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Environmental Regulation and the Doctrine of Scientific Uncertainty: A Case Study of the EPA's Cancellation of 2, 4, 5-T

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ENVIRONMENTAL REGULATION AND THE DOCTRINE OF SCIENTIFIC UNCERTAINTY:

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Winning Essay
1985 Law Student Essay Contest

In 1948, after being tested at the biological warfare testing center at Camp Dietrick and on the dandelions in the Mall in Washington, the phenoxy herbicide, 2,4,5-trichlorophenoxy acetic acid (2,4,5-T) was released as a registered herbicide. 1/ Only one year later, after production was set full scale, 228 workers at a Monsanto 2,4,5-T plant developed chloracne 2/ and four more serious, industrial accidents related to 2,4,5-T occurred over the next ten years worldwide. 3/ In spite of its nearly unsuccessful beginning, 2,4,5-T has since been used extensively in the Vietnam War, incorporated into 424 registered products which contain a total of 5.4 kg 2,3,5-T 4/ and survived on the market for over 30 years, with its cancellation finalized only this spring (1985). The reason for this delay cannot be explained away by government incompetence, however, but evolves from a much more complex problem with its center in the political/bureaucratic inability to act when the science is uncertain.

1/ D. Davis, Herbicides In Peace and War, 29 BIOSCIENCE 90, 91 (1979).

2/ T. Whiteside, A Reporter at Large: The Pendulum and the Toxic Cloud, NEW YORKER, 25 July: 30, 39 (1977).

3/ An explosion occurred in a 2,4,5-T factory in W. Germany, in Amsterdam, in Czechoslovakia, and 70 workers at a Dow 2,4,5-T factory developed cases of chloracne. Id.

4/ A. Galston, Herbicides: A Mixed Blessing, 29 BIOSCIENCE 85 (1979).

The purpose of this paper is to examine the impact of these elusive scientific issues on the administrative process using 2,4,5-T as a case study. The controversy over 2,4,5-T provides an excellent forum for investigation, due not only to the uncertain biological effects of the chemical but also because of the considerable public attention which 2,4,5-T received, particularly with respect to the Vietnam veteran's case, where veterans sued the chemical companies for damages suffered from warfare spraying. The paper is broken down into three sections. The first explores the actual science of 2,4,5-T and sets forth the fundamental problem--the science is unpreventably inconclusive. The second follows the acrobatic bureaucratics of 2,4,5-T regulation when the agency is confronted with this unstable scientific base. The third undertakes a brief analysis of the trans-scientific issues and resulting legal complications and forwards suggestions for more effective action in the future.

I. THE FOUNDATION OF THE PROBLEM--A TRANS-SCIENTIFIC ISSUE

2,4,5-T is a herbicide in the more general family of phenoxy acids, which are widely used on agricultural lands, forests, rangelands, and aquatic habitats, as well as on industrial and urban sites. The chemical is produced via a two-step process, with the second step conducive to the formation of chlorinated dioxins as by-products, including 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), one of the most toxic substances known to man. 5/ Generally, pure 2,4,5-T is not teratogenic 6/ unless the animal (extrapolated to humans) consumes physically impossible quantities of food and drink: 7/

> "Based on presently available data, there is no good evidence that suggests that presently

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5/ A. Galston, supra at note 4, at 86.

6/ Tendency to promote birth defects.

7/ Davis, supra at note 1, at 93.

> manufactured 2,4,5-T, if used according to directions on the label, is significantly hazardous to man, his animals, or wildlife." 8/

Combined with its impurity, dioxin, some impacts have been observed, however, with 2,4,5-T causing health and environmental damage in short-term, highly concentrated conditions such as the occupational accidents mentioned previously, or in accidental 2,4,5-T spills. In contrast, no studies have been done which are capable of indicating the health impacts following a more long-term, less concentrated exposure to the chemical.

The reason for this gap in the research concerning the effects of 2,4,5-T is due to the difficulty in performing the type of scientific experiments required. In examining the effects of a substance such as 2,4,5-T on health, studies must be used which are not models of the real world. Instead, they are controlled simulations of one variable in that world and its effects. This inability of science to develop experiments which can answer certain pressing questions put to it is known as "trans-science". In the case of 2,4,5-T, carrying out the definitive study would require examination of the effects of the herbicide on large populations at various low concentrations over a period of 20 to 50 years. In addition, control populations would have to be isolated which were identical to those populations exposed in order to eliminate the effects of all other variables. Resulting statistics would indicate certain correlations between cause and resulting injuries. Obviously such a study is impossible at present, and instead we must be content with controlled lab studies on mammals, inadequate clinical reports from the field, with no effective method of isolating the crucial variables, or inconclusive epidemiological data. The interpretations and extrapolations from these less definitive studies, then, provide the basis, in most cases, for any understanding of possible effects and consequences of the addition, removal, or alteration of one acting variable in the system. In reality, the choices

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8/ Id. at 94. See also CAST. The Phenoxy Herbicides, Report No. 39, Council Agr. Sci. Technol., Dept. Agron., Iowa State University, Ames, IA (1975); Committee on the Effects of Herbicides in Vietnam. The Effects of Herbicides in South Vietnam, Part A, Summary and Conclusions. National Academy of Sciences, Washington, D.C. (1974).

involved with regard to these extrapolations and assumptions are not merely scientific, but hinge on the scientist's own psychology and risk adversity as well.

Alvin Weinberg, a radiation specialist at Oak Ridge Laboratory, stated this most eloquently in regard to 2,4,5-T:

> "The point missed . . . is that the seemingly simple question 'What is the effect on human health of very low levels of physical insult?' can be stated in scientific terms; it can, so to speak, be asked of science, yet it cannot be answered by science. I have . . . proposed the name trans-scientific for such questions that seemingly are part of science yet in fact transcend science--that is, are incapable of resolution by science . . . [Even] any null experiment--that is, an experiment that shows no biological effect at low levels of insult--does not prove the insult is harmless, since a larger experiment might show effects . . . I must stress that where low-level effects are concerned, there will always be a trans-scientific residue. To decide on standards when science can say neither yea or nay requires some procedure other than the one usually used by scientists in resolving bona fide scientific questions." 9/

In administrative law the fundamental danger is the use of this unresolvable, uncertain "science" in a decision making or an adversarial system which bases its outcome on the most appropriate interpretation of the facts. When there are no facts and only trans-scientific observations, the scientific results begin to enter an every-man's realm where they can be interpreted in the most politically expedient way, depending on the desired outcome.

> "The vacuum of reliable scientific knowledge is such that each side can find scientists who will maintain in courts, in public hearings or in the scientific literature whatever is politically convenient, and it is important to recognize that

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9/ A. Weinberg, Letters to the Editor, 174 SCIENCE 546-547 (1971).

scientists on both sides of this debate now have career interests at stake in it." 10/

There are a variety of complications associated with trans-science, each revolving around an unresolvability and lack of adequate data upon which to base a conclusion. These add still another level of complexity to any finding of cause and effect. For the sake of clarity, three have been defined, and each will be considered separately.

The first involves the variability between substances in how trans-scientific they are. Not all of the substances considered in toxic torts are equally trans-scientific, and some are not trans-scientific in any way. Certain qualities of a chemical or the research existing on its impact on health exert great influence on the level of certainty regarding that substance. For example, if the substance is exceedingly toxic, like dioxin, it may be rather easily determined that no level is safe, or similarly, if a substance is deemed to be of a highly nonreactive nature due to its stable chemical structure, it may be considered safe at any level. A substance also may not belong to the trans-scientific realm if its safety has been established by its nonthreatening presence in the environment for long periods of time and adequate data has been gathered to substantiate that. Although this proof of safety by default is not definitive, data gathered under natural conditions over long periods of time is generally more reliable than extrapolations based on short-term laboratory studies where errors accumulate with the numbers of extrapolations. Finally, certain substances by their very nature have impacts which are so straightforward that research on potential hazards may be conducted relatively easily. For example, many tests 11/ have been developed to determine carcinogenicity. Although they are not foolproof, they are streamlined enough to catch many of the more hazardous substances. In contrast, the effects of a substance on general physiology, such as respiratory clearance

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10/ Peto, "Distorting the Epidemiology of Cancer: The Need for a More Balanced Overview," 284 NATURE 297 (1980).

11/ I.e., the Ames test on bacteria. Scientists have also been able to isolate certain animals which are susceptible to specific cancers in a manner similar to humans. See S. Epstein, "The Politics of Cancer" (1979).

rates, or the teratogenic effects of a substance following dermal exposure are much more difficult to detect, and thus tend to be more unresolvable or trans-scientific. In summary, it appears that the degree of uncertainty or trans-scientific residue which may be associated with particular substances must be considered on an individual basis, depending largely upon characteristics and physical properties of the chemical; the previous data collected in the field; and the nature of the impact commonly associated with that type of chemical.

A second trans-scientific problem emerges when substances are involved that inflict diseases which are not specific to that particular chemical but instead have a high probability of natural occurrence or are "indeterminant". While epidemiological studies are capable of detecting an enhanced risk caused by a specific substance, they cannot move beyond the probabilities to provide more specific evidence for a direct causal link between a specific injury and exposure to a substance. For both asbestos and DES the injuries were unusual and specific to that particular substance so that the proof of mesothelioma or adenocarcinoma coupled with exposure to the substance, indicated an almost undeniable link. In the case of most other substances, such as 2,4,5-T, radiation, indoor air pollutants, and hazardous wastes, the injuries which are inflicted are not specific to that substance, and instead are common in the everyday world. This makes it impossible in most cases to trace the injury to any singular cause.

Finally, a trans-scientific condition is created when a substantial lag time, averaging several decades, is experienced before any injury becomes apparent following use or exposure to a hazardous substance. This causes obvious problems in determining the associated dangers of a chemical, since during this lag time the evidence, data, and other records regarding the duration or extent of exposure may be lost or confused.

In the section following, which traces the history of 2,4,5-T regulation, one should keep these characteristics of trans-scientific issues clearly in mind. The scientific debates and agency indecisiveness appear to revolve universally around the theme of "inadequate". This criticism is not meant in the more common sense of flawed scientific studies which are conducted in dirty labs by incompetent scientists, however, but instead emerges from a fundamental disagreement over the correct assumptions for the experimental design or the proper risks to be considered.

