ORAL HISTORY OF WILLIAM B. SCHULTZ, ESQ.

This is the eleventh 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 Thursday, June 9, 2022, in Washington, D.C.

Mr. Pollak: So, Bill, welcome. We are working from a very excellent outline of Bill's. Bill, who was the Secretary you served at HHS? And talk to us about who she was, what you saw, and how you've evaluated her. And how you evaluated your working relation to her?

Mr. Schultz: It was Kathleen Sebelius. I did not know her before I went to work for her, except I had an interview with her. She was born in Ohio. Her father was John Gilligan, who had been a very progressive governor of Ohio. She came to the Washington area for college. She met her husband, Gary Sebelius from Kansas whose father had been a Republican congressman there. They moved back to Kansas and for ten years she was executive director of the Kansas Trial Lawyers Association and raised two kids. She once told me that she never thought of herself as somebody who would run for political office. But she ended up running for the state House of Representatives.

The first state-wide office she ran for was Kansas Insurance Commissioner. She won, and then was elected governor of Kansas twice. I always thought this was quite a testament to her political skills and her other skills because here she was a pro-choice woman, progressive woman, and she got elected statewide in Kansas four times.

Mr. Pollak: Sounds like a fairy story.

Mr. Schultz: Yes, it does, except it's true. She knew the Clintons. I think her husband had been nominated to be a district judge but was blocked by one of Kansas's Republican senators. Running up to the 2008 election, she made the judgment that she didn't think Hillary Clinton could win. So very early on she endorsed an obscure senator by the name of Barack Obama. When he was elected, initially she told me that she had indicated that she did not want to be in the Cabinet because she felt obligated to finish her term as governor. But when Senator Daschle's nomination to be Secretary of Health and Human Services failed, she was offered the position and she accepted.

I always think of her as a tremendous leader. Not just her vision and the way she understood and explained things, but the way she was able to engender tremendous loyalty among the people who worked directly with her and the people around the Department who were part of her staff and part of her team. In addition to the work, she always found time to have an interest in you. She would ask me about Sari and Rachael and something personal. I had the sense that this was somebody that cared about her staff and colleagues, and so we cared about her. She was also tremendously supportive of anything I wanted to do as General Counsel.

She understood the role of the General Counsel, and she understood that sometimes I would have to tell her that she couldn't do something; that she legally couldn't do something. It could be an ethical issue or a legal issue. She

wasn't always happy about it, but she understood. So that's Secretary Sebelius. I'm a fan.

Mr. Pollak: What were the relationships in that period of the Secretary with the White House, and how did that affect you?

Mr. Schultz: Yes, and one thing I should say if I haven't mentioned it before, Bill Corr was the Deputy Secretary.

Bill had been in the Department before and in Washington his whole career. He and Kathleen Sebelius put together a tremendous team of operating division heads and what we called staff division heads. These are the people who run the many departments of Health and Human Services. So, it was a real joy to enter that job two years in with this team of very skilled and very dedicated public servants.

One difference that stuck me about HHS in contrast to the Justice Department, the last government department I had worked in, is that most of the political appointees at Justice came from law firms and went back to private law firms. In contrast, the political appointees at HHS were more likely to be career public servants. Most of them went to nonprofits or tried in every way they could to continue the kind of work they had done at the Department, and what they had done before they came there.

Kathleen had a good relationship with President Obama. She had strong relationships within the White House, although what I found in the Obama Administration and the Clinton Administration is that the relationships between

Cabinet officials and the White House is a tricky one. Since 1980, the White House has become more dominant, its staff has gotten larger, and the policymaking and press responsibility has really moved from the Cabinet to the White House. There is a natural tension between the two and so while Kathleen had some strong relationships, this doesn't mean the White House was always happy with what we were doing.

Mr. Pollak: Did your Secretary and your Department have particular contacts at the White House with persons that they related to HHS concerns?

