# IN THE CIRCUIT COURT OF WOOD COUNTY, WEST VIRGINIA BEFORE THE HONORABLE J.D. BEANE

JACK W. LEACH, et al, Plaintiffs,

v Civil Action No. 01-C-608

E.I. DU PONT DE NEMOURS AND COMPANY, Defendants.



### STATUS HEARING

Proceedings held before the Honorable J.D. Beane,
Chief Judge, on the Fourth Floor of the Wood County Judicial
Building, No. 2 Government Square, Parkersburg, West Virginia,
on the 18th day of May, 2011.

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BE IT REMEMBERED, the following proceedings were 1 had before the Honorable J.D. Beane, Chief Judge of the Circuit 2 Court of Wood County, West Virginia, on May 18, 2011 in the 3 matter of Jack W. Leach, et al, Plaintiff versus E.I. Du Pont De 4 Nemours and Company, et al, Wood County Civil Action No. 01-C-5 608, as follows, to-wit: 6 THE COURT: Good afternoon. Please be seated. 7 All right, this is 01-C-608, Jack Leach, et al versus E.I. 8 DuPont; and we're here on a status hearing. 9 MR. DEITZLER: Yes Your Honor. Would you like 10 me to summarize the status of the litigation to this point? 11 THE COURT: That would be fine. 12 MR. DEITZLER: All right. A lawsuit affects an 13 estimated seventy to eighty thousand individuals in six local 14 15 water districts, two in West Virginia, four in Ohio. It rises from concerns over DuPont placing perfluorooctanoate acid, 16 commonly known as C-8, in the environment, ultimately into the 17 18 drinking, bathing, and cooking water of affected individuals, 19 many of whom are the room. The lawsuit was filed in Kanawha County, West Virginia on 20 August 30, 2001, almost ten years ago, naming DuPont and Lubeck 21 22 Public Service District as Defendants requesting necessary 23 medical monitoring and relief from personal injuries attributed to exposure of individuals to C-8. 24

THE COURT: Let -- let me just -- since you reflected back that it was nearly ten years ago, I was looking at the Settlement Agreement.

MR. DEITZLER: Yes Your Honor.

agreement it says, [Reading]: The principal reason for the settlement is the ability to provide the collection of unique benefits to the settlement class now. If the lawsuit runs it's expected course, which may take another three years or more including appeals, even if the named Plaintiffs prevails ...

And then it goes on. So we're...

MR. DEITZLER: Yes Your Honor. That's why I was going to explain the chronology here. It was certified in 2002. The settlement with Lubeck was in 2003. The parties had litigated several differences going to the West Virginia Supreme Court. Mediation was ordered by this Court, although Judge Hill was presiding at the time, on May 9th, 2003. Trial was scheduled for October 12, 2004. About a month before the trial the parties finally reached a settlement agreement in principal. They — we appeared before the Court October 22, 2004 to notify the Court of that and then on November 23, 2004 the Court heard the requesting preliminary approval; scheduled the final approval hearing for February 28, 2005, which is, as you pointed out, more than five years ago.

Pursuant to the Settlement Agreement, instead of getting an immediate jury verdict as to medical monitoring, the class member's rights to medical monitoring were -- it was agreed would be decided by an independent medical panel after a probable link is evaluated by an independent science panel, which would be these gentlemen over here.

The time limits on personal injury claims of these people were stayed pending the outcome of a probable link determination. And we've been getting quite a number of calls about that because people were constantly wanting to know why we're not moving forward. So I'm glad you called this status conference so we can — at least the public will know that we can't do anything else right now.

But the settlement boiled down to, in essence, three primary components. One, a medical panel is going to decide whether — what medical monitoring, if any, is — that the class members are entitled to. And the medical panel will be impaneled only after the probable link determination is made where the science panel, using all available scientific evidence, will determine on a more likely than not standard, more probable than not standard, whether or not there is a link between C-8 and human disease after they narrow it down by determining what diseases would — might have an association. In other words, they make association findings to decide what

they're going to study on probable link. And so that's basically a two-step process. So that's the first component of the settlement.

The second is that DuPont would filter the water -- clean up the water to the best degree scientifically possible, of the six affected water districts and the wells that were within the district. And they have -- they have a guy named Andrew Hartin\* who -- who put this together and quite frankly they did an excellent job of that. And so that component -- I don't know, they might want to report on that separately but the last report showed that twenty-two million two hundred and twelve dollars -- two hundred and twelve thousand seven hundred and sixteen dollars and sixty-two cents later they -- they have done it.

And so DuPont definitely stepped up to the plate on that.

The third component of the settlement was that a human health education project would be funded for the benefit of the class to gather detailed health histories and blood chemistry information, to the extent possible, with available funding on the class members. And on that portion the Plaintiffs are prepared to report. We've subpoenaed Dr. Paul Brooks who is the — one of the two principals of Brookmar and he is prepared to tell the Court what — what they did with regard to the C-8 Health Project. They completed their work in about a year; I mean from July to July they were done.

THE COURT: What year?

MR. DEITZLER: 2005 -- July 2005 to 2006 they did their work. And they -- what they did, they gathered the -- the data and then they contracted with one of the specialists up at West Virginia University who had access to epidemiologist, toxicologist, computer people and everything, to put the data together in a readable format. Because if you just take several million lines of data it's not going to mean anything to the public; so they contracted with West Virginia University and Dr. Alan Ducatman -- we subpoenaed him to be here in case the Court would like to hear from him -- and the public, you know, they're going to want to know what -- what was done with all -- all this money. And then Bob Astorg was the Administrator for that portion and he's here with a written final report.

So I didn't know if you wanted to -- since the science panel traveled the furthest if you wanted to proceed and let -- hear from them first and then we can fill in the blanks with what we -- what we had done or, you know, whatever order you'd like for us to report on that.

