ORAL HISTORY OF WILLIAM B. SCHULTZ, ESQ.

This is the sixth in a series of interviews of William B. Schultz conducted by Stephen J. Pollak on behalf of the Oral History Project of the District of Columbia Circuit. This interview was conducted on November 11, 2021, in Washington, D.C.

Mr. Pollak: Good morning. Bill Schultz. We are here in the Pollak kitchen on a bright sunny morning. We pretty much completed your experiences and comments about your long service with the Public Citizen Litigation Group during our last interview in June 2021. So before really closing the book on that, do you want to add anything to what you have said about those years? And would you like to comment about or put in context the many writings and your Congressional testimony that are spread across a summary sheet dated December 2010 that you have provided?

Mr. Schultz: Well, I had to compile a list of articles and testimony before I went to HHS as General Counsel which I will give you to attach to this history.

Mr. Pollak: That would be good.

Mr. Schultz: One of the things about Public Citizen Litigation Group is that you got paid to do almost anything you wanted to do that fell within the general interests of the organization. If I wanted to spend the morning writing an op-ed piece or spend a week writing an article, that was never questioned. In fact, it was encouraged because we were trying to affect public policy, which you do through litigation, legislation, and petitions to agencies, and through writing. And so this is a list of articles I wrote over the years.

There are a couple of articles on the Delaney Clause. I litigated issues about the Delaney Clause, which prohibits approval of cancer-inducing additives, for many years. The articles are mostly about food and drug law, but there are some about nuclear power because of my work on the Price Anderson Act. I wrote op-ed articles in *The Washington Post* or *The New York Times*. Some are in food and drug law journals, and a variety of other places.

There is also a list of Congressional testimony. It turns out that I testified 36 times. And this reflects the fact that in addition to litigation, I was very involved in legislative and oversight activities in Congress. When there is a Congressional hearing on a food and drug issue or regulatory issue, the committee will typically have the agency involved as the first witness. There will always be industry witnesses, but the committee typically wants representation from a consumer or other public interest group. And so to the extent that I had gained expertise, mostly through litigation, I was a candidate to testify.

Mr. Pollak: What was the procedure, starting first with the writings?

Mr. Schultz: I don't remember anybody ever questioning the content of anything I wrote. Like everything we did at the Litigation Group, I am sure anything I wrote, I would show to one or two other people to get their comments.

Mr. Pollak: And who were those other people?

Mr. Schultz: Typically, colleagues at the Litigation Group. But I might show it to Sid Wolfe or somebody at the Health Research Group. I wrote an article with Ralph Nader,

so I obviously traded it back and forth with him. But these were mostly articles that were my idea, something I wanted to write about. I am sure I always showed it to one or two other colleagues and I always got excellent feedback.

Mr. Pollak: And the same thing with your Congressional testimony?

Mr. Schultz: Yes. Very often I would be working with our lobbying group, Congress Watch, so I might show it to someone there. All of this was very much in our control. I suppose if I had offered an opinion that was contrary to something we were advocating, there would have been a discussion about it. But there was really no culture of censorship. I was free to write about my opinions.

Mr. Pollak: And who were the people with whom you worked – was that Congress Watch?

Mr. Schultz: So, when Ralph Nader founded Public Citizen, he set up a litigation group, a health group, and lobbying group. And the Lobbying Group was Congress Watch. I think Mark Green was head of it for a while, but much of the time Nancy Drabble was the director. And there were other people that might have been working on a particular issue.

Mr. Pollak: Do you have anything more that you want to say about those Public Citizen years?

Mr. Schultz: Ralph Nader's involvement was interesting. He formed many public interest groups and then would typically remove himself and send them out on their own. He started Center for Science in the Public Interest, the leading food group, and I've been on its Board for years. When I was at the Litigation Group, Ralph wanted to start a group of trial lawyers to do public interest law. He took me to some of the early meetings. I think mostly because he wanted to convince trial lawyers that they hire good lawyers at a low cost. His original idea was that trial lawyers would want to take six months off and come to Washington to do public interest work. It was called Trial Lawyers for Public Justice.

That was the original idea, but it ended up being another public interest group, this one funded by trial lawyers, that did *amicus* briefs and other kinds of litigation to support policy of interest to trial lawyers.

And it has been very successful.

I talked about case ideas that came from Ralph. Sometimes, I testified with Ralph on matters. In those days, Ralph Nader was such a huge figure, and it was a very big deal to testify with him. He was quite interested in the nuclear power case we brought. And when we won the case in the district court, we had a press conference in our little office jammed with reporters. I was surprised that he seemed kind of nervous before the press conference even though he had done this so many times.

He started Public Citizen with all its component organizations. His pattern was to start an organization and then to step away, which he did with Public Citizen eventually in about 1979 or 1980. He didn't want to manage.

While he was president, he would sign every paycheck and review every expense. He was a true miser. It drove people nuts to some extent, but it wasn't really what he wanted to do. He wanted to write and speak, and he wanted to start the organizations but didn't want to run them.

