

ENVIRONMENTAL PROTECTION AGENCY REGULATION OF ASBESTOS AND  
CARBON NANOTUBES UNDER THE TOXIC SUBSTANCES CONTROL ACT:  
INVESTIGATING THE ROLE OF POLITICS, SCIENCE, AND POLICY IN  
ADMINISTRATIVE RULEMAKING AND IMPLEMENTATION

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## **DEDICATION**

For Izumi, Sarah, and Kent, whose loving support and intellectual contributions made it possible for me to complete this dissertation. For my parents, Charles and Linda Slate, who taught me the importance of service, hard work, perseverance, and continual learning. This is also dedicated to my brother Jeb and sisters, Lillian, Rachel, and Summer.

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## LIST OF ABBREVIATIONS AND SYMBOLS

AFL-CIO.....	American Federation of Labor-Congress of Industrial Organizations
AHERA.....	Asbestos Hazard and Emergency Response Act of 1986
CAA .....	Clean Air Act
CDC .....	Centers for Disease Control and Prevention
CERCLA.....	Comprehensive Environmental Response, Compensation and Liability Act
CVD .....	Chemical Vapor Deposition
CWA .....	Clean Water Act
DHHS.....	Department of Health and Human Services
EDF .....	Environmental Defense Fund
EPA.....	Environmental Protection Agency
FFP.....	Fiber Pathogenicity Paradigm
FIFRA .....	Federal Insecticide, Fungicide and Rodenticide Act
HiPco.....	High-Pressure Carbon Monoxide Conversion
MWCNT .....	Multi-Walled Carbon Nanotubes
NIOSH .....	The National Institute for Occupational Safety and Health
OCSPP .....	Office of Chemical Safety and Pollution Prevention
OIG .....	Office of Inspector General
OIRA.....	Office of Information Review and Regulatory Affairs
OMB .....	Office of Management and Budget
OPP .....	Office of Pesticide Programs
OPPT.....	Office of Pollution Prevention and Toxics
OSCP.....	Office of Science and Coordination Policy
OSHA.....	Occupational Safety and Health Act
OTS .....	Office of Toxic Substances
RCRA.....	Resource Conservation and Recovery Act
SEIU.....	Service Employee International Union
SEM .....	Scanning Electron Microscope
SWCNT.....	Single-Walled Carbon Nanotubes
TEM .....	Transmission Electron Microscope
TI.....	Tobacco Institute
TSCA .....	Toxic Substances Control Act
§.....	section
µm .....	micrometer
nm .....	nanometer

## **ABSTRACT**

### **ENVIRONMENTAL PROTECTION AGENCY REGULATION OF ASBESTOS AND CARBON NANOTUBES UNDER THE TOXIC SUBSTANCES CONTROL ACT: INVESTIGATING THE ROLE OF POLITICS, SCIENCE, AND POLICY IN ADMINISTRATIVE RULEMAKING AND IMPLEMENTATION**

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In this dissertation, four policy models—rational, incremental, interest group, and process streams—are used to examine how the policy-making process worked (or did not work) in the development of statutory law and administrative rules for asbestos and carbon nanotubes. A summary of the policy-making models is provided, followed by predictions about the passage and implementation of public law. Then, the roles Congressional policy entrepreneurs, bureaucrats, lobbyists, and interest groups played in the policy-making process that led to the enactment of the Asbestos Hazard and Emergency Response Act of 1986 are described. A discussion of the common epidemiological and toxicological principles of carbon nanotubes is the next step in the study, followed by a more detailed analysis of the physicochemical properties of chrysotile asbestos and multi-walled carbon nanotubes. Then, the relevant *in vivo* and *in vitro* findings in the scientific literature are analyzed. The findings tend to show multi-walled carbon nanotubes could have asbestos-like effects on the lungs. These findings provide an important backdrop for the examination of the Environmental Protection Agency's existing regulatory framework for carbon

nanotubes. Finally, the predictions about policy making and policy implementation are examined.

In this concluding section, emphasis is placed on the challenges associated with Environmental Protection Agency rulemaking on asbestos and carbon nanotubes and the implementation of the Toxic Substances Control Act.

## **CHAPTER ONE: INTRODUCTION**

### **1. Overview**

Nanotechnology is a term used to describe the science, engineering, and applications of materials in dimensions less than 100 nanometers. Nanotechnology is being used to address critical needs in science and technology and creating new market opportunities (Hubbs et al., 2013). The global investment in nanotechnology totaled \$17.8 billion in 2010 (Lux Research, 2011), with revenue from nano-enabled products increasing to \$731 billion in 2012 (Lux Research, 2014). Lux Research (2014) estimates the value of nano-enabled products, nano-intermediates, and nanomaterials could reach \$4.4 trillion by 2018. The continued growth in nanotechnology research and development could lead to important innovations in a range of industrial and commercial applications in electronics, energy, medicine, water filtration, environmental remediation, sensors, chemicals, coatings, and catalysts (CRS, 2013a; CRS, 2013b).<sup>1</sup>

The number of consumer products containing engineered nanomaterials<sup>2</sup> continues to increase. The Woodrow Wilson International Center reported in 2009 that that it had identified over 1,000 nanotechnology-based consumer products, from cosmetics and toothbrushes to computer chips and building insulation (Fiorino, 2010). The Center's 2014 inventory shows that over 1,600 manufacturer-identified nano-enabled products have entered the market. Carbon nanotubes, seamless nanoscale cylinders

consisting of concentric graphite layers, are now used in lithium batteries, automotive parts, aircraft frames, clothing, sporting goods, boat hulls, water filters, and electrostatic discharge shielding (De Volder et al., 2013; PEN, 2014). IBM is developing carbon nanotube transistors that could increase the speed of microprocessors fivefold, based on performance simulations. IBM hopes to replace their silicon transistors with the nanotube transistors soon after 2020 (Simonite, 2014).

Carbon nanotubes have generated a great deal of interest because of their high chemical stability, remarkable optical and electrical properties, tensile strength, and high surface-to-volume and aspect ratios (Upadhyayula et al., 2010). De Volder et al. (2013) note that some multi-walled carbon nanotubes (MWCNT) are stronger than any industrial fiber and single-walled carbon nanotubes (SWCNT) can have a thermal conductivity that exceeds that of diamond. De Volder et al. (2013) observe that carbon nanotube powders are increasingly used in various commercial applications. The dry spinning of carbon nanotubes into continuous yarns could also have a broad range of applications in bioengineering, composite materials, electrochemical devices, and microelectrodes (Tran, 2014). Ghiazza et al. (2014) estimate annual carbon nanotube production could be in the hundreds of tons. De Volder states manufacturing capacity for carbon nanotubes has grown tenfold since 2006 (Cambridge University, 2014).

Sprynskyy et al. (2011) suggest that the development of carbon nanotube-based technologies has generated renewed interest in potential applications of naturally occurring chrysotile asbestos tubes, which morphologically and crystallographically mimic carbon nanotubes (Olsen et al, 2008). Roveri et al. (2006) observe that chrysotile,

which has a tubular nanostructure phase, consists of densely packed multiwalled hollow nanotubes. Lesci et al. (2014) explain that the chrysotile tubes can be filled with various metals to create new semiconducting and metal quantum wires. Mettraux et al. (2002) showed that chrysotile tubes can be used to manufacture nanowires, representing a potential alternative to carbon nanotubes in this area. Liu et al. (2012) prepared chrysotile/ $\alpha$ -Fe<sub>2</sub>O<sub>3</sub> (alpha-phase ferric oxide, hematite) fibrous composites to enhance the gas sensing properties of sensor devices. Mettraux (2008) suggests that the chief advantage of chrysotile tubes is their low cost relative to carbon nanotubes.

The structural similarities between carbon and chrysotile nanotubes, coupled with carbon nanotubes unique physico-chemical properties, raise concerns about the potential health and environmental risks (Donaldson et al., 2006). The findings in the scientific literature tend to show carbon nanotubes could have asbestos-like effects on the lungs (NIOSH, 2013; EPA, 2012; Fadeel et al., 2012). The lessons learned from asbestos provide a cautionary tale about uncontrolled human exposure to disease-causing fibers.

The U.S. Environmental Protection Agency (EPA) is currently attempting to regulate carbon nanotubes and other engineered nanoscale materials under the Toxic Substances Control Act (TSCA). To this end, the EPA is pursuing a four-pronged regulatory approach: (1) premanufacture notifications under TSCA §5; (2) Significant New Use Rules (SNUR) under TSCA §5(a)(2); (3) informational gathering rules under TSCA §8(a); and test rules under TSCA §4 (EPA, n.d.). It is difficult to assess the effectiveness of this regulatory approach, but the use of policy models can help distill



essential elements from such complicated issues to make predictions on policy outcomes (Hayes, 1992).

The incremental model has been described as the policy model that best explains the American public policy process (DHHS, 1991). The empirical studies of Wildavsky (1964), Wildavsky and Hammond (1965), and Anton (1966) determined the model was valid for some governmental processes (Rajagopalan & Rasheed, 1995). Sexton (2013) observes that political scientists generally agree that bureaucracies and bureaucrats may aspire to make regulatory decisions in a rational (Weberian) manner, but the incremental model more closely reflects the way in which the EPA and other government agencies actually operate.

## **2. Purpose**

This dissertation seeks to assess the ability of the EPA to effectively regulate carbon nanotubes under the TSCA, drawing on the lesson learned from the EPA's regulation of asbestos. It uses four policy-making models—rational, incremental, interest group, and process streams—to examine how the policy-making process worked (or did not work) in the development of statutory law and administrative rules for asbestos and carbon nanotubes.

## **3. Research Questions**

The dissertation attempts to answer the following sets of research questions:

- (1) What is the existing regulatory structure for toxic chemical substances in the United States? Does the EPA have the statutory authority to regulate carbon nanotubes? If

not, why not? If the EPA is attempting to regulate carbon nanotubes, then what has been the response of industry? If EPA is not attempting to regulate, then what are some of the potential consequences? If regulatory activities are emerging slowly, then what steps could EPA take to improve the process? What are the key lessons learned from the regulation of asbestos?

- (2) What do we currently know about the carbon nanotube health and environmental risks? What are the common epidemiological and toxicological principles for assessing the health risks of carbon nanotubes? What relevant insights have we gained from decades of research on the pathology, epidemiology, and toxicology of asbestos?

#### **4. Hypotheses**

(H1) The incremental model will best describe the policy process as it applies to the regulation of asbestos and carbon nanotubes.

(H2) If the EPA can successfully implement all four prongs of its current regulatory approach, then it can effectively control carbon nanotubes under the TSCA.

#### **5. Research Framework**

In order to answer the research questions and test the hypotheses articulated in sections 3 and 4 above, this study will include multiple steps. First, the current scientific literature is reviewed and analyzed to help answer the scientific research questions. The scientific findings provide a backdrop for the examination of the EPA's existing regulatory framework for carbon nanotubes. Second, the existing legislative authorities

that the EPA uses or may use to control the use of engineered nanomaterials encompass nanomaterials<sup>3</sup> and literature on the policy-making process and implementation are examined. Third, several detailed historical case studies on asbestos will be used as a basis for examining the predictions derived from the following four policy models:

**(1) Rational Problem Solving Model.** According to this model, as described by Jones (1984), the policy process consists of six steps. First, a public policy problem is identified. Second, the problem is placed on the legislative agenda. Then, proposals are formulated, and programs are legitimated, implemented, and evaluated. The final stage of the process, evaluation, involves policy makers rendering a decision about the policy on the basis of evidence about whether the policy best meets public interests. The model presumes decision makers will make rational decisions and ignores the influence of political actors and interests on the policy-making process (Field, 2007);

**(2) Incremental Model.** This model is an alternative to the rational problem-solving model. The model differs from the rational model on all points, focusing on the importance of the multiple, competing interests and interest groups that influence policy-making. According to this model, most policy making involves only incremental changes in existing policies. Time constraints, limited knowledge, interest groups, and politics all weigh against pushing for major policy changes (Lindblom & Woodhouse, 1993);

**(3) Interest Group Model.** This model, as articulated by Earl Latham in the early 1950s, holds that interest groups dominate the policy process.<sup>4</sup> Legislators are merely "scorekeepers who ratify and record the balance of power among contending groups" (Conant, 2006). According to this view, environmental laws can be viewed as essentially records of the "balance of power at any given point in time, and they reflect surrenders, compromises, and conquests" (Conant, 2006);

**(4) Process Streams Model.** Kingdon (1995) developed the concept of "process streams" that come together at critical junctures and "the greatest policy changes grow out of that coupling of problems, policy proposals, and politics." The three major process streams in the federal government are problem recognition, the creation and refinement of policy proposals and politics. Kingdon (1995) contends that a "policy window", which he describes as an opportunity to push for action on certain policy initiatives, is essential for enabling policy development. Policy windows consist of crises, events that focus public attention on an issue, or a change presidential administrations, and only stay open for short periods of time.

In this dissertation, I employ a systems approach to assess the effectiveness of policy implementation as it applies to the regulation of asbestos and carbon nanotubes. In using this approach, which was articulated by Schifano et al. (2011), I will examine four factors as part of the analysis: statutory language, procedural framework, political context, and available resources. Each of these factors play a significant role in determining the implementation and outcomes of regulation and policy (Schifano et al., 2011). The research contained in this dissertation incorporate findings from the

Chemical Heritage Foundation's (CHF) full oral interviews of individuals intimately involved in TSCA implementation from 1977 to 2009. The CHF interviews can help academics and policymakers understand the challenges of TSCA implementation against the backdrop of the larger political context (Roberts, 2010).

## CHAPTER TWO: POLICY MODELS

### 1. Modeling Politics: Policy-Making as Chemistry Metaphor

The *iron triangle* and the *hexagon model* are examples of structural metaphors political scientists use to describe the public policy process.<sup>5</sup> For some chemists the mention of such structures might conjure visions of an iron cluster with fixed triangular geometry (Rollman et al., 2006), benzene's hexagonal ring of carbon atoms as described by the Nobel laureate Kekulé,<sup>6</sup> or the many hexagons making up the molecular models of carbon fullerenes and nanotubes.<sup>7</sup>

American political science is a laboratory of many chemicals, each having structures chemists can represent in various ways to show the position of atoms and shapes of molecules. Some represent the "pluralist" structure, in which active groups randomly form new arrangements and 'atomistic' competition reaches an equilibrium. Some are clusters of geometric shapes, each formed by assumptions the world is empirically knowable and measurable; this is the "rational" structure (Mayer et al., 2012). Still others shape the political agenda, making up the "process streams" structure and so on. Political science, like chemistry, is made up of innumerable discrete structures that can be linked to model a process (Krill & Tosun, 2008).<sup>8</sup>

Policy models, to change the metaphor, are snapshots and conceptual representations of certain stages of the policy-making process and real-world situations

(Field, 2007). Political scientists use models to describe how the policy-making process works and to explain why the process works the way it does. Policy models are not as sophisticated as those used in the natural sciences, but they can provide valuable insights for analysis (Hayes, 1992). The examination and synthesis of a variety of competing models can widen perspective, provide a broader understanding of the discipline, and enable predictive analysis (Hayes, 1992).

This dissertation uses four policy models to examine how the policy-making process worked (or did not work) in the development of regulatory policy (statutory law and administrative rules) for two fibrous materials that pose risk to human health: asbestos and carbon nanotubes. The four models are the rational model, the incremental model, the interest group model, and the process streams model.

This chapter first briefly describes the policy-making process. It then details the four policy models. Lastly, it uses each of the models to make predictions about how the policy-making process will work in the regulation of asbestos and carbon nanotubes.

## **2. The Policy Process**

Public policy refers to a series of actions, such as adopting laws or regulations, taken to solve particular societal problems (Davidson & Oleszek, 2004). In the words of David Easton, public policy is the "authoritative allocation" of values or resources for society (Hayes, 1992). The state allocates values and resources for society when it enacts policies that are binding on all citizens (Davidson & Oleszek, 2004).

Policy-making involves the interaction of federal and state governments, numerous private and special interest groups and private citizens, and it goes beyond

legislative and lawmaking activity (Thurber, 1991). The policy-making process is generally considered to consist of four critical stages: (1) problem identification and agenda setting; (2) policy formulation; (3) policy adoption; and (4) policy implementation (Davidson & Oleszek, 2004). These stages are discussed in more detail below.

## **2.1 Problem Identification & Agenda Setting**

This stage of the policy process deals with how issues are chosen for government attention and political action (Davidson & Oleszek, 2004). How is a particular problem identified and put on the national agenda? From the perspective of problem identification and agenda setting, several questions might arise with respect to potentially hazardous materials. For example, what are the most important factors involved in getting a problem, such as dealing with a harmful toxic substance, onto the public agenda? How does the political environment influence the time in which problems are placed on the agenda? What external pressures prompt congressional responses to these problems?

The asbestos problem led to the enactment of new federal laws and regulations. What lessons can be gleaned for carbon nanotubes problem identification and agenda setting?

## **2.2 Policy Formulation**

At this second stage, policy-makers and their staff discuss the political agenda items and explore feasible courses of action on policy problems (Krill & Tosun, 2008). During this "policy incubation" period, members of Congress conduct hearings, write



committee reports, and begin to establish a consensus that a particular problem exists. This period also involves refining existing solutions and applying them to a variety of problems (Davidson & Oleszek, 2004). In the words of Kingdon (2001), formulating policy proposals involves creating solutions that policy makers can attach to problems that are important at the moment.

### **2.3 Policy Adoption**

Policy adoption involves the formal enactment of a policy. Policy adoption is closely related to policy formulation. Some political scientists combine the two concepts to form one stage in the policy process. For the purposes of this dissertation, the two concepts are treated as separate stages. Policy formulation deals with elaborating action alternatives (Krill & Tosun, 2008), whereas policy adoption involves the mobilization of support for a selected alternative and the conflict in Congress over passage of legislation (Hayes, 1992).

### **2.4 Policy Implementation**

The final stage of the policy-making process, policy implementation, begins after Congress passes a law. Vig and Kraft (2006) define policy implementation as the process of effectuating programs by the "provision of institutional resources and administrative decisions." Policy implementation involves fulfilling the legislative intent of a law, which may include creating new institutions (Hayes, 1992).

Congress and the president usually delegate implementation decisions to federal agencies. The executive branch, interest groups, and other administrative agencies, etc.,

are also involved at this stage (Krill & Tosun, 2008). Policy implementation ultimately determines the effectiveness of a statute (Davidson & Oleszek, 2004).

The inability to resolve key issues at the policy adoption stage becomes the source of conflict during policy implementation. The political struggles and compromises that lead to the adoption of legislation often create ambiguous statutory mandates that lead to further conflict in bureaucratic and judicial arenas (Hayes, 1992). Federal or local officials may use methods to thwart a policy. Administrators may also exceed their authority under a statute (Davidson & Oleszek, 2004).

The elected officials and interest groups opposed to a new law can employ a number of levers to delay or block policy implementation. Powerful congressional committees, regulated industries, environmental groups, other federal agencies, and the Executive Office of the President can seek to influence policy implementation. The judiciary plays an important role in the process as well, often required to intervene in agency actions and interpret the laws (Percival et al., 2006).

Presidents can use a number of informal and formal tools, such as executive orders, appointment power, and centralized rule-making management, to influence policy implementation. The Regan administration sought massive reductions in environmental funding in the 1980s, which had a long-term adverse impact on the EPA's ability to implement environmental laws (Vig & Kraft, 2006). Reagan's administrative strategy initially consisted of careful screening of all appointees, close policy coordination with staff, profound reductions in budgets and programs, and greater regulatory oversight to cut or revise environmental laws burdening industry. Reagan cut one-third of the EPA's

operating budget and one-fifth of its personnel, shifted funds from environmental to development programs in the Interior Department, and eliminated and restructured offices in the EPA. The Council on Environmental Quality (CEQ) also lost most of its staff (Vig, 2006).

Congress can also have a major impact on policy implementation. Congress can use its powers to influence policy implementation in the following ways: committee or subcommittee hearings to assess agency programs; formal investigations or evaluations of an agency's programs; and increase or decrease an agency's budget (Rinfret & Furlong, 2013). Congressional appropriations for TSCA implementation, for example, has generally lagged behind other environmental laws (Schifano et al., 2011). From 1981 to 1986, the budget for the EPA's toxics program was reduced 27 percent (Schifano et al., 2011). The resource levels remained relatively constant during the early 1990s, but the EPA's TSCA responsibilities continued to increase substantially (such as the voluntary programs and nanotechnology initiatives). Schifano et al. (2011) observes that this situation led to a significant decline in funding levels for implementation activities.

The federal courts are involved in this stage of the policy process. Regulated industries and various interest groups increasingly seek the courts to resolve disputes (Vig & Kraft, 2006). A study analyzing over two thousand federal court decisions on the EPA's policies and administration suggests EPA compliance with court orders is a top priority that sometimes takes precedence over congressional mandates (O'Leary, 2006).

Public attitudes can also impact policy implementation. TSCA implementation, for example, was set against the backdrop of changing public attitudes about the effects

of chemicals on the environment in the late 1960s.<sup>9</sup> The CEQ's influential 1971 report *Toxic Substances*, and several high-profile environmental court cases in the early 1970s, reinforced the public's desire to see the regulation of toxic substances.<sup>10</sup>

### **3. Summary of Policy Models**

Policy models can help distill the essential elements of a complex problem and make predictions on policy outcomes (Hayes, 1992). The following four sections, 2.1. A-D, contain summaries of the four policy models this dissertation uses to examine the policy-making process.

#### **3.1 Rational Model**

The rational model involves six steps (Jones, 1984). The public policy problem is first identified. The agenda is then set, proposals are formulated, and programs are legitimated, implemented and evaluated. The final stage of the process involves policy makers rendering a decision based on the evidence presented that best meets public interests. The model presumes decision makers will make rational decisions, but does not ignore the influence of political actors and interests on the policy-making process (Field, 2007). The model is useful because it requires specifying goals and conducting robust analysis before making policy decisions (Hayes, 1992).

The rational model assumes policy-makers will accurately identify and define public problems and prioritize them in the appropriate order of importance (Hayes, 1992). After identifying a serious problem, such as the adverse health effects of asbestos, policy-makers will select the right criteria to assess proposed policy solutions and the likelihood

of success (Field, 2007). This could include considering factors such as economic efficiency, effectiveness, equity, organizational capacity, health and environmental effects, and political feasibility (Field, 2007).

After reviewing all possible alternative policy responses and agreeing on trade-offs, such as how much harm to public health they willing to accept for the economic benefits of the production and sale of asbestos products, the policy-makers select the best possible solution to the problem. The solution might include significant responses, such as a total ban of asbestos production, moderate actions such as banning some products or restricting levels of production, studying the problem further, or doing nothing (Field, 2007). At this stage, the policy-makers also have to consider what will happen under each of the various scenarios. For example, if a ban on asbestos is implemented, what effect will this have on the asbestos industry, jobs, public health, national defense, and the overall U.S. economy? In the end, the decision-makers select and alternative that best reflects the interests of the public and the nation (Field, 2007).

After the policy is adopted, the policy enters the implementation phase. Under the rational model, implementation consists of "value-free execution" (Hayes, 1992). In other words, the rational model makes a clear separation between politics and administration (Hayes, 1992). Nakamura & Smallwood (1980) note the model assumes boundaries exist between policy makers and implementers because of their distinct roles and capabilities. Max Weber's description of bureaucracy in Gerth & Wright's (1946) translation of Weber's *Economy and Society (Wirtschaft und Gesellschaft)* is instructive here.

Weber (1922/1946) believed bureaucracy embodied rationality. "Bureaucracy," he states, "has a 'rational' character: rules, means, ends, and matter-of-factness dominate its bearing." The bureaucratic organization is rationally managed and technically superior to all other organizational structures in administration. The bureaucracy makes the optimal use of "precision, speed, unambiguity, knowledge of the files, continuity, discretion, unity, strict subordination, reduction of friction and of material and personal costs" (Weber, 1922/1946). The bureaucracy, then, is in the best position in principle to carry out administrative work in accordance with "purely objective considerations." (Weber, 1922/1946). "[In] principle," Weber (1922/1946) contends, "a system of rationally debatable 'reasons' stands behind every act of bureaucratic administration."

Against this backdrop, government office managers in administrative agencies are professionals who are specially trained to complete administrative tasks in an efficient and objective manner. The politician, who lacks administrative expertise, is not qualified or in the position to best use agency resources (Hayes, 1992). The 'rational' bureaucrat is an expert who can ensure the administrative functions are handled efficiently. "The 'political master'," Weber (1922/1946) observes, "finds himself in the position of the 'dilettante' who stands opposite the 'expert,' facing the trained official who stands within the management of administration." Weber explains that the bureaucracy can simply ignore the decrees of their political masters if they find them the "occasional ideas of a dilettante."

The bureaucracy tends to keep its knowledge and intentions hidden from the outside. This practice of secrecy allows the bureaucracy to avoid criticism and maintain

its superiority. Weber (1922/1946) notes, "Bureaucratic administration always tends to be an administration of 'secret sessions'...everywhere that the power interests of the domination structure toward the outside are at stake...we find secrecy." Despite these efforts, the bureaucracy's knowledge in business remains inferior to the "expert knowledge of private economic interest groups." Interest groups also seek to keep their secrets from the prying eyes of officials. As Weber (1922/1946) points out: "The 'secret,' as a means of power, is, after all, more safely hidden in the books of an enterpriser than it is in the files of public authorities."

This tendency towards secrecy takes on new meaning when considered in the context of Weber's (1922/1946) discussion of the political system's increasing reliance on interest groups to serve on government advisory bodies. According to Weber, the government recruits interest groups "from among the economically and socially most influential strata." Weber contends this practice could "put the concrete experience of interest groups into the service of a rational administration of expertly trained officials...and (increase) the power of the bureaucracy." At the same time, this very relationship increases the interest group's access to specialized knowledge, the power of the bureaucracy, and influence on the state. Weber observes, "Very frequently the measures of the state in the field of capitalism...are made illusory by the superior expert knowledge of interest groups."

### **3.2 Incremental Model**

Charles Lindblom articulated the incremental model in the *Science of Muddling Through* (1959) as an alternative to the rational model. In Lindblom's (1979) words, the

core meaning the incremental model is “political change by small steps.” Hayes (1992) suggests Lindblom's model rejects the concept of policy as a decision, which is a fundamental departure from the rational ideal. The incremental model differs from the rational model at all stages of the policy-making process.

The incremental model starts with effected publics indentifying problems and bringing them to the attention of government decision-makers. Interest groups ensure concrete problems make the agenda (Hayes, 1992). The government sets policy priorities after completing a "disjointed process" involving competition and compromise among a number of disparate interests (Hayes, 1992). Lindblom assumes relevant issues will be addressed in the course of making policy decisions (Hayes, 1992):

In a society like that of the United States in which individuals are free to combine to pursue almost any possible common interest they might have and in which government agencies are sensible to the pressures of these groups the system described is approximated...Without claiming that every interest has a sufficiently powerful watchdog, it can be argued that our system often can assure a more comprehensive regard for the values of the whole society than any attempt at intellectual comprehensiveness (Lindblom, 1959).

Lindblom's model, then, assumes that all voices in society have interest groups that are working in their interest. These "watchdog" groups are also "atomistic"; no sole actor or group can attain a monopoly on political power (Hayes, 1992). Administrative agencies also coordinate and adjust their policies to meet the concerns of other government organizations (Lindblom, 1959).

Lindblom (1959) argues the incremental model best describes how administrators and their policy analysts make policy. Most policy making involves only incremental changes in existing policy. Incremental policy proposals are generally more politically



feasible, prudent, and cost-effective. Time constraints, limited knowledge, interest groups, and politics all weigh against pushing for major policy changes (Lindblom & Woodhouse, 1993).

This does not mean that major policy changes cannot occur under the model. According to Lindblom, significant policy changes tend to take place after a series of incremental policy shifts accumulate and reach a certain threshold (Hayes, 1992). "Policy-making," observes Lindblom, "is a process of successive approximation to some desired objectives in which what is desired itself continues to change under reconsideration" (Lindblom, 1959).

The policy-making process is repetitive, so policy-makers concentrate on the incremental ways in which alternatives vary from existing proposals and past policies (Hayes, 1992). Agency administrators, writes Lindblom (1959), concentrate on marginal values:

Making policy is at best a very rough process...A wise policy-maker consequently expects that his policies will achieve only part of what he hopes and at the same time will produce unanticipated consequences he has preferred to avoid. If he proceeds through a succession of incremental changes, he avoids serious lasting mistakes.

If a certain policy fails, then new rounds of policy-making will emerge to find alternative solutions (Hayes, 1992). "Policy," observes Lindblom (1959), "is not made once and for all; it is made and re-made endlessly." This could involve changing the legislative mandate, providing new statutory powers to agencies, or spending more or less (Hayes, 1992).

The incremental, argues Lindblom (1959), is "certainly superior to a futile attempt at superhuman comprehensiveness." Lindblom (1959) concedes mid-level professionals may engage in rational decision-making to handle minor technical problems in a bureaucracy, but the rational ideal is not attainable in practice (Hayes, 1992):

Ideally, rational-comprehensive analysis leaves out nothing important. But it is impossible to take everything important into consideration..Limits on human intellectual capacities and on available information set definite limits to man's capacity to be comprehensive. In actual fact, therefore, no one can practice the rational-comprehensive method for really complex problems (Lindblom, 1959).

The implementation stage of the process also involves numerous political actors, interest groups, and agencies. As the administrative process is political, elected officials eventually intervene in the implementation process (Hayes, 1992).

The introduction of the incremental model to the literature has had an important impact on the public policy theory and practice. Lindblom (1959) describes the public administrator's likely reaction to the model in 1959:

The reaction of the public administrator to the exposition of method doubtless will be less a discovery of a new method than a better acquaintance with an old. But by becoming more conscious of their practice of this method, administrators might practice it with more skill and know when to extend or constrict its use.

### **3.3 Interest Group Model**

The proliferation of interest groups, coupled with their growing activities, make them an increasingly influential force in environmental policy-making (Cigler & Loomis, 1991). The political science literature details the impact of interest groups on policy implementation (Rinfret & Furlong, 2013). Conant (2006) defines interest groups (also referred to as "pressure groups" or "special interests") as "groups of people—associations

of individuals, private business firms, or other organizations—that attempt to influence public policy.”<sup>11</sup> Although interests groups are mainly interested in securing economic benefit or avoiding regulatory expenses, some groups are interested in other objectives, such as environmental protection, national resource conservation, or consumer health (Conant, 2006).

The interest group and incremental models both recognize that public policy emerges from the interplay of multiple contending groups rather than a "rational-comprehensive" decision-making process (Hayes, 1992). The models, however, sharply contrast with each other on a number of important points throughout the policy-making process. The interest group model stresses the group struggle for power, whereas group interaction in the incremental model is based on cooperation and mutual adjustment. Lindblom views the search for rational policy under time and resource constraints as the proper material for public policy analysis (Hayes, 1992). According to Hayes (1992), Lindblom's model largely ignores "the question of what groups succeed in mobilizing and the critical importance of variations in resources from one group to another."

In contrast to the incremental model, the interest group model emphasizes that some groups are more likely to mobilize, disrupt group equilibrium, and potentially increase their chances of influencing the final legislative outcome (Hayes, 1992). The interest group model thus requires identifying the array of active interest groups, estimating the distribution of political resources and influence, and combining these variables to determine the equilibrium of contending groups (Hayes, 1992). As pluralist scholar Arthur Bentley (1908) points out: "It is only as we isolate these group activities,

determine their relative values, and get the whole process stated in terms of them, that we approach to a satisfactory knowledge of government."

The theoretical work of pluralist scholars, such as Bently, Earl Latham, Robert Dahl, and David Truman, has played a significant role in shaping the development of the interest group model. Pluralists typically believe that members of interests groups share identical interests and lobby government to encourage these perceived legitimate interests (Hayes, 1992; Truman, 1971). The government, in turn, promotes these interests in society in accordance with what is viewed to be a proper government role. Pluralists argue that Congress and the executive branch, in enacting new policies and creating new agencies, promote the interests of competing groups in society in accordance with their relative power and influence (Thurber, 1991).

The interest group model, unlike the incremental model, assumes agenda setting will typically involve conflict over the scope of issues and the definition of alternatives (Hayes, 1992). As Schattschneider (1960) aptly points out: "the definition of alternatives is the supreme instrument of power."

In the more recent version of the interest group model, articulated by Dahl, Truman, and Charles Lindblom, public policy emerges as competing interest groups make compromises to avoid a zero-sum game (Conant, 2006). Conant (2006) writes that such competition is presumed to reach an equilibrium under these conditions; the policy system consists of stable relations among competitors working at the margins of existing policy. Here, the interest group model is distinguished from the incremental model in

that equilibrium is reached not only through the process of mutual adjustment, but also a constant struggle for advantage (Hayes, 1992).

The pluralist ideal assumes politics is a marketplace in which competitors have equal access to the policy-making system (Krill & Tosun, 2008). Schattschneider (1960) finds cracks in this ideal, stressing that bias runs through the whole system.

Schattschneider views organization as "the mobilization of bias." For Schattschneider, the pluralists do not provide a realistic picture of the American political system, which "sings" of powerful business and elite interests (Conant, 2006). Schattschneider (1960) suggests analyzing the conflict of organized special-interest groups, which he calls the "pressure system," to estimate the level of bias in politics. "The class bias of associational activity gives meaning to the limited scope of the pressure system," Schattschneider (1960) observes, "because it gets results by being selective and biased." Lindblom and Woodhouse (1993) describe the role of business groups in policy-making:

Corporate executives, not government officials, set most policies regarding production of electric power, transportation services, entertainment, insurance, steel, housing, food, computers, newspapers, television, toys and many other goods and service...along with the good it achieves, business life simultaneously produces many serious problems: abandoned toxic wastes dumps and other environmental pollution, automobiles with safety defects that kill and maim...Society and government are forever trying...to correct or mitigate the problems introduced by...the business sector.

The number of active groups that compete in the policy implementation stage of the interest group model tends to be less than at the policy adoption stage (Hayes, 1992). The outcome of this drawn-out "war of attrition" is determined by the groups, their resources, and effectiveness (Hayes, 1992). As Hayes (1992) observes, over time an agency finds itself dealing with a small number of interest groups that have the financial

resources to actively monitor implementation in the long-term. With the passage of time, this situation can lead to "capture," in which the agency becomes an industry advocate rather than a regulator (Hayes, 1992). This situation tends to create policy subsystems, or iron triangles, in which agencies, congressional committees, and organized groups lead policy-making (Hayes, 1992).

### **3.4 Process Streams Model**

According to Kingdon (1995), policy ideas float around in a "policy primeval soup in which in which specialists try out their ideas in a variety of ways – bill introductions, speeches, testimony, papers, and conversation." Kingdon, in developing his process streams model, sought to answer the important question posed by Schattschneider (1960): "Why do some ideas gain currency and acceptance and others do not?" According to Kingdon (1995), the question is central to the comprehension of public policy outcomes. Kingdon cites Schattschneider oft-quoted statement – "The definition of the alternatives is the supreme instrument of power" – to underline the importance of agenda setting and the genesis of alternatives in the policy-making process.

The process streams model revises the Cohen et al. (1972) garbage can model of organizational choice to shed light on agenda setting and the creation of alternatives. The process streams model describes the concept of "process streams," which are joined at critical junctures ("coupling") to make way for major policy change (Kingdon, 1995). The three major process streams in the federal government are problem recognition, the creation and refinement of policy proposals and politics. Kingdon contends that a "policy window", which he describes as an opportunity to push for action on certain policy

initiatives, is required to permit regulatory action. Policy windows consist of crises, events that focus public attention on an issue, or a change presidential administrations, and only stay open for short periods of time (Kingdon, 1995).

Kingdon (1995) states public policy making can be defined as a set of processes consisting of the following: “(1) the setting of the agenda, (2) the specification of alternatives from which a choice is to be made, (3) an authoritative choice among those specified alternatives..., and (4) the implementation of the decision.” The *agenda* is defined as “the list of subjects or problems to which governmental officials, and people outside of government closely associated with those officials, are paying some serious attention at any given time...; the *government agenda* (is)...the list of subjects that are getting attention...and the *decision agenda*...(is) the list of subjects within the governmental agenda that are up for an active decision.” The policymakers consider a set of *alternatives* for government action separate from the issues that are on the agenda (Kingdon, 1995).

From Kingdon's (1995) perspective, the rational model is largely impractical. The incremental model may describe aspects of the policy process, such as the slow evolution of proposals or policy shifts, but it cannot account for discontinuity or sudden change in the agenda. Lindblom's analysis also runs into difficulty when considered in light of policy enactments that are major policy departures. Congress, for example, was forced to create new laws and agencies in the 1970s to address the growing environmental pollution problem and risks to public health that had become fixed in the minds of many Americans (Hayes, 1992). As Hayes explains (1992), the incremental model may

describe most policy outcomes, but marginal policy changes are clearly not the only explanation: "Major policy departures receive consideration too often, even where they do not pass; a convincing theory of incrementalism will have to look elsewhere for support."

Kingdon (1995) describes the creation of policy windows in the context of the legislative and executive arenas. Important policy-making on toxic substances also occurs in the courts. The courts shape environmental policy by deciding on standing to sue in court, the ripeness of the case, the standard of review and legal remedies. If the model is modified, then it could be applied to U.S. circuit courts of appeals in the following way: the process streams would consist of the partisan composition of the judge hearing panel (politics stream), the legal issues raised by the litigants and the judges and the lawyers' legal arguments (policy stream), and the legal ambiguity associated with the case (problem stream) (Lee, 2003).

#### **4. Predictions**

This section uses each of the models to make predictions about how the policy-making process will work in the case of asbestos and carbon nanotube regulation.

##### **4.1 Rational Model**

**1. Making Public Law.** We would expect to see public law designed to protect employee and citizen health from the risks of asbestos and carbon nanotubes emerge as a result of the following sequence of events in the policy process: (1) problem identification; (2) agenda setting; (3) formulation; (4) legitimation; (5) implementation;



and (6) evaluation (Jones, 1984). Under this model, we would find decision-makers attempting to discern and define the asbestos and carbon nanotube problems. The policy participants would define the problems in the same manner and with precision (Hayes, 1992). After the set of problems meet the minimum criteria required for problem identification, they would be put on the agenda. The policy-makers would begin to create solutions to reduce asbestos and carbon nanotube risks. We would expect the executive to formulate the proposals and submit them to Congress. Congress becomes involved at the legitimation stage, where members engage in majority coalition building on legislation; a proposal will either be accepted, rejected, or a compromise reached on an amended version of the original proposal (Jones, 1973). In step five of the process, policy is administered on the issues and related activities. During the final stage, the impacts of the policy are evaluated, feedback is provided, and the new information is injected back into the agenda setting stage. This could lead to minor modifications in policy, extensive reform, or policy termination (Jones, 1973).

**2. Implementing Public Law.** The model assumes there would be a clear separation between politics and administration (Nakamura & Smallwood, 1980). The process of implementation would take place in a sequential manner in which implementation follows policy making (Nakamura & Smallwood, 1980). The policy-maker would select an agency to implement the policy according to technical criteria. The implementer would carry out the policies in a rational, objective, nonpolitical, and scientific manner.

## **4.2 Incremental Model**

**1. Making Public Law.** We would expect policy on asbestos and carbon nanotubes to take place in an incremental fashion, building on existing policy. If existing law can be implemented in a small way, and all parties agree, then modifications can be made to existing law. After the identification of the environmental and public health risks, then, we would expect to see public policy on asbestos and carbon nanotubes build on an existing federal role and make small adjustments to this role over time (Hayes, 1992). As major changes to policy requires significant costs and political support, policy-makers would reject major policy changes in favor of more cautious approaches, such as focusing on more research (Miller, 2006). We would expect to see limited information and expertise and various definitions of the problem. The remedies may only be applied to symptoms that are immediate and observable (Jones, 1973). At every stage of the policy-making process individuals and groups would have to compromise, with no one person or group obtaining all that it wants (Jones, 1973). If there is no existing law, then we would not expect to see new law created until after a series a series of incremental policy shifts accumulate and reach a certain threshold for major policy change. With respect to interest groups, so many are active that no one group can corner the political marketplace.

**2. Implementing Public Law.** We would expect to see administrative experts, faced with limited budgets and power, make marginal adjustments to policy in the form of rule making. An implementing agency would likely take great care not to exceed

statutory limits and risk eroding its political support, which would require an incremental approach (Miller, 2006).

#### **4.3 Interest Group Model**

**1. Making Public Law.** We would expect private interest groups to dominate the legislative process. If the passage of certain legislation to address the known risks of asbestos and carbon nanotubes is not in their best interest, then industry interest groups would attempt to block or delay passage of the legislation.

**2. Implementing Public Law.** We would expect private interest groups to dominate the policy implementation process. An implementing agency would find itself dealing with a small number of interest groups that have the financial resources to actively monitor implementation in the long-term (Hayes, 1992). With the passage of time, this situation could lead to "capture," in which the agency becomes an industry advocate rather than a regulator (Hayes, 1992). This situation would create policy subsystems, or iron triangles, in which agencies, congressional committees, and organized groups lead policy-making (Hayes, 1992).

#### **4.4 Process Streams Model**

**1. Making Public Law.** If we use the process streams model as the basis for prediction, then we would expect to see problems with asbestos and carbon nanotubes reach the government and decision agendas after (1) the three streams of problems, politics, and policies coalesce; (2) the policy community finds a solution; (3) and a policy window emerges for legislative action. "Focusing events" and "indicators" would call

attention to problems associated with asbestos and carbon nanotubes.<sup>12</sup> The president and members of Congress would be more effective than government "policy entrepreneurs" in identifying and defining the problem and agenda setting, but less effective than the latter in the policy stream (Kingdon, 1995). The policy entrepreneurs in the policy stream would evaluate alternatives and reduce the range of alternatives for decision-makers (Scheberle, 1994). These alternatives can become viable policy options through "softening-up" the policy area for government discussion and "coupling" alternatives to problems (Scheberle, 1994). If the political environment is favorable and the three process streams coalesce, then a "policy window" could open.

**2. Implementing Public Law.** We would expect to see policy streams continue to impact administrative activity during implementation (Morris, 1999). If a change in party control occurs, then important changes in the agenda could take place. Implementers could bring new issues to the agenda by sharing ideas with the policy elites (Kingdon, 1995). At the time policy implementation brings new problems onto the agenda, then it merges with the agenda setting stage (Lindblom & Woodhouse, 1993).

## CHAPTER THREE: ASBESTOS HAZARD AND EMERGENCY RESPONSE ACT OF 1986

Looking back in the light of present knowledge, it is impossible not to feel that opportunities for discovery and prevention [of asbestosis] were badly missed.

—Sir Thomas Legge, *Industrial Maladies* (Oxford, 1934), p. 191.

[S]ome 15 million children and 1.4 million school employees work in buildings containing friable asbestos,<sup>13</sup> and yet the (EPA's) only response to date has been to require inspection of such facilities and the posting of a notice.

—James J. Florio (D-NJ) (1984)<sup>14</sup>

### 1. Introduction

The U.S. Congress passed the Asbestos Hazard and Emergency Response Act of 1986 (AHERA), which President Ronald Reagan signed at the urging of conservative Republicans and the asbestos industry (Posner, 1998). The Act mandated local U.S. schools to clean up asbestos in their buildings at a cost ranging between \$1 billion to over \$3 billion (Posner, 1998). The administration, intent on reducing costs and regulatory burden, opposed the bill. However, Page and Shapiro's (1983) observation that policy tends to follow shifts in policy preferences was largely borne out on the issue of asbestos in schools. Politicians and industry found it difficult to openly oppose a bill that represented a compelling public health issue and appealed to widely-held public values (Posner, 1998).

The passage of the Act provides an insightful case study on agenda setting, policy formulation, and policy adoption in a political climate otherwise inhospitable towards

environmental legislation. This chapter examines relevant events and documents to illustrate the key roles Congressional policy entrepreneurs, bureaucrats, unions, lobbyists, and interest groups played in the passage of the legislation. It looks at the coalition of policy advocates and interest groups involved in the process and how they continued to define and expand the asbestos and related public health issues. The chapter incorporates findings from the Senator H. John Heinz III (R-PA) archives at Carnegie Mellon University, the Representative James J. Florio (D-NJ) archives at Rutgers University, and the University of California, San Francisco's Legacy Tobacco Documents Library. To the author's knowledge, this is the first time internal documents from these diverse sources have been used to examine the development of public policy on the abatement of asbestos in schools.

## **2. Identifying & Defining a Compelling Public Health Issue**

As many as 3.24 million American children may be exposed to dangerous levels of asbestos in their schools, and the government's control program is inadequate to resolve the hazard.

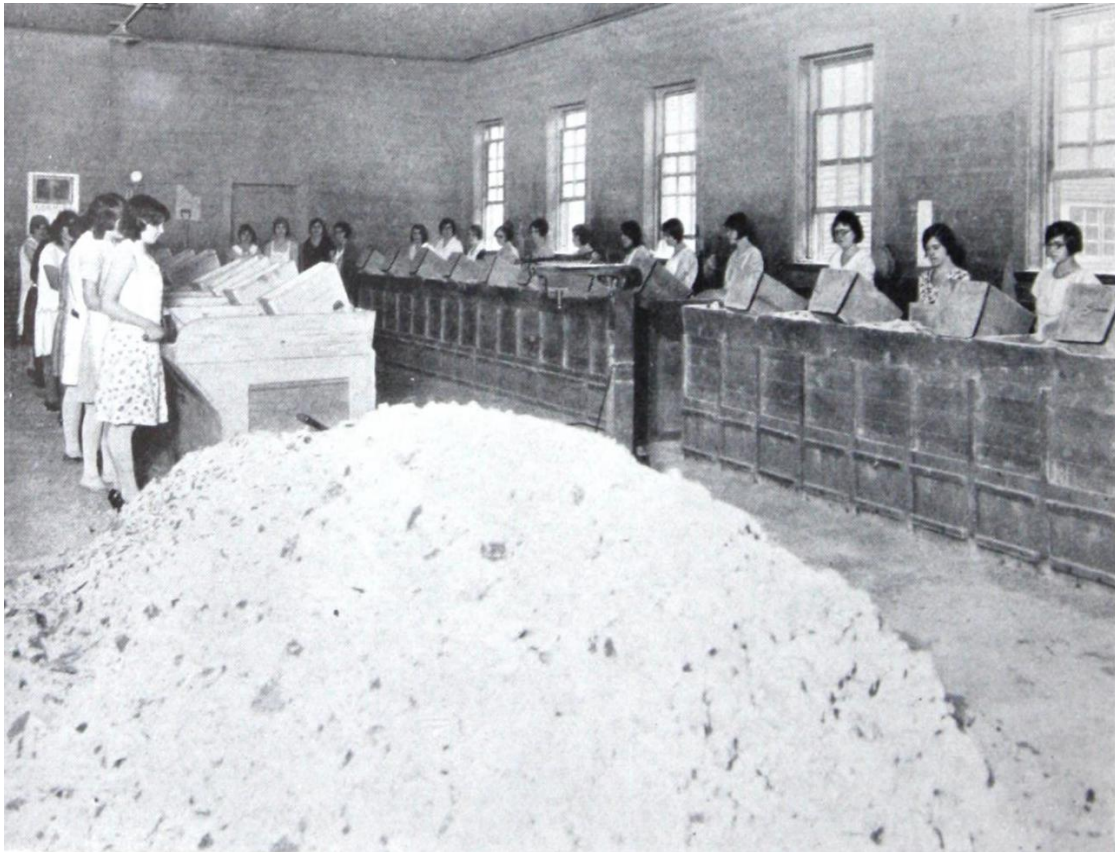
—*Associated Press* (July 1, 1983); published in nearly 500 dailies across the United States

The literature on the history of asbestos point to the vague warnings of asbestos pathogenicity that emerged from reporting on asbestos worker illness and death in Europe during the late 1800s and early 1900s.<sup>15</sup> Frederick L. Hoffman, a statistician who worked for the Prudential Insurance Company in New York, noted the potential adverse effects of asbestos dust in 1918. Showing statistical evidence that the probability of developing respiratory disease was clearly higher in asbestos and other dusty trades than other occupations, Hoffman stressed the importance of government regulation of industry. For

Hoffman, this was problematic because "a lamentable degree of apathy and indifference to the urgency of the necessary changes and reforms" prevailed at the time (Hoffman, 1918). Hoffman pointed out that asbestos was used extensively as material for insulation, and that a study of asbestos weaving and spinning revealed conditions that were "decidedly unfavorable" to health (Sypher, 2002). Hoffman (1918) described the processes of asbestos cobbing—separating asbestos fibers from rock using small sledge hammers—bagging, spinning, and weaving as likely exposing workers to a considerable amount of dust (See Fig. 1 below).<sup>16</sup> A more recent study of operations in a chrysotile asbestos plant in China showed the highest fiber concentrations in the bagging operations, with the second highest level of exposure occurring during spinning, weaving, and carding (Yano et al., 2001). Yano et al. (2001) found that the workers in the raw materials and textiles sections of the plant were always exposed to high-levels of dust in areas without adequate ventilation.

From a historical standpoint, Dr. William E. Cooke's 1924 paper, *Fibrosis of the Lungs Due to the Inhalation of Asbestos Dust*, was a turning point in linking asbestos to lung disease (Selikoff & Lee, 1978). Cooke (1924) examined the lungs of a young woman who had worked in asbestos factories for 20 years and found what he called "curious bodies" (asbestos bodies) inside her lungs. Cooke, then working at Wigan Infirmary in Lancashire England, provided a detailed description of asbestosis, the physico-chemical characteristics of the chrysotile asbestos fibers, and photomicrographs that would inform the British Home Office on the disease and future research on fiber toxicology.<sup>17</sup> Cooke presciently recognized in 1929 that the iron content of chrysotile

fibers may play an important role in the adverse effects of chrysotile asbestos, the importance of which will be revisited in chapter 4 of this dissertation.



**Figure 1: "Cobbing" at the Thetford Mine Plant in Quebec, Canada.**

The employees are using small hammers to separate the highest grade asbestos from the less valuable grades. The open windows in the background are likely the only ventilation in a room that is extremely dusty. An asbestos heap is in the foreground (Source: Canadian Asbestos Company, 1931).<sup>1</sup>

Cooke's finding of asbestosis received formal scientific recognition in 1930 (Selikoff & Lee, 1978). From 1930 to 1970, research on other possible pathological

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<sup>1</sup> Canadian Asbestos Company. (1931). Trade Catalog Reprint: Pierre a coton. *Canadian Geographical Journal* (1930). Retrieved from <https://archive.org/details/AsbestospierreACoton>. License URL: <http://creativecommons.org/licenses/by-nd/3.0/>. No changes were made to the photograph other than resizing. The original caption underneath the photograph is not included.



consequences of asbestos intensified. Lynch and Smith published the first report of carcinoma of the lung in 1935, and by 1960, Wagner and his research collaborators promulgated their findings based on four years of research on mesothelioma, a rare form of cancer. Wagner used histological evidence to show that 33 individuals, 28 associated in some way with crocidolite asbestos, had developed pleural mesothelioma. By 1963, Wagner was able to provide evidence of over 120 cases of pleural mesothelioma linked to asbestos exposure (Selikoff & Lee, 1978).

In 1964, Drs. Irving Selikoff and Jacob Churg of the Mount Sinai Hospital hosted an international conference on the biological effects of asbestos, the results of which became headline news and made asbestos an international public health issue (McCulloch & Tweedale, 2008). The Mount Sinai group presented previously published epidemiological studies that unequivocally showed asbestos insulation work could be deadly.<sup>18</sup> Castleman (2005) states:

The epidemiologists at the Mount Sinai School of Medicine finally showed vividly the devastation to health sustained by insulation workers in 1964. The observation that insulators died from asbestosis was not new, and an excessive incidence of cancer was anything but surprising to find. But such a large number of "excess deaths" was shocking nevertheless. How many men would have knowingly entered a trade with an almost guaranteed chance of developing asbestosis in 30 years and nearly a 50 percent chance of dying from occupation cancer or asbestosis?

Mount Sinai's work added to the studies of Mancuso and Coulter, further chipping away at the reluctance of investigators to view asbestos as a cause of pulmonary cancer. It took many years and a substantial body of evidence before the scientific community could confidently make the etiological connection to asbestos.

By the early 1970s, some of the hazards associated with occupational exposure to asbestos had been addressed in legislation and numerous worker product liability suits. The EPA deemed asbestos a "hazardous air pollutant" in 1970 under the Clean Air Act and the Occupation Safety and Health Act (OSHA) of 1970 set occupational exposure limits for asbestos. In late 1971, at the urging of the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO), the Secretary of Labor issued a temporary emergency standard for the industrial use of asbestos (Selikoff & Lee, 1978).