We --

THE COURT: I guess you can go ahead with the witnesses you have and I think that'll provide a better understanding. And then I'd like -- the reason I set this is because I do want to hear from the science panel.

1 MR. DEITZLER: Okay. 2 THE COURT: I'll cancel the rest of the day, 3 if necessary, so that we can hear from them. So if you'd just -4 - it's not going to take that long if you want to go through 5 with what witnesses you've subpoenaed. MR. DEITZLER: Yes, Your Honor. We'll call Dr. 6 7 Paul Brooks. 8 THE COURT: And did you all have anyone, as 9 well, that you were calling? No, Your Honor. 10 MR. JANSSEN: [WHEREUPON, after being administered the oath, Dr. Paul 11 Brooks testified as follows, to-wit:] 12 13 DIRECT EXAMINATION BY MR. DEITZLER: 14 15 Dr. Brooks, I think everybody in Wood County knows who 16 you are, but for the -- for the record would you state your name 17 and profession? 18 Α. A. Paul Brooks, Jr., M.D. 19 Ο. Were you a medical doctor? 20 Α. Still am. 21 Thank you for correcting me on that, Doctor. You were 22 one of the two principals of the organization identified as 23 Brookmar which the Court, in February of 2005, gave final approval for preceding with the Human Health and Education 24

Project, commonly known as the C-8 Health Project, correct?

A. That's correct.

- Q. Would you give the Judge a report and the community, essentially, a report of what you all did?
  - A. Okay. I have to refer to some notes in order to kind of keep this thing from rambling too much. But what I wanted to do was go through it in a chronological order starting back in September 2004 when we were first contacted and move through, basically, when we finished the collection of data in 2006, July.

In 2004, as in previous testimony at the Fairness Hearing —
- there's a lot recorded there — we gave a full detail of what
we had — had proposed to do. But in September, 2004 myself and
Art Maher, who is a retired hospital administrator at now the
St. Joe campus of the Camden Clark Medical Center, were
contacted by Plaintiffs' attorneys or Class attorneys to ask us
if we would consider carrying out a portion of a Settlement
Agreement that had been reached over the C-8 lawsuit that had
taken place.

We were -- we met and -- for hours and we were brought up to date basically that the settlement was reached and there would be a hearing in November -- I think around the 24th or somewhere in that area -- that would take approval of the Court. So we were put under confidentiality agreements and -- and they

laid out what they would like for us to entertain and look at about doing.

The important parts of it were, number one, that seventy million would be designated to the class of which twenty thousand would -- or twenty million, I mean, would be used for education and health studies. That there were six water districts plus private wells involved in the contamination and they were Little Hocking, Lubeck, City of Belpre, Tuppers Plains Chester, Mason County and the Village of Pomeroy and any contaminated wells that were in those six water districts.

The eligibility of the class was that they consumed water in these districts for a total of one year dating from 1950 to December the 3rd, 2004. So the number that was given in the class was probably sixty to eighty thousand, estimated, and possibly could've been as many as a hundred and twenty thousand that were living and could possibly be tested. It -- there was no way to really determine the total, you know, the accurate number but it was a pretty good guess, I think, at about eighty thousand.

The requirements for the collection of data included a personal health survey of some great detail and a blood test with a number of tests that they generally represent of the bodily function of all the organ systems. And there were a total of sixty-three actual blood tests and then there were nine

perfluorocarbon blood tests to be done, which C-8 is one of the fluorocarbon that was tested for. So it brought the total to about seventy-two.

Also in the Settlement Agreement it was determined that participants would be paid a hundred and fifty dollars for their questionnaire and if they would concede to having blood drawn they'd be given a two hundred and fifty dollar stipend, which made a total of four hundred dollars. For that they agreed to allow de-identified data that was collected to go into the public domain once it was prepared for that.

So -- and it was required that this be accomplished as soon as possible with a high degree of the accuracy of the data, as well as safeguards for the participant's privacy; and to be efficient with the financial resources to test as the finite fund would allow. We had the funds granted to us at the seventy million figure so that's all we could possibly spend to test people and, of course, that would limit -- that obviously limited the number based on what it was costing to test each one; and to follow the Court order and accomplish that without any variance from what the Court had ordered to be done.

So then we proceeded to the November Settlement Hearing after that and in the mean time we had prepared a -- not much of a budget but we'd gotten some numbers on lab tests that were to be required because we knew that would probably be our largest

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cost as opposed to the -- and also with the four hundred dollars. So I think we presented to the Court that we'd had a number of about five hundred and forty-six dollars or something in that range for the blood test and about -- and in the four hundred dollars, which brought the total to nine hundred and forty-six dollars per participant. So we figured well, we could -- with administrative costs and all the -- we had to have employees etcetera, that we might -- we probably could do around sixty thousand but we were also willing to try to negotiate at least all the fees, down with vendors. And looking at the volume that was a possibility we were able, later, to do some pretty -- pretty strict negotiations based on the numbers. other words, you'd do the first twenty-five thousand, say, for a certain price. If we exceed that then they'd do the next ten for a lower price and so on. So we were able to bring that down some. So we couldn't give much testimony at that time about procedural details except to get some general timelines.

In the Fairness Hearing then, in February, after we'd given a fair amount of detailed testimony, that was approved and we were approved to carry out the collection of data as in the order. However we found that in February -- the 28th I believe was the date -- that we weren't going to have -- the seventy million was not going to be released because of a hundred and twenty day waiting period and so that put it into July. The

problem we saw with that was the fact that the settlement had become public knowledge and there was a lot of interest in what was going to be done and, you know, comments, well nothing's going to be done etcetera, etcetera. So we wanted to show that we would get going as soon as possible to keep that momentum. And we were able to get enough funds let out to us that we could go ahead and sort of ramp for a July start date. And also in November we began to assemble a team which -- to -- to form, you know, to form this -- we formed an entity, a legal entity because we knew we'd call it Brookmar because we knew we'd be contracting with various vendors. And that included things like laboratories, consultants, information system companies, legal and accounting. And so we would be able to comply with all federal and state regulations as it pertained to employees and collecting health data on people.