Mr. Schultz: Yes. There was Jeanne Lambrew, a longtime public health person in the Clinton Administration, very dedicated to Medicaid, had been at the Department when the Office of Health Reform was created, which was the office tasked with implementing the Affordable Care Act.

By the time I arrived, she was on the Domestic Policy Council at the White House. Jeanne was the one in charge of all the Affordable Care Act regulations, and there were many, plus Medicaid and Medicare. For regulations, the challenge was to get them cleared by Office of Management and Budget, or specifically its division, the Office of Information and Regulatory Affairs, which is tasked with doing economic analyses of regulations. In fact, OIRA as it is known takes a more aggressive role and the result can be a change in the substance and a very unfortunate delay.

Jeanne was able to cut through all of that. She was absolutely key to the implementation of the Affordable Care Act and other programs. There were

certainly others as well. There were four or five Chiefs of Staff at the White House, and the Secretary had different relationships with different ones. She had some very good relationships with the Secretaries of Education and Treasury, and good relationships throughout the government. The White House is a bunch of different power centers and you can't have good relationships with all of them.

Mr. Pollak: Do you want to identify any that she didn't have good relationships with?

Mr. Schultz: No. I don't think it was so much somebody who didn't like us as much as maybe they had other priorities. Nancy Ann DeParle for the first couple of years of the Obama Administration was the White House person tasked with doing healthcare. Then it was Mark Childress, Phil Schiliro, and Chris Jennings. Chris, Mark, and Phil were people I had a very strong connection to and had previously worked with closely. I had also known Nancy Ann for a long time. Phil Schiliro was Congressman Waxman's Chief of Staff; Mark had been on the Kennedy staff and was set to be Daschle's Chief of Staff if Daschle had become HHS Secretary. I'd known Chris Jennings for years when I worked for Congressman Waxman and in the Clinton Administration. I had known Nancy Ann while on the Hill and during the Clinton Administration. Those relationships were critical. And Secretary Sebelius had good relationships with all of them.

Mr. Pollak: Well, what were the key decisions or where were key decisions in your tenure made? At the White House on HHS area matters or at the Department? That's always in tension.

Mr. Schultz: In terms of the Affordable Care Act, in the first year the effort was to pass legislation, but the law passed in March 2010, before my arrival.

My sense is the project was really run out of the White House. After I came, which was March 2011, it was a constant flow of decisions about the Affordable Care Act, regulations that needed to be issued, and ultimately lawsuits that needed to be defended. But in terms of my time there, I think the locust of the decision-making was at the Department.

The White House had a very strong influence and we always knew they were going to have to clear anything significant that we did. And the decisions would be made not only on the basis of the policy, but also on politics as well. Remember that the Affordable Care Act was enacted in March of 2010 and then 18 months later, the midterm elections were held, the congressional elections in the middle of a president's term.

And, in the interim between the time it had been enacted and building up to those elections, the ACA had become very, very controversial and the Republicans and others had spent enormous sums of money attacking it. The Tea Party was formed, and the Affordable Care Act was seen as just another example of big government. It was a major issue in the 2010 midterm elections. In those elections the Democrats lost 63 seats in the House and the House

flipped back to Republican. So we were facing aggressive oversight and the inability to enact any legislation. The Democrats still had the Senate, which they retained until 2014, year six into the Obama Administration.

Outside the Department, I attended many meetings at the White House that often would convene between the three departments responsible for administering the Affordable Care Act: Labor, Treasury, and Health and Human Services. At some point Politico published a list of who attended the most White House meetings in government and I was number five or six. This reflected the fact that I was over there all the time — mostly on the Affordable Care Act but also on Medicaid, Medicare issues, occasionally Food and Drug Administration issues, sometimes ethics issues, and so on. The other locust was with the Department of Justice, which was in charge of all our litigation.

Mr. Pollak: Under Attorney General Holder?

