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UNITED STATES of America, Petitioner,
and
Dow Chemical Company, Intervening Petitioner,
v.
Dr. James R. ALLEN and John Van Miller, Respondents,
and
James P. Wachtendonk, Mary S. Wachtendonk, Ree Anne Wachtendonk and Zachary James Wachtendonk; Robert W. Green, now Deceased, and Cheryl A. Green, the widow of the veteran Robert W. Green, now Deceased; Charles Chapman and Kuniko Chapman, Individually and on behalf of each of the "Vietnam Veterans" who have been affected, individually and on behalf of those so unfortunate as to have been similarly affected by the toxic effects of phenoxy herbicides such as 2, 4, 5-trichlorophenoxy herbicides such as the 2, 4, 5-trichlorophenoxy aliphatics manufactured, formulated, advertised, promoted, marketed and sold, individually and collectively by the corporate defendants in MDL # 381, although known to be contaminated with the toxic synthetic organic chemical 2, 3, 7, 8-tetrachlorodibenzo p-dioxin (TCDD or "dioxin"), Intervening Respondents.

No. 80-C-133.

United States District Court, W. D. Wisconsin.

June 11, 1980.

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Richard E. Cohen, Asst. U. S. Atty., Madison, Wis., for petitioner.

Richard J. Lewandowski, Madison, Wis., for intervening petitioner.

Robert K. Aberg, Madison, Wis., for respondents Allen and Miller.

David J. Ghilardi, Madison, Wis., for intervening respondents.

CRABB, District Judge.

The United States of America has petitioned this court to enforce administrative subpoenas issued by an Environmental Protection Agency ("EPA") Administrative Law Judge to respondents, Dr. James R. Allen and John Van Miller, for certain documents, records and information related to respondent Allen's scientific studies of the chemical 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin ("TCDD"). The subpoenas were issued pursuant to Section 6 of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136d, concerning the possible cancellation of the registration of the herbicides 2, 4, 5-T and silvex.

Dow Chemical and James P. Wachtendonk, et al., have been allowed to intervene. Jurisdiction of this court is based on 7 U.S.C. §§ 136d(d) and 136n.

For purposes of this proceeding only, I make the following findings of fact.

FACTS

On February 28, 1979, the Administrator of the EPA ordered emergency suspension of the pasture, forestry and rights-of-way uses of 2, 4, 5-T and silvex under Section 6 of FIFRA, 7 U.S.C. § 136d. Along with the suspension orders, the EPA issued cancellation hearing notices under Section 6(b)(1) of FIFRA for each of the suspended uses setting hearings to determine whether these uses of 2, 4, 5-T and silvex should be cancelled.

On February 1, 1980, over the objection of the Office of General Counsel of the EPA, Administrative Law Judge Edward B. Finch issued subpoenas duces tecum to Dr. James R. Allen and to John Van Miller, ordering that they appear before attorneys for the Dow Chemical Company on February 14, 1980, and produce certain documents. Dr. Allen was served on February 5, 1980.

The subpoenas required that Dr. Allen and Mr. Van Miller produce the following materials for the 500 part per trillion

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("ppt"), 50 ppt, 25 ppt and 5 ppt Monkey Studies:

> a. All documents and records related to Dr. Allen's study of TCDD administered to monkeys in the diet at ppt TCDD.
>
> b. All documents and records related to the sources, breeding, care, and maintenance of the animals used in this study.
>
> c. Summaries or data compilations of the ancestral breeding records for animals used in the study.
>
> d. All documents and records related to the possible presence of PCBs or other toxic substances in the tissues of animals used in this study, and all documents and records related to possible routes of exposure for such PCBs or toxic substances, including possible contamination of food or water supplies or previous exposure to PCBs or toxic substances.

The term "documents and records" was defined in the "Schedule of Documents to be Produced" as including:

> All letters, memoranda, correspondence, reports, notes, drafts, working papers, protocols for scientific studies, laboratory notebooks, raw data, data

> compilations, graphs, charts or papers of any kind, whether hand-written, typed, printed, or reproduced photostatically or photographically, all film, photographs, videotapes, drawings, or other visual representations, and all magnetic, mechanical, or electronic recordings or other form of data compilation. The term "documents and records" does not include articles published in recognized scientific journals of wide circulation.

On February 11, 1980, a Motion to Quash the Administrative Subpoenas was filed.[1] Administrative Law Judge Finch granted the motion to quash with respect to the documents relating to the 500 ppt and the 50 ppt studies, and denied the motion with respect to the documents for the 25 ppt and the 5 ppt studies. He also extended the return date of the subpoenas to March 11, 1980.