The team was myself and Art; we were the principals. We were the ones that had been contacted initially to see if we could do this. We added Patsy Flensborg, who is an RN by training; Susan Arnold was a Medical Records Specialist. We had Troy Young who was a very good information systems person. We had Rick Hudson as our legal attorney and Bob Astorg as our financial part of it.

And we -- so we set out with -- with this -- with that team to start to design this process. Our -- the way we looked at it

was, we looked at it as an information system with a collection of data attached to it. And that's kind of in reverse of what you might look at something like this. You probably -- a lot of times you'd look at the data collection part of it and try to fit the information system. What we did, we looked at the information system and fit everything else -- the mechanics to the information system, which is -- which is kind of a unique approach, I believe. It worked out quite well as a matter-offact. We decided we'd use all the computer technology that we could possibly get our hands on because the speed and the accuracy and so on and so forth that that gives you, and it's much more efficient than pushing paper around or whatever.

So when we decided to use the computer technology, of course the questionnaire was to be filled out online; although they were given an option to do the paper and that could then be input by data entry. It was suggested that this would not be successful initially, but we didn't give up on it by any stretch of the imagination. And we'd have all the vendors tied in to the central office, electronic, on a real-time basis. The laboratories, the questionnaire processing, the financial part of it, the central office and all the collection sites were tied in with fiber optics so that we had plenty of power to do what we wanted to do.

We projected, initially, in September when asked by the

class of attorneys what we thought we could do and we said well, if there's eighty thousand we ought to be able to get at least seventy-five percent of them, which made it sixty. And that number was questioned by a lot of individuals, that we could ever manage that number. So we knew we were going to do that number and do it in one year. We'd set the timeline to do it in one year so momentum wouldn't be lost. And we would need to average somewhere between three hundred and fifty and four hundred a day that we would process from start to finish with —in the collection units.

We set up collection units in all the water districts. We used two actual units in Lubeck and two in Belpre because that was a concentration of the population and they needed more volume. And then we had one at Pomeroy and one just north of Point Pleasant off of 61. These units were mobile trailers that were set permanently, hooked up to all utilities including fiber-optic and security. They had — on the end that the participant entered, there was a reception area where they came in, they identified themselves with certain identification that we required, photo, so on — picture taken of them — and if they had the proper documentation then they were started through the process.

THE COURT: Excuse me Dr. Brooks.

WITNESS: Huh?

THE COURT: There's a problem with the mic.

[WHEREUPON the microphone was adjusted]

## BY MR. DEITZLER:

A. These units had four soundproof cubicles in them specially designed by me, basically. And then on the far end where the participant exited there was a lab with drawing -- two drawing stations to -- to make the blood draw if needed. These were also made handicap accessible with ramps and we -- they had plenty of parking and they were all located strategically and easy access to them.

And then we decided that we would schedule the appointments. We gave a lot of thought about how are we going to process sixty thousand people in a year's time at three hundred and fifty to four hundred a day. You just couldn't have them to come all at one place and lineup because the last one, everybody would be there till four o'clock or five so we decided an appointment system was the way to go. And so once we got --we got them entered in database with their questionnaire then we were able to, through a central appointment system we used at the central office, we could call them and schedule them when they could come and when we could see them and it made a nice flow because remember we only had room for about four participants at time in these units. So we couldn't have a hundred people out there on the parking lot.

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The -- the way that the -- I want to talk just -- some of this will be repetitive and some of it goes backwards and forwards because it's very difficult to put it out in an in-line order. But what -- how a participant went through this process was first they filled out the health survey online or paper if they didn't want to do it online. Now we had a high percentage do it online and I'll eventually get to that. Because once they filled it out online it was in our database and it was readily available instantaneously of any of our places that we were tied up. If they did it on paper then we had to have data entry people to put it into the database and, of course, that slowed them being processed because that took a lot of extra time. people soon learned that if they got the -- this questionnaire filled out online they could -- they would be called pretty promptly to get their appointment. So that -- then once they -once they got it online then they could -- they got their appointment then they would come to the unit and usually they tried to come -- they would usually come to the unit that was located in their water district. And they would, again, meet the receptionist; they would provide identification that proved that they were who they said they were. And then they would be asked to give certain documentation to prove that they had consumed the water for the period that I talked about previously. Once that was done then they were asked to sign a

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consent that would allow their data, which was not identified to the individual, but was de-identified, to be placed in the public domain. And then once they -- we could -- they -- they automatically then qualified for the hundred and fifty dollars. The nurse then took them into the soundproof cubicle with a computer screen and went through their questionnaire and verified the information that they had put down. If they had -if they putt "I don't know" the nurse would try to find out, you know, and try to get an answer either one way or the other. they didn't understand a question and so on and so forth. was about a thirty-five minute process and so at the end of the day the data was pretty well verified and I think that showed up in some other numbers -- which I'll get to later -- that was quite helpful to know that they understood -- they understood the question and they could answer the question as accurately as they possibly could. And we could pretty well depend on that being a -- a good answer.

Then after they -- after the nurse finished with the going through the questionnaire and verifying that information then they were asked would they be willing to give a blood sample.

And if they were then we got consent. If they -- if they had reported one of diseases, which we'll list a little later, they were asked to give a consent to go to a medical record to verify that that was what they -- what they reported on their

questionnaire would be the disease that they said it was.

Because that's important, too, that there's no misinformation.

After they completed the blood draw they walked back to the front and received their check for four hundred dollars and walked out the door. And then in two weeks a copy of the lab results were mailed to them with a letter to -- instructing them to take that to their private physician and go over it with them because we weren't making any recommendations as far as what their lab work showed. In fact, we really didn't even look at it. We just stuffed it in an envelope with a letter and sent it out.