Castleman (2005) explains that the personal injury lawsuits brought against asbestos manufacturers involved the failure to test and properly label the asbestos products and use available measures to protect users from the product hazards. The decision in *Borel v. Fiberboard Paper Products et al.* [493 Federal 2d 1076 (5th Circuit, 1973)], *cert. denied* [419 U.S. 869 (1974)] led to a surge in lawsuits. In *Borel*, the U.S. Fifth Circuit Court of Appeals ruled that "a duty to warn attaches, whenever a reasonable man would want to be informed of the risk in order to decide whether to expose himself to it." After the ruling, asbestos workers were allowed to sue under the legal theory of strict liability; they could now show asbestos companies failed to provide adequate warning of the health risks to win cases.<sup>19</sup> During the trial, the asbestos industry employed a tactic, later called the "state of the art defense" in which witnesses testifying for Johns-Manville adamantly stood by the claim that they first learned of the asbestos hazards from Mount Sinai's findings in 1964 (Bowker, 2003). Realizing the *Borel* decision would lead to many similar lawsuits, representatives from 18 insurance companies met in 1976 to discuss the "state of the art defense" and find physicians who

would provide testimony to support it (Castleman, 2005). The asbestos industry effectively used the state of the art defense to prevail in a number of subsequent cases and plaintiffs, when successful, typically received small monetary awards (Bowker, 2003). This changed in 1977 when plaintiff's attorney Karl Asch discovered thousands of asbestos industry documents, later called the "Sumner Simpson Papers," which revealed extensive efforts to cover up the health hazards of asbestos since the 1930s (Bowker, 2003). Bowker (2003) states the findings destroyed the state of the art defense and led to the filing of an estimated six hundred thousand lawsuits against the asbestos industry.

Johns-Manville, realizing that it was becoming increasingly difficult to blunt public awareness of asbestosis because of the English studies on the asbestos hazards, began to sponsor animal studies in the later 1920s to develop scientific evidence to fight non-industry findings (Calhoun & Hiller, 1988). The CEO of Raybestos-Manhattan, Sumner Simpson, and Johns-Manville attorney Vandivar Brown exchanged letters in October 1935 discussing a recent request by the trade journal *Asbestos* to reprint English articles on asbestosis. Simpson (1935) wrote: "I think the less said about asbestos, the better off we are...The magazine "Asbestos" is in business to publish articles affecting the trade and they have been very decent about not re-printing the English articles." Brown (1935) replied: "Even if we should eventually decide to raise no objection to the publication of an article on asbestosis in the magazine in question, I think we should warn the editors to use American data on the subject rather than English." Brown was referring to the "American data" Anthony Lanza produced for the companies and their insurance carrier, the Metropolitan Life Insurance Company. The Lanza study, which

involved the X-rays of 126 asbestos workers who had been exposed to asbestos for three or more years, was finished in 1931 but was still unpublished. Brown and other industry officials edited the findings in 1934 requesting that Lanza portray asbestosis as milder disease than silicosis. Lanza complied and removed findings that 53 percent of the workers had developed asbestosis (Calhoun & Hiller, 1988). Johns-Manville, seeking to avoid the inclusion of asbestosis as a disease in pending New Jersey workman's compensation legislation, hoped "to have an official report to show that there is a substantial difference between asbestosis and silicosis" (Calhoun & Hiller, 1988).

The United States required the use of asbestos-containing insulation, a flame retardant, in school buildings from 1940 to 1973 as a safety measure (Widavsky & Schulte, 1995). The EPA banned the spraying of materials containing more than one percent asbestos in 1973, but continued to allow schools to use sprayed-on materials until 1978 (Widavsky & Schulte, 1995). Some reports claimed the local school boards first became aware of the threat to school children in the late 1970s (Harris, 1984),<sup>20</sup> while others claimed some school boards had known of the dangers much earlier, but took no remedial action.<sup>21</sup> Schools and local government wanted to avoid causing panic, but the lack of transparency and poor public communication added to public fear and mistrust (Harris, 1984).

The Environmental Defense Fund, an environmental interest group that uses the courts to force federal agencies to enforce environmental laws, was instrumental in elevating the issue to the national level (Posner, 1998). In 1978, the Environmental Defense Fund petitioned EPA, under threat of a lawsuit, to put in place a program to

detect the level of asbestos-containing materials in public schools and eliminate the risk of exposure from the materials.<sup>22</sup> The Environmental Defense Fund (1978) detailed the grave risks of asbestos in schools, but also warned that smoking among school employees and children exposed to asbestos could vastly increase their chances of developing lung cancer:

Mesothelioma is an exceedingly rare, always fatal cancer with nearly zero expectation in the general population. Asbestos workers who smoked cigarettes, had approximately 92 times the risk of dying of lung cancer than did workers of equal age who neither smoked nor worked with asbestos....The synergistic relationship between smoking and asbestos is particularly relevant to assessing the health hazards of asbestos containing sprayed material. Obviously, many school children and professionals smoke or will smoke.

The Environmental Defense Fund's definition of the issue in this fashion broadened the number of congressional and interest group participants, set the initial terms of the federal debate on asbestos in schools, damaged the public image of the asbestos industry, and embarrassed the EPA for its failure to act on a compelling public health issue. Drawing greater scrutiny to the adverse synergistic effects of smoking and asbestos helped guide the asbestos and tobacco industries, labor, and environmental interest groups down paths toward increased conflict and coalition building.

### **3. Issue Definition & Politics: Role of Industry & Special Interest Groups**

In terms of issues management, those who define the issue usually win the debate.

—Tobacco Institute<sup>23</sup>

As mentioned in Chapter 2, Schattschneider (1960) suggested that analyzing the “pressure system” can help estimate the level of bias in politics. The following four

groups, representing industry, labor, and environmentalists, figured prominently in the debate on asbestos and disease during the late 1970s and 1980s: (1) Johns-Manville; (2) Tobacco Institute; (3) AFL-CIO; and (4) Environmental Defense Fund. As discussed later in this chapter, the building of a coalition between former foes, the Environment Defense Fund and the AFL-CIO, on common problems such as occupational safety in the early 1980s (Bosso, 1987), created a problem for the asbestos and chemical industries. The Environmental Defense Fund and the AFL-CIO could put pressure on legislators, and labor's decision to back the tobacco industry in its fight against Johns-Manville proved to be decisive.

Prior to the release of the Environmental Defense Fund's EPA petition in 1978, the asbestos and tobacco industries had already been locked in a bitter fight to shift the cancer blame and avoid legal liability (Bosso, 1987). By 1977, the asbestos industry believed it was in a struggle for its very survival.<sup>24</sup> Johns-Manville, a leading asbestos corporation, began an aggressive campaign to define the issue of lung cancer in asbestos workers in a way that drew upon the well-regarded scientific research of Mount Sinai and also placed the blame on the tobacco industry.<sup>25</sup> Johns-Manville's 1978 annual report, for example, claimed that "but for cigarette smoking, lung cancer would not have been a significant health factor among people occupationally exposed to asbestos."<sup>26</sup> The vice-president of the Tobacco Institute, Fred Panzer (1979), wrote in an internal memorandum in June 1979 that Johns-Manville's CEO John McKinney, in his 8 May 1979 testimony before Congress, "repeated the claim (which he said was confirmed by

Dr. Irving Selikoff) that cigarette smoking was the overwhelming cause of lung cancer deaths among asbestos workers."

The Tobacco Institute believed Congress' lack of support for the Johns-Manville-backed Fenwick Bill (H.R. 2740) was a "significant factor motivating the anti-tobacco litigation threats of Johns-Manville."<sup>27</sup> Representative Millicent H. Fenwick (R-NJ) introduced her bill in the House in March 1979. The bill required the tobacco industry to contribute to a victim compensation fund along with the asbestos industry and the federal government.<sup>28</sup> Although the bill had 19 bi-partisan co-sponsors and the support of Mount Sinai's Dr. Selikoff, among others, the bill eventually died.<sup>29</sup> The tobacco industry strongly opposed the bill and labor provided little support. Panzer summed up the situation in a memorandum:

The Fenwick bill—and other bills limited to single substances—are gravely ill, if not actually moribund. Both labor and business and committee staff agree. A Chamber of Commerce analyst told me there is zero chance for passage of what he characterized as "Son of Black Lung" legislation. He included "Brown Lung" bills as well. A high Congressional aide said "you can bet the ranch" that nothing resembling the Fenwick bill will be reported out by the Labor-Education Committee. RECOMMENDATION. Legislatively, we stand today where we stood two years ago. Attached is an analysis of the Johns-Manville legislation which I prepared for the meeting with John McKinney in 1977. Very little has changed since then, except that Mrs. Fenwick now has no co-sponsors where she counted on 19 before. Political alignments and the logic of lobbying approaches are still the same on both sides.<sup>30</sup>

Fenwick reintroduced legislation in 1981 to set up a national compensation fund for asbestos victims.<sup>31</sup> The asbestos lobby was also active during this time, particularly in states such as Pennsylvania with high numbers of victims (this is discussed in more detail in section 5 of this chapter).<sup>32</sup> A Lorillard memorandum commented on the bill:

"Funding would come not from federal coffers, but from payroll deductions and

contributions by the asbestos and tobacco industries. Like prior proposals by Rep. Fenwick, and companion legislation in the Senate sponsored by Sen. Gary Hart of Colorado, this bill has stiff opposition from labor, and is given little chance of passage."<sup>33</sup>

In 1978, the R.J. Reynolds manager for science and information, Dr. Frank G. Colby, who worked closely with the Tobacco Institute, warned of the filing of several liability lawsuits against tobacco companies. Colby sent a letter to his assistant on suits alleging asbestos workers developed lung cancer from exposure to asbestos fibers and cigarette smoking. Colby was concerned many more suits could follow, which would "almost certainly [lead] to a shift in our priorities."<sup>34</sup> The growing threat of lawsuits, and Johns-Manville's efforts to push legislation favorable to the asbestos industry, focused the tobacco industry on finding ways to define the issue of smoking and asbestos exposure in a way more favorable to the tobacco industry. As Panzer wrote in a June 1979 internal memorandum:

For more than a year we have been looking for a clearcut position on the issue of smoking and exposure to asbestos. This need became critical with the introduction of the Fenwick Bill in the last Congress and also with the new Surgeon General's report which contained a damaging chapter on occupational cancer. The attack on smoking as a so-called synergistic factor in occupationally-related diseases has been advanced by Johns-Manville. In addition, a number of scientists inside and outside the government have been speaking in support of the involvement. Our advice from Council committee members has been to keep away from the scientific issue. The concept of synergism, we gather, is too complex and uncertain to rebut directly...[O]ur responses to the "scientific" case have not kept pace with the allegations. In the past two years, the so-called smoking-asbestos synergism has become conventional wisdom. If we are to be able to maintain a degree of credibility on the Hill, we must have a catalogue of responses to it and other changes. These can be original research findings, literature surveys, concessions, etc. (Panzer, 1979).



The tobacco industry continued to monitor the asbestos lawsuit situation closely. Phillip Morris released its first internal quarterly Smoking and Health Report on 7 July 1980, which noted the "asbestos industry has just lost a suit which awarded 1.2 million dollars in general damages to a man who claimed he developed asbestosis." Johns-Manville reportedly conceded that the 'plaintiff's lung trouble resulted from 35 years of heavy smoking.' Phillip Morris warned: "This may be the beginning of the court fight to determine the legal aspects of "interaction" between smoking and occupation exposure to harmful materials."<sup>35</sup>

The tobacco industry aimed to work harder at building coalitions after learning of Johns-Manville's efforts to get labor's support. Panzer heard from a "reliable source in the AFL-CIO" that McKinney met with Steelworkers officials to get "their help in pushing for a bill that would shift the burden of the asbestos problem to the tobacco companies and end the third-party law suits."<sup>36,37</sup> The informant reported that the Steelworkers refused to work with McKinney for two reasons: (1) Johns-Manville spearheaded "lobbying against Labor Law Reform"; and (2) labor was not going to let Johns-Manville "get off the hook by taxing another industry." According to the AFL-CIO source, labor "favored an overall approach to occupational diseases via (a) cleaning up the workplace and (b) comprehensive workers compensation improvement."<sup>38</sup> McKinney allegedly left the meeting upset and threatened to "consider involving unions in future third-party cases against (Johns-Manville)." In his remarks on the matter at the Tobacco Institute's Board of Directors Meeting on 14 June 1979, Jack Mills<sup>39</sup> said: "I believe it is advisable for us (the tobacco industry) to consider covering the same ground.

To do so with any credibility means that we need to make our best case against the charge that it's cigarettes not asbestos that causes lung cancer among asbestos workers."<sup>40</sup>

The tobacco industry learned from its early failure to 'get in front' of the cancer problem, developing strategies and programs to define and manage issues. The Tobacco Institute submitted for internal review in March 1983 an assessment of their ability to respond to public issues in an timely manner.<sup>41</sup> The report stated the Institute had handled issues in the past with "mixed results":

[O]ur handling of the cancer issue over the years has led to the charges of stonewalling and worse ("merchants of death," etc.). On that issue, the public perception is that the industry is entirely interested in profits, and not at all in the health and safety of tobacco users. It is imperative that we "get in front" of the emerging issues facing us so our reputation is not further tarnished...Our recent handling of the sidestream smoke research done by Hirayama<sup>42</sup> was quite successful. His basic research, which concluded that sidestream smoke was inimical to health, was found by us to be faulty. Our findings were widely received with the result that today, while sidestream smoke is still criticized as bothersome, we hear very few broad indictments of it based on health.<sup>43</sup>

The Institute took actions to implement this strategy, which involved creating a propaganda campaign, knowingly manipulating scientific data, and effectively dealing with scientists who published material damaging to industry.<sup>44</sup> The Institute, for example, sought to diminish the impact of EPA scientist Dr. James Repace's "anti-tobacco" manuscripts and keep him on his guard. The following excerpt illustrates the level of effort industry was willing to allocate towards dealing with "anti-tobacco" scientists:

James Repace has been a thorn in the industry's side for years. He has always managed to find a way to take time from his job at the Environmental Protection Agency to present his "research" linking environmental tobacco smoke to 500-5,000 lung cancer deaths a year in nonsmokers in testimony, in anti-smoking articles, and as an expert witness in lawsuits on behalf of workers. Late last year, however, EPA assigned him to its indoor air quality program team -- an

assignment that appears to be a direct conflict with his outside activities, for which he has accepted payment. We quietly provided the documentation on Repace's activities to Rep. Don Sundquist of Tennessee. He wrote SPA Administrator Lee Thomas for an explanation, including that documentation in his letter. That request has triggered an investigation of Repace's activities by the Inspector General, and a call from Repace for scientists to send letters to the EPA in his defense.<sup>45</sup>

According to a memorandum in July 1986 on the Institute's Information Center Plan for 1987, the Center aimed "to increase the positive and blunt the negative media coverage of the tobacco industry and its positions on key issues."<sup>46</sup> The Center planned to achieve this goal, in part, by launching press campaigns, influencing key state- and local-level reporters and editors with targeted issue mailings, appearances on talk shows to present their "agenda of positive issues," and engaging in "aggressive press damage control operations to balance or neutralize the impact of national-level antismoker media events" (Lyons, 1987). The Center sought to "maintain and expand relations with the AFL-CIO and state labor federations, and local labor federations in major cities." It also planned to promote scientific research and publications that characterize environmental tobacco smoke as a minor indoor quality issue to dissuade legislators and institutions from discriminating against those who smoke (Lyons, 1987).

As a result of these early efforts, the tobacco industry was able to more effectively deal with the emerging questions of public health and "environmental tobacco smoke (ETS)," "indoor air pollution," and the "sick building syndrome." The Institute aimed to broaden the issue, use scientists to critique the relevant literature, and persuade the public and policymakers that the issue be considered in a "broader indoor air quality context." The Institute effectively promoted the view that tobacco smoke was much less of a problem than asbestos, radon, and other known carcinogens with regards to indoor air

quality and disease.<sup>47</sup> The following excerpt from an internal memorandum on the Institute's public smoking program explains how this was done:

Gray Robertson and his three colleagues at ACVA<sup>48</sup> paint a vivid picture of the ventilation problems workers in many white collar work environments encounter, whenever a scientific witness appears at a hearing, an ACVA witness usually accompanies him. In Boise, Idaho, in March a Robertson-appearance before a city council was credited with changing three votes and turning a loss on a workplace bill into a victory, in Rancho Mirage, Cal., Robertson discussions with the mayor led to requirements that building owners provide improved ventilation/filtration devices as part of a weakened smoking restriction ordinance. Robertson is approaching the end of the first year of a media tour, placing ETS in the proper context for reporters and talk show hosts throughout the country in the first ten months of the tour, he has visited 55 cities in 20 states, and spoken with representatives from more than 330 media organizations, in Austin, Texas, recently, reporter Kathy Cronkite (Walter's daughter), left him virtually speechless as she took most of his lines...Robertson also is a much-requested speaker for labor unions, who are focusing-their attention increasingly on indoor air quality issues.<sup>49</sup>

The tobacco industry was keenly interested in asbestos in lawsuits against school districts to remove asbestos, some of which involved introducing evidence at trial on asbestos, smoking, and radon on lung cancer.<sup>50</sup> In terms of legislation and lawsuits, the tobacco industry helped keep the focus and blame on asbestos and the asbestos industry.

#### **4. Keeping Asbestos in Focus & on the Agenda**

Legislation is like a chess game more than anything else. It is a seemingly endless series of moves, until ultimately somebody prevails through exhaustion, or brilliance, or because of overwhelming public sentiment for their side.

—John D. Dingell, Jr. (D-MI), *Washington Post*, June 26, 1983, p. A14

By early 1979, the asbestos in schools issue had entered a phase of "crisis politics" and arrived on the formal congressional agenda. Congress enacted the first piece of legislation, the Asbestos School Hazard Detection and Control Act (ASHDC) of

1980, dealing with the issue.<sup>51</sup> The asbestos problem continued to evolve and become more complex as interest group coalitions became less stable and the policy community more diffuse under Reagan and the 97th Congress (1981-1982); competing problems and budgetary pressures tended to push toxic substance matters to the margin (Posner, 1998). Asbestos policy, like that of pesticides, was caught in political, regulatory, and economic crosscurrents making progress difficult (Bosso, 1987). The 97th Congress failed to enact a single new environmental law; only two of eight major environmental statutes were thoroughly debated and reauthorized. At the same time, Reagan's new political appointees at the EPA began to delay the implementation of environmental statutes and rules (Wenner, 1990).

Nevertheless, the question of asbestos in schools did not end in 1980, but arrived on the formal congressional agenda again in 1984 and 1986. The problem affected tens-of-thousands of school children across the United States, generated parent and student anxiety, and led to parent protests and lawsuits. The threat of asbestos was real, salient, and from the perspective of some policy entrepreneurs, solvable. The issue thus became one of the most effective ways for congressional policy entrepreneurs and special interest groups to keep focus on the asbestos problem generally and formulate policy for eventual adoption.

Despite the many problems competing for the attention of policymakers after the passage of legislation in 1980, congressional policy entrepreneurs, special interest groups, asbestos lawsuits, and the media ensured the issue remained in the public's consciousness. Representative James J. Florio (D-NJ), for example, played a significant

role in getting the issue back on the agenda and formulating a policy response that was strengthened in a Republican-controlled Senate and eventually adopted as law in AHERA. During an interview in 2012, Florio described the understanding of the legislative process as key to his success as a policy entrepreneur:

The thing that I did that I guess is somewhat uniquely was to appreciate the fact that the inside players are really very much influenced by the outside players. So I went and played a lot to the outside players... [F]or example, in Congress, the inside players would be my members of my committee and then the members of the full committee, then the members of the House. Put it together, well, literally a book on inside players. You know, John Jones was very much involved with environmental issues. Frank Smith is a union guy... So you'd almost have a book on everybody and then you'd figure out how it is I'm going to get to this person on the basis of outside interests. So we'd go appeal, and you'd have to person by person put together the majorities that you wanted to. And that's what the legislative process is about. Some people were persuaded on the merits. Some people have no interests in the merits whatsoever. You have to go find out what their interest is prompted by.

Florio chaired and participated in numerous congressional hearings on the asbestos hazards and occupational health issues. He also participated in outreach program designed to persuade government bureaucrats and industry representatives to support related initiatives.<sup>52</sup> Katherine Becker, whom the tobacco industry sent monitor the Toxic Torts Clearinghouse Workshop held in DC on 27 September 1983,<sup>53</sup> described Florio's talk at the conference as one of the most substantive.<sup>54</sup> Florio discussed H.R. 2582, a bill that he co-sponsored, which would create an administrative scheme in which 'the toxic victim's burden of proof for recovery would be less than that in the traditional tort system.' Florio ended his talk with the comment that 'this [new toxic victim compensation proposal] is an idea whose time has come.' Lastly, he requested industry support for the legislation.<sup>55</sup> In her report to the Tobacco Institute, Becker made the

following observations about the potential risks and benefits of joining the

Clearinghouse:

If the Institute [Tobacco Institute] were to join this Clearinghouse, it may be funding an information-sharing mechanism that conceivably could be used against tobacco industry interests. After all, the asbestos industry and members of the Chemical Manufacturers Association, when faced with toxic victim litigation, if feasible, are going to use the "synergism" argument as a defense. Marshall Coleman and, as industry has seen, others have made it clear they view tobacco smoking as an important component of the "synergism" argument. Clearly, what TI [Tobacco Institute] does not want to do is facilitate a communication or cooperation among chemical companies that could be the vehicle for anti-tobacco legal or legislative action...Finally, political coalition building must be seen as a theme of this Clearinghouse. With the exception of Representative Florio and the GAF attorney, the panelists were fairly well-united--for different reasons, of course--in their opposition to the toxic victim compensation proposals. So, aside from the potential information-sharing function of the Clearinghouse, it would bring together potential allies for joint political action.

The Service Employees International Union (SEIU), the fourth largest union in the AFL-CIO with close to 850,000 members, spearheaded the coalition's push for improved EPA abatement standards in public schools. The SEIU's counsel, seeking to raise public awareness and congressional support for the standards, filed a formal rulemaking petition with the EPA under Section 21 of the TSCA in March 1983 (Posner, 1998). In July 1984, the EPA released a survey in response to the petition showing 15 million children and 1.4 million school employees were exposed to friable asbestos in 30,800 schools across the United States. The SEIU filed a lawsuit in the U.S. District Court in January 1985 to force the EPA to promulgate a time table for abatement rules in schools. The Environmental Defense Fund joined the lawsuit as a co-plaintiff later that same year. The SEIU also began drafting federal legislation on asbestos in schools for Florio's office. Florio and Senator Stafford introduced the legislation in 1986.<sup>56</sup>

Johns-Manville supported the AHERA legislation because it was in the asbestos industry's best interest at the time. The asbestos industry wanted some protection from what they considered unreasonable demands and lawsuits from panicked parents and schools. From the perspective of industry, strong and predictable federal guidance was preferable to a multitude of different state standards. The asbestos industry was concerned that hasty, ill-advised removal of asbestos from schools could release more fibers into the air and lead to more lawsuits (Posner, 1998).<sup>57</sup> At the same time, Johns-Manville was actively trying to persuade lawmakers to support the Asbestos Workers Recovery Act (AWRA) legislation, which Representative Austin Murphy (D-PA) reintroduced in the House as H.R. 3090. Senator Armstrong introduced similar legislation, S. 2708, in the Senate in 1985. The Heinz staff presented background on the asbestos situation and the AWRA legislation to Senator Heinz in a memorandum dated 4 June 1985:

There are presently close to 25,000 asbestos cases pending in Federal courts, and 8,000 pending in State courts. New cases are being filed at the rate of more than 500- per month. Claimants are forced to wait several years before their case is tried, and only one-half are successful. In those cases that are successful, nearly two-thirds of the money paid by the defendant to the plaintiff goes to attorney fees. Many plaintiffs are bankrupted before their cases can be resolved. AWRA would construct a no-fault administrative mechanism (in lieu of litigation) for the fair and prompt compensation of asbestos disease victims, and to do so in such a way that the program costs are affordable and predictable. There are presently 2-3 million asbestos victims who could seek compensation under this new program. AWRA would create a trust fund to compensate the victims of asbestos-related diseases. The trust fund would be funded by imposing assessments on the defendants in the current asbestos litigation, including the United States. The Federal Government would contribute one-half (not to exceed \$150 m per year); the other half would be paid by private entities responsible for the mining of asbestos and the manufacturing of asbestos products (not to exceed \$150 m per year). Under AWRA, a worker with an asbestos related disease would first file a claim with the appropriate State or Federal workers' compensation program. In most cases, approval of the claim would automatically entitle the worker to AWRA benefits. When State workers' compensation laws fail to protect victims



because of unreasonable time limitations or other technical deficiencies, AWRA would permit affected persons to apply directly to the feds for benefits.<sup>58</sup>

The Johns-Manville bill had 48 cosponsors and the Senate bill four cosponsors; however, the AFL-CIO's efforts to gain support for their bill, the Federal Occupational Disease Compensation Act (FODCA), which Representative Williams (D-MT) introduced and garnered 20 cosponsors in the House, produced a stalemate.<sup>59</sup>

Perhaps suggestive of the extent of Johns-Manville's desperation, in early December 1985, the Johns-Manville representative in Washington sent to the Tobacco Institute a fact sheet, cosponsor list, concept paper, and copy of the AWRA legislation. The material was sent to Panzer in advance of John McKinney's planned phone call to Horace Kornegay, the president of the Institute, about the matter. After receiving the material, Panzer wrote to Kornegay: "This is reminiscent of that firm's interest in our view of a similar piece of legislation several years ago."<sup>60</sup>

Johns-Manville's focus on gaining political support for AWRA may have diminished the interest Johns-Manville had in fighting AHERA legislation. Section 5 below provides further detail on lobbying efforts for the AWRA and AHERA legislation.

## **5. Senator H. John Heinz III Archives: Policy Process Behind the Scenes**

The asbestos situation in Pennsylvania was particularly acute. Pittsburgh, Lancaster, and Philadelphia had some of the largest numbers of asbestos victims in the state. By 1980, the state reportedly had one of the highest numbers of asbestosis claims in the country, many of which involved former employees of the two major navy shipyards in Philadelphia.<sup>61, 62</sup> Pennsylvania and Tennessee were considered to be the

two neediest states in terms of abatement-related assistance; this was based on the number of schools requiring abatement and the funds available.<sup>63</sup> Senator H. John Heinz III (R-PA) and his legislative staff were actively involved in agenda setting and policy formulation on asbestos during this time, which is evidenced in the numerous internal memoranda discussing politics and policy. This section relies on the Heinz archives to provide a snapshot of the many significant and competing public and environmental issues at the time; the influential role of labor and special interest groups; local, state, and federal politics; and the important role of the Heinz legislative staff in the policy process.

This analysis of the Heinz archives focuses on internal memoranda, which were often detailed, containing hand-written comments from Senator Heinz and several staff members on important issues of the time. Senator Heinz and his staff would also write questions on the documents, which would require producing a follow-up memorandum with answers to the questions. The office policy required authors and readers of the memoranda and comments to initial and date the content accordingly. The "JH Decision/Action" memoranda are particularly important because they outline the specific set of options "JH" (John Heinz) considered, the arguments for and against the issues, and the decision (which sometime received some hand-written elaboration).

## **5.1 Environmental Policy Entrepreneur**

The Senator's personal interest in environmental issues, support for labor and environmentalist groups,<sup>64</sup> and Pennsylvania's acute environmental and occupational health problems, sometimes put Heinz at odds with the Reagan Administration and the executive branch agencies over funding for clean-up of the hazardous waste sites and

asbestos abatement programs. Heinz sent a letter to David Stockman, OMB Director, dated in late February 1981, regarding Superfund supplemental appropriations. In the letter, Heinz pointed out that he had succeeded "in amending the FY-1980 supplemental appropriations measure to provide funding...to its authorized level (then \$30 million)," but "the unobligated balance in the Superfund has dwindled to less than \$2 million" (Heinz, 1981). Heinz (1981) acknowledged the budgetary constraints (created by Stockman with the approval of the Administration), but warned that "if additional funding is not made available in advance of the normal appropriations process, the Federal government may be unable to respond in case of environmental emergencies."

## **5.2 Asbestos Issue in Context: Complex & Competing Problems**

Asbestos was described in several memoranda as a "fairly big deal in Pennsylvania."<sup>65</sup> Pennsylvania was not only dealing with asbestos in schools and the problem of growing numbers of asbestosis victims, but was burdened with the clean-up of large asbestos and toxic chemical dump sites, such as Ambler and the Rohm & Haas Co. landfill in Bristol Township, for which funds were limited (Fountain, 1987; Fountain, 1988).<sup>66</sup> Heinz and his staff were continually faced with new and emerging problems, such as unusually high levels of radon in homes, but had to continue to make progress on the "monster" problem—Three Mile Island (TMI) (the most serious nuclear disaster in the history of commercial nuclear power plant operations).<sup>67</sup> Senior legislative assistant Jason Hall, in a memorandum to his replacement in late February 1982, described TMI as a "monster which will eat a lot of your time."<sup>68</sup> Senator Heinz, the leading player in the

Congress on TMI, and his staff were reportedly under considerable time pressure in late February 1982 to move on the Nuclear Regulatory Commission Authorization (S. 1207) bill.<sup>69</sup> As chairman of the Senate Special Committee on Aging, Heinz was also concerned with the Committee's legislative goals, longer-term issue development, and on-going program oversight.<sup>70</sup> One of those legislative goals, the fire-safe cigarette bill (S. 1935), which is discussed as a case study later in this section, was to put him into open conflict with the Tobacco Institute, creating yet another major issue competing for the Senator's time and attention.

### **5.3 Asbestos Crisis in Philadelphia Schools**

Senator Heinz sought to understand the asbestosis, lung cancer, and asbestos in schools issues, as evidenced by the numerous marked memoranda, hand written summaries, requests for information, legal documents, field studies, EPA regulations, and articles and reports dealing with the issue. Heinz, through his study, was able to develop a baseline understanding of the asbestos problem and helped him handle the emerging asbestos crisis in Pennsylvania. The Heinz papers, for example, contained a marked copy of a report on the results of air sampling for the presence of airborne asbestos fibers at the Dr. R. F. Nicely School in Philadelphia in February 1979 (Esmen & Dixon, 1979). The report found that the levels of airborne fibers at the school were 1000 to 10,000 times greater than found in the environment. The report noted the asbestos spray on the ceiling was deteriorating throughout the building, greatly contributing to the high levels of airborne fibers. The report characterized the situation as "dangerous" and possibly holding "grave future health consequences to the exposed population."<sup>71,72</sup> The

following excerpts from the report, among many others, were underlined or marked with a star<sup>73</sup> to presumably highlight the importance to the reader. In early May 1979, the Senator's office received a compilation of inspection and asbestos findings in Pennsylvania public schools (Sentz, 1979). The study results, showing numerous school buildings containing sprayed asbestos, put Heinz and his office on notice regarding this issue, which became a crisis in 1980.

Pennsylvania was embroiled in local struggles regarding asbestos in schools by late 1980. The public's reaction to the asbestos issue in Philadelphia schools, and the response of Senator Heinz to the problem, is illustrative of how the problem remained on the Congressional agenda.<sup>74</sup> In Pennsylvania, a state that reportedly had one of the highest numbers of asbestosis claims in the country at the time,<sup>75</sup> the danger to children was real and palpable to parents. In Philadelphia, for example, local newspaper articles began to expose the dangers of friable asbestos to school children, sparking protests (Harris, 1984). The *Philadelphia Inquirer* published a series of articles chronicling the emerging crisis, all of which were found in the Heinz papers. The public's knowledge of the situation was informed by the articles, such as the one appearing in the paper on 6 December 1980:

Parents worried that asbestos may be contaminating a Fishtown elementary school...picketed in the morning outside Adaire Elementary School...and some carried placards demanding: "Remove Asbestos Now...The protest yesterday was inspired by the successful efforts of parents from the Cramp Elementary School in Kensington who blocked the school's doorways for four days, seeking removal of flaking asbestos there. On Thursday, the school board closed the school after hearing a report from its consultants, Rossnagel & Associates of Medford, N.J., that the falling dust from asbestos ceiling insulation was "potentially" unhealthful. About 200 parents and children from Cramp were told yesterday to which area schools the students would be transferred for about three months while the asbestos is removed...The teachers' union--the Philadelphia

Federation of Teachers (PFT)--also expressed its dissatisfaction with the school board action...Kiner said teachers are angered that for years school officials insisted that Cramp was safe and then suddenly decided it was necessary to shut the school down. "We've been demanding this shutdown for two years," Kiner said (Kiner is a PFT spokesman).<sup>76</sup>

In response to the protests, Senator Heinz agreed to meet with the Hugh Community Organization in Philadelphia on 12 December 1980 to "air the facts and explore solutions to a problem that affects the well-being of our children" (Murray, 1980). In a press release prior to the meeting, Heinz stated that "serious questions had been raised as to whether appropriate action was being taken to detect the specific toxicity levels of asbestos in many of Philadelphia's schools" (Murray, 1980). In preparation for the meeting, the Heinz staff prepared a series of memoranda providing background on the problem and recommendations. The memoranda provide a snapshot of the staff's understanding of the problem and the influence on Heinz decision-making process. A staffer provided background information on the issue in a memorandum to Heinz on 9 December 1980:

Recently a series of news reports and articles by Herb Denenberg exposed serious asbestos contamination in 24 Philadelphia Public Schools. His reports tended to zero in on the fact that the Philadelphia School District had knowledge of this problem for the past 10 years and had done absolutely nothing about it claiming that the Philadelphia Health Department has assured that the asbestos posed no health threat to the children of these schools...[A]nxious parents of the Cramp School, which is the one concern to the Hugh Community Organization, blockaded Cramp School and refused to permit students to enter. The School District consultant also certified that the schools were safe despite a report by consultants hired by Denenberg that they were not. As a result of parent actions rather than consultants reports, the Cramp School was closed and repairs and removal of the asbestos started.<sup>77</sup>

The following day, press secretary Dave Murray submitted a follow up memorandum to Heinz, noting the staffer's memorandum omitted "the major points of controversy that

make it necessary for you and the EPA to answer the questions of skeptical (if not fearful) parents." <sup>78</sup> Murray listed the following ten popular complaints against the School Board and Rossnagel & Associates, which he believed would be the focus of parent concerns at the meeting:

(1) Rossnagel bases its claim that asbestos-contaminated schools are safe on air samples. This approach has been rejected by almost all experts including the EPA...Experts say the only way to assure safety is to remove dangerous (friable) asbestos; (2) Rossnagel took air samples in deserted buildings...Critics say samples should be taken when 800 students are tamping (sic) around the halls (that is, under real life conditions); (3) Asbestos samples were taken from the air for only two hours. Experts say samples should be taken over 4-8 hours for a representative reading; (4) In the first two school building they inspected, Rossnagel found flaking asbestos dust--a certain sign of intolerable health hazard. However, they affirmed the safety of both school buildings and neither was closed; (5) Rossnagel took an inadequate number of air and bulk samples. In the Cramp School four bulk samples were taken; in the Rush School only two bulk samples were taken. Experts say asbestos content and condition could not be gathered from so small a sample...; (6) Rossnagel failed to take samples in some of the rooms in Cramp that showed the worst deterioration. This suggests that air samples come from lower hazard area. Denenberg claims "Rossnagel was hasty to show that the schools were safe."; (7) Rossnagel relies on views of OSHA and the Nat'l Institute of Occupational Safety and Health (NIOSH), not the EPA...EPA, which has responsibility for regulating exposure in schools, says no level of asbestos is safe. Same experts say children may be more vulnerable to toxic chemical than adults; (8) Rossnagel did not get history of prior reports...Denenberg says that if you look at City's Health Departments 1977, 1979, and 1980 surveys show that asbestos deterioration has become progressively worse and that contamination will become more serious over time. The School Board made no attempt to look at past records...; (9) Rossnagel did not consult legal rules that govern asbestos contamination in Philadelphia. The City Health Department works under "Regulations to Govern Construction of Occupied Buildings and Places of Employment"...; (10) Rossnagel has presented...a pile of statistics without conclusions or recommendations for remedial action <sup>79</sup>

Finally, Murray informed Heinz that a group of parents filed suit against the Board of Education and requested he read the School Boards rebuttal on the parent claims for "a balance of views." <sup>80</sup> Heinz and his staff's actions helped alleviate some of the concerns of parents, as did the passage of the ASHDC Act in 1980. The asbestos in schools

problem did not go away, but, as mentioned, the 97th Congress did not pass a new environmental law. As the chairman of the Special Committee on Aging, Heinz was also obligated to focus his energy on Committee issues, which explains his increased focus on the issue of fire-safe cigarettes. The issue competed for the Senator's time on formulating asbestos policy from 1983 to 1984.

#### **5.4 Fire-Safe Cigarettes: Industry Influence on the Legislative Process**

At a hearing before the Special Committee on Aging in late July 1983, Heinz called the Tobacco Institute "a disgrace to the American business community" for their stance on developing a fire-safe cigarette.<sup>81</sup> Heinz said in a speech that he was "outraged at their (Tobacco Institute) attitude" and "[t]o settle the charges and countercharges once and for all, I, along with Senators Danforth and Cranston, introduced S. 1935 (in October 1983), to study the feasibility of manufacturing a fire safe cigarette."<sup>82</sup> The Institute viewed the fire-safe cigarette issue as having a broad "cross-impact factor" closely tied to the matter of smoking and health.<sup>83</sup> For the Institute, this was another conflict over defining an issue, which they intended to deal with accordingly:

Our opponents will attempt to define issues on terms advantageous to their view. The latest example is the term "self-extinguishing cigarette" as opposed to "product abuse." Such definitions are crucial to the public perception of the issues...One must but scratch the surface of the fire safety issue to find smoking and health. Such overlap can either help or hinder us depending upon the quality of our communications with each other and our member companies. The pitfalls of redundant effort and missed opportunities must be avoided.

The Tobacco Institute proved to be a formidable adversary. According to a Heinz staff member, the "stiff opposition from the tobacco lobby, which claimed Congress was moving too fast" forced Heinz to develop a compromise bill.<sup>84</sup> The amended bill



incorporated the language of Representative Joseph Moakley's (D-MA) companion bill in the House, which the tobacco industry accepted; the amended bill was signed into law in October 1984 (P.L. 98-567).<sup>85,86</sup> At the meeting of the Tobacco Institute of Committee of Council on 14 November 1983, it was reported that the Institute president had met with Carlton Kern, a Representative Moakley (D-MA) "staff man," who "advanced another draft (fire-safe cigarette) bill." The Institute decided to "deal with" Moakley through "local people." The Institute's Massachusetts representative reportedly persuaded Moakley to have Kern revise the latest draft bill.<sup>87</sup> Thus, the Institute had a lot to do with developing the language that found its way into the legislation.

The legislation provided for the establishment of an Inter-Agency Committee, headed by the Consumer Product Safety Commission (CPSC) to oversee a study group's work on a "3-year study of the technical and commercial feasibility of the fire-safe cigarettes."<sup>88</sup> As early as July 1983, a Philip Morris lobbyist had learned of the possible role of the CPSC and distributed a inter-office memorandum, which was forwarded to the Tobacco Institute, exploring ways to possibly shape the situation via the so-called "Moakley project."<sup>89</sup> The Technical Study Group included a representative of the tobacco industry, which gave the industry a chance to shape the outcome of the report. As Senator Heinz learned after the completion of the study in 1987, the tobacco industry began to work against efforts to institute the standards they ostensibly supported. The Institute managed to persuade the Interagency Task Force to recommend to Congress that "further studies, taking several years, be undertaken before fire-safe standards are developed."<sup>90</sup> Senator Heinz was forced to consider shifting to a "middle position which

would involve further study of...a fire-safe performance standard" to bring the tobacco industry to the negotiating table. "Moving the legislation against the tobacco industry," wrote a staffer, "may be very difficult given their support within the Administration and the fact that Sen. Hollings chairs the Commerce Committee."<sup>91</sup>

## **5.5 Asbestos Abatement Funding Crisis of 1984**

As mentioned in Chapter 2, formulating policy proposals involves developing solutions that policy makers can connect to issues that are important at the time.<sup>92</sup> After meeting with School Administrators in March 1984 to discuss asbestos removal and other education-related matters, the Heinz staff looked to do just that. The Philadelphia school district superintendent, Constance Clayton, expressed concern at the meeting on asbestos abatement in local schools.<sup>93</sup> According to a staffer's notes, Philadelphia had already spent \$3 to \$4 million on removal and required an additional \$17 million.<sup>94</sup> Heinz reportedly suggested that there was "zero-chance" for the asbestos question as it stood;<sup>95</sup> Heinz and his staff sought potential answers. The day after the meeting with Clayton and the other administrators, legislative assistant Carol Michel produced a memorandum suggesting a potential solution to the problem. Michel pointed out that Senators James Sasser (D-TN) and Dee Huddleston (D-KY)<sup>96</sup> had recently introduced a bill in the Senate that would set up an emergency grant program for asbestos abatement in public schools. Michel suggested the bill, which would give grants to needy school districts, could provide a potential solution to the problem in Pennsylvania:

The bill would authorize \$100 million for FY85-88. PA is one of the neediest states with a high level of health problems in its school systems, which means they will probably receive a fair amount of money from this program (PA and

TN are targeted as the states with the most substantial problems). Under the Asbestos School Hazard Detection and Control Act of 1980, the EPA can sue any local school district that does not comply with the guidelines outlined in the 1980 Act. Philly may be one of the local districts that will be sued. As Clayton pointed out in the meeting, the reason for non-compliance is the lack of funding.<sup>97</sup>

Finally, Michel recommended Heinz cosponsor the bill "considering the possibility of a lawsuit and the concerns of both Philly and Pitts. on this issue." The legislative director agreed with Michel, writing the following: "[A]gree, since program is relatively inexpensive and PA has one of the worst asbestos problems." Another staffer underlined the term "inexpensive" and also put a "?" next to the word. The same staffer also wrote the following comments on the memorandum: "I don't understand from this why the situation wasn't covered in the 1980 Act and what rationale? Also how could the \$100 million figure be reliably arrived at?...how does that fit w/other legisl. (legislative) reality?" Senator Heinz initialed the memorandum on 23 March and planned to discuss the issue further with his staff.

At the request of Senator Heinz, the Congressional Research Service transmitted materials on the topic of asbestos in schools on 4 April 1984. According to the request, Heinz specifically inquired about the cost of removing asbestos from public schools. Among the documents submitted were a copy of a previous Congressional Research Service issue brief on an earlier request and two articles from *Education Week* magazine. According to one of the articles, the Department of Education estimated that it would cost \$1.4 billion to remove friable asbestos from schools throughout the United States. Heinz, wanting to better understand the problem, requested the Congressional Research Service prepare a report on the program and policy issues of asbestos in schools, which he

received in 1984. The Congressional Research Service (CRS) (1984) warned about the potential for the EPA to file lawsuits against Philadelphia for non-compliance with the Asbestos School Hazard Detection and Control Act of 1980. The EPA did in fact sue Philadelphia for \$378,000 for non-compliance, which was the subject of a meeting with the Pennsylvania School Board Association on 28 June 1984. According to a 27 June memorandum, 14,000 school buildings contained asbestos; the cost of abatement was estimated at \$100,000 per building. The memorandum noted the solution was a Senate amendment, passed by a voice vote on June 6, 1984, that would provide financial assistance through grants and loans to Philadelphia, one of the neediest school districts. The EPA was also required to establish an abatement program to provide guidance to states dealing with the problem.<sup>98</sup>

## **5.6 Asbestos Compensation: Lobbying & the Issue of Competing Bills**

Johns-Manville and the asbestos industry continued to lobby members of Congress and were very active in Pennsylvania from 1984-1986. According to Senator Arlen Specter (R-PA), Senator Gary Hart (R-CO) accompanied a Johns-Manville's representative in an office visit with Specter in 1984.<sup>99</sup> As mentioned in Section 4 above, Representative Murphy introduced Johns-Manville's AWRA bill in the House the following year. Johns-Manville was also lobbying Senator Heinz, which resulted in the production of numerous decision memoranda on the legislation. Paul Quinn, a Washington Attorney representing the company, and CEO John McKinney requested a meeting with Senator Heinz to discuss AWRA, according to a June 1985 memorandum. William Janss, a member of the company's board, also expressed interest in setting up a

meeting. As Representative Murphy and Senator Armstrong had already agreed to introduce the measure, Johns-Manville allegedly only wanted to present their case to Senator Heinz (RJC, 1985). The asbestos lobby contended the majority of claims filed under AWRA could be settled in one year for less than \$300 million; however, the trust fund could be extended as long as required with \$150 million from the government and \$150 million from industry (RJC, 1985).

The staff was divided on whether Heinz should meet with Johns-Manville, weighing the potential risks and benefits. Several staffer recommended Heinz meet briefly with the lobbyists because "this is an issue we may want to become heavily involved in" and a meeting could "generate some good press and at least a good labor mailing if we handle it right." On the other hand, argued another staffer, a meeting with this company on asbestos "conjures up nameless fear for me (colluding w/bad guys...); AWRA procedures are reminiscent of Black Lung red tape." Heinz decided to do the meeting, but indicated he wanted it handled at the staff level (RJC, 1985). In the end, however, Heinz met with CEO McKinney in July 1985, according to an internal memorandum.<sup>100</sup> By late July 1985, Heinz and his staff were deciding whether to support the AWRA or AFL-CIO's FODCA legislation. After receiving the following advice from three staffers, Heinz indicated on July 31 that he would stay off both bills:

(1) I think JH (John Heinz) should steer clear of endorsing either asbestos compensation proposal. The AFL-CIO bill is extremely expensive and anathema to business; the John-Manville measure, while acceptable on the merits, would gain us zero gratitude from Labor (inasmuch as they support a more comprehensive approach to occupational diseases). During the month of July, we have received only about 36 letters from Pennsylvanians regarding asbestos legislation. We can get by with a simple assurance to these people that JH is concerned about the matter and will continue to investigate the various proposals pending before Congress...(2) Cosponsoring AWRA will non-plus labor;

cosponsoring FODCA will incense business..(3) This looks very expensive-- health programs in existence and private health plans should meet most of the cost.

Heinz indicated in a draft CMS (Correspondence Management System) letter on the AWRA in early September 1985 that he supported the concept of AWRA, but was considering the merits of FODCA as well. "Please be assured," concludes the letter, "that I will be closely examining all bills in this area with your comments in mind."<sup>101</sup>

On 15 November 1985, the staff provided Heinz with an update on the legislation. The memorandum noted that Johns-Manville had obtained a copy of the Heinz CMS letter (presumably the draft letter mentioned above, detailed in endnote 141) "that espouses goals and stated purposes of their bill, and presented this as reason JH should support bill."<sup>102</sup> In response to this Johns-Manville attempt to use the CMS letter in this way, press secretary Murray wrote the following: "Our CMS language is hardly specific enough to imply JH support for the Armstrong bill."<sup>103,104</sup> Heinz decided on 19 November 1985 to continue to remain off both bills, but to "keep a close eye on compromise developments to secure potential lead next session."<sup>105</sup> Heinz made this decision based on the following recommendations from his staff:

Continue to stay off both now, but maintain active interest. Based on discussions I've had, there is potential for compromise. In addition, asbestos is a big PA issue, and an increasingly important policy issue, as more companies go into bankruptcy, and as litigation delays mount. JH could create good opportunity if we helped with compromise. There is also a political opportunity in introducing labor bill now, since it won't move this year. Industry, of course, would be upset by such a move...Keeps JH in position to play compromise role next year...[K]eep options open for now.

Johns-Manville continued to press Heinz in early 1986. On 28 February, 1986 William (Bill) T. Kendall of Kendall and Associates, a lobbying firm for Johns-Manville,

wrote a letter to staffer Edward Rogers requesting an appointment to meet with Senator Heinz:

Recently I spoke with Senator Heinz about the Manville situation and the desire of Mr. John McKinney, Chief Executive Officer at Manville, to see the Senator about recent developments regarding the asbestos legislation. As background, Mr. McKinney and Mr. Aaron Gold had a meeting last year with the Senator and Senator Specter. Mr. Gold is a member of the Board of Manville and knows both Senators. The purpose of the meeting would be to bring the Senator up to date on the Chapter 11 proceedings and to outline an idea Mr. McKinney has for a legislative solution that would not involve government outlays.<sup>106</sup>

The letter generated a memorandum for action, which was sent to the staff and Senator Heinz on 4 March 1986. Heinz indicated on 7 March that he would meet again with John McKinney and Aaron Gold, "but not too soon—no urgency."<sup>107</sup>

## **5.7 Constituents Keep the Asbestos Problem in Focus**

As Johns-Manville was lobbying Heinz over AWRA, the Senator and his staff were preparing for meetings with constituents, such as the Pennsylvania School Board Association (PSBA), over asbestos and other issues. The memoranda show that Heinz and his staff were proactively trying to respond to the concerns of constituents on the 'thorny' problem of asbestos. They also wanted to avoid alienating key constituents who could become thorns in their sides as well. On 26 June 1985, the PSBA held their 16th annual PSBA Congressional lunch, which Senator Specter attended (he reportedly "came late" and "stormed out after 5 mins.").<sup>108</sup> The PSBA noted the following concerns at the meeting:

They need \$300 million for asbestos removal from the public schools. They're having terrible insurance problems because they can't get reinsurance from foreign companies like Lloyd's, and the primary insurers are unable to accomodate (sic) them. No one wants liability for the asbestos (gets into products liability, personal injury, a real mess).

The legislative assistant met the PSBA government relations officer and the executive director and they agreed to meet again. However, the PSBA president, Calvin Wolfberg, was allegedly "not friendly." This concerned the legislative assistant, which generated the following response from another staffer: "Asbestos is very thorny issue. Just the individual cases in which we have been involved are one mess after another. Can't imagine why PSBA Pres was off-putting. Shall I call to follow up?"

In May 1986, Senator Heinz planned to meet with ten members of the PSBA, who, according a staffer, generally "love JH." The PSBA favored federal financing of abatement in local schools and supported "the concept that any federal standards for inspection and abatement of asbestos hazards must be clear and reliable." However, the PSBA had "serious concerns about the potential administrative and cost burdens for local districts" under the AHERA legislation. The Pennsylvania school districts main problem, however, was securing liability insurance for contractors to remove the asbestos (Bill, P. 1986).

## **5.8 Voting with Labor on AHERA**

The Heinz staff closely monitored labor politics. Key union groups had supported Heinz during his election and Heinz tended to vote with labor on most of the issues (Hall, 1982). In early 1985, a Heinz staff member provided him with a plan for handling Pennsylvania labor leaders in the coming years to ensure reelection in 1988. According the memorandum, some members of the Executive Board of the State AFL-CIO harbored some resentment against Heinz for not voting as "pro-labor" as they had expected.<sup>109</sup> The



plan to improve communications with labor included treating all union letters as "V.I.P" with an "immediate call to the individual who wrote" and a response "ASAP." The author of the memorandum went on to recommend "a meeting between JH, staff, and John Perkins' staff to discuss their targeted votes for the upcoming session." "We can and should make it clear," emphasizes the staffer, "that they certainly can't expect our vote on every subject but we would appreciate it if they would be honest with us in regards to what is important and what is not." The Heinz archives contain many documents showing the importance the office attached to labor relations. In one memorandum, for example, a legislative aide described the labor politics behind the High Risk Occupation Disease Notification Act (S.79),<sup>110</sup> Republican co-signers of the bill,<sup>111</sup> business politics,<sup>112</sup> and recommendations.<sup>113</sup> Labor kept pressure on Heinz by rating him on his voting record. The pressure could be effective, according to internal memoranda.<sup>114</sup>

It was against this backdrop that Senator Heinz received a letter from SEIU vice-president on 15 April 1986 requesting he support the AHERA legislation.<sup>115</sup> On 16 June 1986, Heinz sent a letter to the EPA Administrator in support of the Pennsylvania School District's request for \$7.3 million in federal funding for asbestos abatement in four contaminated schools.<sup>116</sup> By September 1986, congressional staff had completed a compromise agreement between the House and Senate over AHERA. The agreement passed the House and the Senate shortly afterwards in an unanimous voice without objections. President Reagan signed the Act into law on 14 October 1986.<sup>117</sup>

## CHAPTER FOUR: CARBON NANOTUBE TOXICOLOGY & EPIDEMIOLOGY: LESSONS FROM ASBESTOS

*Non pussunt naturam noscere rerum* (The eyes cannot know the nature of things).

—Lucretius, quoted by Torbern Bergman in *Dissertatio Chemica de Terra Asbestina* (1782)

### 1. Introduction

The Swedish chemist Torbern Bergman (1735-1784) could not have selected a more apt quotation to introduce the reader to his dissertation. The work analyzed the properties and chemical composition of asbestos, employing methods that would serve as a foundation on which later scientists could build.<sup>118</sup> Dr. W.E. Cooke, a pathologist skilled in microscopy and geology,<sup>119</sup> and Noble Laureate Sir Lawrence Bragg<sup>120</sup> succeeded in furthering Bergman's quest to determine the nature of asbestos. Cooke (1929) revealed that chrysotile fibers split into "ultra microscopic" spicules under certain conditions, which were "beyond the limits of resolution." Cooke suggested the fibers' iron content could play a key role in their adverse effects.<sup>121</sup> Familiar with Bragg's X-ray diffraction technique (Cooke, 1929), Cooke sent a letter to Bragg's colleague in June 1928 seeking to determine the composition of the "curious bodies" he had isolated from a patient's lungs.<sup>122</sup> In September 1928, Bragg himself was corresponding with his doctoral student Bertram Warren<sup>123</sup> on work involving asbestos. The following year Cooke concluded that chrysotile was diagnostic of asbestosis (Cooke, 1929), Warren solved the structure of tremolite asbestos, and Bragg and Warren put forward their

suggestion on the arrangement of chrysotile's atoms.<sup>124</sup> Today, scientists continue to build on these early successes to 'know the nature' of carbon nanotubes and inform assessments of the potential risks.