Mr. Pollak: Was he a good judge of personnel?

Mr. Schultz: He certainly did a good job hiring managers for Public Citizen. As I've discussed, Sid Wolfe, Alan Morrison, and Joan Claybrook were exceptionally talented. Mike Jacobson, director of the Center for Science in the Public Interest, is a dedicated advocate for food safety and science. Clarence Ditlow, director of the Center for Auto Safety for forty years, played a role in many auto recalls like the exploding Ford Pinto gas tanks. This was an enormously talented group, and they were in these jobs or in public interest for their entire careers.

Mr. Pollak: Do you want to cover meeting Sari Horwitz, your wife?

Mr. Schultz: It was 1986, and I was still at Public Citizen Litigation Group. I had become close friends with Bill Corr, who worked for Congressman Waxman and was his FDA health person, and his wife Susan. And they are wonderful people.

After they got engaged, I wanted to take them out to dinner. We went to a little restaurant in Adams Morgan, and when the check came, they insisted on paying their share because I was a public interest lobbyist. They were very, very ethical. They both worked on the Hill at that time.

Later, Susan got the idea to introduce us or to set up Sari and me. And Bill called me and asked me if I was interested. I think it took a long time for it to happen. It turned out one of Sari's colleagues at *The Post*, Anne Swardson, who was dating my friend Kerry Scanlon, also wanted to set us up. So we had two people try to set us up. We first went out on May Day..

Mr. Pollak: In 1986?

Mr. Schultz: In 1986. And we had dinner at the Thai Taste on Connecticut Avenue. I knew Sari worked in Rockville at the Maryland Bureau for *The Post's* Metro section. And I assumed she must live out there. When I talked to her, it turned out that she lived essentially a block from me. I lived on Woodley Place and she lived on Connecticut Avenue in an apartment building -- and could practically see my house from her apartment.

We went on a blind date, and then saw each other all the time. I took her sailing, and introduced her to my friends John Sims and Nancy Drabble.

And then at the end of the month, Sari went to Coronado Island, near San Diego. Her mother had won some kind of raffle and had a place to stay out there for a week. I took her to the airport, and when she got to California, she called me and said, "You should come." And I said, "Really." She said, "Yeah, yeah, yeah. You should come." I talked to my friend Kerry Scanlon and he said, "Yeah, you should do it." So I went out there and we spent the weekend. I met her mother and her sister. We never made a decision to live together, but soon after we were.

Mr. Pollak: When did you marry?

Mr. Schultz: We got married two years later, June 19, 1988.

Mr. Schultz: The summer after we met, we went to Italy.

Mr. Schultz: We were in Rome first and had gone to this restaurant that had been recommended to us, a wonderful restaurant in Trastevere. We had spent all our money, and we were walking back to the place where we were staying in Rome. We were walking through an area where there were bars and people in the street and everything. It was a wonderful evening. And I just grabbed her and proposed to her. And Sari's reaction is, "You can't do this now. We have to be somewhere where I know where it is." And we went to the Trevi Fountain and I proposed there. And then we stayed up all night talking.

And interestingly in 2016, when we went back to Rome, we decided to find the spot where I proposed, which was very difficult, but we found it. We actually found it.

Mr. Pollak: And was there a plaque there? Memorializing…

Mr. Schultz: There should be. It was a little different than we remembered but we are quite sure that we found it. I remember people spilling out of a bar, but it turned out that there was a bar there and people being served while standing outside. It wasn't a bar with people spilling out. Sari couldn't believe that as a journalist she hadn't written down the name of the street.

Mr. Pollak: And where were you married?

Mr. Schultz: We were married here. The wedding was in Maryland, at an estate. We didn't want to be married in Maryland, so we got our license in D.C. and had Judge Bryant marry us the day before in our house on Woodley Place. At the wedding we didn't tell anybody, and the guests witnessed us being married by a rabbi.

Mr. Pollak: So, you've been married about thirty-seven years.

Mr. Schultz: Thirty-three years.

Mr. Schultz: It's been a good long time. Not as long as you.

Mr. Pollak: No. But you will be.

Mr. Schultz: It's been a great and wonderful marriage. I'm very fortunate.

Mr. Pollak: Well. What next?

Mr. Schultz: So next is Henry Waxman and the Energy & Commerce Committee's Subcommittee on Health and the Environment.

Mr. Pollak: And how did that come about?

Mr. Schultz: At some point, I learned that there was an opening to be staff director for Senator Metzenbaum on the Subcommittee on Competition Policy, Antitrust,

and Consumer Rights, a subcommittee of the Judiciary Committee. I had worked with the Committee staff on the Bork hearings and other matters, and I applied for the position. I was interviewed by Senator Metzenbaum. One of the other applicants, Bill Corr, my good friend in Congressman Waxman's office, got the job.

Bill then talked with me about taking his job as staff counsel of the Subcommittee on Health and the Environment. It's a staff of about ten and they supported Henry Waxman on all his work.