Alert values were something that we anticipated. And what I mean by alert values, when you do blood tests, you know, you may discover things that are -- that the patient didn't have.

And so we had several alert values on high sugar or diabetes, some low blood counts, some low electrolytes, some high electrolytes. Some of these were -- these were -- alert values are considered to be potentially life-threatening. And as soon as the laboratory run that we got -- we got a call to the office saying, you know, this lab number -- they didn't have the individuals, they just had the number -- has a whatever it was, high sugar, whatever. And we immediately contacted them and we stayed after that until we got a hold of them. And then we would find out, you know -- and some people said oh, I know it

was high, you know. But most of the time, or a lot of the time, they didn't know. And particularly with some of the things like low potassium, say, which can cause cardiac arrhythmias and very, you know, life-threatening. We also -- I remember one nineteen year old we had with an acute leukemia that didn't know it and was pretty close to getting into trouble. So we ran these down and we followed up the next day to make sure that they had been seen by a medical person to take care of the problem.

I think we had, as I recall, around thirty-five or forty of those out of the group that had the alert values that -- that we had to follow. I mentioned before that momentum was terribly important. We tried to figure out how we could keep that going so we thought the best thing to do was number one, to do focus groups. We had focus groups in Lubeck, Washington, Belpre,
Little Hocking and Gallipolis area. And these were held on almost consecutive days, you might say. And they were carried out -- we watched through a one-way mirror, if you will, and we got a pretty good idea about what the people in the area knew about the litigation, what was coming down the road. And it seemed like the Little Hocking, Washington area was well informed. Even a question come out of Point Pleasant, we don't know -- we never heard of it. So they ran the gambit because if we were going to go out and speak to people in a large venue we

needed to know what they wanted to know and -- and we wouldn't waste our time by talking about a lot of things that weren't pertinent.

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So after we evaluated those, it also helped us determine our TV spots, radio spots, print media and so on; what information -- we printed brochures, a whole lot of detail there. Because we -- we got -- we knew what questions that we needed to answer and answer them honestly and right up front. We felt like keeping them informed over the period of time that we were doing this, you know, to keep -- to keep the interest up was very important, too, to continue to get the participation we were looking for. We subsequently had town meetings on July 11th at Blennerhasset Junior High, the 12th at Belpre Middle School, the 14th at the Point Pleasant Moose Lodge and July the 15th at the Meigs County School for the Pomeroy area. And we really -- well Belpre we had to have two sessions because they packed the -- the middle school gym and so we did one group and dismissed them and brought in another and still didn't get all of them. And every place we went we had a basically standing room only or even out in the parking lots and we passed out brochures and things if they couldn't really hear the presentation. We also conducted meetings with the local physicians to indicate that they would be getting -- what they would be getting from the participants and so they understood

what was being done and they weren't blind-sided with that.

That was not as successful as we would have liked but we did the best we could.

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I had a little summary of what we -- a little summary -when we first started to look at this, what we thought we had to cover and I'm just going to beg your indulgence and just read them. Here's what we -- and this is not all-inclusive but I think it covers the major parts. We looked at the project and said well, we've got to set up a headquarters with the six modular units; we doubled them in Belpre and Lubeck, so that was four of them. The other two single at Pomrey and at Point Pleasant. We had to find locations that had the fiber optic, and the utilities, and the parking and easy access. We needed to decide how to publicize the C-8 Project, which I've touched on, to the public and physicians. We had to hire and train employees. Training procedures had to be determined and that total number come up to a hundred and thirty when we were running full -- full blast. So that was a lot of people to train and get on board rather quickly. We couldn't really start training and hiring them till the seventy million came down in July but we -- we had isolated a lot of names and so on and so we were -- we were a little bit ahead of the curve. We conducted the focus groups; we wrote the health survey; we coordinated all of the information technology issues. We

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determined the process for eligibility requirements, which was -- which varied a lot because, you know, who -- who -- say a delivery guy who goes over from Parkersburg to Belpre and delivers around and drinks a little water, you know, is that -does that qualify them. And he's been doing it for ten years. Well there's a lot of issues that weren't really spelled out in the documents and we had to try to come up with what was a reasonable exposure and how do you prove your exposure. We found out that school records, you had to live -- actually the -- you had to live, work, or go to school in a district for that -- for a period of time that was from 1950 to December 3, for at least one year. So the school records probably panned out to be our best total thing but we used other things like water bills, tax tickets and on and on and on. We have that all listed in great detail. We had to hire the nurses, phlebotomist, for the test sites. Phlebotomist is the one that drew the blood. is a special type of technical person. We had to -- we had to find the laboratories. We had visited two laboratories for the perflurocarbon testing; one was in -- in Vancouver in Canada, the other one was in State College, Pennsylvania. We went there, made an on-site inspection. We selected the lab to do the volume at State College and we used the lab in Vancouver as a quality control lab to make sure that the first -- the lab that was doing the bulk of them, they were getting comparable

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results. And so they -- we also, at that time, when we told them, we said -- they said "How many you going to do?" We said, "Well, we think we could do three hundred and fifty a day." Well it takes a special piece of equipment to run the perflurocarbon test and those things were half a million dollars apiece at that time, I think; or six hundred thousand, somewhere in that range. And they had maybe two. Well they couldn't run -- they couldn't run fifty tests in a day on two. And so they had to kind of take a risk and buy enough of those spectrophotometers to run the test without knowing if they were going to get sixty thousand tests or not. But we thought -- so they -- they bought in and they purchased the equipment and we were -- we were good to go. For the actual blood work, the things like -- that you usually get at your doctor's office, you know, blood sugar, etcetera, etcetera, we used LabCorp. which is a national lab. They had -- they're in Columbus. We also visited with them and inspected them. They could -- they had the manpower to handle this type of volume rather quickly. They were nationwide so if we had people that lived out of the area that wanted to qualify because they could do it online, we -- we would have a place to send them to get their blood drawn. And we had about seven hundred or seven hundred and fifty of those individuals throughout the testing period.

