

CHEMICAL HERITAGE FOUNDATION

**THE TOXIC SUBSTANCES CONTROL ACT:
FROM THE PERSPECTIVE OF
CHARLES F. LETTOW**

Transcript of Interviews
Conducted by

Jody A. Roberts and Kavita D. Hardy

at

U.S. Federal Court of Claims
Washington, D.C.

on

23 April 2010

(With Subsequent Corrections and Additions)

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CHARLES F. LETTOW

1941 Born in Iowa Falls, Iowa

Education

1962 B.S., Chemical Engineering, Iowa State University
1968 LL.B., Stanford University
2001 A.M., History, Brown University

Professional Experience

1962-1963 Proctor & Gamble, Co., Cincinnati, Ohio
Engineer, Soap Products Research Department

1963-1965 U.S. Army, 3rd Infantry Division, Germany
2nd Lt. , 1st Lt.

1968-1969 U.S. Court of Appeals for the Ninth Circuit, San Francisco, California
Law Clerk to Benjamin C. Duniway

1969-1970 U.S. Supreme Court, Washington, D.C.
Law Clerk to Chief Justice Warren E. Burger

1970-1973 Council on Environmental Quality, Executive Office of the President,
Washington, D.C.
Counsel

1973-1976 Cleary, Gottlieb, Steen & Hamilton, LLP, Washington, D.C.
Associate
1976-2003 Partner

2003-Present U.S. Court of Federal Claims, Washington, D.C.
Judge

ABSTRACT

Charles F. Lettow grew up as a “Sputnik kid,” choosing to study chemical engineering as an undergraduate. He held one job in the chemical industry before serving in the U.S. Army; after his military service he moved into the field of law. He undertook two clerkships, one with the Hon. Benjamin C. Duniway and one with the Hon. Warren E. Burger, and he was then invited to work for the President’s Council on Environmental Quality. There he was involved in the creation of U.S. Environmental Protection Agency (EPA) and several environmental laws, including the Toxic Substances Control Act (TSCA). He and J. Clarence Davies used the Federal Food, Drug, and Cosmetic Act as their primary model for writing a toxics law that would include both a premarket review and imminent hazard provision. According to Lettow, the law was intentionally not prescriptive in order to give the EPA the flexibility to adapt to innovations, changing uses of materials, and new knowledge about materials. Because of the multifunctional nature of chemicals, they opted for a use restriction provision rather than an FDA-style approval process.

At the end of the interview Lettow discusses his belief that the law should have been workable with a creative bureaucracy. He also talks about the debates surrounding the issues of preemption, citizen suits, judicial review, penalties, administrative searches, and confidentiality. While the law underwent changes during the Congressional debates, Lettow believes it was not substantially different from his and Davies’s draft.

INTERVIEWERS

Jody A. Roberts is the Associate Director for the Center for Contemporary History and Policy and the Manager of the Environmental History and Policy Program at the Chemical Heritage Foundation. Roberts received his Ph.D. and M.S. in Science and Technology Studies from Virginia Tech and holds a B.S. in Chemistry from Saint Vincent College. His research focuses on the intersections of regulation, innovation, environmental issues, and emerging technologies within the chemical sciences.

Kavita D. Hardy is a research assistant in the Environmental History and Policy Program at the Chemical Heritage Foundation. She received a B.A. in Chemistry and Economics from Swarthmore College.

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INTERVIEWEE: Charles F. Lettow

INTERVIEWER: Jody A. Roberts and Kavita D. Hardy

LOCATION: U. S. Court of Federal Claims
Washington, D.C.

DATE: 23 April 2010

HARDY: [...] Thank you for joining us. My name is Kavita Hardy. I'm here with Jody Roberts and Charles Lettow. Today is 23 April, and we're here in [Washington], D.C. for the TSCA [Toxic Substances Control Act] Oral History Project. What we wanted to start with was, sort of, your educational background, if you can start that far back?

LETTOW: I'm going to go really far back...I have a somewhat unusual background. I grew up on a farm in Iowa. My father raised purebred livestock, and I went to a rural high school. I graduated in a class of fourteen, and went to Iowa State [University] as a chemical engineer, and graduated from Iowa State.

[I] had an academic interest in chemical engineering, had a National Science Foundation grant for undergraduates while I was there, and so on. But [I] did not, then, go to graduate school in chemical engineering. Instead I worked for Proctor & Gamble [Co.] in products research for a year in Cincinnati, [Ohio], which was a chemical engineering job. Thereafter, I went in the army with an infantry division for a couple of years, and then went to Stanford Law School.

I guess, you'd include as part of my education clerking for a circuit judge on the [United States Court of Appeals for the] Ninth Circuit, and then for the chief justice of the Supreme Court, [Warren E. Burger], which brought me to Washington [D.C].

HARDY: What brought you to law school, having been a chemical engineer?

LETTOW: I was a capable chemical engineer, but actually, academically, that was not my best subject matter. The law fitted my subject matter and intellectual interests even better than chemical engineering. I was a Sputnik kid. I could do chemical engineering and do it reasonably quite well... I graduated from high school in 1958. That was the Sputnik year. Anybody who was reasonably intelligent then and could do it went off into a technical area. And I certainly could do it, so it wasn't a problem. It's hard to convey an understanding of that to someone like yourselves.

ROBERTS: Why is that?

LETTOW: You just don't have the context, the historical context to understand what was happening in this country in 1958.

ROBERTS: So, when you're in law school, was there an area in which you focused?

LETTOW: Well, not really. I mean, Stanford is not a big school. It doesn't really have subject matter areas that it emphasizes. It rather emphasizes broad areas. There were several areas that were quite attractive to me. One of them was jurisdictional issues, federal-state relations, that sort of thing. There was a course called Federal Courts that you probably haven't run into that is kind of intellectually demanding, but great fun. I did like administrative law. I did like certain litigation topics.

HARDY: So, once you got to Washington, what brought you to the CEQ [President's Council on Environmental Quality] in particular? Or is that directly where you went?