Consequently, disputes focused more on the initial study set up and subsequent interpretation than what actually went on in lab and other reproducibility questions. Simply put--all of the scientific controversy concerned unresolvable questions.

The implications for agency action are startling, with the EPA having no arguable or judicially reviewable basis for any choice it makes. In fact, Ruckelshaus and Miller were reported to be ". . . surprised to find that scientists could disagree among themselves as much as lawyers do." 12/ As the following section will illustrate, the end result for the EPA when faced with these circumstances was either to withdraw decisions once made, or ultimately, to avoid ever having to make a decision at all.

II. THE BUREAUCRATICS OF 2,4,5-T REGULATION

A. The Hypothesis Stage: Controversy Over the Dangers of 2,4,5-T

1. The Bionetics Study and its Reverberations.

In spite of the various outbreaks of chloracne and other associated symptoms following industrial explosions, concern over 2,4,5-T and TCDD was not expressed until the late 1960's, when testing by the Bionetics Research Laboratories indicated that offspring of mice and rats given relatively large oral doses of 2,4,5-T during early stages of pregnancy showed a higher than expected number of deformities. Based on this, 13/ Dr. Lee DuBridge, Science

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12/ Wade, Decision on 2,4,5-T. Leaked Reports Compel Regulatory Decision, 173 SCIENCE 610, 612 (1971).

13/ Although no acknowledgement was made, various other studies done concurrently also suggested that 2,4,5-T was hazardous. For example, reports of dioxin impurities in 2,4,5-T were published in major scientific journals such as Medical World News and Nature. [11 MEDICAL WORLD NEWS, No. 9. pp. 15-17 (1970); 226 NATURE 309-311 (1970).] In addition, reports were published in the Saigon press of new and unexplained birth abnormalities starting in 1967, when the spraying program in Vietnam became massive. They blamed the increases on the chemical used for defoliation. [Whiteside, THE NEW YORKER, February 7, p. 32 and March 14, p. 124 (1970).]

Advisor to President Nixon and Executive Secretary of the President's Environmental Quality Council, announced on October 29, 1969, the discontinuance of most 2,4,5-T uses. 14/

> ". . . although it seems impossible that any person could receive harmful amounts of this chemical from any of the existing uses of 2,4,5-T, and while the relationships of these effects in laboratory animals to effects in man are not entirely clear at this time, the actions taken will assure safety of the public while further evidence is being sought." 15/

Early the following year, in 1970, hearings on the environmental and health effects of 2,4,5-T were held before the Senate Subcommittee on Energy, Natural Resources, and the Environment with the honorable Philip Hart of Michigan presiding. 16/ In April of that same year, the Secretaries of Agriculture, Interior, and Health, Education, and Welfare issued a joint suspension 17/ of the registration of 2,4,5-T for all aquatic uses and liquid formulations for home and recreation. 18/ Only one month later, the secretaries

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14/ The Bionetics testing was actually completed in 1966, but was not released until 1969, when it was allegedly leaked to the press via one of "Nader's Raiders". (The suggestion was made that the USDA was trying to hide the results.) [Davis, supra at note 1, at 93.]

15/ Bovey and Young, The Science of 2,4,5-T and Associated Phenoxy Herbicides, at 109 (1980).

16/ Id. at 13.

17/ Under the FIFRA statutory scheme in effect at the time, suspension required a finding of imminent hazard to the public. This was a more drastic measure than cancellation, which became effective only 30 days after service and could be delayed by a request for a public hearing or referral to an advisory committee. 7 U.S.C. § 135b(c), as amended by Act of May 12, 1964.

18/ Davis, supra at note 1.

cancelled 19/ all 2,4,5-T uses on food crops intended for human consumption and all granular formulations of the herbicide used for home and recreational use, basing their decision on the Bionetics teratogenic study and an attempt to minimize the environmental impact:

> "The actions recommended for suspension and cancellation will minimize the probability of exposure of pregnant women to hazardous exposure of 2,4,5-T or contaminant dioxin around the home, in aquatic areas, and through food and water." 20/

That following November, Dow and Hercules Powder Co., both large manufacturers of 2,4,5-T, submitted a petition to the USDA Hearing Clerk appealing the cancellation of the registration for rice, a major food crop treated with 2,4,5-T, and requested referral to an advisory committee to investigate the scientific data available on the effects of 2,4,5-T. 21/ One of the major sources of debate revolved around legitimate criticisms of the quality of research in the Bionetics study, the same study which had initiated the whole suspension and cancellation process. Suspicion was stimulated still further by the companies' suggestion that the 2,4,5-T used in the Bionetics study was contaminated by high concentrations of dioxin. At the time of research it was already known that the contaminant TCDD was highly toxic when administered to laboratory animals or allowed at too high a concentration in the finished 2,4,5-T product. Further investigations in fact revealed that the 2,4,5-T used in the Bionetics study was produced by a manufacturer who had since stopped production. The product contained approximately 31 ppm TCDD, well in excess of

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19/ Cancellation orders have no effect on the manufacturer's right to ship and market its product until the administrative cancellation process has been completed and the ultimate decision is adverse. (Dow Chemical Company v. Ruckelshaus, 477 F.2d 1317 (8th Cir. 1973)).

20/ Id. at 1319.

21/ Two other producers, Amchem, Inc., and Thompson Hayward Chemical Co., invoked their statutory right to a public hearing to review the cancellation order, but the hearing was deferred pending the scientific advisory committee report. 36 Fed. Reg. 14777 (1971).

levels considered safe for workers involved in manufacturing (Dow was down to 0.1 ppm). 22/

Although use of the highly contaminated 2,4,5-T in the Bionetics study was characterized as a major flaw in the experiment, this oversight may be attributed more to the failure of the scientists to realize exactly what they were testing or, in scientific terms, to formulate a workable hypothesis than to incompetent or unqualified scientists. Obviously, little was known about the effects of 2,4,5-T at the time of this initial testing, and the scientists, both government and industrial, may have been pushed into research before the experiments could be adequately designed, if at all.

Another interpretation is possible as well. While testing for the toxicity of a substance, many scientists prefer to use a worst case experimental design. Although this motive was never articulated, it is highly probable that use of a contaminated 2,4,5-T was a conscious choice to ascertain whether even the worst case analysis would produce evidence of a hazard at the outset of the research. Since the Bionetics Lab did detect effects, it may have been

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22/ Dow labs proceeded to repeat the Bionetics studies using their own regular production grade 2,4,5-T and concluded that this concentration of TCDD in the finished 2,4,5-T did not cause birth defects in rats or rabbits at relatively high doses during gestations. (Bovey and Young, supra at note 15.)

Although this criticism of the Bionetics study played a large part in the future political decision-making by severely weakening the government's evidentiary support for its actions, Dow's and Hercules's attempts at research were laden with scientific flaws as well. A National Institute of Environmental Health Sciences (NIEHS) repeat of the Bionetics study was conducted at the same time as the Dow and Hercules tests. These studies found that pure 2,4,5-T (less than 0.5 ppm dioxin) did reveal birth defects in rats. When Hercules again objected, its data was reviewed, and it was discovered that the Hercules scientists had made a mistake with a decimal point; they had fed their rats with one tenth of the dose of 2,4,5-T used in the NIEHS study. (Wade, supra at note 12.)

holding back the public presentation of its study until more reasonable, industrial grade 2,4,5-T was researched.

2. The Advisory Committee Report.

As required by statute, an Advisory Committee was established by the Senate to investigate the problem. The nine-member Committee, chosen by the Secretary of Agriculture, submitted its report to the Administrator of the EPA on May 7, 1971, 23/ in which it recommended that registrations for 2,4,5-T use be limited to 0.5 dioxin concentrations for existing stores, and 0.1 ppm for newly manufactured 2,4,5-T. 24/

At the same time, the regulation of pesticides was transferred from the USDA to the EPA effective December 2, 1970. 25/ Rather than following the traditional USDA policy of suppressing reports, even after an official decision on their recommendations had been taken, Mr. Ruckelshaus, the EPA Administrator at the time who had inherited the task of pesticide regulation, ordered that all reports of scientific advisory committees on pesticides be made public as soon as they were completed. 26/

Upon its release in June, then, the report served almost as a lightning rod, airing the controversy and disagreement within the scientific community over the fundamental issue of whether 2,4,5-T was dangerous at all. One scientist 27/ concluded that no basis could be found for

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23/ Office of Science and Technology, Report on 2,4,5-T: A Report of the Herbicides of the President's Science Advisory Committee. March 1971.

24/ This determination was based on a review of all relevant scientific studies, including the pattern of use, environmental absorption and breakdown, pathways in animals, toxicity tests, and reports concerning congenital malformation in children. 36 Fed. Reg. 14777 (1971).

25/ Bovey and Young, supra at note 15, at 16.

26/ Wade, supra at note 12.

27/ J. G. Wilson, Causes of Developmental Abnormality.
(Footnote Continued)

regarding 2,4,5-T as teratogenic in man. He asserted that none of the recent adequately controlled studies relating to this subject presented data indicating that this herbicide, as presently marketed, posed any risk to any aspect of human reproduction under likely conditions of exposure. 28/ In addition, many groups, such as the Society of Toxicology, agreed with the committee's findings:

> "Let us assure you that the 'verdict' of the committee does indeed represent the majority view of toxicologists." 29/ "Certainly much of the concern over the continued use of phenoxy herbicide has centered on the presence of toxic chlorinated dibenzo-p-dioxins (dioxins) as contaminants. The dioxin impurities, especially TCDD (although highly toxic itself), do not appear to alter the toxicity of 2,4,5-T . . . to animals using present standards of 0.1 ppm or less of TCDD in the finished product." 30/

In contrast, other scientists, primarily those whose careers were associated with more long-term goals such as the detection of cancer, objected strenuously:

> "[t]here is sufficient apparent evidence of adverse reproductive effects in Vietnam following exposure to herbicides to indicate the need for continued and expanded investigation . . . Some in vitro tests suggest that dioxin, a contaminant associated with the phenoxy herbicide 2,4,5-T, is a mutagen and thus perhaps as well a mammalian (including human) carcinogen. Direct tests for dioxin carcinogenicity using rodents have confirmed that the chemical does cause cancer in animals, but whether it does so in humans has not

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(Footnote Continued)
Pesticides. In Environmental and Birth Defects. Environmental Sciences. 79 (1973).

28/ Bovey and Young, supra at note 15.