Current scientific and technical methods allow scientists to more accurately analyze the physicochemical properties and the chemistry of tissue reaction to the fibrous materials. Pascolo et al. (2013), for example, describe the use of synchrotron-based scanning X-ray microscopy to reveal the interaction of asbestos and iron in the lung. Such approaches are critical for determining whether carbon nanotubes can elicit effects similar to asbestos, the etiological agent of asbestosis,<sup>125</sup> bronchogenic carcinoma,<sup>126</sup> mesothelioma,<sup>127,128</sup> pleural fibrosis,<sup>129</sup> and pleural plaques.<sup>130</sup> The findings in the scientific literature suggest some nanotubes have significant disease potential depending on their physicochemical characteristics, particularly for the respiratory system (NIOSH, 2013). As the nanotechnology industry shifts from research and development to large-scale industrial production, the potential for carbon nanotube inhalation exposure in occupational settings could increase (Fadeel et al., 2012).

This chapter describes the common toxicological and epidemiological principles required to assess the potential hazards of carbon nanotubes, with an emphasis on the physicochemical properties of chrysotile (white asbestos) and multi-walled carbon nanotubes (MWCNT). The lessons learned from chrysotile, a naturally occurring fibrous mineral that is morphologically similar to MWCNT (Porter, 2012), provide a cautionary tale about the potential consequences of uncontrolled human exposure to carbon nanotubes.

## 2. Common Toxicological & Epidemiological Principles

Warheit (2013) and Nel et al. (2013) identify three common toxicological principles required to inform risk assessments on carbon nanotubes. The three principles, physicochemical properties, *in vitro* assays and *in vivo* assays, are required to produce data for risk or fate assessment (Nel et al., 2013). Warheit (2013) recommends researchers accurately assess a material's physicochemical characteristics before starting toxicological testing to ensure the value and significance of a study's hazard findings. The following physicochemical properties are deterministic with regard to biological response (e.g., cell uptake and toxicity) and fate (e.g., absorption, distribution, metabolism, and excretion ecosystem-wide effects): chemical composition, size and size distribution, shape, agglomeration, surface area, charge, porosity, surface coatings, surface reactivity, method of synthesis and modification, purity of sample, dose, and relevant media (Hubbs et al., 2013).<sup>131</sup> The specific biological interactions caused by reactive surfaces, ligands, or release of toxic ions could also play a role in toxicity (Warheit, 2013). There is also the specific issue of interaction with tobacco smoke, discussed extensively in the literature on asbestos, which to the author's knowledge has been rarely, if at all, addressed in the studies on carbon nanotube toxicology.<sup>132</sup>

Epidemiological studies and case reports typically made the first connection between exposure to fibrous dust and the onset of disease; toxicology helps prove that exposure is the cause of a disease (Donaldson & Seaton, 2012). Rothman (2002) defines epidemiology as the "study of the distribution and determinants of disease frequency" (Rothman, 2002). Rothman (2002) considers the following as fundamental principles of

epidemiologic research: (1) causation;<sup>133</sup> (2) measures of disease frequency;<sup>134</sup> (3) measures of effect.<sup>135</sup> Historically, epidemiological studies played a significant role in linking exposure to fibers, such as asbestos, to disease production (Donaldson & Seaton, 2012). In the case of uncontrolled exposure to asbestos fibers, many years were to pass before pathological changes were observed. After elucidating the molecular mechanisms involved in asbestos-induced diseases and analyzing the fibers, scientists were able to confirm that free radical generation, oxidative stress, and inflammation were primarily involved in toxicity (Bergamaschi et al., 2014). The epidemiologic studies showed a dose-response connection between asbestos exposure and the risk of lung cancer (fiber dose/fiber burden tends to increase lung cancer risk); the long latency period, starting more than 15 years after initial exposure, is characteristic of asbestos-induced lung cancer (Roggli, 2014). Rothman (2002) makes an important point to keep in mind: "An elementary but essential (epidemiological) principle...is that a person may be exposed to an agent and then develop disease without there being any causal connection between exposure and disease."

To date, no case reports or epidemiological studies have been published that show causation between the exposure to carbon nanotubes and lung disease in humans (NIOSH, 2013). First responders were exposed to carbon nanotubes contained in the dust that covered Manhattan and areas of Brooklyn, New York after the collapse of the World Trade Center (WTC) on 11 September 2001 (Wu et al., 2010), but the significance of the findings with regards to causation have not been established (de la Hoz, 2010). Researchers and workers involved in manufacturing of carbon nanotubes may be at risk

of developing some of the adverse lung effects seen in *in vivo* studies (inflammation, fibrosis, etc). The limited data on occupational exposure demonstrates aerosolization of carbon nanotubes can occur during research, production, and use (including transferring, blending, weighing, and mixing).<sup>136</sup> The Centers for Disease Control and Prevention (CDC) is currently conducting a cross-sectional epidemiologic study of U.S. workers exposed to carbon nanotubes and nanofibers, which is scheduled to be completed in 2016 (CDC, 2013).

Wu et al. (2010) published a case report that describes their clinical, pathologic, and mineralogic findings in seven formerly healthy WTC responders who developed severe respiratory impairment and lung disease.<sup>137</sup> The analysis of lung biopsy specimens showed the presence of varying sizes and amounts of carbon nanotubes, chrysotile asbestos, sheets of aluminum and magnesium silicates, calcium phosphate, calcium sulfate, and glass shards.<sup>138</sup> The histopathology revealed interstitial lung disease, bronchiolocentric parenchymal disease, and nonnecrotizing granulomatous condition (Wu et al., 2010). The lung specimen of one patient, who worked as a custodian sweeping out dust near the pile/pit at the World Trade Center site for 10-12 hr/day for 8 days, contained carbon nanotubes (230,000/g), chrysotile asbestos (36,800/g), and silicates (184,000/g).<sup>139</sup> In 2007, the lung biopsy revealed peribronchiolar fibrosis;<sup>140</sup> high-resolution computerized tomography revealed the progression of parenchymal disease in 2009. The lung biopsy of another patient, a nurse who lived nearby and worked at the site for 41 days, revealed honeycombing, severe peripheral fibrosis, and peribronchiolar usual interstitial pneumonitis-like fibrosis (Wu et al., 2010). The

minerologic and fiber burden analyses showed carbon nanotubes (110,400/g) and silicates (165,000/g) (Wu et al., 2010). It is not clear to what extent any one of the substances may have contributed to the lung pathology, but the combination of the fibrous dust and compounds, coupled with the reported levels of fiber concentrations, likely played a role in the respiratory impairment.<sup>141</sup>

Warheit (2013) examined the epidemiological studies conducted on workers involved in titanium dioxide (TiO<sub>2</sub>) manufacturing and people exposed to TiO<sub>2</sub> particles in the scope of their work. Warheit notes no studies directly investigated the effects of nanoscale or ultrafine exposures in TiO<sub>2</sub> production workers. The analysis of pulmonary toxicity and available epidemiological data can assist in the development of occupational exposure levels for worker safety. Warheit (2013) emphasized that exposure concentrations in hazard testing for toxicological studies should not reflect lung overload conditions because the toxicities expressed may not reflect exposures in the workplace.

Donaldson and Seaton (2012) examined the history of the toxicology of inhaled particles and fibrous dusts. In the case of asbestos and other fibrous dusts, the concern that the dust may cause disease generally developed in the following manner:

1. Cases reported that workers were exposed to the dust;
2. Toxicopathological studies suggest a link between the inhaled dust and disease;
3. Epidemiological investigations show the nature of relationship; estimate an exposure-response connection;
4. Toxicologists conduct *in vivo* and *in vitro* studies to confirm the relationship;
5. Toxicologists investigate the role of the physicochemical characteristics of the dust.

Donaldson and Seaton (2012) suggest that, in the case of engineered nanomaterials, such as carbon nanotubes, this process is working in the opposite direction. That is, the process for determining whether carbon nanotubes will have adverse effects on the body has thus

far been one that is predictive: (1) Toxicologists investigate the role of the physico-chemical characteristics of the nanotubes; (2) Toxicologists conduct *in vivo* and *in vitro* studies to predict the disease or pathological reactions that might occur from exposure (Donaldson & Seaton, 2012). Donaldson and Seaton (2012) warn that this predictive approach can lead to false-positives, particularly if substantial exposures do not occur.

Several studies of workers have attempted to identify sensitive and specific biomarkers of exposure, effects, and susceptibility to carbon nanotubes that could provide early indications of toxicity and perhaps pathogenicity.<sup>142,143</sup> One cross-sectional study examined the biomarkers of small airway damage (CC16) and inflammation (hsCRP), NF-κB levels, the activity of myeloperoxidase (MPO) and esterase, vascular cell adhesion molecule (VCAM) and heart-rate variability (HRV) parameters. There were statistically significant changes in CC16, hsCRP, and inflammatory cell activation (increased ICAM-1 in macrophages) among production workers (Liou et al., 2010).

Nel et al. (2013) used high-throughput screening (HTS) to identify carbon nanotube physicochemical characteristics and developed a predictive toxicological paradigm for pulmonary toxicology for carbon nanotubes. The approach attempts to identify the fiber properties that could generate pathology or disease outcomes *in vivo*; examines biophysicochemical interactions at the nano/bio interface; and creates structure-activity relationships (SARs) to allow hazard scoring and modeling to assess potential risks. This approach reportedly allows researchers to carry out the majority of the screening analysis and the high-volume data generation *in vitro*, followed up by limited validation studies in animals or whole organisms (Nel et al., 2013). This work resulted in



the development of a quantitative dispersal method to conduct a series of cellular assays that predict carbon nanotube-induced fibrogenic potential and pulmonary fibrosis. The research showed MWCNT dispersal state played a key role in the production of biomarkers<sup>144</sup> TGF- $\beta$ 1, PDGF-AA, and IL-1 $\beta$  (Nel et al., 2013).<sup>145</sup>

### **3. Chrysotile Tubes & Multi-Walled Carbon Nanotubes**

This section focuses on describing the physicochemical characteristics of chrysotile, accounting for approximately 95 percent of the asbestos in world-wide commercial use, and MWCNT (Kanarek, 2011). Chrysotile fibers, actually tubes consisting of mineral layers rolled into a spiral (Bonewitz, 2005), are strikingly similar morphologically to carbon nanotubes (especially MWCNT) (Murr & Soto, 2004; Aitken et al., 2010; Sprynskyy et al., 2011). Murr & Soto (2004) suggest comparative assessments of chrysotile fibers are applicable to MWCNT, particularly since they are "essentially indistinguishable, microstructurally, from common forms of MWCNT."

Chrysotile can contain iron (Fe) at varying levels in its structure and has an intrinsic ability, along with other asbestos fibers, to attract Fe from the surrounding environment in the lungs (Foresti et al, 2009; Pascolo et al., 2013). Iron is the most common element used in carbon nanotube catalyst formulations and many nanotube samples contain varying quantities of residual catalyst (Hurt & Kane, 2005). Harington and Roe (1965) suggested that trace metals in asbestos may be associated with carcinogenicity (Morgan & Holmes, 1971). As discussed in more detail later, the presence of iron in these fibers appears to be connected to their toxicity (Pascolo et al., 2013).

The term asbestos is used to refer to two main categories of naturally occurring silicates, the serpentines and the amphiboles. Dr. Cooke's work focused on chrysotile, which is a serpentine mineral that is fibrous (See Fig. 2 below). The amphiboles include the fibrous forms of tremolite, actinolite, crocidolite (blue asbestos), anthophyllite, and amosite (brown asbestos) (Bonewitz, 2005). The physical crushing and processing of the minerals separates them into flexible fibers that can be used in manufacturing (EDF, 1978. Cooke (1929) observed that the process of manufacturing chrysotile created dust containing fiber fragments and "translucent spicules" of varying lengths and diameters.



**Figure 2: Photograph of Studied Chrysotile Sample (Source: Sprynskyy et al, 2011).<sup>2</sup>**  
This sample was used for the SEM and TEM micrographs in Figures 4-6 below (Sprynskyy et al, 2011).

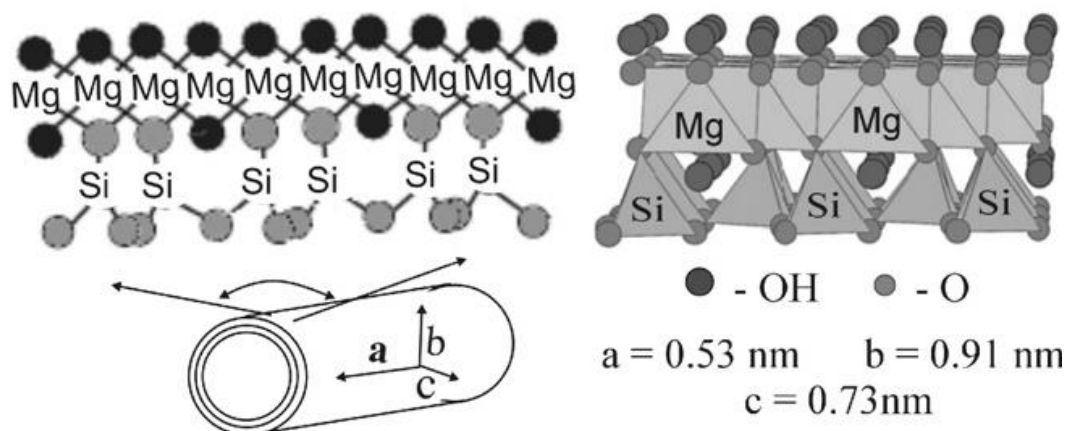
The silicate tetrahedron,  $\text{SiO}_4$ , is the typical building block of asbestos minerals (USGS, 2002; Bonewitz, 2005). Chrysotile contains the basic chemical unit  $(\text{Si}_2\text{O}_5)_n$ , which is typical for the serpentine group of minerals (Sporn, 2014). Chrysotile  $[\text{Mg}_3\text{Si}_2\text{O}_5(\text{OH})_4]$  is a hydrated (about 13% water in crystal form) magnesium sheet

<sup>2</sup> Reprinted from *Journal of Physics and Chemistry of Solids*, Vol. 72, Sprynskyy, M., Niedojadlo, J., & Buszewski, B., Structural features of natural and acids modified chrysotile nanotubes, 1015-1026, 2011, with permission from Elsevier.

silicate (phyllosilicate) (Ndlovu et al., 2011). Fe, the most common impurity in chrysotile, exists in the form of ferrous ( $\text{Fe}^{2+}$ ) or ferric ( $\text{Fe}^{3+}$ ) ions (Foresti et al., 2009; Speil & Leineweber, 1969); Fe content was 0.6 to 4.8% in some samples (Selikoff & Lee, 1978). The geothermal processes creating chrysotile formations can lead to the co-deposition of Fe-containing minerals, such as magnetite [ $\text{Fe}_3\text{O}_4$ ] or chlorite [ $\text{Mg,Al,Fe}_{12}\text{Si}_8\text{O}_{20}(\text{OH})_{16}$ ]. The mineral can contain traces of scandium (Sc), cobalt (Co), and chromium (Cr) (Morgan & Holmes, 1974). Mining and milling processes can also contaminate the chrysotile with dust particles from the host rock (USGS, 2002).

Chrysotile fiber consists of octahedral coordinated magnesium sheets bonded to silica-centered tetrahedral sheets in a pseudo-hexagonal network (Foresti et al, 2009). The fiber walls consist of multiple layers, which are roughly 0.73 nm thick (See Fig. 3 below). The internal layer of tridymite ( $\text{SiO}_4$ ) is covalently bonded with the brucite ( $\text{Mg}(\text{OH})_2$ ) outer layer (Sprynskyy et al., 2011). The tetrahedral-octahedral layers form the structure of the fibrils, curving spirally or concentrically into a hollow tubular structure or tight spiral with the magnesium hydroxide on external surface (Foresti et al., 2009) (See Figs. 4 and 5 below). The spatial imbalances between the magnesium and silica ions strains the tetrahedral-octahedral lattice, causing the layers to roll into long, continuous hollow concentric cylinders (Ndlovu et al., 2011; Sporn et al., 2104). The silica sheet is on the inside of the tubes and the magnesium layer is on the outside. Ndlovu et al. (2011) point out that this configuration likely results in the tetrahedral-octahedral edge occurring at the length and terminus of each tube.

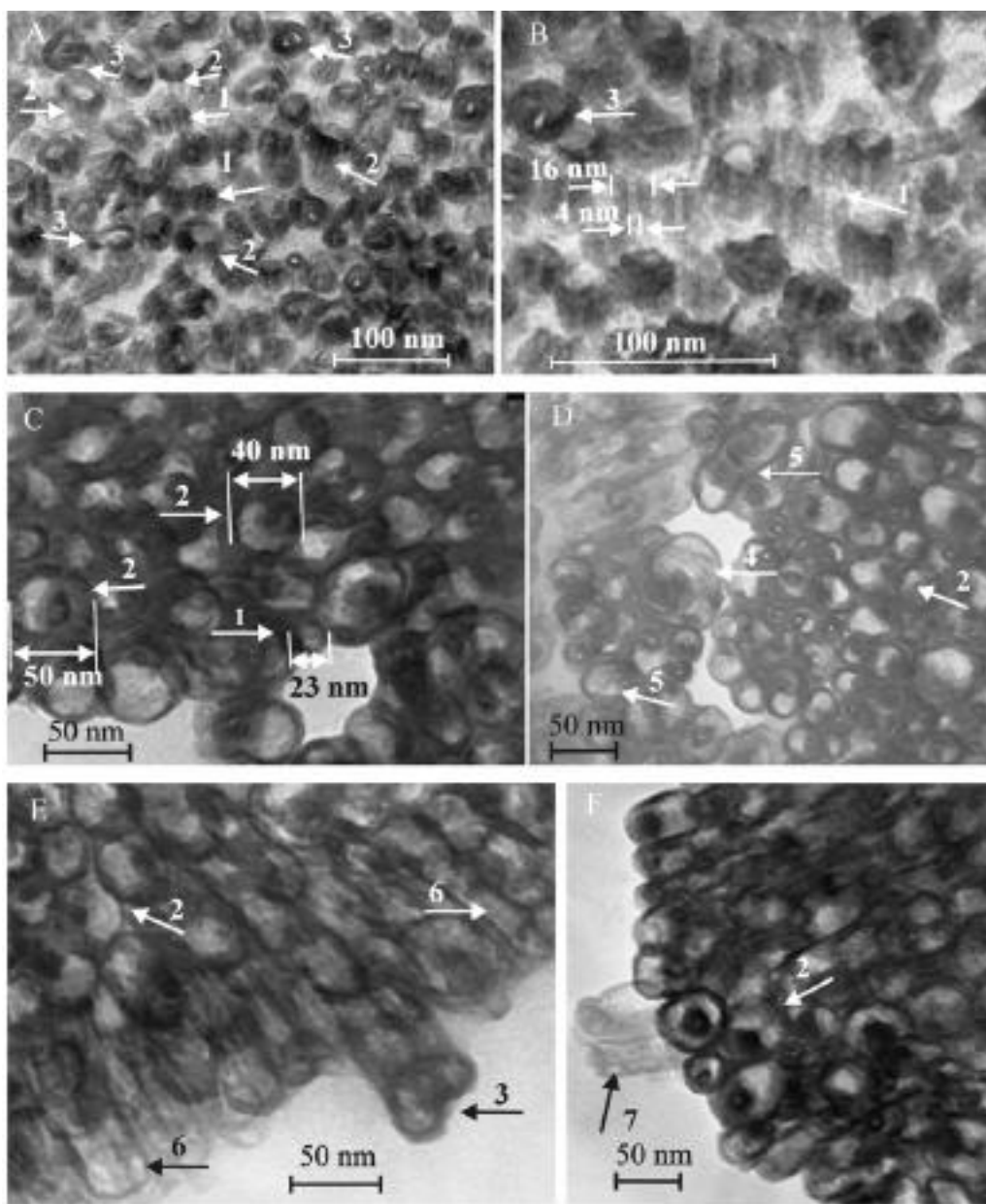
The stacking of the tetrahedral and octahedral sheets creates three types of fibers, clino-chrysotile (stacks of monoclinic layers), ortho-chrysotile (orthorhombic stacks of the layers), and para-chrysotile (180° rotation of two-layer structures), of which the clino-chrysotile are the most abundant (USGS, 2002). Foresti et al. (2009) state the outer diameter of these tubular structures measure approximately 22-35 nm and the hollow of the rolls have a diameter of about 7 nm (Foresti et al., 2009). Sprynskyy et al.'s (2011) study found the outer diameters of the chrysotile nanotubes were between 15 to 30 nm and the inner diameters ranged from 2 to 6 nm. The mean values were 20 nm and 4 nm for the outer and inner diameters, respectively. Sporn (2014) reports the diameter of the roll can measure between 2-4.5 nm.



**Figure 3: The Schematic Crystalline Structure of Chrysotile (Source: Sprynskyy et al., 2011).<sup>3</sup>**

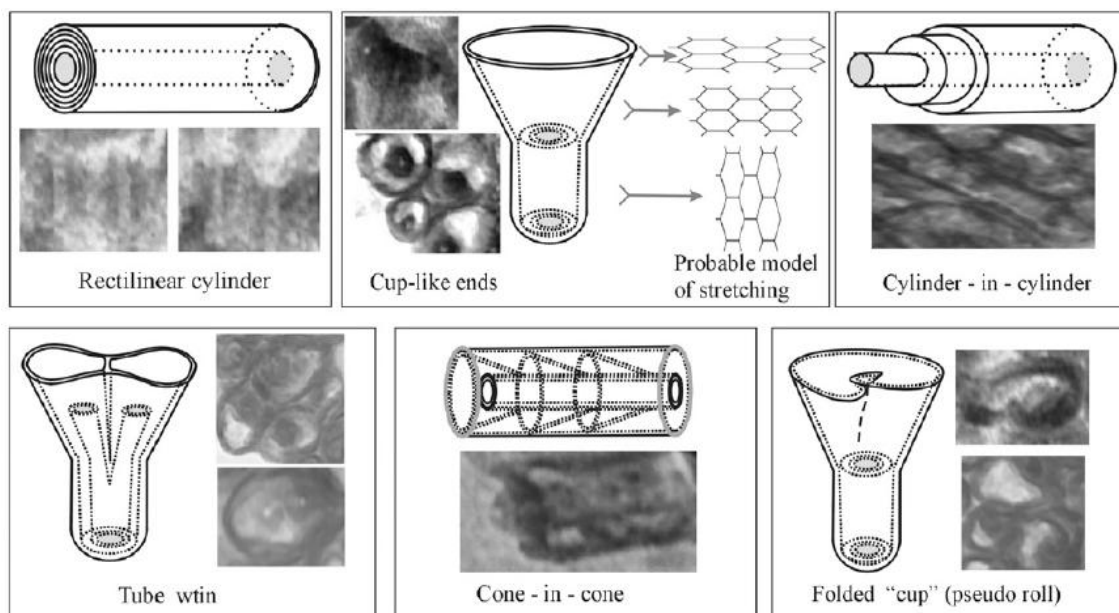
The chrysotile fibers are fibril cylinders bunched together. The crystalline structure of chrysotile remains stable until about 550°C, subject to the period of heating (Sporn, 2014). The tensile strength of the fibers ranges from 1.1-4.4 gigapascals (GPa). The higher tensile strengths are generally obtained from the short and thin fibers (Sprynskyy et al., 2011; USGS, 2002).

<sup>3</sup> Reprinted from *Journal of Physics and Chemistry of Solids*, 72, Sprynskyy, M., Niedojadlo, J. & Buszewski, B., Structural features of natural and acids modified chrysotile nanotubes, 1015-1026, 2011, with permission from Elsevier.



**Figure 4: The TEM Images of the Chrysotile Fiber Structures (Source: Sprynskyy et al., 2011).**  
 (The forms of the chrysotile nanotubes: 1—rectilinear, 2—cylinders with cup-like ends, 3—cylinders with deformed "cups", 4—folded structure of the "cup" walls, 5—phenomenon of tubes twinning, 6—cylinder-in-cylinder, 7—cone-in-cone).<sup>4</sup>

<sup>4</sup> Reprinted from *Journal of Physics and Chemistry of Solids*, 72, Sprynskyy, M., Niedojadlo, J, & Buszewski, B., Structural features of natural and acids modified chrysotile nanotubes, 1015-1026, 2011, with permission from Elsevier.

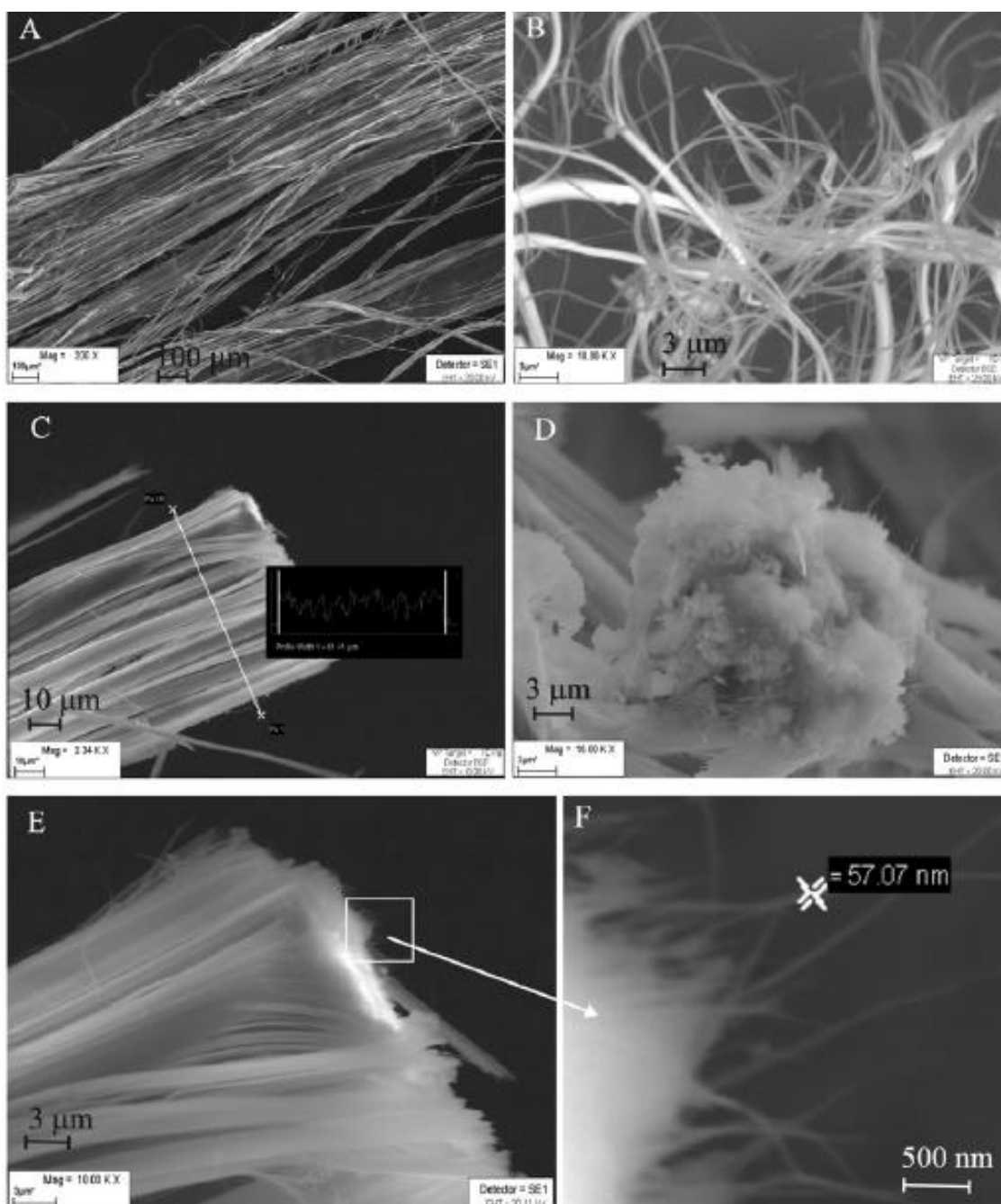


**Figure 5: Schematic Diagrams of Chrysotile Nanotubes Based on TEM Analysis (Source: Sprynskyy et al., 2011).<sup>5</sup>**

The fibers can become quite long and thin, sometimes exceeding 100  $\mu\text{m}$ , but the diameter tends to increase as the fiber lengthens (Sporn, 2014). The USGS (2002) reports that naturally occurring unit fibers have a mean diameter of about 25 nm, but industrial fibers typically have diameters between 0.1 (100 nm) to 100  $\mu\text{m}$  as aggregates of the unit fibers. Murr et al. (2005) conducted a TEM comparative analysis of chrysotile and MWCNT, noting the chrysotile fiber bundles have mean geometrical sizes ranging from 0.5  $\mu\text{m}$  to 15  $\mu\text{m}$ . The individual chrysotile tubes Murr et al. (2005) measured ranged from  $\sim 0.5$   $\mu\text{m}$  to over  $\sim 15$   $\mu\text{m}$  in length; their diameters were between 15 nm to  $\sim 40$  nm. Selikoff and Lee (1978) state the chrysotile fibril "is the finest natural fiber known" (See Fig. 6 below). While individual chrysotile fibers range from 0.75  $\mu\text{m}$  (750

<sup>5</sup> Reprinted from *Journal of Physics and Chemistry of Solids*, 72, Sprynskyy, M., Niedojadlo, J, & Buszewski, B., Structural features of natural and acids modified chrysotile nanotubes, 1015-1026, 2011, with permission from Elsevier.

nm) to 1.5  $\mu\text{m}$  in diameter, fibril diameters can range from 0.02 (20 nm)  $\mu\text{m}$  to 0.04  $\mu\text{m}$  (40 nm) (Selikoff, 1978). These smaller fibrillar units can split off from the frequently splayed ends of chrysotile's serpentine fibers (Sporn, 2014). A single fiber may fragment into 1000 fibrils or more (Wagner, 1973).



**Figure 6: SEM Micrographs of the Chrysotile Fibers at Different Magnifications** (Source: Sprynskyy et al, 2011).<sup>6</sup>

<sup>6</sup> Reprinted from *Journal of Physics and Chemistry of Solids*, Vol. 72, Sprynskyy, M., Niedojadlo, J., & Buszewski, B., Structural features of natural and acids modified chrysotile nanotubes, 1015-1026, 2011, with permission from Elsevier.



Gray (2012) reports asbestos toxicity tends to rise with greater aspect ratios (ratio of length to diameter). Englert et al. (2014) note that for aspect ratio between 10 and 100, a fiber's aerodynamic equivalent diameter is three to four times greater than the actual diameter. Murr et al.'s (2005) research suggests chrysotile fiber aspect ratios can reach between 50 to over 1500. Popescu et al. (2013) reported chrysotile ranges between  $10^5$ - $10^6$  for individual fibrils and  $10^4$ - $10^5$  for bundles (Popescu et al., 2013). By comparison, Gray (2012) states carbon nanotube aspect ratios can range from  $10$ - $10^8$ —greater than that of any other material. Al-Rub et al. (2012) studied the effects of MWCNT with aspect ratios of 1250-3750 in cement paste. Popescu et al. (2013) provided data on MWCNT and SWCNT, with aspect ratios ranging from  $10^2$ - $10^3$  to  $10^4$ - $10^5$ , respectively. The aspect ratio of SWCNT matched that of the chrysotile bundles (Popescu et al., 2013). Based on the information provided in Englert et al.'s (2014) study, chrysotile and MWCNT fibers with an aspect ratio of 10 or more can only reach the lower respiratory tract of a rat if the diameter of the fiber measures approximately 2  $\mu\text{m}$  or less.

Some studies reportedly show fiber surface area is the key factor in determining the seriousness of pulmonary fibrosis (Englert et al., 2014). The surface area of fibers generally depends on the degree of their openness or porosity (WHO, 1998). Fibrous erionite, which has an internal surface area of 200  $\text{m}^2/\text{g}$  because of "pores" in its crystal lattice, reportedly has much higher potential to induce mesothelioma than asbestos fibers (Englert et al., 2014). The surface area of chrysotile, higher than that of the amphiboles,<sup>146</sup> typically reaches 4  $\text{m}^2/\text{g}$  when separated manually from block ore, but increases to 50  $\text{m}^2/\text{g}$  as the sample is broken down into smaller fibers (Selikoff, 1978).

The New Idria (Coalinga) chrysotile, with a mean fibril diameter of 0.0275  $\mu\text{m}$  (27.5 nm), has surface area of approximately 78  $\text{m}^2/\text{g}$  (WHO, 1998). The average fibril diameter of Canadian commercial grade 7R chrysotile is 0.0375  $\mu\text{m}$  (37.5 nm) (WHO, 1998); the surface area is about 50  $\text{m}^2/\text{g}$  (WHO, 1998). Chrysotile readily absorbs gases, especially those with highly polar molecules such as water, because of its structure and relatively large surface area (Selikoff, 1978). MWCNT generally have a surface area that ranges between 253-400  $\text{m}^2/\text{g}$  (Martinez et al., 2014).

The surface charge of fibers can play an important role in their toxicity. Englert et al. (2014) states highly charged fibers are more likely to be deposited in the lung, particularly with respect to long fibers. Davis et al.'s (1988) study shows that electrostatically charged chrysotile fibers cause more fibrosis than charge neutralized fibers (Englert et al., 2014). The fibers of chrysotile are strongly cationic and toxic, increasing their oncogenic potential (Ndlovu et al., 2011). The lung's degradation of the soluble magnesium molecules on the outside of chrysotile's tubular structures helps reduce the concentration of magnesium, which changes the surface charge to negative and decreases toxicity (Sporn, 2014). Chrysotile fibers also tend to aggregate (chemically bond) with adjacent fibers, becoming entangled within themselves and adjacent fibers (Ndlovu et al., 2010). MWCNT have a tendency to agglomerate (physically bond) when aerosolized, which can impact inhalation and deposition in the lung. By comparison, Li et al. (2013) showed that relative to pristine MWCNT *in vivo*, strongly cationic MWCNT can induce substantial lung fibrosis.

Englert et al. (2014) suggest the importance of chrysotile magnesium leaching for *in vivo* studies is controversial, but potentially significant because the reduction of magnesium *in vitro* is linked to a decrease in cytotoxicity and carcinogenicity. Sporn (2014) suggests the lung's ability to degrade the chrysotile fibers is facilitated by magnesium leaching at the surface of chrysotile's structure. This leaching process reportedly helps the lung breakdown the fibers which are weakened by the acid conditions associated with alveolar macrophages, into gradually smaller fibrils, which can be phagocytized and readily cleared from the lung when they are sufficiently short (Sporn et al., 2014). At the same time, the fibers tend to split longitudinally into individual fibrils during degradation, which creates fibrils with smaller diameters. Englert et al. (2014) suggest this process increases fiber number and surface area. McClellan (1995) suggests chrysotile fibers almost completely disperse in the human lung as fibrils during their long residence time in the lung, which increases the surface area of the retained chrysotile.

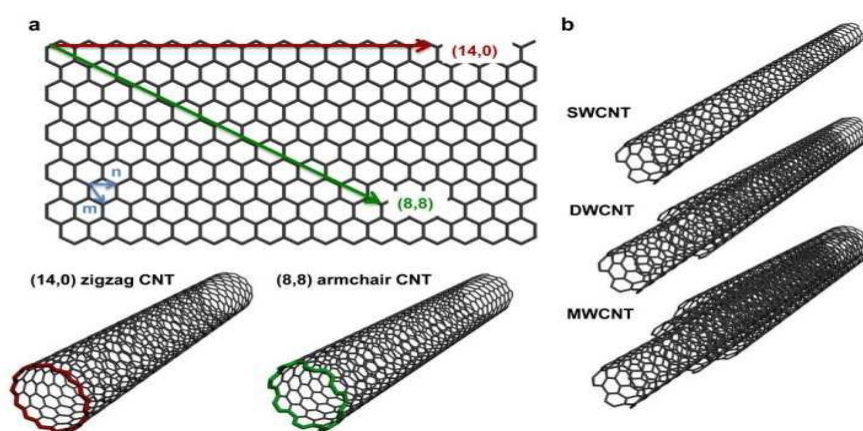
The USGS (2002) suggests the process of magnesium leaching could increase the surface area of the fibers; extensive acid leaching of amorphous silica, for example, can increase the surface area to  $450 \text{ m}^2/\text{g}$ .<sup>147</sup> Sprynskyy et al. (2011) performed acid treatments on chrysotile samples, which removed mineral admixtures and raised the volume of pores, increasing the surface areas from  $15.3 \text{ m}^2/\text{g}$  to  $63.6 \text{ m}^2/\text{g}$ . Hume and Rimstidt (1992) provide a dissolution model for chrysotile fibers in the human lung based on the chrysotile's stoichiometric chemical composition  $[\text{Mg}_3\text{Si}_2\text{O}_5(\text{OH})_4]$ , concluding that damage to the lung tissue must take place soon after exposure because the mineral

starts to dissolve in the acid (Hume & Rimstidt, 1992). Hume and Rimstidt (1992), however, did not address the issue of Fe content in chrysotile and the possible impact on dissolution and toxicity. Sprynskyy et al. (2011) report that their acid treatments of chrysotile did not reduce the Fe content of the samples (they assume the Fe contaminants consist of weakly soluble accessory minerals or exist in the isomorphic form in the tetrahedral layers). The mean mass of the Fe content increased from 1.1% to 1.6% relative to the other elements in the leached samples.<sup>148</sup>

The nanotube structures found in inorganic chrysotile are similar morphologically to the nanotubes of carbonic frameworks (Sprynskyy et al., 2011). Carbon nanotubes are generally described as seamless nanoscale cylinders consisting of concentric graphene sheets (Schnorr & Swager, 2011). The physicochemical characteristics of engineered carbon nanotubes depend on the conditions, materials, methods, and techniques used to manufacture and process the nanotubes. As a result, carbon nanotubes often vary in shape, dimension, chemical composition, physical characteristics, surface coatings, and surface functionalization (NIOSH, 2013; Li et al., 2013). This chapter focuses on MWCNT, which are the subject of numerous recent toxicity studies.

SWCNT typically have a diameter of about 1-2 nm, whereas the diameter of MWCNT can range from 2-170 nm, depending on the number of single-walled tubes making up the MWCNT structure (NIOSH, 2013). Carbon nanofibers have diameters that range from 40 to 200 nm and tens of micrometers to several centimeters long. Carbon nanofibers, which are morphologically similar to MWCNT, are mainly distinguished from MWCNT based on graphene plane alignment (i.e., when the plane

does not align with the fiber axis) (See Fig. 7 below). According to international standards, a MWCNT structure is one in which the graphene plane is parallel with fiber axis (IOS, 2008). The length of MWCNT ranges from 20 nm to 200  $\mu\text{m}$  long (NIOSH, 2013; EPA, 2013). For example, some MWCNT produced by Cheap Tubes® have lengths between 10-30  $\mu\text{m}$ , outer diameters between 20-30 nm, and inner diameters ranging from 5-10 nm (Wang et al., 2010). MWCNT typically have a Young's modulus approaching 1000 GPa, tensile strengths ranging from 20-100 GPa, bundle size between 0.9-100  $\mu\text{m}$ , melting point of 3652-3697  $^{\circ}\text{C}$ , zeta potential (mV) of -23-0,<sup>149</sup> a density of 2.1 g/mL at 25  $^{\circ}\text{C}$ , and remain stable up to 600  $^{\circ}\text{C}$  (EPA, 2013). In comparison to the strongest steel, MWCNT possess a tensile strength 100 times stronger, an elasticity modulus five times greater, an elastic strain capacity 50 times more, and a specific gravity that is six times less than steel (Al-Rub et al., 2012).



**Figure 7: Structural Variety of Carbon Nanotubes** (Source: Schnorr & Swager, 2011).<sup>7</sup>

(a) The direction of the red arrow depicts the orientation of the carbon network in the zigzag carbon nanotubes ( $n, 0$ ) and the direction of the green arrow shows that of the armchair carbon nanotubes ( $n, n$ ). (b) Graphical depiction of the structure SWCNT (single-walled carbon nanotube) (single graphene sheet), double-walled

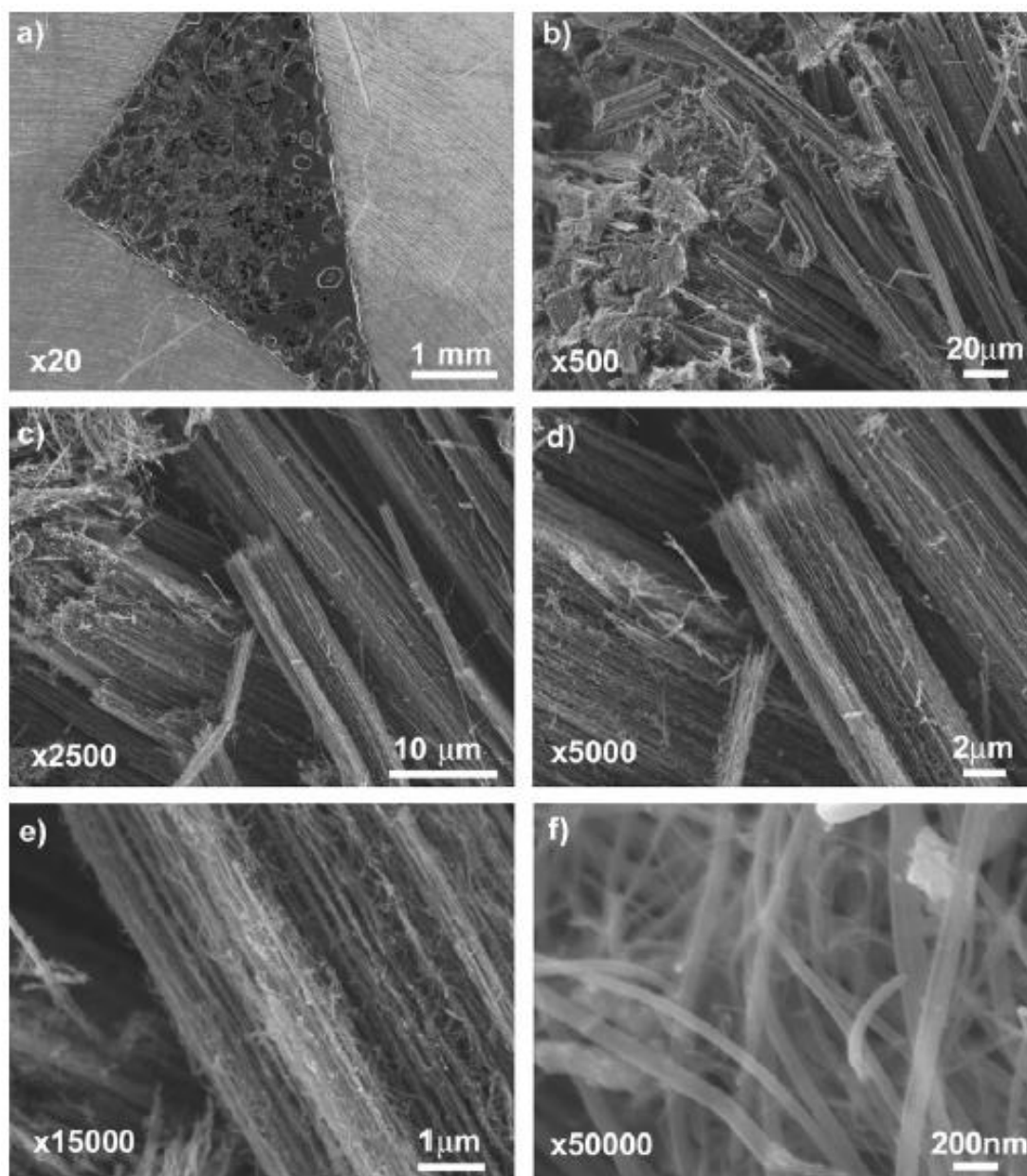
<sup>7</sup> Reprinted with permission from *Chemistry of Materials*, 23(3), Schnorr, J.M., & Swager, T.M, Emerging applications of carbon nanotubes, 646-657. Copyright (2011) American Chemical Society.

carbon nanotubes (DWCNT) (two single-walled tubes), and MWCNT ( a number of SWCNT stacked one inside the other) (Schnorr & Swager, 2011; NIOSH, 2013; Monthieux et al., 2014).

MWCNT are produced using synthetic methods that consist of the thermal vaporization of carbon and metal catalysts (Lam et al., 2006). Carbon sources, such as graphite, gaseous carbon-bearing compounds, methane or other hydrocarbons, and energy sources are needed for synthesis (Carrero-Sanchez, 2006). Lam et al. (2006) note that commercial vendors use arc discharge or pulsed laser vaporization techniques to vaporize carbon atoms or clusters from graphite, producing carbon nanotubes; a chemical-vapor deposition (CVD) method, which thermally and catalytically generates carbon atoms from hydrocarbon precursors, can also produce carbon nanotubes. Richard E. Smalley's laboratory at Rice University developed the patented HiPco (high-pressure CO conversion) process, which involves growing SWCNT from carbon atoms produced from a continuous high-pressure stream of carbon monoxide (Lam et al., 2006).

The synthesis process, carbon source, metal catalysts, temperature, and reaction time all influence the dimensions, shape, symmetry, growth rate, and crystallinity of the MWCNT generated (See Figs. 8 and 9 below) (NIOSH, 2013). As the MWCNT are typically synthesized in an inert atmosphere ranging from 600 to 1200°C, metal catalysts such as Fe, cobalt (Co), nickel (Ni), and molybdenum (Mo) are often used because they are catalytically active and molten at the temperature of MWCNT synthesis (Lam et al., 2006). These conditions allow for the dissolution of carbon atoms into the metals (Lam et al., 2006). The purity of MWCNT varies based on the production methods, but they are typically over 90 percent pure (EPA, 2012). Levine et al. (2014) note that MWCNT

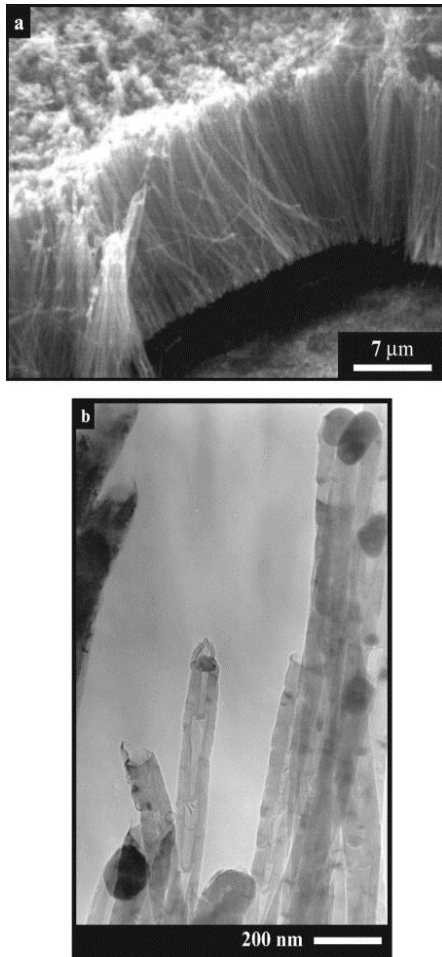
impurities can include Fe, Co, Ni, Mo, or yttrium because these elements are commonly used as catalysts for MWCNT synthesis. The contents of some Cheap Tube® MWCNT, for example, measured 4.49% Ni and 0.76% Fe (Wang et al., 2010). MWCNT products can also include carbon impurities, such as fullerene, soot, and graphite (Lam et al., 2006).



**Figure 8: SEM Images of Nanotube Sample Produced by CVD Process (Source: Lehman et al., 2011).** (Nanotube area defined by triangular carbon tape in (a)). The images were recorded at different magnifications in order to visualize the overall sample and the morphology of the tubes and way they are arranged. In this case, the sample contains bundles of aligned nanotubes (or nanofibers), and the amount of unwanted particles is relatively small.<sup>8</sup>

<sup>8</sup> Reprinted from *Carbon*, 49, Lehman, J.H., Terrones, M., Mansfield, E., Hurst, K.E., & Meunier, V., Evaluating the characteristics of multiwall carbon nanotubes, 2581-2602, Copyright (2011), with permission from Elsevier.





**Figure 9: SEM (a) and TEM (b) Micrographs of Multi-Walled Carbon Nanotubes (Source: Zilli et al., 2005).<sup>9</sup>**

Levine et al. (2014) used energy dispersive X-ray fluorescence to analyze 24 samples of non-functionalized MWCNT purchased from seven different commercial vendors. All 24 of the samples contained Fe, with concentrations ranging from .00733 to 7.16%; Ni was detected in 22 samples (<limit of quantitation (LOQ) to 5.54%), Co in 16 samples (<LOQ to 4.72%), and Mo in 16 samples (<LOQ to 14.3%). Yttrium was <LOQ for all samples, but the analysis detected lanthanum, lead, or chromium in 10 of the study

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<sup>9</sup> Reprinted from *Polymer*, Vol. 46/16, Zilli D., Chiliotte C., Escobar, M.M., Bekeris, V., Rubiolo, G.R., Cukierman, A.L., & Goyanes, S., Magnetic properties of multi-walled carbon nanotube–epoxy composites, 6090-6095, Copyright (2005), with permission from Elsevier.

samples (the LOQ was 0.004% weight for each element; metal concentrations that fell below the LOQ were not provided in the summed value) (Levine et al., 2014). The scanning electron microscopy (SEM) data collected showed the MWCNT length's generally did not correlate with the vendor specifications. In addition, the high-resolution transmission electron microscopy (HR-TEM) data showed the MWCNT diameters were uniformly lower than the specifications for the MWCNT with diameters between 60-100 nm (Levine et al., 2014). These findings led to a vendor's subsequent revision of their certificates of analysis, reinforcing the importance of fully analyzing the physicochemical properties of a particular MWCNT type before conducting a toxicological investigation. Levine et al. (2014) suggest the variability in MWCNT properties play a key role in the current challenges associated with reproducing the findings in many toxicological investigations on MWCNT.

Post-synthesis treatments can be applied to remove residual metals from MWCNT and increase purity (NIOSH, 2013). Manufacturers typically remove the impurities by oxidizing the amorphous carbon at a controlled temperature. Afterwards, the materials is washed or sonicated in an acid (HCl, HNO<sub>3</sub>, H<sub>2</sub>SO<sub>4</sub>) or base (NaOH).<sup>150</sup> Pristine MWCNT can have low solubility and dispersibility in organic and inorganic solutions (they are insoluble in water). By contrast, chrysotile fibers are slowly soluble in water (Selikoff & Lee, 1978). Functionalization treatments, however, can alter MWCNT solubility. Manufacturers attempt to improve dispersibility by introducing hydrophilic chemical groups to the material surface (Li et al., 2014). These treated carbon nanotubes are used as catalysts, absorbents, intracellular carriers, imaging agents and electrodes (Li

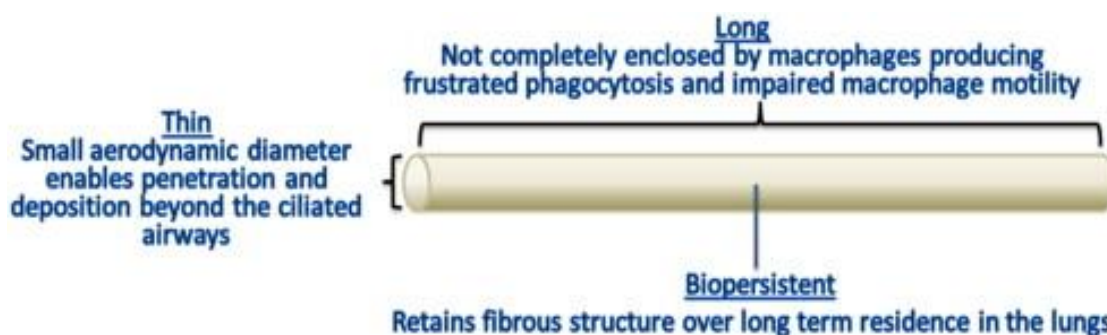
et al., 2013). Manufacturers can use covalent and noncovalent methods to synthesize functionalized carbon nanotubes; terminal carboxylation and sidewall modifications of the tube surface are approaches most often employed in covalent functionalization.<sup>151</sup>

#### **4. Fiber Pathogenicity Paradigm**

The fiber pathogenicity paradigm (FPP), which predicts fiber pathogenicity based on the fiber's length, diameter, and biopersistence, was developed from decades of research on asbestos and synthetic fibers.<sup>152,153</sup> Donaldson et al. (2010) describe the FPP as follows:

The FPP identifies the geometry of fibers as their most important toxicological characteristic and not the chemical make-up, except in so far as the composition makes a contribution to biopersistence. This independence from composition is evidence in the fact that the paradigm embraces fibers composed of diverse materials including amphibole and serpentine asbestos minerals, vitreous and ceramic fibers and organic fiber. Diameter is important because of the central role that fiber diameter plays in defining aerodynamic diameter and the dependence of pulmonary deposition on aerodynamic diameter. Clearance from beyond the ciliated airways is dominated by slow, macrophage-mediated clearance and so fibers which deposit there have the potential to contribute most to build-up of dose...The penetration of long fibers (>50  $\mu\text{m}$ ) beyond the ciliated airways is explicable on the basis that the aerodynamic diameter of a straight fiber is around 3 times its actual diameter...The experience with asbestos highlighted that high aspect ratio particles (fibers) pose an additional hazard to the lung beyond that produced by conventional compact particles and gave rise to the discipline of fiber toxicology.<sup>154</sup>

Donaldson et al. (2010) and others have used the FPP as a means to develop insights on MWCNT toxicity.<sup>155</sup> Carbon nanotubes and nanofibers, some of which are long, thin, and biopersistent, have been associated with the induction of inflammatory and fibrogenic asbestos-like effects in the lung (See Fig. 10 below) (Donaldson et al., 2013).