We were able to -- because of the volume we were able to,

again like I mentioned, we were about to bring down the cost of the perflurocarbons as well as the other blood tests with LabCorp. which gave us an opportunity to process a lot more individuals because we could save money in a fixed cost like that and then we could use it to -- to add to the number.

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We needed to determine a process to assure the validity of the survey data; determine the process of scheduling participants; create time models; set-up employee contracts with insurance, rental agreement, utilities and so on and all vendors; determine the process to pay the participants for blood surveys and, you know, we've -- like I said, we would write them a check as soon as they finished. That had to automatically go into the banking system and show that a check had been drawn on the bank and so it was a constant update so that the next -tomorrow they could put more money over in the checking account and so on. And we also wanted to protect these funds with security and we spent a lot of time with firewalls -- that's a computer term -- so some hacker couldn't get into the bank and hack seventy million dollars out of there. So there's a lot -a lot of things to think about. And we determined how we were going to get the medical records and verify the claimed diseases. We would work and be very open and available for the media. Work with the science panel once -- it wasn't empanelled, you know, until sometime later, I think like March

or April -- but we would work with them as best -- you know, see what their interests were and then other consultants that we felt we needed. And then that's when we began to use Dr.

Ducatman quite a bit to offer us advice from his field of expertise, which turned out to be really a very good thing. And then we needed to determine a process for settling any legal matters or questions and try to determine how former residents would -- who had moved away that heard about this and could qualify would participate. So that was quite a -- quite a lengthy list to go through but I -- a lot of detail as we looked at it; and that's not all inclusive, obviously. Things came up during the process that we had to make some mid-course adjustments and so on.

We started the media -- let me get back to my notes so I won't get too lost. So to summarize a little bit, we -- we verified the health survey which included water usage, employment history, military history, past medical history, pregnancy history, family history of diseases and health habits as regard to tobacco use and exercise. The diseases that we asked to be reported to us, and this is not too lengthy of a list but it was -- and some of the diseases maybe some of lay people in here won't -- won't recognize but they may recognize them all -- is Addison's Disease, Lou Gehrig's Disease or ALS, anemia, birth defects, cancer, stroke or cerebral vascular

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accident, Cushing's Syndrome which has to do with a glandular problem, diabetes -- of course sugar -- heart disease, liver disease, lupus -- which is a connective tissue disease -multiple sclerosis, pregnancy complications, Prognoze\* -- which has to do with a spasm of the small arteries in the extremities usually -- rheumatoid arthritis, scleroderma -- which is another collagen disease -- Sjogren's Syndrome and thyroid disease. And they -- if we'd had this probably to have done over we would probably have added a couple. We asked for rheumatoid arthritis, we probably should have asked for osteoarthritis, I think we picked up some when the nurse talked to them because they would confuse one with the other anyway. were able to probably pick up some. Osteoarthritis, although it was not a particular question; and we would have probably asked for Gout which is -- has to do with uric acid in the blood and also it can cause a very painful arthritis. So we weren't perfect in it but we were close. We -- we took advice or we consulted with the science panel to try to see what they were looking for. We were able to tweak it here and there. We also looked at other health surveys, probably four or five. other words, we didn't reinvent the wheel although we did have to tailor-make it somewhat for the water usage and the people moving about, you know, people moving around a lot. So we had to have a lot of address changes and things like that which

ordinarily you probably wouldn't have in a health survey. So it was a -- it was a little bit tailored to some extent but by and large pretty standard questions were asked.

So from July the 8th to July of 2006 was when we closed down the collection of all the specimens. And it -- I think it's -- it gives you an idea of how fast we really moved. And I'm going to read this because I think for the record, [Reading]: On July the 8th we announced that we were ready to begin collecting health information and blood samples from those wishing to participate.

And we had gotten out a lot of TV ads, etcetera, etcetera. In fact there were so many people we had a collection data -people that did surveys were in Vermont, ORC, I believe was the
-- the abbreviation. And we told them that we expected to
really get bombarded. Well what happened was that their servers
would not take the load and that shut us down for three or four
days until they could get enough hardware and get the software
straightened out so -- because we just -- the old term the
computer guys used, we smoked it. And they had to -- they had
to really make some adjustments because they never -- they told
us we'd get two thousand is what they told us. We got twentytwo hundred the first four hours. So -- so, you know, it just it just overwhelmed the system. We began testing on July the
25th at Lubeck; August the 12th in Belpre, Little Hocking

District; August the 25th Pomeroy, Ohio. And on September the 8th the final testing site was opened in Point Pleasant. So by September the 26th we were in full swing in all the six districts. At that time nearly thirty-five thousand people had submitted the seventy-three page document that they needed to take care of. That's about three months. So somewhere around twelve thousand a month that were going into the database, filling out the questionnaire at that time. On October the 27th we had received forty thousand questionnaires. On November the 23rd we were at fifty thousand questionnaires and — and had signed up those people for appointments and blood testing.

January the 13th we reported that we were seeing three hundred and sixty a day, average, in six units. On January the 25th we began to push data, I believe, to the science panel so they could begin their work.

- Q. 2006?
- 17 A. Huh?

- Q. 2006? Was that January 20th of 2006?
- A. No, January the 25th is the date I have here that we began to really feed them data.
- 21 Q. I'm just -- the year was 2006, though?
  - A. Yeah, oh yeah, 2006; I'm sorry. January the 30th we had more than sixty-seven thousand people had submitted questionnaires and we were still shooting for a goal of seventy.