LETTOW: No. I had worked as a law clerk for the Chief Justice. It happened that he was acquainted with Russell [E.] Train who was the first head of the Council on Environmental Quality. Russell had just been confirmed as the head, and he wanted some lawyers. I was recommended and was convinced to take the job. It turned out one of my classmates, also, had matching clerkships—classmates at Stanford—and also joined the Council at the same time.

ROBERTS: And who was that?

LETTOW: Bill Lake, William [T.] Lake.

HARDY: What was the perceived need for lawyers at that time?

LETTOW: Oh, I don't think there was much doubt about the need. One of the first things we ended up doing... was drafting a set of executive orders allocating the responsibilities under... a set of acts that dealt with oil pollution control. There was no other central place in government for environmental matters but this little tiny office in the executive office. And that's what we did.

Then, I was one of the people who worked on the reorganization plan to actually create the EPA [United States Environmental Protection Agency] and NOAA [National Oceanic and Atmospheric Administration], and that happened. And then, anyway...I went on to other things. Primarily, well, a lot of it was treaty...I wouldn't say primarily, but a lot of it was treaties and conventions in the environmental area, especially shipping in the early days of the [United Nations Convention of the] Law of the Sea negotiations.

ROBERTS: Did you have much interaction with what might now be perceived as environmental issues during either of your clerkships? Was there anything during those two clerkships that might have prepared you for time at the CEQ?

LETTOW: No. Well, yes. But if you talk about purely environmental issues, the answer is no. If you talk about federal-state relations, if you talk about various enforcement mechanisms and how they actually work, and what happens, if you talk about judicial review, if you...all those things. Those were things I became necessarily more familiar with than most people who had just finished law school.

HARDY: So, are those the concepts that you were drawing in when you're...when you're participating in this creation of an environmental framework?

LETTOW: Definitely. And in fact, I guess I ought to say that...usually law students do some writing in law school. I had been on the [Stanford] Law Review. Early on in my second year, [I had...] a note on an administrative law topic dealing with maritime laws.¹ So I, from fairly early times, started on those areas.

HARDY: So, at what point did you start getting involved in toxics stuff, and what was...why was that an issue?

LETTOW: That became...well...

HARDY: Or if you prefer, rather, how you...what other things you...

LETTOW: No. I was working on other things primarily. As I mentioned, these shipping matters, control of pollution, ocean pollution, ocean discharges, that sort of thing, water

¹ Charles F. Lettow, "The Disclosure-Hearing Dilemma in Maritime Subsidy Disputes," *Stanford Law Review* 19(2) (1967): 420-47.

pollution issues. I had responsibility...responsibility is too strong a word for it. I had some work on the [United States Army] Corps of Engineers, implementation of the National Environmental Policy Act at the very early stages. People knew I had been a chemist...chemist is too strong. Actually, I probably took more than enough courses in chemistry to get a chemistry major, but I really was a chemical engineer. And people were aware of that. I don't think there's any doubt about that.

ROBERTS: Did there seem to be a lack of expertise in those areas?

LETTOW: No. I'll tell you why. We had, [...] as one of the three members of the Council on Environmental Quality, a man who had been a geophysicist at CalTech [California Institute of Technology]. He was about as technical as you could possibly get. I did work with him fairly frequently.

ROBERTS: And who was that, do you remember?

LETTOW: Gordon [J.] MacDonald.

HARDY: So, what were the expertises that were brought to CEQ? So, you have this very technical, scientific...what else were they looking for?

LETTOW: Well, Russell Train had been, almost, a classically trained...well, you can...he's still alive. You can read all you want about him. But he had worked on [Capitol] Hill. He had worked in the executive branch. He had been a judge of the [United States] Tax Court, for heaven's sake. He's an interesting man. Mr. [Robert] Cahn had been a reporter for the *Christian Science Monitor*. He was an interesting guy. So, those were the main people. Then we had a couple of...you've heard about the chief staff people. I don't have to tell you about Al [Alvin L.] Alm and people like that. You've already heard about that probably.

ROBERTS: I'm sure we could hear more.

LETTOW: Okay. Well, not from me necessarily. His office was right across the hall. He was an interesting man. He was almost a consummate bureaucrat. I don't mean that unkindly. It sounds like I do, but that's not what I mean. He knew all sorts of things about how to get things done in government.

ROBERTS: Can you talk about the relationship between all of you folks, since it's a pretty small group?

LETTOW: It was. It was a very professional group. How to describe this? People recognized and valued, I suppose, the talents of each of the people, and tried to work constructively in light of those talents. It's amazing. The group actually turned out a fairly substantial annual volume of reports on what was going on with the environment, even while carrying forward with all these substantive initiatives. It was a rather remarkable, interesting group.

Terry [J. Clarence Davies] was among the more interesting people. You've talked with him, you know he has a personality that is very...easy, in the sense that he's a softly spoken person, and fairly precise. And so, he and I got along very well. We actually wrote a chapter in a book that West Publishing [Company] issued called *Federal Environmental Law*.² It dealt with institutional arrangements [...]. I was going to bring a copy with me this morning and forgot to bring it along. I had [also] written [another chapter in the book] on ocean pollution.³

ROBERTS: So, can you talk about your work with him on the construction of what becomes the Toxic Substances Control Act.

LETTOW: Only in general terms. I actually pulled out the current act [...] as enacted in 1976, and then, as it's subsequently been amended.

HARDY: It's very different than that 1971 version.

LETTOW: Well, it is and it isn't. It is and it isn't, because it's just a lot of things are rearranged, but you'd expect that. Yes, I think the short answer is yes. One can say we started basically from a model that drew upon the experience with the [Federal] Food, Drug [and Cosmetic] Act. He probably told you that. I don't know if he did, or...maybe he didn't, but that's the...

HARDY: Not really.

ROBERTS: It didn't come out that way.

