

IN THE CIRCUIT COURT OF WOOD COUNTY, WEST VIRGINIA

JACK W. LEACH, et al.,

Plaintiffs,

vs.

E. I. DU PONT DE NEMOURS
AND COMPANY,

Defendant.

CIVIL ACTION NO. 01-C-608



**ORDER FILING C8 HEALTH PROJECT DATA AND
ESTABLISHING CRITERIA FOR FUTURE USE OF DATA**

This day came Robert G. Astorg, CPA, Health Project Settlement Fund Administrator (the "Health Project Administrator"), by his counsel, Richard A. Hudson, and tendered to the Court for filing, under seal, two sets of the data acquired in and through conduct of the Court approved Health Project by Brookmar, Inc., which Health Project was previously approved and endorsed by this Court in its Order dated February 28, 2005. The filed data consists of two groups. The "first group" consists of 1 DVD disk labeled "De-Identified Dataset DVD 1" containing de-identified data about Health Project participant demographic data, health histories, blood chemistries, and C8 related blood levels, and 1 DVD disk labeled "Quality Assurance Data" containing data collected by Exygen Laboratories and Axys Laboratories to assure accuracy of the testing procedures and results within appropriate scientific parameters. The De-Identified Dataset DVD 1 contains a Data Dictionary defining the data fields and elements in the database spreadsheet, the Microsoft SQL 2000 database backups, the Microsoft SQL 2000 database raw text exports and creating scripts, and Internet Browser-based software to view the database contents and images. The "second group" consists of 1 DVD disk labeled "Identified Dataset DVD 1" that contains all of the data from the first group plus all of the

identifying data about Health Project Participants, together with a Data Dictionary defining the data fields and elements in the database spreadsheet, the Microsoft SQL 2000 database backups, the Microsoft SQL 2000 database raw text exports and creating scripts, and Internet Browser-based software to view the database contents and images, 1 DVD disk labeled "Science Panel Dataset DVD 1" containing all of the data from the first group plus the identifying data about the Health Project Participants who gave their consent to provide identifying information to the Science Panel appointed by this Court, 1 DVD disk labeled "Science Panel Consent Form Images" containing images of all the consent forms for Health Project Participants who gave their consent to provide identifying information to the Science Panel, and 26 DVD disks labeled "Images DVD 1 through 26" containing image files of all of the scanned documentation used to verify identity and eligibility of the Health Project Participants.

All of the disks making up the "first group" and the "second group" are hereby ORDERED Filed and Sealed.

Based upon prior testimony herein, the Court finds that the C8 Health Project and the data contained on the disks is unprecedented as to scope and significance in the scientific, epidemiologic, and medical communities. The Court notes the quarterly financial reports from the Health Project Administrator (previously filed herein) and the substantial cost of the project that culminated in the filing of these disks, and finds that the disks and the data contained thereon are of incalculable value. Therefore, the Clerk of this Court is ORDERED to take appropriate measures to physically protect and preserve the filed disks to ensure that the disks will be properly safeguarded and the purposes of this Order can and will be implemented through the foreseeable future. Furthermore, it is ORDERED that the disks shall not be "archived" (as

closed files eventually are archived) except upon court approval of a procedure to ensure proper preservation of the data contained on the disks and continued access as further provided herein.

The prior order of this Court approving the use of settlement funds for the C8 Health Project allowed for the collection of confidential information from the participants, and further provided for submission of health data and blood test information to the Science Panel subject to appropriate confidentiality provisions. In addition, the testimony of witness A. Paul Brooks, Jr., M.D. included a description of the C8 Health Project and his affirmation that the information from the C8 Health Project would benefit the class membership if placed in the public domain, but that the identification of the individual participants would never be released.

Therefore, the Health Project data contained in the "first group" and the "second group" filed pursuant to this Order shall be sealed, and shall not be revealed, copied, or otherwise made available in any form to any person, court, or entity, with or without a subpoena, except upon further order of this Court as further prescribed and outlined herein.