29/ Society of Toxicologists, Letters, 174 SCIENCE 546 (1971).

30/ Bovey and Young, supra at note 15, at 450-451.

as yet been established . . . Careful follow-up studies are recommended." 31/

Another particularly vocal group, the Committee for Environmental Information (CEI), claimed that the report relied heavily on unpublished data, ignored other relevant data, and was replete with "unwarranted assumptions . . . many of the experiments the study relied upon were simply not sophisticated enough to supply a basis for judgments". 32/

More specific criticisms were levied by a reporter for SCIENCE who asserted that the committee essentially relied on two unproved assumptions: 1) that there is a "no effect" level of 2,4,5-T and dioxin and 2) the substances do not accumulate in the environment and in food chains. The unproved status of these assumptions completely invalidated or at least made the report inadequate. Mr. Sterling, the only dissenter in the results reached by the Advisory Committee, also asserted that the committee's mistaken impressions and the resulting assumptions could be largely attributed to the bad design of the relevant experiments, many of which either failed to study the effects of small doses (less than 100 kg) of 2,4,5-T, or used too few animals to show an effect. 33/

Finally, another source of dispute was the level of validity awarded to "suggestive but not definitive" studies. The committee had largely discounted any value in the results 34/ of Vietnam studies conducted by Meselson under AAAS grants, 35/ asserting that they were " . . . predestined to failure" due to the complexity of variables, the reliance on unsupported extrapolations, the incompleteness of existing records.

31/ A. H. Westing, ed. Herbicides in War: The Long-Term Ecological and Human Consequences, at 148 and 164 (1984).

32/ C. Holden, Critics Weigh EPA Herbicide Report, Find it Wanting, 173 SCIENCE 312 (1971).

33/ Wade, supra at note 12.

34/ Reported by Wade, id.

35/ See note 56.

Close review of these scientific debates, however, reveals that criticisms were generally not based on a claim of ignorance or incompetence of the opposing side, but instead on differing interpretations or scientific philosophies for the same problem. At the heart of the debates lay the trans-scientific nature of the 2,4,5-T issue, where scientific data conflicted and no satisfactory experiments could be conducted which could provide some basis for the interpretations and hypothesizing. Harrison Wellor of the Nader Center characterized the problem best: The subject of 2,4,5-T:

> "has become a battlegound of opposing philosophies about the relationship between technological risk and human safety. Arrayed on one side . . . are typically . . . the classical toxicologists, food technologists and agrichemical engineers, who are trained to look for the short-term effects of pesticides, both in their impact on the human body and on the pests in the field. On the other side are typically the microbiologists and geneticists, the specialists in the causes of cancer, birth defects and mutations, who are professionally concerned with the long-term effects of chemical contaminants on human health. At stake is the question of who is to set the standards upon which the proposed safety of a pesticide (or any chemical) is to be judged." 36/

A claim of bias in the choice of the committee members for the Scientific Advisory Panel further confused the scientific loyalties engendered in the dispute. Investigations revealed that the Secretary of Agriculture, not the EPA Administrator, chose the committee members. It was also discovered that no attempts were made to prevent bias in the selection process, and the committee members were screened as to their financial interest only. In fact, when supplied with a list of names by the Academy of Science, the USDA requested additional lists due to the lack of pharmacologists and oncologists in the first list. 37/ Furthermore, the USDA interpreted the FIFRA provision, which stipulates that the advisory committees "shall be composed of experts . . .

36/ Wade, supra at note 12, at 614.

37/ Id.

selected by the National Academy of Sciences" to mean that the Academy would supply the names and the department would choose the committee. This serves as still another example of the importance of a scientist's specific career interests, whether it be the solution of short-term crises or the solution of more longer-term problems, in coloring his conclusions.

Clearly, this disclosure of the report, whether deliberate 38/ or inadvertent, complicated Ruckelshaus's final decision with its concomitant scientific uproar. 39/ Consequently, confronted with the realms of outside criticism Ruckelshaus rejected the committee's report and ordered the cancellation to remain in effect until the next and final stage in the appeals process; a public hearing to be held in the fall: 40/ In the official Determination and Order of August 6, 1971, the EPA acknowledged the advisory committee report, highlighting the fact that "the committee found that the data concerning the effects on human beings in exposed areas was inconclusive". 41/

38/ It is possible that Ruckelshaus's policy of making reports public was motivated by the desire to air all USDA biases and allow the EPA to act more objectively in regulating the herbicide. In fact, Wade concluded: "At two crucial points . . . the intervention of outside scientists has been essential in keeping the government machinery on the rails and in motion. And only through by-passing the existing machinery of the advisory committee's report and the review of it by the EPA Office of Pesticides did Ruckelshaus and his aides arrive at the correct decision to maintain the existing restrictions." (Id. at 615.)

39/ Id.

40/ The hearing process also continued to further Ruckelshaus's implications that outside scientists were invaluable in reaching an objective decision: "While this agency could undertake to create these studies and compile an informal record which could be the basis for the required findings, the agency believes this evidence should be gathered through an open public hearing." 36 Fed. Reg. at 14777 (1971).

41/ Id.

3. The Dow Challenge to the EPA's Interpretation of Uncertain Science.

Dow immediately challenged this order, 42/ asserting that it did not comply with the requirements of Section 4(c). Since the record was admittedly incomplete, the order "purported to order a public hearing" to gather further data and did not "set forth the findings of facts" required by statute. 43/

The Administrator, although noting that there was no provision under FIFRA with which to grant Dow relief, nevertheless treated Dow's challenge as a "petition for reconsideration" and reaffirmed the conclusions:

> "The basis for my August 6 determination to continue the order of cancellation previously issued was the many questions I had concerning the safety of and need for 2,4,5-T. Specifically, that action was mandated by the following facts."

The Administrator then proceeded to list ten items 44/ of uncertainty, which he found weighed heavily in favor of

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42/ The motion requested withdrawal of the August 6 order and the entry of a new order complying with the statute. Dow also, under protest, filed objections to the order and requested a hearing. (Dow, 477 F.2d at 1320.)

43/ Id.

44/ "1. A contaminant of 2,4,5-T--tetrachlorodibenzoparadioxin (TCDD, or dioxin)--is one of the most teratogenic chemicals known. The registrants have not established that one part per million of this contaminant--or even 0.1 ppm--in 2,4,5-T does not pose a danger to the public health and safety.

2. There is a substantial possibility that even 'pure' 2,4,5-T is itself a hazard to man and the environment.

3. The dose-response curves for 2,4,5-T and dioxin have not been determined, and the possibility of 'no effect' levels for these chemicals is only a matter of conjecture at this time.

4. As with another well-known teratogen,

(Footnote Continued)

cancellation. Once again, it was the interpretation of this uncertainty which was in dispute--not a disagreement over the original facts or resolvable scientific issues.

Following this reaffirmation, Dow filed an action in the United States District Court for the Eastern District of Arkansas seeking injunctive and other relief against the decision. Dow argued that the Administrator was acting contrary to the statute and a finding of fact was necessary

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(Footnote Continued)
thalidomide, the possibility exists that dioxin may be many times more potent in humans than in test animals (thalidomide was 60 times more dangerous to humans than to mice, and 700 times more dangerous than to hamsters; the usual margin of safety for humans is set at one-tenth the teratogenic level in test animals).

5. The registrants have not established that dioxin and 2,4,5-T do not accumulate in body tissues. If one or both does accumulate, even small doses could build up to dangerous levels within man and animals, and possibly in the food chain as well.

6. The question of whether there are other sources of dioxin in the environment has not been fully explored. Such other sources, when added to the amount of dioxin from 2,4,5-T, could result in a substantial total body burden for certain segments of the population.

7. The registrants have not established that there is no danger from dioxins other than TCDD, such as the hexa- and hepta-dioxin isomers, which also can be present in 2,4,5-T, and which are known to be teratogenic.

8. There is evidence that the polychlorophenols in 2,4,5-T may decompose into dioxin when exposed to high temperatures, such as might occur with incineration or even in the cooking of food.

9. Studies of medical records in Vietnam hospitals and clinics below the district capital level suggest a correlation between the spraying of 2,4,5-T defoliant and the incidence of birth defects.

10. The registrants have not established the need for 2,4,5-T in light of the above-mentioned risks. Benefits from 2,4,5-T should be determined at a public hearing, but tentative studies by this agency have shown little necessity for those uses of 2,4,5-T which are now at issue."

Dow, 477 F.2d at note 14.

before the registration of 2,4,5-T was cancelled. 45/ The District Court agreed with Dow that the Administrator was not following proper statutory procedure in rejecting the Advisory Committee Report: In their suggestion the court asked that the Administrator enter a new order " . . . as the statute requires of making findings from the Advisory committee report". 46/

In compliance with the district court's recommendation, the Administrator issued an additional order on April 13, 1972, repeating previous conclusions and continuing the cancellation order. The ten findings of fact were set forth again (see ftn. 44), with the conclusion that:

> "These facts made it abundantly clear to me that the registrants have not met their burden of proof, i.e., their continuing obligation to establish the elements necessary to entitle their products to registration . . . Accordingly the cancellations must be continued." 47/

The district court found this response to be inadequate 48/ and further directed the Administrator either to enter a new order or amend his April 13, 1972 affirmation requiring that, in addition, the Administrator:

> "A. Set forth separately his findings of fact and his ultimate conclusions.
> B. Include . . . a reasoned statement setting forth (i) the portions of the Advisory Committee Report and the 'other data' being relied upon; (ii) the manner in which defendant's findings are based upon the Advisory Committee Report and such 'other data'; and (iii) the manner in which defendant's ultimate conclusions are derived from the findings." 49/

45/ Id. at 1324.

46/ Id. at 1321.

47/ Id. at 1321.

48/ Id. at 1322.

49/ Id.

The district court then directed that all further EPA proceedings be held in status quo until an order was entered complying with the court's interpretation of FIFRA.