² J. Clarence Davies and Charles F. Lettow, "The Impact of Federal Institutional Arrangements," in *Federal Environmental Law*, ed. Erica L. Dolgin and Thomas G. P. Guilbert (St. Paul: West Publishing Co., 1974), 126-91.

³ Charles F. Lettow, "The Control of Marine Pollution," in *Federal Environmental Law*, ed. Erica L. Dolgin and Thomas G. P. Guilbert (St. Paul: West Publishing Co., 1974), 596-681.

LETTOW: ...legal construct. From my perspective, that's where we were starting. During my year as a chemical engineer at Procter & Gamble, I had worked on what, for that company, was the first new drug application put forward from the soap division. Do you know of Safeguard soap?

ROBERTS: Um-hmm.

LETTOW: And the claim...you don't. Okay. But in any rate, it's an antibacterial [...] [and because they] wanted to make antibacterial claims and deodorant quality claims, they realized or recognized they had to go forward with the new drug application.

I had worked pragmatically from the standpoint...of an engineer, as a very junior engineer on that project. So, I had a half a clue what the Food and Drug Act was all about. I wouldn't say more than a half a clue, but I did have that. And with what people had in mind, that seemed the best model. You'll find as you go through, even the current act, there are hints that that was the model.

HARDY: So, two things on that. What did people have in mind? And what did you end up drawing from the Food and Drug Act?

LETTOW: Well, there were basically two things. At least two things, let's put it that way. First, the goal was to try to get a mechanism of pre-marketing and distribution and sale review of certain chemical substances. As soon as you say that, you think, "aha, that looks a little like the Food and Drug Act, and it's regulation of drugs and devices."

There also is a section buried in here that was viewed as quite important at the time—it's less important now, and in historical context, I guess, although I never litigated these things—an imminent hazard provision, because the FDA [United States Food and Drug Administration] also has the authority to go in and deal with, you know, food recalls. You've all heard of food recalls and things like that. And there's something akin to that, built in here. So, that's why I say what I said. Now, I don't know if Terry said that, but...

ROBERTS: Well, I think he doesn't. And, I think, part of our interest in wanting to talk to you was that his story is that he didn't have the legal background to understand how to make something like this law look like a law. He had ideas on how it might function bureaucratically and from a governance perspective, but not the legal wit to understand how one actually turns those ideas into a law. And that was where he really relied on you, was to provide a legal basis for how and why you might be able to do some of these things.

LETTOW: Well, I just...with those two really basic fundamental points, indicating to you why that model was chosen. It isn't that it was a necessary or assumed thing. It's just, given what he wanted to do, that was the best form that...people would understand.

ROBERTS: Would you say that using that model for this law made this law look different than some of the other environmental statutes?

LETTOW: Yes.

ROBERTS: What was the model for some of the other environmental statutes being used?

LETTOW: Well, [the others were] more of a direct regulation by way of either permits or approvals or that sort of thing. This one works a little different.

ROBERTS: Can you talk about how?

LETTOW: Well, I can. It basically requires a notice if you're planning to use a new substance. It requires...it contemplates review. You have to come forward.

HARDY: Is this TSCA now or TSCA as you and Terry wrote it?

LETTOW: Both.

HARDY: Okay.

LETTOW: It doesn't...as I say, some of the elements are rearranged, and I was looking at this yesterday afternoon and I had to smile. But, you know, some of these are carried forward. When you come forward with your initial notice, you have to come forward with what information you have on the physical and other characteristics, including safety and health characteristics. And then, there's a mechanism for further review, and indeed testing. There is a mechanism for allowing sale or distribution or marketing while the testing is going on, and then there are others that don't. There are also limitations on...limitations, that's too strong a word. There's the ability of the administrator to call for testing of something that has been marketed, as well.

There are a couple of things in the act, like PCBs [polychlorinated biphenyls], that we just didn't deal with. There's a special section on PCBs. We said, "well, fine." There were issues like that that we didn't try to deal with, because that came later. There was a special concern about PCBs. There still is, in a sense.

HARDY: You mentioned that you were looking to get the information that the companies had, submitted. Was there...

LETTOW: Not submitted. They might not have submitted it anywhere. They might just have completed internal studies.

HARDY: Okay.

LETTOW: I was very familiar...very, that's too strong of a word. Having worked for Proctor & Gamble, where I...Proctor & Gamble is a very competent company. It was then, anyway. I presume it still is. I don't know. But it was a very competent company. And the health and safety testing they did before they marketed something was quite extensive. So, I was aware of the kinds of internal tests that might be in hand, but not published necessarily.

HARDY: So, you expected that by asking companies for what they already had, that would be...

LETTOW: No. Well, that would...they would get a fair amount of information. Some of it—a lot of it, actually—might be confidential, and there were provisions for confidentiality shot through this thing. But...

HARDY: But that would be enough for EPA to, sort of...

LETTOW: To get started. So, they wouldn't have to deal with generic chemical families of compounds, and that sort of thing, and try to extrapolate.

ROBERTS: Are you the only one who'd had prior chemical industry experience who was working on the CEQ at this point?

LETTOW: Probably.

ROBERTS: So, that seems like it was pretty important that you knew, more than some of these others, that these companies already generate a lot of internal testing.

LETTOW: Oh, I don't know about that. Because I think there were a number of people who had been fairly experienced generally with the world. I wasn't that old at that time, you have to recognize. But... I'd done what I had done.

ROBERTS: So, there's a couple of interesting pieces. One is that you talk about the open flexibility that the system you're designing has, like the FDA, and that the addition of very specific mandates in the statute— like PCBs, et cetera—come in at the last minute.

LETTOW: Well, they come in...

ROBERTS: Later.

LETTOW: ...later.

ROBERTS: Not the last minute, later.

LETTOW: Driven by, in this case, political concerns as much as anything else.

ROBERTS: One of the things that we've encountered time and again over the course of some of these interviews, however, is that it was those specific mandates that were very easy to enforce, and that it was the inherent flexibility of the system that tripped them up very often, because they weren't exactly sure what to do. I don't know...there's a couple of different ways that one might look at that, and I'm curious about your take. One is that, TSCA doesn't look like the other environmental statutes which made it a problematic statute inside of EPA.