I was disappointed that I didn't get the Senate subcommittee job and didn't think I was really interested in the House position. I wanted to be a staff director, but not a staff member. But I talked to Bill and he was very persuasive. And my friend Pat McLain, who had worked for Dingell's Oversight Committee and had become a good friend, was very persuasive. And then I decided to see if I could talk to Abner Mikva about it because Judge Mikva was both a judge on the D.C. Circuit and had been a Congressman for a number of years. I didn't know him personally but had argued several cases before him, and he agreed to talk to me, so I went to his chambers and we talked about it.

Judge Mikva was encouraging. I don't remember the details but he must have talked about Congressman Waxman's talent as a legislator. He said that Waxman was a tough boss. If you didn't make the cut, he would get rid of you.

After thinking about it, I decided I didn't have anything to lose. I had always been interested in working in government but almost my whole career at Public Citizen had been during Republican administrations, and it wasn't clear when that was going to end. So I decided to do it.

Mr. Pollak: And did you then deal with the Committee Chair? Waxman?

Mr. Schultz: Bill Corr arranged for me to be interviewed by Congressman Waxman. I was interviewed by him and Karen Nelson, who was staff director of the Subcommittee. The full committee was the Committee on Energy and Commerce, was chaired by John Dingell of Michigan, a very powerful long-time representative. Congressman Dingell also chaired the Energy and Commerce Oversight Subcommittee. That's where Pat McLain had worked. But there were others, on communications and on various topics that the full committee covered. The committee had very broad jurisdiction. The Subcommittee on Health and the Environment had jurisdiction over the Food and Drug Administration, Medicare, the Centers for Disease Control and Prevention, and many of the public health agencies. It also had broad environmental jurisdiction over EPA.

Mr. Pollak: Would you pause and explain who controlled the House at that time.

Mr. Schultz: The Democrats controlled the House and had since the mid-1950s. I don't remember much of the interview, but I asked Congressman Waxman whether he had designs on running for Senate from California. And his answer to me was, "Why would I want to do that? I'd have to be junior to Teddy Kennedy."

Senator Kennedy was chair of the Senate Health Committee. Today it's called the Senate HELP Committee because it covers health, education, labor, and pensions. Although Congressman Waxman was chair of a House subcommittee, he was very powerful and considered himself to be an equal of Senator Kennedy.

Congressman Waxman was often in conflict with Congressman Dingell, particularly over environmental issues, because Congressman Dingell represented Detroit and the auto makers. Congressman Waxman was seeking to strengthen the environmental laws and particularly the Clean Air Act. On health issues, they had common goals but theirs was never a close working relationship and there were plenty of conflicts.

Mr. Pollak: You spent four years at least, or maybe a little more, in what position with the Waxman subcommittee?

Mr. Schultz: I was counsel to the committee for five years. Karen Nelson was staff director, and there were seven other staff members. I was one. It was an extraordinary staff, as talented as the Litigation Group. The difference was they didn't get credit for their work. As a staff member, you are not the one signing the briefs or signing the bills; you're very much in the background. The staff was extremely dedicated, and most planned to stay with Congressman Waxman for their careers. The Director, Karen Nelson, was probably the most talented staffer I worked with on the Hill, and even more in the background than the rest of us.

I didn't know her well before I began working with the Committee because even though I had been in many meetings with her, she was always very quiet. She just never pushed herself forward, but she was a master of both substance and procedure.

Karen is an extraordinary person. She left work around six every night because she always had a full evening scheduled. She had season tickets to the Wizards. She had tickets to the Baltimore Orioles in those days. She had tickets to the opera. She had a regular bridge game and book groups. Every year she would have a party because she would buy eight season basketball tickets and the party was attended by much of the Washington Democratic public health community. You would sign up for a certain number of these tickets at this party and you would draw a number, and then you would get to pick the games you were going to go to. And then she would spend the year rearranging the schedule to accommodate everyone's busy lives.

Karen brought people together. She had and still has a Kentucky Derby party every year. And after the staff moved on, except during Covid we've had lunch every month. We have a holiday party every year at our house, all for the same group. It's been a group that has really kept together.

Phil Barnett and Greg Wetstone, both environmental lawyers, are enormous talents. Phil Schiliro was the staff director of Congressman Waxman's personal office. Tim Westmoreland went to Yale Law School and

started working on AIDS issues and legislation, including the important Ryan White CARE Act, while he was law school.

He began working for the subcommittee, even though he had not graduated from law school. When Democrats lost the House majority twenty years later, it was time for him to leave and he wanted to teach at Georgetown University Law Center. Only then did he complete his final his paper and receive his law degree.

Andy Schneider was the expert on Medicaid. He and Henry Waxman completely transformed the Medicaid law and figured out a way to fund the Children's Health Insurance Program and to expand Medicaid in various ways. Mike Hash was the Medicare expert. Each of these people were probably the most knowledgeable on the Hill on whatever their subject area was.

Mr. Pollak: Did any of them become members of the executive branch? And leave the Hill?