February the 7th we had to stop taking questionnaires because we had exceeded the seventy thousand by a few and we knew with the limited resources that we -- we -- we couldn't -- we couldn't have any more questionnaires. It wasn't fair to have people fill them out knowing that we weren't going to be unable to test them. It so happened, however, that when we got through those and they came to be qualified, etcetera, a lot of them didn't qualify so we were able to open it back up on May the 23rd and take another fifteen hundred questionnaires. And we officially ended in July of 2006, pretty early in July. And total testing was sixty-nine thousand sixty-nine. So we -- we didn't quite get to seventy but we came close. So that was the chronology of that.

So I want to speak just briefly about Dr. Ducatman. We've 
-- once he came on board, probably early fall of 2005, and 
worked -- and worked with us basically continuously ever since. 
And he is head of the Department of Community Medicine at West 
Virginia University School of Medicine and he was very 
instrumental in giving us guidance in certain areas and 
particularly when it comes to assimilating the database and 
clean -- as they call cleaning it so it was -- people who wanted 
to look at the de-identified data would -- could reasonably be 
able to do that. We fed the data, basically, online to the 
science panel by the end of the -- by the end of collection

period; and they were getting it real-time. I think it's in Atlanta.

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So then after we got the data, which it took a lot longer to get the data in a presentable form of cleaning it and so on and making sure there was no identification markers in that one database, and we delivered that to the Court and I don't remember the exact date that we brought it down here but I think it was late 2006 or early 2007; I can't remember that date. But we delivered it along with the demographic data which -- which linked the participant to the data in the database and couldn't be identified. That database, the one that the participant could -- that had their demographic data, their picture, all their documents were scanned and put on disk -- that is under lock and key and can only be accessed through a court order. there's no way that -- that with the database that is open to the public that anybody could -- and we promised that initially -- could identify an individual's result inside the deidentifiable database. And that's -- so that's under lock and key down here at the court.

The serum, that's one thing I kind of haven't mentioned.

When we tested these people, of course they -- the LabCorp. lab only kept the serum like five days because they spin it down and they take off and they run the values. And they only stored it five days which was okay. But when it came to the

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perfluorocarbon testing we determined that it was best that we save any excess serum from the laboratory -- which was the one in State College, Pennsylvania -- and subsequently all that serum, on every participant, all sixty-nine thousand was kept and eventually transferred to the tissue bank at West Virginia University. It's actually the property of the individual person whose serum it is, but it was funded by the class to put in there. And that turned out to be Godsend because after we tested about twenty-five people -- or twenty-five thousand people we noticed that -- we determined that there was glitch -it was determined that there was glitch in some of the results because we had one lab, as I reported earlier, doing the quality against the other lab that was doing the volume. And apparently there was a standard that got interpreted wrong, mixed or whatever, so when they standardized their machine to run the perfluorocarbon it wasn't the proper standardization; we had a glitch. So we had to go back and re-test the -- once we figured out what the problem was, we had to go back and re-test that twenty-five thousand but we had the serum to do it. And then the re-testing was okay; it worked out just fine. There's still serum, I think, on every individual still stored at the tissue It's under restrictive type -- you can't just -- an individual could get their sample if they wanted it. I don't see what they'd want it for but they could. But the -- but in

order for a researcher or somebody, there's a restriction on -on how that's to be used. And as far as I know it will be
stored up there for a long period of time; there was no time
limit on -- on, you know, moving it out. So it's -- that was a
-- that really turned out to be a good move. And although you
wouldn't -- you don't like to have to re-test but sometimes that
happens in a biological world.

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And then I'll just point out what I think was kind of unique about this collection. We basically collected data on an entire exposed population. And ordinarily that's not done that way. You would look at representative -- you would select at random a number, some number, and then you would test those people and then you extrapolate out those results into the population. But this -- this study basically encompassed the entire population, as far as we could tell, that was exposed. We verified the survey information. Ordinarily I think that's not done with the medical personnel. So that turned out to be very important. We were able to -- the medical record verification of -- verification of reported diseases, that again was something unique that usually is not done. It's a very costly thing to do, by the way. But it paid great dividends. We had thirty-six thousand participants to report that they had disease; we were able to validate sixty-five percent of that The reason we couldn't validate them all were -number.

everything from records were destroyed. Remember we had the big floods and the records in Marietta were destroyed? Records other places were destroyed. Physicians had died. The records just got, you know, dispersed out into space and so on. But we did get sixty-five percent of the thirty-six thousand. And the interesting thing we found that the ones -- of the sixty-five percent we were able to validate with ninety-seven percent accuracy. So every hundred diseases reported, ninety-seven of them were -- were verified to be -- that was the -- the participant had reported accurately and maybe sometimes with the help of the verification. So we felt that was -- was -- was different and pretty impressive.

And also long-term storage of serum. That's probably not something that's done at least routinely.

So in a final summary, this was a very large database on a very large population, obviously. I think there's something like fifty million columns of data in the database. I think that's what my IT guy told me at one time. Of course to those guys that's -- you know, that's like your wristwatch but I mean, in our world that's unbelievable -- but he said fifty million columns. I don't know of any health data collection of this magnitude in such a short period of time that's ever been done, to the best of my knowledge. It's an unbelievable wealth of information in this data to be studied on this population for

years to come, notwithstanding the C-8. I'm talking more about

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the -- the blood tests that were done and some of the unsuspected diseases that we found in people. We found several cancers that weren't known about because of the cancer markers. These are grateful people; we saved several lives, probably, over the period of the time. And hopefully that it can be studied in years to come to improve the health status of the Mid-Ohio Valley. And in enclosing, my Brookmar team would like to thank the Court for its confidence in Brookmar in appointing us to undertake this project and hopefully all will benefit from our effort. Q. I don't have any other questions of Dr. Brooks. MR. JANSSEN: No Your Honor. I'm Larry Janssen for DuPont; no questions. THE COURT: I guess I had some question but

WITNESS: I think he'd probably better speak to that because he's studied the database a lot more.

whether it be you or Dr. Ducatman with regard to the diseases.