LETTOW: It should not have been problematic.

ROBERTS: So, talk about that.

LETTOW: Well, when was the Food, Drug, and Cosmetic Act enacted? I don't know. I don't have it. It had to be around the turn of the century, the prior century. It had a similar set of goals, but with foodstuffs in mind. One thing a good lawyer realizes fairly quickly is that ambiguity and studied ambiguity can be a very useful thing, because it...you say flexibility. Well, it allows adaptation to different circumstances. Put it that way.

One of the things I had written...there was a symposium on Chief Justice Burger, and it had to do with...the title is "Looking at Federal Administrative Law with a Constitutional Framework in Mind."⁴ One of the things it does, if I can find it, is look at—I'll find it—interpreting older statutes in new circumstances.

HARDY: Sounds relevant.

LETTOW: Well, if you think about it though, there are a set of statutes that have a fairly broad sweep, and might have detailed provisions built into them, but they've been inserted there. That's not the main thrust. One of them is the Food, Drug, and Cosmetic Act. Another are the patent statutes, which go back to the first Congress. The copyright statutes...the Sherman Antitrust Act is one of those, for example. You can go down through...and you can think about a set of statutes that affect our lives in terms of providing a, kind of, general overlie.

That was the idea. What people did with it, you know...you get to it. [...] You get to a certain point and you realize, well, everybody has their own approach to things, and you're not going to be able to dictate to somebody ten, let alone fifty years, what they're going to do with something. So, well, I'll stop there and won't make critical comments.

HARDY: So, it's interesting that you, kind of, create that framework for TSCA, because a lot of the other environmental laws, well, at least Clean Water [Act], Clean Air [Act]...

LETTOW: And I worked on the Water Act. The legislative changes to the Water Act. I certainly knew the difference.

HARDY: Okay. But, they...

LETTOW: Even as a young...

⁴ Charles F. Lettow, "Looking at federal administrative law with a constitutional framework in mind," *Oklahoma Law Review* 45(1) (1992): 5-31.

HARDY: Right. But they continued to be reauthorized, to be reworked, right, over the next few decades, and yet, TSCA has never been touched.

LETTOW: No. But you have to also recognize that that...maybe I'm defending the approach, but that's not what I'm trying to do, because actually, I...well, I'll explain in a minute why. But if you look at what the European Union has done with their REACH regulations, it's very like this.⁵ For good reason.

ROBERTS: Very like what we have? Or, very like what you and Terry assembled?

LETTOW: What we assembled is not that different from what's actually in there. I mean, I can go through and say, "okay, this got moved from a separate section to the definitions." It just looks a little different, but the pieces are there, with some additions like the PCBs and so on and so forth.

ROBERTS: So, it's interesting you say that though, because I think people who are less familiar with the longer history and the longer story of this statute would...wouldn't see that connection. That it's...it looks like this. And that many of the pieces that—especially in some of Terry's more recent writings—that he's arguing for in reform efforts, make it look more like what he thought it was supposed to be, implying that there's something missing. That some of those original pieces went missing. I think, they might be around things like a mechanism for pre-market review, and how that gets played out. So, it might not be that that element is missing from this statute...

LETTOW: It's not.

HARDY: Right.

ROBERTS: ...but that the mechanism for actually enforcing it...

LETTOW: In fact, it's one of the two...

⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. O.J. L 396/49 (2006).

HARDY: Right, but I think the point is, rather, that things...not that things are missing, but that over the course of the next five years, that they become more bureaucratic. There's this process of making things much more complicated, so that you lose that initial purpose and that weakens what you can do.

LETTOW: See, I think that's...I'd say, right now, about 20 to 25 percent of the docket I get as a sitting judge on this court are tax cases. Right. Did I ever...I was a litigator for thirty years, a little over thirty years. Did I ever litigate a tax case? No. Is it easy to cope with the tax code? No. People have made it so complicated that...you get down in the weeds so rapidly, that it's just difficult.

I always have been a little bit of a conceptual thinker. So, you'll pardon me. I think a lot of these things are misguided.

HARDY: We're not critiquing you, or asking you to defend yourself in anyway.

LETTOW: I'm just telling you that...

HARDY: Yeah. I mean, because...it takes a different form, again, from the Clean Water and Clean Air Acts, because those seem to be much more...

LETTOW: Prescriptive.

HARDY: Right. And, that they're not quite as conceptual. But we understand why [prescriptive] would have...

LETTOW: Would not have worked.

HARDY: Right.

LETTOW: You would have put...

HARDY: But why it would have seemed like a good idea.

LETTOW: To whom?

HARDY: Well, when you...I mean, I guess, I shouldn't try to be this assertive..

LETTOW: If you had to...no, if you had to work with it, it would...I'm sorry, [a more prescriptive statute] would have been easy for a bureaucrat, but that's not a good idea.

ROBERTS: So, for someone who argues that TSCA doesn't work, would you...would your response be that they're just not using it properly, that there are mechanisms inside of it that could address the things that they're concerned about?

LETTOW: Oh, that's definitely true. But if you just think about the Food, Drug, and Cosmetic Act, and put that right here and TSCA right here, you know, fine. You can work with that. It's just, don't think about it in the same way [as the more prescriptive laws].

ROBERTS: Yeah.

LETTOW: I mean, I was working at the same time, as I say, with potential changes to the Clean Water Act, which subsequently were adopted...right about the time I left CEQ, actually. I had also worked on a fairly prescriptive regime in ocean dumping. There was a convention in implementing. So, I knew the difference. Boy, did I know the difference. That would not have worked here.

HARDY: Do you have any insight on that process of...again, you say it hasn't changed that much, but it did go through some negotiations both within the administration...

LETTOW: Yes.

HARDY: ...and then Congress. Do you have insight on either of those processes, probably more of the former?