Mr. Schultz: Bill Corr, my predecessor, was a Deputy Assistant Secretary of Health and Human Services and Chief of Staff to HHS Secretary Donna Shalala in the Obama Administration, he was the Deputy Secretary of HHS. Phil Schiliro became counsel to Senate Majority Leader Tom Daschle and then had positions in the Obama White House, among them Assistant to the President and Director of Legislative Affairs. Mike Hash was head of the HHS Centers for Medicare and Medicaid at the end of the Clinton Administration. During the Obama Administration he worked in the White House on the enactment of the Affordable Care Act and then as head of the Center for Consumer Information

and Insurance Oversight, or CCIIO, the component of HHS charged with implementing the ACA. Andy Schneider had a role in the Medicaid Agency during the Obama Administration. Ruth Katz became Dean of the George Washington School of Public Health. Phil Barnett and Karen Nelson stayed with Congressman Waxman. Phil Barnett briefly worked for David Kessler and me in the Clinton Administration. He then returned to the Hill as staff director of the House Oversight Committee after Congressman Waxman became chairman when the Democrats regained control of the House. Everyone continued to work supporting the goals they had achieved with Congressman Waxman.

Mr. Pollak: So, what were relations with the Republican staff members? What were the relations between Congressman Waxman and others in the majority with the minority juxtaposed against, you might say, today?

Mr. Schultz: He understood that as a member of the majority party, he had to work with the minority and formed solid working relationships with some of his Republican counterparts, including Ed Madigan, the top Republican or ranking member of the full committee, and Tom Bliley, the ranking member of the subcommittee. Tom Bliley was from Richmond and congressman for tobacco giant Philip Morris. Madigan was a conservative as well. But it was a productive working relationship, and we forged a number of deals.

We knew we couldn't pass legislation without getting Republicans on board. I worked most with Republican staffers Mary McGrane and Howard Cohen. Mary was viewed as a very difficult person. The first time I was to meet

with her, we were working on a bill to amend the Orphan Drug Act. I was working on the bill with Tim Westmoreland, and as we were scheduling the meeting Tim said, "We go visit her. We go to her office." This was a way of showing respect.

It was clear that she was suspicious of me because I had come from one of Ralph Nader's groups and she probably assumed that I would be an uncompromising progressive ideologue. In the end we formed a very close relationship. It was a matter of trust. Like most people, Mary didn't want to look bad. And I made sure that I protected her wherever I could, and we reached agreements on a number of important bills. In fact, that first year, she was working on the first amendments to the Medical Device Act since 1976 with another member of our staff with whom she didn't get along. It looked like the bill could pass but she refused to work with this other member and asked to work with me. We became friends and it ended up being an excellent relationship.

Mr. Pollak: And how did you understand the objectives that the Republicans were seeking to achieve as compared to what Congressman Waxman was seeking to achieve?

Mr. Schultz: With respect to staff, there were lots of good relationships across party lines. There were a lot of friendships, even though on many things we had real disagreements. And it's not as though there weren't arguments or accusations. It wasn't all smooth, but there were real friendships.

Mr. Pollak: So how was this experience different from being in a litigation shop?

Mr. Schultz: In a number of ways. First of all, litigation is endless. I mentioned one case, a challenge to FDA's review of over-the-counter drugs, that I was assigned my first day at the Litigation Group. A version of that case was still active when I left fourteen years later. That was an extreme example, but it wasn't unusual for a case to take five years or longer. Legislation is on a two-year cycle. Each Congress lasts for two years and then you start over again. Anything you wanted to accomplish you had to get done within that two-year cycle. This created a deadline that moved things along. And at the end of the Congress, we worked constantly. It was not unusual to be up all night. Once I was up two nights in a row.

During my first year, which was the second year of that Congress, Congressman Waxman had ten bills on the House floor that he was trying to pass, including the Clean Air Act of 1990, the Nutrition Labeling Act, medical device amendments, and Orphan Drug Act amendments. And, of course, once a bill passes in the House, it still has to pass in the Senate.

It was a very exciting job with a lot of negotiating, a lot of back and forth. And I've alluded to the importance of relationships. In litigation, you are presenting to a judge. You have to deal with counsel for your opponent. Those relationships matter to some extent but on Capitol Hill it's all about relationships. You're aware that one staff member can block a lot of good work by another.

Also, the opportunities for impact are enormous. If you're working for a member who is passing legislation, which I was, the staff typically writes and negotiates the legislation as well as the committee report. If the bill has been negotiated with Republican staff, there typically won't be a minority report. I used to think that you could resolve a hundred lawsuits in a single committee report. The members paid little or no attention to the committee reports and rarely to the language of the legislation. The work was done by the committee staff of both parties, which had to reach agreement for legislation to be enacted.

The process of finalizing documents was different. Like a Supreme Court brief, a committee report is printed professionally. After I wrote my first report, it was reviewed, everybody signed off on it, I proofread it, and then sent it to be printed. And unlike a brief, there was no opportunity to review proofs. I simply received the printed version.