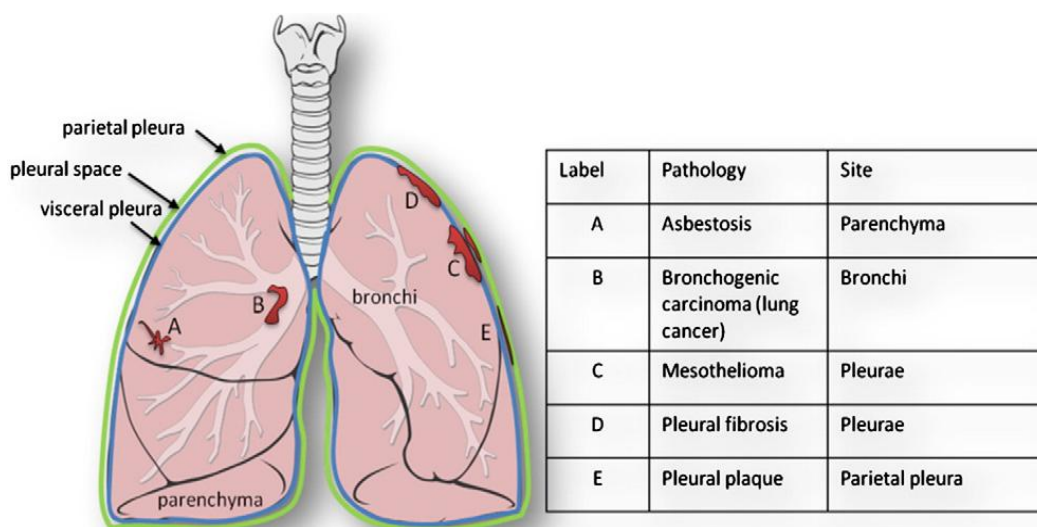


**Figure 10: Diagram Summarizing the Fiber Pathogenicity Paradigm. Three Biophysical Characteristics Govern Whether a Fiber will be Pathogenic — Length, Thinness and Biopersistence (see text for clarification) (Source: Donaldson et al., 2013).<sup>10</sup>**

Van Berlo et al. (2014) state that lung fibrosis is one of most dangerous pathologies linked to asbestos (See Fig. 11 below). Lung fibrosis involves the replacement of healthy tissue with connective tissue. The connective tissue, which is inflexible, decreases breathing efficiency; severe fibrosis can reduce activity and lead to major organ failure and death (Hinkley et al., 2014). Fibrous dust can create a pro-fibrotic environment in the lung via immune-mediated mechanisms:

[I]nhaled particles that lead to a type 2-dominant T helper cell profile with induce an inflammatory response leading to IL-13 release; IL-13 will then induce TGF- $\beta$ 1 release, producing several pro-fibrotic downstream effects. Particles can also create these inflammatory conditions through the induction of TNF- $\alpha$  release, which, like IL-13 will induce TGF- $\beta$ 1. Both collagen deposition and release of connective tissue growth factor are downstream effects of TGF- $\beta$ 1 release, increasing the likelihood of developing fibrosis (Hinkley et al., 2014).

<sup>10</sup> Reprinted from *Advanced Drug Delivery Reviews*, Vol. 65, Donaldson, K., Poland, C. A., Murphy, F. A., MacFarlane, M., Chernova, T., & Schinwald, A., Pulmonary toxicity of carbon nanotubes and asbestos — Similarities and differences, 2078-2086, Copyright (2013), with permission from Elsevier.



**Figure 11: Diagram Showing the Situation of the Types of Pathology Caused by Fibers** (Source: Donaldson et al., 2013).<sup>11</sup>

Van Berlo et al. (2014) point out that *in vivo* studies investigating the fibrotic potential of MWCNT have produced both positive<sup>156</sup> and negative<sup>157</sup> findings. They also note the inconsistencies in the scientific findings on MWCNT granuloma formation. Van Berlo et al. (2014) showed that both short and long MWCNT caused granuloma formation in the mouse lung, but the long MWCNT induced a stronger inflammatory and pro-fibrotic response. The longer MWCNT (about 5-6  $\mu\text{m}$  long) were typically rigid and needle-shaped, whereas the shorter nanotubes frequently existed in highly entangled forms, like a ball of wool (Van Berlo et al., 2014). Donaldson et al. (2013) point out that long carbon nanotubes that take on a fibrous, high-aspect structure behave like fibers, as opposed to short tangles or bundles (in which case they act like particles) (Donaldson et al., 2013). Their study, in keeping with the FPP, revealed the physicochemical properties

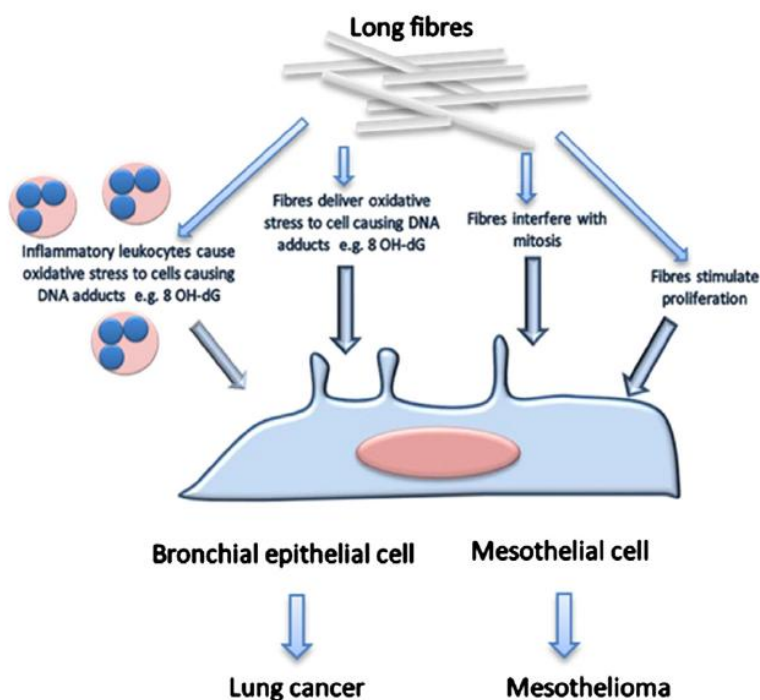
<sup>11</sup> Reprinted from *Advanced Drug Delivery Reviews*, Vol. 65, Donaldson, K., Poland, C. A., Murphy, F. A., MacFarlane, M., Chernova, T., & Schinwald, A., Pulmonary toxicity of carbon nanotubes and asbestos — Similarities and differences, 2078-2086, Copyright (2013), with permission from Elsevier.

of MWCNT, such as length, rigidity, and associated agglomeration properties, play an important role in determining the inflammatory and pro-fibrotic responses in the mouse lung (Van Berlo et al., 2014). Against this backdrop, notes Donaldson et al. (2013), it is important to know whether the exposure is to particulate or fibrous forms of carbon nanotubes (See Fig. 12 below).

The FPP illustrates the role long, rigid fibers play in frustrating phagocytosis and causing inflammation in the lung. The alveolar macrophages, which are the cells that predominantly engage the chrysotile and MWCNT fibers deposited on the pulmonary tissue, surround the shorter inhaled fibers and fold back onto its cell body (Selikoff & Lee, 1978). The alveolar macrophages can engulf and clear the shorter fibers from the lungs, but not the longer ones. This inability to enclose the longer fibers leads to inflammation (Donaldson et al., 2010).

The hallmark of asbestos exposure is the identification of asbestos bodies in histologic sections of the lung (Roggli, 2014). The "curious bodies" (asbestos bodies) that Cooke investigated can form after the process of fiber phagocytosis. Roggli (2014) states asbestos bodies are dumbbell-shaped, beaded or segmented, and golden brown in color. The bodies typically form in the manner Roggli (2014) describes below:

Asbestos bodies form when an asbestos fiber is inhaled and deposited in the distal regions of the lung parenchyma. Here the free alveolar macrophages phagocytose the fiber...[T]hrough a process which is poorly understood, the fiber becomes covered with a layer of iron-protein-mucopolysaccharide material...[T]his process (may be) a means of host defense, since *in vivo* as well as *in vitro* studies have shown that asbestos bodies are nonfibrogenic and noncytotoxic in comparison to uncoated asbestos fibers...[T]he iron coating is bound in such a way that it does not efficiently participate in the generation of reactive oxygen species...Ghio *et al.* have proposed that coating process is a marker for particle-induced oxidative stress.



**Figure 12: Diagram Summarizing the Hypothesized Mechanistic Events Mediated by Long Fibers that Lead to Genotoxic and Carcinogenic Effects in Bronchial Epithelial or the Mesothelial Target Cells (Source: Donaldson et al., 2013).<sup>12</sup>**

The asbestos bodies found in chrysotile workers, such as miners or millers, typically have chrysotile fiber cores. The thicker chrysotile bundles are more likely than the fibrils to become coated (Roggli, 2014). Roggli (2014) states asbestos bodies typically form on fibers that are 20  $\mu\text{m}$  or more in length. As chrysotile readily fragments into many smaller fibrils, this could account for the fact that chrysotile asbestos bodies are relatively rare compared to the amphiboles. Roggli (2014) suggests the dimensions of carbon nanotubes, particularly MWCNT, makes it possible for carbon nanotubes to form the cores of ferruginous bodies. Sporn (2014) states that the animal

<sup>12</sup> Reprinted from *Advanced Drug Delivery Reviews*, Vol. 65, Donaldson, K., Poland, C. A., Murphy, F. A., MacFarlane, M., Chernova, T., & Schinwald, A., Pulmonary toxicity of carbon nanotubes and asbestos — Similarities and differences, 2078-2086, Copyright (2013), with permission from Elsevier.

models show that the carcinogenic potential of fibrous dust increases as the diameter of fiber decreases and shorter fibers tend to be less oncogenic than longer fibers; the physical characteristics are generally more important than chemical composition in inducing adverse effects in the lung.<sup>158</sup> The latest study Sporn cites to make this point, however, is 1998. There have been a number of papers published on the matter since, some of which are discussed in this chapter. While longer fibers have more potency to induce cell injury, proliferation, inflammation, and the release of oxidants, Sporn posits it is the durability of the fibers that makes them biopersistent and capable of inducing malignant disease (Sporn, 2014).

Donaldson et al. (2010) point out that fiber length and biopersistence interact to determine whether the body can clear the fibers from the lungs. The extent to which diameter and fiber lengths are more important in inducing toxic responses depends on the composition of the fiber, the experimental models, exposure, and other physicochemical factors. Li et al.'s (2013) *in vivo* experiments using raw and functionalized MWCNT, for example, suggest surface charge plays a key role in determining the potential for functionalized MWCNT to induce pro-fibrogenic effects in the lung (Wang et al., 2011). Hurt and Kane (2005) note that Fe, the most common element used in carbon nanotube and nanofiber catalysts, is the redox-active species (ROS) in asbestos, which can generate free radicals in the presence of physiologic reductants such as ascorbate. Foresti et al. (2009) suggest the substitution of Fe ions for Mg and/or Si in the crystal framework can increase the dehydroxylation temperature and influence the toxic effects on biological systems.<sup>159</sup> Pascolo et al. (2013) suggest the presence of Fe in asbestos fibers is an



important factor for toxicity and the formation of asbestos bodies. Pascolo et al. (2013)

explain this phenomenon in their study:

The formation of an asbestos body...results in the deposition of endogenous iron, iron containing proteins (as ferritin), mucopolysaccharides and other material on bio-persistent fibres in the lungs. On one hand, it is believed that the shell that is formed isolates the fibre from the tissue and reduces its damaging effect. On the other hand, the locally altered homeostasis of iron produced by the reaction to asbestos fibres and body formation, together with the presence of a potentially reversible iron reservoir constituted by the iron-containing protein aggregates, is considered as responsible for an increase of iron mediated ROS production. This may trigger asbestos related diseases, with potential DNA damage and apoptosis resistance...It is interesting that according to the most recent views, the central role of iron in asbestos toxicity and related diseases pathogenesis is consistent with a more general picture of a steadily growing number of diseases characterized by imbalance of the iron metabolism in cells and tissues.

Some studies suggest iron trace metals in MWCNT may generate ROS, potentially through the Fenton reaction (Cheng et al., 2009). The Fe contaminant in MWCNT are mainly in the form of metallic or metal oxide cluster or nanoparticles, which may be exposed to the solvent contact or embedded in the nanotube (Aldieri et al., 2013). Aldieri et al. (2013) investigated the toxicity of MWCNT containing Fe impurities; data showed that Fe-rich MWCNT were cytotoxic and genotoxic to murine alveolar macrophage. Li et al. (2013) found that exposure to MWCNT with high Fe content can diminish the viability of rat pheochromocytoma (PC12) cells. Cheng et al. (2009), however, exposed human macrophage cells to purified MWCNT, which were primarily contaminated with  $\text{Fe}^2\text{O}^3$ . They report that the MWCNT structure, not its chemical composition, was toxic to the cells (Cheng et al., 2009).

Donaldson et al. (2010) hypothesize in their study that MWCNT, like other long fibers, can reach the pleura, where their retention in the parietal pleura can cause

inflammation and pleural pathology (e.g., mesothelioma). They provide evidence that some particles are cleared from the pleura through the stomata in the parietal pleura, but some long fibers cannot be negotiated out of the stomata. This leads to inflammation in the parietal pleura, which they argue is mesothelioma's site of origin (Donaldson et al., 2010). Stone et al. (2012) suggest oxidants on the surface of carbon nanotubes, as with asbestos fibers, could contribute to the adverse effects their structure potentially has on the mesothelial cells. The Fe content of asbestos, however, is not likely to be the only source of ROS production; oxidants on the fiber surface are likewise not the sole reason for asbestos effects (Foresti et al., 2009). Stone et al. (2012) suggest direct and indirect oxidant production play a role in mesothelial cell responses to asbestos.

The interaction of other particulates and chemicals in lung, such as tobacco smoke, is also a major factor in disease risk and development. The CDC released preliminary findings from a laboratory study in 2013, which showed mice receiving an initiator chemical (a known carcinogen) and then MWCNT were 90 percent more likely to develop tumors than mice exposed solely to the initiator.<sup>160</sup> Donaldson and Seaton (2012) emphasize that cigarette smoke exceeds asbestos in terms of risks of cancer and ill health, but remains a marginal issue for particle toxicologists:

[A]part from a smattering of papers in the early years, particle toxicology has not embraced cigarette smoke. This has become even more marked in the last 20 years, when the ability to publish toxicological (as opposed to epidemiological) research on cigarette smoke effects has been greatly impaired and those studying cigarette smoke, or taking funds for that purpose, have become to an extent marginalised by the scientific community. To our knowledge no papers on cigarette smoke have ever appeared in the journals *Particle and Fibre Toxicology* nor in *Nanotoxicology* and very few have ever appeared in the *Inhaled Particles* series or the *Particle Toxicology* series. From the point of view of toxicology the relationship between the main pathological consequences in the lungs—cancer and COPD—and particulate

versus the gaseous and organic phases is not resolved and particles themselves may not play the primary role. Cigarette smoke remains (a)...complicated political and social issue.

## **5. *In Vivo* & *In Vitro* Studies**

The National Nanotechnology Initiative (NNI) Environmental, Health, and Safety Research Strategy lists the ability to develop and apply reliable and reproducible *in vivo* and *in vitro* assays and models as critical to predicting *in vivo* human responses to carbon nanotubes and other engineered nanomaterials.<sup>161</sup> Table 1 below provides a summary of published *in vivo* studies using chrysotile and MWCNT. The table is not intended to be an exhaustive account of the relevant literature. It was anticipated that the degree and nature of biological responses to chrysotile and MWCNT would vary among studies based on the physicochemical properties of the fibers, animal species, administration method, and experimental design (Nagai & Toyokuni, 2010; Popescu et al., 2013). While the biological responses vary, the findings in recent *in vivo* and *in vitro* studies suggest carbon nanotubes can induce granulomatous inflammation, early onset and persistent pulmonary fibrosis, interstitial fibrosis, epithelioid granulomas (microscopic nodules), mesothelial cell proliferation, cellular atypia, DNA binding and damage, errors in chromosome number, mutations and disruption of the mitotic spindle, and hypertrophied and hyperplastic bronchiolar and alveolar epithelial cells (NIOSH, 2013; Sargent et al., 2010).

The findings suggest differences in the potency of SWCNT and MWCNT to cause interstitial fibrosis and the ability of the fibers to penetrate the lung's subpleural tissue, visceral pleura, and translocation to the intrapleural space. Carbon nanotubes,

whether purified, unpurified, dispersed or agglomerated, have been shown to induce adverse responses in the lungs of rats and mice at relatively low doses (NIOSH, 2013). These findings are important and relevant to consider for potential human exposure (NIOSH, 2013). The time period of the toxicity studies largely did not extend over the whole lifetime of the experimental animals; only three of the studies extended beyond six months: two years (chrysotile); nearly one year (MWCNT), and six months (MWCNT).

**Table 1: Effects of Chrysotile & Multi-Walled Carbon Nanotubes *in Vivo***

Length (µm)	Diameter (nm)	Fiber/Purity/ Charge	Surface Area/AS	Admin- istration	Time Period	Species/ Sex	Findings
6-15 (mean)	200 (0.2 µm)	Chrysotile; Fe: 2.8% ±0.4	Not provided	Inhalation (4h/d.); 47.9 mg/m <sup>3</sup> ±3.0 (mean)	2 yrs (4d/w, 1480 hrs total)	Mice, Rats, Rabbits, Guinea pigs, gerbils; M & F	Lung: Rats: proliferative fibrosis, low-grade fibrosarcoma (617 d; death); papillary carcinoma (608 d; death), squamous cell carcinoma (43 d; death); Mice: mild to moderate fibrosis linked to pulmonary deposits of fibers (Reeves et al., 1974).
3.86 (med.)	49 (mean); 40-90	MWCNT; Fe: 1.06 %	SA: 26 m <sup>2</sup> /g	Inhalation (5h/d), 5 mg/m <sup>3</sup>	12d (4 x w/3w); 336d	Mouse, C57BL/6 J; M	Lung: fibrotic response developed and persisted out to 336 days after exposure (Mercer et al., 2013; Stapleton, et al., 2012).
0.5 ≤; ≥16	191 (.191 µm, mean)	Chrysotile	SA: 4.4 mm <sup>2</sup> (day 1)	Inhalation (3h/1 day); 10 mg (respirable)/ m <sup>3</sup> (about 5000 fibers ≥ 5 µm length)	1, 8, 15, 19d	Rat	Lung: longitudinal splitting of the fibers occurred, but no substantial leaching of Mg 30 days after deposition. fibers above 16 µm deposited abundantly in the peripheral region 1mm from the visceral pleura (Coin et al., 1994; Coin et al., 1992).
5.9 ± 0.05; 0.7 ± 0.07	9.7 ± 2.1; 11.3 ± 3.9	MWCNT; (CNT g): Al: 1.97%; Co: 0.49%; Fe: 0.48%	Not provided	IT instillation; 2 mg	3 & 60d	Rat, Wistar; F	Lung: lacticodehydrogenase significantly increased after exposure; macrophages and neutrophils accumulated; levels of IL-1β and TNF-α greatly increased; after 60 days, numerous granulomas containing collagen formed in the parenchyma; MNCB frequency significantly higher (Muller et al., 2008; Fenoglio et al., 2008; Muller et al., 2005 ).
<0.5(50 %); >10	100 (0.1 µm) (4T30);	Chrysotile; 4T30 (Fe:	4T30 (SA: 38 m <sup>2</sup> /g);	IT instillation;	1, 7, 14, 21, 60d	Rat, Wistar; M	Lung: UICC chrysotile B caused significant

(21%)	150 (0.15 $\mu$ m) UICC B	2.5%.; UICC B (2.6%)	UICC B (SA: 26.8 m <sup>2</sup> /g)	5 mg			pathological changes after 7 days; inflammatory cells, fibroblasts, collagen deposition; 4T30 fibers caused alveolar and interstitial accumulation of inflammatory cells, no fibrosis apparent after 60 days. Short 4T30 fibers much less fibrogenic than UICC B (Lemaire et al., 1985; Lemaire, 1991; Kohyama et al., 1996).
0.2-1.0 (Pauluhn, 2010)	10-15	MWCNT; Co:.52% to.12%	SA: 257 m <sup>2</sup> /g	Inhalation (6h, single); 11 & 241 mg/m <sup>3</sup>	3m	Rat, Wistar; M	Lung: "supports the conclusion that the predominant response to inhaled MWCNT is mainly related to the assemblage structure and not catalyst impurities (if in the range of $\leq 0.5\%$ )" (Ellinger & Pauluhn, 2009).
.9 (mean, 4T30); <5 (58%, UICC B)	100 (0.1 $\mu$ m); 150 (0.15 $\mu$ m) UICC B	Chrysotile; 4T30 (Fe: 2.5%); UICC B (2.6%)	4T30 (SA: 36 m <sup>2</sup> /g) (AR: 12.3); UICC B (SA: 26.8 m <sup>2</sup> /g)	IT instillation; 1, 5, or 10 mg	30d PE	Rat, Wistar; M	Lung: UICC B caused significant lesions with fibroblastic proliferation and collagen deposition in tissues of the bronchiole. 4T30 were linked to multifocal septal thickening and alveolar distortion. This was caused by interstitial mononuclear cell infiltration (primarily macrophages and epithelioid cells). No fibrosis was observed (Lemaire et al., 1985; Lemaire et al., 1989).
3.86 (med.)	49 $\pm$ 13.4	MWCNT; Na:.41%; Fe:.32%	SA: 26 m <sup>2</sup> /g	PA; DM 10, 20, 40 or 80 $\mu$ g	1,7, 28, & 56 d PE	Mouse; C57BL/6J; M	Lung: pulmonary inflammation and damage peaked at 7d post-exposure. After 56d, 40 $\mu$ g group only showed high levels of damage markers; granulomatous inflammation persisted in 56-day post exposure period. MWCNT can reach the pleura. Fe in MWCNT not capable of ROS generation (Porter et al., 2010).
3.0; author based this on DHHS and WHO data	37.5 (mean); author based this on DHHS and WHO data	Chrysotile (SFA), Grade 7 & 7R (study does not provide data)	SA: 50 m <sup>2</sup> /g	IPL instillation; .5, 1, 2, 4, 8, 20 mg	1-4m	Rat, Wistar	Lung: number of mesotheliomata linked to the dose of SFA. The SFA were highly carcinogenicity. Carcinogenicity was not linked trace metal content. Experiments show mesotheliomata is related to the presence of fine fibers in the pleural cavity (Wagner et al., 1973; WHO, 1998).
0.1-10	10-15	MWCNT; Al: 2.40%; Fe: 2.21%	100-200 m <sup>2</sup> /g (Arkema Data; see note 9)	IN instillation, 75 $\mu$ g (group 1); 225 $\mu$ g	7, 14 & 21d	Mouse, BALB/cByJ; M	Lung: levels of innate cytokines thymic stromal lymphopoietin (TSLP) and IL-25 were significantly increased in group 2

(group 2)							(Bernstein, 2008; Rosani et al., 2012; Rosani et al., 2014).
5.9 ± 0.05; 0.7 ± 0.07	9.7 ± 2.1; 11.3 ± 3.9	MWCNT; C: 97.8±0.2; 98.0±0.2; Co: .95%	SA: 378 m <sup>2</sup> /g ± 20; 307 ± 15	IT instillation; 0.5, 2 and 5 mg	28 & 60d	Rat, Sprague-Dawley; F	Lung: inflammatory & fibrotic responses; granuloma formation; significant increase in TNF- $\alpha$ (Muller et al., 2005) .
.295 ± .234	10 ± 3	MWCNT; Al: 5.3%; Fe: 0.4%; Co: 0.2%	SA: 250–300 m <sup>2</sup> /g; AR: 31 ± 26	IT instillation; 4 x 67 $\mu$ g (268 $\mu$ g)	8, 11, 15 & 18d	Mouse; C57BL/6J ; F	Lungs: histopathological changes at 6 weeks: bronchiolar subepithelial edema, perivascular edema, hyperplasia of bronchiolar epithelial cells, single macrophages; 4 months: desquamation of bronchiole epithelium, edema of bronchiole, infiltration of mononuclear cells, macrophage aggregates (Hougaard et al., 2013; Shvedova et al., 2014).
3.86 (med.)	49 ± 13.4	MWCNT; Na: .41%; Fe: .32%	SA: 26 m <sup>2</sup> /g	PA; DM 10, 20, 40 or 80 $\mu$ g	1, 7, 28, & 56 d PE	Mouse; C57BL/6J ; M	Lung: FESEM analysis showed MWCNT were quickly incorporated in the alveolar epithelium and later found penetrating into the vascular space. Fibers can readily penetrate all cell membranes/boundaries of the lungs. MWNCT cause acute inflammation, a progressive fibrotic response, and granulomatous lesions (Mercer et al., 2011).
5-15	10-20	MWCNT; C: 97.90%; Ni: 0.50%; Fe: 0.50%; HS	SA: 100 m <sup>2</sup> /g	Inhalation (6h/d); 0.3, 1 & 5mg/m <sup>3</sup>	7 & 14d	Mouse, C57BL/6; M	Lung: histopathology showed aveolar macrophages containing black particles; no inflammation or tissue damage; diminished T-cell-dependent antibody response and T-cell ability to proliferate in presence of mitogen; decreased NK cell function; spleen: IL-10 & NAD(P)H oxidoreductase mRNA increased in spleen (Mitchell et al., 2007).

IN, intranasal; IP, intraperitoneal; IPL, intrapleural; PA, pharyngeal aspiration; SA, surface area; AR, aspect ratio; DM, dispersion medium; Med, median; PE, post-exposure; ROS, reactive oxygen species; SFA, Super Fine Asbestos (Chrysotile); HS, herringbone structure; MNCB, micronucleated binucleated cell; MWCNT-f, MWCNT-functionalized; COOH, caboxylate; PEG, polyethylene glycol; NH<sub>2</sub>, amine; sw-NH<sub>2</sub>; PEI, polyetherimide; AP, As-Prepared (raw); AG, aggregates; h, hour; d, day; w, week; m, month; M, male; F, female. Format adapted from Nagai et al. (2010).<sup>162</sup>

## 6. Conclusion

The *in vivo* and *in vitro* findings of the adverse effects of MWCNT highlight the importance of ensuring protective measures are taken in occupational setting to reduce MWCNT exposure. The available evidence also suggests MWCNT could potentially have chrysotile-like effects on the lungs, inducing inflammation that over time leads to pleural pathology and mesothelioma (NIOSH, 2013). Popescu et al. (2013) contend the *in vitro* studies tend to distort the results toward weak or no adverse MWCNT effects; they also emphasize that the time scale of *in vivo* studies should scale with the biotoxicity time scale of the fibers and extend over the lifetime of the animal.<sup>163</sup> Therefore, more long term *in vivo* inhalation studies are required to determine whether MWCNT can induce cancer in experimental animals at doses equivalent to potential exposures in occupational settings (NIOSH, 2013). *In vivo* studies of the interaction between MWCNT and tobacco smoke, to the author's knowledge, have not been conducted or published in the open literature. There is also limited discussion about the synergy between tobacco smoke and carbon nanotubes in the scientific literature.

## **CHAPTER FIVE: EPA EXISTING REGULATORY FRAMEWORK FOR CARBON NANOTUBES**

### **1. Introduction**

The EPA has the authority under existing statutes to regulate carbon nanotubes during various steps in their manufacture, use, and disposal (EPA OIG, 2011). This chapter describes the following existing legislative authorities that the EPA is using and could potentially use to regulate the manufacture, use, and disposal of carbon nanotubes in the United States: U.S. Toxic Substances Control Act (TSCA); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); Clean Air Act (CAA); Clean Water Act (CWA); the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA); and the Resource Conservation and Recovery Act (RCRA).

This chapter focuses on the TSCA, which the EPA uses to regulate carbon nanotubes (GAO, 2010). As discussed below, the EPA is pursuing a four-pronged strategy under the TSCA to regulate carbon nanotubes and other engineered nanomaterials: (1) premanufacture notifications under §5; (2) Significant New Use Rules (SNUR) under §5(a)(2); (3) informational gathering rules under §8(a); and test rules under §4 (EPA, n.d.).



## 2. Toxic Substances Control Act

The TSCA grants the EPA the legal authority to regulate the manufacturing, formulation, commercial distribution, use, testing, and disposal of carbon nanotubes.<sup>164</sup> The Act was enacted during what has been described as the most active stage of federal environmental law-making in U.S. history (Trevisan, 2011). The statute, set against the backdrop of changing public attitudes about the effects of chemicals on the environment in the late 1960s, sought to prevent the "unreasonable risk" of harm that unregulated chemicals potentially posed to public health and the environment.<sup>165</sup> The Council on Environmental Quality's (CEQ) influential 1971 report *Toxic Substances*, and several high-profile environmental court cases in the early 1970s, highlighted the need to pass the TSCA to regulate toxic substances.

The TSCA gave the U.S. EPA the broad legal authority and tools to regulate the manufacturing and use of toxic substances.<sup>166</sup> At its inception, the statute was lauded for its wide jurisdictional reach, covering almost any chemical substance not regulated under other federal statutes. Jeffrey O'Reilly, an industry attorney who co-authored the "mixture" exception of the statute, states that pro-environmentalists believed TSCA was a "capstone passage of a law that brings other laws into a coordinated whole" (O'Reilly, 2010). The TSCA has been described as the 'queen statute,' designed to preclude the need to enact the CERCLA legislation in 1980 (Roberts, 2010).<sup>167</sup> However, as discussed in more detail in Chapter 6, the EPA has failed to implement much of the TSCA's regulatory agenda (Schifano et al., 2011).<sup>168</sup>

The TSCA, 15 U.S.C. §§ 2601-2629, was enacted on October 11, 1976 “to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use or disposal of chemical substances.” TSCA §6(a), §2605 (a) The TSCA is a risk-benefit balancing statute that grants the EPA broad authority to regulate almost any chemical substances, excluding those found in food, drugs, cosmetics, and pesticides (Percival et al., 2006; Ferry, 2010). The TSCA regulates products and the introduction of new chemical substances into the stream of commerce; this distinguishes the TSCA from some other federal environmental statutes in that the TSCA focuses on pollution prevention rather than control and remediation (Ferry, 2010). The TSCA includes four titles: Title I, Control of Toxic Substances; Title II, Asbestos Hazard Emergency Response; Title III, Indoor Radon Abatement; and, Title IV, Lead-Based Paint Exposure Reduction (15 U.S.C. §§ 2601-2629).

The TSCA authorizes the EPA to require chemical testing under §4, regulate significant new uses of existing chemical substances and new chemical substances under §5, restrict or ban hazardous chemicals substances under §6, promulgate rules requiring reporting and retention of information on chemical substances under §8, and regulate the import and export chemicals substances that pose a substantial risk to health and the environment under §13 (15 U.S.C. §§ 2601-2629).

The TSCA jurisdictional reach is extremely wide, covering almost any “chemical substance” or “mixture” falling outside the jurisdiction of other federal agencies and statutes (e.g., the Federal Drug Administration (FDA) and the FDCA) (Ferry, 2010).

The TSCA differs from the FDCA and the FIFRA in that it is not a licensing statute; the EPA, under the latter two statutes, must approve the registration of new food additives, drugs, cosmetics and pesticides before the products are marketed. The TSCA, on the other hand, requires EPA receive a pre-manufacture notice (PMN) 90 days prior to the manufacture or processing of a new chemical substance and the use of an existing chemical in a significantly new manner under §5 (Naidu, 2009).

TSCA §3(2) defines term “chemical substance” as “any organic or inorganic substance of a particular molecular identity,” to include “any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and...any element or uncombined radical.” The term “chemical substance” excludes any mixture and the following substances regulated under other federal statutes:

[T]obacco or any tobacco product; any source material, special nuclear material, or by-product material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act); any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954...any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the (FFDC) Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device (TSCA§ 2(A)).

TSCA §3(2) stipulates that the term “mixture” refers to “any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction.” The term “does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were

combined.” Therefore, a mixture containing a new chemical substance would be excluded, but the specific “new” chemical substance would be subject to TSCA regulation (Naidu, 2009).

The TSCA regulates manufacturers, processors and distributors. TSCA §3(7) defines a “manufacturer” as any person who is engaged in traditional notions of manufacturing and production for commercial purposes to include importation into the United States. Manufacturers must generally do the following: “(1) sponsor tests and submit data to EPA regarding chemicals they manufacture; (2) submit a PMN before manufacturing a chemical substance not on the TSCA Inventory or before manufacturing a chemical for a significant new use; (3) avoid manufacture of polychlorinated biphenyls (PCBs); (4) maintain records and submit reports as required by §8; (5) submit to EPA inspection and subpoenas as authorized by § 11; and (6) certify compliance with TSCA upon importation as required by §13” (Landfair, 2007).

TSCA §3 (11) defines a “processor” as any person who “processes a chemical substance or mixture” after its manufacture for distribution in commerce. Processing also includes the incorporation of a chemical substance into an “article” that is “distributed in commerce” (Landfair, 2007). Ferry (2010) notes: “If one purchases raw materials and manufactures products that contain a listed chemical substance, one can be regulated as a processor. The EPA will consider a company as a “processor” if it uses a TSCA-covered chemical substance and fabricates an article that is later distributed in commerce, and that article contains the substance or a mixture containing that substance, or a reaction product of that substance. It is important to note that even if one is a processor, TSCA will not

regulate that entity unless there is “distribution in commerce” and ultimate end use of the product” (Landfair, 2007; Ferry, 2010).

TSCA § 3(4) defines a “distributor” as any person who introduces, sells, delivers chemical substance or mixture into the stream of commerce or holds a chemical substance or mixture after it has been introduced into the market (Landfair, 2007; Ferry, 2010). TSCA regulates distributors – those who are not also manufacturers or processors – of chemical substances into the stream of commerce must comply with the TSCA and report “substantial risk information” to EPA under §8(e) (Landfair, 2007; Ferry, 2010).

The EPA needs to obtain data to determine whether or not to regulate a chemical substance. The TSCA differs from the FIFRA regulatory system because the TSCA must meet threshold standards under §4 to require testing of chemical substances. The FIFRA regulatory system requires the manufacturer prove the safety of the product (Naidu, 2009). The EPA must prove the need for the initial testing and the regulation under the TSCA (Landfair, 2007). The EPA must show the following three requirements of §4 to mandate testing:

(1) Insufficient data exist on the chemical substance and its effects on health and the environment; (2) Testing of the chemical substance is necessary to develop sufficient data; and (3) Either (a) the manufacture, distribution, processing, use, or disposal of the chemical substance may present an unreasonable risk of injury to health or the environment, or (b) the chemical substance is, or will be, produced in substantial quantities and may enter the environment in substantial quantities or there may be significant exposure to it (Landfair, 2007).

The EPA may require the manufacturer or processor test the product if these standards are not met. The manufacturer bears the time and cost of conducting the test,

must determine the potential public health and environmental impact, and provide the testing results to the EPA (Landfair, 2007). The EPA uses the test requirement to obtain the necessary information and data to make a determination on the potential regulation of the chemical substance (Landfair, 2007). The EPA may mandate the manufacture perform this work after the EPA has promulgated a rule or negotiated a binding consent agreement with the manufacturer (Landfair, 2007).

The TSCA §5(a) gives the EPA statutory authority to regulate an “existing” substance if it is used in a significantly new way that could risk harm to public health or the environment and to regulate new chemical substances.<sup>169</sup> The EPA may promulgate a Significant New Use Rule (SNUR) for a carbon nanotube substance if it is (1) the subject of a §5(e) Consent Order<sup>170</sup> or (2) the use of the carbon nanotubes may "result in significant changes in human exposure or environmental release levels" and/or (3) "that concern exists about the substance's health or environmental effects."<sup>171</sup> Under §5(e), the EPA may ban or restrict carbon nanotubes if it finds the following: there is insufficient information to evaluate the risk; the carbon nanotubes present an unreasonable risk to humans and the environment; the carbon nanotubes will be manufactured in substantial quantities for release into the environment or there could be significant human exposure.<sup>172</sup> The EPA's Office of Research and Development (ORD), which received most of the EPA's federal funding for nanomaterials, has regulated engineered nanomaterials based on the TSCA §5(e) new chemical requirements (EPA OIG, 2011).

### **3. Other Regulatory Authorities**

The FIFRA grants EPA the authority to regulate the sale, distribution, and use of pesticides in the United States. The EPA can regulate carbon nanotubes and other engineered nanomaterials used in pesticides under FIFRA (Gwinn & Sokull-Kluttgen, 2012). The EPA issued a notice in 2011 proposing a plan to collect information on engineered nanomaterials contained in pesticide products. The EPA announced its intention to potentially use Section 6(a)(2) of FIFRA to collect existing information on carbon nanotubes or other engineered nanomaterials contained in pesticides and the impact on humans or the environment. This approach would require manufacturers to include information on "unreasonable" adverse effects on health or the environment with applications to register a pesticide product containing carbon nanotubes (Gwinn & Sokull-Kluttgen, 2012).

The EPA could regulate carbon nanotubes released into the environment using the CAA, the CWA, the CERCLA, or the RCRA. The CAA and CWA both allow the EPA to impose limits on pollutants released into the air and water in the United States (Gwinn & Sokull-Kluttgen, 2012). The CAA could be used to control the release of carbon nanotubes into the environment—this does not include unintentionally produced nanoparticles, such as diesel exhaust particles. The provisions of CAA §112(r), which is intended to preclude the accidental release of very hazardous chemicals into the environment, "offers a theoretically better fit for the future regulation of nanoparticle emissions than do the particulate national ambient air quality standards established under §§ 108 and 109" (Bergeson & Hester, 2008). The regulatory fixes to the CAA in this

case, however, would also require "meeting time-consuming procedural requirements for an agency rulemaking process" (Bergeson & Hester, 2008). Under CWA, the EPA could require companies to provide information on discharges potentially containing carbon nanotubes or other engineered nanomaterials into the environment (GAO, 2010). CERCLA and RCRA could be used to cover the evaluation and management of carbon nanotubes in waste sites.

The EPA states that it does not currently have the technology required to monitor engineered nanomaterial pollutants, such as carbon nanotubes, to enforce conventional air pollutant standards; to "reliably and economically" measure the release of carbon nanotubes in effluents to enforce Clean Water Act (CWA) limitations; or to adequately test and characterize carbon nanotube waste hazards (GAO, 2010). The EPA has not exercised its authority to use the information-gathering provisions of the CWA to obtain information on potential effluent discharges containing carbon nanotubes or other engineered nanomaterials (EPA OIG, 2011).

#### **4. TSCA & Nanoscale Materials**

The EPA has been at the center of considerable debate on whether nanoscale materials are "new" or "existing" chemicals because of their size and unique chemical and physical properties. If a nanomaterial is considered an "existing" chemical, then the EPA also has to assess whether the use of "existing" chemical constitutes a "significant new use." These designations are important because, as outlined below they can trigger TSCA's PMN notice and approval requirements (Landfair, 2007). Against this backdrop, the EPA promulgated guidance in January 2008 clarifying its definition of "new" versus



“existing” chemicals with regards to nanomaterials. The guidance stipulated the EPA would only consider nanoscale material “new” if the nanoscale substance’s molecular identity was distinct and not shared with other chemicals in the TSCA’s existing chemical substance inventory.<sup>173</sup>

The EPA first applied this nanomaterials policy to carbon nanotubes in October 2008. The EPA stipulated that EPA did not consider carbon nanotubes identical to graphite or carbon allotropes at the molecular level; unless manufacturers can prove otherwise, then, carbon nanotubes are new chemical substances that are subject to the TSCA PMN requirements.

TSCA §5(a) gives the EPA statutory authority to regulate an “existing” substance if it is used in a significantly new way that could risk harm to public health or the environment. The EPA must issue a SNUR requirement notice for the category of the new use involved to trigger a “significant new use notice” (SNUN). Under this §5, a manufacturer must submit the SNUN to the EPA 90 days prior to the manufacturing or processing of such chemical substances.

TSCA §5 gives the EPA the statutory authority to regulate new chemical substances. The 90-day PMN allows the EPA to determine whether to ban or restrict the production of the chemical substance. If a chemical substance is not listed in the TSCA Inventory database, then it is considered to be a new chemical that cannot be produced or distributed until a PMN is submitted. The EPA may regulate a PMN substance under §5(e) if the following three requirements are met:

- (1) The information available to the EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the substance, and (2)

Either (a) absent such information, the manufacture, processing, distribution, use, or disposal of the substance may present an unreasonable risk of injury or (b) the substance will be produced in substantial quantities and either will enter the environment in such quantities or may cause “significant or substantial human exposure.

Secondly, the EPA may issue a “proposed rule” or “proposed order” to temporarily ban the PMN substance under §5(f). Lastly, the EPA may impose a complete ban on the PMN substance under §6(a).

Many carbon nanotubes could be potentially new chemicals under TSCA §5. Therefore, manufacturers of carbon nanotubes that are not listed in the TSCA Inventory must comply with TSCA reporting requirements. The EPA anticipates concentrating its resources on tracking carbon nanotube manufacturers compliance with TSCA §5.

The EPA recommended further testing to help characterize the health effects of carbon infused nanostructures. The EPA sought more information on the dimensions, characteristics, and physical-chemical properties of the PMN substance.<sup>174</sup>

The EPA promulgated a final SNUR on the carbon black derivative, which was the subject of an 16 May 2011 consent order under TSCA §5(e).<sup>175</sup> The consent order was based on the following PMN:

The PMN states that the generic (non-confidential) use of the substance will be as carbon black for general industrial use. Based on test data on carbon black and SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for immunotoxicity, pulmonary toxicity, and carcinogenicity. In addition, based on aquatic toxicity data on carbon black, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1,000 ppb of the PMN substance in surface waters. The consent order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that this substance may present an unreasonable risk of injury to human health and the environment.<sup>176</sup>

In early May 2013, the EPA promulgated SNURs under the TSCA for 15 chemical substances. The rule included a PMN substance that included the term "carbon nanotube" (The confidential business information (CBI) claims of companies prevent a more detailed description of the structural characteristics of the substance).<sup>177</sup> The PMN (P-12-44), chemical name "functionalized multiwalled carbon nanotubes (generic)," describes the non-confidential use the substance containing the carbon nanotubes. The substance is used as an additive for rubber and batteries. The EPA conducted research on analogous chemical substances and identified concerns related to inhalation exposure of the substance. The PMN holds that inhalation exposure is not expected, however, because of the manufacturing and use processes outlined in the PMN and availability of personal protective equipment.<sup>178</sup> The EPA recommended an inhalation toxicity test and post-exposure observation be conducted, along with a microscopy analysis.<sup>179</sup> On February 12, 2014, the EPA issued SNUR for 35 PMN substances, which include four that were listed as multi-walled carbon nanotubes in a previous TSCA Section 5(e) consent order.

On 23 May 2014, the EPA released its 2014 Regulatory Agenda. The Agenda includes RIN 2070-AJ54, "Nanoscale Materials; Chemical Substances When Manufactured, Imported, or Processed as Nanoscale Materials; Reporting and Recordkeeping Requirements; Significant New Use Rule," which was published on the OIRA website. The abstract of the rule is as follows:

EPA is developing a proposal to establish reporting and recordkeeping requirements under the Toxic Substances Control Act (TSCA) for chemical substances when manufactured (defined by statute to include import) or processed as nanoscale materials. Specifically, EPA is developing a significant

new use rule (SNUR) under TSCA section 5(a)(2) that would require persons who intend to manufacture, import, or process this/these chemical substance(s) for an activity that is designated as a significant new use by the proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs to prevent unreasonable risk to human health or the environment (OMB, 2014).

The 2014 Agenda merges the SNUR with a separate proposed rule—originally submitted in 2010—to collect information on nanoscale materials based on TSCA § 8 (a) (OMB, 2014). Section 8 (a) "authorizes the Administrator to promulgate rules, which require each person (other than a small manufacturer, importer, or processor) who manufactures, imports, processes, or proposes to manufacture, import, or process a chemical substances, to maintain such records and submit such reports as the Administrator may reasonably require" (EPA, 2010). This rule has been held up in the regulatory review process, which is discussed in more detail in the following chapter.

## CHAPTER SIX: TSCA ADMINISTRATIVE RULEMAKING & IMPLEMENTATION

If one is always looking for unusual circumstances and dramatic events, he cannot appreciate how difficult it is to make the ordinary happen. People now appear to think that implementation should be easy; they are, therefore, upset when expected events do not occur or turn out badly. We would consider our effort a success if more people began with the understanding that implementation, under the best circumstances, is exceedingly difficult.

—Jeffrey L. Pressman & Aaron Wildavsky, *Implementation* (1984)

### 1. Introduction

The Toxic Substances Control Act (TSCA) gives the Environmental Protection Agency (EPA) the authority to regulate carbon nanotubes and other engineered nanomaterials in the United States. The TSCA provides the EPA the following regulatory options in managing the potential risks of carbon nanotubes: banning or restricting manufacturing, processing, use, and distribution; requiring specific methods of disposal; requiring warning labels; mandating methods of quality-control in manufacturing processes; collecting data; and mandating testing and the production of data and information (Schifano et al., 2011). The EPA efforts to collect data and information on carbon nanotubes and other engineered nanoscale materials from manufacturers through voluntary programs has been largely unsuccessful, requiring the EPA to shift to regulatory approaches under the TSCA to obtain risk data from carbon nanotube producers (EPA OIG, 2011).

The EPA's development of regulatory approaches for carbon nanotubes and other engineered nanoscale materials, however, has involved many challenges and considerable delay. For example, a proposed rule to set manufacturer reporting requirements for specific engineered nanoscale materials has been under review at the Office of Management and Budget (OMB) since 2010. Some critics have suggested the TSCA's statutory language and insufficient provisions are the sources of such problems (Schifano et al., 2011).<sup>180</sup> As Schifano et al. (2011) observe, this tells only part of the story. The statutory language, procedural requirements, administrative rulemaking process, resource constraints, organizational problems, interest group pressures, political challenges, judicial review, case law, confidential business information (CBI), and leadership all shape the manner in which the EPA is able to exercise its authorities (Schifano et al., 2011) and implement<sup>181</sup> the TSCA.

The problems encountered in regulating asbestos under the TSCA is instructive for considering the likelihood that EPA will be able to regulate carbon nanotubes under the current regulatory framework. The asbestos case demonstrated that even when there was extensive evidence linking inhalation of asbestos fibers to cancer and death, EPA was unable to promulgate rules to phase out the use of asbestos in consumer products. The implications of the lessons learned from this chapter are discussed in chapter 7.

This chapter incorporates findings from the Chemical Heritage Foundation's (CHF) full oral interviews of the following individuals intimately involved in authoring, drafting, and implementing the TSCA from 1977 to 2009: J. Clarence Davies, the primary author of the TSCA as a staff member on the CEQ (1970-1973); Steven D.

Jellinek, First Assistant Administrator of the Office of Toxic Substances (OTS) (now the Office of Pollution Prevention and Toxics (OPPT) (1978-1981); Marilyn C. Bracken, Associate Director of OTS) (1978-1980); Don R. Clay, Director of OTS (1981-1988); Victor Kimm, Deputy Assistant Administrator and Assistant Administrator for Pesticides and Toxic Substances (1985-1994); and Charles L. Elkins, Director of OTS (1987-1990). The chapter also includes excerpts from a CHF oral interview of James R. Von Ehr, II, founder and CEO of Zyvex Group,<sup>182</sup> which provides an industry perspective of the impact of EPA regulation on carbon nanotube production in the United States. In addition, it quotes from the EPA's oral history interviews of William D. Ruckelshaus (Administrator 1970-1973, 1983-1985);<sup>183</sup> Russell E. Train, Administrator (1973-1979);<sup>184</sup> Alvin L. Alm (Deputy Administrator, 1983-1985);<sup>185</sup> and William K. Reilly (1989-1992).

## **2. Organizational Structure of the Environmental Protection Agency**

Max Weber's description of the ideal type of bureaucracy, as discussed in chapter 2, applies to the EPA in a number of respects (Fiorino, 2013). The EPA has a formal hierarchical structure, is organized by function and expertise, is managed by rules, maintains a career staff, relies greatly on expert knowledge, and is shielded to some extent from political influence (Fiorino, 2013). At the same time, the EPA is representative of the typical American model of administrative policy making as described in previous chapters (Fiorino, 2013).

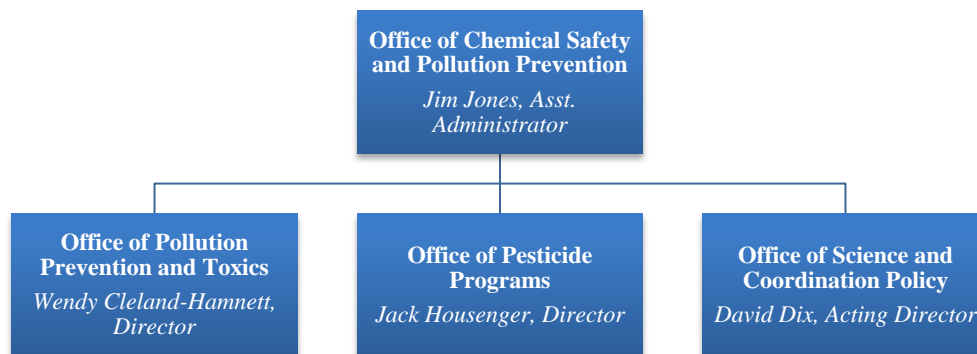
Fiorino (2013) notes the EPA is not a pure science agency nor a conferrer of benefits. The EPA accomplishes its goals through regulating the behavior of others in

society. As conflicts among societal values and interests undergird almost every decision of the EPA, it is not surprising that agency administrators, manager, and staff consistently bemoan the high level of politics and controversy involved in the work (Fiorino, 2013). As Rosenbaum (2006) aptly points out, "[T]he EPA always walks a political tightrope, on which balance is essential and never predictable" (Fiorino, 2013). The EPA is required by law to keep some industry and EPA data and information confidential from the public.<sup>186</sup> Some administrators and program implementers in federal agencies have viewed the data and information they control as a political resource to be kept from the outside to avoid criticism or used for political advantage (Nakamura & Smallwood, 1980).

Prior to the establishment of the EPA in the Clean Air Act on 1970, EPA's current environmental functions were divided among a number of different agencies and the federal government played a limited role in environmental protection and pollution control (Fiorino, 2013). The EPA was originally organized to align with the laws that it administers and the congressional committees and subcommittees that oversee implementation; this structure has remained largely intact since the EPA was established (Fiorino, 2013). The EPA is divided into the following four national program offices focusing on air, water, waste, and chemical issues: Office of Air; Office of Water; Office of Solid Waste and Emergency Response; and the Office of Chemical Safety and Pollution Prevention. The rest of the agency is organized according to functional and geographic responsibilities. As of 2010, the EPA employed about 18,000 people, most of



whom were located in regional offices and research labs outside the Washington, DC area (Fiorino, 2013).



**Figure 13: Organizational Chart of the Office of Chemical Safety and Pollution Prevention.**

The Office of Chemical Safety and Pollution Prevention (OCSPP) is responsible for implementing the TSCA, FIFRA, FFDCA, and the Pollution Prevention Act (PPT) (See Figure 13 above).<sup>187</sup> The OCSPP evaluates and regulates the risks of industrial chemicals that enter the stream of commerce in the United States. The OCSPP contains the Office of Pollution Prevention and Toxics (OPPT), the Office of Pesticide Programs (OPP), and the Office of Science and Coordination Policy (OSCP). The OCSPP disseminates manufacturer data obtained through TSCA and FIFRA data calls to offices within the OCSPP.<sup>188</sup>

The OPPT, the office primarily responsible for TSCA implementation, manages programs under the TSCA and the PPT.<sup>189</sup> The OPPT also manages some environmental stewardship programs. The OPPT relies on industry self-reported data, which reduces its ability to assess the potential chemical risks manufacturers do not voluntarily disclose.<sup>190</sup>

The EPA recently announced the reorganization of OPPT, which involves eliminating its Pollution Prevention Division and shifting all aspects of risk assessment to the Risk Assessment Division (Acta, 2014). The Economics, Exposure, and Technology Division was renamed the Chemistry, Economics, and Sustainable Strategies Division (CESSD). The CESSD's responsibilities will include the TSCA inventory and chemical nomenclature. The reorganization will not alter OPPT's current responsibilities; the changes were effective on 9 June 2014 (See Figure 28 below) (Acta, 2014).