LETTOW: In February of 1972, I shifted from thinking conceptually and legislatively about some of these things to litigating cases. And that's what I did for the next thirty years. Did I...and I litigated a fair number of environmental cases, along with a whole variety of other

kinds of cases. But they were not...I never litigated a TSCA case, ever. So, did I have anything to do with that statute? No.

ROBERTS: Can you think of any difference that there would be in using TSCA on chemicals and using the Food, Drug...Food and Drug Act on a new drug substance? So, I'm trying to...I'm trying to feel my way...

LETTOW: You tell me.

ROBERTS: Well, I'm trying to...

LETTOW: Well, there is a difference, and it's readily apparent. It ought to be so apparent, you immediately say, "oh, yes. There is." Can you tell me what it is?

ROBERTS: Well, I can think of a few, but I'm curious what yours are.

LETTOW: Alright, let's try.

HARDY: We're looking for your thoughts.

ROBERTS: So, my one...I'm thinking ...

LETTOW: There is one just astonishing difference. Go ahead. Tell me.

ROBERTS: With a drug you assume that there's a pharmaceutical effect. When you're testing the chemicals, you're not really always sure what you're testing for. So, there's a...there's a bit of a difference in approach of when the FDA goes to work on a drug compound, they both know what the efficacious effect of that drug's supposed to, is supposed to be. And it also has an idea of what it's trying to avoid, what are problematic flags. I think this...

LETTOW: I'm not sure about the latter.

ROBERTS: Well, I mean, you would be concerned about potential adverse effects...

LETTOW: You get...that's right.

ROBERTS: ...and you have an idea of what those adverse effects might be.

LETTOW: Ah, maybe you do and maybe you don't. You really get surprised once in a while.

ROBERTS: But I think...you might be surprised.

LETTOW: But you're on the right track.

ROBERTS: I think with TSCA, what I'm trying to draw out a little bit is, there's the architecture of the law, and then there's the implementation of it. And I think...

LETTOW: You can't...

ROBERTS: You can't separate them. But I think...

LETTOW: Not really.

ROBERTS: ...this is where it's interesting is that, when they started having to implement TSCA, they had to start from virtually no record. It seems like they very quickly got caught up in the mechanisms of the statute that had to do with collecting information about what's already out there...within the way in which the Food and Drug Act operates.

LETTOW: Even I was familiar...I guess, it's Section 8(a). I'd have to look, because I never... as I say, this is not something I ever did, so. I've heard about it.

ROBERTS: Sure. But I think that there's...with the Food and Drug Act, you're dealing with one thing at a time coming through.

LETTOW: Well, let's be more explicit though. What you're actually dealing with...you're right on the efficacy, because when the food and drug commission approves something, it approves it for a specific use...which is why you get lots of people saying, I want to use drug X for my condition Y, and it's not approved for that, and people get in real trouble if they prescribe for that. So, there's a real difference. That is...does not appear here. And one of the reasons is, this deals in...I had to smile when I looked at the definition of chemical substance, because it includes radicals. You know, to a chemist, yes, that's, kind of, right, because often what's active about something is its dissociation radical, which has the ability to do lots of things. But you couldn't prescribe what a given chemical substance would be used for. It just could be used for all sorts of things. So, you didn't have an end point in mind. That's the difference. But you were on the right...you were on the right track, from my standpoint.

ROBERTS: I'll take some comfort in that.

LETTOW: No, I mean...[...] there's a little difference there, too.

ROBERTS: But I think that there are these pieces about the ways in which one tracks chemicals is different than the ways in which one submits a drug to be approved. So, there's also this approval mechanism, right. That the FDA approves that chemical for a use, and I think that gets back to your use issue.

LETTOW: Or a number of uses.

ROBERTS: The tension inside of EPA around TSCA sometimes seemed to be, are we here to track all of the chemicals that are in commerce, or are we here to approve? But if the FDA...if the Food and Drug Act is the model, then, for TSCA...

LETTOW: [...] It's a model. You know, it's just like the models that were used financially. They work up to a certain point and then they stop, and you have to realize, kind of, what's happening, and it doesn't work after that point.

ROBERTS: So where are the places in which that model starts to breakdown for TSCA?

LETTOW: If you start prescribing uses, which EPA can do. There's a possibility of that. But once they do that, then they have a potential for getting into real trouble, because a chemical substance might have its highest and best use someplace else, and they would never know that. They wouldn't have the background to figure that out. They just wouldn't have a clue.

ROBERTS: Were there ideas or provisions that Terry had, that he had in earlier drafts or he had that he wanted to have included in the bill, that you had to tell him weren't feasible inside of this model?

LETTOW: I don't think we had...we did have...somewhere buried—I hadn't even thought about this yesterday when I was going through it, I just kind of treated it as a given—there is a use restriction possibility definitely in there. There are also references...there are explicit references in here to the Food, Drug, and Cosmetic Act, the Atomic Energy Act. Oh, I don't know. There are a variety of...and each of those also has that possibility.

The big case that I told you we had papers piled all over here...I'm working on a what we call a "SNF case," a spent nuclear fuel case, because Yucca Mountain [Nevada] is not available for the government to take spent fuel. And the NRC [United States Nuclear Regulatory Commission]... regulates all this stuff...and, anyway, you get the idea. I'm familiar with that exercise. Somewhere in here, there's the definite use restriction possibility, and I guess it...one of the things I was amused at is the fact that...all these provisions on coordination with other laws, which took a lot of time when we were going through the OMB [United States Office of Management and Budget] clearance process.

Well, here. I forgot about—I don't know how I could have forgotten about, but—the Federal Insecticide, Fungicide and Rodenticide Act. Now, I don't know why the EPA would complain about this [Act], since that one is very like the Food, Drug, and Cosmetic Act.

ROBERTS: Right. But in the ways it which you were just talking about.

LETTOW: Yes, exactly.

ROBERTS: It approves and it provides labels for proper use. So, it is much more specific. But you're also dealing with a much...