Mr. Schultz: Yes, and the Solicitor General. When I came, it was Acting Solicitor General Neal Katyal, and then Don Verrilli became Solicitor General. My interactions were mostly with the Solicitor General's Office and to some extent with Civil Appellate, the division I had run at the end of the Clinton Administration. A lot of those discussions were about litigation, but sometimes we would go to them for advice –pre-litigation advice.

Mr. Pollak: Well, how did you spend your time as General Counsel? Who was your secretary? Identify the range of issues you were asked to deal with and how you preserved your records and what ones you didn't preserve.

Mr. Schultz: I had a wonderful secretary. Her name was Samantha Austin. When I started, like most of our secretaries, she was under contract. This was something that the Republican Administration had done, so one of the first things I asked her was whether she wanted to be a government employee, and she did. I was able (with some trouble) to make that conversion. She was very loyal, very capable, and is a wonderful person.

I think I mentioned this, but early on I set up monthly meetings with the ten Associate General Counsels, and she attended all those meetings. I wanted her to be a part of everything I did. And then in addition to that, I had weekly meetings with all my deputies at lunch, and she came to all of those as well. What you find when you work in this kind of government job is that your days are consumed with meetings. In those days, they were mostly in person. Today I think it's Zoom calls, but many of the meetings are in the Department, and as I mentioned some were at the White House or the Justice Department.

It's a struggle to find time to actually read and to think about things. So you have to give in during the weekday hours of 10-4 or 10-5. Those times are consumed by meetings or crises. I would arrive at work between 7:30 and 8:00 a.m., and I would try to block out on that schedule any meetings until 10:00 a.m. I was often successful with that. I had those hours to do what I call real work.

There was parking in the basement, and frequently I would ride my bike to work. My office included a large space with a conference table in the main office, a separate conference table and library, and a bathroom with a shower. I

could ride my bike to work and take a shower, put on a suit, and start the day. After 5 p.m. there was time for reading and writing. Typically, I'd leave around 8 p.m., but I would also often work at home. I also worked every hour that I could on the weekends. It was a job where you had to satisfy your personal obligations, but other than that you spent every free hour you could working. The work was endless.

The range of issues was wide. I talked a lot about the Affordable Care Act because that was the central mission of the Department. I oversaw the ethics lawyers for the Department, and we had periodic ethics issues; we had personnel issues both within my office (we had 500 lawyers) and outside. One example involved the special pay scale that had been discovered and applied to scientists within the Department. It applied to the National Institutes of Health, FDA, and other divisions. It was called Title 42, and it allowed going far above the government pay scale so that there were a few scientists in the Department making as much as $400,000 a year.

Mr. Pollak: And the Deputy Secretary made what?

Mr. Schultz: Less than $200,000 annually. The problem was NIH had classified ministers, janitors, all sorts of people in this pay scale and they were being paid above what the government salary would have been. While you could make the argument for a scientist, we were at risk of losing the entire program. That is just one example of the kind of problems the General Counsel has to address, and you can end up spending a lot of time on them.

It was not just the legal issue; it was also a political issue. I worried about how the Hill was going to react; how to present it with a Director of NIH (who was pretty defensive and wanted to hold on to what he had), but we worked through it. I think in this case it was Francis Collins, the head of NIH, and Bill Corr, HHS Deputy Secretary, who was very involved. All the legislative people would be involved and we'd work through it. That's just an example.

There were other ethics issues that would come up. For example, one Assistant Secretary came to the government from academia. There is a provision in law that if you have to sell a stock holding because you have a conflict of interest, there is a way you can sell it and purchase a mutual fund or some holding that doesn't have a conflict and avoid paying the capital gains tax. The basis would be transferred to the new stock or bond, but under the rules you can't do that until after you take office. One Assistant Secretary was extremely conscientious, and he made the sale before he took office. This meant under the strict rule he wasn't entitled to escape the capital gains tax. Under the law the White House could make an exception, so I asked Secretary Burwell to ask the White House for the exception, which would have shown real loyalty to the Assistant Secretary. But Secretary Burwell didn't want to do it, so I couldn't find a way around his having to pay the capital gains tax.