**Figure 14: OPPT Organizational Chart.**

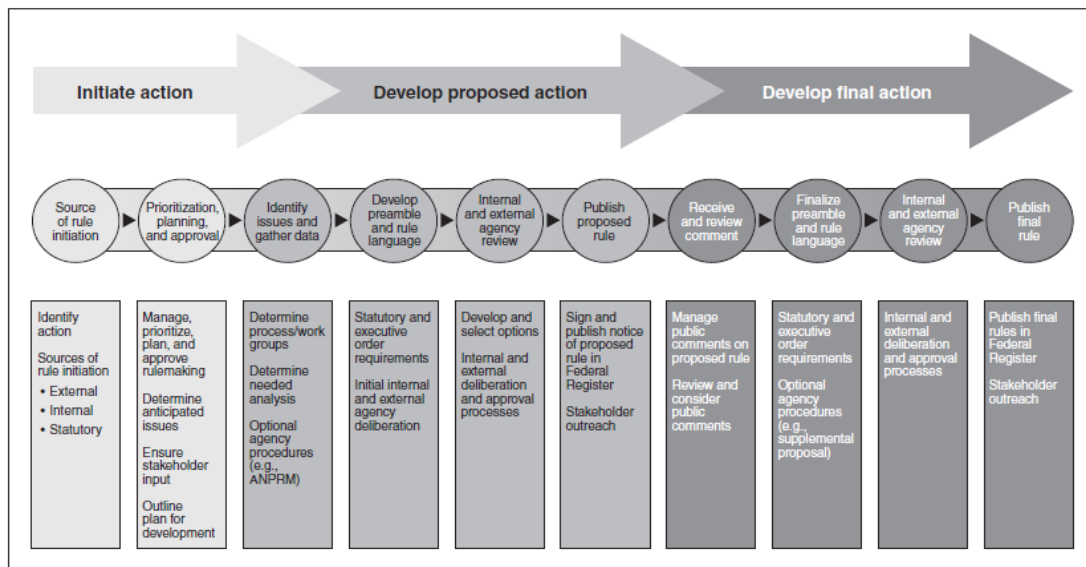
Directors head the division-level offices, chiefs are in charge of the ranches, and leads manage the teams (adapted from the new EPA OPPT chart).

The OPP regulates the production and use of all pesticides in the United states (EPA, 2014).<sup>191</sup> The OPP evaluates potential new pesticides, some of which now contain nanomaterials. The OPP manages the FIFRA, the Pesticide Registration Improvement Extension Act, and parts of the Food Quality Protection Act, the Federal Food, Drug, and Cosmetic Act, and the Endangered Species Act. The OSCP is responsible for providing peer review, coordination, and leadership on science and science policy-related matters in the OCSPP (EPA, 2014). The OSCP manages the Endocrine Disruptor Screening Program, the Scientific Advisory Panel, and Biotechnology Team (EPA, 2014).

The EPA receives dedicated funding from the U.S. government's National Nanotechnology Initiative (NNI), which was established in 2001 to bring together 20 federal government departments, commissions, and agencies in sharing data, knowledge, and expertise on research and development on nanotechnology,<sup>192</sup> for research on the potential public health and environmental risks of nanomaterials (EPA OIG, 2011).<sup>193</sup> The EPA appropriates most of its federal nanomaterial funding to the Office of Research and Development (ORD), which is the EPA's scientific research unit.<sup>194</sup> The ORD has six research programs,<sup>195</sup> three national laboratories,<sup>196</sup> four national centers,<sup>197</sup> and two offices.<sup>198</sup> This office is reportedly the first one within the EPA to regulate nanomaterials based on the TSCA §5(e) new chemical requirements. The ORD requires manufacturer data to set work priorities and adequately assess risk.<sup>199</sup> As of 2011, the ORD intended to create a Chemical Safety and Sustainability Research Program that couples nanomaterials research with toxicology efforts that employ high-throughput chemical screening and prioritization methods.<sup>200</sup>

The Office of Enforcement and Compliance Assurance (OECA) is responsible for enforcing enacted nanomaterials regulations. The OECA relies heavily on OCSPP expertise to develop enforcement cases for nanomaterials. The Office of Air and Radiation (OAR), the Office of Solid Waste and Emergency Response (OSWE), and the Office of Water (OW) all have statutory authority to regulate nanomaterials in their areas of environmental responsibility. As of late 2011, the OW had not exercised its authority to use the information-gathering provisions of the Clean Water Act to obtain information on potential effluent discharges containing nanomaterials (EPA OIG, 2011).

The EPA organization and mission shapes the way it coordinates policies across various parts of the agency and makes regulatory decisions. The EPA's decision making model is largely bottom-up and team-oriented, allowing for coordination across multiple programs and offices focusing on technical, scientific, legal, and economic issues. This model requires staff-level groups work to build consensus and develop recommendation for senior-level officers. The EPA also has a Science Advisory Board (SAB), which is reportedly made up of politically neutral experts who advise on the technical and scientific matters. The SAB was established to reduce bias and add credibility to EPA decisions (Fiorino, 2013). This model generally defines the majority of EPA regulatory decision making (Fiorino, 2013). Figure 29 provides a diagram of the EPA rulemaking process.



**Figure 15: Phases of the Rulemaking Process.**  
(Source: GAO, 2009)

On the other hand, notes Fiorino (2013), senior managers may take a more top-down approach on high-profile and controversial issues.<sup>201</sup> This could involve referring politically charged and highly controversial scientific issues to the SAB for review. In addition, EPA managers and staff officers must anticipate the OMB's Office of Information and Regulatory Affairs (OIRA) review of their significant proposed and final regulatory actions (Copeland, 2013). The OIRA review and approval process can involve extensive coordination between the concerned EPA and OIRA desk and senior-level officers (Copeland, 2013). This process adds another layer of bureaucratic oversight to EPA regulatory actions (Livermore & Revesz, 2013).

### 3. Office of Management and Budget's Role in EPA Rulemaking

David Stockman took charge of the OMB in 1981 with the intent to expand OMB's power and increase executive control over policy implementation in the

bureaucracy.<sup>202,203</sup> This involved overseeing the enforcement of a series of presidential directives aimed at centralizing the management of agency rulemaking activities, limiting regulations that overly burdened industry, and reducing the size and resources of government agencies.<sup>204,205</sup> Reagan's new directives were important pillars of the "Reagan Revolution," which Stockman himself claims to have designed.<sup>206</sup> The president issued Executive Order (EO) 12291 in February 1981, which required the following:

[T]o the extent permitted by law, all agencies must adhere to the order's substantive criteria in their regulations. These include: (1) refraining from regulatory action unless potential benefits outweigh potential costs to society; (2) choosing regulatory objectives that maximize net benefits to society; (3) selecting the alternatives that will impose the least net cost to society while achieving regulatory objectives; and (4) setting regulatory priorities to maximize aggregate net benefits to society, taking into account factors such as the condition of the national economy and of particular industries.<sup>207</sup>

The EPA and most federal agencies were required to submit new regulations to the OIRA for approval. The OIRA was given the authority to delay the publication of new regulations in the *Federal Register* (Livermore & Revesz, 2013; Vig, 1984).

Reagan's delegation of implementation to loyal political appointees from industry in the EPA and other federal agencies was key to the success of this administrative strategy (Vig, 1984). Jim Tozzi, chief of OMB's Environmental Branch during the Nixon administration and the Carter administration's "point man" on the Paperwork Reduction Act,<sup>208,209</sup> said that he was chosen "well before (Reagan's) inauguration" to become the Deputy Administrator of OIRA.<sup>210</sup> Vig (1984) states Stockman and his colleagues viewed environmental programs as a key target for deregulation and budget cuts.<sup>211</sup> Administrator Reilly confirms that Stockman "made it a matter of great personal interest

to engage specific regulatory choices and argue against EPA proposals."<sup>212</sup> Reilly reports only about nine or ten percent of all regulations came from the EPA, but EPA regulations tended to be more controversial than those of other agencies and received more scrutiny as a result.

The Reagan administration sought to use the OIRA as a means to carry out deregulation and slow EPA rulemaking (Vig, 1984; Andrews, 1984). Christopher DeMuth, the OIRA administrator from 1981 to 1984, stated in 1982 that significant administrative reform was required for statutory reform in the last half of Reagan's first term (Vig, 1984). In 1982, Tozzi stated in an interview that environmental regulations accounted for 'a very considerable part of (his) personal time' at the OIRA.<sup>213</sup> Tozzi quickly became known as a "black hole" for regulations (Revesz & Livermore, 2008). Tozzi remarked: "Under the Reagan administration, every environmental regulation had to come to me. I was heavily criticized by the environmental groups and we were frequently called up to [congressional] committee hearings. It was bloody. I loved it. It was the action."<sup>214</sup> In 1983, the Tobacco Institute's Fred Panzer described Tozzi as "a former official OMB in charge of shaping favorable policy on chemical carcinogenesis" (Panzer, 1983).

Livermore and Revesz (2013) state that all of the later presidents largely continued to follow EO 12291, adopting or adding to the directive.<sup>215</sup> Presidents Obama and Clinton issued EO 13563 in 2011 and EO 12866 in 1993, respectively, which now define OIRA's main responsibilities with regards to the review of rules (Sunstein, 2013).



EO 13563 reaffirms and builds on EO 12866, mandating that each agency do the following as permitted by law:

(1) [P]ropose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity) (Sunstein, 2013).

Executive Order 12866 Section 6(b)(2) requires the OIRA to waive review or make a determination on "significant" proposed and final regulatory actions within 90 days of agency submission; the review process may be extended for no more than 30 days. There are no penalties for violating the directives requirements and review time limits are not enforceable through the courts (Copeland, 2013).

Revesz and Livermore (2008) assert the EPA and OIRA have always had an "especially antagonistic relationship." Revesz and Livermore (2008) state the OIRA scrutinizes EPA rulemaking because of high economic costs associated with environmental rules and the EPA's perceived tendency toward creating overly burdensome regulations on the rules EPA submits for review because they tend to have high economic costs. The EPA History Program conducted oral interview of four former EPA Administrators—William Ruckelshaus (Administrator 1970-1973, 1983-1985);<sup>216</sup> Russell Train, Administrator (1973-1979);<sup>217</sup> Alvin Alm (Deputy Administrator, 1983-1985);<sup>218</sup> and William Reilly (1989-1992)—all of whom bemoaned the bad relationship between the EPA and OMB. Reilly, in his oral interview in late 1995, stated former

Budget Director Richard Darman's opposition to an informational briefing he provided on the Clean Air Act was "so fundamental" that he "startled" Reilly.<sup>219</sup>

Reilly discussed the role of Vice President Quayle, the Council on Competitiveness—the Council, directed by businessman Alan Hubbard, was established in 1989 and worked closely with OIRA to review regulations<sup>220</sup>—and Darman in reviewing and coordinating EPA legislative and policy actions.<sup>221</sup> He argued that the White House must have an agency that is responsible for coordinating policy, as it would be unreasonable for the EPA to solely make decisions on issues that may have an impact on energy, economic, development, agricultural, and housing policy. Reilly suggested a coordinating agency needs "needs to be quite specifically circumscribed, respect procedures everyone understands, and not involve wholesale disregard for the kinds of constraints that affect a regulatory agency." Reilly said that the White House process of reviewing EPA regulatory actions lacked transparency, showed "a disregard for regulatory procedures," "undermined our credibility," and "certainly contributed to a great deal of criticism and suspicion." Reilly describes his deep frustration with the White House review process:

It is profoundly frustrating to an EPA Administrator to go through all of the careful control processes of arriving at a regulatory decision or proposal and to respect all of the rules against *ex parte* contact - make sure any contact with the regulated community is recorded, noted, memorialized, public, on the record - and then to have it go to the White House and see many of the same parties engaged in influencing other people who have influence over such decisions without any public record, without any acknowledgment that this is going on. The secrecy that characterized that process, I think, is a source of great mistrust and, potentially, of corruption. Corruption in the sense that it violates process, not that it involves anyone taking any money. The Competitiveness Council was layered onto the so-called Office of Information and Regulatory Affairs (OIRA) review when the President became distressed about articles in the *Wall Street Journal* and other

places indicating he was reregulating society and repudiating the Reagan era reforms.

Reilly provided the following example of OMB and the Council's actions that had a "demoralizing effect on EPA": "It was not uncommon in my time to get back comments from the Office of Management and Budget or the Competitiveness Council that incorporated verbatim documents that we had seen from trade associations three or four months before on particular matters of concern in legislative or regulatory policy."<sup>222</sup>

In January 1992, President Bush announced in his State of the Union Address a 90-day moratorium on agency rulemaking. The moratorium was later extended for an addition 120 days on 29 April 1992. The Council on Competitiveness monitored this initiative (Zank, 1996) and reviewed current agency rulemaking and cost estimates.<sup>223</sup> On 16 April 1992, Thomas J. Bliley, Jr. (R-VA), a staunch supporter of the tobacco industry,<sup>224</sup> sent a letter to Vice-President Quayle requesting the Council examine the EPA's revised risk assessment on Environmental Tobacco Smoke (ETS). Bliley (1992), anticipating that the assessment would conclude that ETS is a known human carcinogen, claimed EPA was using the same "shoddy science" it used in the cases of asbestos and dioxin to establish risk for ETS. Bliley (1992) stated the assessment "amounts to de facto regulations with critical ramifications for smokers and the tobacco industry." Bliley (1992) called into question EPA's methods for determining a substance's carcinogenic risk:

The agency's risk assessment on ETS failed to account for known sources of bias—misclassification and recall bias—that could explain the association purportedly found between ETS and lung cancer. Confounders, such as diet, lifestyle and other exposures to carcinogenic substances, were not considered. EPA employed a strictly statistical approach to ETS with consideration of routes of exposure or physical and chemical properties of ETS. Finally, animal data

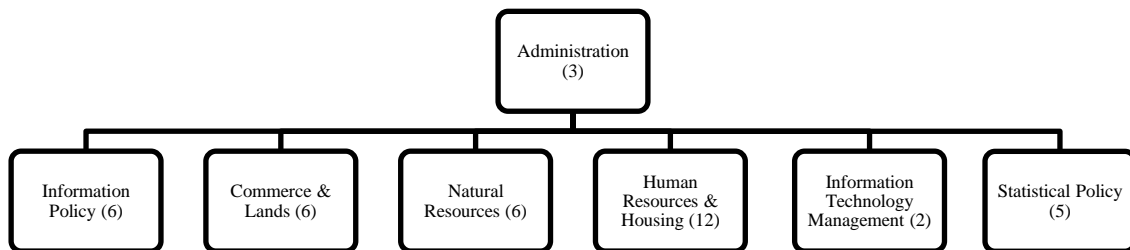
showing no association between ETS exposure and health effects were ignored...A very recent report of an expert panel appointed by the EPA Administrator found that: (1) EPA has not always been a source of unbiased scientific information; (2) EPA science is perceived by many people, both inside and outside of the agency, to be adjusted to fit policy; (3) EPA's scoping studies or other preliminary assessments frequently are carried out without the benefit of peer review or quality assurance; and (4) the interpretation and use of science is uneven and haphazard across programs and issues at EPA.

According to the U.S. House Subcommittee on Oversight and Investigations in late 1985, their two-year investigation of the EPA revealed serious abuses within the agency and OMB interference with EPA rulemaking.<sup>225</sup> John E. Daniel, a political appointee at the EPA during the Reagan administration, reported in his testimony to Congress in 1983 that OMB had attempted to "dictate regulations," persuade EPA to use cost factors in establishing health rules "when the Clean Air Act prohibited them," "threatened reprisals against the agency," and provided proposed rule changes to industry representatives prior to public release.<sup>226</sup> The EPA submitted a proposed rule to ban asbestos in 1984, but the EPA withdrew the rule because of OMB interference.<sup>227</sup> A memorandum OIRA staff prepared for Stockman in the fall of 1984 highlighted OIRA's strong opposition to EPA's asbestos rules.<sup>228</sup> As a result of OMB pressure, the Acting Deputy Administrator, James Barnes, "stunned the public, the Congress, and the EPA staff by announcing that the Agency had no choice except to withdraw its proposals to regulate asbestos under TSCA and to refer the asbestos regulatory activities...(to) the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC).<sup>229</sup> The Subcommittee added: "But for OMB's imposition of its will—subverting a fully-considered policy previously endorsed by every responsible EPA official—the Agency's proposed regulation to control asbestos would have been

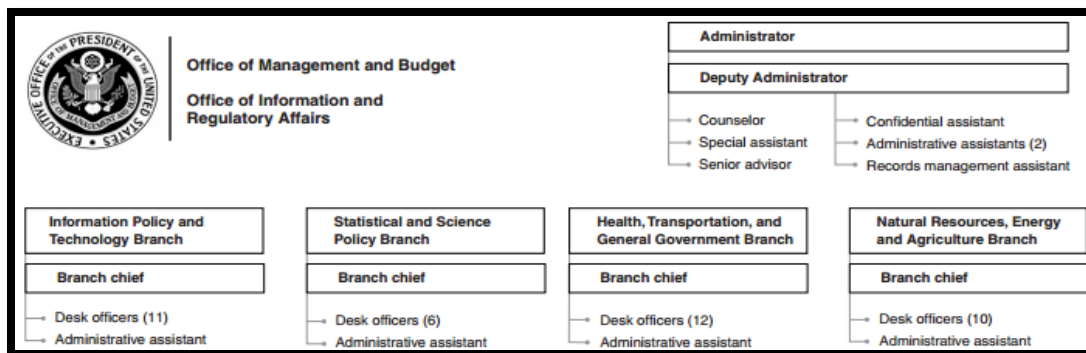
published...over a year ago, moving the public closer to the comprehensive protection from significant risks that EPA felt was necessary."<sup>230</sup>

#### 4. Office of Information and Regulatory Affairs

The structure of the OIRA has remained largely the same since 1981. The OIRA was divided into six branches as of 1989; by 2003 OIRA had four branches: (1) Information Policy and Technology, (2) Statistical and Science Policy, (3) Health, Transportation, and General Government, and (4) Natural Resources, Energy, and Agriculture (the original Information Policy and Information Technology Management branches appear to have been merged into one branch as well as the Natural Resources and the Commerce & Lands branches) (GAO, 2003) (See Figs. 16-17 below).



**Figure 16: OIRA Organization Chart (1989).**  
(Adapted from GAO, 1989)

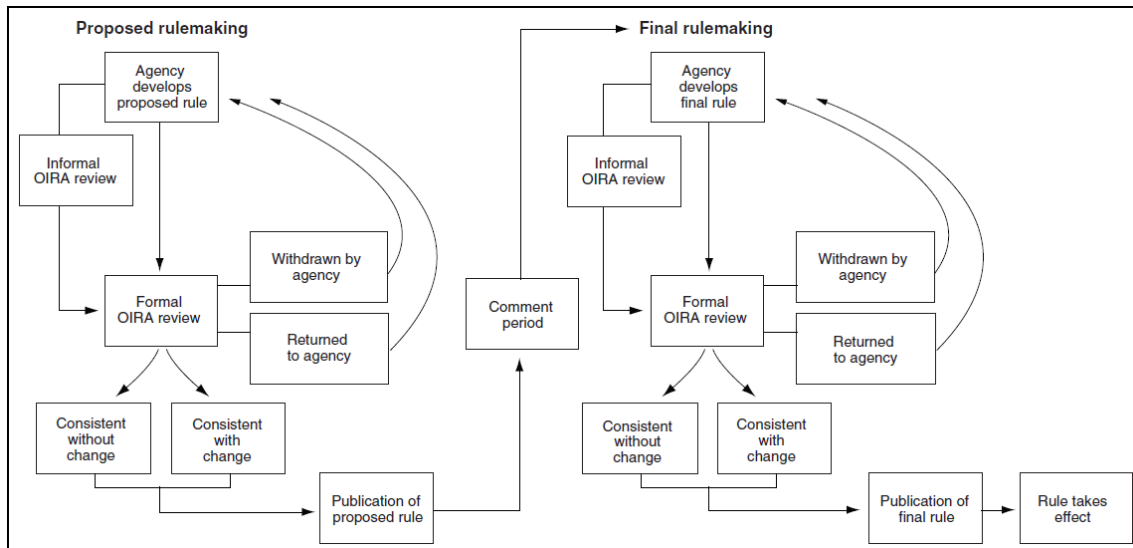


**Figure 17: OIRA Organization Chart (2003).**  
(Source: GAO, 2003)

The OIRA staff authorization levels have dropped from about 90 FTEs 1981 to a projected 44 FTEs in fiscal year 2014.<sup>231</sup> Cass Sunstein (2013), OIRA administrator from 2009 to 2012, notes that almost all of the FTEs are career staff.<sup>232</sup> The careers of several long-time OIRA staff officers provide examples of the continuity of career staff. Donald Arbuckle was hired in 1981 as an analyst (desk officer) and eventually served as the deputy administrator of OIRA from 1996 to 2006. As an analyst and deputy branch chief in OIRA from 1981 to 1996, Arbuckle (2008) states he was responsible for analyzing regulatory and information policy for the EPA and other federal agencies.<sup>233</sup> Arbuckle's responsibilities as the non-political executive manager of OIRA included overseeing a staff of 40 people, coordinating all OIRA policy reviews with White House officials, meeting with Congressional staff to explain OIRA activities, and testifying before Congress when serving as acting administrator.<sup>234</sup> Dr. Art Fraas, an economist who joined OIRA in 1981, served as chief of the OIRA's Natural Resources, Energy, and Agriculture Branch for more than 20 years and retired in 2008 (Fraas, 2011). Fraas, as discussed later, played a key role in OIRA's review of controversial EPA rules on

asbestos and other regulations. Jim Laity, a long-time OMB staffer, is now chief of the same branch (Bravender & Yehle, 2014).

Sunstein (2013) states branch chiefs, all of whom have a great deal of experience and expertise, closely supervise the desk officers assigned to each branch. The desk officer are assigned to focus on one or several agencies and receive detailed advice on performing regulatory reviews (See Fig. 18 below).<sup>235</sup> Sunstein (2013) notes that soon after a federal agency submits a proposed rule to OIRA, the relevant desk officer typically circulates the rule to a range of concerned offices and departments at the White House and other federal agencies. The OIRA may send an EPA rule, for example, to the Department of Energy, the Department of Transportation, the National Oceanic and Atmospheric Administration, the Department of Agriculture, the Department of Justice, the Department of the Interior, and the Office of Advocacy within the Small Business Administration (if the rule has a particular impact on small business) (Sunstein, 2013). Sunstein (2013) emphasizes that the OIRA review process is intended to obtain the perspectives of all appropriate federal agencies before finalizing rules.<sup>236</sup>



**Figure 18: OIRA Review Process.**

**The OIRA conducts close to several hundred reviews annually (Sunstein, 2013).**

**(Source: GAO, 2003)**

Sunstein (2013) contends that the majority of rules are completed during the required 90-day period and "are generally changed (and improved) as a result."<sup>237</sup>

Regulatory actions estimated to have an economic impact of \$100 million or more in any one year is deemed economically significant, triggering OIRA review. Sunstein reports that less than 20 percent of the rules reviewed are economically significant.<sup>238</sup> These proposed rules may raise unique legal or policy issues that interest a number of individuals and offices in the executive branch and must be review under EO 12,866 (Sunstein, 2013). Sunstein explains how the interests of Congress and the White House might inform OIRA's determination of a rule significance:

If members of Congress are concerned about a rule, there is some reason to think that it raises novel questions, and that use of the OIRA process would be a good idea. A rule might also be deemed significant because other offices and agencies are interested in the rule and would likely have views. If a rule is connected with presidential priorities, it is highly likely to be deemed significant...To say the least, it would be unusual for OIRA to conclude that a rule is not significant if



two other Cabinet departments have substantial concerns, or if DPC thinks that it should be subject to an interagency process. Indeed, such a conclusion would be highly inappropriate. A chief goal of the OIRA process is to ensure that diverse voices are heard...OIRA cannot legitimately refuse to engage in that process if diverse voices within the federal government seek some kind of hearing.

Sunstein (2013) notes that rules are considered significant if they would cause 'a serious inconsistency or otherwise interfere with an action taken or planned by another agency.' Some scientific questions may include significant policy issues that need to be "elevated." Sunstein (2013) provides the following explanation of what happens when it is not clear whether a regulatory action is significant:

In the vast majority of cases, the issue is resolved at the staff level without involving the OIRA Administrator. But the category of “novel” issues is hardly self-defining, and while disagreements are infrequent, they do occur between agencies and OIRA. An agency might contend that the rule is minor, routine, and not novel at all. OIRA staff might question this conclusion. In the very rare cases in which the issue is difficult to resolve, agency policy officials and the Administrator or Associate Administrator of OIRA might engage in further discussion, and the Administrator will ultimately decide the significance question — sometimes following the recommendation of OIRA staff, and sometimes following the recommendation of the agency.

Federal agencies may also withdraw rules for their own reasons or in accordance with OIRA's request. Sunstein (2013) states "[i]t is noteworthy that 162 rules were withdrawn from OIRA review between January 21, 2009, and September 21, 2012."

## **5. Factors Impacting TSCA Implementation**

I write today as the last remaining foot soldier of the small squad of industry players in 1975-76 who negotiated the details of the TSCA. This was a lobbying effort so effective, in retrospect, that TSCA has been far less successful than its sponsors had hoped...TSCA has failed and left us with a mere facade of effective environmental action. Industry in the United States dodged the bullet.

—Jeffrey T. O'Reilly, *Torture by TSCA: Retrospective of a Failed Statute* (2010)

## 5.1 Statutory Language

The political context in which the TSCA was created and enacted helps explain its shortcomings. For instance, Jeffrey O'Reilly, who helped negotiate the details of TSCA on behalf of industry in 1975-1976, suggested proponents of the legislation at the time did not effectively control the terms of the statute and lacked the support of strong institutional players and legal specialists (O'Reilly, 2010). J. Clarence Davies, the main author of the TSCA as a staff member on the CEQ from 1970-1973, states that the U.S. Department of Commerce wanted to kill the bill, but lacked the 'political muscle' (Roberts & Hardy, 2010a).<sup>239</sup> Davies suggests, however, that he did not control the terms of the statute well, deferring to the wording of the James T. Lynn, then the General Counsel for the Department of Commerce. Schifano et al. (2013) notes that early versions of the TSCA placed the burden on industry to provide evidence proving a chemical's safety, but that burden was ultimately placed the EPA (Schifano et al., 2011). For Davies, his negotiations with Lynn were the genesis and likely source of the procedural and substantive legal hurdles that were incorporated into the bill:

Jim [James T.] Lynn was then the General Counsel for the Department of Commerce. Hyde [James F. C. Hyde, Jr., Director of Legislation in the Budget Bureau]. didn't literally lock the door, but he closed me and Jim Lynn in a room for two days to come to an agreement on what should be in the bill [TSCA]. A lot of the perverse things that are in the law now got in there in that negotiation, because [...] Lynn started with the goal of trying to subvert the bill, in effect. The fact that he was a lawyer—and a pretty good lawyer—and that I was not gave him a distinct advantage. So, you know, a lot of the procedural, legal hurdles in TSCA really are due to that couple of days in negotiation...I think most of the stuff that, in effect, made it clear that the burden of proof was on EPA and not on the manufacturer was his [Lynn's] doing. The provision about substantial evidence in the record as being the criterion for judicial rulings on most of the TSCA rules—which to me is single most egregious provision in the law—that, I think, came from him. Now again, you know, we're talking forty years ago. If you uncovered evidence that, in fact, that got put in on the Hill, it wouldn't shock me because

there were people on the Hill who were not real enthusiastic about the law either.<sup>240</sup>

Steven Jellinek, first Assistant Administrator of the OTS from 1978-1981, argues that the fact industry wrote the TSCA "discouraged some people" at the EPA and made it difficult to generate interest in the statute.<sup>241</sup> The TSCA was reportedly called the Heckert-Eckhardt bill at the time because of industry's involvement.<sup>242</sup> "When I got to the agency," states Jellinek, "I discovered that the real environmentalists at the agency—in other words, the guys who were controlling air and water pollution...—called TSCA the "Toxic Substances Conversation Act," because there was so much conversation about it [and so little action]."<sup>243</sup>

From Jellinek's perspective, the statutory language of the TSCA is the primary reason for its downfall, or the failure of its implementation.<sup>244</sup> He asserts that many people knew early on that the law would not work. Charles Elkins, who directed OTS from 1987 to 1990, echoed Jellinek's frustration with the way the Act was written:

I had trouble figuring out from the statute whether there was, in fact, and [Congressional] goal--besides implementing the individual pieces of it. Because [of] the way the statute was written [with all its required findings, it was nearly impossible to implement in a way that achieved any overall goals of public health protection. I emphasize this because this conclusion is not obvious to the casual reader. It is only after one tries to implement the act on a day-to-day basis that one realizes that one is working, so to speak, with one hand tied behind one's back].<sup>245</sup>

Jellinek suggests that the fact the TSCA early on became an "orphan" in the Congress—one without an advocate or sponsor—is one reason the law has not changed since its enactment.<sup>246</sup>

## 5.2 Procedural Requirements

The EPA procedural requirements are very cumbersome and time consuming (Schifano et al, 2011). The EPA issuance of a rule requires the EPA follow extensive procedural requirements. The EPA must issue a rule to allow it to require testing under §4, use aspects of its notice-related authority under §5, ban or restrict chemicals under §6. The EPA issues chemical testing rules "largely on a chemical-by-chemical basis" (Schifano et al., 2011). These requirements have made it difficult for the EPA to require testing or collect information. This process 'generally requires a minimum of about two years to identify the testing needs, go through the proposal, take public comment, and get a rule finalized' (Schifano et al., 2011). Donald Clay, who directed TSCA implementation efforts in the Office of Toxic Substances from 1981-1988, expressed his frustration with §4 testing rules:

It...was frustrating in the sense of the Section 4 testing rules...I remember being told by one of my division directors at the time that, "Well, we're going to do this testing rule, and it's going to take X days to do this, and Y weeks to do this, and Z days to do this, and what have you. And so that, you know, and a year and a half from now, we're going to miss it by two weeks." I'm saying, "that doesn't seem right, that you can do it that way."<sup>247</sup>

The Government Accountability Office (GAO) reported in 1994 that, according to the EPA, it can take between 24 to 30 months to promulgate a §4 test rule.<sup>248</sup> At the same time, EPA must adhere to the Administrative Procedure Act's (APA) rulemaking requirements and additional requirements mandated by Congress.<sup>249</sup>

## 5.3 Judicial Decisions

The courts shape environmental policy by deciding on standing to sue in court, the ripeness of the case, the standard of review, and legal remedies. A study analyzing

over two thousand federal court decisions on the EPA's policies and administration suggests EPA compliance with court orders is a top priority that can take precedence over congressional mandates.<sup>250</sup> Court decisions can lead to significant environmental policy change.<sup>251</sup> Clay points out that the EPA frequently misses statutory deadlines, but "pays much more attention to court-ordered deadlines" for the following reasons:

Statutory deadlines are often put in, and there's a great connection between the career staff at EPA and the Congress. So, oftentimes everybody agrees at the informal level that they'll put deadlines in, then when they're missed, then you get a court schedule.<sup>252</sup> [William D.] Ruckelshaus almost got put in jail one time for—by a judge, the [United States Court of Appeals for the] Eighth Circuit out in California—for missing a deadline. Ever since then, administrators are very careful not to miss court ordered deadlines, because you make judges grumpy. Statutory deadlines are dime a dozen. You just miss them all the time. And general counsel doesn't do a good job of defending you. It said you're supposed to do this three years ago, [but] you didn't do it. What are you going to say?<sup>253</sup>

#### **(1) Chemical Testing Under §4**

As stated in the previous chapter, §4 gives EPA the authority to require manufacturers test chemical substances. This authority is exercised once the EPA issues a rule requiring manufacturers to conduct testing on the chemical to assess its effects on public health and the environment.<sup>254</sup> The EPA has to establish that a chemical may present an unreasonable risk prior to requiring testing. The fact that Congress did not provide a specific definition of "unreasonable risk" has allowed for various EPA and court interpretations of the term. For example, the courts have explained that the qualifier "may" in the statute supports a broad interpretation of the term with reference to the EPA's power to require testing under §4 (Schifano et al., 2011). Applying the analysis from the Supreme Court decision in *Chevron U.S.A. Inc. v. Natural Resources*

*Defense Council, Inc.*,<sup>255</sup> the D.C. Circuit Court in *Chemical Manufacturers Association v. EPA* held in 1988 that the EPA could make inferences to show exposure and require testing "where there is a more-than-theoretical basis for suspecting that some amount of exposure takes place and that the substance is sufficiently toxic at that level of exposure" to pose an unreasonable risk of harm.<sup>256</sup> The DC Circuit pointed out that its holding was the rulings of other circuit courts (Trevisan, 2011). In *Ausimont USA Inc. v. EPA*, for example, the 3rd Circuit in 1988 held that the EPA can require testing "when an existing possibility of harm raises reasonable and legitimate causes for concern."<sup>257</sup>

In *Chemical Manufacturers Association v. EPA* the U.S. Court of Appeals for the Fifth Circuit in 1990 remanded a rule that required the manufacturers and processors of cumene (isopropyl benzene) "to perform certain toxicological testing" to assess cumene's health and environmental effects. The Court instructed the EPA "to articulate the standards or criteria on the basis of which it found the quantities of cumene entering the environment from facilities to be 'substantial.'" As discussed in the previous chapter, it took the EPA about three years after the decision to promulgate guidance in the *Federal Register* on the standards and criteria EPA decided to use in making findings under §4(a)(1)(B)(i) of TSCA.<sup>258</sup> Protracted litigation has put a drag on EPA resources, use of time, and ability to issue test rules under TSCA §4 (Haemer, 1999).

## **(2) EPA's Attempt to Ban Asbestos Under §6**

[Asbestos] was, kind of, going to be the test case of how TSCA can do things. So, when the rule blew up because of the legal issues, [...] the office was completely demoralized. There were people who really weren't the same after that, because they had worked almost ten years on something they felt desperately was important, and the office did too. Suddenly, it was taken away.

—Mark A. Greenwood, Director of the former OPPTS from 1990-1994<sup>259</sup>

I knew that we had lost not just the asbestos rule. We had lost Section 6. [...] The regulation of existing chemicals got written out of the Act, basically. I mean, the (EPA) doesn't even tell anybody it's there anymore. I can't believe that. But why tell people something that's there if you can't use it?

—Charles L. Elkins, Director of the former OTS from 1987-1990<sup>260</sup>

The Fifth Circuit's ruling in *Corrosion Proof Fittings*<sup>261</sup>—and the EPA's subsequent decision not to appeal—has had the most significant, long-term negative impact on the authority and implementation of §6. In 1989, the EPA promulgated a rule that aimed to phase out most uses of asbestos in consumer products.<sup>262</sup> According to the EPA, TSCA §6 was the "ideal statutory authority to regulate the risks posed by asbestos exposure" because it was the "least burdensome means of controlling the exposure risks posed throughout the life cycle of asbestos-containing products."<sup>263</sup> The asbestos industry challenged the rule in *Corrosion Proof Fittings*.

Ruckelshaus, in his letter to Representative John Dingell 23 April 1984, explained the EPA's reasons for seeking a ban on asbestos in consumer products: "EPA is proposing to substantially eliminate rather than control asbestos because we believe the risks from the life cycle of asbestos (i.e., mining, milling, manufacturing, use, removal and disposal) are unreasonable even when asbestos is controlled."<sup>264</sup> The senior managers and staff intimately involved in developing the rule regarded asbestos as the best chemical for trying to set up standards for implementing §6.<sup>265</sup> As Victor Kimm, Deputy Assistant Administrator and Assistant Administrator for Pesticides and Toxic Substances (1985-1994), recalled: "If you had to pick a substance that was [generally accepted as creating

adverse health effect on exposed populations], it was asbestos. So, we promulgated a rule [to phase out the use of asbestos in most consumer products over a ten year period." <sup>266</sup>

The EPA continued to work on asbestos after withdrawing the 1984 rule. Elkins, who was aware of past regulatory development efforts at EPA, wanted to get a rule on asbestos through OMB and published. During a panel discussion on the TSCA held at the American Association for the Advancement of Science (AAAS) in early March 2011, Elkins described himself as "a regulator" who was "like a moth drawn to a flame"; he decided to focus on §6 knowing that he would have to work hard to show that the statute could work (AAAS, 2011). The proposed asbestos rule was expensive and vehemently opposed by the global asbestos industry. According to the EPA, the estimated costs of the rule "for the 13-year period of the analyses performed" would total about \$456.89 million or \$806.51 million "if a 1 percent annual decline in the price of substitutes is not assumed" (EPA, 1989). The EPA (1989) estimated the banned products would account for about 94 percent of U.S. asbestos consumption, based on 1985 data. The EPA correctly anticipated it would receive a great deal of opposition from industry. The EPA had also invested a great deal of money, resources, and time on the rule. The EPA reportedly spent over ten years<sup>267</sup> and about five million dollars developing the rule; it had also "produced an immense record which filled several rooms" (the record totaled 45,000 pages) (Percival et al., 2006). Clearly, there was a lot at stake for the EPA and the asbestos industry.

The Fifth Circuit Court invalidated the ban on asbestos.<sup>268</sup> The court held the EPA had provided insufficient evidence to justify the prohibition, despite ten years of EPA



activity collecting and analyzing data.<sup>269</sup> The court pointed out that under the "substantial evidence" standard of review, "even if the challenger to a rule's assertions has a solid evidentiary backing, the court will not overturn the rule as long as 'substantial evidence to support [EPA]'s decision' to issue the rule exists."<sup>270</sup> The court took a strict interpretation of the TSCA, stating "the very language of the TSCA requires that the EPA, once it has been determined what an acceptable level of non-zero risk is, choose the least burdensome method of reaching that level." The court noted the EPA had selected the harshest remedy under the TSCA – §6 total banning of a substance – giving itself the highest burden in meeting TSCA requirements, and that the "EPA's regulation cannot stand if there is any other regulation that would achieve an acceptable level of risk as mandated by the TSCA." The Court opined:

While the EPA may have shown that a world with a complete ban of asbestos might be preferable to one in which there is only the current amount of regulation, the EPA has failed to show that there is not some intermediate state of regulation that would be superior...[T]he EPA cannot discharge its TSCA burden of showing that its regulation is the least burdensome available to it.

The court found the TSCA to be a proper statute to combat a multi-industry problem, but faulted the EPA for the manner in which the EPA conducted its analysis. In this vein, the court noted the EPA did not weigh the potential risks of substances that could be substituted for asbestos, despite the fact EPA had obtained much better data on the health risks of asbestos than other toxic chemical substances.<sup>271</sup> For the court, the EPA's chosen standard of review, inability to show that the selected regulation was least burdensome, and failure to show there may be some intermediate form of regulation in between no regulation and complete prohibition made it "impossible, both for the EPA and for this court on review, to know that none of these alternative was less burdensome

than then ban in fact chosen by the agency.”<sup>272</sup> The court noted the EPA must use a cost-benefit analysis to make this showing.<sup>273,274</sup>

The court remanded the asbestos rule to the EPA, sending shock waves throughout the agency. According to Davies, the Fifth Circuit made it clear that it was not possible to meet the legal standard of §6:

But certainly the toxicological evidence and the epidemiological evidence on asbestos and mesothelioma is more clear-cut than almost anything you’re likely to find, because you have—unlike the vast majority of chemicals—a, sort of, unique disease pattern which only relates to asbestos. So, if you get somebody with that disease, you know where that person got it from, and that’s not true of 99 percent of the chemicals. So, in short, the scientific case—and in every dimension you can name—the case against asbestos was better than it’s likely to be on anything else. Despite that the court said, “no, you don’t have enough evidence to support a ban on asbestos.” The way the court got to that made it clear that there was no humanly possible way to meet the legal criteria that were in the act. I mean, it’s stupid to try, because if you took the court’s verdict as the final word, then you were never going to regulate an existing chemical under TSCA.<sup>275</sup>

This decision took away what was believed to be the TSCA most powerful authority. Since the decision, the EPA has not used the authority to successfully ban a chemical.<sup>276</sup> After the decision, the EPA indicated it would deemphasize reliance on §6 and consider emphasizing the use of its significant new use authority under TSCA §5(a)(2) (Brown, 1999).

## 5.4 Politics & Leadership

Emberizing ash was a packet of friable asbestos they sold in a plastic bag, and was designed to be put on a gas fireplace so the ash would emberize, you know. Here was air blowing in and air blowing out, and you’re putting asbestos on it. And by God, we got that banned. That’s about all we did. I mean, everything else was always on the come, but it never really happened. And so, they couldn’t get anything done, and it was frustrating.

—Don R. Clay, Director of the Office of Toxic Substances in 1981<sup>277</sup>

### **(1) EPA Under the Gorsuch Administration (1981-1983)**

As the EPA is part of the executive branch, presidents can influence EPA decisions through constitutional and political means (Rosenbaum, 2006). After taking office, the president can appoint a new administrator and select a number of political appointees to fill upper- and mid-level management positions, review and modify the proposed budget, direct the OMB, and review the EPA's proposed rules (Rosenbaum, 1984). The arrival of new presidential administrations has influenced the EPA's various approaches to TSCA implementation over the years. The most substantial shift in the direction of TSCA implementation occurred during the Reagan administration. The Reagan appointment of Anne M. Gorsuch (later Burford) and Rita Lavelle as the EPA Administrator and Assistant Administrator, along with the other high-level Reagan political appointees who came from the private sector and regulated industries in 1981 (Cohen, 1984), was aimed at reducing the EPA's enforcement presence and regulatory burden on industry.<sup>278</sup>

Gorsuch and other political appointees were soon fighting with Congress, the bureaucracy, and environmental groups over the Superfund program; Gorsuch reduced staff and resources, transferred senior career managers without justification, and sought ways to weaken existing environmental regulation and limit rulemaking (Fiorino, 2013). In 1981, a group of EPA staff employees, concerned about Gorsuch impending changes and job security, came together to organize a union (the union played a role the asbestos conflict with OMB over the 1984 asbestos rule) (NTEU, n.d.). Marilyn Bracken, the Associate Director of OTS from 1978-1980, like many other EPA personnel, either

resigned or were asked to leave as part of Gorsuch's major reductions in career staff.

Bracken describes her reasons for resigning from the EPA after the arrival of Gorsuch:

It was not a productive environment. I don't know whether it was too many committees, or the concern on Congress that this new administration—Anne [M.] Gorsuch and company—that there was...too much cooperation with industry... I think it was the concern that...under this new administration, there was going to be more voluntary regulation. So, you know, let's get those people out that were...the ones that were really pushing, that were strong managers of their programs, that had the authority, say, under TSCA to regulate. Let's get that shut down. I felt very much that way. You know, we came in and one day you were...saying that dioxin's a concern, and the next day, you were supposed to go over internationally and say, "well, it's really not a concern." And that was when I left the agency...I felt that the agency—the way it was being structured [then] under Gorsuch—was not carrying out the responsibilities of the act...<sup>279</sup>

Under the new administration, EPA employment reportedly fell from 14,269 in early 1981 to 11,474 by the end of 1982; about 2,200 personnel had been cut from headquarters staff by September 1982 (Vig, 1984). By 1983, the EPA's operating budget had been cut by about one-third; funding for research and development had decreased over fifty-percent. Vig (1984) states the reductions "crippled EPA" and led to claims that the Reagan administration was trying to deprive the EPA of the resources required for the implementation of environmental laws. The departure of key managers and career staff working on the TSCA negatively impacted existing implementation efforts.

The lack of trust between the Gorsuch administration and the remaining career staff contributed to her failure and problems with implementation. Don Clay, the director of OTS in 1981, experienced first-hand the relationship between the political appointees and career staff under the Gorsuch administration. Clay states political appointees to the EPA would try to "reinvent the wheel," but the appointees did not have any "regularized institutional history (at the EPA) that they could trust."<sup>280</sup> He states the political

appointees "wanted to make their own decisions" and they were afraid of being "captured" by career staff.<sup>281</sup> Clay recalls the inability to accomplish the toxics mission: "I did remember being frustrated we weren't sued, because—particularly with the Burford administration—how you got things done was to be sued. We actually spent one meeting one time deciding if we should form a nonprofit to sue ourselves so that we could get things done."<sup>282</sup>

The politicization of the Superfund program, conflicts of interest, unethical conduct, and lack of trust of the career staff under Gorsuch's leadership eventually led to the firing or resignation of Gorsuch, Lavelle, and the whole political management of EPA (Cohen, 1984; Vig, 1984).<sup>283</sup> According to William Ruckelshaus, who President Reagan selected to replace Gorsuch, 11 or 12 of Reagan's 13 political appointees were fired. Ruckelshaus stated in a 1992 interview that the "big mistake" Gorsuch made was "[s]he showed she didn't trust the people in the agency, and if you do that...they will return that lack of trust in kind."<sup>284</sup>

Ruckelshaus slowly began to repair the damage after his arrival in 1983. Ruckelshaus visited all the EPA regions in 1983 in his effort to "calm down the staffs as a result of Anne Burford's (Gorsuch's) tenure." He described his visits: "I invited all hands—500 to 600 people per region—to attend my talks. I asked each of these large crowds how many had worked for EPA from the beginning. Sometimes as many as two-thirds of the audience stand up. So these people persevered through some *very tough* periods in the agency's development. I think they stood it in very good stead." Ruckelshaus said that he also worked hard to "start off on the right foot with OMB

Director David Stockman and improve the relationship between the agency, the OMB, and the White House."<sup>285</sup>

## **(2) Decision Not to Appeal the *Corrosion Proof Fittings* Ruling**

There was much speculation at the time about the reasons the EPA decided not to appeal the *Corrosion Proof Fittings* ruling. The managers and staff who had worked on the rule for so many years were deeply upset by the ruling and the fact the EPA did not appeal. Kimm said the staff observed that, "[I]f the decision was not reversed, EPA's ability to exercise Section 6 authorities in the future would be severely restricted" (Kimm, 2011).<sup>286</sup> For Elkins, the court ruling was particularly galling. Elkins stated that he "felt fervently that the Agency should appeal this decision in order to set the record right and hopefully maybe move back the interpretation of the court with regard to the depth of the analysis that would be required particularly on a least burdensome issue" (AAAS, 2011). Elkins discussed the ruling and his reaction in more detail:

I did imagine all kinds of challenges in the room from OMB and people above me in the agency, but I really did not anticipate the kinds of what I have to say and I believe was outrageous reasoning by this circuit court of appeals in corrosion proof fittings case that overturn the rule. I didn't foresee the court would require...a cost-benefit analysis on every alternative as we tried to show that we were choosing the least burdensome measure...But the court said, and of course it was correct in this regard, that we did not do a cost-benefit analysis of every alternative, such as labeling the product or whatever instead of banning them. Instead we worked on doing a cost-benefit analysis about which chemicals ought to be added to the ban. So we obviously didn't focus correctly...I am trying to report to you how I felt in 1990/91 when this came through, this is part of the history, I felt that the court had really overstretched its reading of the act to require that we do that much detailed analysis...But in contrast, in turning to another part of that court case, I did foresee that we would be held accountable for making sure that we were not simply banning the product and allowing the substitute of an equally hazardous or more hazardous chemical in its place as a substitute, so we did worry a great deal and analyzed, in my mind, in my view, the substitutes for asbestos and we took this responsibility very seriously...So when I read the court

decision, if you are familiar with it, you can see that I was outraged by what the court said, which was basically that we did not do the analysis (AAAS, 2011).

Kimm argues that the 5th Circuit Court misread the language of §6, which "needs to be clarified through legislative amendments." He states that the judge's reading of the statute, as it stands, makes "an impossible standard to meet for any substance like asbestos which is used in so many types of products."<sup>287</sup> Kimm assessed that the asbestos case was EPA's strongest and "believed that there was some real public health protection in trying to get [asbestos] out of products."<sup>288</sup>

The EPA filed several procedural actions with the Fifth Circuit Court after the decision. According to an EPA document released pursuant to a Freedom of Information Act request in 2011, the EPA took the following actions in response to the ruling: (1) Filed a "Motion for Clarification" with the Court on 4 November 1991 "because ambiguities in the decision suggest that the Court may not have intended to vacate the portion of the rule banning products that were no longer being manufactured"; (2) After the Fifth Circuit clarified that the Court did not vacate aforementioned portion of the rule, EPA filed with the Fifth Circuit a "Petition for Rehearing" on 15 November 1991 to have the court remove its opinion, stating the Court's ruling contained 'serious errors of law' and was 'inconsistent with the basic principles of judicial restraint.' The petition maintained that "the Court erred by including in its opinion discussion of some issues which were not raised or briefed by the parties, and...the Court erred by substituting its interpretation of TSCA and its policy choices for those of the agency"; (3) Waited for the Court's decision on the petition; (4) Considered possible future regulatory actions on

asbestos. The EPA would have 90 days after the Fifth Circuit's ruling on the petition "to determine whether to seek review by the U.S. Supreme Court" (EPA, 1991).<sup>289</sup>

Schneider and Smith, in an article they co-authored for the *Seattle Post-Intelligencer* in February 2000, reported that on 6 February 1992 the EPA's general counsel requested the U.S. Department of Justice (DOJ) to appeal the decision, but DOJ never officially replied to the request. In the words of John Melone, the director of EPA's National Program Chemical Division in 2000: 'All we got was a verbal reply from Justice saying the administration didn't want to go forward, and by administration it was fairly obvious they meant the White House' (Schneider & Smith, 2000). Citing a 1992 letter written by Linda J. Fisher, the former EPA Assistant Administrator for Policy, Planning and Evaluation (1988-1993), Barry Castleman (2006) states the EPA sought to appeal the ruling to the Supreme Court and twice requested the DOJ take action on the appeal, but DOJ turned down both requests.<sup>290</sup> Elkins stated that he argued for the appeal, but in the end the Agency decided not to appeal the ruling.<sup>291</sup> Kimm explained that the leadership transition—President Bush appointed Reilly as the new administrator—was the primary reason for not appealing because "the policy interests of the new administration were largely unknown."<sup>292</sup>

The EPA also decided not to pursue a revised asbestos rule. According to Fisher in a publically available oral interview abstract, she decided not to revise the rule "because the industry was changing too quickly and, for the most part, moving out of asbestos."<sup>293</sup> However, Kimm argues, "It was a time when there were [safer substitutes



entering] the marketplace....Had we prevailed, I think that asbestos would have come out of a lot products [much more rapidly].<sup>294</sup>

Elkins provided additional insight into the political reasons for not appealing. According to Elkins, a political appointee had initially advised Moore against submitting the rule to OIRA for review.<sup>295</sup> Elkins (2010) provided a readout of his meeting with Moore and the political appointee about the rule and the subsequent decision not to appeal:

I had an argument that went this way: "Jack, you've been the assistance administrator over this [toxics] program for the last ten years while [the staff has developed this regulation]...You've known it was coming [and you didn't stop it]. We've now got it final, and you really ought to let it go. [If you] didn't want to do it, we should have [told the staff to stop its development] a long time ago."...I knew [this was a really important regulation for the office and ten years of work would go down the drain if the agency did not approve it]. I knew [Jack] was reluctant to send it over [to OMB and then to publication]...Sitting there in the room with me during this [meeting with Jack] was (a political appointee)...I [made my arguments and then left, and (the political appointee) stayed behind and talked to the administrator. This seemed appropriate because they both were political appointees and I was a civil servant.] Ultimately, [Jack] did approve [the regulation] to go over to OMB.

(The political appointee) was arguing against sending the rule over [to OMB], you know, for substantive reasons. [That was in keeping with] (the political appointee's job) ...And I was not able to persuade (the political appointee) to make the request for an appeal]. We got into arguments [over whether] I thought that the risk of asbestos was greater than (the political appointee) [thought it was]. I think it was (the political appointee's) decision on the substance...[our office had overstated] the risk—that we were over-regulating for the amount of risk. [This might be] a legitimate reason not to appeal... but it wasn't focused on the reason for the court's decision and it threw away ten years worth of work and our best chance to show we could regulate existing chemicals and it put nothing in its place]...I was not able to persuade (the political appointee), and we did not appeal.

## 5.5 Regulatory Review

The OIRA process for reviewing and approving EPA's proposed TSCA rules, often opaque and involving substantial delays and costs, is internal to the executive branch and not subject to judicial review (Shaffer, 2013; Livermore & Revesz, 2013).

Elkins anticipated the challenges associated with getting OMB to approve the rule:

As a regulator, like a moth drawn to a flame, I thought I would focus on section 6. I knew that working in a conservative administration as I was and having a very active OMB in reviewing those rules that we needed a good horse to ride and we needed to really do a thorough job to make a strong section 6 rule on a chemical that was not mandated by Congress. It was a pretty simple choice based on five years of research that had already gone on in the office was to choose asbestos. I think without too much major contradiction that during this 5 years and over the following 3 years, we did more analysis and deeper analysis that probably that has been done on any other consumer product in order to write that rule. We spent about five million dollars and spent about 8-10 years doing it ... We did do lots of economic analysis, in fact I held up the rule for a year to make sure we had enough analysis so we could get through Art Fraas in OMB. He in fact wrote an article later stating that was one of the best pieces of analysis he ever saw... I told Art Fraas you got 5 million dollars and ten years worth of work on this, but you are never going to see us do this much work again. I did not know how truthful that was (AAAS, 2011).