On appeal, the eighth circuit reversed, finding that the Administrator had not yet entered a final order subject to judicial review. Additionally, after reviewing the legislative history 50/ the court concluded that the Administrator was not restricted to issuing:

> "a cancellation order ONLY and solely upon proofs that the substance involved does not meet the statutory standards evolved for the safety of the public . . . Since the registrant has a continuing burden of proof to establish that its product is entitled to registration, . . . if the Administrator has a substantial doubt as to safety, it is his duty as well to issue the cancellation order. And the cancellation order will remain in effect until the registrant satisfies the Agency that registration is warranted." 51/

In this decision, the court placed the discretion in the administrator and the burden of proof on the manufacturer. Faced with the burden of proof, the manufacturer was destined to failure, since in a trans-scientific issue such as this, where the data and facts are grossly incomplete and conflicting, it is virtually impossible to prove anything definitively. In addition, rather than allowing lengthy disputes over uncertainty, the court insisted on a brief and complete hearing:

> "We here consider a recent and largely untested act, not without its ambiguities . . . it is a situation of extreme complexity, interweaving economic pressures with the most basic considerations of human safety. In this situation the Act, wisely we think, contemplates no interlocutory

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50/ I.e., "The legislative history supports the conclusion that Congress intended any substantial question of safety to trigger the issuance of cancellation notices, shifting to the manufacturer the burden of proving the safety of his product." EDF v. Ruckelshaus, 439 f.2d 593 (1971).

51/ Dow, 477 F.2d at 1324-1325.

judicial jousting which experience has taught us can go on for years. It was the intent of the Congress that matters under the Act proceed expeditiously to a final order subject to judicial review and without judicial intervention prior thereto. Such is our ruling." 52/

B. Establishing the Methodology to Ascertain the Magnitude or Harm Posed by 2,4,5,-T

Following the termination of the Dow suit, the EPA resumed its cancellation proceedings. On July 19, 1973, the Administrator issued a notice of intent to hold a hearing 53/ on all registered uses of 2,4,5-T, including the use for rice scheduled for April, 1974. 54/ The hearing was delayed to permit the agency to complete an ongoing environmental and human monitoring project on 2,4,5-T on the extent to

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52/ Id. at 1326.

53/ The Administrator also added to his list of ten issues of uncertainty, three more which would be addressed in the hearing. These were:

1. The health hazards to man and other animals which may be caused by 2,4,5-T and TCDD, with emphasis on teratogenicity, other adverse reproductive effects, mutagenicity, carcinogenity, sub-lethal chronic health effects, and delayed lethality from chronic, low-level exposure.

2. The extent of the health risk posed by 2,4,5-T and TCDD, including thermal generation of additional TCDD in the environment, persistence and bioaccumulation of 2,4,5-T and TCDD, avenues of human and animal exposure (such as aerial drift and water transport), accumulation of residues in the human food supply and in human and animal tissue, presence in 2,4,5-T of contaminants other than TCDD, other environmental sources of dioxins, current levels of dioxins in 2,4,5-T products, and current methods of manufacture of 2,4,5-T.

3. The necessity for the continuation of the registered uses of 2,4,5-T.

(38 Fed. Reg. 19859-19860 (1973)).

54/ 38 Fed. Reg. 19860 (1973).

which the dioxin could adversely affect human and animal health.

The EPA study was especially valuable since it was intended to utilize a new, extra-sensitive dioxin detection technique 55/ developed earlier that same year by two Harvard scientists, Meselson and Baughman. 56/ As is the case with many new inventions, the EPA encountered difficulties with the new technique and requested additional time before the hearings were scheduled. The request to delay the hearing until November 1, 1974, submitted by the Environmental Defense Fund on behalf of the EPA, was refused by an administrative law judge in early 1974, when the technical complications in the experiment became apparent. 57/ The EPA found administrative channels by which it could delay the hearings however, and on May 10, 1974, issued an order postponing the consolidated hearing until November 1, 1974, so that the hearing could be expanded to all registered herbicides derived from 2,4,5-T, including silvex and erbon, herbicides chemically similar to 2,4,5-T and with high TCDD contamination. 58/

In spite of this increased time allowed to reach results, the methodological problems persisted. The EPA researchers found that their results were largely inconclusive due to the numerous variables which could not be eliminated or controlled outside of the laboratory, a plight common to many field experiments where uncontrollable climatic and human factors often interfere with the experimental process. They concluded that definitive results could be reached "only after a long involved period of basic

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55/ It was reported to achieve accuracy in detecting TCDD in the part per trillion range.

56/ Baughman, R., and M. Meselson. 1973. Analytical method for detecting TCDD (dioxin); levels of TCDD in samples from Vietnam. Environ. Health Perspect. 5:27-35.

57/ Bovey and Young, supra at note 15, at 19.

58/ 39 Fed. Reg. 17466 (1974).

research investigation and idealization of instrumentation." 59/

As a result, on June 24, 1974, the EPA withdrew the cancellation of 2,4,5-T for use on rice 60/ along with the notice of intent to hold a public hearing on all registered uses of 2,4,5-T and other herbicides derived from 2,4,5-T. 61/ The statement accompanying the notice outlined the scientific inadequacies and the resulting inability of the agency to take action:

> "The residue monitoring program was the only means available to determine if TCDD is bioaccumulating in man and the human food chain. Without the answer to the question of bioaccumulation, the danger of TCDD cannot be assessed . . . the methodological problems have not been solved. No date for completion of the TCDD residue monitoring can be given, and in fact, completion of the project by the Agency may be two or more years away . . . Under the circumstances, it does not seem appropriate to continue administrative proceedings when the evidence which would largely determine the outcome of those proceedings remains scientifically unavailable. The Agency will continue its TCDD residue monitoring program and will take such further action as it deems appropriate once the results of the monitoring project are available." 62/

The withdrawal of the cancellation of 2,4,5-T use on rice appears to signify a changed attitude by the agency which previously erred in favor of safety when interpreting

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59/ Cited in Citizens Against Toxic Sprays, Inc. v. Bergland, 428 F. Supp. 908, 917 (1977).

60/ The order left all suspensions unaffected, and those cancellations for which no hearing was requested (i.e., the use of 2,4,5-T for granular formulations for home and recreational use and all uses on food crops intended for human consumption except rice. (39 Fed. Reg. 24048 (1974)).

61/ Id.

62/ Id. at 24050.

uncertain scientific information. The reason for this shift in interpretation is not clear. It could be attributed to sheer incompetence by EPA researchers in conducting the tests; a change of outlook on uncertainty inspired by a new administration; a withdrawal of public support following bad press; or a partnership or carefully guided action with Dow and other 2,4,5-T manufacturers. Perhaps the best explanation, however, may come from the shift of the burden of the proof on the agency itself, with the requirement that the final orders resulting from the hearings be based on fact as indicated by the court in the previous Dow v. Ruckelshaus suit. 63/ Faced with the burden of proving some certain and definitive basis for its agency order, the EPA undoubtedly felt that it had no recourse but to stall and withdraw cancellation until the proper studies had been completed. It should be noted that this requirement or interpretation of FIFRA that all final orders be judicially reviewable and based on clearly articulated fact, was a requirement which made many cancellations impossible given the trans-scientific nature of the questions in need of resolution and affected many administrative decisions to follow.

C. Interpretation of Results: Controversy Over the Implications of Controlled Animal Studies and Inconclusive Epidemiology Studies

The EPA monitoring program continued following the June 24, 1974 order, directed by a Dioxin Implementation Plan issued in February 1975. 64/ The Plan emphasized refinement of the analytical methodology, particularly in relation to the environmental interferences which made it difficult to assess the relevant variables. In this Plan monitoring of TCDD in beef samples from cattle grazing in areas of high 2,4,5-T use were emphasized most heavily. The monitoring was conducted under the 2,4,5-T Ad Hoc Task Force with representatives of the EPA, USDA, the Environmental

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63/ Dow, 477 F.2d 1317.

64/ The Plan was created on July 25-26 at a Dioxin Planning Conference held in Washington D.C. for those parties interested in the withdrawn 2,4,5-T/dioxin hearings. Bergland, 428 F. Supp. at 917.

Defense Fund, and Dow Chemical. 65/ Ultimately, however, the results were inconclusive and the study failed to determine whether dioxin entered the food chain. 66/

At the same time that the EPA study failed in providing proof for cancelling all uses of 2,4,5-T, research in nongovernment laboratories began to show a definite and immediate hazard in even the most minute concentrations of dioxin. 67/ Prompted by these studies, the EPA began collecting information about 2,4,5-T through its Rebuttable Presumption Against Registration process (RPAR) 68/ in order

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65/ While the EPA was investigating the effects of 2,4,5-T, a citizen subjected to USFS spraying brought suit against the Forest Service and USDA to seek relief from an inadequately done Environmental Impact Statement in Bergland, id.

66/ Of the 67 beef fat samples taken from cattle grazing in areas treated with 2,4,5-T, only eight showed any detectable concentrations of dioxin.

67/ Allen and associates at the University of Wisconsin fed monkeys a diet containing dioxin contaminated food at a concentration of 500 ppt. After 12 months over 65% of the animals contaminated had died. The study demonstrated " . . . the ability of dioxin to persist and accumulate in the living tissues of primates." (J. R. Allen, D. A. Busotte, F. P. VanMiller, L. J. Abrahamson, & J. J. Lalich. Morphological changes in monkeys consuming a diet containing low levels of 2,3,7,8-tetrachlorodibenzo-p-dioxin. Food Cosmet. Toxicol. 15:401-410.) In a second study conducted by Dr. Allen, 33 out of 60 rats fed dioxin (as low as 5 ppt/day) developed tumors. Dr. Allen, et al. concluded that the tumors suggested the carcinogenic potential of dioxin. (J. P. VanMiller, J. J. Lalich, and J. R. Allen. Increased incidence of neoplasms in rats exposed to low concentrations of 2,3,7,8-tetrachlorodibenzo-p-dioxin. CHEMOSPHERE 10:635-632. (1977).)

68/ The purpose of the RPAR process is to facilitate the identification of pesticide uses which may not satisfy the statutory standard for registration and provide a structure for the gathering of information about the risks and benefits of these uses. The rebuttable presumption arises

(Footnote Continued)

to decide whether registration of the pesticide should be continued. 69/ Based on these studies, as set forth in the 2,4,5-T Position Document prepared by the 2,4,5-T working group of the EPA, 70/ the agency concluded that the risk criteria 71/ relating to oncogenic effects and teratogenic and/or ferotoxic effects in mammalian test species were exceeded. 72/ 73/ Following this notice of rebuttable presumption, all registrants and applicants for registration

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(Footnote Continued)
if a pesticide meets or exceeds any of the risk criteria set forth in the regulations. After an RPAR is issued, all interested persons are invited to rebut the presumption by presenting information showing that either the agency's determination of risk was in error or that the exposure associated with use of the pesticide does not result in a significant risk. (44 Fed. Reg. 72317 (1979); See also National Research Council, Regulating Pesticides. (1980)). Although this relieves the need for strong evidence before holding an initial cancellation hearing, the RPAR process does nothing for reaching conclusions on uncertain science once the hearings are in effect.