When I started reading my first report, I spotted at least five typos. And when I raised this with the clerk for the full committee who was in charge of printing she said, "There's nothing we can do about it. You just have to live with it." There was a lot to get used to.

The laws were written by legislative counsel. If you were getting ready to draft a law, you would outline it and then go to the House legislative counsel, the experts on drafting legislation. They would create a draft, and then there would be a lot of back and forth. As the negotiation was done or as amendments were drafted, those were also typically drafted by legislative counsel. I had the

service of real legislative expertise, and the House legislative counsel in those years was far superior to the Senate counsel.

Mr. Pollak: Now who was that? By name.

Mr. Schultz: David Meade headed the office. He was also the counsel who drafted FDA legislation and almost everything I did. Some of the people in that office were absolutely brilliant. And again, they are all unsung heroes. You never read about them in the newspapers, but they are skilled experts at what they do.

I should also note Henry Waxman's management style. His philosophy was to give his staff enormous responsibility and always to back them up. Everybody on the Hill knew that if a Waxman staff member presented something, he was really speaking for Henry Waxman. And it gave Henry enormous influence.

I'll give you an example that relates to federal preemption of state laws. This was often a business priority since businesses were seeking ways to avoid state regulation. The over-the-counter drug industry sought preemption to avoid state laws requiring, for example, special labeling, such as pregnancy warnings about drugs and so on. At the Litigation Group I had gotten to know Jim Cope who was president of the Proprietary Association, the trade association for the over-the-counter drug industry. They intervened in our case about over-the-counter drug review.

Jim was a lobbyist and had a friendship or relationship with Congressman Waxman. He was trying to get me to agree to some language that

would preempt state laws for over-the-counter drugs, and he wasn't getting anywhere, so he asked to meet with Congressman Waxman without staff. Henry granted the meeting and afterwards Jim asked to meet with me. The meeting with Waxman hadn't gone well. Jim told me that Henry said Jim had to talk to me and persuade me of Jim's position. That was Henry's way, and everybody on the Hill understood they had to deal with his staff and that the staff spoke for him.

Mr. Pollak: Talk about how Congressman Waxman then worked his own will through his staff.

Mr. Schultz: Well, we were expected to brief him on the issues that were important enough to rise to his level. There were a lot of things we did that, in our judgment, he wouldn't be interested in or we knew would be consistent with what he wanted. But we were expected to keep him informed and tell him what we thought he needed to know. For me, it worked out very well.

I don't remember making a decision and Henry later saying: "That was a mistake." It was a small staff, and we had a lot of contact with him. He stayed in the background of a lot of the negotiations, but he was always there when you needed him.

Once there was a deviation from this practice. It's recounted in a book called *The Waxman Report* that Henry wrote with Josh Green about his years in Congress. In the book he recounts when the industry was trying to get legislation passed that would weaken FDA's regulation of dietary supplements. It was very,

very contentious and the House and Senate negotiated the details of the bill. Henry recounts in this book an important issue about whether certain kinds of claims were going to be allowed on dietary supplement labels. These were not claims about treating diseases but about what is called structure and function. For example, a claim that a dietary supplement will boost your immune system, increase antibodies, or make your bones stronger. The Senate and the industry had been advocating for this provision, and Henry had been opposing it. During negotiations, Congressman Dingell, whom we were trying to keep close to us on this, suggested a disclaimer: "Well what if we just had a disclaimer. So, we allow the claim but the label says this isn't approved by the FDA." Henry agreed to it. And he says in his book that he looked at his staff, and I suspect he was referring to me, who looked crestfallen. He realized that he didn't do what he'd always done, which was never to agree to anything without consulting his staff, whom he regarded as the experts. And years later at a party, he apologized to me for this. It was seared in his memory because it was so different from the way he usually managed his staff.

Mr. Pollak: Very, very interesting. Well. You were going to look at your first year on Capitol Hill, what legislation you worked on, and what became of it. I'd like you to identify whether your first year was the ending year of a Congress.

Mr. Schultz: It was. My first year, 1990, was the second and last year of the 101st Congress. So, we had to either pass the legislation or start over in the following Congress.

Mr. Pollak: What was the focus of your first year and your own role?

Mr. Schultz: I worked on several bills: The Nutrition Labeling Act, which was the most important one; the Medical Device Amendments, which were the first amendments to the 1976 Medical Device Act; and amendments to the Orphan Drug Act, a law that provides special rules for the approval of drugs for very rare diseases. The phrase "orphan drug" comes from the idea that there were drugs that could treat rare diseases but were never developed because they weren't profitable enough for the drug companies.

The Orphan Drug Act created a structure that provided incentives for industry. The key incentive was that if a company had an orphan drug, even if the patents expired they got seven years of marketing exclusivity, guaranteeing seven years with no competition. There was also a grant program and the law conferred tax credits for clinical testing. However, by 1990 to almost ten years later, the Orphan Drug Act had been used for some very profitable drugs. Even though to qualify the disease population had to be under 200,000, it turned out with increased prices drug manufacturers could make a lot of money in a population of fewer than 200,000 patients. Among them were AIDS drugs and human growth hormone, a drug sold to stimulate growth in children who were of short stature that cost $10,000 or $25,000 that was seen as an enormous opportunity for profit. Of course, today, drugs can cost $100,000 or even $500,000 per year.