Kimmm confirmed that after the office decided to move forward with the rule, they spent another year to work out the details and "fight it through [the] OMB [clearance process]."<sup>296</sup>

Copeland (2013) interviewed senior employees in 11 federal department and agencies for a study about the length of OIRA reviews. The average time for OIRA reviews from 1994 to 2011 was 50 days. The time increased to 79 days in 2012 and 140 days during the first half of 2013. Copeland (2013) noted the employees provided the following perspectives on this increase in time:

(1) concerns by some in the Executive Office of the President (EOP) about the issuance of potentially costly or otherwise controversial rules during an election

year, (2) lengthy data or analytical requests from OIRA desk officers and a perceived lack of management of those desk officers, (3) a broadened definition of what constitutes a “significant” regulatory action, (4) lengthy coordinative reviews by other agencies and offices within the EOP, (5) the absence of any review time limit when OIRA directs the agencies to request review extensions, (6) a reluctance by OIRA to use return letters, and (7) OIRA staffing issues. Some of these observations appear to be long-standing criticisms (e.g., agency concerns about desk officers), and OIRA and the agencies are likely to have very different perspectives regarding when additional analysis is needed and which rules should be considered “significant.”

Some agencies were disproportionately impacted by the increase in review times and some rules remained under OIRA review well-beyond the 90 day period. As of June 30, 2013 38 rules had been under review for over one year, the most of which, 12, were from the EPA. Six and two of the EPA rules had been under review since 2011 and 2010, respectively (Copeland, 2013). The EPA decided to withdraw two draft regulations aimed at improving chemical oversight after several years at OIRA. An EPA-OCSP proposed rule still in review at the OIRA, "Nanoscale Materials: Reporting Under TSCA Section 8(a)," (RIN: 2070-AJ54), is one of the two rules that was submitted in 2010.

There are many White House offices other than the OIRA that have been involved in EPA rule-making. Bressman and Vandenberg (2006) interviewed the top political officials who worked at the EPA from 1989 to 2001 to provide data for their study on the "presidential control" model of agency decision-making.<sup>297</sup> The EPA respondents revealed that the following White House offices have played some role in EPA rule-making: (1) Chief of Staff; (2) Legislative Affairs; (3) Public Liaison; (4) Intergovernmental Liaison; (5) Press Secretary (also Communications); (6) Domestic Policy Counsel; (7) White House Counsel; (8) Political Affairs; (9) National Economic Council; (10) Office of the Vice President (also the Council on Competitiveness in the

Bush I administration); (11) Office of Policy Development; (12) OMB (other than OIRA); (13) Council of Economic Advisors; (14) Council on Environmental Quality; (15) Office of the United States Trade Representative; (16) Office of Science and Technology Policy; (17) and the National Security Council (Bressman & Vandenberg, 2006). According to the EPA respondents, White House offices other than OIRA can exert the most influence on major EPA regulatory actions. The respondents confirm that OIRA's influence largely extends to daily issues, whereas other White House offices take the lead on high-publicity or very important issues (Bressman & Vandenberg, 2006).

White House offices often form coalitions based on their views on a particular rule and use the OIRA as a weapon or shield to batter or defend the EPA (Bressman & Vandenberg, 2006). The respondents revealed that the White House offices helped foster "a climate of internal combat" in the review of EPA rules and the OIRA was often in the middle of the conflict (Bressman & Vandenberg, 2006). Bressman and Vandenberg (2006) describe how the offices were rarely on the same page with regards to proposed EPA rules:

Rather, they competed for influence over the content of those proposed rules, enlisting other offices, the vice president, and even the president himself to mediate the disputes. As one respondent commented, "Normal constituency groups--CEQ, the Vice President--were almost always on our side. [Others in the White House] were on the other side; [still others] brokered the disagreement." Similarly, another commented that "[Y]ou fight with another agency and hope to get White House offices on your side--CEQ, CEA [Council of Economic Advisors]--against DOE...the DOE tries as well." Finally, one offered that "[t]here was some inter-agency conflict that the White House had to mediate because it got so ugly...A respondent commented, "[W]hen you had a big fight with OIRA, that's when you brought in the other [White House] offices. Then it becomes who wins." Another remarked that on some occasions OIRA "helped to shield EPA from being battered by other [White House] offices, even though dealing with [OIRA] was excruciating.

Bressman and Vandenberg (2006) note that EPA respondents also expressed concern about the independence of OIRA career staff. While proponents of OIRA review contend such independence safeguards against politicization of issues, EPA respondents suggest OIRA career staff inject personal and institutional bias against regulation in their review of EPA rules (Bressman & Vandenberg, 2006). A former EPA officer remarked: OIRA was 'pursuing a national policy of deregulation' and of 'minimum costs of regulation' (Bressman & Vandenberg, 2006). 'It did seem that the civil servants in OIRA,' commented another EPA respondent, 'who had been there largely since the Reagan administration and Bush I, were more conservative and suspicious of EPA regulations than the political appointees' (Bressman & Vandenberg, 2006). According to another EPA officer, the OIRA staff with whom they worked were 'entrenched career people who wouldn't listen to their political bosses' (Bressman & Vandenberg, 2006).

A Senate report in 1986 suggested new OIRA desk officers, most of whom lacked scientific and technical training, were more vulnerable to OMB anti-regulatory bias. The report quoted a former OIRA desk officer who reviewed EPA regulations:

I didn't have the technical expertise to work on EPA issues. I would receive studies on both sides of [a toxic substance] issue and I just didn't know [how to evaluate the conflicting arguments]. I knew I would do well from my boss' perspective if I got rid of rule on [the toxic substances]....A good desk officer does change a rule. To make your mark, you get changes made. I felt kind of funny handing [my supervisor] back a rule saying it was consistent [with Executive Order 12291]....It would have been very difficult to advocate EPA's position. OMB has squashed some regulations I would have agree with.<sup>298</sup>

Professor Lisa Heinzerling, the Senior Climate Policy Counsel to EPA Administrator Lisa P. Jackson from January to July 2009 and Associate Administrator of the Office of Policy from July 2009 to December 2010, published an essay in March

2104 based on her experiences with OIRA and regulatory review. She makes the following revelations about OIRA review of EPA regulations:

OIRA's actual practice in reviewing agency rules departs considerably from the structure created by the executive order government OIRA's process of regulatory review. The distribution of decision-making authority is ad hoc and chaotic rather than predictable and ordered; the rules reviewed are mostly not economical significant but rather, in many cases, are merely of special interest to OIRA staffers; rules fail OIRA review for a variety of reasons, some extra-legal and some simply mysterious; there are no longer any meaningful deadlines for OIRA review; and OIRA does not follow—or allow agencies to follow—most of the transparency requirements of the relevant executive order (Heinzerling, 2014).

Heinzerling (2014) claims the OIRA places more sustained scrutiny on the EPA than any other federal agency, even to the extent of monitoring the EPA's public website "to make sure EPA does not sneak something passed it."

Heinzerling (2014) states she decided to write the article after reading the claims Sunstein made in his recent publications on OIRA, which, in many respects, did not match her personal experience at the EPA. In response to Sunstein's discussion in the *Harvard Law Review*, as outlined in section three above, she observes:

Sunstein's account of the OIRA process at least helps me to understand why we were all so confused about exactly what the process was...In another respect, though, Sunstein's account in the *Harvard Law Review* is puzzling rather than clarifying. From my vantage point at EPA, it certainly often appeared that OIRA—not other White House offices, not other agencies—was calling the shots. OIRA decided what to review, offered line-by-line edits of regulatory proposals, convened meetings with outside parties, mediated disputes among the agencies, decided whether an agency's cost-benefit analysis was up to snuff, and more. It often appeared, from the agency's perspective, that other White House offices were brought in to bolster, not to question, OIRA's position on regulatory matters.

Heinzerling's (2014) account of her experience with the OIRA review process is in keeping with the findings in the Bressman and Vandenberg study. She also cites excerpts from Sunstein's 2013 book, *Simpler: the Future of Government*, to illustrate the power of the OIRA Administrator:

Referring to OIRA as 'the cockpit of the regulatory state,' Sunstein informs us that, as OIRA Administrator, he had the power to 'say no to members of the president's Cabinet'; to deposit 'highly touted rules, beloved by regulators, onto the (*expletive*) list'; to make sure that some rules 'never saw the light of day'; to impose cost-benefit analysis 'wherever the law allowed'; and to transform cost-benefit analysis from an analytical tool into a 'rule of decision,' meaning that '[a]gencies could not go forward' if their rules flunked OIRA's cost-benefit test. This account – in which OIRA plays a central and often decisive role in determining which rules move and which don't – is much more consistent with my own experience at EPA than is Sunstein's account of OIRA as a kind of neutral 'information-aggregator.'

## 5.6 Interest Groups

As seen in chapter 3, interest groups and industry lobbyists can have an important impact on the implementation of a statute. The theme that ran throughout the transcripts of the CHF's oral interviews of those intimately involved in TSCA was that industry played an important role softening TSCA legislation and blunting implementation efforts. O'Reilly (2010) states that industry groups played a major role in constraining §§5 and 6 of the statute, effectively using mandates to shift control of chemical safety issues, and creating exclusions and exemptions in the statute favorable to industry. In O'Reilly's words:

The mandate for EPA regulators to pass control of a chemical safety issue to another federal agency, a command used effectively by the Corrosion Proof Fittings Co. in ...(*Corrosion Proof Fittings v. EPA*), undercut the potency of TSCA. The clause subordinates TSCA enforcers to other bureaucrats with softer approaches and slower timelines. This requirement in Section 6 imposes unnecessary and time-consuming requirements for findings as to the relative efficiency of the proceedings under TSCA. Also inhibiting regulation under TSCA were the exclusions and exemptions in the statutory definitions, such as the "mixture" exemption that I coauthored. The mixture exemption shields from close scrutiny combinations that might pose synergistic problems, whose ingredients were combined from "old" chemicals.

[T]he terms of confidentiality in Section 14 discourages transparency of safety data. Qualifiers and conditional clauses in the intricacies of Section 14 precluded much of the sharing that the EPA staff desired because they lacked the legal

means and resources to rebut claims of secrecy. The lockdown of physical security on EPA employees who were handlers of the incoming paperwork containing CBI, the tight controls required for its release to other governments, and the mutual distrust among regulators and innovators made TSCA far less transparent than its sponsors had intended.

Industry and environmental groups' advocacy for certain positions can make a difference in the creation of legislation and reform. Davies discusses the role of environmental groups in the TSCA process:

The environmental groups...a lot of the groups—I would say, a majority of groups—either said, “this (TSCA) was too esoteric” or [it] just wasn’t the kind of thing they wanted to worry about. Both NRDC [National Resources Defense Council] and EDF [Environmental Defense Fund] did maintain an interest in it. But [they] essentially became more and more discouraged as, again, they realized more and more just how limited the act was, and that, given the political climate, that nobody was about to change it. The Environmental Working Group, Ken [Kenneth A.] Cook’s organization, is probably one of the few groups that has really been strongly interested in TSCA, and in some ways, started the campaign, almost, for reforming the act.<sup>299</sup>

Elkins echoed this sentiment, stating environmental groups began to lose interest in the EPA after Reagan took office. According to Elkins, environmental groups reduced their lobbying efforts, essentially creating a “two-way conversation” between the EPA and industry.<sup>300</sup> The environmental groups decided the most effective way to deal with the EPA during the Gorsuch administration would be to bring action-forcing litigation against the agency.

Public interest groups have used the citizens' petition provision in the TSCA to prod the EPA to take regulatory action. TSCA § 21(a) stipulates: “Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or an order under section 5(e) or (6)(b)(2).” The EPA must grant or deny the petition 90 days after the filing of the petition. If EPA fails to



answer the petition within the 90-day period or denies the petition, then the person may file a civil action in a U.S. district court to force the EPA to start the rulemaking proceeding requested in the original petition.<sup>301</sup> "The combination of a tight deadline for EPA to respond to petitions and a cause of action to challenge petition denials in court provides petitioners with a potentially significant tool to stimulate agency action" (Percival et al., 2006).

Elkins stated citizens petitions actually forced them to take action under the TSCA within a certain time period. Elkins said his office really had to "move quickly" to provide a final decision by the deadline. Elkins described the importance the office placed on responding to the petition before the mandatory deadline:

You had to prepare a case, take it up to the administrator, bring it back down, [all within the deadline]. If you didn't meet the deadline, [the petitioners] could take you to...district court, and [have a *de novo* trial, not one based on a record. The legal advice we got was], "don't ever [put] yourself in that box." So, a lot of [the effort] was negotiating with the petitioners to try to come out with something [that you could actually implement under the act...Given the statute, this was quite a challenge.] The people petitioning you had absolutely no sense of how difficult it would be to do [something] under [that] statute. And so, we often would try to look for things that we could do, sort of, around the statute as opposed to through the statute, [so that we could accomplish something worthwhile]. I mean, if that statute had been written more powerfully, then those petitions could have really become a way of setting the agenda.<sup>302</sup>

Public interest groups use the petition provision to force the EPA to take certain actions under the TSCA and to draw wider attention to a public health or environmental problem. As noted in chapter 3, the Environmental Defense Fund petitioned the EPA under TSCA § 21 to control asbestos in public school buildings in 1978, which elevated the issue to the national level.

Interest groups and lobbyists may seek to influence EPA, OMB (OIRA), and other federal agencies, prevent or delay the passage of a proposed TSCA rule, and put pressure on White House offices and Congress. As noted in chapter 3, interest groups and lobbyists were able to persuade members of Congress to push for White House action on matters important to industry at the time. Of course it is not unusual for interest groups and lobbyists to meet with the OIRA to discuss a review that is under formal review. As Sunstein (2013) notes, the OIRA is immediately available to have "12,866 meetings (EO 12,866)" with members of the public after the rule in question has been formally submitted to OIRA.<sup>303</sup> Industry groups that oppose a proposed rule have the resources and time to monitor proposed rules and set up meetings with OIRA to air their concerns about the rule. Sunstein (2013) addresses the issue of OIRA's open-door policy and the speculation of interest group "capture":

[C]onsiderable attention has been devoted to the role of meetings in the OIRA process, with the suggestion that they compromise the process and lead to a form of interest-group "capture," or at least capitulation. Ironically, one reason for the attention is that OIRA has a high degree of transparency. Meetings with those outside the federal government are docketed on the OIRA website, and OIRA also works to make available all documents received during meetings...For those who express such concerns, the essential problem is that businesses and others subject to regulation arrange a strong majority of meetings, and public interest groups arrange far fewer. With regard to many regulatory actions, those who are in opposition, or seek to scale them back, meet with OIRA far more often than do those who support such actions and seek to make them more protective. Of course OIRA...is not responsible for this asymmetry...But at least in theory, there is a possible risk of "epistemic capture," in the sense that a view might develop, at OIRA or within the Executive Office of the President, because of the distinctive set of people who have provided relevant information. Some people have speculated that the asymmetry...has real consequences and that rules are affected and even compromised (or "weakened")...At least in the abstract, the speculation cannot be dismissed.

Victor Kimm suggests the Canadian asbestos industry played a major role in lobbying against the EPA asbestos rules:

I was told at the time, I don't know this is with certitude, but that the real opposition came from Canadian mining interests. Their concern was their international market [for...] large diameter [asbestos cement pipe would be adversely impacted, even though pipe was not on our list for phase out. The major health concern related to asbestos cement pipe related to...]occupational exposures. [...At that time our concern was with inhalation and not with ingestion as a prime route of exposure].<sup>304</sup>

The Canadian government was also concerned about the EPA's proposed rule on asbestos. The Canadian Ambassador sent an aide memoire to the U.S. State Department in October 1983 on the proposed rule. The memoire notes: "These developments are of concern to Canada as Canada supplies over 90 percent of the asbestos consumed by the USA...The EPA initiatives, if implemented, would immediately eliminate approximately one-half of total US asbestos consumption."<sup>305</sup> According to Ruckelshaus, the Canadian government officials also met with the EPA in February 1984 to review the EPA's proposed regulation of asbestos and EPA rationale and criteria for the regulation.<sup>306</sup>

## **5.7 Resource Constraints**

EPA offices responsible for TSCA implementation have historically lacked necessary financial and human resources (Schifano et al., 2011). From the outset, Congressional appropriations for TSCA implementation generally lagged behind other environmental laws (Schifano et al., 2011). Although the budget increased steadily in the late 1970s, the budget decreased throughout much of the 1980s. From 1981 to 1986, the budget for the toxics program was reduced 27 percent (Schifano et al., 2011). The resource levels remained relatively constant during the early 1990s, but the EPA's TSCA

responsibilities continued to increase substantially (such as the voluntary programs and nanotechnology initiatives). Schifano (2011) observes: "These new responsibilities, taken with constant resource levels, resulted in a significant decrease in the levels of funding for core implementation activities, including efforts on new chemical, existing chemicals, testing, asbestos, and PCBs." The TSCA budget was \$30 million in 1999 and reached \$50 million in 2008, with staffing levels remaining at approximately 270 people (Greenwood, 2009).

The lack of adequate financial and human resources, coupled with increasing TSCA responsibilities, plays a critical role in the effectiveness of TSCA implementation. The EPA reported in 2011 that it requires a yearly appropriation of approximately \$105 million to implement and enforce the TSCA (this supports approximately 360 employees and about \$5 million in grants to states to enforce TSCA) (CBO, 2012). The efficiency of the rulemaking process depends on the availability of financial resources, personnel, and time. According to the 1994 GAO report, the EPA stated that it decided not to exercise its authority to require more testing because the rulemaking process is prohibitively costly and time-consuming. The EPA estimated that, as of 1994, the costs of developing and publishing a §4 test rule have ranged between \$68,500 and \$234,000 (GAO, 1994). Victor Kimm, an assistant administrator who was involved in TSCA implementation from 1985 to 1994, stated "regulatory programs with a fairly significant scientific component" can take "four or five years at best to promulgate a regulation under existing procedures."<sup>307</sup>

The EPA received approximately \$18 million for nanotechnology research in 2010. The proposed EPA NNI investment for fiscal year 2015 is \$16.8 for environment, health, and safety research (EPA OIG, 2011).<sup>308</sup> The ORD employed an estimated 35 full-time employee (FTE) equivalents—about 60 ORD scientists spent some work hours conducting nanotechnology research—as of 2010. As of 2011, the OCSPP employed approximately five FTE equivalents who conducted nanomaterials research (EPA OIG, 2011).

## **6. Carbon Nanotubes: Management Challenges & TSCA Implementation**

The EPA established the Nanoscale Materials Stewardship Program (NMSP) in early 2008 to promote industry and research organizations voluntary submission of data and information on nanoscale materials (EPA, 2009). The EPA divided the program into two sub-programs, the Basic and In-Depth Programs, which did not likely achieve the desired results. Although 29 companies and associations submitted information to EPA on nanomaterials under the Basic Program, only four companies agreed to participate in the In-Depth Program (EPA, 2009). The program was terminated in January 2010.

The EPA announced in 2009 plans to regulate some of the most toxic, yet unregulated chemicals under the TSCA through a series of "Chemical Action Plans" (Trevisan, 2011). According to Charles Auer, who directed OPPT from 2002 to 2009, the initiatives were unprecedented in the history of EPA's implementation of the statute. Auer (2010) states: "EPA has never previously announced so many actions under [TSCA], nor has it ever cited use of §6 so widely." The EPA later began to develop approaches under Sections 4, 5, and 8 (a), respectively, to require testing of certain

engineered nanomaterials, the manufacturers submission of notices at 90 days before manufacturing and new engineered nanomaterials, and submission of additional information (Cleland-Hamnett, 2009).

As mentioned earlier, the EPA submitted a proposed rule to OIRA in 2010 on the review of nanoscale materials under TSCA § 8(a) to set reporting requirements for specific nanoscale materials. The rule would require producers of these materials disclose production volume, manufacturing and processing methods, information on exposure and release, and available health and safety data. The abstract of this rule noted EPA required the information to determine appropriate TSCA action to lessen potential risk to public health and the environment (EPA, 2010).

Schifano et al. (2011) describe four chemical management problems that are important to meeting the regulatory agenda of the TSCA: (1) prioritizing chemicals of concern; (2) setting a minimum chemical data set for new and existing chemical substances; (3) providing access to chemical data and information; (4) taking action on chemicals in an appropriate and timely manner. The EPA has carbon nanotubes as one of its priority nanomaterials, but continues to face challenges in establishing a minimum chemical data set and providing access to risk data and information. Many manufacturers of carbon nanotubes also make CBI claims, which slows EPA efforts to collect risk data on carbon nanotubes. In 2013, the EPA decided to withdraw a proposed rule it had submitted to OMB in 2011 that would have clarified that manufacturers cannot claim CBI on health and safety studies of pre-market chemicals (InsideEPA, 2012).

## **7. Impact of EPA Regulations on Carbon Nanotube Production & Products**

James R. Von Ehr, II, founder and CEO of Zyvex Group, which includes separate companies that design, create, and commercialize advanced molecularly engineered materials and products, provides his perspective on the impact of carbon nanotube production.<sup>309</sup> Von Ehr states the EPA and other regulatory agencies make it difficult to start a company and manufacture carbon nanotubes in the United States these days:

When you do start, the EPA is there to shut you down. OSHA is there to shut you down. There are a lot of agencies. My guy at Zyvex Performance Materials listed off about half a dozen at our last board meeting that are all making our life difficult, telling us that we can't make this stuff, we can't sell this stuff, we can't use this stuff, we can't have employees around the stuff. Our testing indicates that there's no problem. But when the government says you can't, you can't. So there are lots...in fact, there was a professor here at UT-Dallas that wants to sublease some space from me. He makes nanotubes. I said, "I'm not going to make nanotubes in my facility." ...I don't think nanotubes properly handled are a problem at all. But I don't think he properly handles his nanotubes...So that may be an issue for him.

...On the flip side, in my materials company, right now it looks like the EPA may shut down our adhesives business, which is a two-part epoxy with nanotubes for fear that the nanotubes will somehow slither out of the epoxy and go up your nose and get into your lungs and act like asbestos and kill you. I have not seen that possibility in this universe. Knowing what I know about thermodynamics, there's no way for the nanotubes to get out of the epoxy. But, facts don't necessarily lead to regulation.

Von Ehr appreciates the fact that his company has been made aware of the potential hazards of carbon nanotubes. He is also keen on avoiding the problems experienced with asbestos. However, he is also concerned that the potential risks are overstated:

Our nanotubes come from Arkema. They make them in a totally sealed environment. No human ever comes in contact with them. We handle them in a negative pressure room, in a glove box. We never come in contact with them. Our HEPA [High-Efficiency Particulate Air] filters in the negative pressure room have never detected any nanotubes. We've [monitored] this...the dust from sawing

them. We can't find any nanotubes. So, I think we have the maximum concentration in the facility that makes them. We don't see any nanotubes. So, I think customers are not going to have a nanotube problem. We thank the environmentalists for sensitizing us to it, because nobody wants to be the next asbestos.

I was talking to the guy from Bayer recently and he said they've done a lot of tox tests, and find that they're harmless. Not just, you know, safe enough to use, but they can't find them doing anything bad. A lot of the studies have been done with single-wall nanotubes from CNI [Carbon Nanotechnologies, Inc.]...which are [claimed] to have about 25 percent nano iron particles, which is a known problem. Nano iron is not good for people. So these things have a lot of the catalyst still in them. The people doing the testing don't have a good way to get the tubes dispersed. They don't have our magic Kentera molecules that disperse and solubilize and functionalize the tube, so they boil them in nitric acid, ultrasonicate them, which damages the ends, opens up the sidewall defects, inserts some functional groups at random spots in the tubes, in order to get them into water solution. Then they inject them, somehow, directly into the animal and find some harm. I say, "Okay. Did you do a material analysis? How much of that is nano iron and how much of that is catalyst?" Nickel and cobalt in nano particle form are also not very good, a couple of other popular catalysts.

The tubes are not nanotubes. They're damaged functionalized nanotubes [and catalysts] if you analyze what those really are. But I'm not a toxicologist. So, I'm just a business guy. I don't know...I don't want to make the point too strongly that they're safe, because who knows. I mean, if they were ever found to be other than, less safe than pure water, then people say I'm a liar. So, it's a difficult situation. All I can say is we're taking a lot of precautions. We handle them as safely as we know how. Once they're in our boat, they're not going anywhere. They're not getting out of that epoxy. That's the whole point of our molecules. It bonds it to the matrix. It's stronger than epoxy. So, it's locked in place. If you want to dispose of it, at about 400° in air these things...it spontaneously decomposes into carbon dioxide [as] the nanotubes [burn up]...They're good till 4,000 C in a vacuum or in inert atmosphere, but in air they oxidize at 400. So they burn up before the other stuff into harmless CO<sub>2</sub>. I won't accept any arguments that [this amount of] CO<sub>2</sub> is damaging the planet, because the total volume of nanotubes made in the world...is approximately zero. Not only that, but the guys at Arkema make their nanotubes out of ethanol.

Von Ehr implies the EPA rules are applied in an uneven fashion depending on the company. He suggests the difficulty dealing with multiple federal agencies has compelled his company to first manufacture the products in China and later sell them in the United States. In his words:



Seem to be different rules for different companies. Bayer has some different rules with their tubes, even though they're pretty much the same as Arkema's tubes. They don't call theirs nanotubes, so they have different regulations, different consent orders. But, their physical structure is the same, but they're in a different form and...[O]n the one hand, the EPA's saying you can't sell this stuff. On the other hand, the State Department is telling us, you can't export...advanced material. The sporting goods that used to be made with our tubes mostly have moved to China now. The manufacturing of these things is in China. So, we design them here. We market them here. Make them in China. Ship them back here. Sell them. We can't send our material to China anymore because nanotubes have been embargoed going to China...The nanotubes are French nanotubes. China makes more nanotubes than the French company. They make their own nanotubes...I'm having trouble understanding quite how this helps American enterprise...We're trying to make finished goods with products. The EPA doesn't have a problem once the product is in a solid form. They just don't like liquids, and epoxy, I guess, is liquid enough that they consider it a liquid. We're hoping that they don't consider our prepreg a liquid, because it's in solid form at room temperature. It only becomes a liquid at high temperatures...during the cure cycle...If they shut us down there and shut us down in the epoxy, then I don't think we have a business anymore.

## **CHAPTER SEVEN: RESULTS & ANALYSIS**

### **1. Overview**

This study set out to determine whether the Environmental Protection Agency could effectively regulate carbon nanotubes under the Toxic Substances Control Act (TSCA), drawing on lessons learned from the EPA's regulation of asbestos. The study made predictions derived from the rational, incremental, interest group, and process streams models. The study detailed several case studies as a basis for testing the predications.

### **2. Summary of Results**

The EPA was not able to effectively regulate asbestos under the TSCA. The EPA promulgated a rule to regulate asbestos in 1989, but the Fifth Circuit Court of Appeals vacated the regulation in 1991. The administration decided not to appeal the decision, which precluded the EPA from banning existing uses of asbestos under TSCA §6. The only asbestos-containing products that remain banned are flooring felt, rollboard, and corrugated, commercial, or specialty paper.

The EPA is currently using a four-pronged strategy to control carbon nanotubes production and use: (1) premanufacture notifications under §5; (2) Significant New Use Rules (SNUR) under §5(a)(2); (3) informational gathering rules under §8(a); and test

rules under §4. The EPA has not been able to effectively regulate carbon nanotubes using this strategy because of ongoing problems with implementation. For example, the proposed rule under §8(a) has been under OIRA review since 2010. The EPA is not likely to try, nor is it likely to succeed, in prohibiting or controlling carbon nanotubes under §6 because of the high procedural hurdles to rulemaking discussed in the previous chapter.

The four policy models used in this study help explain the factors responsible for the slow development of statutory law and administrative rules for asbestos and carbon nanotubes. The interest group model most closely predicted the ability of private sector interests to almost completely dominate all stages of the policy process. The incremental model predicted the slow modifications to existing law, but it did not foresee that EPA implementers would risk their reputations and careers trying to make nonincremental change to existing policy through the rulemaking process.

### **3. Discussion**

This section uses the case studies and relevant information presented in previous chapters to examine the predictions derived from the policy models. It discusses the development and implementation of public law on asbestos and carbon nanotubes in the context of the four policy-making stages—issue identification and agenda setting, policy formulation, policy adoption, and policy implementation—introduced in chapter 2.

### **3.1 Issue Identification & Agenda Setting**

The rational model presumes decision makers will precisely identify, define, and agree upon potential solutions to a problem. On the basis of the research contained in this study, it seems reasonable to conclude that the policy process did not work in a "rational manner." As shown in each of the case studies, private companies and interest groups almost completely dominated all stages of the policy process. Private sector interests were able to control issue identification, the scientific data used for analysis, prevent items from getting on the agenda, and weaken serious efforts to solve problems. In some instances, however, competing interests managed to have a voice at the table or provide some input to the policy process. The prediction that the policy process would be "rational" does not fit with what was reported in chapter 3. Instead the policy-making process was dominated by private sector interests and interest groups.

Lindblom's articulation of the rational model does not rule out the possibility of conflict, but assumes administrators and elected officials will try to find solutions to a problem. In fact, the case studies revealed a highly conflict-ridden process in which private interests and groups try to block any attempt to identify or define a problem that negatively impacts their interests. The participants in the struggle to identify and define the asbestos hazards, occupational safety, environmental tobacco smoke, fire-safe cigarette, and asbestos worker compensation issues, among others, viewed the issues differently and chose to define them in ways they perceived beneficial to their position. As shown in the asbestos case, the health problems with asbestos emerged in the literature in Europe, but the impact of the literature was effectively weakened by the

asbestos industry in the United States. The Sumner Simpson Papers revealed that Raybestos-Manhattan had conspired with Johns-Manville to cover-up the results of medical tests showing numerous asbestos-related diseases among workers and prevent the publication of papers that were detrimental to the interests of the asbestos industry (Bowker, 2003).

The case for the interest group model was especially strong during the issue definition and agenda setting stage because the asbestos issues involve complex technical and scientific questions that required specialized knowledge and expertise. The secrets hidden in asbestos industry documents tipped the scales of power in the industry's favor. Johns-Manville and the asbestos industry had been aware of the dangers of asbestos, but minimized public awareness of the problem for decades as discussed in chapter 3. With its secret knowledge, Johns-Manville was able to influence how the problem was perceived and defined by other participants, giving it a tremendous advantage. According to the typical rational process, no public problem would go unnoticed for a very long time, and when it is noticed, it is prioritized in order of importance with the agreement of all participants involved (Hayes, 1992). Even after asbestosis was brought to the U.S. government's attention, Johns-Manville sought to manipulate or falsify scientific findings to define the problem in a way beneficial to Johns-Manville and the industry. As shown in chapter 3, the Tobacco Institute effectively used similar tactics and strategy to define issues, which the Institute perceived as critical to winning the debate. This backdrop helps explain similar tactics and strategy used today to "seed" the scientific literature (LaDou et al., 2010). LaDou et al. (2010) point out:

Industries have the resources to seed the literature with strategic science that is less likely to be subjected to the same scrutiny routinely applied to science that is explicitly case specific. Many articles, published primarily in toxicology journals, are termed "product defense" science articles and are frequently sponsored by asbestos interests such as the defendants in personal injury asbestos litigation in the United States. These articles are distinguished from other science papers in that they are written by scientific consultants and consulting firms that are approached and paid millions of dollars to publish and promote articles to try to defeat liability claims. General Motors, Ford, and Chrysler sponsored the writing of review articles and meta-analyses of previously published work, and paid almost \$37 million between 2001 and 2008 to scientist-consultants at ChemRisk and Exponent, Inc., for presentations of these papers at scientific meetings and expert testimony on the articles. These companies were defendants in damage suits brought by mechanics over their asbestos exposures and disease arising from automotive friction materials.

LaDou et al. (2010) emphasize that all forms of asbestos cause asbestosis, malignant mesothelioma, lung and laryngeal cancers, and other cancers. Malignant mesothelioma caused the deaths of about 43,000 people globally as of 2000; the number of lung cancer deaths from asbestos exposure reported greatly exceeded this number (LaDou et al., 2010). The British government's Health and Safety Executive (HSE) released provisional data in early July 2014 showing that 2,535 people in the UK died from mesothelioma in 2012, which is an increase from 2,291 the previous year. Judith Hackitt, the HSE Chair, stated: "The high numbers of deaths relating to mesothelioma are a reminder of historically poor standards of workplace health and safety, which decades later are causing thousands of painful, untimely deaths each year...[T]hese statistics are a stark reminder of the importance of keeping health standards in the workplace on a par with those we apply to safety" (HSE, 2014). Hodgson et al. (2005) estimate that by 2050 mesothelioma will have caused about 90,000 deaths in the United Kingdom, with 65,000 of the deaths taking place after 2001.

There is still debate over whether chrysotile asbestos is less "potent" than the amphiboles. For example, some scientists, claiming that chrysotile does not cause mesothelioma, have attempted to delay the implementation of policy on asbestos (Kanarek, 2009). The 'amphibole hypothesis,' which has been put forward for over thirty years and is still pushed by several scientists linked to industry, holds that chrysotile is not an etiological agent of mesothelioma (Kanarek, 2011).<sup>310</sup> LaDou et al. (2010) observe: "The only people who have an incentive to continue to fund research on the health effects of chrysotile are those with an economic incentive to raise doubt about its harm...As a result, subsequent literature reviews that report a predominance of articles reaching a certain conclusion may then mistakenly report there is a new "consensus" in the literature." David Bernstein, an asbestos industry-affiliated scientist, provided the following observation on chrysotile in a July 2014 publication:

Chrysotile, the only type currently used, has been shown to have little biopersistence in the lung and to produce no pathological response in both short-term and sub-chronic inhalation toxicology studies in either the lung or pleural cavity. In contrast, similar exposures of amphibole asbestos are highly pathogenic quickly producing interstitial fibrosis with fibers translocating to the pleural cavity and initiating pathological response there as well (Bernstein, 2014).

The research for this dissertation revealed that the scientific findings of several current academic researchers and scientists linked to industry—one of whom, Dr. Kenny Crump, was formerly a scientific advocate for Johns-Manville and involved in tobacco litigation—continue to influence the scientific debate over chrysotile biopersistence relative to amphibole asbestos.<sup>311</sup> An R.J. Reynolds interoffice memorandum in 1986 described Crump's work as an expert witness for the asbestos industry:

A school district in Tennessee was being sued to get rid of asbestos. Dr. K. Crump was an expert witness at a two-week trial. He prepared a chart and showed that while one out of ten people who smoke get lung cancer, nine out of ten do not...(There is 50 deaths per one million people on school buses, four deaths per million people living in brick houses from radon. Life expectancy from smoking is reduced by two to five years; from contaminants in water, two to three hours; asbestos in school, less than six minutes life expectancy reduction). The trial jury came out with the verdict "no damages were owed by the school district...There have now been six cases of this type. No damages were allocated by the jury in three out of the six where the data such as Crump presented was allowed as evidence."<sup>312</sup>

Sporn (2014) cited a report co-authored by Drs. Crump and Wayne Berman, to help explain "reported reductions in oncogenicity for this species (chrysotile) in humans in contrast to the amphiboles and for the epidemiologic studies that conclude that motor vehicle mechanics performing brake repair are not at an increased risk for developing mesothelioma."<sup>313</sup> Bohme et al. (2005) state that the EPA commissioned Drs. Crump and Berman to determine the risk of developing cancer from asbestos using a mathematical model.<sup>314</sup> Based on the model, Crump and Berman judged chrysotile does not heighten the risk of developing mesothelioma (Bohme et al., 2005).

Private interests are still trying to downplay the adverse health effects of chrysotile asbestos in the scientific literature and these findings are in turn used to develop arguments in ongoing asbestos litigation. Bohme et al. (2005) note that asbestos companies used the Crump and Berman findings to request for the dismissal of thousands of lawsuits in the court system. In the 2013 case *Strickland v. Union Carbide*, Union Carbide argued before a California appeals court panel that Union Carbide's Calidria chrysotile is different from other forms of chrysotile and the expert witness provided no evidence that Calidria causes mesothelioma.<sup>315</sup> Union Carbide further argued: "According to Dr. Hammar, there is 'abundant proof' that amosite and crocidolite [that is,



amphibole] causes peritoneal mesothelioma; even a single day of exposures to these forms of asbestos can be sufficient; and the asbestos bodies in Mr. Strickland's lungs prove that he was likely exposed to heavy doses of amphibole asbestos."

Even prominent toxicologists such as Donaldson and Seaton (2012) have suggested chrysotile is less harmful than the amphiboles because it is less persistent both *in vitro* and *in vivo*; however, many research groups in the past found chrysotile to be more toxic than crocidolite or amosite (Wright et al., 1983). In fact, Donaldson's scientific impartiality has recently come into question as a result of a New York Supreme Court Appellate Division ruling in 2013. The Court upheld an earlier decision that found Georgia-Pacific, a subsidiary of Koch Industries, funded a series of academic studies and academic papers that "were intended to cast doubt on the capability of chrysotile asbestos to cause cancer" and to "aid in its defense of asbestos-related lawsuits."<sup>316</sup> The Court, reasoning the case involved potential crime-fraud, ordered Georgia-Pacific to hand over the raw data and internal communications involving the studies, three of which were co-authored by Donaldson (O'Neill, 2013; Van Noorden, 2013). Donaldson did not declare a conflict of interest on the papers and reportedly alleged that he was not connected to asbestos interests (Van Noorden, 2013). Donaldson reportedly received about \$6,000 for his work, but his six co-authors were paid a total of \$2.3 million (Van Noorden, 2013).

Soto et al. (2005), rather cryptically, note: "Human exposure to airborne chrysotile asbestos fibers remains a complex issue in spite of its general regard a significant respiratory health risk." Qi. et al. (2013) point out the question of whether chrysotile is a causative agent for mesothelioma is complicated by the fact that billions of

dollars in chrysotile exports and litigation could be impacted by scientific research connecting mesothelioma to chrysotile. Peacock (2011) states the asbestos industry is spending "millions of dollars to assure India and convince any other developing nation that may be in the market that white asbestos, or chrysotile, is safe."

This discussion is important because about 95 percent of the asbestos in global commercial use is still chrysotile (DHHS, 2001).<sup>317</sup> In addition, chrysotile is the only asbestos fiber currently imported and used in the United States (USGS, 2013). The U.S. Department of Health reported in 2001 that 94 percent of the chrysotile used in consumer products was Grade 7 chrysotile (about 3  $\mu\text{m}$  in length).<sup>318</sup> Although chrysotile is banned in the European Union and other countries, it is still exported to the United States. Russia and China produced 1,000,000 and 440,000 tons of chrysotile in 2012, respectively, making them the largest producers in the world (USGS, 2013). In 2012, India was the largest importer of asbestos in the world, with imports reaching 473,240 tons (Ruff, 2013). Courtice et al. (2010) estimate over one million people in China are employed in asbestos-related industries, with about 230,600 workers directly mining or processing asbestos. Courtice et al. (2010) suggest Chinese asbestos workers typically receive high-levels of exposure to asbestos because of poor working conditions. The smoking rates among male Chinese asbestos workers also remains high; smokers accounted for 78 percent of an asbestos cohort in a separate study (Courtice et al., 2010; Wang et al., 2012).

Against this backdrop, it is clear that the "seeding" of the literature produced on carbon nanotubes could occur as well. Rory O'Neill, a professor in the occupational and

environmental health research group at the Stirling University in the UK, aptly states: "The professor's (Donaldson's) willingness to deliver a rationale for continued chrysotile use, while making a flat and flatly untrue denial of links to asbestos interests, raises further serious questions" (Rose, 2013). Indeed, the papers on carbon nanotubes written by authors linked to Georgia-Pacific asbestos case may also require closer scientific scrutiny. As illustrated in chapter 4, significant scientific uncertainty remains with respect to the toxicity of carbon nanotubes. The findings suggest the chemical composition, surface charge, and other physicochemical characteristics may enhance pulmonary toxicity under specific conditions. The lack of standard methods for risk assessment and the variability in the physicochemical properties of the carbon nanotubes used also limits the researcher's ability to compare and draw analytic insights from the data (Ghiazza et al., 2014). O'Neill (2013) aptly states: "Good, impartial science can help save lives, by identifying life-threatening exposures at work and identifying measures—controls, safer standards, bans on the deadliest substances—to remedy them...For those for whom the science came too late, the ones forming part of the body count, it can mean at least some compensation for a life cut short."

As we have seen, the participants in the asbestos case study had conflicting values: profits, economics, and national security versus worker safety, public health and the environment. The issues impacted unions, environmental groups, the asbestos industry, the tobacco industry, and government in different ways. This led to the emergence of distinct interests and intense struggle. Where the environmental groups and unions warned about the risks to occupational safety and public health, asbestos

manufacturers fought to maintain the status quo and prepare for the deluge of impending lawsuits. When interests converged, groups built coalitions to increase their chances of success in defining the problem. The AFL-CIO formed coalitions with the tobacco industry and the Environmental Defense Fund to combat Johns-Manville over asbestos workers health and compensation issues. Labor's decision to back tobacco in the fight against Johns-Manville proved to be decisive.

As discussed in chapter 3, asbestos was a serious occupational and public health problem long before the asbestos in schools issue reached the final congressional agenda in early 1979. Asbestos in schools was only one of many issues that were contending for placement on the institutional agenda. Issue definition and placement on the agenda impact the later stages of the policy-making process (Hayes, 1992).

### **3.2 Policy Formulation & Adoption**

Hayes (1992) states: "[F]or any given issue, the policy equilibrium will be a function of who participates (the configuration of demand), what resources each participant brings to bear, and how effectively each group translates its resources into influence." The asbestos and tobacco industries had significant monetary and personnel resources they could bring to bear to influence the policy process. The asbestos and tobacco industries were able garner support from various Republicans and Democrats in both houses of Congress on legislative issues, especially from those members of Congress whose states were heavily dependent economically on those industries. Representative Bliley (R-VA) was an ardent supporter of the tobacco industry and Senator Heinz III (R-PA) was especially supportive of labor interests. The tobacco

industry also hired former high-ranking government officials who had worked in key federal agencies and maintain strong ties to legislators and regulators. The tobacco industry, for example, retained former OIRA director Jim Tozzi's services. Craig Fuller, senior vice president of corporate affairs for Phillip Morris, provided a check for \$200,000 to Tozzi in 1993 for the "ongoing efforts of Federal Focus, Inc." (Tozzi was Chairman of Federal Focus, Inc.) (Fuller, 1993). A Phillip Morris interoffice memorandum in 1998 recommended retaining Tozzi for \$5,000 per month plus expenses for the following reasons:

Jim has long done high quality and important work for WRA and has always been willing to help the WRO when the need arises. The WRO will undoubtedly need Tozzi's help and expertise as 1998 continues to roll out. His contacts at OMB are second to none, and OMB will continue to be a key player as Congress considered the PR this session. He also has great relationships on Capitol Hill and at the FDA--again, places where we can surely use his help and where we need his help. Given the new lobbying registration laws, Jim will have to register as a lobbyist for the WRO and he had told me he is willing to do so. I hope you agree with me on the need to move expeditiously on this front (Nicoli, 1988).

As pointed out in chapters 3 and 6, industry possessed substantial resources, great access, and were sometimes the only group lobbying the EPA on TSCA issues. There was, however, a major shift in the equilibrium of the groups as litigation began to drain Johns-Manville resources after 1977 and the tobacco industry was dragged into the conflict.

The legacy tobacco archives showed the steps the tobacco industry was willing to take to stave off the threat from the asbestos industry. The Tobacco Institute maintained some strong supporters in the administration and Congress and played an important role in the legislative process. The Institute was able to build coalitions as well, helping the tobacco industry outmaneuver the politically weakened Johns-Manville. The effective

opposition to the Fenwick bill and shaping of the fire-safe cigarette legislation are but two examples of the industry's impact on the policy process.

The Senator Heinz papers provided unique insights into the public policy process and the influence of industry and special interest groups. The papers not only illustrated the Senator's decision process, but also the extent to which he depended on the input from his staff. Heinz would ask for staff recommendations on the merits of bills that came before the Senate, labor politics, and controversial environmental and public health issues. The papers often addressed an issue in the context of congressional politics, labor and business politics, and likely responses from constituents.

The process streams model holds that a "policy window" is required for legislative action on a matter, which typically involves a crisis, focusing event, or change in administration. Despite the rising asbestosis claims and the asbestos crisis in schools, the election of Ronald Reagan and appointment of Gorsuch as EPA administrator resulted in a shift toward deregulation and "voluntary" approaches to control of asbestos. The lessons learned from the passage and implementation of the 1980 and 1984 Acts and related regulations dealing with asbestos in schools influenced the manner in which policy entrepreneurs attempted to define the scope of the problem and make the case for the 1986 AHERA legislation. The policy entrepreneurs and environmental interest groups supporting the legislation still had to define the issue in a way that appealed to widely-held public values, garner conservative Republican support in Congress, build coalitions, and avoid potentially overwhelming opposition from industry.

### 3.3 Policy Implementation

The rational model assumes there is a clear separation between politics and implementation. It also assumes the implementer would carry out policies in a rational, objective, nonpolitical, and scientific manner. As the case studies in chapters 3 and 6 show, politics is an integral part of implementation. The policy implementation stage brings in participants who are spread throughout the three branches of government (Hayes, 1992). The White House and Congress can use a number of formal and informal tools to influence policy implementation. Chapter 6 contained a detailed discussion of OIRA and the influence of political appointees at the EPA. Representative Florio, Senator Heinz and other members of Congress often used formal and informal tools to influence the policy process. Senator Heinz, for example, planned to meet with Don Clay, then EPA's new Assistant Administrator, in early January 1990 to "encourage Mr. Clay to be receptive to the use of economic incentive mechanisms (for solid waste)" (McHugh, 1990a) and "to press Mr. Clay in order to neutralize reported EPA staff opposition" (McHugh, 1990b).

As discussed in chapter 6, the judiciary plays an important role in during the implementation stage, particularly with respect to environmental policy. Within the boundaries of the definition of policy presented in chapter 3, "judicial policy making is in some respects quite similar to but in other respects distinct from policy making in the executive and legislative branches of government" (Nakamura & Smallwood, 1980). As seen in the *Corrosion Proof Fittings* case, the decision of a three-judge panel had long-range ramifications on the EPA's ability to regulate asbestos and other hazardous

substances under §6 of the TSCA, which, in turn, has had very broad and important impacts on society from a public health standpoint. Prior to this decision becoming final, the EPA and the Bush administration had an opportunity to appeal it, but they did not do so. It is difficult to know, in retrospect, whether the appeal would have resulted in an opinion favorable to the EPA.

Hayes (1992) points out that corporations are in the strongest position to affect policy during the implementation phase. As noted in chapter 6, environmental groups began to reduce their lobbying efforts once Reagan took office, essentially creating a "two-way conversation" between the EPA and industry. The environmental groups decided to bring forcing-action litigation against the EPA instead of trying to compete with industry during the Gorsuch administration.

As stated earlier, issue definition can impact the later stages of the policy-making process. As mentioned in the preceding chapter, Elkins remarked that Art Fraas, the OIRA economist who reviewed and approved the 1989 asbestos rule, published an article on the EPA analysis used for the rule. In his article, titled *The Role of Economic Analysis in Shaping Environmental Policy*, Fraas (1991) wrote that the impact analyst of the rule was thorough, but contained flaws:

In its decision regarding asbestos products, EPA argued that its analysis did not estimate accurately the increase in actual exposure to the general population from continued asbestos use. EPA also argued that the (regulatory impact analysis) overstated the costs of a ban/phasedown because it made conservative assumptions about the cost of substitutes. EPA did not acknowledge, though, that other assumptions in its analysis probably overstated actual health risks. For example, the EPA's analysis did not reflect the continuing controversy over the relative potency of different types of asbestos or the substantial latency period for asbestos-caused cancer.



Fraas cited a 1990 study favorable to the asbestos industry, *Asbestos: Scientific Developments and Implications for Public Policy*, to make the last point in above paragraph.<sup>319</sup> Fraas (1991) states in the footnote citing the paper: "There were alternative estimates of potency available to EPA. Arguably, EPA chose conservative estimates to be cautious. But these upper-bound risk estimates were presented, without qualification, as representing the risk associated with asbestos use." Soon after the study was published in January 1990, Richard Kronenberg, M.D., stated that the article was detrimental to the control of asbestos for the following reasons: "The authors are known for having done excellent work in the field of asbestos-related diseases. Unfortunately, these so-called studies do not present a balanced view. Thus they are guilty of the very thing they are critical of—a biased analysis of the facts.' Paul Brodeur, author of the book *Outrageous Misconduct: The Asbestos Industry on Trial*, claimed that three of the authors of the study—Mossman, Gee, and Corn—"have either been paid consultants to asbestos companies who are engaged in litigation, or have testified as paid consultants...of asbestos companies in court cases, or both.' Dr. Orn Eliason, a physician from Baltimore, published a letter to the editor in *The New England Journal of Medicine* on 11 January 1990 claiming the study 'subtly present[ed] the view of the asbestos industry' "by implying that the health hazard from asbestos is low and that exposure to asbestos alone does not cause cancer."<sup>320</sup>

#### **4. Analysis**

Given the way in which private interests and groups dominated decision making in the asbestos case, it should not be surprising that TSCA implementation has turned out

poorly. The general consensus among environmental and industry groups is that the TSCA is flawed and has not met the expectations of its original sponsors, highlighting the need for reform (Evans, 2012). An important question is whether reforming the TSCA, which has received increased attention in Congress since 2010, will solve the problem. This increased interest has led to the introduction of several bills in the House and Senate (ELI, 2014). In April 2010, for example, the Senate introduced the Safe Chemicals Act of 2010 to overhaul the TSCA, which would have placed the burden on companies to prove the safety of chemicals. The major provisions of the proposed Act, as revised in 2011, would have greatly increased EPA responsibilities (CBO, 2012). The Congressional Budget Office (CBO) (2012) estimated that there would be significant costs involved in implementing the reforms (\$128 million over five years, assuming appropriation of the required amounts). The CBO (2012) also estimated, based on historical information on EPA's implementation of other large programs, that the EPA's workload would increase by approximately 30 percent each year; the EPA would require an additional \$30 million annually for new personnel, contractors, and other administrative activities associated with implementation of the reforms.

The Congressional Research Service released a report to Congress on 3 January 2013 stating that TSCA reform remains a high-priority for some members of Congress (CRS, 2013). Senator Tom Udall (D-NM), who chairs the Senate Environment and Public Works Subcommittee on Superfund, Toxics, and Environmental Health, wrote in a recent article that the bill introduced by the late Senator Frank Lautenberg (D-NJ) and David Vitter (R-LA) in 2013, entitled the "Chemical Safety Improvement Act," was a

"rare legislative breakthrough" (Udall, 2014). On 29 April 2014, the House Subcommittee on Environment and the Economy, Committee on Energy and Commerce, held a hearing to discuss the revised draft bill called "The Chemicals in Commerce Act" aimed at reforming and improving the TSCA. The general consensus seems to be that reforming the TSCA will magically erase decades of TSCA woes. As this and previous chapters have illustrated, the TSCA and any subsequent reforms are, in the words of Eugene Bardach (1979), "only a collection of words" unless they are implemented.

For Pressman and Wildavsky (1984), the key is to join the challenges of implementation to initial policy formulation. They suggest closing the divide between policy design and implementation "by gearing programs more directly to the demands of executing them." They further state: "[A]n appreciation of the length and unpredictability of necessary decision sequences in implementation should lead the designers of policy to consider more direct means for accomplishing their desired ends."

Pressman and Wildavsky (1984) note, "No suggestion for reform is more common than 'what we need is more coordination.'" The OIRA is a lasting legacy of Stockman and the Reagan Administration. The Reagan Administration was able to slow TSCA implementation by creating the OIRA, giving it a say in EPA rulemaking, and increasing the level of coordination and delay. Increasing EPA personnel numbers and the timely production of rules will not necessarily solve the problem of getting rules through the OIRA. If the EPA is able to generate and submit rules for review at a greater rate because of reforms, it could increase the OIRA workload and could actually lead to longer delays in regulatory review.

Although Sunstein (2013) argues the OIRA process improved regulations, which may or may not be the case, the fact of the matter is that EPA regulations that are withdrawn or sent to OIRA also impose economic and societal costs, in terms of EPA labor and time and public health. Sunstein's (2013) discussion on OIRA capture takes on new meaning when one considers private interest groups only have to focus minimal resources on one small office to have a significant impact on EPA rulemaking and TSCA implementation. The formulation of new chemicals regulation should be more closely linked to implementation to ensure that we do not repeat the same errors in the race to enact a new law that becomes just another "collection of words."

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<sup>1</sup> Carbon nanotubes have been identified for use in field-effect transistors, transparent electrodes for light-emitting diodes and organic solar cells. Carbon nanotubes could play an important role in future developments in aerospace, nanoelectronics, and nanomedicine (Chen et al. 2008).

<sup>2</sup> Engineered nanomaterials are classified as materials with at least one dimension less than 100 nanometers in size (Bhatt & Tripathi, 2011).

<sup>3</sup> This review will place a specific emphasis on the on the TSCA, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Clean Air Act (CAA), the Clean Water Act (CWA), the Safe Drinking Water Act (SDWA), the Comprehensive Environmental Response, Compensation, and Liability Act and Resource Conservation and Recovery Act (CERCLA/RCRA), relevant case law, and government documents used in developing draft administrative rules and the promulgation of final rules.