One thing I want to mention, we have been working on a chronicle; and we don't have it complete and this is sort of what I was summarizing as best I could. We want to get that completed and when we get it completed in the next few months we'd like to bring that down to court to put it in the public

1 record. Okay? 2 THE COURT: Very well. 3 MR. DEITZLER: I don't have any further questions. If it's okay with Court when he gets set down we'll 4 just call --5 6 THE COURT: That would be fine. Thank you, Doctor. 7 MR. DEITZLER: Call Dr. Ducatman next. 8 [WHEREUPON, after being administered the oath, Dr. Ducatman 9 10 testified as follows, to-wit:] 11 DIRECT EXAMINATION 12 BY MR. DEITZLER: Would you identify yourself for the record please, Dr. 13 Ducatman? 14 15 Α. My name is Allen Ducatman. 16 And your profession? Q. 17 Α. I'm a physician and I work at West Virginia 18 University. 19 And Dr. Brooks said you had some additional help with 20 regard to this; did you have other consultants that you used 21 with regard to your work on this particular project? 22 Yes we have -- we have a research team at West Virginia University. 24 Q. Could you just kind of describe what that team

consists of for the Judge?

- A. Certainly, we have on the team -- currently at this moment -- there are three epidemiologists an endocrinologist, a research immunologist, a biostatistician and a number of students. And I'm sure I'm leaving someone out.
- Q. Okay. You -- Dr. Brooks said you were contacted by him or somebody from the Brookmar organization to do something with regard to data. Would you tell the Court what you did and, you know, what -- what your participation was?
- A. Initially Dr. Brooks called me with -- to request to review a project that was to be rolled out in the very near future and to comment on certain aspects that he asked me about. And the other substantive part of the request was that WVU consider being responsible for public affairs back to the people; that is to say to give general information back to the people of the Mid-Ohio Valley about the status of the data and what -- you know, what could be publicly framed fairly quickly. And so those were the two initial roles that Dr. Brooks called me about probably just a month or two before the survey began to roll out. I'm not sure of the exact timeframe but it wasn't long before.
- Q. And would you tell the Court and the public here what -- what you and West Virginia University did with regard to this project?

- A. We -- we did advise, initially -- we did advise Dr. Brooks initially about the -- some questions he had about the survey, some other issues about serving populations. And we did complete a contract with Brookmar to reflect data back to the population. And then the next thing that happened -- something that Dr. Brooks already mentioned -- and that was because of an observation by Dr. Fletcher of the science panel, there was -- there was reason for concern about the quality assurance at the major laboratory. And because of that concern, it was expedient that West Virginia University become intimately involved with the actual data analysis very quickly in order to the figure out if, in fact, there was a quality assurance problem; to characterize it's nature and to figure out what to do about it. And from that moment forward, West Virginia University also began to analyze the database in a scientific way.
- Q. Would you report as to the -- the analyziation of the data that you did, because I understand Dr. Brooks just had millions of columns of data and then you were supposed to convert it into something and then report back?
- A. I think you're asking me about that latter role where we began to analyze the data. What we -- what we determined, based on several rounds of looking at data, was that Dr.

  Fletcher's hypothesis that there was a problem was right on the money that there was. We determined an approximate, within a

couple of weeks date that Dr. Fletcher predicted we would find, concerning the nature of the problem where the levels in blood shifted dramatically for no accountable reason other than a quality assurance problem; and we determined a likely reason and then we went on to re-test people based on the different -- based on a date in the sequence of when they got tested to re-test those serum. The other thing we could have done is modeled the difference. For a variety of reasons we thought it better to re-test those individuals based on the serum they had already donated and which were being stored at West Virginia University.

- Q. Now you've separated the data into cortiles, different -- different types like male-female, age -- that sort of thing -- and C-8 exposure and that sort of thing so it could be reported in a meaningful manner. Could you -- could you tell the Court what you did with regard to that?
- A. You're now moving on from the quality assurance problem to analysis of data, is what --
- Q. Yes.

A. -- I think you're asking me? For -- for any study it's very important to analyze the population data in a way that makes sense. And that's often based on things you already know about -- in case of an exposure -- an exposure of interest. For example, you may already have reason to believe that there will be things that are different about children versus adults;

things that will be different based on age in general; things that may be different based on body mass; things that may be different based upon habits such as smoking or alcohol. Or, in the case of C-8, there could even be some dietary issues. And all of those things are part of different analysis. And then for each analysis it's also good to look at the actual concentration, the biomarker, of the particular perfluorocarbon in the patient's serum. They're not a patient at this point, they're -- they're a participant. And that can be reflected out as cortiles or it can be modeled as a -- as a whole population. It depends on how you want to communicate the data for clearest understanding. Sometimes you do both and then what is reported to a peer review journal and the others available in an appendix. There's lots of ways to look at it so that you do a good study that others can evaluate and investigate and understand what's been done and what the outcomes are.

Q. And you did?

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- A. We did, others have done. Our work is in no sense unique in that sense. We and the science panel did it for this population but many other investigators around the world have done it for other perfluorocarbon populations as well.
- Q. So did -- did you separate it out by diseases, ages, and reach any results that you reported back that you can tell the Court about?

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- Α. There are a fair number of peer review papers. Some for the science panel without West Virginia University, some from the science panel with West Virginia University; conversely, some from West Virginia University with the science panel and -- and a few -- we always do try to collaborate -- and a few from West Virginia University, just us. So there are a number of papers, a number of outcomes, ranging from cholesterol to uric acid, to -- some to be published in the future. are -- I'm on the stand and a little nervous. There are a wide variety of outcomes that we've looked at, even laboratory outcomes or codeable diagnosis outcomes or things that are reported but not really defined as either a codeable diagnosis or a laboratory test, age at beginning of menstruation or the sensation of menstruation would be two recent examples of that. So there are lots of studies.
- Q. I think Dr. Brooks mentioned cholesterol. Is hypercholesterolemia a human disease?
- A. It's -- it's been coded -- so this was done at the time of the ICD-9 and it's coded as a human disease under it.

