IN THE CIRCUIT COURT OF HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE, et al., individuals residing in West Virginia, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

Case No. 04-C-296-2
Thomas A. Bedell, Circuit Judge

E.I. DU PONT DE NEMOURS AND COMPANY, et al.,

Defendants.

ORDER PERMITTING THE ESTABLISHMENT OF A PROGRAM DATABASE TO FACILITATE AND ASSIST IN FUTURE SCIENTIFIC AND MEDICAL RESEARCH

Pending before the Court is the issue of whether a program database containing the depersonalized information of the medical monitoring candidates of the Perrine / Dupont settlement should be made available to facilitate future scientific research. This Court was first made aware of this issue in the Claims Administrator's *June 1, 2011 Report.*

Accordingly, it set out a *Briefing Schedule* regarding the database issue on June 3, 2011. Pursuant to that *Schedule,* Defendant E. I. du Pont de Nemours and Company ("Defendant") filed a *Submission in Opposition to the Maintenance of a Database of Claimants' Medical Test Results for Potential Future Scientific Research* on June 6, 2011. The Plaintiffs' *Memorandum Regarding Third Party Administrator Issues in the Spelter Medical Monitoring Program* and the *Submission of Guardian Ad Litem to*

Unresolved Issues in the Health Care Provider Third Party Administrator Agreement on that same day.

After the initial round of submissions, the Plaintiffs' Finance Committee Representative filed her *Response to DuPont's Brief Regarding Maintenance of a Database* on July 20, 2011. Also on that day, this Court received *DuPont's Reply in Further Opposition to the Maintenance of a Database of Claimants' Medical Test Results for Potential Future Scientific Research.* Finally, the Guardian Ad Litem filed a *Submission of the Guardian Ad Litem in Response to Defendant's Opposition to Maintenance of Medical Monitoring Program Database* on July 21, 2011.

This Court has reviewed these submissions and responses and conducted a thorough examination of the record and pertinent legal authority. Accordingly, it hereby **ORDERS** that, after a claimant provides informed consent, that claimant's information may be placed into a research database and provided upon request to assist in a legitimate medical or scientific purpose.

Relevant Procedural History

1. This action was initially filed on June 15, 2004, against Defendants E.I. du Pont de Nemours and Company ("DuPont"), T. L. Diamond & Company, Inc., Meadowbrook Corporation, Matthiessen & Hegeler Zinc Company, Inc., Nuzum Trucking Company ("Nuzum"), and Joseph Paushel ("Mr. Paushel").
2. On September 14, 2006, this Court granted class certification and certified both a Property Class and a Medical Monitoring Class ("Plaintiff Classes") in this case pursuant to the provisions of Rule 23 of the West Virginia Rules of Civil Procedure. Upon appeal, the certification of both classes was upheld by the W.

Va. Supreme Court. "Having found no error in the circuit court's disposition of each of the elements to be considered in certifying a class under Rule 23(a) and (b), we find that certification was proper. Consequently, DuPont's claim that class certification violated its due process rights by preventing it from presenting individualized evidence and individualized defenses is without merit." *Perrine v. E.I. du Pont de Nemours and Co.* 694 S.E.2d 815, 861 (2010).

3. After extensive discovery and pre-trial litigation, this matter proceeded to trial beginning on September 10, 2007, and the trial lasted for approximately six weeks. The trial consisted of four phases, and the jury returned verdicts in favor of the Plaintiffs. The verdicts were ultimately rendered as awards of fifty-five million five hundred and thirty-seven thousand five hundred and twenty-two dollars and twenty-five cents ($55,537,522.25) for property damage and associated remediation costs, an estimated award of approximately one hundred and thirty million dollars ($130,000,000.00) for a future medical monitoring program to last for 40 years, and a punitive damages award of one hundred and ninety-six million and two hundred thousand dollars ($196,200,000.00).
4. Said verdicts were the result of the jury finding that the Plaintiffs' property and persons were exposed to elevated and dangerous levels of lead, cadmium, and arsenic, among other heavy metals, due to the long operation of a smelting facility in Spelter which polluted the class area.
5. On November 16, 2007, this Court entered an *Amended Final Judgment Order* finalizing the jury's verdict in the amounts described above against Defendant DuPont.

6. Thereafter, both the Plaintiffs and Defendants appealed numerous aspects of this Court's pre-trial, trial, and post-trial rulings to the West Virginia Supreme Court of Appeals.

7. On March 26, 2010, after a lengthy appellate process, the West Virginia Supreme Court of Appeals remanded this litigation to the Court with directions to conduct a trial on DuPont's statute of limitations defense.

8. The Supreme Court modified the punitive damages award, but conditionally affirmed the remainder of the verdict, which then consisted of approximately three hundred million dollars ($300,000,000.00). The Supreme Court determined that this Court erred in granting judgment as a matter of law in favor of the Plaintiffs on the affirmative defense of the statute of limitations and directed this Court to hold a second trial to determine if the defense was merit worthy.