The "Order Granting In Part and Denying In Part Motion to Quash Subpoenas Duces Tecum Against Dr. James Allen and Mr. John Van Miller" contains the following paragraph:

> The court is aware of the distinction and usefulness of both complete and incomplete scientific studies and between third party witnesses as opposed to party witnesses. However, this distinction is overcome by the desire of the parties to have before them at the outset any and all relevant evidence which might bear on the final decision. There is no question as to the relevance of the data to be discovered. This is not to say that there has been a determination at this time as to whether or not any such discovered data will be probative or substantive in nature. If any of the data finds it sic way into the record of this proceeding, such evidence will be considered as to its weight.

Respondents notified Judge Finch on March 10, 1980 that they declined to honor the subpoenas.

At the time the subpoenas were issued both Allen and Van Miller were employed by the Department of Pathology of the University of Wisconsin Medical School.

The studies which Dow seeks to discover are studies of the effect of the chemical TCDD on primates. In a grant application to the Department of Health, Education and Welfare prepared for the 50 ppt and the 5 ppt studies[2] the objectives of the studies were described as follows:

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> The injurious effects of *2, 3, 7, 8-tetrachlorodibenzo-p-dioxin* (TCDD) at doses as low as 500 parts per trillion (ppt) on general health and reproductive efficiency of non-human primates, the presence of TCDD at levels ranging from 10 to 30 ppt in the milk fat of lactating humans, and the development of tumors in rats fed doses that ranged between 1 ppb and 5 ppt, indicate the potential danger that may be experienced by man and lower animals exposed to this toxic

> compound. Since exposure to TCDD is continuing through the use of contaminated industrial materials, it is of prime importance to establish a clearer understanding of the injurious effects that may arise from low level, long term contact of primates to this compound. . . . These studies will clarify what may be expected to occur in the human population as a result of low level, long term TCDD exposure.

In the same application the methods of procedure were summarized as follows:

> In the proposed experiments the animals will be placed on a diet containing TCDD for 6 months prior to breeding. During this time the general body health of the animals will be evaluated. . . . Once the animals are bred, their ability to conceive and carry their infants to term will be determined. Following birth the infants will be evaluated clinically for abnormalities and for levels of TCDD in the tissues. After four months of nursing, the animals will be weaned and evaluated for learning and behavioral abnormalities.
>
> Following approximately 2 years of exposure to the TCDD and after having given birth to infants and nursing them for 4 months, the animals will be placed on a normal diet. The rate of recovery from TCDD intoxication will be determined in the manner outlined below. After the adult female animals have been off of the TCDD diet for 6 months, they will be bred again and the residual effects of TCDD on conception and fetal and neonatal development evaluated. Following birth, the levels of TCDD in the infants sic tissues as well as that which is present in the milk they are nursing will be determined. After 4 months the infants will be weaned and evaluated for behavioral and learning abnormalities, similar to that of the original group. Following the completion of the psychological evaluation, a portion of the animals will be sacrificed, and a thorough gross and microscopic evaluation of the tissues conducted.

The 25 ppt study was begun on November 11, 1978, by starting the monkeys on the experimental diets, and the 5 ppt study was begun on March 23, 1979, in the same manner.

In his affidavit filed in this court on June 3, 1980, Van Miller explains that a "cumulative no-effect level"[3] can not be determined even tentatively until the total amount of TCDD ingested by the study animals reaches the level[4] at which effects have first been observed in earlier studies of higher doses. This is not disputed by the affidavits of R. J. Kociba, an associate scientist employed by Dow Chemical. In his affidavit Kociba states that useful information should be available from the 5 ppt and the 25 ppt studies, that whether there is a no effect level of TCDD is likely to be an issue in the EPA hearing; and that Allen's studies may "shed light" on a no-effect level for TCDD toxicity in primates.

At the dosage of TCDD given to the monkeys in the 25 ppt study it will be 60 months before the animals will have ingested the amount of TCDD which was found to produce adverse effects on adult female monkeys (maternal toxicity) in an earlier study using higher

doses. It will be substantially longer for the 5 ppt study. No "critical intake level" has yet been established at which adverse effects on the reproductive capability are observed because

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in all studies conducted so far adverse effects on reproductive ability have been observed on the first breeding. Because of this a determination of a cumulative no-effect level for reproductive toxicity will take even longer than necessary for the determination of maternal toxicity.[5]

OPINION

Dow Chemical has argued that the decision of the Administrative Law Judge to issue the subpoenas should be upheld by enforcing those subpoenas unless the decision is found to be arbitrary and capricious. However, an action to enforce an administrative subpoena is a *de novo* proceeding before a district court. *EEOC v. United States Fid. & Guar. Co.,* 414 F.Supp. 227 (D.C.Md.1976), aff'd 538 F.2d 324 (4th Cir. 1976). Therefore the decision of the Administrative Law Judge is not binding on this court.