Our bill aimed to place some limit on which drugs could qualify, and it was vigorously opposed by the drug industry that was by then making vast sums

of money from orphan drugs. I negotiated a deal with Mary McGrane, our Republican counterpart, in which we got part of what we wanted. It passed in the House, maybe almost unanimously, and I think it was passed in the Senate unanimously. It went to President George H. W. Bush to sign, but he vetoed it even though it essentially had unanimous support in both the House and the Senate. It appeared somebody from the industry got to him, or to his staff.

Mr. Pollak: You have any comments? Special comments to make about these other major pieces of legislation in that first year?

Mr. Schultz: It's worth talking about the Nutrition Labeling Act because it is such an important piece of legislation and the negotiations were interesting. This is the law that requires nutritional information on food labels. So today if you buy almost any canned or frozen food, there is a label that says how many calories and various other nutrients it contains. The bill also regulated health claims and established the rules for claiming that a food will prevent disease or is otherwise beneficial. It was a highly contested piece of legislation. Before the bill passed when you bought food, you had no way of knowing how many calories it had, its cholesterol level, or \the fat content. And our position benefited from the fact that many middle-aged, senior male members of Congress were watching their calories and cholesterol and were very frustrated that they couldn't get information on what was in the food they were purchasing. The National Academy of Sciences issued a study of food labels, and then Congressman

Waxman and Senator Metzenbaum sponsored legislation. Senator Kennedy may have indicated he wasn't interested in the topic.

They introduced the Nutrition Labeling and Education Act, or NLEA. The Subcommittee held a hearing before I joined the staff, but it was a very contentious hearing and there were questions about the bill's fate.

The NLEA had been skillfully drafted by Bill Corr. One of the big concerns, not surprisingly, had to do with preemption. This derived from the fact that California had adopted an initiative called Proposition 65. Proposition 65 required that any product, including food products, that had a carcinogen known to the State of California had to be labeled as such in California. This applied to food, to drugs, to gasoline, and to all other consumer products. Industry hated Proposition 65, and ordinarily a food labeling bill would have been a perfect vehicle to preempt Proposition 65 as it applied to food. Proposition 65 was a California initiative designed to make products safer by eliminating carcinogens, and Congressman Waxman didn't want to support a bill which would have preempted or nullified this home state initiative.

Bill Corr knew this when he drafted the Nutrition Labeling Act, so as the Waxman staff often did, he consulted with the House Parliamentarian to figure out how to draft legislation in which a Proposition 65 Amendment would not be germane, meaning that the amendment couldn't be added to the bill because it wasn't relevant. Bill drafted a food labeling bill that never mentioned food; instead it referred throughout to nutrients. He did so because food has

nutrients, but it also has carcinogens, and a Proposition 65 Amendment would have been germane. But nutrients are not carcinogens. The NLEA was drafted that way and having the approval of the Parliamentarian gave us protection on the House Floor that there couldn't be an amendment to preempt Proposition 65.

When I negotiated with the Madigan staff, who were representing the Republican members, we resolved many issues. but we could not reach an agreement on Proposition 65. In the full committee markup, everything went smoothly until Congressman Madigan introduced his amendment to preempt Proposition 65, followed by Congressman Waxman raising a point of order to argue that the amendment wasn't germane. We understood that the Parliamentarian doesn't control the committee, and that Chairman Dingell could rule either way. Chairman Dingell was generally supportive of the bill, but he didn't have the greatest relationship with Congressman Waxman because the Clean Air Act amendments were also being negotiated at that time. We didn't know how he was going to rule.

We made our arguments to Dingell's staff. We told him about the Parliamentarian's ruling, thinking that would mean something to him, but there was no guarantee. And if he allowed the amendment, then we had no protection on the House floor. The amendment would be in the bill, and after that the germaneness of the amendment didn't matter.

After Congressman Waxman made his point of order, Dingell, who was a very large man, ordered his staff to bring in the largest dictionary I had ever

seen. He opened the dictionary, turned to the word "nutrient," and read the definition. He then turned to the word "carcinogen" and read the definition. After all this drama and some time to think, he ruled that the amendment is not germane.

This meant it could not be voted on in the full committee, which created the pathway to pass the Nutrition Labeling and Education Act.

Mr. Pollak: Do you think he had prepared with his staff to consult this big dictionary?

Mr. Schultz: Yes. His staff had that dictionary ready, and it was very dramatic. This meant that we could get the bill passed in the House, but it was questionable whether we could get it passed in the Senate, particularly since we were at the end of a Session and time was very precious. At the end of a Session, it's not possible to allocate the time needed to invoke cloture to defeat a filibuster.