9. The effect of the Supreme Court's directive created an all or nothing proposition for the parties. If the Plaintiffs prevailed on the statute of limitations issue, they would receive the relief obtained in the 2007 trial, as modified by the Supreme Court opinion. If DuPont prevailed, this Court would set aside the 2007 verdicts and render judgment in favor of DuPont, and the Plaintiffs would receive nothing. *Perrine v. E.I. du Pont de Nemours and Co.*, 694 S.E.2d 815, 854 (2010).

10. The Plaintiffs and Defendant both considered the directives of the Supreme Court's opinion and prepared for trial, which was set for the month of March, 2011. The Parties reached this settlement after considering the substantial amount of risk and expense remaining in the case for both sides. On November 19, 2010, the Parties advised the Court that a proposed compromise and settlement had been

reached. Thereafter, on November 24, 2010, the Court set a December 30, 2010, hearing to hear the Parties and to receive evidence and argument as to the fairness of the proposed settlement.

11. On December 6, 2010, the Court appointed Meredith McCarthy, a discrete and competent attorney practicing before this Court who is familiar with the facts involved in this case, to serve as guardian *ad litem* to protect the interests of any minors who may be members of the Plaintiff Classes. Mrs. McCarthy previously served as a guardian *ad litem* in this matter and is uniquely familiar with this issues presented.

12. After determining that proper notice of the settlement was given to all members of the Plaintiff classes and determining that the settlement was fair, this Court entered its *Final Order Approving Settlement* on January 4, 2011.

13. Alongside that *Final Order Approving Settlement*, this Court entered a *Final Order Setting forth the Scope and Operation of the Medical Monitoring Plan.* ("Medical Plan Order").

14. In that Medical Plan Order, this Court ruled that the scope of the medical monitoring plan should be in accordance with the plan suggested by Dr. Werntz, the Plaintiffs' medical monitoring trial expert.

15. Dr. Werntz testified in post-trial proceedings about the potential maintenance of a database that could be used to assist in future scientific studies regarding the types of injuries sustained by the Plaintiffs and how monitoring programs address those injuries.

16. Dr. Werntz also wrote that "a central repository of screening, referrals, and outcomes data will be maintained and depersonalized data made available for epidemiological evaluations" in his *March 30, 2007 Report.*

17. In his *June 1, 2011* report, Perrine / Dupont Claims Administrator Ed Gentle requested that this Court issue a ruling on whether a database maintained during the course of the medical monitoring program could provide depersonalized medical information to facilitate future scientific studies.

18. In response, this Court issued a *Briefing Schedule* for submissions regarding that issue.

19. In their submissions, the Plaintiffs' Representative and the guardian ad litem for the minor children and incompetent adults both advocated for making the database available for scientific studies. To support this notion, they suggested the following:

    a. that the database would better serve the Plaintiffs themselves by allowing for the authoring and distribution of summaries quantifying the observed effects, of any, of the toxic exposures to arsenic, cadmium, and lead; and

    b. that the database would be a substantially beneficial resource for the medical, scientific, business and legal communities by establishing a large database which could be utilized, in good faith, by researchers to evaluate the possible impacts of the toxic exposure to the Plaintiff class during the run of the Medical Monitoring Program.

20. The Defendant advocated against the maintenance of the database for future scientific research. It listed its reasons for doing so as follows:

a. there was no notification for the class claimants of the database,

b. the database was not a part of the settlement, and

c. the Claims Administrator failed to explain with specificity what was meant by "scientific research."

Analysis

The grounds shared by the Guardian Ad Litem and Plaintiffs' Representative on this matter are policy-based and simple to understand. The Defendant's assertions, however, are more specific and provide a better structure with which to frame this Court's reasoning. Accordingly, their grounds will be addressed in turn.

i. Problems regarding a lack of notice to the plaintiffs regarding the disclosure of their depersonalized data can be dispelled using a consent form at a plaintiff's first monitoring appointment.

The lion's share of the Defendant's argument is dedicated to the notion that, because no notification to the participants of the medical monitoring program to this date, test results cannot be retained for research purposes. It asserts that the option for the creation of a database has expired, and that now, it is simply "too late now" to ask the monitoring participants if they would consent to their depersonalized data to be used for such purposes. (*Defendant's Submission,* p. 9)

In support of that argument, the Defendant lists several opportunities that the Claims Administrator and Class Counsel might have mentioned the research database, beginning at the commencement of the medical monitoring program establishment process. It relies heavily on the fact that there was no indication at the onset of the program that data might have been used for scientific research.

It also relies on *Tolbert, et al. v. Monsanto Company, et al.*[1] in its assertion that that "claimant[s] should execute a written medical authorization [...] for the purpose of complying with the applicable laws relating to the use of medical information for research purposes and to facilitate certain studies and surveys that may be performed." *Id.* at par. 14.