LETTOW: But how are you going to tell somebody? That's why there's a possibility of a use restriction here. But you have to, kind of, get there first. I was looking at source material under the Atomic Energy Act, DOT [United States Department of Transportation] on transportation of hazardous materials—that's more like the limitations—[and] Occupational Safety and Health Act...there are certain kinds of things they require or can require. Anyway, you get the gist.

HARDY: So, you just briefly brought up that OMB clearance process. Can you talk a little bit about that?

LETTOW: If you want.

HARDY: Yes.

LETTOW: What would you like to know?

ROBERTS: How that dynamic works.

HARDY: Yeah.

ROBERTS: Like so, the taking of your draft that you constructed with Davies, the need for approval from...

LETTOW: Well, actually, it was more than that. It wasn't just the two of us plugging along, because this was a fairly coherent and cohesive group over there. You had all sorts of other people who could have a definite role, and then you'd bring in, also, certain agency people to try to figure out what some of those problems might be before you even went to the OMB process.

ROBERTS: So, now you're at the OMB process...

HARDY: Who were you bringing in to help inform...

LETTOW: On this one?

HARDY: ...yes, what you were constructing?

LETTOW: Well, who were we...you know, I can't remember.

HARDY: Okay.

LETTOW: I can remember who we brought in a couple of other instances, but I can't remember this one. We did.

ROBERTS: So, these are people from outside of CEQ?

LETTOW: Yes, other agencies.

HARDY: Okay.

ROBERTS: Do you remember where they would have been from?

LETTOW: No.

ROBERTS: Even if you don't remember the...

LETTOW: That's what I was trying to remember. I can remember working with the [United States] State Department on a variety of things, the oceanographer of the [United States] Navy. I mean, I could...but completely different context than this.

ROBERTS: So, I mean this would be...I guess, the potential issues that would be there, there would be state and international cooperation. You know, the ways in which this extends...

LETTOW: Well, that's true. But that wasn't...preemption was a big issue. But that was more of a hyper-technical...

ROBERTS: What about [United States Department of] Commerce? I mean, since this...when it finally makes it to Congress, it's the [Committee on Commerce] that really takes it up in the Senate.

LETTOW: Oh, we knew the Commerce Committee, all right. Even I did.

ROBERTS: So, was there discussion within...

LETTOW: I had worked with them, the staff on another bill, actually. I knew who those people were.

ROBERTS: So, was there discussion within the White House, with Commerce?

LETTOW: I didn't, I would not have gotten involved with that sort of thing. Well, if I were asked...that's not exactly true. If I were asked a question, I would obviously respond. But was I trying to set the legislative wheels in...no. That wasn't what I was trying to do. They didn't pay me to do that.

ROBERTS: No, I wasn't...I guess, I wasn't meaning it in that way. I just mean in terms of the review, before this goes to...before it gets the official OMB stamp, what were the other executive cabinet level agencies that you were having to work with? I mean, so...

LETTOW: Well, you have to recognize...

ROBERTS: So, I mean, this is going to affect the entire chemical industry.

LETTOW: Yes, but, you have to recognize, this is the President's 1971 Environmental Program.⁶ We had just finished the reorganization plans and things like that. You really didn't have an EPA, in the sense that you thought about it for twenty years, twenty-five, thirty years. So, you know, you were dealing with different folks, because the environmental responsibilities were scattered around.

ROBERTS: So, there weren't other groups that were as interested in what was happening with the formation of TSCA.

LETTOW: Oh, yes. There definitely were, because this was supposed to cover a whole variety of different...

⁶ *The President's 1971 Environmental Program*, compiled by the Council on Environmental Quality (Washington, D.C.: U.S. Government Printing Office, 1971).

ROBERTS: So, what was their response to what was drafted?

LETTOW: Well, we had...I should start by saying that, [at] the time, the person at OMB who was responsible for legislative reference was a fellow named Jim Hyde [James F. C. Hyde, Jr.]. Has his name come up?

ROBERTS: Um-hmm.

HARDY: Yes. Terry mentioned him.

LETTOW: He was wonderful. He really was. He was a gentleman of the first order, very old-fashioned...blind, had been blinded through a wound at Anzio, [Italy]. Or... it might not have been exactly at Anzio, but it was very shortly thereafter. Had a wonderful memory, had...people read to him, and he would remember. But he had a manner about him which was just terrific. He could listen to people and try to sift through what they were saying to get at what was really bothering them, because often [...] we speak in elliptical terms, shall we say. Or, we're saying one thing and what we're really driving at is something else, whether we realize it or not. And he had a young staff, who were very supportive of him in the best possible way. It was, from that standpoint, a great process, because he knew how to manage it.

ROBERTS: So, who were the other...were there other interested parties that he brought together to review what the CEQ had developed in terms of its TSCA bill before it became a part of the president's environmental program?

LETTOW: Absolutely.

ROBERTS: Can you talk about who some of those people might have been?

LETTOW: Oh, gosh...

ROBERTS: Or what interest they had, or concerns they had, or support...

LETTOW: Well, I can even remember dealing with the [United States] Atomic Energy Commission [AEC], believe it or not. Isn't that amazing? Anyway. I say the Atomic Energy Commission, because they were an independent commission, and they had to be handled in a

different way than one of the departments...let's say, the predecessor of HHS [United States Department of Health and Human Services], or [United States Department of the] Interior, or one of those. So, [...] you had some problems here that had to be solved. You had to get their comments.

In fact, I just yesterday—was it yesterday or the day before...I guess, it was the day before—was a part of a group at the [United States] Court [of Federal Claims] who were asked by...the group was asked by the administrative office of the U.S. Courts to comment on a draft bill implementing a convention that the State Department had sent over. It had to do with enforcement of foreign judgments, and so on and so forth. We had some comments on it. They finally realized the administrative office and the U.S. Courts might know something about that, and they ought to be consulted. And, you know, it's...consulting with the judiciary is a very different kettle of fish than consulting even with the AEC. But you wouldn't want to have something float up from the State Department that caused all sorts of heartburn from the judiciary, I don't think. So, somebody had the wit to use the right path, because we can't as a court comment, but the administrative office can. And we can say, "look at X, Y, and Z."