<sup>4</sup> Some interest groups will try to “shape the content of state statutes, define standards used in administrative rules and regulations, and get courts to block – or sometimes to uphold – legislative and administrative decisions... They also play a role in state government elections through campaign contributions to political parties and candidates, direct mail and telephone efforts aimed at mobilizing a block of voters, and through political action committees (PACS) that deliver independent television and radio advertisements” (Conant, 2006).

<sup>5</sup> “The iron triangle metaphor, linking executive bureaus and agencies, congressional committees, and interest group clienteles... is used to describe a fixed, closed, autonomous system for making policy” (Thurber, 1991).

<sup>6</sup> Kekulé’s recollection of his discovery of the benzene structural formula, for which he is most famous, is sometimes referred to as the “ouroboros dream.” The following account of the discovery was given in 1898: ‘I was sitting, writing at my text-book; but the work did not progress; my thoughts were elsewhere. I turned my chair to the fire and dozed. Again the atoms were gambolling before my eyes. This time the smaller groups kept modestly in the background. My mental eye, rendered more acute by repeated visions of the kind, could now distinguish larger structures, of manifold conformation: long rows, sometimes more closely fitted together; all twining and twisting in snake-like motion. But look! What was that? One of the snakes had seized hold of its own tail, and the form whirled mockingly before my eyes. As if by a flash of lightning I awoke; and this time also I spent the rest of the night in working out the consequences of the hypothesis’ (Aldersey-Williams, 1995).

<sup>7</sup> Buckminsterfullerene (C<sub>60</sub>), also known as the “Buckyball” or carbon fullerene, consists of many Kekulé structures. Drs. Richard Smalley, Robert Curl, and Harold Kroto discovered C<sub>60</sub> in 1985, for which they shared the Nobel Prize in chemistry in 1996.

<sup>8</sup> This section was inspired by Bosso’s work on politics and pesticides, which used an art metaphor to describe policy-making (Bosso, 1987).

<sup>9</sup> Conant & Balint (2011) note that an oil spill off the coast of Santa Barbara and other environmental events fueled changing public attitudes, evidenced by polling data in 1969 showing elevated public concerns about the environment; the first decade of the CEQ’s existence in the 1970s witnessed the enactment of key environmental laws, such as the Clean Air Act, the Clean Water Act, the Marine Mammal Protection Act, the Coastal Zone Management Act, and the Endangered Species Act in 1973.

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<sup>10</sup> *Reserve Mining Company v. EPA*, 514 F.2d 492 (8th Cir. 1975) and *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976).

<sup>11</sup> Conant (2006) observes that some interest groups will try to “shape the content of state statutes, define standards used in administrative rules and regulations, and get courts to block – or sometimes to uphold – legislative and administrative decisions... They also play a role in state government elections through campaign contributions to political parties and candidates, direct mail and telephone efforts aimed at mobilizing a block of voters, and through political action committees (PACS) that deliver independent television and radio advertisements.”

<sup>12</sup> “Focusing events are highly public events that call attention to a particular issue...” Indicators” such as regularly conducted surveys or published reports can also raise awareness of an existing condition, but focusing events tend to be more effective. The media also plays an important role in shaping the saliency of a particular issue” (Smith & Larimer, 2009).

<sup>13</sup> Friable asbestos-containing material is “any material containing more than one percent asbestos (as determined by Polarized Light Microscopy) that, when dry, may be crumbled, pulverized, or reduced to powder by hand pressure” (EPA, n.d.). As noted in a technical field report of the Dr. R. F. Nicely School (Greensburg, PA) conducted for the Greensburg-Salem School District in Westmoreland County, PA in 1979: “The ease with which sections of the ceiling broke off was quite disturbing to this investigator, since large areas of the ceiling appeared to have been tampered with by students” (Esmen & Dixon, 1979).

<sup>14</sup> U.S. House of Representatives, Committee on Energy and Commerce, *Federal Efforts to Control Asbestos Hazards*, Report No. 98-174, 98th Congress, 2nd Session (Sep 1984).

<sup>15</sup> “In 1906 H. Montague-Murray reported to a Departmental Committee on Industrial Diseases in England concerning a case of pulmonary fibrosis in an asbestos worker on which he had done an autopsy in 1900, but an account of the case seems not to have been published... In 1906 Auribault reported numerous deaths in a French asbestos spinning mill and weaving factory over the period 1890-1895... In 1918 as well, Pancoast, Miller, and Landis noted radiological evidence of pneumoconiosis in the lungs of asbestos workers. The report, however, did not attract attention at the time” (Selikoff & Lee, 1978).

<sup>16</sup> Selikoff (1978) states Hoffman's findings reportedly influenced Prudential's decision not to issue life insurance policies on asbestos workers.

<sup>17</sup> Cooke's research helped Dr. E.R.A. Merewether, medical inspector of the factories for the Home Office, identify 26 cases of asbestosis in textile workers from 1929 to 1930 (Widavsky & Schulte, 1995).

<sup>18</sup> “Selikoff's first study published in 1964 covered workers who were on the union rolls in 1943. When these men were tracked to 1962, they showed that insulators had an excess death rate of 25 percent, with a heavier mortality than normal from not only asbestosis, but also lung cancer, mesothelioma, and stomach/colon/rectal cancer” (McCulloch & Tweedale, 2008).

<sup>19</sup> “By 1982, 30,000 claims had been filed against 260 asbestos firms.” Scheberle, D. “Radon and Asbestos: A Study of Agenda Setting and Causal Stories.” *Policy Studies Journal*, Vol. 22, No. 1, 1994 (74-86)

<sup>20</sup> The assistant school superintendent in Montgomery, Alabama, claimed that Montgomery school board members and administrators knew little about asbestos and the hazards in their schools until reading an article on the matter in the *American School Board Journal* in late 1978 (Harris, 1984).

<sup>21</sup> “Recently a series of news reports and articles by Herb Denenberg exposed serious asbestos contamination in 24 Philadelphia Public Schools. His reports tended to zero in on the fact that Philadelphia School District had knowledge of this problem for the past 10 years and had done absolutely nothing about it claiming that the Philadelphia Health Department had assured that the asbestos posed no health threat to the children in these schools.” Borden, Catherine (Staff Member to Senator Heinz III), *Memorandum: Meeting with Hugh Community Organization Friday December 12, 1980* (9 DEC 1980). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>22</sup> “EDF indicated they have been negotiating with EPA and Johns-Manville, the primary producer of raw asbestos, over the last six months but have received no action from EPA. EDF said its petition was a last resort... The National Education Association, the American Federation of Teachers, and the National Parent-Teachers Association also issued endorsements for the EDF action urging EPA to promulgate rules to adequately control asbestos in public schools.” Asbestos, Chemical Regulations Reporter, The Bureau of



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National Affairs, Inc. (12 Dec 1978), pp. 1740-1741. *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>23</sup> Albinson, R.D., & Cline, B.B. (1983, March 10). *Issues Management*. [Internal Memorandum for Samuel D. Chilcote, Jr., Tobacco Institute]. University of California, San Francisco; Legacy Tobacco Documents Library. Retrieved from <http://legacy.library.ucsf.edu/documentStore/d/f/i/dfi20g00/Sdfi20g00.pdf>

<sup>24</sup> 'It is now clear...that the asbestos industry, internationally, is literally engaged in a struggle for survival. Recent developments, an increasing concern with potential environmental hazards (i.e. risk to the general public) and associate with cancers other than lung cancer and mesothelioma have greatly increased the scope of the problem' McCulloch & Tweedale (2008) (citing an internal Raybestos Manhattan report).

<sup>25</sup> In an internal memorandum on 6 March 1978, the vice-president of the Tobacco Institute, Fred Panzer, summarized a presentation given by a representative of Johns-Manville at a seminar in Washington, DC on proposed OSHA Generic Cancer Standards. The memorandum focused on Johns-Manville statement on smoking, which used some of the same Mount Sinai statistics on the synergistic effects of asbestos and smoking cited in the EDF report to support the Johns-Manville claim that eliminating smoking is the easiest way to prevent lung cancer in asbestos workers (Panzer, 1978).

<sup>26</sup> Draft Tobacco Institute Response to Johns-Manville Anti-Tobacco Claims (7 Dec 1979), citing Johns-Manville Corporation 1978 Annual Report, p. 26. (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>27</sup> Jack Mills, *Remarks: Board of Directors Meeting*, New York City (14 June 1979) (internal Tobacco Institute document). *Legacy Tobacco Documents Library, University of California, San Francisco*.

<sup>28</sup> "The bill was referred to the Education and Labor Committee, Subcommittee on Labor Standards. Hearings were held on May 1, 2, and 8, 1979. Memoranda from Cook & Henderson and Fred Panzer of the Tobacco Institute follow. Hearings scheduled to be held in Long Beach, California on July 6, and 7, 1979 and Providence, Rhode Island on October 1, 1979, were postponed. No hearings have been rescheduled. Representative George Miller (D-Calif.) testified before the Subcommittee on Crime, House Judiciary Committee, in support of his bill H.R. 4973 which would penalize corporate officials who knowingly conceal hazards from their employees and the public. His reference to tobacco indicates the increased chances that an asbestos work who smoked would develop asbestosis (emphasis in original document)." Memorandum: F. Eugene Wirwahn (Cook, Purcell, Hansen & Henderson Law Firm). Memorandum to Jack Mills. Report on Tobacco Legislation/Regulation, Jan 8, 1980 (report given to Tobacco Institute's Kornegay). Tobacco Institute Collection. Area TI Box 515, Box 258 (Sep 25, 2002). Legacy Tobacco Documents Library, University of California, San Francisco.

<sup>29</sup> Dr. Selikoff sent a letter on 8 November 1978 to Representative Joseph Gaydos (D-PA), Chairman of the House Education and Labor Subcommittee on Compensation, Health and Safety, in support of the bill: "It is urgent that adequate help and care be provided to asbestos workers, in view of the increasing disease among them... Various programs are being proposed. One that I have considered potentially effective would involve the federal government, the asbestos industry and all other involved or related parties... It was introduced by Millicent Fenwick (N-NJ) and 19 bi-partisan co-sponsors as HR 8680. This bill is currently before your Committee for consideration. I am hopeful that the Committee will consider this bill, with whatever modifications might be needed to make it even more equitable to all. President Haas of the Asbestos Workers Union has diligently worked to help provide assistance to men in his and other unions, and I support these efforts." Selikoff, Irving (Mount Sinai School of Medicine). Letter to Representative Joseph M. Gaydos (8 Nov 1978). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>30</sup> Panzer, Fred. *Asbestos Situation Report*. Internal Tobacco Institute Memorandum (8 June 1979), citing Testimony of John A. McKinney, Chairman of the Board and Chief Executive Officer, Johns-Manville Corporation, presented to the House Committee on Education and Labor Subcommittee on Labor Standards, May 8, 1979. (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>31</sup> Stevens, Arthur. *Lorillard Inter-Office Memorandum* (30 Dec 1981). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>32</sup> LA J. Hall met with Pittsburgh Corning, John Baldwin, President, and another Corning rep and lobbyist. (BW saw initials and signed the meeting report) Subject of meeting: Pitt Corning used to make asbestos

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products. Both asbestos manufacturing now under siege? by circa (15,000?) lawsuits from asbestos workers over lung problems due to asbestosis. Hart has introduced asbestos legislation (?). Comments: Last and this year to deal with problem; bill is a compromise signed off on by asbestos workers' ( ) industry. These would be federal share, since Feds are employer ( ), asbestos is ( ) and feds are (?focusing on) suits problem to the tune of 9,000 suits. However, cost to Feds not yet estimated, and administrator position (?) not yet established. They want you to cosponsor legislation, but I made it clear that until those two points were estimated, we weren't in a position to decide (Hart has no cosponsors for this year; more on last year's bill. Hart (?) is doing it because of Johns-Manville in Colorado. This if FYI--this may be the new Black Lung. Hall, J. LA Meeting Report: Meeting with Lobbyists ( 29 Oct, 1982). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>33</sup> Stevens, Arthur. *Lorillard Inter-Office Memorandum* (30 Dec 1981). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>34</sup> Colby, Frank G. *Memorandum: Liability Suits on Asbestos and Cigarette Smoking against R.J. Reynolds and Other Tobacco Companies*. (14 Dec 1978). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>35</sup> Seligman, Robert B. Dr. Phillip Morris U.S.A: Intern-Office Correspondence: Quarterly Report--Smoking and Health--First Six Months (7 July 1980). *Legacy Tobacco Documents Library, University of California, San Francisco*.

<sup>36</sup> Jack Mills, *Remarks: Board of Directors Meeting*, New York City (14 June 1979) (internal Tobacco Institute document). *Legacy Tobacco Documents Library, University of California, San Francisco*.

<sup>37</sup> Fred Panzer. Internal Memorandum: *Asbestos Situation Report*. Sent to Horace R. Kornegay and Jack Mills of the the Tobacco Institute. June 8, 1979 (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>38</sup> Jack Mills, *Remarks: Board of Directors Meeting*, New York City (14 June 1979) (internal Tobacco Institute document). *Legacy Tobacco Documents Library, University of California, San Francisco*.

<sup>39</sup> Jack Mills was the chief lobbyist of the Tobacco Institute.

<sup>40</sup> The Tobacco Institute's 1980 federal activities report discussed the goal of creating coalitions with non-tobacco congressional staff. According to the report, their success depended on the "ability to analyze issues, identify mutual interests, develop mutual positions and follow through with effective lobbying support": Examples: (a) working with a broad coalition of business, mayors, and labor in support of federal aid to cities; this alliance expanded our contacts with the New York delegation and the black caucuses, (b) joint cooperation in defense of agricultural price supports; this strengthened our ties with the entire farm bloc, (c) defending our industry against incrimination from the asbestos industry, the chemical industry, uranium mining, and certain insurance companies; this extends our contacts to labor, consumer and environmentalist members." Tobacco Institute. Internal Report: Federal Activities 1980. (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>41</sup> Albinson, R.D. and Cline, B.B. Internal Memorandum for Samuel D. Chilcote, Jr. Subject: *Issues Management*. Tobacco Institute (10 Mar 1983). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>42</sup> Takeshi Hirayama, chief of epidemiology at Tokyo's National Cancer Center Research Institute. Later, Hirayama dealt another blow to the industry when he released a study that "tracked almost 100,000 non-smoking women for 14 years and reported in the early 80s that the incidence of lung cancer was significantly higher in those married to smokers." Thomas, Hedley and Gagliardi, Jason. "Conspiracy: Industry Plants Scientists to Give Friendly ETS Data," *South China Morning Post* (18 JAN 1999). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>43</sup> Albinson, R.D. and Cline, B.B. Internal Memorandum for Samuel D. Chilcote, Jr. Subject: *Issues Management*. Tobacco Institute (10 Mar 1983). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>44</sup> The Center for Indoor Air Research (CIAR) -- a tobacco-funded-and-directed group set up by cigarette companies in 1988 -- conducted indoor air studies that were favorable to industry.

<sup>45</sup> Stuntz, Susan. Memorandum to Peter Sparber (Tobacco Institute): Re: Public Smoking Program (23 May 1987). *Legacy Tobacco Documents Library, University of California, San Francisco*

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<sup>46</sup>"The mission of the Information Center is to provide efficient service to individuals responsible for developing policy and communicating positions on behalf of the Tobacco Institute's member companies. This service primarily involves the timely collection and dissemination of useful information and analysis." Lyons, John. Memo to John Lyons: RE: *1987 Plan* (18 July 1986). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>47</sup>"Mr. Jay Webb has been informed of our attempts to define the issue of indoor air pollution as it relates to tobacco smoke. The major causes of indoor air pollution or the "sick building syndrome" are improper air exchanges, improper air filtration and contaminated or dirty air ducts." RJ Reynolds Internal Report. Biochemical/Biobehavioral R&D Group, *Second Quarterly Report*, 1985. Box RJR4465. (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>48</sup> Dr. Gray Robertson, then the President of AVCA Corporation located in Fairfax, VA, was a consultant for the Tobacco Institute. He not only provided non-public information to the Tobacco Institute, but also assisted them in propaganda campaigns. His company did indoor inspections randomly, then used that data to bolster their case. In his presentation to the National Research Council, Dr. Robertson says, "ACVA's primary finding -- that environmental tobacco smoke rarely is the cause of the indoor air pollution problems found in these buildings -- it important to this committee's work. In fact, the confounding variables presented by a number of potential contaminants prevents a quick analysis establishing a single source of contamination." Gray, R. Presentation Report: Investigating the "Sick Building Syndrome": ETS in Context. Presentations to the National Research Council by Members of the Indoor Air Pollution Advisory Group on Environmental Tobacco Smoke. National Academy of Sciences. Washington, D.C. (29 Jan 1986). Phillip Morris Collection. Box 24611; 25091 (30 July 1999). Legacy Tobacco Documents Library, University of California, San Francisco.

<sup>49</sup>The Service Employees in Maine and New Hampshire recently launched an indoor air quality awareness campaign with a conference on the issue. Panelists included Robertson and John Spengler of Harvard...When the conference was over, the unions asked Robertson for his continued help on their campaign; we will meet with them June 4 to follow up on that request. Our 1987 plan stated a goal of 100 indoor air quality briefings with officials from labor, industry, trade, environmental groups and the media. We've met that goal already this year. We're not as far along with our goal to conduct 75 building studies; employers are reluctant to agree to such studies. But federal employee unions are pushing hard for the General Services Administration to live up to its promise to conduct comprehensive indoor air quality studies as a part of its new smoking restrictions; New England employees want ACVA building studies. And a project we've agreed to fund jointly with the National Energy Management Institute (NEMI) will provide us with additional expertise to conduct those studies. NEMI, a cooperative effort of the ventilation industry and the sheet metal workers union, trains ventilation contractors in building codes and standards, and building inspection techniques. The Tobacco Industry Labor Management Committee will work with NEMI to train those contractors -- currently some 200 across the country -- to address the ETS issue in their building studies." Stuntz, Susan. Memorandum to Peter Sparber (Tobacco Institute): Re: Public Smoking Program (23 May 1987). Legacy Tobacco Documents Library, University of California, San Francisco.

<sup>50</sup> Dr. John C. Kirschman. RJR Interoffice Memorandum to Dr. A. W. Hayes: Trip Report -1986 Washington Conference on Risk Assessment, Hyatt Regency-Crystal City, Arlington, VA, October 27-28 1986 (12 Nov 1986). Legacy Tobacco Documents Library, University of California, San Francisco.

<sup>51</sup> The Asbestos School Hazard Detection and Control Act of 1980 established "a program for the inspection of schools to detect the presence of hazardous asbestos materials, to provide loans to States or local educational agencies to contain or remove hazardous asbestos materials from schools and to replace such materials with other suitable building materials." Congressional Record, Senate. May 30, 1980.

<sup>52</sup> See, e.g., Federal Efforts to Control Asbestos Hazards, Hearing Before the Subcommittee on Commerce, Transportation, and Tourism of the Committee on Energy and Commerce, House of Representatives, 98th Congress, 2nd Session, Serial No. 98-174 (26 SEP 1984) (Florio Chaired);

<sup>53</sup> "On September 27th, Hill & Knowlton and Valis Associates sponsored the Toxic Torts Clearinghouse - Workshop I, held here in Washington. Alerted to the conference by Fred Panzer, Arthur Stevens requested that I monitor this meeting. A half-day seminar which addressed the topics of "Economic Consequences of

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Toxic Victim Compensation" and "Political and Legal Implications of Toxic Victim Compensation," the workshop was attended by about 40 persons representing various trade organizations, corporations, law firms and governmental entities...The more subtle focus of Workshop I was to demonstrate to attendees why it is in the best interests of the organizations they represent to finance the apparently nascent Toxic Torts Clearinghouse. Wayne Valis, "formerly a White House business liaison," told me additional information (e.g., contribution solicitation) would soon be mailed out. If The Institute chose to participate in the Clearinghouse, I, or someone else designated by TI [Tobacco Institute], would be placed on the Clearinghouse steering committee/board, according to Valis. Unaware of recent organizational changes at TI, Valis asked that I convey this information to Fred Panzer and Jack Mills. After a brief explanation, I assured him Howard Liebergood and other senior staff members would be kept informed about the Toxic Torts Clearinghouse" (Becker, 1983).

<sup>54</sup> "In one of the most substantive talks of the meeting, Florio spoke of the need for legislative changes in the existing compensation system for victims of environmental toxic torts. Citing the §301(e) Report completed under the Comprehensive Environmental Response, Compensation, Liability Act (CERCLA) or "Superfund", Florio states there are "great obstacles" to victim compensation recovery under current law. These obstacles include: long latency period between exposure to other chemicals during the latency period, hindering establishment of a causal link; and, inadequate statutes of limitation. He pointed to the third obstacle--the lapsing of statutes of limitation before injury is or can be known--as the "most unfair aspect of the problem" (Becker, 1983).

<sup>55</sup> "In his presentation, Thorne Auchter, head of OSHA, devoted much of his time to criticizing a recent Nader report on OSHA and to answering Washington Post reports on his actions in the ethylene dibromide matter. Auchter told the audience industry must be "equally concerned about appearance, as well as substance." Referring to the Nader and Post items, he said "this type of public relations problem" can be avoided through a centralized information-sharing entity -- a clearinghouse. In his view, such a clearinghouse would help industry deal with the "subculture of health activists" (Becker, 1983).

<sup>56</sup> Corn, Jacqueline Karn. *Environmental Public Health Policy for Asbestos in Schools: Unintended Consequences* (CRC Press: 1999), pp. 65-66.

<sup>57</sup> The year after the enactment of the AHERA legislation, however, the EPA promulgated stricter EPA abatement rules to do just that. The Safe Buildings Alliance, an umbrella group of companies that formerly made asbestos materials, warned the new rules would 'drive schools toward unnecessary removals of asbestos-containing materials, increase exposures to building occupants and spark a future wave of asbestos-related disease among abatement workers.' Shabecoff, Philip. U.S. Issues Asbestos Safety Regulations for Schools. *New York Times* (21 Oct 1987).

<sup>58</sup> RJC. Memo: Action/Decision. To: JH. Subject: Asbestos Legislation (4 June 1985). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>59</sup> Rogers, Edward. Memo to JH: Re: Update on Asbestos Compensation Legislation (15 Nov 1985). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>60</sup> Panzer, Fred. Memo to Horace Kornegay. RE: Asbestos Workers Recovery Act HR 1626/S 1265 ( 5 Dec 1985). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>61</sup> "Nearly half of all asbestos victims contracted their disease at a government shipyard." RJC. Memo: Action/Decision. To: JH. Subject: Asbestos Legislation (4 June 1985). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>62</sup> "William Wenner worked at the Philadelphia Naval Shipyard as a pipe insulator. "The dust he carried home on his worksuit was passed to his four sons, now in their late 20s and early 30s. His wife, Ruth--who says "all I did was wash his clothes"--has had surgery for asbestos-related lung cancer. Only two of his sons can work--all get winded with the slightest exertion. They suspect they will die young. Almost everyone Wenner carpooled with until he retired in 1978 has died. . .Wenner and his family are among an estimated 20,000 asbestos victims across the USA, many of them shipyard workers from World War II...The logjam in the courts is building. In Philadelphia, five judges have assigned to a backlog of 2,500...An estimated 13 million American workers were exposed to asbestos between 1940 and 1980. More than 9,000 of them and members of their families with die from asbestos-related cancers each year

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until the turn of the century, experts say." Mauro, Tony. "Its toll: Death, Lawsuits." *USA Today* (20 July 1983). Legacy Tobacco Documents Library, University of California, San Francisco.

<sup>63</sup> Michel, Carol (LA). JH Decision/Action Request: *Subject/Issue: Education/Asbestos* (20 March 1984). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>64</sup> "JH has expressed a strong wish to spend his time somewhat differently than in the past. While I am sure we will continue to protect our bases in Pennsylvania, the fact that he is 4 years out from re-election gives him time to delve into some areas more deeply than his usual travel planning allows. In other words, fewer in-and-out quick news conferences and more time spent building constituencies in his areas of special interest. His areas of interest, off the top of his head, were listed as: Trade/competitiveness; technology and science; capital formation (savings/pensions emphasized); environmental issues which he sub-categorized as sustainable development, source recycling, debt-for-nature, biodiversity, energy conservation, Project '88... Regarding "constituency development"... Targeting some of the environmental movers was of special interest to him, since it would be possible (and advisable) to determine what corporations are on the boards of environmental groups, like the National Wildlife Federation and the Environmental Defense Fund... He also wants a meeting with Allen Bromley early in the year on climate change after strategy meetings with corporate CEOs and reps from major environmental groups." JAM and KMT. Memo to Cliff and Richard: RE: JH's Desire for Strategic Scheduling Planning (20 Dec 1989). *Senator H. John Heinz III Collection, Legislative Assistants' Files--1970-1991, Carnegie Mellon University Digital Collections Library*

<sup>65</sup> RJC. Memo: Action/Decision. To: JH. Subject: Asbestos Legislation (4 June 1985). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>66</sup> "From 1867 to 1962 Keasby & Mattison, once the world's largest asbestos manufacturer, dumped asbestos wastes into two large piles in Ambler. The operation and piles were split and sold respectively to CertainTeed Corp. and Nicolet, Inc., who continued dumping until 1974. Both piles are covered, but pose a health hazards to the surrounding residential area" (Fountain, 1988).

<sup>67</sup> U.S. Nuclear Regulatory Commission. Three Mile Island; RJC (Staff Member), Memorandum: ACTION/DECISION, to JH (John Heinz), Re: Asbestosis Compensation (29 July, 1985), *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>68</sup> Hall, Jason. Memo to BW and My Successor: RE: *Pending Projects and Advice* (26 Feb 1982). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>69</sup> "Nuclear Reg. Commission Authorization (S. 1207). This bill is due to come the floor on March 18. JH will present and amendment on core removal at TMI-2.... TALK TO JIM ASSELSTINE. He has been a good friend of this office on Three Mile Island (TMI) and will help you on the floor with this." "Three Mile Island. This is a monster which will eat a lot of your time. JH is the leading player on this problem in both the House and the Senate at this time, and we are right in the middle of revising his bill on the issue with the help of the Edison Electric Institute... WE ARE UNDER SEVERE TIME PRESSURE. WE MUST MOVE TO MARKUP IN THE ENERGY COMMITTEE BY MID-MARCH BECAUSE OF THE PRESS OF OTHER ENERGY COMMITTEE BUSINESS. You will necessarily be very dependent on other people at first on this issue since both the substance and politics are quite complex. Trust the political judgment of Chuck Trabandt, Chief Counsel of the Energy Committee. He of course must consider Sen. McClure's interest first, but McClure has met with JH recently and is pretty much on board with the basic idea of our revision..Don't move without Chuck's advice when you start out." (more political if you need it)...First Steps for You. 1. GAO Report. The first thing to do is to read the GAO report on TMI... That will give you everything that's happened of any substance to Aug. 28 of last year. Then call Cliff Gardner, head of the Gov't Accounting Office team that wrote the report..and have him come and brief your on JH's Oct. 20 hearings on TMI and subsequent events... Note: Cliff is probably the best "neutral" observer of the whole scene and has a wider access to information than anyone else. He's also sympathetic to our efforts, and GAO works for Congress, not the Executive." Hall, Jason. Memo to BW and My Successor: RE: *Pending Projects and Advice* (26 Feb 1982). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>70</sup> Rother, John. Memorandum to Senator Heinz: *Overview for 1984* (U.S. States Senate Special Committee on Aging) (5 Dec 1983). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

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<sup>71</sup> Underlined and marked with a star: "Unfortunately, the state of knowledge to date cannot predict the consequences of exposure to asbestos (at the levels found) to a population at this age range. If the levels determined by the sample were to show concentrations within 100 times the environmentally usual concentrations, it would have been prudent to take control measures to eradicate this totally unnecessary exposure, but there would have been little reason for a sense of urgency. However, the results suggest that the eight hour average concentration of airborne fibers longer than 5 um is 1000 to 10,000 times higher than the environmentally usual levels. This finding suggest (sic) possibility of an undeterminable increase in the risk of cancer to the exposed population." p. 7.

<sup>72</sup> "Numerous studies have independently confirmed an increased risk of lung cancer in various occupational groups exposed to asbestos. It is also known that cigarette smoking increases the risk of lung cancer. Although both cigarette smoking and occupational asbestos exposure individually increase the risk of lung cancer, together, they act to produce a risk that exceeds the sum of their separate risks." p. 6

<sup>73</sup> "The exposure to asbestos at the Dr. R. F. Nicely School must immediately cease for the children and the employees (this paragraph was marked with a star). This may be accomplished : a. By closing the school until a permanent solution can be found; b. By closing the school until the asbestos containing material can be covered by a thick coating of a sealant as a temporary measure and effectuating a permanent control measure such as the proper removal of the material during the summer vacation; 2. All present and past employees, as well as the students should be contacted to inform them of the possible asbestos exposure; 3. All employees and students (past and present) should be urged to stop smoking; and if they do not smoke they should be urged not to start smoking; 4. Possible provisions of instituting a medical follow up of the exposed population should be investigated." Esmen, N.A. and Dixon, C. Report on the Results of Field Sampling of the Dr. R. F. Nicely School Submitted to the Greenburg-Salem School District (20 February 1979), p. 2. *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library.*

<sup>74</sup> "New York State, for instance, enacted legislation in 1979 requiring local schools to inspect for asbestos and to remove the substance where warranted...A 1979 EPA survey found that thirty-one states already had programs to address asbestos in their schools." *Whither Federalism?*, p. 98.

<sup>75</sup> RJC (Staff Member), Memorandum: ACTION/DECISION, to JH (John Heinz), Re: Asbestosis Compensation (29 July, 1985), *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library.*

<sup>76</sup> "Joan Anderson, one of the parents, said she is concerned that asbestos dust had sifted from the ceiling onto the carpeting in the kindergarten classroom where her daughter, Dawn, 5, attends school. Adaire and Hackett Elementary School, at East York Street and Trenton Avenue, were the two schools most recently inspected in a new asbestos-detection program that school officials began after parents challenged test data from the city health board. Health officials have been monitoring the schools for air-borne asbestos since 1977...Safe exposure limits for children have not been determined." Nichols, Rick. Asbestos Protests Continue: Parents Picket at Adaire School. *Philadelphia Inquirer* (6 Dec 1980), Section B. *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library.*

<sup>77</sup> "The Hugh Community Group requested this office's assistance on setting up a meeting with EPA similar to a meeting we set up for the community when there was a PCB spill in the neighborhood last year. The purpose of the meeting is basically educational--concerned parents want to know about asbestos, what it does, how it gets in the air, what the long range health effects are. This group is familiar with and appreciative of JH as a result of the PCB meeting and subsequent town meeting held at St. Hugh's. The community is basically blue collar, fairly low income and uneasily racially mixed... Questions Likely or Points to be Raised. Are there any federal financial assistance programs to help? Congress recognizing the danger of asbestos, especially to small children, passed the Asbestos School Hazard Detection and Control Act of 1980 on June 14, 1980, P.L. 96-270. This act allows for grants and loans to Local Educational and State Educational Agencies for detection and removal of asbestos. For reasons to be detailed by the appropriate LA, no funds were allocated for this program. So, in actuality, until funds are made available, under EPA regulations, it is the responsibility of local and state educational agencies to use their funds to remove the asbestos."

"Borden, Catherine. Memo: Asbestos Problem in Philadelphia School (9 Dec 1980). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library.*

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<sup>78</sup>"Consumer columnist Herb Denenberg has said that the School District (Board of Education) has been, since asbestos became a recognized health problem ten years ago, all to inactive in doing anything to protect the kids in the schools. Denenberg says: "The School Board has depended upon advise that is invalid, unscientific and inappropriate." The School Board has hired several different consulting firms to survey asbestos in the schools. They now employ Rossnagel and Associates of Medford, NJ. Rossnagel is now in the process of inspecting 24 Phila. schools suspected of having asbestos problems. As a result of its findings thus far the Cramp Elementary School has been closed for 90 days. The Rush School in Northeast Philadelphia will be repaired during Christmas recess. However, Denenberg believes Rossnagel--like the consultants before it--is doing a (sic) unscientific job and that the School Board is looking the other way. Parents, who have formed community groups, agrees with Denenberg. They distrust the School Board and would much rather have the EPA do school inspections. They see EPA as a more objective and authoritative source of information about public health." Murray, Dave. Memo to JH: Subject. Asbestos Problem in Philadelphia Schools (10 Dec 1980). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>79</sup>Murray, Dave. Memo to JH: Subject. Asbestos Problem in Philadelphia Schools (10 Dec 1980). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>80</sup>Ibid

<sup>81</sup>Gemperlein, Joyce. "Heinz Assails Failure to Develop a Self-Extinguishing Cigarette," *Philadelphia Inquirer* (29 July 1985). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>82</sup>Heinz, John. *Burn Foundation Speech* (2 July 1984). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>83</sup>Albinson, R.D. and Cline, B.B. Internal Memorandum for Samuel D. Chilcote, Jr. Subject: *Issues Management*. Tobacco Institute (10 Mar 1983). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>84</sup>Larry, Laura. Memorandum to JH: *RE: Fire-Safe Cigarettes* (14 Sep 1987). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*

<sup>85</sup>Chilcote, Samuel. The Tobacco Institute Memorandum to the Members of the Executive Committee and the Committee of Counsel: Re: *"Self-Extinguishing" Cigarette Legislation* (8 May 1984). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*

<sup>86</sup>Larry, Laura. Memorandum to JH: *RE: Fire-Safe Cigarettes* (14 Sep 1987). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*

<sup>87</sup>The Institute had also met with fire fighters and fire chiefs in New York in early November. Tobacco Institute. *Report of Meeting of Committee of Counsel at The Tobacco Institute*, Washington, D.C. (14 Nov 1983). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>88</sup>Larry, Laura. Memorandum to JH: *RE: Fire-Safe Cigarettes* (14 Sep 1987). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*

<sup>89</sup>Demita, Michael. Philip Morris Incorporated Inter-office Correspondence. *Memo to Distribution: Fire-Safety - Cigarettes* (17 Aug 1983). (University of California, San Francisco; Legacy Tobacco Documents Library).

<sup>90</sup>Laura, A (LA). JH Decision/Action Request. Subject: *Fire-Safe Cigarettes* (24 Feb 1988). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>91</sup>"Attached please find a letter signed by Sen. Cranston and Rep. Moakley which they would like you to sign. Comments from staff: no downside; sign. JH agreed to approve and sign the letter." Laura, A (LA). JH Decision/Action Request. Subject: *Fire-Safe Cigarettes* (24 Feb 1988). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>92</sup>"My favorite example is the case of urban mass transit, which is a constant policy proposal, and has been promoted, seriatim, as a solution to the problems of traffic congestion, then as a solution to the problem of pollution, then as a solution to the problem of energy shortages. It has even been promoted as a solution to the problem of drunk driving. What is driving this is that it is a constant proposal that its advocates push; they hook it onto whatever problem is hot at the moment." Kingdon, J.W. *A Model of Agenda Setting, with Applications*, L. REV. M.S.U.-D.C.L. 331 (2001).

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<sup>93</sup> Michel, Carol (LA). JH Decision/Action Request: *Subject/Issue: Education/Asbestos* (20 March 1984). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>94</sup> Michel, Carol (LA). Memo: To File: Subject: March 19th Meeting with School Administrators from Pittsburgh and Philadelphia (21 March 1984). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>95</sup> Ibid

<sup>96</sup> It is interesting to note that Huddleston joined the Tobacco Institute in January 1985 as legislative consultant after an unsuccessful bid for a third term in the Senate. Toohey, William. *Tobacco Institute News*. Washington, D.C. (4 Jan 1985).

<sup>97</sup> Michel, Carol (LA). JH Decision/Action Request: *Subject/Issue: Education/Asbestos* (20 March 1984). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>98</sup> CAM. June 28th PA Delegation Meeting with the PA School Board Association (27 June 1984). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>99</sup> U.S. Senate Hearing Before the Committee on Judiciary, 109th Congress, 1st Session, Serial No. J-109-2A, *The Fairness in Asbestos Injury Resolution Act* (11 Jan 2005).

U.S. House of Representatives Hearing Before a Subcommittee of the Committee on Government Operations, 98th Congress, 1st Session, Report No. 25-994, *Failure to Regulate Asbestos, A Lethal Legacy* (28 June 1983).

<sup>100</sup> On 28 June, Heinz underlined Wolfberg's name and wrote: "Where is he from/what Bd (Board)?" RJC (Staff Member), Memorandum: ACTION/DECISION, to JH (John Heinz), Re: Asbestosis Compensation (29 July, 1985), *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>101</sup> BR. Staff Drafted Letter. JH Reply Re: Asbestos Workers Recovery Act (4 Sep 1985). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>102</sup> Rogers, Edward. Memo to JH: Re: Update on Asbestos Compensation Legislation (15 Nov 1985). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>103</sup> Ibid

<sup>104</sup> "In general, I support the idea of supplanting the current inefficient and complex asbestos tort litigation procedures with an effective administration compensation system. However, any asbestos-disease compensation legislation should yield fair and adequate benefits to injured workers, should deliver compensation swiftly to those who need it, and should fully replace the present time-consuming and inequitable system of asbestos tort litigation. In addition, a new asbestos compensation program should be financed by all parties who have contributed to the problem--including businesses, their insurers and the Federal government--in proportion to their responsibility. Asbestos compensation legislation is currently under review in both houses of Congress. Representative Pat Williams has introduced H.R. 3090, the Federal Occupational Disease Compensation Act. Representative Austin Murphy has reintroduced the Asbestos Workers' Recovery Act as H.R. 1626, and Senator Armstrong has introduced similar legislation, S. 2708, in the Senate. Please be assured that I will be closely examining all bills in this area with your comments in mind." BR. Staff Drafted Letter. JH Reply Re: Asbestos Workers Recovery Act (4 Sep 1985). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>105</sup> Rogers, Edward, Memo: JH Decision/Action Request. Subject: Asbestos Workers Legislation (14 Nov 1985). *John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>106</sup> Kendall, William (Johns-Manville Lobbyist). Memorandum to Edward Rogers. Subject: Request for Appointment with Senator Heinz. (28 Feb 1986). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library*.

<sup>107</sup> Several staffers recommended Heinz not meet with Johns-Manville because the legislation "remains mired in Finance Committee...and (the meeting) seems ill-timed and redundant." The legislative assistant made the following comment: "Of course, if JH does in fact want to meet with these people, it would be a nice gesture that they would appreciate, esp. if they convince JH to get on the bill." The legislative director concluded the recommendations as follows: "If JH indicated he would meet (and if Bill Kendall said that, I believe it) he should--could just (do it?) in conf. rm. for 5-10 minutes." Rogers, Edwards (LA). Memo: JH



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Decision/Action Request: Subject: Labor--Asbestos Legislation (4 Mar 1986). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library.*

<sup>108</sup> McElwaine, Andrew (LA). LA Meeting Report. Meeting with Constituents (Pennsylvania School Board Association). Issue: Education. Subissue: Misc. (26 June 1985). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library.*

<sup>109</sup> JPK. Memorandum to JH: RE: Pennsylvania Labor Plan (28 February 1985). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library.*

<sup>110</sup> "Labor Politics. The main mover behind the bill is Dave Mallino, Leg. Dir. of the AFL-CIO's Indus. Union Dept., who also wants you to sign the letter. The bill is esp. big with certain indus. unions like Oil, Chemical, Atomic Workers, USW, UAW. How important it is to PA labor folks who matter to us is somewhat unclear. I told Mallino that he could strengthen his case for involving you further if he could translate incremental action by you into specific benefits with Exec. Council members. In response, he talked to Johnny Reck (USW voting member), who said he would not oppose you this time as he had in the past. But Mallino admitted he or other WDC AFL bureaucrats couldn't get us a quid pro quo, which is no surprise." Rogers, Ed. Memorandum to Senator John Heinz: RE: Follow-up on S.79, High Risk Occupational Disease Notification Act (23 Feb. 1988). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library.*

<sup>111</sup> "Other Republican Co-signers. To date, Metzenbaum is only targeting Durenberger to co-sign the DC with you (prob. because Stafford and Weicker have signed other letters, which leaves only Chafee as remaining Repub. cosponsor, who has at least as tough a race as Durenberger). Like you, Durenberger got on the bill in 1986, and has been hearing from industry more recently, as floor action approaches. As such, he's asked his staff for more info, to assess whether to sign the letter." Ibid

<sup>112</sup> "Business Politics. Some big companies with a PA presence have endorsed the bill Rohm and Haas, ARCO, Manville but the vast majority of businesses oppose it strongly. It's difficult to assess how much more you irk them by signing a letter on a bill you've already cosponsored." Ibid

<sup>113</sup> "Recommendation. Although I'm fairly sold on the merits of the bill, and see the letter as rather innocuous, I'm a little uncomfortable recommending whether to sign it or not because I don't have a clear sense of what it buys you and what it costs you in terms of interest group politics, although I've tried hard to assess this. Having said this, I think you prob. ought to agree to sign the letter if Durenberger does." Ibid

<sup>114</sup> "Groups select major issues and then publicize the members' scores (one a scale of zero to one hundred) based on their right or wrong votes on these issues. Members are often warned by colleagues that certain votes will be scored...Scorecards not only attract the attention of lawmakers, but they also are used by interest groups to influence members' decisions on selected issues." Davidson, R.H. and Oleszek, W.J. *Congress and Its Members*. (Washington: CQPress, 2004), pp. 380

<sup>115</sup> "The Service Employees International Union represents several thousand workers employed in Schools Districts throughout the Commonwealth of Pennsylvania. Among the most critical of the health hazards faced by school district workers and by the children of all of our members is the grave danger posed by air concentrations of asbestos. The need for federal regulation to insure universal asbestos detection and abatement plans in the nation's school districts is overwhelming. Medical experts agree that there is no safe level of exposure to asbestos. It is estimated that up to 265,000 workers will die from asbestos related disease over the next thirty years. And the long term potential development of the disease from asbestos among children can be far greater...In joining us in our commitment to the protection of the lives and health of our school children and school workers, we urge that you join in co-sponsoring the Asbestos Hazard Emergency Response Act of 1986 and work for its passage." Trump, Rosemary (SEIU VP). Letter: Re: Asbestos Hazard Emergency Response Act of 1986 H.R. 4311 - S. 2083. (15 April 1986). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library.*

<sup>116</sup> Woodwell, Bill. *Heinz-Backed Proposal Targets Asbestos in Philadelphia Schools* (news release) (16 June 1986). *Senator H. John Heinz III Collection, Carnegie Mellon University Digital Collections Library.*

<sup>117</sup> Thomas, Lee M (EPA Administrator). *Signing of Asbestos Hazard Emergency Response Act* (U.S. Environmental Protection Agency: Washington, DC, 1986); *Whither Federalism?*, p. 115.

<sup>118</sup> Torbern O. Bergman, a professor of chemistry at the University of Uppsala in Sweden, made important advances in chemical analysis and in the theory of crystal structure (Encyclopedia Britannica, 2014).

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Bergman's most important dissertation is perhaps his *A Dissertation on Elective Attractions* (1775), which contained tables of elements listed in the order of their affinity. Hey (1973) notes that many of Bergman's results "were of no great accuracy," but his "surprisingly good" chemical analysis of tremolite asbestos served as a foundation for later research.

<sup>119</sup> As mentioned in Chapter 3 of this dissertation, Cooke is known for his work linking asbestos dust to lung disease. Obituary: W.E. Cooke, M.D., F.R.C.P. Long. and Ed. (1881-1939), Consulting Pathologist, Wigan Infirmary. *The British Medical Journal* (5 Aug. 1939), 314.

<sup>120</sup> Sir Lawrence Bragg (1890-1971) developed Bragg's equation, "which tells at what angles X-rays will be most efficiently diffracted by a crystal when the X-ray wavelength and distance between the crystal atoms are known. This equation is basic to X-ray diffraction, a process used to analyze crystal structure by studying the characteristic patterns of X-rays that deviate from their original paths because of the closely spaced atoms in the crystal." In 1915, he and his father were jointly awarded the Nobel Prize for Physics for "demonstrating the use of X-rays for revealing the structure of crystals. (New Encyclopedia Britannica, 1994).

<sup>121</sup> "The iron content may be important. It will be interesting to see whether the effects of the iron-free dusts of some...asbestos are the same as in chrysotile workers" (Cooke, 1929).

<sup>122</sup> The papers of Sir Lawrence Bragg contain correspondence between Cooke and James A. Darbyshire. Cooke wrote to Darbyshire with a request to meet with Prof. Robinson in 1928 to get his opinion on the "three curious bodies" Cooke had isolated from the lungs of the patient with asbestosis. The Royal Institution's summary of the correspondence suggests Bragg conducted, or had conducted, an analysis of the powder (asbestos). Cooke later wrote to Darbyshire that "the results of analyses show that the brown bodies contain about 4% of iron and the black final deposit 3.45%." W.L. Bragg. The Papers of Sir Lawrence Bragg 1890-1971 [W.L. BRAGG/77K/154]. Royal Institution of Great Britain (See, e.g., Research Correspondence, W.L. Bragg/77c 1928-1929: W.E. Cooke [letter] to [?] Darbyshire. W.L. Bragg/77C/1 29 June 1928; W.E. Cooke [letter] to [?] Darbyshire W.L. Bragg/77C/2 1 July 1928; W.E. Cooke [letter] to [?] Darbyshire W.L. Bragg/77C/3 9 July 1928; W.E. Cooke [letter] to [?] Darbyshire W.L. Bragg/77C/4 18 July 1928).

<sup>123</sup> Bertram E. Warren, a graduate student in the Department of Physics, took advantage of Bragg's presence in the Physics Department to do the research for his doctoral thesis under Bragg's supervision. Bragg had become interested in the arrangements of atoms in minerals, and had solved the arrangement in the orthorhombic mineral olivine, (Mg, Fe)SiO<sub>4</sub>. He suggested that Warren try solving the crystal structure of a monoclinic metasilicate like diopside, CaMgSi<sub>2</sub>O<sub>6</sub>. The two succeeded in this solution and published their results in the *Z. Kristallographie* 69 (1928) 168-193" (Shrock, 1982).

<sup>124</sup> "Warren received his Sc.D. degree from M.I.T. in 1929. He was also granted a five-month leave in order to accompany Bragg to Manchester, England, where he solved the structure of the monoclinic amphibole tremolite, Ca<sub>2</sub>Mg<sub>5</sub>Si<sub>8</sub>O<sub>22</sub>(OH), and was able to explain the compositions of other monoclinic amphiboles. He and Bragg also investigated the structure of chrysotile asbestos, H<sub>4</sub>Mg<sub>3</sub>Si<sub>2</sub>O<sub>9</sub>, and suggested an arrangement of atoms for it." Shrock, R.R. *Geology at MIT 1865-1965: A History of the First Hundred Years of Geology at Massachusetts Institute of Technology: Department of Operations and Projects*. MIT Press: Boston, 1982, pp. 533-534.

<sup>125</sup> "Asbestosis is a bilateral interstitial fibrosis with accumulation of fibrous/scar tissue in the interstitium of lung, obstructing the diffusion of gas from the blood to the airspaces and restricting lung expansion" (Donaldson et al., 2013)

<sup>126</sup> "Bronchogenic carcinoma is a malignant cancer of the cells lining the bronchi or airways and is the same as the lung cancer that is common in smokers" (Donaldson et al., 2013).

<sup>127</sup> "Mesothelioma is an unusual tumor arising from the mesothelium lining the pleural space that is slow-growing and that does not metastasize and so is well-advanced before diagnosis leading subsequently to a very poor prognosis" (Donaldson et al., 2013).

<sup>128</sup> "Mesothelioma, literally "tumor of the mesothelium," is a term often used synonymously with malignant (diffuse) mesothelioma, the malignant neoplasm arising from the serosal linings of the pleural, pericardial, or peritoneal cavities...The prognosis of malignant (diffuse) mesothelioma is poor. In most series, a

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median survival between 4 and 18 months is expected for the pleural forms. Death typically results from respiratory failure or infection" (Pavlisko & Roggli, 2014).

<sup>129</sup> "Pleural fibrosis is a diffuse accumulation of scar tissue in the pleura that may lead to pleural effusion, an accumulation of fluid in the pleura seen in individuals exposed to asbestos" (Donaldson et al., 2013).

<sup>130</sup> "Pleural plaques are raised hard fibrous lesions that arise on the parietal pleura that are smooth and composed of a basketwork of pure collagen; they are almost acellular and do not appear to cause any adverse effects on the lungs. Since, in the classical toxicology, paradigm response follows dose it is evident that fibers depositing in the lungs accumulate to high dose at various sites in the lining epithelial cells and parenchyma, leading to the pulmonary effects and that they accumulate in the pleura, where they cause the pleural pathologies" (Donaldson et al., 2013).

<sup>131</sup> National Science and Technology Council. National Nanotechnology Initiative (NNI): Environmental, Health, and Safety Research Strategy (Washington, DC, 2011), available online at <http://www.nano.gov>.

<sup>132</sup> Donaldson, K., and Seaton, A. (2012) A short history of the toxicology of inhaled particles. *Part Fibre Toxicol* 9: 13.

<sup>133</sup> This covers multi-causality, strength of causes, interaction between causes, sum of attributable fractions, and induction time (Rothman, 2002).

<sup>134</sup> This includes risk, incidence rate, and prevalence (Rothman, 2002).

<sup>135</sup> This includes risk, incidence rate, and attributable fractions (Rothman, 2002).

<sup>136</sup> "Worker exposure to airborne CNT (carbon nanotubes) and CNF (carbon nanofibers) has frequently been observed to be task-specific and short-term in duration, with exposure concentrations...found to exceed background exposure measurements when appropriate engineering controls are not used to reduce exposures...Results from studies also suggest that the airborne concentration and the physical-chemical characteristics of particles (e.g., discrete versus agglomerated CNT) released while handling CNT may vary significantly with production batch and work process" (NIOSH, 2013).

<sup>137</sup> Video-assisted thoracoscopic (VATS) biopsies were conducted on Wu, M. et al. (2010). Case Report: Lung Disease in World Trade Center Responders Exposed to Dust and Smoke: Carbon Nanotubes Found in the Lungs of World Trade Center Patients and Dust Samples. *Environmental Health Perspectives*, 118(4): 499-504. the patients because of the severity their impairment (Wu et al., 2010).

<sup>138</sup> The patients reported that they had either never smoked or smoked in the distant past (Wu et al., 2010).

<sup>139</sup> The lung biopsy specimens of three individuals contained carbon nanotubes, all of which were single-walled, roped, and of various lengths (Wu et al., 2010).

<sup>140</sup> "Observations of lung tissue obtained at autopsy from asbestos workers, as well as experimental models, have demonstrated that the earliest microscopic abnormality is the presence of increased collagen in the walls of respiratory bronchioles...termed peribronchiolar fibrosis" (Sporn & Roggli, 2014).

<sup>141</sup> Wu et al. note: "The finding of carbon nanotubes in four of seven WTC patients in concentrations ranging from 11,000/g to 230,000/g of wet weight and in four of seven dust samples collected from the WTC site, although unique and important, cannot be construed as evidence for WTC exposure. Likewise, their absence should not be used as evidence of lack of exposure."

<sup>142</sup> Carbon nanotubes have not been on the market for a long time as in the case of asbestos; "possible target people or groups have not had long and consistent exposure leading to appreciable effects" (Bergamaschi et al., 2012).

<sup>143</sup> Warheit, D.B. How to measure hazards/risks following exposures to nanoscale or pigment-grade titanium dioxide particles. *Toxicology Letters* 220 (2013) 193-204

<sup>144</sup> "[B]iomarkers usually mean molecular biomarkers and can be divided into...Those that track disease progression over time and correlate with known clinical measures...Those that detect the effect of a drug...Those that serve as surrogate endpoints in clinical trials" (Jain, 2014).

<sup>145</sup> Nel et al. (2013) suggest the current scientific research highlights the potential to apply a systems biology approach to HTS. A systems biology approach, as described by Gillevet, Bajaj and Sanyal (2012), could help identify other possible biomarkers related to carbon nanotube health effects.

<sup>146</sup> The specific surface area of amphibole fibers range from 5 to 15m<sup>2</sup>/g. (Selikoff & Lee, 1978).

<sup>147</sup> "Industrial defiberization (opening) can also impact the specific surface area of asbestos fibers, measuring between 1 and 30 m<sup>2</sup>/g...As measured by BET (Brunauer, Emmett, and Teller) nitrogen

adsorption, chrysotile fibers exhibit surface areas between 15 and 30 m<sup>2</sup>/g. With regard to amphibole fibers, surface areas of 1.8 to 9 m<sup>2</sup>/g have been reported for crocidolite and 1.3 to 5.5 m<sup>2</sup>/g for amosite" (USGS, 2002).

<sup>148</sup> The remaining elements were: O: 57.2%; Si: 18.1%; Mg: 17.4%; Al: 0.5% (Sprynskyy et al., 2011).

<sup>149</sup> "Surface charge is determined by using zeta potential measurements. These charges would be positive or negative as function of the chemical groups attached the (carbon nanotubes)" (Martinez et al., 2014).