This Court wholeheartedly agrees with this last assertion. Claimants *should* execute a written medical authorization for the purpose of complying with the applicable laws relating to the use of medical information for research purposes and to facilitate certain studies that may be performed. However, it disagrees with the Defendant in that it sees no reason why this authorization could not be obtained at the onset of the claimant's visits with medical monitoring professionals.

The Defendant asserts that the Plaintiffs "have not given appropriate notice of and information concerning the Medical Monitoring program's terms." (*Defendant's Submission,* p. 9). It states that the Plaintiffs should "have been so advised *prior* to signing up to participate such that they could make a fully informed decision." *Id.*

Again, this Court disagrees. It fails to see why the claimant, when presented with an authorization packet that informed them of the applicable laws, their statutory rights, and the purposes of the database could not make a rational and well-informed decision. Although some matters in this case are hugely complicated and would be outside of the domain of a laymen's understanding, this decision is not. The decision to make one's depersonalized information available for future research does not require any specialized degree of understanding. Claimants will be perfectly capable of making that decision

[1] *Tolbert, et al. v. Monsanto Company, et al.*, Dec 31, 2003 Order, N.D. Al. CA No. CV-01-C-C-1407-S)

when presented with sufficient information at their initial screenings or other first monitoring participatory visit.

That being said, this Court wants to emphasize to all parties involved that the claimant, before effectively consenting to his or her depersonalized information being used for research purposes, must be presented with sufficient information to make this decision. This information, alongside the authorization form, must give the claimant all the information he or she needs to possess the requisite knowledge to give informed consent pursuant to all applicable statutes and regulations.

ii. The maintenance of a medical monitoring database was anticipated and understood throughout the litigation process.

In its second argument, the Defendant asserts that the creation and maintenance of a medical monitoring program was not a part of the Perrine / Dupont settlement or part of the Medical Plan Order. However, the express writing of Dr. Werntz, the Plaintiff's expert, rebuts this notion:

> That a central repository of the screening, referrals, and outcomes data will be maintained, and depersonalized data made available for epidemiological evaluations. It is clear from my literature review in preparing this document that there is incomplete scientific evidence in the literature on screening programs, participation rates, referral rates, etc. This data could serve as the basis for answering many of these scientific questions.

This idea was reinforced by this Court's adoption of the medical monitoring plan envisioned by Dr. Werntz "in its entirety" in this Court's *Final Order Regarding the Scope, Duration, and Cost of the Medical Monitoring Plan*, entered February 25, 2008. Prior to its current *Submission*, the Defendant never made an objection or appeal to Dr. Werntz's idea of a database used for research. Furthermore, any modification of the

original entry of the Medical Plan Order or *Final Order Approving Settlement* did not affect Dr. Werntz's idea of a database used for research.

iii. The meaning of "scientific research" can be determined on a case-by-case basis by the Claims Administrator.

Instead of issuing a broad decree on what constitutes "scientific research," this Court finds it prudent for the Claims Administrator to make that determination on a case-by-case basis. Requests for such information contained in the database should only be given out after approval from the Claims Administrator, and this approval should be subject to objections by the Defendant. If such an objection is made, this Court will decide if such an objection shall be sustained.

This Court believes that the legitimacy of each request calls for a very subjective assessment. Therefore, a broad definition of what constitutes scientific research, or even a set of parameters that must be followed regarding database information distribution, would be clumsy and awkward if applied by this Court at this time. By approving requests on a case-by-case basis, they may be screened to ensure that they assist in a legitimate scientific or medical purpose.

Conclusion

Underlying this Court's current decision is the immense value that a database of this kind would provide to both the Plaintiffs and the scientific and medical community at large. Testimony in this case has already established that this field of study is barren of the kind of knowledge that the proposed database could provide.[2] This data could be tremendously helpful in assessing the sorts of harms, if any, that prolonged exposure to arsenic, cadmium, and lead can incur. It would also assist in determining the interplay

[2] See *Overall Medical Surveillance Assumptions*, Werntz, at 10.

between these potential harms and the medical monitoring process. Furthermore, any privacy concerns may be dealt with by a waiver. Because the benefits of such a database far outweigh the costs, it would be a mistake to neglect this opportunity.

Accordingly, it is **ORDERED** that the that the program database may be used to facilitate and assist in future scientific research so long as monitoring participants are informed of the database and its uses, and they explicitly consent to their unidentifiable information being used in this manner.

It is further **ORDERED** that the Claims Administrator of the Dupont / Perrine settlement shall determine, on a case-by-case basis, which requests for access to this database shall be granted. Access to the database should only be granted for legitimate scientific or medical purposes.

It is further **ORDERED** that this Court shall have jurisdiction over all objections stemming from requests for medical monitoring data.

Finally, it is **ORDERED** that the Clerk of this Court shall provide certified copies of this Order to the following:

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ENTER: August 24, 2011

THOMAS A. BEDELL, Judge