HARDY: So, what were...you briefly said the word "resolve," that things needed to be resolved between these different interests. Do you remember any of those discussions, or what the concerns were?

LETTOW: Well, I can. Some of them appear in the draft bill, and the statute and some don't. Preemption was a big issue.

HARDY: What do you mean by "preemption"?

LETTOW: What do I mean by "preemption"? Let's find... what do I mean? Now, we're off the thrust of the statute, you realize. But...this is still a hot topic today. State regulation, Section 218 of the bill put forward [in 1971]. And somewhere in the current statute, there's an even broader non-preemption provision.

This is important, not so much...well, it can be important for the regulators, because they don't...they could do something—a state could do something—that could be at cross-purposes with what they're trying to do. But it's more, much more important for the regulated parties. Preemption here is [Section 18 of the act], and I remember reading this yesterday. It's actually much less preemptive of state regulation, which can be a problem. There are, you know, interesting Supreme Court cases on the drug area on exactly this topic. That was one issue.

The second issue that we...I remember we spent a lot of time on, because it had an echo—more than an echo—in other statutes was *qui tam* suits...anybody ever talk to you about *qui tam* suits?

ROBERTS: [No.]

LETTOW: Citizen suits? Talk with you about that? Terry talk with you about that?

ROBERTS: No.

HARDY: Nope.

LETTOW: Yes, I suppose I got...this is the topic on which I got more grief than he did. It's just our perspectives were different. In the Clean Air Act and the Clean Water Act, there are provisions for citizens to sue for violations of law. Not the government, citizens... it caused all sorts of problems, because you end up with an executive function being taken over by citizens. Well, sometimes it works and sometimes it doesn't. Here, we didn't have any such thing in this act. [...] It was not what we were trying to do. But it is in the...[...] Water Act. Particularly, if you look at the Water Act, there is a citizen suit provision in there.

There is in this act too, [Section 21] is citizens petitions. That actually is not really important. [Section 20] is citizens civil actions. When I say important, I don't mean that it's unimportant, because it can be important insofar as the administrative aspect of the thing.

ROBERTS: So, you're comparing for us what was submitted in 1971 as part...

LETTOW: To what it ended up. But this was an issue...

ROBERTS: And what it ended up in 1976.

LETTOW: This was an issue when we submitted it, because it had been something that was mooted or discussed in these other contexts. We certainly knew what those other contexts were.

ROBERTS: So, is it relatively safe to say, without generalizing, that the different...the places where there are differences in the piece submitted in 1971 versus what's passed in 1976 might also reflect some of the tensions that existed prepublication of the draft in 1971?

LETTOW: Yes, sure.

ROBERTS: And that those tensions just came back out during Congressional manhandling.

LETTOW: You'd expect that, I think.

ROBERTS: Yes.

LETTOW: But I mean that...let's say, the citizens suit provision. That's not a central part of what's going on here. It's kind of a, you know, another aspect. But we had debates about judicial review. This follows a pattern much more like that in the Food, Drug, and Cosmetic Act than that which you would find in the Clean Water Act and Clean Air Act. I could tell you chapter and verse what the differences are, but do you really want to know that? I doubt it.

Let's just think of...penalties always have...gets people excited. We had debates on... there were actually...penalties are actually much, in the current act, are much closer to those that we put forward. There [is] very little change in substance. We had debates about search warrant authority, administrative searches. That's not a central part of this, but it can...

ROBERTS: What about issues around...

LETTOW: Confidentiality was a really big issue.

ROBERTS: Can you talk about that?

LETTOW: Sure.

ROBERTS: That'd be great.

LETTOW: Any time you're...we talked about it previously, in the context of requiring people to submit data that they might have that they were holding on a proprietary basis. And sometimes, I think it was fairly evident that even the identity of the chemical substance might be confidential. In fact, it could very frequently happen...and that's held forward or it carried forward. We had to work our way through all those little things. And then, the subsequent testing, to what extent were you going to make the subsequent testing results available?

ROBERTS: What about questions of who would be responsible for doing the testing?

LETTOW: Oh, I don't think there was much doubt about that. If somebody was going to come forward with a potential use of [...] a new substance, they had to provide some testing. And then, you ended up with groups who were proposing to use it, and the sharing of costs in the group. You always have the problem of free riders, if they come along very shortly thereafter. I mean, that's been a big topic. Again, I'm going to go back to the Food, Drug, and Cosmetic Act, because you have generic drugs, and all sorts of provisions regarding testing. There you have patent protection. Well, you kind of have patent protection here, too.

ROBERTS: And yet, under TSCA, one of the primary complaints is that the burden of testing and proof lies with the EPA and not on the company submitting...

LETTOW: That's not proof. Who says that?

ROBERTS: I think pretty much every group out there petitioning for reform of TSCA would argue that...

LETTOW: Well, see you're...I don't know any of this, because this is not what I deal with, at all. I just don't.

HARDY: You're very right that in the bill, it says that manufacturers are held responsible. But that's not quite how it's worked out.

LETTOW: Well, they can be. You have...provisions for test rules and all this other stuff.

ROBERTS: And I think that's what I was trying to get at in terms of thinking about the ways in which the law was written versus the ways in which it was actually put into use. That despite the fact that there are provisions that say things like "the EPA can..." those qualifiers...the

ways in which they have actually been put to use over the last thirty years have created an institutional setting in which the EPA does not pursue those sorts of pieces.

LETTOW: That's their problem. I'm sorry. Actually, I should say that the only brush I've had with this statute over however many years it's been—thirty-nine years, or I guess, thirty-four years, because it took a while to get it adopted—is this...I had mentioned before we started that [my] son is running a startup business with a substance that was discovered by his university professors. Well, they have a patent on it, just recently issued. They're plugging away, and it's subject to both TSCA and the REACH regulations in Europe. And so, I'm very familiar with, kind of, what has happened in that area. It happens to be an area that is somewhat sensitive.