As you know under the Senate rules, if a single senator objects and demands a vote, the matter can be debated or filibustered indefinitely. To cut off debate takes many hours which are not available at the end of the Session. This means that a single senator could block any bill unless it's designated as very high priority.

Mr. Schultz: As a result, we engaged in an extended negotiation with the food industry because we knew if we could get their agreement, we would have a much better chance of getting it passed in the Senate. The industry was represented by Peter Barton Hutt of Covington & Burling, who was the lead lawyer for the Grocery

Manufacturers Association. We also had to satisfy the Food Processors Association and trade associations representing grocers and other interests.

There were many details to be worked out, but ultimately we agreed to preempt the states as to some aspects of the food label, but not on Proposition 65. For example, FDA has standards that define certain foods. In the case of cream cheese, FDA might have one definition while a state might have another. Similarly, FDA might require that maple syrup have a certain percentage of maple syrup and a state might require a different percentage, as Vermont did for maple syrup.

In these long negotiations, we agreed to narrow preemptions of some of these provisions. That empowered Peter Hutt to go to the industry and say, "Look. You're getting a great deal. You've gotten Henry Waxman to agree to preempt some state laws." And Congressman Waxman didn't really have a problem with it. I think he felt that with a strong FDA, strong national standards, and national products, it wasn't necessarily a good idea to have individual state standards particularly when you are talking about the label. This wasn't about food safety or food carcinogens. It was about what was on the label.

The compromise angered the lobbyists for the consumer groups, who were unhappy with me. The Center for Science in the Public Interest had sponsored the bill, but the consumers' lobbyists wanted to oppose it because of the preemption. It did pass and today CSPI sees it as one of their greatest

achievements. But there were some rough moments during the negotiations. We reached a deal with the grocery stores that the labeling there would be done by signs rather than directly on the fresh produce. We agreed to various exemptions for small businesses.

One of the interesting things about legislating in the House is that after the committee reports the bill out, you can rewrite the entire bill, as we did here, as long as support is strong enough to qualify for the suspension calendar. The suspension calendar is a decision made by House leadership where all the Rules are suspended. The bill doesn't go through the Rules Committee and there are no amendments. Debate is limited to 40 minutes for each side and 60 percent of the members must vote to pass it. This was the path we used for a lot of our legislation, including the NLEA.

Mr. Pollak: Tell me, how did you spend your days? What did you do?

Mr. Schultz: In addition to negotiations, I spent some time drafting legislation. I spent time preparing for hearings.

Mr. Pollak: What's the substance of what you did to prepare for a hearing?

Mr. Schultz: Often I spent time preparing witnesses. David Kessler often jokes about the timing of my preparation with him. When he became Commissioner of FDA, he testified at a number of hearings including the tobacco hearings, which I'll talk about at some point. I always wanted to make him look good. I would call at eleven o'clock at night after I had finished the questions, read him the questions,

and we'd discuss the answers. The result could be a very successful hearing. I spent considerable time with Administration officials.

We conducted both legislative hearings and oversight hearings. For the oversight hearings, there can be an enormous amount of preparation, including witness interviews and document review.

Sometimes the negotiations were to satisfy a single member. In the case of the NLEA, one member, Roy Rowland, a Democratic congressman from Georgia, wanted us to resolve an issue about Vidalia onions sold in liquor stores in Georgia. The liquor stores did not want to be required to have a nutrition label on their Vidalia onions, which seemed reasonable as long as it didn't drive a hole through the rest of the bill. So we wrote an amendment exempting Vidalia onions and any store that had a very small food sales.

Mr. Pollak: Did you draft the Committee Reports?

Mr. Schultz: Yes. I drafted the reports for the bills on which I worked. If it was an agreed-to bill, we would show it to the minority staff and get their comments in an attempt to avoid a dissenting report.

I'll mention something about office space. I was forty years old and had always had my own office, but it didn't work that way on the Hill. Everybody shared offices. The primary offices were in the Rayburn Building because that's where the hearings were held and that was where the congressmen had their offices. Most of the staff offices were in House Annex One near the Rayburn Office Building. The Republicans were in House Annex Two, which was much

farther away. House Annex One, where I had my office, was an old building that was so precarious the file cabinets could only be two drawers high.

When I moved in, I replaced Bill Corr. Moving in essentially amounted to sitting at Bill's desk. The nameplate on the mailbox said Bill, so we didn't even have to change that. I shared an office with Phil Barnett, and the first time I heard him talking on the phone it was jarring. I wasn't sure how this would work since we were on the phone fairly frequently. But it worked out. I shared an office with Phil for five years and most of the time we worked on completely different topics because he worked on the Clean Air Act and environmental legislation. At the end, we worked together on tobacco.

Mr. Pollak: And having been a litigator, did you bring a special awareness when you worked on reports about the legislation?

Mr. Schultz: Yes, I think the litigation background, the regulatory background, and the administrative background were very helpful. Because of my litigation background, I had some sense of what issues could be litigated. I tried to do everything I could to resolve as much potential litigation as I could in legislation and in the Committee Reports. In those days, courts actually paid a lot of attention to legislative history, and I knew very well how the courts weighed reports as opposed to floor statements as opposed to testimony at hearings. It was quite helpful and people on the other staff looked to me for that expertise.