Any person, court, or entity that desires to access the "first group" data in any manner whatsoever shall file a petition with this Court identifying the requestor, stating the purpose or purposes for which disclosure of the data is requested, affirming that the data shall be used for no other purpose except those which are stated in the petition, and providing documentation and proposed protocols that reasonably satisfy the Court that the identities of the health project participants shall be protected through the utilization of Institutional Review Board (IRB) methods or other reasonably reliable protocols to assure no breach in the de-identification of the data acquired by the requestor. All costs of duplicating or accessing the data, and all costs

of securing court approval for access to the data, shall be the responsibility of the person requesting copies or access.

Notice of hearing to consider access to the data shall be made upon attorneys of record for the parties, or their successors, but only for purposes of allowing the parties to provide the court with additional information that may assist the court with implementation of the goals and limitations of the Health Project as stated in this Order and the prior Order of the Court and testimony before the Court regarding the Health Project at the hearing previously conducted by this Court on February 28, 2005. The parties or their attorneys shall not be required to attend the hearings regarding petitions to access Health Project data except to the extent that the Court so orders after filing of the petition.

With or without utilization of a "third party mechanism" as further described below, upon filing of any petition as provided herein, the Court shall appoint one or more "independent scientific evaluator(s)," at the expense of the petitioner, for the purposes of advising the Court regarding scientific and other technical or ethical issues related to the petitioner's request for access to the dataset filed herein and assisting the Court at the hearing mandated by this Order.

After conducting a hearing, the Court may order that the non-identifiable data shall be provided to the requestor subject to such conditions as the Court may find reasonable and necessary to protect the anonymity of the health project participants, while at the same time giving due consideration to the goals and purposes described during the hearing at which the health project approved by this Court on February 28, 2005.

At the February 28, 2005 hearing for final approval of the settlement, the attorneys for the class action plaintiffs, the attorneys for the defendant, and the principals of Brookmar, Inc., the primary contractor to the Health Project Administrator ("Brookmar") jointly represented to the Court that the de-identified results of the health project would be placed in the public domain at the conclusion of the C8 Health Project, and that the data shall not remain the property of any person (including individuals, associations, and corporations). For that reason, when considering whether or not to allow duplication or access to the de-identified data by any person, the Court will encourage such access for purposes of any study of the de-identified data that will benefit science, medicine, human health, the class, or society in general.

When access to the data is approved, parties requesting data shall limit their analyses to the specific purposes requested. Stored data will be returned or destroyed, and access to shared data will end when the specific request is completed.

The provisions of this Order limiting access to the "first group" data are included only for the following purposes: (1) to ensure that the identities of health project participants are not discovered or revealed except as necessary to protect the life or health of a participant to whom it is reasonably necessary to convey newly discovered information that is critically necessary to ensure the continued survival or well-being of that person; and (2) to ensure that requests for data reasonably meet minimal, customary guidelines for data sharing within the academic/scientific community. The Court shall not unduly restrict reasonable access to the de-identified data after the Court is satisfied that sufficient action has been taken to assure continued protection of the privacy of the health project participants.

This Court presently has no infrastructure for data sharing with regard to data disks filed in the Office of the Circuit Clerk. Therefore, a third-party mechanism may be implemented to ensure that needed infrastructure and expertise for data sharing will maintain: (1) confidentiality of participants, (2) scientific purposes expressed in the proposals, and (3) institutional review boards or reasonably similar processes. The third party may be designated by the Court to hold the data, to evaluate and report to the Court regarding requests for data, and to implement data sharing if approved by the Court.