On the other hand, [...]...the chemical substance is very familiar to us all. Its form is not, shall we say, and it has very unusual properties. But it isn't something that you can just say, "it has this use, and it doesn't have any other uses." That is just as far from the truth as possible, because they're marketing conductive inks made with this material now, and there are all sorts of other potential uses. People are coming forward with tests, and they're doing tests, and so on and so forth. So, I'm familiar with it. But how you would possibly deal with something like that in this context without this model, I don't know.

HARDY: So, how much was there a concern or debate over the need to not impede this type of technological innovation?

LETTOW: What type of technological innovation?

ROBERTS: Well, just innovation in the chemical industry that...

LETTOW: Yes. But, I mean, why would anybody want to do that?

ROBERTS: Do what, impede?

LETTOW: Yes.

ROBERTS: Well, I think ...

HARDY: But inherently some of the provisions do that, right.

ROBERTS: Well, that's the concern that comes up, right. That the formulation of any regulation over chemical substances—especially since this was broad reaching, this was all chemical substances—would discourage innovation within the chemical industry. So, I think...

HARDY: And the perception of the need to do testing or to spend money on that...

ROBERTS: So, I think...I hear Kavita's question as trying to say, how was the need to protect that space for innovation broadened to discussions about how you would go about framing a regulation that is so broad, and yet, needs to allow space for the innovations within these companies to continue as unimpeded as possible?

LETTOW: That's part of the big...well, we had a discussion fairly early on about the policies certain companies apply in terms of making sure that the products they put out at all levels, actually [are safe to use]...but I had worked with a company that had consumer products. You probably have used a number of Proctor & Gamble products in your time. Do you expect them to hurt you in any way? No.

ROBERTS: I hope not.

LETTOW: Right. Do you expect them to do what they're supposed to do and not have any untoward consequences? Well, they test fairly adeptly to try to figure it out. I suppose they get surprised once in a while. But I'm just not aware of too many surprises.

ROBERTS: Well, I think, outside of the surprises, I think it's more about this balancing of whether or not it...if one might be able to point back and gesture about whether or not TSCA has inhibited innovation in the chemical industry in the United States since its passing in 1976. That has gone quietly un-talked about. I think it only arises when new changes might be on the horizon. And so, this happened obviously, with air and water over the years, and with new bills being introduced in both the House and the Senate to reform TSCA. Very recently that's re-emerged that, you know, we were all in favor of reform, but we need to balance the ability to have oversight with the ability to innovate.

I actually think there's a more interesting piece that I heard you saying before Kavita [asked] her question, which is protecting the ability of the regulatory agency to adequately handle the products of that new innovation. That in constructing this...

LETTOW: That's what we were driving at. That's why there are potential use restrictions in there.

ROBERTS: Right. And that, by becoming overly prescribed in their statute you miss what might be this new novel material that is...

LETTOW: Of great ...

ROBERTS: Looks like your old material, but is actually, radically different and you'd have...

LETTOW: In terms of...

ROBERTS: In its properties and it's uses.

LETTOW: Yes, exactly.

ROBERTS: That you wouldn't have the ability to have oversight over that if you didn't have this built-in ambiguity or flexibility.

LETTOW: Yes. That was the point. You got the point.

ROBERTS: Right. I got the point. I think, we got the point when we first talked to Terry, that that was his idea. That what was revolutionary about this approach was that it was cross-media. It was systematic. It was complex. And yet, when we talked to the people who were the directors of the Office of Toxic Substances or the assistant administrators, their...the difficulties of actually putting that statute to work were large.

LETTOW: I fear for us, as a country, if that's true. Because this was pretty carefully designed, so that you could deal with something that caused a problem without having all sorts of adverse, untoward consequences.

ROBERTS: So, how would you take what you've been telling us over the last hour and comment on—almost an hour, about an hour, yes—and think about the call for reform. How would you...

LETTOW: I don't know what the call for reform is. I apologize for my ignorance.

ROBERTS: Oh, no. It's fine. So, imagine there is call for reform. I mean, would you basically just tell them...

LETTOW: Yes, but that could mean anything. I mean, it could mean, to my mind, retrogression. Just means change.

ROBERTS: Yes. I mean, I think what we're trying to highlight in the project is really these sorts of...the discussion we've gotten from you, which is you need to better understand what was actually in the original version.

LETTOW: Yes. What the basic purposes of the exercise were, not all the... we had a discussion about the forest and the trees, or getting down in the weeds, before. We ought not to be...the people who run this ought not to be doing that at a certain level. They ought to be, at a certain level, conceptual thinkers. The people who actually set the use restrictions or the test rules, and so on and so forth, have to be concerned with the trees and the weeds. But, they ought not to [always focus on the trees and weeds].

HARDY: Is there anything else you'd like to add about this process and what you remember?

LETTOW: It was actually instructive for me, because I remember litigating a couple of, to me, quite interesting cases that, actually, I had a different approach to after...because of this exercise. One of them had to do with administrative search warrants and confidentiality. And somewhere...I have to find it. Oh, here it is.

There was a case in the Supreme Court that I remember arguing called *United States of America vs. Stauffer Chemical Company*. It had to do with administrative search warrants. Anyway, it's 464 U.S. 165. It was decided in 1984. So, it wasn't that much after this, but I was litigating. The company...the EPA had, under the Clean Air Act, had hired contractors to conduct a search or searches of certain kinds of chemical plants. And the people who ran the plants were quite concerned that the contractors would gather all sorts of information and not be subject to the same confidentiality restraints that EPA would [be] in their subsequent work. And that [...] started off with a motion to quash an administrative search warrant in Cheyenne, Wyoming. The Federal District Court in Cheyenne, Wyoming. But... you never know how your past life can come around. So, I knew a little bit about that issue when I started. And...for an odd reason.

ROBERTS: Yes. Well, thank you so much. [...]

[END OF AUDIO, FILE 1.1]

[END OF INTERVIEW]

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