Mr. Pollak: What happened to the Nutrition Labeling Act? Was it adopted in that Congress?

Mr. Schultz: Yes. It passed the House and we had to go to the Senate. Even though the industry was on board, a number of senators had things they wanted as a condition to passing the bill. We were particularly disadvantaged because our sponsor was Senator Metzenbaum, who was famous for blocking legislation through what was called "hold." When a bill was ready to go to the Senate floor for a vote, a notice was sent around to the senators. If a senator places a hold, the bill is blocked until that hold is resolved unless the leadership is willing to go through cloture procedures to override a filibuster.

In this case there were a number of holds I had to resolve one-by-one. The one that I remember was by Senator Jim Jeffords of Vermont who was upset because the bill preempted state food standards, including the food standard for maple syrup. The FDA food standard required a certain percentage of maple syrup in products labeled "maple syrup," but Vermont had its own special food standard requiring a higher percentage. Senator Jeffords wasn't going to allow a bill to be enacted that overrode what was so special about Vermont maple syrup, one of his state's signature products.

As a result, if you read the Nutrition Labeling Act very carefully, you'll see an exemption for the preemption of the food standards for maple syrup. We added that provision for Senator Jeffords. We resolved all the holds, and the bill passed the Senate unanimously. It had to be unanimous at that time of year in order to pass.

Mr. Pollak: And how did it fare once it was out in the world?

Mr. Schultz: I think it's seen as a great success. Consumers love the nutrition label. David Kessler was by this time the FDA Commissioner and he hired an outside group to design the label.

Before the bill became effective, FDA had to issue detailed regulations standardizing such things as the serving size for each product. FDA was notorious for taking forever to issue regulations. The prospect was that we would pass this important legislation and it might be ten years before the implementing regulations were issued. To address this possibility we added a unique provision, and this is where I benefited from my experience litigating administrative law cases. The provision said the agency had one year to do a proposed rule and one year to do the final rule. If the agency missed the deadline for the final rule, the proposed rule would become final. That's what passed, and it worked. FDA got this regulation out in two years. Part of that was due to the focus of David Kessler and, I think, part of it was the pressure of that provision.

The other half of the bill regulated health claims, and this was the most controversial part. The NLEA set a standard for claiming that a food product improved health. The FDA issued a regulation defining the health claim standard, which required significant scientific agreement, limiting the kinds of claims made on food to those that are supported by scientific evidence and approved in advance by FDA.

I should mention that Senator Hatch's price for agreeing to the bill was the addition of provisions about dietary supplements. He wanted legislation that would loosen the standards for dietary supplements. We ultimately agreed to a compromise provision directing FDA to adopt a regulation that would decide the procedure and standards for approving dietary supplements. And FDA issued a regulation that said the procedures for health claims on dietary supplements would be the same as for food product claims, and the standard is also going to be the same. It wasn't what Senator Hatch wanted. But our way forward was to agree to this compromise. Senator Hatch may have thought that because David Kessler had worked for the senator, Kessler would look on this favorably, but he didn't.

In the next Congress, I spent an enormous amount of time on dietary supplement legislation as well as the Prescription Drug User Fee Act, President Clinton's health care reform initiative, and the tobacco hearings.

Mr. Pollak: You've described relationships between Democrat and Republican representatives and their staff and how things were worked out. How does that compare to today?

Mr. Schultz: From my perspective, the Hill unfortunately is an unpleasant place today. I don't want to say everything was perfect or everybody got along perfectly during my tenure, but Republicans' and Democrats' interest in legislating was the driving force. Also, we had an advantage because the Democrats had been

in power in the House for so long that everybody recognized their leadership and that they were in charge of setting the agenda.

When I was there, there were a few members who were extreme. There were members of our committee who were homophobic and opposed any kind of AIDS legislation, but they were outliers. And the Republicans were willing to negotiate over legislation that had provisions they thought would benefit them, even if the legislation ended up making the Democrats look good because they passed it. That is just not the case today.

An example of collaboration was what began as the Children's Pesticide Act to strengthen standards for pesticides. It was ultimately passed in 1996 as the Food Quality Protection Act after the Republicans took over the House. Congressman Waxman made a deal with Congressman Bliley because Waxman wanted the legislation and the Republicans wanted to be able to claim credit for legislating. Later there was a time when Congressmen Bliley and Waxman reached an agreement on tobacco legislation, but Newt Gingrich by then was Speaker of the House and would not approve it. Gingrich didn't want to make Henry Waxman and the Democrats look good. That was not consistent with his agenda.

Mr. Pollak: So, where will we pick up in the next session?

Mr. Schultz: I think the two pieces of legislation we should touch on are the Prescription Drug User Fee Act and the Dietary Supplement Health and Education Act. And then in 1993 to 1994, the Clinton health care plan and the tobacco hearings.