<sup>150</sup> This process also plays a role in determining the levels of residual metals and trace elements remaining in the final product (Hou et al., 2008).

<sup>151</sup> "Carboxyl-modified CNTs (COOH-CNTs) were first reported in 1998, following which a variety of further functionalizations based on COOH attachment, such as amine (NH<sub>2</sub>), polyethylene glycol (PEG), and polyetherimide (PEI) derivatives, were developed for specific use, such as for polyethersulfone membranes, gas sensors, and intracellular carriers" Li, R. et al. (2013) Surface charge and cellular processing of covalently functionalized multiwall carbon nanotubes determine pulmonary toxicity. *ACS Nano* 7, No. 3 2352-2368 (www.acsnano.org).

<sup>152</sup> "The Wagner, Davis and Stanton groups all identified critical roles for fibre type and length, igniting a substantial amount of research on the role played by length, fibre type and biopersistence in toxic potency that continues to the present day and which has defined the first real structure:toxicity model for a pathogenic dust." Donaldson, K., and Seaton, A. (2012) A short history of the toxicology of inhaled particles. *Part Fibre Toxicol* 9: 13.

<sup>153</sup> Donaldson, K. et al. Carbon nanotubes: a review of their properties in relation to pulmonary toxicology and workplace safety. *Toxicological Sciences* 92(1), 5-22 (2006).

<sup>154</sup> Donaldson K, Murphy FA, Duffin R, Poland CA (2010) Asbestos, carbon nanotubes and the pleural mesothelium: a review of the hypothesis regarding the role of long fibre retention in the parietal pleura, inflammation and mesothelioma. *Particle Fibre Toxicol* 7:5

<sup>155</sup> Donaldson, K. and Poland, C. "Respiratory System," in *Adverse Effects of Engineered Nanomaterials: Exposure, Toxicology, and Impact on Human health*, Fadeel, B., Pietroiusti, A, and Shvedova, A., eds., Academic Press: 2012, pp. 122-134; Donaldson, K. et al. Pulmonary toxicity of carbon nanotubes and asbestos—Similarities and differences. K. Donaldson, F.A. Murphy, R. Duffin, C.A. Poland, Asbestos, carbon nanotubes and the pleural mesothelium: a review of the hypothesis regarding the role of long fibre retention in the parietal pleura, inflammation and mesothelioma, *Part Fibre Toxicol.* 7 (2010) 5; Donaldson, K. et al. Utilising the concept of the biologically effective dose to define the particle and fibre hazards of carbon nanotubes. Chapter 3, in: Ken Donaldson, Craig A. Poland, Rodger Duffin, James Bonner (Eds.), *The Toxicology of Carbon Nanotubes*, Cambridge University Press, Cambridge, 2012, pp. 63–72.

<sup>156</sup> Mercer RR, Hubbs AF, Scabilloni JF, Wang L, Battelli LA, Friend S, Castranova V, Porter DW (2011) Pulmonary fibrotic response to aspiration of multi-walled carbon nanotubes. *Particle Fibre Toxicol* 8:21; Muller J, Huaux F, Moreau N, Misson P, Heilier JF, Delos M, Arras M, Fonseca A, Nagy JB, Lison D (2005) Respiratory toxicity of multi-wall carbon nanotubes. *Toxicol Appl Pharmacol* 207:221–231; Wang X, Katwa P, Podila R, Chen P, Ke PC, Rao AM, Walters DM, Wingard CJ, Brown JM (2011) Multi-walled carbon nanotube instillation impairs pulmonary function in C57BL/6 mice. *Part Fibre Toxicol* 8:24.

<sup>157</sup> Kobayashi N, Naya M, Ema M, Endoh S, Maru J, Mizuno K, Nakanishi J (2010) Biological response and morphological assessment of individually dispersed multi-wall carbon nanotubes in the lung after intratracheal instillation in rats. *Toxicology* 276:143–153.

<sup>158</sup> Sporn (2014) cites the following publications: Davis JMG (1989) Mineral fibre carcinogenesis: experimental data relating to the importance of fiber types, size, deposition, dissolution and migration. In: Bignon J, Peto J, Saracci R (eds) Non-occupational exposure to mineral fibres. IARC Scientific Publication, Lyon, 90, pp 33–45; Mossman BT, Churg A (1998) Mechanisms in the pathogenesis of asbestosis and silicosis. *Am J Respir Crit Care Med* 157:1666–1680; Stanton MF, Wrench C (1972) Mechanisms of mesothelioma induction with asbestos and fibrous glass. *J Natl Cancer Inst* 48:797–821; Davis JMG, Jones A (1988) Comparison of the pathogenicity of long and short chrysotile asbestos in rats. *Br J Exp Pathol* 69:717–737.

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<sup>159</sup> "In fact the generation of reactive oxygen species and other radicals appears catalyzed by iron ions and closely related to Fe ions organization in specific crystallographic sites having a capability to activate free radical generation. The Fe substitution to Mg and/or Si in the chrysotile structure appears important for asbestos health hazard investigation."

<sup>160</sup> Centers for Disease Control and Prevention. NIOSH Publications and Products (available at <http://www.cdc.gov/niosh/docs/2013-145/>) (accessed 1 May 2014).

<sup>161</sup> National Science and Technology Council. National Nanotechnology Initiative (NNI): Environmental, Health, and Safety Research Strategy (Washington, DC, 2011), available online at <http://www.nano.gov>.

<sup>163</sup> "These differences might be due to differences in exposure method (i.e. intratracheal instillation/pharyngeal aspiration versus inhalation) but can also reflect species- or nanotube composition-specific differences" (Popescu et al., 2013).

<sup>164</sup> TSCA <http://www.epa.gov/oppt/nano/> §6(a), §2605 (a)

<sup>165</sup> TSCA §2(a), 15 U.S.C. §2601(a) (2006)

<sup>166</sup> Council on Environmental Quality, Toxic Substances 21 (1971), reprinted in H. Comm. on Interstate and Foreign Commerce, 94th Congress., Legislative History of the Toxic Substances Control Act.

<sup>167</sup> CERCLA established a "strict liability system for releases of hazardous substances and create(d) a "Superfund" to finance actions to clean up such releases" (Percival et al., 2006).

<sup>168</sup> Mark Greenwood, who worked for the EPA's Office of the General Counsel from 1978 to 1983 and later became the Assistant General Counsel for Pesticides and Toxic Substances, suggests EPA's efforts at TSCA implementation largely failed (Roberts, 2010).

<sup>169</sup> U.S. Environmental Protection Agency (EPA). 2008. *TSCA Inventory Status of Nanoscale Substances – General Approach*. Washington, DC: EPA.

<sup>170</sup> 40 CFR §721.160

<sup>171</sup> 40 CFR §721.170

<sup>172</sup> 15 U.S.C. §2604(e)(1)(A)

<sup>173</sup> U.S. Environmental Protection Agency (EPA). (2008). *TSCA Inventory Status of Nanoscale Substances – General Approach*.

<sup>174</sup> 77 Fed. Reg. 20300 (to be codified at 40 C.F.R. §721.10287).

<sup>175</sup> 77 Fed. Reg. 61118 (to be codified at 40 C.F.R. §721.10553).

<sup>176</sup> 77 Fed. Reg. 61118 (to be codified at 40 C.F.R. §721.10579).

<sup>177</sup> 40 CFR 721.10663

<sup>178</sup> 40 CFR 721.10663

<sup>179</sup> 40 CFR 721.10663

<sup>180</sup> From Jellinek's perspective, the statutory language of the TSCA the primary reason for its downfall, not implementation. The Toxic Substances Control Act: from the perspective of Steven D. Jellinek, interview by Jody A. Roberts and Kavita D. Hardy at The Chemical Heritage Foundation, Philadelphia, Pennsylvania, 29 January 2010 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0653).

<sup>181</sup> Pressman & Wildavsky (1984) contend that "[i]mplementation may be viewed as a process of interaction between the setting of goals and the actions geared to achieving them."

<sup>182</sup> Zyvex Group includes separate companies that design, create, and commercialize advanced molecularly engineered materials and products (Zyvex, 2014).

<sup>183</sup> "The relationship between EPA and OMB was a very difficult one, and remains so. It's the hardest job for Bill Reilly, although the Competitive Council headed by Vice President Quayle has displaced OMB as the chief EPA nemesis within the administration. But White House reorganizations don't really matter. When Douglas Costle was administrator, the culprit was the Wage and Price Council. There is *always* going to be somebody in the White House handling the regulatory agencies who will resist--and resist with some justification--the EPA's initiatives. Yet, many such programs are pushed very hard by the Congress, which has an incomplete understanding of the countervailing White House pressures.... This predicament puts the administrator right in the middle of conflicting currents, and it is a *very* complicated thing to deal with. It began to occur almost as soon as I got to the agency. The first sign of the problem

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manifested itself during the issuance of the Clean Air Standards, as provided by the Clean Air Act. Under this statute, we had 90 days to issue ambient air quality standards for the whole nation... We made some modifications, but not many, and announced the standards. The impact on industry was quite dramatic. Its leaders got very agitated and charged the White House. Nixon's staff then formed a Quality of Life Review Committee, which was the precursor of all of the White House oversight and led to so much rancor between OMB and EPA. No matter which political party is in office, this tension will persist. I couldn't resolve it then, and when I went back to the agency in 1983, I got right back in the middle of it! The *same people were there!* The *same* people in the agency, the *same* people in OMB, fighting each other over what should happen to these standards!" Ruckelshaus, William, interview by Dr. Michael Gorn in November 1992, (Washington: U.S. Environmental Protection Agency, EPA 202-K-92-0003).

<sup>184</sup> Russell Train, Administrator (1973-1979), during a 1992 interview: I would also like to make a general comment on EPA relationships with the White House and OMB. I gave an interview not long ago to public radio, and the interviewer said, "Isn't it awful how the White House and OMB interfere with EPA in carrying out its responsibilities?" I reminded them that this is nothing new. It's been going on for a long time. I do think it's become more intrusive, more pervasive. It does seem to me that the White House today pays more detailed attention to what EPA does than was ever true in my day. Having said that, the White House and OMB always had a fairly lively interest in our regulations. While we didn't have a Competitive Council, we did have something called the Quality of Life Review. But it acted more to delay than to prevent initiatives. In my opinion, in the 1970s, EPA did not have the difficulties with the White House that it has today. My point is that such interference is not really something new, not something dreamed up by the Bush Administration or Reagan Administration. There was a good deal of it in the Carter Administration, and it certainly went on in the Nixon and Ford Administrations. But, I do think it has become more difficult." Train, R. Interview conducted by Dr. Michael Gorn on May 5, 1992 at the World Wildlife Fund Office, Washington, D.C. (Washington: U.S. Environmental Protection Agency, EPA 202-K-93-001).

<sup>185</sup>"In general, that relationship (with OMB) has been a pretty uneasy one. And one of the problems has been the OMB regulatory review process. Within it, junior people have a lot of power, particularly to delay decision-making. It creates a lot of tension between OMB and EPA. Perhaps an expedited process for reaching decisions between EPA and OMB and the White House would help. During the time I was there, the problem was that you never really knew where things were. It just seemed like the issues would wind up in OMB, and unless there was some sort of real pressure, like a court deadline, it was very hard to break them loose." Alm, Alvin, interviews by Dr. Dennis Williams on April 12, 1993 and June 23, 1993 at SAIC, Inc., McLean, VA, 12 April 1993 (Washington: U.S. Environmental Protection Agency, EPA 202-K-94-005).

<sup>186</sup> The EPA, for example, protects data that industry claims as confidential and personal health information of participants in environmental health studies. Erickson, BE. "EPA Strives to Navigate Privacy, Data Access Concerns." *Chemical Engineering News* (14 April 2014), p. 21.

<sup>187</sup> Environmental Protection Agency, "About the Office of Chemical Safety and Pollution Prevention," <http://www.epa.gov/aboutepa/ocspp.html> (accessed 18 December 2012).

<sup>188</sup> At the time of the report, the EPA had not established a formal process to disseminate this data to offices external to the OCSPP. *Manage Nanomaterials*, p. 9.

<sup>189</sup> About the Office of Chemical Safety and Pollution Prevention (OCSPP). U.S. Environmental Protection Agency (available at <http://www2.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp#oscp>) (accessed on 18 June 2014).

<sup>190</sup> *Ibid*, p. 10.

<sup>191</sup> Environmental Protection Agency, "About the Office of Chemical Safety and Pollution Prevention," <http://www.epa.gov/aboutepa/ocspp.html> (accessed 18 December 2012).

<sup>192</sup> *The National Nanotechnology Initiative: Supplement to the President's 2015 Budget*. Subcommittee on Nanoscale Science, Engineering, and Technology Committee on Technology National Science and Technology Council. Washington, D.C. (March 2014).

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<sup>193</sup> *The National Nanotechnology Initiative: Supplement to the President's 2015 Budget*. Subcommittee on Nanoscale Science, Engineering, and Technology Committee on Technology National Science and Technology Council. Washington, D.C. (March 2014).

<sup>194</sup> Environmental Protection Agency, Office of Inspector General. EPA Needs to Manage Nanomaterials Risks More Effectively. Report No. 12-P-0162 (Dec. 2011), p. 6. (hereafter cited as *Manage Nanomaterials*)

<sup>195</sup> Air, Climate, and Energy Research Program; Chemical Safety for Sustainability Research Program; Human Health Risk Assessment Program; Homeland Security Research Program; Safe and Sustainable Water Resources Research Program; Sustainable and Healthy Communities Research Program

<sup>196</sup> National Exposure Research Laboratory; National Health and Environmental Effects Research Laboratory; National Risk Management Research Laboratory

<sup>197</sup> National Center for Computational Toxicology; National Center for Environmental Assessment; National Center for Environmental Research; National Homeland Security Research Center

<sup>198</sup> Office of the Science Advisor; Office of Science Policy

<sup>199</sup> Ibid.

<sup>200</sup> As of 2011, the EPA was in the process of testing a new high-throughput screening system called ToxCast. This system "examines hundreds of thousands of chemicals to identify potential effects. In phase 2 of ToxCast, EPA is testing additional chemicals, 50 to 60 of which will be nanoscale materials." Ibid.

<sup>201</sup> Fiorino, D.J. "Environmental Bureaucracies: The Environmental Protection Agency," in *The Oxford Handbook of U.S. Environmental Policy*, Kamieniecki, S. and Kraft, M., eds., Oxford University Press: 2013, p. 337.

<sup>202</sup> "Stockman...understood the potential of the budget office, which functions like the brain of the sprawling federal bureaucracy. Virtually every executive-branch activity crosses the desk of the budget director at some point. The post can be even more potent when a President who likes to delegate power chooses a director who outstrips other Cabinet officers in energy, intelligence and creativity. Which is what happened on Dec. 11, 1980, when President-elect Ronald Reagan took a chance on a young, untested man half his age." Ullman, O. *Stockman: The Man, the Myth, the Future*. New York: Donald I. Fine, Inc., 1986, p. 17; See also Vig, NJ. "The President and the Environment: Revolution or Retreat?," *Environmental Policy in the 1980s: Reagan's New Agenda*, Vig, NJ and Kraft, ME (eds.), Washington, DC: CQ Press, 1984, p. 81.

<sup>203</sup> U.S. House of Representatives, Committee on Energy and Commerce, *EPA's Asbestos Regulations: Report on a Case Study on OMB Interference in Agency Rulemaking*, Report No. 52-564, 99th Congress, 1st Session (Oct 1985), p. iii.

<sup>204</sup> U.S. House of Representatives, Committee on Energy and Commerce, *EPA's Asbestos Regulations: Report on a Case Study on OMB Interference in Agency Rulemaking*, Report No. 52-564, 99th Congress, 1st Session (Oct 1985), p. iii.

<sup>205</sup> Wenner, L.M. "The Reagan Era in Environmental Regulation," *Conflict Resolution and Public Policy*, Mills, M.K. (ed.) (New York: Greenwood Press, 1990), p. 41.

<sup>206</sup> Stockman, D.A. *The Triumph of Politics: How the Reagan Revolution Failed*, New York: Harper & Row Publishers, 1986, pp. 75-76. "Now came the final link. I soon discovered that it would be up to me to design the Reagan Revolution....I sketched out an action plan for launching the entire Reagan Revolution for economic recovery within a few weeks of the inauguration. To my surprise, they both agreed with it."

<sup>207</sup> Vig, NJ. "The President and the Environment: Revolution or Retreat?," *Environmental Policy in the 1980s: Reagan's New Agenda*, Vig, NJ and Kraft, ME (eds.), Washington, DC: CQ Press, 1984, p. 89, citing Liroff, RA.. "Cost-Benefit Analysis in Federal Environmental Programs," in *Cost-Benefit Analysis and Environmental Regulations: Politics, Ethics, and Methods*, ed. Daniel Swartzman et al. (Washington, D.C.: Conservation Foundation, 1982), 39.

<sup>208</sup> Davidson, D., *Jim Tozzi, Center for Regulatory Effectiveness, Nixon's 'Nerd' Turned Regulations Watchdog*, FederalTimes.com, Nov. 11, 2002.

<sup>209</sup> *Profile--OMB's Jim Joseph Tozzi*, The Environmental Forum (May 1982) (available at [http://www.thecre.com/pdf/20110922\\_20060612\\_ELI\\_EnvironmentalForum.pdf](http://www.thecre.com/pdf/20110922_20060612_ELI_EnvironmentalForum.pdf)) (accessed 10 June 2014)

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<sup>210</sup> Tozzi, J. OIRA's Formative Years: The Historical Record of Centralized Regulatory Review Preceding OIRA's Founding. *Administrative Law Review* 63: 37-69 (Special Edition) 2011.

<sup>211</sup> Vig, NJ. "The President and the Environment: Revolution or Retreat?," *Environmental Policy in the 1980s: Reagan's New Agenda*, Vig, NJ and Kraft, ME (eds.), Washington, DC: CQ Press, 1984, p. 86.

<sup>212</sup> "I had a memorandum from my General Counsel basically boxing me in, saying that the approach that the Competitiveness Council wanted was not a lawful approach. Well, once I had that, I didn't have a lot of flexibility. Finally, after months and months of wrangling, and public wrangling at that, Congressional hearings and the rest, the President made a policy call and resolved that as a policy matter, he considered that the Competitiveness Council was correct, i.e., that no hearing was necessary. The Chief of Staff and others in the White House thought that should be the end of it, and didn't fully grasp that lawfully, legally, I had the statutory authority and the President didn't. I recall explaining to Chief of Staff Sam Skinner that I would respect the President's view on the policy, provided that I could be authoritatively assured that such an approach was lawful. Absent an opinion from the Attorney General, I said I would decline to sign a regulation waiving a hearing requirement. The White House got an opinion from the Attorney General fairly quickly which said that the Competitiveness Council was right on the law and my General Counsel was wrong. That provided the basis for accommodating their view, and then, of course, we'll only know what the truth is after it's been tested in court. The announcement of our final position on the issue was front-page news in the *New York Times*, and occasioned a lot of negative publicity, so much so that President Bush asked his counsel, Boyden Gray, "Who put me in the middle of this?" (Gray told him it was the Vice President's staffer, McIntosh.)" Williams, Dennis. EPA History Program, "William K. Reilly: Oral History Interview," U.S. Environmental Protection Agency, EPA 202-K-95-002 (September 1995) <http://www2.epa.gov/aboutepa/william-k-reilly-oral-history-interview> (accessed June 16, 2014).

<sup>213</sup> *Profile--OMB's Jim Joseph Tozzi*, The Environmental Forum (May 1982) (available at [http://www.thecre.com/pdf/20110922\\_20060612\\_ELI\\_EnvironmentalForum.pdf](http://www.thecre.com/pdf/20110922_20060612_ELI_EnvironmentalForum.pdf)) (accessed 10 June 2014)

<sup>214</sup> *Profile--OMB's Jim Joseph Tozzi*, The Environmental Forum (May 1982) (available at [http://www.thecre.com/pdf/20110922\\_20060612\\_ELI\\_EnvironmentalForum.pdf](http://www.thecre.com/pdf/20110922_20060612_ELI_EnvironmentalForum.pdf)) (accessed 10 June 2014)

<sup>215</sup> "President Nixon initiated a "Quality of Life Review," which required the Environmental Protection Agency and the Occupational Safety and Health Administration to engage in an interagency consultation process and provide an estimate of the costs of proposed regulation along with a set of alternatives." Livermore, MA and Revesz, RL. "Regulatory Review, Capture, and Agency Inaction." *The Georgetown Law Journal*, Vol 101:1337-1390 (2013), citing, McGarity, TO. Reinventing Rationality: The Role of Regulatory Analysis in the Federal Bureaucracy 18 (1991).

<sup>216</sup> "The relationship between EPA and OMB was a very difficult one, and remains so. It's the hardest job for Bill Reilly, although the Competitive Council headed by Vice President Quayle has displaced OMB as the chief EPA nemesis within the administration. But White House reorganizations don't really matter. When Douglas Costle was administrator, the culprit was the Wage and Price Council. There is *always* going to be somebody in the White House handling the regulatory agencies who will resist--and resist with some justification--the EPA's initiatives. Yet, many such programs are pushed very hard by the Congress, which has an incomplete understanding of the countervailing White House pressures.... This predicament puts the administrator right in the middle of conflicting currents, and it is a *very* complicated thing to deal with. It began to occur almost as soon as I got to the agency. The first sign of the problem manifested itself during the issuance of the Clean Air Standards, as provided by the Clean Air Act. Under this statute, we had 90 days to issue ambient air quality standards for the whole nation... We made some modifications, but not many, and announced the standards. The impact on industry was quite dramatic. Its leaders got very agitated and charged the White House. Nixon's staff then formed a Quality of Life Review Committee, which was the precursor of all of the White House oversight and led to so much rancor between OMB and EPA. No matter which political party is in office, this tension will persist. I couldn't resolve it then, and when I went back to the agency in 1983, I got right back in the middle of it! The *same people were there!* The *same* people in the agency, the *same* people in OMB, fighting each other over what should happen to these standards!" Ruckelshaus, William, interview by Dr. Michael Gorn in November 1992, (Washington: U.S. Environmental Protection Agency, EPA 202-K-92-0003).



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<sup>217</sup> Russell Train, Administrator (1973-1979), during a 1992 interview: I would also like to make a general comment on EPA relationships with the White House and OMB. I gave an interview not long ago to public radio, and the interviewer said, "Isn't it awful how the White House and OMB interfere with EPA in carrying out its responsibilities?" I reminded them that this is nothing new. It's been going on for a long time. I do think it's become more intrusive, more pervasive. It does seem to me that the White House today pays more detailed attention to what EPA does than was ever true in my day. Having said that, the White House and OMB always had a fairly lively interest in our regulations. While we didn't have a Competitive Council, we did have something called the Quality of Life Review. But it acted more to delay than to prevent initiatives. In my opinion, in the 1970s, EPA did not have the difficulties with the White House that it has today. My point is that such interference is not really something new, not something dreamed up by the Bush Administration or Reagan Administration. There was a good deal of it in the Carter Administration, and it certainly went on in the Nixon and Ford Administrations. But, I do think it has become more difficult." Train, R. Interview conducted by Dr. Michael Gorn on May 5, 1992 at the World Wildlife Fund Office, Washington, D.C. (Washington: U.S. Environmental Protection Agency, EPA 202-K-93-001).

<sup>218</sup>"In general, that relationship (with OMB) has been a pretty uneasy one. And one of the problems has been the OMB regulatory review process. Within it, junior people have a lot of power, particularly to delay decision-making. It creates a lot of tension between OMB and EPA. Perhaps an expedited process for reaching decisions between EPA and OMB and the White House would help. During the time I was there, the problem was that you never really knew where things were. It just seemed like the issues would wind up in OMB, and unless there was some sort of real pressure, like a court deadline, it was very hard to break them loose." Alm, Alvin, interviews by Dr. Dennis Williams on April 12, 1993 and June 23, 1993 at SAIC, Inc., McLean, VA, 12 April 1993 (Washington: U.S. Environmental Protection Agency, EPA 202-K-94-005).

<sup>219</sup>"The Budget Director...doubted the seriousness of the air pollution problem in the United States. It was a philosophy that [David] Stockman had also espoused - in fact, I think Stockman had greatly influenced Darman." Williams, Dennis. EPA History Program, "William K. Reilly: Oral History Interview," U.S. Environmental Protection Agency, EPA 202-K-95-002 (September 1995) <http://www2.epa.gov/aboutepa/william-k-reilly-oral-history-interview> (accessed June 16, 2014).

<sup>220</sup>"On 15 June 1990 the President expressly directed the council to exercise the same authority over regulatory issues as the former Task Force on Regulatory Relief. Executive Orders 12291, issued on 17 February 1981, and 12498, issued on 4 January 1985, set forth the specific procedures for regulatory review process and served as the legal authority for council activities." The Center for Regulatory Effectiveness. *Scope and Content Note* (1999-0129-F). Retrieved from <http://www.the cre.com/ombpapers/1999-0129-F.htm>

<sup>221</sup> Williams, Dennis. EPA History Program, "William K. Reilly: Oral History Interview," U.S. Environmental Protection Agency, EPA 202-K-95-002 (September 1995) <http://www2.epa.gov/aboutepa/william-k-reilly-oral-history-interview> (accessed June 16, 2014).

<sup>222</sup> Williams, D. (1995, September). EPA History Program, "William K. Reilly: Oral History Interview," U.S. Environmental Protection Agency, EPA 202-K-95-002. Retrieved from <http://www2.epa.gov/aboutepa/william-k-reilly-oral-history-interview> <http://www2.epa.gov/aboutepa/william-k-reilly-oral-history-interview> (accessed June 16, 2014).

<sup>223</sup>The Center for Regulatory Effectiveness. *Scope and Content Note* (1999-0129-F). Retrieved from <http://www.the cre.com/ombpapers/1999-0129-F.htm>

<sup>224</sup> Meier, B. (1997, 14 November). In Apparent Shift, Tobacco Defender Seeks Industry Documents. *New York Times*. Retrieved from <http://www.nytimes.com/1997/11/14/us/in-apparent-shift-tobacco-defender-seeks-industry-documents.html>

<sup>225</sup> *EPA's Asbestos Regulations: Report on a Case Study on OMB Interference in Agency Rulemaking by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce*. U.S. House of Representatives. (99th Congress, 1st Session) (Oct. 1985).

<sup>226</sup> Kraft, ME and Vig, NJ. "Epilogue," *Environmental Policy in the 1980s: Reagan's New Agenda*, Vig, NJ and 8 May 1986), Kraft, ME (eds.), Washington, DC: CQ Press, 1984, p. 369.

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<sup>227</sup> *EPA's Asbestos Regulations: A Case Study of Interference in Environmental Protection Agency Rulemaking by the Office of Management and Budget*. Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce. House of Representatives (99th Congress, 1st Session) Serial No. 99-2, 16 April, 1985, p.2.

<sup>228</sup> *EPA's Asbestos Regulations: A Case Study of Interference in Environmental Protection Agency Rulemaking by the Office of Management and Budget*. Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce. House of Representatives (99th Congress, 1st Session) Serial No. 99-2, 16 April, 1985, pp. 128-130.

<sup>229</sup> "[T]he real reason EPA abdicated its responsibility to deal with major asbestos risks is clear: it was directed by the Office of Management and Budget (OMB). OMB had pressed an incorrect reading of TSCA, requiring EPA to refer asbestos regulation to other agencies, and the Acting Deputy Administrator, with the tacit approval of the Acting Administrator, quickly capitulated." *EPA's Asbestos Regulations: Report on a Case Study on OMB Interference in Agency Rulemaking by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce*. U.S. House of Representatives. (99th Congress, 1st Session) (Oct. 1985).

<sup>230</sup> *EPA's Asbestos Regulations: Report on a Case Study on OMB Interference in Agency Rulemaking by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce*. U.S. House of Representatives. (99th Congress, 1st Session) (Oct. 1985), p. 2.

<sup>231</sup> The following are the numbers of FTEs authorized for other years: FY1997 (47 FTEs); FY2001 (51 FTEs); FY2003 (55 FTEs); 2009 (46FTEs). Copeland, CW. *Length of Rule Reviews by the Office of Information and Regulatory Affairs*. Administrative Conference of the United States (2013), p. 62.

<sup>232</sup> Sunstein, C. (2013) "Commentary: The Office of Information and Regulatory Affairs: Myths and Realities," *Harvard Law Review* 126: 1838-1878.

<sup>233</sup> Arbuckle, D.R. Clinical Professor of Public Administration, University of Texas at Dallas. Curriculum Vitae (6 June 2008) (see <http://www.utdallas.edu/~dra062000/DA%20Resume%2006-2008.pdf>) (accessed 20 May 2014).

<sup>234</sup> "I served in OIRA from shortly after its creation on April 1, 1981 to June 2006, when I retired from Federal service. For more than ten years, from 1996 to 2006, I was OIRA's Deputy Administrator, that is, the career manager of the division. I worked closely with Professor Katzen in her various roles as OIRA Administrator, Deputy Assistant to the President for Economic Policy, and OMB Deputy Director for Management. I also worked with all five of her predecessors (James C. Miller 1981, Christopher C. DeMuth 1981-1984, Douglas H. Ginsburg 1984-1985, Wendy Lee Gramm 1985-1987, Jay Plager 1987-1989) and two of her successors (John Spotila 1998-2000 and John D. Graham 2001-2006). Additionally, I served as Acting Administrator for 18 months between Katzen's departure from OIRA and John Spotila's confirmation, and for six months between Spotila's departure and the confirmation of John Graham." Arbuckle, DR (2008). *OIRA and Presidential Regulatory Review: A View from Inside the Administrative State*. ExpressO (available at: [http://works.bepress.com/donald\\_arbuckle/1](http://works.bepress.com/donald_arbuckle/1)); See also Arbuckle, D.R. Clinical Professor of Public Administration, University of Texas at Dallas. Curriculum Vitae (6 June 2008) (see <http://www.utdallas.edu/~dra062000/DA%20Resume%2006-2008.pdf>) (accessed 20 May 2014).

<sup>235</sup> Sunstein, C. (2013) "Commentary: The Office of Information and Regulatory Affairs: Myths and Realities," *Harvard Law Review* 126: 1838-1878.

<sup>236</sup> "Under relevant statutes, of course, agencies are required or authorized to issue numerous rules. Agencies begin to draft rules long before OIRA is formally engaged — sometimes on their own, sometimes in consultation with other agencies, sometimes in consultation with one or more offices within the Executive Office of the President. OIRA may be aware of such rules, perhaps because of general discussion within the executive branch, or perhaps because they were included in the Annual Regulatory Plan and Unified Agenda of Regulatory and Deregulatory Actions, whose components are submitted to OIRA every year" (Sunstein, 2013).

<sup>237</sup> "For example, OIRA reviewed 2304 regulatory actions between January 21, 2009, and August 10, 2012. In that period, 320 actions, or about 14%, were approved without change; 161 actions, or about 7%, were withdrawn; and 1758 actions, or about 76%, were approved "consistent with change." Sunstein, C. (2013)

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"Commentary: The Office of Information and Regulatory Affairs: Myths and Realities," *Harvard Law Review* 126: 1838-1878.

<sup>238</sup> "If a regulatory action is ultimately found to be significant, it is usually because it would have a major economic impact or raise serious policy questions (for example, if it would involve a serious question of civil rights or civil liberties). However, a rule might be projected to cost \$50 million, well below the \$100 million threshold, but its impact might be concentrated in a small sector, or the agency's cost estimate might seem optimistic, and thus deserve a degree of interagency scrutiny. Recall that a rule counts as economically significant if it will "adversely affect in a material way . . . a sector of the economy," and even if a \$50 million price tag does not automatically make a rule economically significant, it might well be enough to trigger a judgment of significance in certain circumstances" (Sunstein, 2013).

<sup>239</sup> "When we circulated the bill (TSCA) —and, I mean, it was mandatory, obviously, to circulate any proposed legislation around to the government agencies before you sent it to the Hill, and especially something as broad as a chemicals bill. We circulated it to the agencies, and the [United States] Department of Commerce, in particular, opined as to how not only wasn't this bill a very good bill, but they would be quite happy doing without a chemicals bill altogether, and what was a conservative Republican administration doing proposing something like this? They did their best to kill it outright, but didn't succeed. I've never been sure why, except that there was so much pressure to do anything possible on the environment at that point that, I think, they just didn't have the political muscle. But how it played out was that...I mean, Commerce really said, "we are strongly and firmly opposed to this bill. In those days, as now, and as before, disputes like that over proposed legislation wound up in OMB, in the Budget Bureau. The director of legislation in the Budget Bureau in those days—or in...it was OMB then—was a fairly extraordinary fellow by the name of Jim Hyde [James F. C. Hyde, Jr.]. So, he was totally blind...but he had an audio-graphic memory...But Jim said to me, "you and Commerce are going to have to work this out"

<sup>240</sup> Ibid.

<sup>241</sup> The Toxic Substances Control Act: from the perspective of Steven D. Jellinek, interview by Jody A. Roberts and Kavita D. Hardy at The Chemical Heritage Foundation, Philadelphia, Pennsylvania, 29 January 2010 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0653).

<sup>242</sup> Richard E. Heckert served as vice president of E. I. du Pont de Nemours and Company. Robert C. Eckhardt (D-TX), was the U.S. Representative who sponsored the TSCA.

<sup>243</sup> The Toxic Substances Control Act: from the perspective of Steven D. Jellinek, interview by Jody A. Roberts and Kavita D. Hardy at The Chemical Heritage Foundation, Philadelphia, Pennsylvania, 29 January 2010 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0653).

<sup>244</sup> The Toxic Substances Control Act: from the perspective of Steven D. Jellinek, interview by Jody A. Roberts and Kavita D. Hardy at The Chemical Heritage Foundation, Philadelphia, Pennsylvania, 29 January 2010 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0653).

<sup>245</sup> The Toxic Substances Control Act: from the perspective of Charles L. Elkins, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 9 April 2010 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0643).

<sup>246</sup> "When it was enacted, the sponsoring committees were the commerce committees in both houses [United States Senate Committee on Commerce and United States House of Representatives Committee on Interstate and Foreign Commerce]. Within two months...well, I don't know, I can't say that, but early in the Congress that started, I think, in 1978, jurisdiction in the Senate was switched from the Commerce Committee to the Environment and Public Works Committee...In the House, [Robert C.] Eckhardt, who was a sponsor of the bill, left the Congress. He was succeeded by a [series of] subcommittee chairmen who had no real interest in it...So, here you have a new law that people have very high expectations for, and unlike most laws, it has no advocate or sponsor in the Congress. The guys in Environment and Public Works made sure EPA did—or they tried to make sure EPA did—what they had intended when it came to Clean Water, Clean Air. They were very much involved, pushing the agency on the policy, and on implementation. When it came to TSCA, the Senate guys could care less. They just kind of ignored it, because they hated it." The Toxic Substances Control Act: from the perspective of Steven D. Jellinek, interview by Jody A. Roberts and Kavita D. Hardy at The Chemical Heritage Foundation, Philadelphia,

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Pennsylvania, 29 January 2010 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0653).

<sup>247</sup> The Toxic Substances Control Act: from the perspective of Don R. Clay, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 16 March 2012 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0684).

<sup>248</sup> U.S. GAO, *Toxic Substances Control Act--Legislative Changes Could Make the Act More Effective* (1994) (GAO/RCED-94-103).

<sup>249</sup> "The Administrative Procedure Act (APA), 5 U.S.C. §§551 et seq., establishes the basic procedural requirements agencies must follow in conducting informal rulemaking. Its basic requirements—that agencies provide public notices and an opportunity to comment prior to promulgating regulations—are implemented through notices published daily in the Federal Register describing agency actions and how to comment on them...Some environmental statutes supplement the APA by specifying additional procedures agencies must follow before taking certain actions. See, e.g., §6(c) of TSCA." Section 6(a) of TSCA "requires that EPA provide an opportunity for oral testimony and authorizes the submission of rebuttal testimony and cross-examination if the EPA administrator determines that it is necessary to resolve disputed issues of material fact." Percival, R.V. et al., *Environmental Regulation: Law, Science, and Policy*. Aspen Publishers: New York, 2006, p. 147.

<sup>250</sup> O'Leary, R. "Environmental Policy in the Courts," in *Environmental Policy: New Directions for the Twenty-First Century*, Vig, N. and Kraft, M., eds., CQ Press:2006, p. 148-167, citing O'Leary, R. *Environmental Change: Federal Courts and the EPA* (Philadelphia: Temple University Press, 1993).

<sup>251</sup> After eight years of litigation, for example, the court ruled in favor of the Environmental Defense Fund to permanently suspend "the registration of pesticides containing DDT in the United States." O'Leary, R. "Environmental Policy in the Courts," in *Environmental Policy: New Directions for the Twenty-First Century*, Vig, N. and Kraft, M., eds., CQ Press:2006, p. 148-167, citing *Environmental Defense Fund v. Ruckelshaus*, 439 F.2d 584 (1971).

<sup>252</sup> The Toxic Substances Control Act: from the perspective of Don R. Clay, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 16 March 2012 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0684).

<sup>253</sup> The Toxic Substances Control Act: from the perspective of Don R. Clay, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 16 March 2012 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0684).

<sup>254</sup> TSCA §4, 15 U.S.C. § 2603 (2006).

<sup>255</sup> Trevisan, L. (2011) Human Health and the Environment Can't Wait for Reform: Current Opportunities for the Federal Government and States to Address Chemical Risks Under the Toxic Substances Control Act. *American University Law Review* 61:385-430, citing *Chemical Manufacturers Association v. EPA*, 859 F.2d 977, 19 ELR 20001 (DC Cir. 1988). See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984).

<sup>256</sup> *Chemical Manufacturers Association v. EPA*, 859 F.2d 977, 19 ELR 20001 (DC Cir. 1988).

<sup>257</sup> See *Ausimont U.S.A. Inc. v. EPA*, 838 F.2d 93, 97 (3d Cir. 1988); See also *Shell Chem. Co. v. EPA*, 826 F.2d 295, 298 (5th Cir. 1987) ('remanding to explore additional evidence without deciding how strong a showing of "unreasonable risk" must be to warrant a test rule'). Trevisan, L. (2011) Human Health and the Environment Can't Wait for Reform: Current Opportunities for the Federal Government and States to Address Chemical Risks Under the Toxic Substances Control Act. *American University Law Review* 61:385-430.

<sup>258</sup> TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure, 58 Fed. Reg. 28,736 (May 14, 1993).

<sup>259</sup> Roberts, J.A. Webinar Presentation: From Inception to Reform: An Oral History Project of the Toxic Substances Control Act. Hosted by the Environmental Leadership Program (available at <http://www.chemheritage.org/research/policy-center/projects/tsca-oral-history.aspx>).

<sup>260</sup> *Webinar Presentation*

<sup>261</sup> *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

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<sup>262</sup> The rule was called the Asbestos Ban and Phase-Out Rule. Federal Register. Part III Environmental Protection Agency 40 CFR Part 763 (12 July 1989).

<sup>263</sup> EPA. *Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions*. 54 Fed. Reg. 29, 460 (1989).

<sup>264</sup> "EPA's approach is very clear: (1) asbestos is a significant risk at levels below which asbestos can be controlled; (2) suitable substitutes are generally available for asbestos-containing products; therefore, the risks from the entire life cycle of asbestos-containing products are unreasonable" (Ruckelshaus, 1985).

<sup>265</sup> Victor J. Kimm, interview by Jody A. Roberts at Ropes & Gray, LLP, Washington, D.C., 3 February 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0679).

<sup>266</sup> Victor J. Kimm, interview by Jody A. Roberts at Ropes & Gray, LLP, Washington, D.C., 3 February 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0679).

<sup>267</sup> The Toxic Substances Control Act: from the perspective of Charles L. Elkins, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 9 April 2010 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0643); Roberts JA, Hardy KD. The Toxic Substances Control Act: from the perspective of Charles L. Elkins. Philadelphia (PA): Chemical Heritage Foundation; 2010 Apr 9. (Oral History Transcript No. 0643).

<sup>268</sup> *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

<sup>269</sup> *Environmental Regulation*, p. 242. The EPA provided "an advance notice of proposed rulemaking in 1979 and a data collection rule promulgated under §8(a) of TSCA in 1982." "EPA had held 22 days of public hearings, taken thousands of pages of testimony, and received 13,000 pages of comments from more than 250 interested parties. The Agency and its contractors had prepared ten major regulatory analysis documents in support of the rule." Ibid.

<sup>270</sup> Trevisan, L. (2011) Human Health and the Environment Can't Wait for Reform: Current Opportunities for the Federal Government and States to Address Chemical Risks Under the Toxic Substances Control Act. *American University Law Review* 61:385-430

<sup>271</sup> Ibid, p. 245.

<sup>272</sup> *Environmental Regulation*, p. 242.

<sup>273</sup> *Human Health*, p. 400.

<sup>274</sup> The legislative history of the TSCA suggests that sections of the regulation go beyond the original intent of Congress in several important areas. Congress did not contemplate, for example, that the EPA would assume responsibility for performing quantitative risk assessments and formal cost-benefit analysis. The House Committee report 94-134, 94<sup>th</sup> Cong., 2d sess. 14 (1976) on the legislation stated that the balancing requirement under §6 'does not require formal benefit-cost analysis' because 'such an analysis would not be very useful' because of the challenges associated with ascribing dollar values to the benefits and costs of the regulation. *Environmental Regulation*, p. 231.

<sup>275</sup> The Toxic Substances Control Act: from the perspective of J. Clarence Davies, interview by Jody A. Roberts and Kavita D. Hardy at Resources for the Future, Washington, D.C., 30 October 2009 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0640). (hereafter cited as Chemical Heritage Foundation, Oral History Transcript # 0640).

<sup>276</sup> *Human Health*, p. 401.

<sup>277</sup> The Toxic Substances Control Act: from the perspective of Don R. Clay, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 16 March 2012 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0684).

<sup>278</sup> "Virtually all high-level positions thus were turned over to political appointees who came from the private sector and from the regulated industries. In EPA, for example, Rita Lavelle, a public relations officer for Aerojet-General, became assistant administrator for hazardous and toxic wastes; Kathleen Bennett, a lobbyist for the American Paper Institute, became assistant administrator for air, noise, and radiation; and Robert Perry, a lawyer from Exxon Corp., became EPA general counsel. The same was true of bureau chiefs and office heads within the Interior Department." Vig, NJ. "The President and the Environment: Revolution or Retreat?," *Environmental Policy in the 1980s: Reagan's New Agenda*, Vig, NJ and Kraft, ME (eds.), Washington, DC: CQ Press, 1984, p. 87.

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<sup>279</sup>The Toxic Substances Control Act: from the perspective of Don R. Clay, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 16 March 2012 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0684).

<sup>280</sup>The Toxic Substances Control Act: from the perspective of Don R. Clay, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 16 March 2012 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0684).

<sup>281</sup>The Toxic Substances Control Act: from the perspective of Don R. Clay, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 16 March 2012 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0684).

<sup>282</sup>The Toxic Substances Control Act: from the perspective of Don R. Clay, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 16 March 2012 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0684).

<sup>283</sup>"In 1982 the...president refused Congress's request for hazardous waste enforcement files, claiming executive privilege. This focused media attention on the issue, eventually resulting in Gorsuch's contempt citation. A second major error was made when a bureaucratic power struggle was made public. Gorsuch had accused Lavelle of going over her head to Edwin Meese, counselor to the president, and asked for the hazardous waste chief's resignation. When Lavelle refused to resign and had be fired by Reagan, the issue became front-page drama" (Vig, 1984).

<sup>284</sup>Ruckelshaus, William, interview by Dr. Michael Gorn in November 1992, (Washington: U.S. Environmental Protection Agency, EPA 202-K-92-0003).

<sup>285</sup>"I think (the relationship with Stockman) was okay for a couple of months, but then began to deteriorate again." Ruckelshaus, W. (1992). Interview by Dr. Michael Gorn in November 1992, (Washington: U.S. Environmental Protection Agency, EPA 202-K-92-0003).

<sup>286</sup>Victor J. Kimm, interview by Jody A. Roberts at Ropes & Gray, LLP, Washington, D.C., 3 February 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0679).

<sup>287</sup>Victor J. Kimm, interview by Jody A. Roberts at Ropes & Gray, LLP, Washington, D.C., 3 February 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0679).

<sup>288</sup>Victor J. Kimm, interview by Jody A. Roberts at Ropes & Gray, LLP, Washington, D.C., 3 February 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0679).

<sup>289</sup>"EPA's petition focuses on two major aspects of the Court's decision: (1) the Court's interpretation of the requirement in TSCA that EPA use the 'least burdensome requirements' in regulating a particular substance; and (2) the Court's interpretation of the factors EPA must consider in determining whether there is an 'unreasonable risk' and the precise manner in which EPA is to implement that determination" (EPA, 1991).

<sup>290</sup>Castleman (2006) cites Fisher L. U.S. EPA, letter to Z. Anavi, Israel Ministry of Environment, Aug. 17, 1992.

<sup>291</sup>"The Agency did not appeal. The effect of that ruling I think is what the interesting issue is and I can only speak to some of this...my sense is that the effect was devastating, and even more devastating than I had anticipated in arguing for appeal" (AAAS, 2011).

<sup>292</sup>Victor J. Kimm, interview by Jody A. Roberts at Ropes & Gray, LLP, Washington, D.C., 3 February 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0679).

<sup>293</sup>Chemical Heritage Foundation. Abstract: *The Toxic Substances Control Act: from the perspective of Linda J. Fisher* interview by Jody A. Roberts and Kavita D. Hardy at the E. I. du Pont de Nemours and Company, Washington, D.C., 5 March 2010 (Interview No. 0645). Philadelphia, PA. Retrieved from <http://www.chemheritage.org/discover/collections/oral-histories/details/tsca-fisher.aspx>.

<sup>294</sup>Victor J. Kimm, interview by Jody A. Roberts at Ropes & Gray, LLP, Washington, D.C., 3 February 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0679).

<sup>295</sup>The Toxic Substances Control Act: from the perspective of Charles L. Elkins, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 9 April 2010 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0643).

<sup>296</sup>Victor J. Kimm, interview by Jody A. Roberts at Ropes & Gray, LLP, Washington, D.C., 3 February 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0679).

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<sup>297</sup> "The target population for the survey was the group of EPA presidential appointees subject to Senate confirmation ("PASs") during the Bush I administration (1989-1993) and the Clinton administration (1993-2001). These appointees were the highest political managers in the agency, holding positions including Administrator, Deputy Administrator, General Counsel, and Assistant Administrator. The target population included all EPA PASs with the exception of the Inspector General, who is responsible for oversight rather than policy-making" (Bressman & Vandenberg, 2006).

<sup>298</sup> "OIRA staff who review EPA rules may not have the scientific or technical expertise necessary to evaluate conflicting interpretations of factual data presented by the agency and by interested industry representatives. At the same time, the weight carried by OMB's views may reduce the role of agency scientific and technical skills. OIRA staff graduate degrees are in public policy, business administration, and economics. In contrast, the staff who develop EPA regulations tend to have training in engineering, chemistry, toxicology, law, and public policy. Thus the four EPA desk officers in OIRA must review all proposed and final rules, in addition to the regulatory program established by Executive Order 12498, of an agency with a staff of about 10,000, most of whom are experts in their fields." U.S. Congress, Senate Committee on Environmental and Public Works, Office of Management and Budget Influence on Agency Regulations, 99th Cong., 2d sess., May 1986, pp. 1-34.

<sup>299</sup> The Toxic Substances Control Act: from the perspective of J. Clarence Davies, interview by Jody A. Roberts and Kavita D. Hardy at Resources for the Future, Washington, D.C., 30 October 2009 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0640). (hereafter cited as Chemical Heritage Foundation, Oral History Transcript # 0640).

<sup>300</sup> Elkins notes: "When Ronald Reagan came [into the] presidency, the whole world changed. The environmental groups decided that there was no receptive ear at the agency...This resulted in what Elkins described as a "'two-way conversation.' It was between [EPA] and industry, and there was nobody [else]. There was no environmental group[that we could find to come in and sit] there pounding on the table." Schifano, J.N. et al., "The Importance of Implementation in Rethinking Chemicals Management Policies: The Toxic Substances Control Act," *Environmental Law Reporter*, Vol. 41, 10527-10543, 2011, citing Interview by Jody A. Roberts & Kavita D. Hardy with Charles L. Elkins, Former Director of the Office of Toxic Substances, U.S. EPA, in Washington, D.C. (Apr. 9, 2010).

<sup>301</sup> TSCA § 21(B)(3),(4) 15 U.S.C. § 2605

<sup>302</sup> The Toxic Substances Control Act: from the perspective of Charles L. Elkins, interview by Jody A. Roberts and Kavita D. Hardy at Koch Industries, Inc., Washington, D.C., 9 April 2010 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0643).

<sup>303</sup> "OIRA has an open-door policy...If representatives of affected companies want to come in person to make an argument for or against a draft rule, OIRA is available. The same is true for public interest groups, state and local governments, and members of congressional staffs. In these meetings, OIRA's role is passive. It does not encourage or spur meetings, nor does it affirm positions, volunteer information, or answer questions. The central goal is to hear what people have to say" Sunstein (2013).

<sup>304</sup> Victor J. Kimm, interview by Jody A. Roberts at Ropes & Gray, LLP, Washington, D.C., 3 February 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0679).

<sup>305</sup> *EPA's Asbestos Regulations: A Case Study of Interference in Environmental Protection Agency Rulemaking by the Office of Management and Budget*. Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce. House of Representatives (99th Congress, 1st Session) Serial No. 99-2, 16 April, 1985, pp. 612-615

<sup>306</sup> "EPA's approach is very clear: (1) asbestos is a significant risk at levels below which asbestos can be controlled; (2) suitable substitutes are generally available for asbestos-containing products; therefore, the risks from the entire life cycle of asbestos-containing products are unreasonable" (Ruckelshaus, 1985).

<sup>307</sup> Victor J. Kimm, interview by Jody A. Roberts at Ropes & Gray, LLP, Washington, D.C., 3 February 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0679).

<sup>308</sup> *The National Nanotechnology Initiative: Supplement to the President's 2015 Budget*. (2014). Washington, DC: Subcommittee on Nanoscale Science, Engineering, and Technology Committee on Technology National Science and Technology Council.

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<sup>309</sup> James R. Von Ehr, II, interview by David C. Brock at Zyvex Labs, Inc, Richardson, Texas, 24 January 2011 (Philadelphia: Chemical Heritage Foundation, Oral History Transcript # 0685); See also the Zyvex Website at <http://www.zyvex.com/> (access on 18 May 2014).

<sup>310</sup> Kanarek (2011) cites Mossman et al. (1990).

<sup>311</sup> Dr. Kenny Crump was a consultant for the Asbestos Information Association legal team. He testified against OSHA regulations that sought to reduce asbestos exposures in 1984. Bohme, S.R. et al. (2005). Maximizing Profit and Endangering Health: Corporate Strategies to Avoid Litigation and Regulation. *International Journal of Occupational and Environmental Health* 11: 338-348.

<sup>312</sup> Dr. John C. Kirschman. RJR Interoffice Memorandum to Dr. A. W. Hayes: Trip Report -1986 Washington Conference on Risk Assessment, Hyatt Regency-Crystal City, Arlington, VA, October 27-28 1986 (12 Nov 1986). Legacy Tobacco Documents Library, University of California, San Francisco.

<sup>313</sup> Sporn (2014) cites Berman DW, Crump KS (2008) A meta-analysis of asbestos-related cancer risk that addressed fiber size and mineral type. *Crit Rev Toxicol* 38(S1):49-73.

<sup>314</sup> Bohme et al. (2005) cite Berman, DW, Crump, K. *Final draft: Technical Support Document for a Protocol to Assess Asbestos-related Risk*. EPA# 9345.4-06.2003. Washington, DC:EPA).

<sup>315</sup> *Strickland v. Union Carbide Corp.*, No. B234459, 2013 BC379088 (Cal. Ct. App., 2d Dist., Div. 7) (June 16, 2013)

<sup>316</sup> *Weitz & Luxenberg P.C. v. Georgia-Pacific LLC*, No. 9535, 2013 WL 2435565 (N.Y. App. Div., 1st Dep't) (June 6, 2013).

<sup>317</sup> "Around 1970, asbestos, especially chrysotile ( $\text{Mg}_3\text{Si}_2\text{O}_5(\text{OH})_4$ ), and crocidolite...had been used to fabricate nearly 80,000 miles of asbestos--cement (AC) water pipe in the United States, alone, hundreds of millions of tons of asbestos insulation...and a host of other commercial products" (Murr & Soto, 2004).

<sup>318</sup> "Only chrysotile is presently used for manufacturing in the United States. Ninety-four percent of chrysotile consumed was grade 7, a short (3  $\mu\text{m}$ ) fiber. Only 0.4% of the asbestos used were long fibers (6-9.5  $\mu\text{m}$ ); these were mostly used in plastics" (DHHS, 2001).

<sup>319</sup> Fraas (1991) cites Mossman et al. (1990).

<sup>320</sup> Eliason furthered: "The article by Mossman and Gee is biased against the interests of the patient, and could be used by the asbestos industry in defense against product-liability lawsuits. It was not a coincidence that an attorney representing an asbestos manufacturer presented me with a copy of the article three days before I received my own copy of the Journal in the mail" (Bricher, 1990).