There was a tricky issue involving Secretary Sebelius. Under the Hatch Act, the Secretary could support political candidates in her own name but not as Secretary. She made a mistake in a speech she was giving in North Carolina,

which caused a referral by a hostile member of Congress and a high-profile investigation by the Office of Special Counsel.

Mr. Pollak: And how did Secretary Sebelius know before you were in office not only to want you but to hold that office open for you?

Mr. Schultz: I don't know that I know the answer to that. I had worked very closely with Mark Childress and Bill Corr. I know they both highly recommended me to her. I think other people did as well and then I interviewed with her. After we had worked together, I think she came to have faith in me.

Mr. Pollak: So, identify, one by one, other problems that the General Counsel confronted in your time. Starting perhaps with the Medicare billing data issues.

Mr. Schultz: Sure. I made a list of a few, just to convey a rough sense of the work. These types of issues come at the General Counsel every day. One example involved Medicare, which had a lot of data about what doctors charged Medicare and for what kinds of surgery or medical procedures they charged. And when you looked at the data there was a wide variation of doctors about whether they did surgery, or when they did them, how much they charged, and other data points. Reporters from *The Wall Street Journal* had filed a Freedom of Information Act requesting the data. They didn't want to know the names of doctors, but they wanted to see the patterns within different parts of the country. There had been a case that was brought maybe 20 years before. Whoever brought it received some data and there may have been a court order and some other resolution.

Now *The Wall Street Journal* reporters wanted to open up the agreement. The government, up until my tenure, always resisted this.

The lawyer for the Justice Department, Leonard Schaitman, had litigated this case 20 years before and negotiated the settlement that protected all the data. He was still there and was adamantly opposed to releasing the data. I went to the head of CMS, the Medicare agency, and said, "What do you want to do? The *WSJ* wants this data." I think the lawyer for the *WSJ* had called me about it, and given my Nader background, I'm very favorable of the government releasing this information. I asked what the HHS position should be.

Don Berwick was about to leave, and he said, "I guess I should leave this to Marilyn Tavenner," who was going to take his place as CMS administrator. I went to Marilyn, who said she wasn't really interested in releasing the data, and then Don came back to me because he was still head of the agency and said he had second thoughts.

Don was a visionary. He understood the big picture. He said, "You know what, I changed my mind. I do want to make this decision and I want you to push for this." He understood that this wasn't just about the *WSJ* dinging doctors and saying, "Look at this disparity in surgeries for this exact same condition and look at what this means about medical practices." That was the article they wanted to write. But Don said it's also about the fact that if doctors see what other doctors are doing, it's going to favorably affect medical practice. This is really important.

I now had to convince the leadership of the Department of Justice to basically overrule this career lawyer, which is not an easy thing to do and not a thing you want to do very often. But I did and we reached an agreement with the lawyer for the *WSJ* and the data was released. I think they won a Pulitzer prize for it. It was a fun project.

Another example concerned the Innovation Center. The Affordable Care Act set up a lot of programs, one of which was a program that was given $10B over ten years to fund innovation in Medicaid and Medicare. Under the law, they had the authority to waive Medicare and Medicaid requirements. So, for example, under Medicare the general requirement was that medical procedures be paid per procedure. If you get a hip replacement, Medicare pays separately for the implant, the anesthesia, and the physical therapy afterwards. The Innovation Center could adopt a test program that waived all of that and instead adopts what's called a bundled payment. Medicare would make one payment for the entire package of the procedure. The Innovation Center would do an experiment and see whether this saves Medicare money and what the impact is on medical care. If it's a success, Medicare can adopt a regulation that makes it universal.