69/ On-going TCDD studies continuing under the Dioxin Implementation Plan included: An analytical method validation study to produce statistically defensible data; monitoring for residues in human milk in the Pacific northwest; additional beef fat residue studies; additional technical pesticide residue studies; and an environmental monitoring program for TCDD residues in soil, water, and biota. (43 Fed. Reg. 17116, 17124 (1978).)

70/ Id. at 17116.

71/ 40 CFR 162.11(a)(3).

72/ Title 40, § 162.11 of CFR for FIFRA as amended provides that a rebuttable presumption against registration may arise if the Agency determines that a pesticide meets or exceeds any of the risk criteria relating to acute and chronic toxic effects as set forth in § 162.11(a)(3).

73/ Some data also suggested an association of 2,4,5-T and/or TCDD with mutagenic effects in test animals and TCDD with toxic effects in humans, but the data was not sufficient to warrant the issuance of a Rebuttable Presumption. (43 Fed. Reg. at 17117.)

were entitled to submit evidence to rebut the oncogenic 74/ and other chronic or delayed toxic effect presumptions 75/ within 45 days. 76/ In addition, registrants were required by law to submit to the EPA any additional information regarding any adverse effects of the pesticide, whether published or unpublished, pursuant to Section 6(a)(2) of FIFRA and 40 CFR 162.8(d).

During the next ten months the Agency received copious information about 2,4,5-T through the RPAR process. Among the studies submitted was the pivotal report by eight women living in the vicinity of Alsea, Oregon, who experienced a total of 13 miscarriages from 1972 to 1977, which occurred over only a four to six-week period after the spring application of 2,4,5-T in the forest areas nearby.

> "The Agency's preliminary analysis of the data . . . indicates that:
> (1) the spontaneous abortion index . . . for Alsea study area where 2,4,5-T was used was significantly greater than the index for the urban and

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74/ Information relating to oncogenic risks must conform with the Agency's Interim Procedures and Guidelines for Health Risk and Economic Impact Assessment of Suspected Carcinogens (May 25, 1976; 41 FR 21402).

75/ In case of a pesticide presumed to be toxic, the registrant may rebut the presumption by proving that the use is not likely to result in any significant acute adverse effect (40 CFR 162.11(a)(4)(i)); that when considered with proposed restrictions on use and practices of use, the pesticide will not concentrate or persist in the environment to levels in man likely to result in any significant chronic adverse effects. (40 CFR 162.11(a)(4)(ii)); or the criteria set by the agency for risk was in error (40 CFR 162.11(a)(4)(iii)). In addition, § 162.22(a)(5)(iii) provides that a registrant may submit evidence on the economic, social, and environmental benefits of the pesticide use. If the risk presumptions are not rebutted, the benefit evidence is considered by the Agency in determining subsequent regulatory action, or if the benefits greatly outweigh the risk additional hearings may be held pursuant to § 6(b)(2) of FIFRA.

76/ 43 Fed. Reg. at 17117.

control areas where there was little or no known use of 2,4,5-T;
(2) there was a dramatic increase in the spontaneous abortion index for the study area relative to the urban and control areas in the months of June and July; this increase followed, by approximately two months, a period in March and April when 2,4,5-T was used to control vegetation in the forested study area; and
(3) statistical analyses of these data indicate that there was a significant correlation between the amounts of 2,4,5-T used in the study area during the spraying season and the subsequent increase in the spontaneous abortion index in the study area." 77/

The agency then concluded:

"In view of the laboratory data establishing that 2,4,5-T and its contaminant TCDD have embryolethal effects in test animals and the susceptibility of the young embryo to fetotoxic and teratogenic agents, the increased spontaneous abortion index in an area of 2,4,5-T use may reasonably be interpreted to be a consequence of the exposure of women residents of the area to the 2,4,5-T used for forest management." 78/

77/ 44 Fed. Reg. 15874, 15880 (1979).

78/ Id. at 15883.

Based on this and other information, the Administrator ordered emergency 79/ suspensions of the forestry, rights-of-way, and pasture uses 80/ of 2,4,5-T. 81/

> "I am ordering emergency suspension of these uses because I find that they pose an 'imminent hazard' 82/ to humans and because I also find that an 'emergency' exists because there is not enough time to complete a suspension hearing before the next spraying season." 83/

In addition, as required by FIFRA Section 6(b)(1), the Administrator issued notices of intent to cancel the registrations of the suspended uses of the pesticides published in the same issue. 84/ Hearings could be requested by affected registrants within 30 days of the publication of the notices in Federal Register (on March 14, 1979).

79/ In order to issue an emergency suspension, the Administrator is required to prove that the pesticide poses an "immiment hazard" and that an "emergency" exists; when the situation is an immediate threat, the continuation of a pesticide use is likely to result in unreasonable adverse effects during a suspension hearing. Unlike an ordinary suspension, then, an emergency suspension order is issued without prior notice to registrants and takes effect immediately, halting the distribution, sale, and use of 2,4,5-T for the uses specified until the completion of further administrative proceedings. If an expedited hearing is requested, which must occur within five days and may only be requested by a registrant, the order continues until the issuance of a final suspension order (id. at 15875).

80/ Id. at 15874.

81/ Id. at 15874. These suspended uses comprise about 74% of the estimated 9.3 million pounds of 2,4,5-T used annually in the U.S. (id. at 15876).

82/ In order to find an imminent hazard, it is necessary to find that the risks of use during the period likely to be required for cancellation outweigh the benefits.

83/ Id. at 15874.

84/ Id. at 15874 and dated March 8, 1979.

The Alsea study, which was relied upon to establish this sudden and definitive suspension, was much more positive than those of the past and furthermore, was an epidemiological study where the normal U.S. population served as the guinea pigs. The agency's conclusions illustrate this new-found confidence in their scientific evidence, now backed by the power of a human study:

> "In my judgment, the information which has recently come to my attention as a result of the Alsea study constitutes a dramatic and troubling new point of departure for analysis of TCDD exposure concerns . . . " As indicated above, these data show a striking relationship between 2,4,5-T use and increased incidences of spontaneous abortions among women residing in the use area. This effect is a result which could have been predicted as a likely outcome of human exposure, based upon previous animal data of almost unprecedented conclusiveness. The Alsea study contained no data showing actual exposure. Nevertheless, concern for the health of humans who may be exposed to 2,4,5-T and its contaminant, TCDD, was heightened because scientists had not demonstrated that there was a level of exposure that has no adverse effects in humans . . . "Thus, in the face of the highly significant relationship which the study showed, and the animal data, I conclude it is reasonable and in the public interest to assume that the women in the Alsea study were exposed to TCDD." 85/

In spite of the apparent strength of the Alsea study, it was not long before industrial scientists attacked the study for failing to connect the increased incidence of miscarriages with dioxin exposure. The EPA, without admitting directly to the failings, immediately returned to the Oregon site to collect tissue samples from affected infants and animals. If dioxin was found in these tissues, it would provide the missing causal link between the 2,4,5-T sprayings in the area 86/ and the abnormally high incidence of

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85/ Id. at 15884.

86/ The exposure would be proved by the presence of dioxin in human and animal tissues.

spontaneous abortions and birth defects. The results from these studies still have not been released. 87/

Emergency suspension hearings before the agency were commenced in May 1979 and halted when the registrants withdrew from the proceedings. This withdrawal affirmed by operation of law under FIFRA Section 6(c) the emergency suspension order. Soon after, on July 9, 1979, the EPA announced its preliminary determination for the RPAR review of the remaining non-suspended uses. 88/ These uses included rangeland, rice and non-crop, the uses in which the 2,4,5-T allegedly has the chance of entering the food chain. This action was followed by referral of the Position Document (PD 2/3), summarizing the EPA's preliminary findings, to the Secretary of Agriculture and the FIFRA Scientific Advisory Panel (SAP) for comment as required by Sections 6(b) and 25(d) of FIFRA. Although not required, the agency also opened the report up to interested parties and invited comments. 89/

On December 3, 1979, a notice of intent to hold hearings under FIFRA Section 6(b)(2) to determine whether to cancel products for the remaining non-suspended end uses of 2,4,5-T was announced. 90/ Along with the announcement was the agency's final determination to cancel the non-suspended uses following RPAR review. In its supporting position

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87/ Personal communication with Michael Axline, Pacific Northwest Resources Clinic, University of Oregon Law Center. Mr. Axline is presently the plaintiff's attorney in a Freedom of Information suit to acquire the results of these studies.

88/ 44 Fed. Reg. 41531 (1979).

89/ 44 Fed. Reg. 72316 (1979). "Although not required to do so under FIFRA, the Agency has determined that it is consistent with the general theme of the RPAR process and the Agency's overall policy of open decisionmaking to afford registrants and other interested persons an opportunity to comment on the bases for the proposed action during the time that the proposed action is under review by the Secretary of Agriculture and the Scientific Advisory Panel." (Id. at 72317.)

90/ Id. at 72316 and 72328.

documents, the EPA did not mention its much-criticized "Alsea study", but instead relied on a combination of animal test data and exposure estimates to support its case. 91/

> "In brief, the Agency has determined that the potential oncogenic, fetotoxic and teratogenic risks associated with these uses of 2,4,5-T do not appear to be justified by offsetting economic, social, or environmental benefits," 92/ . . . "the Agency [then] recommends holding a hearing, in part because the available data indicates that these uses appear to have unreasonable adverse effects on the environment. However, the Agency did not act to suspend these uses as it would have done had it had found an imminent hazard." 93/

In reviewing the agency's proposed scientific findings, the Science Advisory Panel (SAP) disagreement came not over the studies but over their interpretation and other questions of public policy. The SAP expressly agreed with the agency's choice of studies and the credence given to them 94/ as set forth on a point-by-point basis in Appendix B of the Federal Register Publication. 95/ But the Panel concluded that it had found no evidence of an "immediate or substantial hazard", 96/ and given the uncertainty and serious scientific gaps, hearings were inappropriate at the time. In direct opposition, the EPA insisted that hearings

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91/ Chemical Regulation Reporter pg. 1507 (12/21/79).

