CHEMICAL HERITAGE FOUNDATION

THE TOXIC SUBSTANCES CONTROL ACT: FROM THE PERSPECTIVE OF DON R. CLAY

Transcript of Interviews
Conducted by

Jody A. Roberts and Kavita D. Hardy

at

Koch Industries, Inc. Washington, D.C.

on

16 March 2010

(With Subsequent Corrections and Additions)

CHEMICAL HERITAGE FOUNDATION Oral History Program FINAL RELEASE FORM

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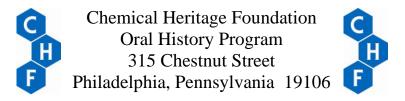
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DON R. CLAY

1937	Born in Washington Courthouse, Ohio on 26 June	
<u>Education</u>		
1960 1960	B.S., Chemical Engineering, Ohio State University M.S., Chemical Engineering, Ohio State University	
	Professional Experience	
1960-1961	The Monsanto Company, Springfield, Massachusetts	
1961-1963	U.S. Army, Fort Bliss, Texas Second Lieutenant	
1963-1968	Operations Research, Inc., Silver Spring, Maryland	
1968-1970	Research Management Corporation Program Director	
1970-1971	Resource Allocation, Inc. Executive Vice President	
1971-1972	Commission on the Organization of the Government of the District of Columbia, Washington, D.C. Group Leader	
1972-1972 1972-1974	U.S. Food and Drug Administration, Washington, D.C. Planning and Evaluation, Bureau of Drugs Deputy Assistant Commissioner, Planning and Evaluation	
1974-1976 1976-1981	U.S. Consumer Product Safety Commission, Washington, D.C. Director, Office of Program Planning and Evaluation Deputy Associate Executive Director, Engineering Sciences	
1981-1985 1985-1986 1986-1989	U.S. Environmental Protection Agency, Washington, D.C. Director, Office of Toxic Substances Acting Assistant Administrator, Office of Pesticides and Toxic Substances Deputy Assistant Administrator, Office of Air and Radiation	
1700 1707	Deputy Assistant Administrator, Office of All and Radiation	

1989-1993	Assistant Administrator, Solid Waste and Emergency Response	
1993-1998	Don Clay Associates, Inc., Washington, D.C. President	
	Koch Industries, Inc., Washington, D.C. Director of Environmental and Regulatory Affairs Vice President, Environmental and Regulatory Affairs	
<u>Honors</u>		
1983 1987 1988	Administrator's Award, U.S. Environmental Protection Agency Presidential Rank Award, Meritorious Executive, U.S. Government Presidential Rank Award, Distinguished Executive, U.S. Government	

ABSTRACT

Don R. Clay received bachelor's and master's degrees in chemical engineering from the Ohio State University, where he was required to participate in the Reserve Officers' Training Corps. He took a job at Monsanto Company, but after six months entered the U.S. Army, serving two years at Fort Bliss, Texas, performing air defense simulation modeling. On his return to Monsanto he decided he did not like the way chemical engineering was done there, and he went to Operations Research, Inc. For a number of years there and at several subsequent companies he worked in operations research.

Leaving those companies Clay began work in the Bureau of Drugs at the U.S. Food and Drug Administration (FDA); there he spent several years as Deputy Assistant Commissioner of Planning and Evaluation. Next he took his talents and experience to the U.S. Consumer Product Safety Commission's Office of Program Planning and Evaluation. His risk assessment work included being liaison among the U.S. Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the U.S. Consumer Product Safety Commission (CPSC), and the FDA, which gave him a chance to learn more about the EPA. Frustrated with the bureaucracy at the FDA, Clay moved to the Office of Toxic Substances, where he became Acting Assistant Administrator of what is now the Office of Pesticides and Toxic Substances (OPTS). Asbestos occupied much of his attention there, but only emberizing ash was banned. Industry testing was legislated. PCBs became regulated. Nevertheless, Clay's disenchantment with having to "look for causes" led him to the Office of Air and Radiation (OAR) and, for his final position with the EPA, to Assistant Administrator of the Office of Solid Waste and Emergency Response (OSWER). After about five years, Clay believes, one becomes stale and should move to a different area; he chose OAR because it had interesting problems. Clay received a number of government honors, and he now works in the private sector.

Clay discusses the cultural differences among agencies; their different goals and processes; the differences between career staff and political appointees; and the difficulties of the regulatory process itself. He talks about what he perceives as successes and failures, focusing on asbestos regulation. He says that asbestos was never regulated, and that the costs of determining that it would not be regulated—he cites schools causing illness by tearing out the asbestos—far outweighed the benefits, especially since the market has itself eliminated asbestos. On the other hand, emberizing ash was done away with. In fact, he believes that in his day decisions were taken on the basis of benefits exceeding costs, whereas now bodies "just do it" (regulate). This he attributes to a more recent politicization of the process, citing the return of the formaldehyde debate. He talks about his relationship with the U.S. Congress and the influence of the European laws known as REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). He notes that legislation is usually enacted within two months of a general election.

Scientists ask, "What is the risk?" but consumers ask, "Is it safe?" Reconciling these two approaches in order to determine the optimum amount and kind of regulation is not an easy job. Clay's philosophy and practice have always been to "do the right thing."

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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Education and Early Career

B.S., and M.S. in Chemical Engineering from Ohio State University. Monsanto Company in Springfield, Massachusetts. Air defense simulation modeling in U.S. Army at Fort Bliss, Texas. Operations Research, Inc. Program Director at Research Management Corporation. Executive Vice President at Resource Allocation, Inc. U.S. Food and Drug Administration Bureau of Drugs. Planning and Evaluation; then Deputy Assistant Commissioner of Planning and Evaluation; several years there. U.S. Consumer Product Safety Commission. Director, Office of Program Planning and Evaluation. Deputy Associate Executive Director, Engineering Sciences. IRLG under President Carter. Liaison among EPA, OSHA, CPSC, FDA. Risk assessment. Frustration with bureaucracy. Leaves for EPA.

U.S. Environmental Protection Agency

Director, Office of Toxic Substances, then Acting Assistant Administrator, Office of Pesticides and Toxic Substances (OPTS). Discusses cultural differences among agencies. Career staff versus political appointees. Differences in goals and processes. Difficulties of regulation process. Looking for causes.

Perceived successes and failures

Failed to regulate asbestos, but got rid of emberizing ash. Costs exceeded benefits of warning about asbestos. Illnesses resulting from asbestos removal. Market eliminated asbestos without regulation. PCB regulation successful. Industry testing legislated.

Decision-making Process

Philosophy: "Do the right thing." Testing difficulties. PMN (premanufacturing notice). Unreasonable risk. Early decisions dependent on analysis of costs versus benefits; now "just do it." Politicization recent; e.g. formaldehyde redux. Relationship with U.S. Congress. Influence of REACH. General elections as stimulus for legislation. Resources dependent on lawsuits against TSCA; feasibility of suing own department. Advocating for program.

Office of Air and Radiation (OAR); Solid Waste and Emergency Response

Career move in OPTS from Acting Assistant Administrator would not be upward, so decided to leave department. Chose OAR for its interesting problems. Found TSCA boring; felt that about five years was right time frame for avoiding staleness. Went to Office of Solid Waste and Emergency Response (OSWER).

Final Thoughts

Frustrations with getting things done. Testing process too costly, too drawn out. Defining universe of old chemicals to test impossible. REACH perhaps too onerous for American industry. Confidential business information (CBI) forces

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