Early on the decision had been made by the Office of the General Counsel that these were contracts, so when this money was given out, it was given as a contract to the doctors, or hospitals, or other providers. Don Berwick came to me and said, can you revisit this? He said the government contracting

procedures are extremely onerous. He asked whether there was a way this can be viewed as a grant, which would be much better in terms of the operation of the program. I worked with David Cade, the Deputy in charge of overseeing the General Law Division, and Jeff Davis, who was in charge of the division.

You'll find out very early on in one of these government positions that just because you disagree or want to do something or think you have a legal theory, it doesn't mean that it can be imposed on others who disagree, even if they report to you. You can do that, but you'll never be effective if you take that approach as a matter of course. The better approach is to convince your colleagues to come around to your way of thinking – to get them on board. This was a time when I disagreed with the experts who really should know a lot more about grants and contracts than I did. But we talked it through, and I was able to convince them to change their opinion so that this could be a grant program instead of a contract program.

And I have to say, I found the lawyers at the Office of General Counsel were terrific lawyers. There were times, though, when their thinking was pretty narrow. Fortunately, they were willing to rethink things. Sometimes I would convince them, sometimes they convinced me, but it was important to me to know that I had their support. To know that they thought my interpretation, even if they disagreed, was a reasonable interpretation. Sometimes we just didn't get there, and it would be a rare case in that instance where I didn't defer. So, it was always extremely important to get their support.

Mr. Pollak: How – given the time available and the pressures of your work – how did you have enough background on these many issues to put a stake in the ground and disagree with the experts?

Mr. Schultz: That's great question.

Mr. Pollak: Is some of that what attracted the Secretary to you; an innate ability, on a limited amount of information, on the judgment of people's recommendations, for you to make the right decision?

Mr. Schultz: I don't know. And there were certainly times when I just didn't have the background and I had no choice but to defer. I had five terrific Deputies and they were doing the same thing I was doing, but they had more time to gain expertise in their areas.

Mr. Pollak: How did you have enough confidence to work your way – or to give way? That was a major requirement.

Mr. Schultz: I don't really have an answer to that question except I had had a range of experiences inside and outside government, and that I had excellent Deputies, Associate General Counsels, and other lawyers to work with and to learn from.

Mr. Pollak: You may not finish this today, but what about sticking your nose in the tobacco and e-cigarettes, and what the Department's and General Counsel's role in your time with those fundamental issues was.

Mr. Schultz: Sure, and it may not take much time. First, I'll talk a little about the FDA. The typical Secretary doesn't have the time to engage much on FDA issues. In the case of Secretary Sebelius, she was occupied with the Affordable Care Act and

Medicaid and Medicare, unaccompanied minors, and all the crises. And typically, General Counsels don't get involved in FDA issues because it's a complicated area of law that they don't have time to learn.

My time was different because three of us in my office had deep FDA experience. I did; David Horowitz, my Deputy who oversaw FDA; and Peggy Dotzel, my Deputy who oversaw other things who also did pieces of FDA. And so, we were more involved typically, which meant we could be very supportive, and we could raise questions. In terms of tobacco, the two big issues were menthol cigarettes and e-cigarettes.

Mr. Pollak: Issues in terms of banning them or. . . .

Mr. Schultz: For menthol, the issue was whether menthol cigarettes should be banned. When the Tobacco Control Act was passed all flavors were banned except for menthol. But FDA was explicitly given the authority to ban menthol after a regulatory process. And so this process had started. It was difficult because maybe a third of all cigarettes are menthol and they were disproportionately purchased by the African American community. At times there have been many African American members of Congress who opposed the menthol ban, many of whom get money from the tobacco industry. It's a hugely controversial issue. Suffice it to say there were meetings about this, and I don't think FDA did a very good job. But it was put on the back burner and we in the Obama Administration had an opportunity to make progress.