92/ 44 Fed. Reg. at 72316.

93/ Id. at 72323.

94/ "The SAP's assessment of the scientific data on the reproductive and the oncogenic effects of 2,4,5-T, silvex, TCDD in test animals is generally consistent with the Agency's position. Also, consistent with the Agency's current efforts were several SAP recommendations for obtaining additional data." (Id. at 72323.)

95/ Id. at 72324.

96/ The EPA conceded, in response, that had it been an "imminent hazard", the use would have been suspended by an emergency action. Id. at 72323.

were necessary based on the very same uncertainty which the SAP felt made them unnecessary. 97/ Whether due to economic loyalties or differences in training, the tension between different scientific/technical bodies interpreting uncertainty in a light most consistent with their perspective was revealed once again. Once again, the party in control, the EPA, had the authority to avoid potential deadlocks and reach a decision.

In addition, this Federal register notice also expressed a decision by the agency, later validated by EPA Administrative Law Judge Herbert Perlman 98/ to consolidate the hearings for non-suspended uses, pursuant to FIFRA Section 6(b)(2), with the hearings on cancellation for previously suspended uses, pursuant to FIFRA Section 6(b)(1). 99/

> "Not only will this action be administratively convenient for the Agency, registrants, and

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97/ "The Agency has taken the Panel's recommendations into account but has decided that such a hearing is appropriate, based on . . . the Agency's and the SAP's conclusion that more information is necessary to resolve the issues involved." Id.

98/ Chem. Regulation Reporter 12/21/79 pg. 1508.

99/ Two types of proceedings are available under Section 6(b) of FIFRA, which it is within the sole discretion of the Administrator to determine. If the Administrator determines that the risks of a pesticide use outweigh the benefits, he may issue a 6(b)(1) proceeding, which, if there are no requests for a hearing following a notice within a period prescribed by statute, the cancellation takes effect automatically, by law.

If the Administrator determines that the balance between risks and benefits is in need of further study, a (b)(2) may be issued: "to determine whether or not its registration should be cancelled". Unlike (b)(1), however, Section 6(b)(2) does not include a proposed regulatory solution which would take effect automatically if a hearing is not requested. Thus, the hearing period will continue until the Administrator takes a definitive action. (44 Fed. Reg. at 72317.)

interested parties, entailing more efficient use of resources, but it will also ensure that the Agency's concerns on all uses of 2,4,5-T and silvex are addressed consistently." 100/

Following several postponements 101/ the consolidated hearings were set for March 14, 1980, before Administrative Law Judge Edward Finch. Initially the hearings were divided into two phases which were expected to last over a period of two years. The first dealt only with the risks posed by use, while the other was to consider potential benefits. Further, the issues to be considered, distilled from the larger PD 2/3 and PD 4 documents, led the agency to narrow the questions for the hearing as follows:

> "(1) whether the uses of 2,4,5-T on [rice; non-crop and rangeland] generally causes unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice;
>
> (2) whether the use of 2,4,5-T on rice, rangeland, or non-crop areas will generally cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice unless the terms and conditions of registration are modified to be more restrictive than those currently in effect;
>
> (3) whether, if modifications to the terms and conditions of registration are adopted, the labeling of 2,4,5-T products for these uses will comply with the applicable provisions of FIFRA; and
>
> (4) whether, despite modifications to the terms and conditions of registration, the use of 2,4,5-T on rice, rangeland, or non-crop areas will generally cause unreasonable adverse effects on the environment when

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100/ Id. at 72323.

101/ The hearings on suspended uses were begun earlier, with four prehearing conferences held, but the active phase of the hearings was delayed to await EPA's determination on whether to consolidate hearings for all uses. (Chem. Reg. Rep. 12/21/79.)

used in accordance with widespread and commonly recognized practice and should thus be cancelled." 102/

As it turned out, both sides, represented almost entirely by the EPA and Dow, presented convincing and well-prepared evidence, including presentations by over 100 witnesses, 1,500 exhibits, and 23,000 pages of transcript.

Other developments in the hearings included a subpoena by Dow for four studies conducted by James Allen and the dioxin/monkey studies from the University of Wisconsin. Dr. Allen requested that the subpoena be quashed, since a scientist should not be required to publish before he is satisfied with the reliability and accuracy of his data. 103/ Administrative Law Judge Finch modified the subpoena before issuing it by directing Dr. Allen to provide documents from recently completed studies, but only "available information" from the ongoing studies. By EPA request, Finch did grant a protective order preventing the parties from publicly disclosing the data from ongoing studies. Also, not long into the hearings, on October 24, 1980, Monsanto voluntarily cancelled registration of all products containing 2,4,5-T, effective December 3, 1980, thus removing itself from the battle. 104/

After an exhausting and inconclusive first hearing further proceedings were suspended in March, 1981 for settlement negotiations between Dow 105/ and the EPA. Following the full year of presentations, the agency had moved for settlement, apparently inspired by the threat of many years of expensive hearings ahead. The trans-scientific nature of the problem had clearly put the agency in this spot. While the existing evidence was controversial and extensive enough to warrant thousands of pages of testimony and one full year of presentations, no resolution was in

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102/ 44 Fed. Reg. at 72319.

103/ Chem. Reg. Rep. pg. 1875 (1980).

104/ 45 Fed. Reg. 72722 (1980).

105/ Even though almost 70 other firms and associations were involved in the cancellation hearings, Dow was the major voice in the proceedings and spent about $10 million fighting cancellation. (Env. Reporter pg. 1056 (1983).)

sight. Furthermore, EPA priorities made settlement almost a necessity. The time the underfunded agency had already put into the hearings far exceeded the herbicide's priority in relation to other problems facing the agency.

The negotiations themselves lasted over two years and dealt primarily with the proper methods for withdrawing the pesticide, informing farmers and end users, etc., rather than with the questions of scientific uncertainty which had dominated past debates. 106/ From the EPA's perspective, by delaying until all parties had lost interest, the EPA avoided having to make a decision and risk having its determinations later challenged or overturned. 107/

On October 14, 1983, four years after the initial emergency suspension was issued, Dow ended its fight 108/

106/ Personal communication with Mark Tucker, a Dow attorney involved in the hearings.

107/ See, i.e., Industrial Union Department v. American Petroleum Institute, 448 US 607 (1980). Also, one of the agency's primary concerns is precedent and avoiding any chance of an unfavorable ruling. (Personal communication with Pamela Rekar, General Counsel, EPA-Region 5).

108/ Although the suit is still in the courts, there is also a claim that in the settlement Dow actually bargained with the EPA, voluntarily cancelling all products containing 2,4,5-T in return for the promise that the EPA's follow-up study on the original Alsea report would not be released. (Personal communication with Michael Axline, Director of the University of Oregon Environmental Law Clinic.) The tissue and environmental samples were taken in 1979, as part of Alsea Phase II, with the assurance to affected parties that the laboratory results would be released within several months. (C. Van Strum, A Bitter Fog (1983).) Six years later a Freedom of Information suit was brought against the agency in an attempt to get the results of the study, along with some unsuccessful discovery attempts associated with a companion EIS 2,4,5-T spraying suit. (Merrell v. Block, No. 83-6138-E (9th Cir. 1985).)

Although the agency is slowly releasing the information, plaintiff's lawyers (Michael Axline) did find a

(Footnote Continued)

and asked the EPA to cancel all current registrations for Dow products containing the chemicals. Dow's withdrawal was motivated by the unreasonable expense, particularly in light of the relatively insignificant market value of 2,4,5-T; the ready availability of substitutes for most 2,4,5-T uses; and the fact that it felt the EPA was ignoring scientific evidence so that nothing more could be done. 109/ Furthermore, the firm said that it believed that "emotional and

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(Footnote Continued)
leak, communicated by a consulting toxicologist. This led to the much publicized Table VII, released by one of the investigators participating in the study. The Table revealed abnormally high dioxin concentrations from the tissue of an encephalitic child and a four-eyed cat born during the spring spraying season in the Alsea region. (The only possible means of dioxin exposure was through the 2,4,5-T spraying.)

The same group alleges that the primary motive for the EPA withholding this study was the promise by Dow that it would end all challenges immediately, hoping that all remaining parties would quickly follow Dow's example. Dow's interest, obviously, was fear that even if the study were flawed in some respects, it established a dangerous causal link between 2,4,5-T and birth defects, a fact which would not only speed up 2,4,5-T cancellation, but also provide the much needed epidemiological link for the pending Agent Orange suit. This was a liability that could put Dow into bankruptcy and the future of the nation in an equally precarious position. In fact, information inside the negotiations indicated that at one point--before it was learned that Table VII had been uncovered by the public at large--the EPA was considering revoking some of its use cancellation notices. In any case, the agency's actions may be attributed once again to the previous discussion of the inability to act effectively when faced with scientific uncertainty. Withholding information is obviously not a valid agency action, yet the EPA's motives almost seem justified when viewed in relation to the prevailing outside pressures.

109/ The protests by Dow were not economical, however. Dow viewed its challenge to the EPA as a mission to make the agency more scientifically accountable. Since "the Agency refused to listen", Dow realized that its protests were no longer worthwhile. (Mark Tucker, supra at note 108.)

political concern about dioxin contamination in the herbicides made it unlikely the agency could reach a purely scientific decision on the chemicals' safety in the near future." 110/ Dow spokesman Terry Witt added that Dow still maintained that 2,4,5-T was safe and that its scientific mission was over, given the EPA's inability to receive it in an objective light. 111/

On the same day, EPA issued an intent to cancel all registered uses of 2,4,5-T under 9(1)(b) of FIFRA, thus revoking the hearings to determine whether certain uses of 2,4,5-T would be cancelled. 112/ This (b)(1) notice 113/ gave participants only 30 days to notify EPA if they wished to contest the cancellation, an exceptionally heavy burden following Dow's voluntary cancellation. If no protests were heard within the 30 days, cancellation would be automatic for all registrations. The new announcement also affected end-use registrations, allowing sale and distribution of existing end-use stocks (for non-suspended uses) only for one year after the effective date of cancellation. 114/

In its notice, the agency strongly encouraged the remaining industries to follow Dow's example:

> "Dow's actions suggest that the incentives to pursue this litigation may not be as great as they were two and one-half years ago. It is reasonable to surmise that other litigants share Dow's perspective and may no longer be interested in pursuing the hearing. In light of these developments, it now seems appropriate to take steps intended to determine whether any party is

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110/ Env. Rep. pg. 1056 (1983).

