids around the office and the Library, he understood the role of moments in history of this country. He understood the way his brothers captured the magic. That's part of his makeup. Whether this was part of getting angry at what happened in South Carolina—you have to believe that that's secondary to believing that there was something that was aspirational, and a degree of enchantment, an enchantment of people who had not been enchanted before, that he had not seen in American politics in 30 years.

**Heininger:** Particularly the appeal to youth.

**Kessler:** And so it was, *Wow!* As much as I, for political purposes, didn't want to hurt Mrs. Clinton in this—He saw that, and you could understand why he did what he did, because he

believed. Whether Caroline was the one who—how he got to the point where somebody told him there is a magic that is happening, he believed that. And when he understood that—he hadn't seen that since his brothers. That had not happened in this country since his brothers.

He's still like a kid in the Kennedy Library—well, he was with my daughter. To him it was still aspiration of what we, as a country, could build. That's what he's believed in healthcare, and he probably will not see it in his lifetime. But that didn't stop him from all the accomplishments along the way.

**Heininger:** Well, that's one reason why he's so interesting to do an oral history on.

**Kessler:** What's fascinating about him as an individual is how he is as steady, he is as loyal, he is as persistent, he is as commanding, he is as disciplined, he is as wise in his Senatorial professional life as could be. And yet, we all know, and it's fascinating to watch, how you can be as in-command and as disciplined and as persistent over the long haul, but that wasn't always the way he was, personally. You know much more, but it's interesting how you could have certain parts of your personality—In certain spheres you are one way, and in certain other ways, you're not.

**Heininger:** I think your use of the word “authentic” is a very interesting word to apply to him, because of the principles not changing.

**Kessler:** It's remarkable. When you read the book in '72 and you look at where that came from—

**Heininger:** Larry had a lot to do with that book, too—Larry and Phil Caper.

**Kessler:** We're always made better by those around us. But he put his name on it. You get to believe your own—you say certain things, it sounds right, and then you believe it too. You said certain things and they resonate, they stick with you, and you're able to— It's not the first time you say it that's important; it's when you say it and you know it sounds right and you stick with it for 30 years.

How old was Larry when he did this?

**Heininger:** Very young. It's '71 or '72?

**Kessler:** This is '72.

**Heininger:** He, at that point, was a fellow for Kennedy. I'm going to turn off the recorder. Thank you.