Mitch Zeller, who was later made director of the tobacco program at FDA, took this on as part of his mission, and now progress is being made. The Biden Administration has initiated the process of banning menthol cigarettes and it might actually happen.

E-cigarettes raised difficult legal issues because when the Tobacco Control Act was passed, e-cigarettes were not contemplated. E-cigarettes are electronic cigarettes. They look like a cigarette. You get nicotine from them, but there is no burning tobacco. There are reasons to believe that they are safer than tobacco because a lot of the diseases from smoking come from the burning tobacco and its byproducts that enter your lungs.

On the other hand, there is good reason to think that e-cigarettes pose health risks to non-smokers. When the Tobacco Control Act was passed, Congress essentially grandfathered cigarettes and cigars and tobacco products on the market and provided for a process where minor changes in flavors or other ingredients were permitted. But new products were prohibited until they had been approved by FDA.

Another legal nuance was that the Tobacco Control Act only gave FDA the authority to regulate cigarettes and smokeless tobacco products. To gain jurisdiction over other products, it had to issue a regulation. So, initially FDA didn't even have jurisdiction over e-cigarettes. But when they were going through the process of issuing this big regulation, they did the research and realized they did not have a basis to grandfather e-cigarettes. This meant that if

they were going to declare jurisdiction over e-cigarettes, they had no authority to allow them to remain on the market without an approved application. This became a difficult challenge.

We and FDA decided to use enforcement discretion to allow e-cigarettes to remain on the market for a period of time. During this period, the manufacturers would be required to do studies to identify the risks to children, and the benefits to adults switching to e-cigarettes from regular cigarettes. But there was an important debate about how long a time the industry ought to be given to come into compliance. This was a complicated issue because Mitch Zeller, who was the head of the Center for Tobacco, had a strategy. His ultimate goal was to ban all nicotine and cigarettes and switch all smokers to nicotine replacement products, and e-cigarettes seem like the most attractive option. That strategy would not work if e-cigarettes were banned. I don't remember the numbers, but he proposed to leave e-cigarettes on the market for a long time – I think two years or more. He also had a proposal to ban nicotine in cigarettes, and his idea was that smokers could transition to e-cigarettes.

Bill Corr and I talked about this, and we had a different view. Bill had been very involved in tobacco during the Clinton Administration and had been the Executive Director of the Campaign for Tobacco-Free Kids during the Bush Administration, so he had deep tobacco experience. Our view was that any kind of ban on nicotine in the near term was politically impossible and completely unrealistic: it wasn't going to happen.

When you put that issue aside the question is, how long can you leave e-cigarettes on the market? And we were very concerned that the longer you allowed them to be marketed the bigger this industry was going to grow, and the harder it would be ever to do anything about a potentially serious public health problem. This was an issue that was ultimately presented to HHS Secretary Sylvia Burwell, and she ended up deferring to FDA. I think in part because she didn't know what the initial reaction would be on Capitol Hill, and in part because Secretaries usually defer to FDA. So the Obama Administration put that longer ban in place. I was opposed to it, but I had no decision-making role.

When the Trump Administration came in, Mitch Zeller convinced FDA Commissioner Scott Gottlieb to extend the enforcement discretion. When the extension was announced, it was also announced that FDA would begin the process of banning nicotine. That of course went nowhere, and the sales ballooned out of control. Now the agency is still grappling with the legacy of those decisions.

Mr. Pollak: So even though you were talking about accomplishing something in the last years of the Obama Administration, it then gets past the end of that administration, four years of Trump, and a year-plus of Biden, and nothing has been done?

Mr. Schultz: Under Biden, FDA has started the process to eliminate menthol. Juul Labs, the biggest producer of e-cigarettes that ended up addicting millions of kids, ultimately voluntarily eliminated flavors, so there has been some progress. The

real issue with e-cigarettes is the flavor, and that's what attracts kids. There are still thousands of flavored products on the market, including liquid vaping products, but FDA is finally making some decisions. Not the happiest story.