111/ Id.

112/ 48 Fed. Reg. 48434 (1983).

113/ In effect, replacing the Section 6(b)(2) notice with a Section 6(b)(1) notice reaffirmed the agency's 1979 decision that the non-suspended uses cause an adverse effect on health and the environment. (Chem. Reg. Rep. pg. 980 (10/21/83).)

114/ 48 Fed. Reg. at 48435.

interested in continuing the hearing in Dow's absence and, if not, to bring the time-consuming and costly adjudicatory proceeding to an end in a manner which removes 2,4,5-T and silvex from the market." 115/

The EPA's plea was not effective, however, and the cancellation was contested 116/ by two separate groups of petitioners: a coalition of 14 industry groups 117/ in a consolidated hearing and the Union Carbide Agricultural Products Co. Inc. on its own. 118/ In the requests, filed November 16 and 17, 1983, the petitioners claimed that 2,4,5-T did not present an adverse environmental effect when used in an approved manner. They further claimed that the notice of cancellation by the EPA in October 1983 was "procedurally defective" since:

> "it fails to provide due notice of the reasons and factual basis and evidence in support of the

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115/ Id. at 48435.

116/ 49 Fed. Reg. 5186 (1984).

117/ The coalition was made up of the Celamerck GMBH & Co. KG; Chemie Linz Ag; EM Industries Inc.; Vertac Chemical Co.; Gilmore Inc.; The Pesticide Producers Association; The National Cattleman's Association; The National Association of Wheat Growers; The National Agriculture Aviation Association; The National Agriculture Legal Fund; the International Agriculture and Aviation Consortium; Oregonians for Food and Shelter; The National Arborists Association; and The Pesticide Public Policy Foundation.

118/ Interestingly, these same contesting companies had already cancelled their registrations for certain 2,4,5-T products indirectly by failing to submit the required data. (This could be done by either failing to take appropriate steps to submit an updated confidential statement of formula, or to submit a signed confirmation that the confidential statement of formula currently on file with the Agency satisfies all of the requirements of the Section 3(c)(2)(B) notice. (49 FR 7444 (2/29/84).) It is clear, then, that this unprofitable pesticide was the symbol of unfair cancellation based on unclear scientific evidence, regardless of whether anyone produced it or not.

> proposed cancellation of 2,4,5-T as required by Section 6(b)(1) and the agency's regulations . . . The notice does not contain sufficient information to enable adversely affected persons to properly and fully state their objections or to determine the issues with respect to which a dispute is raised."

Fortunately, the hearings were consolidated with the existing 2,4,5-T proceedings in progress since 1979 and began in 1983 with a consideration of the benefits. The hearings lasted less than one year when the new Administrative Law Judge, J. R. Greene, dismissed all parties on January 2, 1985. 119/ This decision paralleled the prior decision 120/ by ALJ Edward B. Finch following the EPA/Dow settlement, in which the Judge ordered the case terminated following the failure of any of the participating pesticide registrants to push forward with a continued industry challenge to the administrative cancellation efforts.

The products were formally cancelled on February 11, 1985 by operation of law when the EPA's chief judicial officer, Ronald L. McCallum, refused to review the ALJ's actions against the product. 121/ In the order, Ronald L. McCallum said his decision cancelling the chemical came only after no appeal or exceptions were filed by industries in response to the January 2 orders by ALJ Greene to dismiss. 122/ Although there were accompanying complications regarding what uses and how long sales and transport could be continued, it appeared that Union Carbide received the most favorable settlement, with the ability to sell and transport its remaining stocks of non-suspended uses until

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119/ In re: Union Carbide Agricultural Products, Inc., FIFRA No. 522.

120/ In Re: The Dow Chemical Co., FIFRA No. 415.

121/ Pesticide & Toxic Chemical News pg. 2 (2/27/85).

122/ "The effect of these orders is to dismiss all registrants and intervenors as participants in the proceedings; to dismiss and terminate the proceedings; and to cancel all registrations of pesticide products containing 2,4,5-T or Silvex." (Chem. Reg. Rep. pg. 1406 (3/1/85).)

November 1985. 123/ In any case, the stocks existing by 1985 were so small that in less than a year 2,4,5-T would no longer be legally available in the U.S. marketplace. 124/

III. ANALYSIS AND PROPOSALS FOR REFORM

A. Analysis

While a review of the EPA actions sheds some light on the regulation of 2,4,5-T, a deeper understanding of the trans-scientific dimensions of the problem is necessary before improvements can be made. This problem, simply stated, is that the uncertainty of science is not properly handled by traditional administrative mechanisms. The impacts of this trans-science as it enters the legal and political arenas are complex and interwoven, but for the sake of analysis three general consequences may be discerned. First, the nature of the unresolvable science itself causes many decisions to be based on the current state of the art of science rather than according to the fundamental characteristics of the problem. Second, the placement of the burden of proof, or power, has a profound impact on the resulting regulatory policy regarding that trans-scientific issue. Third, the nature of science, coupled with this trans-scientific dimension, make any interpretations of science by nonscientists largely impossible or unpredictable at best. Each of these considerations will be treated separately.

123/ Interestingly, the disposal of remaining stocks posed more of a health and environmental problem than the actual use. Thus, products labeled for suspended uses had to be disposed of, while identical products labeled for other non-suspended uses could be used until supplies were exhausted. Obviously, the EPA placed itself in an environmentally hypocritical position in demanding disposal of only some of the chemical--according to the label and not the contents. (Personal communication with Richard Wunrow, Office of Pesticides, EPA, Region 5.)

124/ Chem. Reg. Rep. pg. 1406 (3/1/85). Attempts to discern how much 2,4,5-T did remain in the marketplace were met with failure, since the pesticide annual production reports are confidential with respect to the volume still available--even for cancelled products.

1. The Nature of the Uncertainty in Trans-Science Obliterates the True Level of Hazard Associated with the Issue.

In trans-scientific issues, where the hazardous condition of a product is uncertain, there are often no facts for the policy maker or judge to decide upon. In the case of 2,4,5-T, determining the maximum level of human exposure to the chemical was highly speculative, as was the determination of environmental and health impacts following exposure. Everything was based on interpretation, which varied radically from one scientist to the next.

Therefore, decision on the proper regulatory strategy for 2,4,5-T were made almost completely according to the limitations of science, or whether science was capable of quantifying the nature of the risks associated with the chemical. Similarly, judicial review of the EPA's regulations were limited by the evidence provided by the agency and independent researchers. This reliance on the state of the art in science to determine which actions we choose to regulate has the ultimate effect of supporting the validity of the regulations in a random fashion, not according to the severity of the harm, but instead according to the way the research is funded, and the nature and complexity of the scientific question.

2. The Placement of the Burden of Proof Exerts a Marked Influence on the Outcome of the Resulting Decision.

In most situations an analogy can be drawn between a party who does not have the "burden of proof" when the issue is before the court, 125/ and the party that has the greater political power when the issue is in the negotiating stage. In both cases it seems that the placement of the power, either when the opposing party has the burden of proof, or by possessing the greatest amount of political power, determines almost exclusively who will prevail in trans-scientific issues, regardless of the underlying hazards associated with the issue.

125/ It is a well established legal principle that the party with the burden of proof in cases where the facts and evidentiary record are incomplete is often at a severe disadvantage.

In the case of 2,4,5-T, for example, the inconsistent actions of the EPA seemed to be caused largely by the agency's fluctuating power. At the start of the proceeding, the EPA had little support since most participating parties were seeking economic benefits, including the USDA, 126/ the industries, 127/ and the end-users (forest companies, railroads, farmers). 128/ It was also at this time that the EPA was concerned with finding effective and inexpensive alternatives for 2,4,5-T if the product was cancelled. Consequently, the agency, confronted with uncontrollable impacts emerging from the one cancellation, may have been initially hesitant to take action, particularly when the information was as uncertain as it was. The lack of cohesion within the government and absence of public support more generally was also responsible for the initial EPA indecisiveness over the hazards of 2,4,5-T, illustrated most clearly by the EPA Administrator's disavowal of the Scientific Advisory Panel's suggestions 129/ and ultimate conclusion that 2,4,5-T was not hazardous.

126/ Interestingly, the major proponents for continuing uninterrupted use were the fellow governmental agencies in the USDA. Adverse comments and complaints were heard around the country against the U.S. Forest Service's spraying of 2,4,5-T. Not only did the USDA make cancellation difficult for the EPA, but exacerbated potential danger through wide use of the product. (See, i.e., VanStram, supra at note 110.) For example, on February 13, 1970, Congressman Richard McCarthy of New York chaired a hearing on the U.S.F.S. applications in the Tonto National Forest in Globe, Arizona. (Bovey and Young, supra at note 15 at 11.)

127/ Although Dow asserted that from a business sense, 2,4,5-T was not very profitable for the company. (Mark Tucker, supra at note 108, pers. comm.)

128/ This included the diffuse user problem, since 2,4,5-T was incorporated into almost all agricultural and forestry uses, even to the point of keeping the apples from dropping off the trees early. (Personal communication with Richard Mountfort at the Office of Pesticides, EPA headquarters.)

129/ In fact, this action occurred when the herbicide regulation was transferred from the USDA to the EPA.

The public tide shifted several years later and the EPA began to gain support for its cancellation efforts. Following extensive use of the questionable pesticide on residential areas in Oregon, 130/ all of the agencies were sued for their failure to file an adequate environmental impact statement. 131/ Moreover, at that same time, research began uncovering equally effective and efficient alternatives, making 2,4,5-T much less important in the marketplace. 132/

Aside from the more localized environmental pressures regarding 2,4,5-T spraying, the largest concern was disposal of wastes from production of anything containing dioxin. Following Love Canal and associated disasters, the Vertac 133/ case posed a very serious threat to continued production of 2,4,5-T. In Vertac, controversy emerged about the best methods of cleaning up serious dioxin spills from the industry's 2,4,5-T manufacturing process. Release of this information to the public at large began a tide of suspicion towards dioxin products and a tendency to err on the side of caution.

Finally, the Vietnam veterans suit, 134/ which was brought to recover damages for injuries sustained by the

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130/ See Bergland, 428 F. Supp. 908.