In selecting a third party to assist the Court with data custody and sharing, the Court will consider the following relevant issues: the third party's familiarity with this type of environmental health data; the third party's ability to scrub and clean data to recognized standards of confidentiality; the third party's presence or absence of an active institutional review board process that can correspond with institutional review boards of requesting parties; and the third party's ability to hold, deidentify, and store the data for data-sharing purposes on behalf of the Court. If a third party is designated for that purpose, the third party may review requests and advise the Court whether the proposed data sharing can be confidential to accepted standards, and whether the proposed study of the de-identified data that will benefit science, medicine, human health, the class, or society in general. Such third party may also be designated as the "independent scientific evaluator(s)" as provided for above.

The Court recognizes that any third party data custodian (government agency, university, individual, or private corporation) and/or the Clerk of this Court holding the data will have legitimate costs associated with the data-sharing enterprise. In that regard, any petitioner seeking access to the data will bear the cost of (a) third party consideration and reporting to the

Court regarding proposals, and (b) de-identifying and storing the specific parts of the data needed to meet the request.

To ensure safe data sharing for scientific purposes, the petitioner may present evidence to satisfy the Court that the following standards (or such revised standards as are scientifically appropriate or legally necessary at the time of the request) for data sharing will be met:

- 1) Central disclosure control to prevent inappropriate sharing of individual, identifiable data. This may be accomplished by control over data access through a third-party mechanism, described above.

- 2) Data-access controls which enact restrictions on who can use the data, how the data can be used, where the data can be accessed, and by making informed decisions about what elements of the data are redacted or suppressed before they are stored transferred. If necessary, for example in the instance of birth dates, or very rare diseases in a limited geographic area, data keepers may choose to apply additional, statistical-disclosure control tools so that individuals may not be identified by unique attributes. The degree to which this is done is part of a process called deidentification.

It is the intention of this Order that only de-identified data be transferred to the petitioning party. The disclosure-control process therefore may include statistical methods of de-identification, such a briefly described above; and restricting access to those with legitimate scientific interests through various release options, including reliance on reciprocal arrangements between institutional review boards, or unilateral reviews to a single standard at the home institution holding the data in the absence of such arrangements.

The Court is advised by the Health Project Administrator that when a petitioning party is granted access to the de-identified raw data that is filed pursuant to this Order, the petitioner is likely to receive the requested data through the mechanism of a restricted-use microdata file. The entire database contains so many elements for each participant that unwanted intrusions, also called data snooping, are not fully preventable in a public-use file. Therefore, data transfers will likely consist of a restricted-use data set limited to the specific interest of petitioning party and the specific purposes which the petitioning party articulates and which are approved under a data-use agreement. In that regard, petitioning parties that are granted access may be required to fill out a data-use agreement form that allows the requesting researcher to use a restricted-use microdata file. Such an agreement will usually require:

- a) nonidentification of individuals,
- b) nonlinkage with other data resources (except by individual consents),
- c) a computer security plan,
- d) a specified time of usage, including an agreement of return or destruction of data at the end of that time period,
- e) a specified use, including specific research needs, and
- f) an agreement for third-party review before release of work product to ensure that privacy is protected

The Court has been informed by the Health Project Administrator that while this kind of restricted-use microdata file sounds daunting, it is routine in the scientific community. Petitioning requestors can envision all the questions in the survey, and all the lab values available, and request those needed, making their case for their need as part of their proposal. The Health Project Administrator has further informed the Court that this procedure is routine for institutional review boards.

In order to achieve privacy without denying data use, any court designated third party holding the data will be entitled to use standard statistical methods such as data suppression

(for example, use of personal identifiers); data coarsening (for example, year of birth rather than birth date, or removal of very rare diagnoses in some cases); recoding (for example, combining certain types of rare diagnoses that “go together” so that most of the value of the data is retained yet still deidentified; “top coding” and “bottom coding” (for example, replacing outlier variables with an arbitrary highest or lowest value, so that the abnormality is available for scientific review, but individuals cannot be identified).

The Health Project Administrator has advised the Court that such efforts at privacy protection are an essential part of good science, and they require substantial infrastructure and work. The agency doing this work is entitled to take the steps necessary to ensure that privacy is in place, including but not limited to the routine steps described above, and to charge the receiver reasonable costs associated with the process.