Even if this were not a *de novo* proceeding, the standard of review would be something other than the "arbitrary and capricious" standard applied to decisions of administrative agencies when judicial deference to such decisions is required. There are not present in this situation elements of administrative decision-making which give rise to deference. For example, the administrative law judge's decision to issue the subpoenas is not the sort of decision which reflects either a "considered judgment" or any "in-depth study of the problem." *Cf., Pittston Stevedoring Corp. v. Dellaventura,* 544 F.2d 35, 50 (2d Cir. 1976). Moreover, his decision was made in an "umpiring" rather than in a "policy-making" function. A "policy-making" decision would be entitled to greater deference, *See, Tri-State Terminals, Inc. v. Jesse,* 596 F.2d 752, 757 (7th Cir. 1979), citing *Pittston Stevedoring Corp.,* 544 F.2d at 48-49. Finally, the decision at issue here was made by an administrative law judge rather than by an agency administrator. It has not been subject to review within the agency and therefore is not entitled to the deference which might be due an administrator's decision.

The United States contends that the subpoenas at issue in this case should be enforced as long as "the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant." *United States v. Morton Salt Co.,* 338 U.S. 632, 652, 70 S.Ct. 357, 369, 94 L.Ed. 401 (1950). However, *Morton Salt* and the other cases cited in support of the United States' position involved the use of an agency's investigative authority to acquire business records. In those cases subpoenas were issued pursuant to statutes which show that Congress intended the various agencies to have broad investigative powers.[6] In *Morton Salt* the Supreme Court found that administrative investigatory power is "analogous to that of the Grand Jury, which does not depend on a case or controversy to get evidence but can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." 338 U.S. at 642-643, 70 S.Ct. at 364.

This case involves subpoenas for discovery issued not in the EPA's investigatory capacity, but rather in the context of adjudication regarding the registration of certain herbicides. The subpoena was issued not on behalf of the Administrator but rather at the request of Dow Chemical, a party to the adjudicative hearing. In fact, the EPA's Office of General Counsel opposed the issuance of the subpoenas. The statute involved here is not one granting

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broad authority to an agency to investigate but rather one apparently aimed at providing for the production of evidence necessary to a fair adversary proceeding. The provisions of 7 U.S.C. § 136d(d) read in part:

> Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpoena to compel testimony or production of documents from any person. . . . On contest, the subpoena may be enforced by an appropriate United States District Court in accordance with the principles stated herein.

Applicable federal regulations promulgated by the EPA limit the issuance of subpoenas for the purpose of pre-hearing discovery. Section 164.50, 40 C.F.R. Chapt. 1, provides for "primary discovery," that is, the exchange by the parties of witness lists, documents and exhibits expected to be used at the hearing. Section 164.51, 40 C.F.R. Chapt. 1 regulates all "other discovery." This section provides that discovery, other than that covered by section 164.50, is permitted "only upon determination by the Administrative Law Judge (1) that such discovery shall not in any way unreasonably delay the proceedings, (2) that the information to be obtained is not otherwise obtainable and (3) that such information has significant probative value."

Both the United States and Dow Chemical contend that the requirement in § 164.51 that information sought to be discovered have "significant probative value" means no more than that the information must be relevant and material. Neither proponent of this position offers any real support for it. Specifically, neither has explained why § 164.51 contains the term "significantly probative" if what was meant was "relevant and material" as those terms are used in § 164.70.

Even if the terms "probative" and "relevant" were exact synonyms, which they are not,[7] the adverb "significantly" used in § 164.51 indicates that what is required for pre-hearing discovery is more than just relevance.[8] Dow Chemical next contends that if § 164.51 requires a higher standard than "relevance" the rule must be held invalid as contrary to Section 6(d) of FIFRA, 7 U.S.C. § 136d(d). I find it unnecessary to address this argument because even under 7 U.S.C. § 136d(d), without reference to the federal regulations, enforcement of the subpoenas at issue here must be denied.

7 U.S.C. § 136d(d) provides in part that "the Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced . . .." This reference to protective orders is an explicit recognition that prospective witnesses are to be protected from undue burden resulting from a party's request for information. It follows logically that a subpoena request must be denied altogether when the burden imposed is too great. Whether a subpoena duces tecum is unduly burdensome "is, of course, a matter to be decided in the light of all the circumstances of the case, with an eye to the need for the material on the one hand, and the burden imposed and the possibility of lightening it through a protective order on the other. *See In re Zuchert* (D.D. C.1961) 28 F.R.D. 29. . . ." 5A Moore's Federal Practice ¶ 45.052 note 44.[9]

Dow's basic contention is that the material sought is important to a determination of the issue of whether there is a no-effect level of TCDD. Dow also contends

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that data "should be" available from the study which would be relevant to the Agency proceeding generally.