131/ Merrell v. Block, supra at note 110. It is interesting to note that the district court, later overruled by the Ninth Circuit, found that the plaintiff had not used all of the available administrative remedies, such as petitioning EPA to conduct special reviews or to restrict, suspend, or cancel roadside uses. (Chem. Reg. Rep. pg. 1101 (12/21/84).)

132/ This is further verified by Dow conceding that its challenge turned into more of a scientific mission. In fact, long before the company entered into negotiations, the production of 2,4,5-T had ceased. (Mark Tucker, supra at note 108.)

133/ United States v. Vertac Chemical Corp., 489 F. Supp. 870 (1980).

134/ In re "Agent Orange" Product Liability Litigation, 597 F. Supp. 740 (E.D.N.Y. 1984).

spraying of Agent Orange during the war, initiated a further tide of public suspicion and fear when it was learned that the EPA had contemplated banning the uncertain pesticide for over a decade. Even though causation was not resolved in this case, 135/ the public emotions further encouraged cancellation. This may explain the strength and initial excitement over the Alsea study, viewed almost as the missing link, and the ability of the EPA to be persistent in standing by the validity of the study even when flaws were exposed. 136/

These events, acting in concert, served to focus public attention in favor of strict regulation of 2,4,5-T and provided the EPA with the necessary political sway to invoke cancellation of the chemical. While the EPA had taken action restricting the uses of 2,4,5-T prior to the administrative hearings in 1981, the Vietnam veterans' suit provided the final push for cancellation, supported by the fact that the EPA settlement with Dow and cancellation actions occurred simultaneously with the initial stages of the filing of the Agent Orange complaint.

Similar to the placement of political power, the placement of the legal burden of proof had a profound impact on which party prevailed. More specific examples of the influence which shifting of the burden of proof had on the outcome of each individual debate are noted at specific points in the narrative text. More generally, since throughout much of the ten-year debate on 2,4,5-T regulation the EPA was the initiator of all cancellation actions, when challenged, they had the burden of proof in establishing the validity of their actions and were frequently forced to revoke their decisions due to inadequate scientific studies and research. When the dispute moved to the courts, however, the burden of proof was shifted to the companies who were responsible for proving that the EPA's actions were not in accordance with the bulk of the scientific evidence. It was at this point, when the 2,4,5-T manufacturers sustained the entire burden of proof in establishing that cancellation was not appropriate, that the companies conceded, the dispute ended, and the cancellation was finalized.

135/ Id.

136/ Richard Mountfort, supra at note 130.

Placing the burden of proof on the opposing party or allowing one party more power generally does have some influence on the progress and resulting decision in most situations. In the case of trans-scientific issues, however, where the facts are uncertain and there is a tendency to look to all other sources for guidance, placement of the power is determinative, or at least has a most marked impact, on the resolution of the problem.

3. Science, By its Nature, is Not Easily Transferred to Nonscientists.

A third problem emerges when courts are forced to evaluate and interpret scientific findings. Although review of administrative actions do not demand rigorous step-by-step proof of cause and effect, the courts must nevertheless evaluate whether, based on the incomplete and conflicting evidence, the agency's actions or determinations are appropriate, not "arbitrary and capricious". Unfamiliar with the terminology and fundamental principles, judges are forced to make subtle scientific distinctions between the more certain, "factual" scientific evidence and the more trans-scientific, conjectural evidence in determining the validity of a regulation. While this can be done with some satisfaction by the experts entrenched in the discipline, it is next to impossible for a judge largely unfamiliar with that science. It is at this point, when nonscientists must rely exclusively on scientific concepts and the current state of the art to determine what constitutes an acceptable causal link, that unpredictability and inconsistency begin. Simply stated, the problem is that the uncertainty of science is not properly understood by nonscientists, which in turn may be attributed to the nature of the scientific process itself. Instead of addressing questions as they arise, science typically proceeds in a building block fashion with each new question and experiment building on and guided by the results of previous experiments. 137/ Students of

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137/ Lauden, a philosopher of science, states this most clearly: the working knowledge within a science " . . . rationally suggests certain sorts of solutions. That is, there are good reasoning patterns which allow one to conclude, on the basis of such information, that a particular approach to eliminating theoretical inadequacies is appropriate . . . hence, whether something is regarded as
(Footnote Continued)

science immerse themselves in its concepts and "paradigms" by practicing laboratory experiments and engaging in hypothesis testing of their own. Through the span of years scientists become familiar with the assumptions and the limits of their discipline, and from that learn how to assess a finding in relation to its significance and uncertainty. 138/ Nowhere is this esoteric quality more apparent than in the fields of toxicology and epidemiology. The tools of research are so limited in these disciplines that the practicing scientist not only interprets his results with caution but further realizes the limitations of his discipline and can accept the necessity of the inherent errors. 139/

(Footnote Continued)
an empirical problem will depend in part, on the theories we possess." Lauden, Progress and its Problems at 15 (1977).

138/ In his highly regarded work, the Structure of Scientific Revolutions (1970), Thomas Kuhn emphasizes the entrenched, almost insulated nature of scientific knowledge and understanding: "Then imagine what the words, though all well known, can have said to a man who did not know even the problems." The scientist " . . . learn[s] something, prior to the law, about the situations that nature does not present. That sort of learning is not acquired by exclusively verbal means. Rather it comes as one is given words together with concrete examples of how they function in use; nature and words are learned together . . . what results from this process is 'tacit knowledge' which is learned by doing science rather than by acquiring rules for doing it." (Id. at 191.)

139/ " . . . put simplistically, a research tradition is . . . a set of ontological and methodological 'do's' and 'don't's . . . to attempt what is forbidden by the metaphysics and methodology of a research tradition is to put oneself outside that tradition and to repudiate it . . . what we must preserve, if we are to understand either the logic or the history of the natural sciences, is the notion of the integrity of a research tradition, for it is precisely . . . that integrity which stimulates, defines and delimits what can count as a solution to many of the most important scientific problems." (Lauden, supra note 139, at 15.)

This interpretation is more difficult for the nonscientist. Given his lack of familiarity with the processes, sources of error, and the methods and tools ultimately available, it is easy to imagine the difficulties and frustrations he will inevitably encounter. The saccharine issue serves as an exemplary case. In that instance scientists testing for potential cancer risks caused by ingestion of saccharine utilized the standard acute toxic testing on mice and extrapolated these results to humans. Although the technique was based on a variety of unproven assumptions, it was a standard well accepted within the scientific community and was the best that science could do. Ultimately, the majority of FDA scientists concluded that the product was unsafe and should be removed from the market. Faced with the potential loss of a highly valued product, the general populace became outraged, ridiculing the extrapolations the scientists were forced to make, while simultaneously continuing to demand answers to unresolvable questions and refusing to acknowledge the absence of alternatives. Congress responded to the public pressure and overrode the scientists' recommended ban.

Similarly, when this scientific decision making becomes incorporated into the judicial process, it is not uncommon to observe widespread frustration, high courtroom costs and expensive delays, both socially and financially. Judges are briefed on the basic principles of science for weeks and proceed to grapple with sorting out the more certain science from the less certain. This problem may be seen in the 2,4,5-T issue where the judges in the hearings were regarded by both sides as excellent and objective. 140/ Nevertheless, much time was spent briefing the court on the more basic scientific concepts so that it could more effectively interpret the sophisticated studies to follow. 141/ Furthermore, the studies were multidisciplinary, involving analytical chemistry, toxicology, epidemiology, etc., making the analyses even more complex. Faced with only a superficial understanding of the vital scientific problems, the judges were forced to rule on testimony solely on the basis of its internal consistency, its reliability (published), and the way in which it was presented. A successful

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140/ Mark Tucker, supra at note 108.

141/ Id.

testimony, in turn required only that the scientist be articulate, not necessarily qualified or objective.

B. Proposals for Reform

The fact that certain questions cannot be adequately answered by science will not prevent their being asked or the necessity of an answer for them. Ideally, if decision makers were endowed with the scientists' working knowledge of the proper tools and methodology, they would vary the reliance they placed on scientific findings in relation to the nature of the question asked and how compatible it is with the state of science at the time. This would, in turn, lend more direction to the traditionally expensive, time-consuming and largely inconclusive hearings and fact-finding sessions conducted by the agency.

If the EPA had such a policy--beyond RPAR and extending to the substance of the hearing, not just to the legitimacy of calling one--more satisfactory results might be obtained. This could be achieved by categorizing the issue according to its level of certainty: the statistically resolvable; the estimable; and the unresolvable. In each category the content of trans-scientific residue, or uncertainty, increases according to the number and nature of extrapolations involved and the type of substance.

For substances such as 2,4,5-T, the agency could review regulation under the unresolvable category and conduct hearings accordingly: Rather than focusing on conflicting studies and/or scientific perspectives, the agency could develop a policy, based on the public's risk adversity, for dealing with this uncertainty directly and explicitly. In reality, in regulating 2,4,5-T, the EPA was following an unpublished, possibly unarticulated decision to err on the side of caution. Had this valuation been universally recognized, agency decision making could become more forthright, more upfront, and fairer. Judges would be supplied with some basis for review of agency action, and industries could plan according to these explicit rules rather than being caught offguard by EPA delay tactics.

In most cases, however, regulatory decision makers and administrative law judges do not have the power to insist on legislatively mandated standards or other more universal regulatory policies. Perhaps the most realistic method of managing trans-scientific issues on an individual basis, then, is by the anticipation of problems resulting

from uncertainty. 142/ Although recognition of a problem certainly does not solve it, it may play a large part in the subsequent resolution of that problem.

The fact that the administrative branch today is confronted with numerous trans-scientific issues cannot be denied. Although most suggestions for reform involve mechanisms beyond the reach of most of the participants in he administrative process, hopefully this paper has estab- ished some method for recognizing and addressing the roblem, along with all of its legal complications. Al- hough a reliance on this recognition may be naive or therwise unworkable, implicit in this suggestion is the ope that decision making concerning trans-scientific issues ill be made more explicit and efficient in the future. EPA egulation of 2,4,5-T serves as a clear example of past istakes. Hopefully, it may also serve as a spring board rom which to learn and make decision making more effective n the future.

142/ See, i.e., the Judge Wright insightful opinion in thyl Corporation v. Environmental Protection Agency, 541 .2d 1 (D.C. Cir. 1976).