Separate from the “first group” de-identified data that may be disclosed pursuant to notice and hearing as stated above, the Health Project Administrator has filed a “second group” of disks consisting of all data and records of any kind or nature that were examined, acquired, or utilized in conducting the C8 Health Project. The Court finds that this “second group” set of records are private and confidential and shall not be made available under the procedures outlined herein.

The Health Project Administrator has also advised the Court that he, along with the principal C8 Health Project contractor – Brookmar, Inc., entered into agreement dated April 27, 2006 with West Virginia University Medical Corporation d/b/a University Health Associates for storage of the remaining blood sera samples drawn from participants in the C8 Health Project and for use in subsequent scientific research, including without limitation use by the Science

Panel (the "Pathology Services Agreement"). A copy of the Pathology Services Agreement is attached to this Order as Exhibit "A." The Court finds the provisions of the Pathology Services Agreement concerning the maintenance of the privacy of C8 Health Project participants and the conditions under which the blood sera samples will be made available for appropriate scientific research are consistent with the principles enunciated in this Order. Accordingly, the Court hereby ORDERS the Pathology Services Agreement be filed.

WHEREFORE, the Court hereby ORDERS that the information contained in the "second group" of disks shall be sealed and shall not be disclosed in any manner or form except in a circumstance where the disclosure is unquestionably necessary for purposes of a matter critical and essential to the life of the C8 Health Project participant for whom disclosure is requested. Therefore, it is the order of this Court that no disclosure of the private records shall be made, and no request for disclosure or subpoena of those records shall be made by any person or attorney for any person except in the circumstance where the requestor contends that disclosure is solely in the best interest of the C8 Health Project participant whose records are requested.

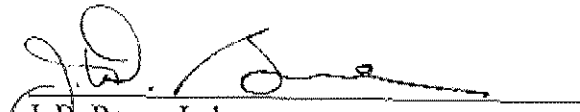
It shall be a violation of this Order and a contempt of this Court for any attorney to request or acquire an order of any other court or a subpoena in an effort to circumvent the hearing requirements of this Order regarding disclosure of the C8 Health Project data filed in this civil action pursuant to this Order.

Nothing contained herein shall prevent an individual C8 Health Project participant from requesting and receiving his or her "second group" personal information or identifying number at his or her own expense from Brookmar or the Clerk of this Court at any time for any

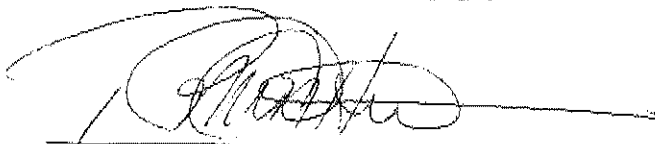
purpose, and the fact that such person requests or receives his or her information from Brookmar, the Clerk, or Court shall not be disclosed by the Clerk to anyone except with permission of the person who requests such information. In the event of an individual request for records, the person making the request shall deposit sufficient funds with Brookmar's information technology representative or other court designated and approved technician to cover the cost of accessing the sealed disks, recovering the requested data, and re-sealing the disks and dataset. It shall be a contempt of this Court for the designated and approved technician to access, review or copy any information beyond that which is necessary to comply with the participant's request.

It is ORDERED that no access to the disks filed herein shall be allowed by the Clerk of this Court at any time except after thirty days notice to the Court, and that any person requesting such access shall also provide a copy of this Order to the Judge to whom the request is made.

Entered this 16th day of May, 2008.


J. D. Beane, Judge

PREPARED AND SUBMITTED BY:



Richard A. Hudson (WV Bar #1808)
Bowles Rice McDavid Graff & Love, PLLC
501 Avery Street, Fifth Floor
P.O. Box 49
Parkersburg, WV 26102
(304) 420-5511, (304) 420-5587 *facsimile*
rhudson@bowlesrice.com