There is little question that the information is in fact relevant, but its probative value at this stage of the study is quite limited. Dow does not dispute Van Miller's statement that it is not possible to conclude even tentatively that there is a cumulative no-effect level for maternal or reproductive toxicity at this point of the studies. Absent the ability to infer a no-effect level of TCDD, information that the test animals are showing no effects is not particularly probative. If the studies were to show that the animals are already adversely affected by the TCDD the information might be important for the EPA rather than for Dow. Dr. Allen will now apparently not be a witness at the hearing,[10] and even when he was planning to be a witness he did not intend to discuss the 5 ppt and 25 ppt studies. Since the EPA did not exchange the documents and information Dow seeks to discover pursuant to 40 C.F.R. § 164.50, apparently it does not intend to introduce any of it as exhibits at the hearing. Therefore denial of enforcement of the subpoenas does not mean that Dow will be surprised at the hearing.

Dow also contends that it needs the information regarding the 25 ppt and 5 ppt studies because it "may be useful" in evaluating earlier studies by Allen at the 500 ppt and 50 ppt levels about which Allen had been expected to testify at the hearing. As noted above, Allen is no longer planning to be a witness at the hearing and, in any event, his uncontroverted statement is that the protocol for all four studies are the same "in all meaningful aspects, and the protocols have been made a part of the public record (filed with the National Health Institute)."

For the reasons stated above I find that, although the data may be relevant to the issues of the hearing, it is not likely to be particularly probative. Therefore, I conclude that Dow's need for the information is not great.

I take judicial notice that it would be a substantial burden on respondents to force them to produce the information requested from the 5 ppt and 25 ppt studies which are nowhere near completion and which have not been subjected to peer review. In the early stages of any research project there are likely to be false leads or problems which will be resolved in the course of the study with no ultimate adverse effect on the validity of the study. To force production of all information demanded by the subpoenas is likely to jeopardize the study by exposing it to the criticism of those whose interests it may ultimately adversely affect, before there has been an opportunity for the researchers themselves to make sure the study is the result of their best efforts. This is not the kind of burden which can be lightened by a protective order. Putting this study in jeopardy would be a heavy burden not only on those involved in the research, but also on the public which has helped to fund it through tax money and which ultimately stands to gain from knowledge of the final results.

Thus I find that the probative value of the information sought by Dow is minimal; that it does not outweigh the substantial burden enforcement of the subpoenas would place on respondents; and that it could not be relieved by a protective order.

For the reasons stated above the United States' and Dow Chemical's petitions to enforce the subpoenas issued against James R. Allen and John Van Miller are hereby DENIED.

Respondents' motions pursuant to Rule 12(b), Federal Rules of Civil Procedure, to dismiss the petition filed by the United States and that filed by Dow Chemical are hereby DENIED. Respondents' motion for enlargement of the time in which to file affidavit supplementing their answer to the petition of Dow Chemical to noon, June 2, 1980, is GRANTED.

Notes:

1 The United States and Dow both claim that respondents filed the motion to quash. In their answer, respondents claimed that it was the EPA that attempted to modify the subpoenas, and that respondents were not notified of any of the hearings before the Administrative Law Judge. The Motion to Quash appears to have been signed by someone from the EPA on behalf of respondents. There is no evidence that respondents prepared or were personally responsible for the preparation of the motion.

2 Although, apparently this was not the grant application for the 25 ppt study, Dr. Allen stated in his affidavit that the protocols for "all four studies are identical in all meaningful aspects." The four studies involve 500, 50, 25 and 5 ppt levels of TCDD. Allen's statement was not disputed by Dow or the United States.

3 A "cumulative no effect level" is a dosage at which a toxin produces no adverse effects on a species regardless of the length of time for which the dosage is continued.

4 This is known as the "critical intake level".

5 I have made no finding as to whether Allen and Van Miller have the necessary possession and control of the documents subpoenaed. This issue is in dispute, but its resolution is not necessary for the disposition of this case.

6 For example, Section nine of the Federal Trade Commission Act provides that:

For the purposes of the FTCA the Commission, or its duly authorized agent or agents, shall at all reasonable times have access to, for the purposes of examination, and the right to copy any documentary evidence of any person, partnership, or corporation being investigated or proceeded against; and the Commission shall have power to require by subpoena the attendance and testimony of witnesses under investigation. . . . 15 U.S.C. § 49.

7 See Black's Law Dictionary.

8 The United States contends that it is absurd to require the Administrative Law Judge to determine whether information sought to be discovered will be "significantly probative" before he or she has seen it. However, in this case such a determination can be made by considering what scientific conclusions the studies could support with any scientific certainty at this stage under the best of conditions.

9 This passage from Moore's and the case cited therein refer to Rule 45, F.R.C.P. which is not specifically applicable to the issuance of the subpoenas at issue in this case. However, they are "in pari materia" and are persuasive regarding the meaning of § 136d(d).

10 See Affidavit of Robert K. Aberg filed June 2, 1980.