  If you -- if you -- there are opinions as to whether you should think of it as a risk factor or as a human disease. For me, as a clinician, when people have lipids above a certain level we give them a very real drug, very real side effects, that they may endure. And if I go on the National Library of Medicine

and, you know, and I want to look at cholesterol and disease management, which is the way a physician would do what's called at Boolean search to see, you know, what they would do in the example of somebody who's cholesterol needed disease management, I'm reasonably sure I'd get well over a thousand hits and I think it's probably safe to say over ten thousand. I -- I'm -- I mean it's not a question to counter, it was just a point that this is not a -- it's a real problem. We manage the disease.

#### CROSS EXAMINATION

# BY THE COURT:

- Q. And I guess if somebody came in with high cholesterol and you did absolutely nothing as a physician you'd find yourself back here in Court?
- A. I'm not going to speculate about that, Your Honor. But I certainly wouldn't rule it out.
- Q. Let me ask you, about the quality assurance issue that you touched on, were you talking about what Dr. Brooks had mentioned about the calibration that was done at Penn State or State College, I guess the lab there? Their testing of twenty-five thousand?
- A. Thank you. I don't want to affiliate this with Penn State. I -- we believe that this is -- I think it's reasonable -- very reasonable -- to believe that this was a calibration issue and that it resolved with the resolution of a calibration

issue.

- Q. So it has been completely resolved?
- A. Well, of course, we're no longer getting samples. But we have a paper in which these data are reported and we have the old data about the calibration. But the essential calibration issues already been reported in the methods paper which is in the peer review literature.
- Q. Okay. Just -- just so I can understand as well, because I guess the lingo that -- that you use as far as your profession and the science panel, can it be said that you did testing that you would have determined either no probable link or a probable link to any of these diseases or other issues such as cholesterol or uric acid?
- A. So probable link is a -- is a term this court uses and I may need a little guidance, Your Honor. For sure, beyond a shadow of a doubt, uric acid and cholesterol -- cholesterol more notably -- are associated with higher levels of PFOA. There is zero doubt of that.

For cholesterol and probably for uric acid, I think there's a really good chance that the association is causal, but none of the studies done so far absolutely prove that beyond a shadow of a doubt. That would require, to be absolutely certain, I believe that -- that most people who do these studies would want an enrollment population to be followed over time. And of

course as the exposure goes down there are complexities in doing that. Having said that, we see this in -- we see this in children, the same association. We don't think this is a confounding or risk factor issue. We don't think it's confounding by measurement. If it were confound by measurement I think people would long ago have discovered it; there may be other explanations. I think for those two there's a good chance they're causally associated. And then I leave to others as to whether or not -- because I have not had to think about before whether or not that relates to something about a probable link.

- Q. Well we're not really talking, I guess as far as the science panel, causation and just to use the term that was defined in the agreement. Under 1.49 it says, [Reading]: Probable link shall mean that based upon the weight of the available scientific evidence, it is more likely than not that there is a link between exposure to C-8 and a particular human disease among class members.
- A. If -- okay, so for cholesterol, because we treat the high levels, I would have to say that they are linked. For uric acid, we are not sure that the strength of the association is such that there are necessarily more uric acid gout patient.

  Gout has a number of different causes, one of which is uric acid. So we don't know that; I think there's a good chance but we really don't know. So I'll confine my comments for papers

that have already been published, to cholesterol. I think assuming we accept high cholesterol as a disease that we treat with real medications with real side effects and real consequences for patients, there is, based upon what you read to me, a probable link.

#### RE-DIRECT EXAMINATION

## BY MR. DEITZLER:

- Q. Doctor, did you place the data that West Virginia
  University compiled and any associations that you noted on the
  West Virginia University website?
- A. The initial associations are all on the website.

  However, we rapidly have moved to peer review which we think is actually much more in the population's interest.

I think there's a lot of dedication to this population. As an aside, I would like to commend all the parties to how this activity that, you know, started with a dispute, I guess, has ended up serving the public health of the population. I think everybody who's involved can say we did the right thing here.

And that makes me feel very good. So I guess that's my answer.

- Q. So -- so if the people here in the courtroom want to go to the West Virginia University website they can see the compiled results of the data and any associations that were initially reported or --
  - A. They can see the initial associations but I would

really -- if they're really interested in finding out detailed associations at this point, they would go to the peer review literature. Now we could -- we could also put the peer review papers up onto our website with some copyright issues. They -- they could -- they are, you know, the ones that aren't on web publications already have copyright issues so we have to just point out what they are. But there are a number of them and there are more coming with additional links.

- Q. And then the database itself, would it serve -- as Dr. Brooks has said -- purposes far beyond the scope of this -- this litigation in that it's now available under proper protections from the court if anybody wants to study it?
- A. There are -- there are two ways that the database could and -- only my opinion -- should go beyond. One is in continuing to serve the health of people who are interested to continue to participate if there's a funding source, which is for enrolled populations, often the federal government. And federal government did not enroll this population. So there's some complexity there in finding the means to do it. But that it should happen, this is an extremely rich database. And the central Appalachian area, the people of this region, have unique health issues which are insufficiently studied. And this is an extraordinary opportunity that goes beyond perfluorocarbons.

A second -- and I hope that opportunity, somehow, in some

way, comes to fruition. In addition, right now the only access 1. to the database are the three scientists and my group; and 2 3 there's a reason for that and that is because the data is not de-identified to federal de-identification standards nor is it 4 in the hands of the federal government to ensure that everything 5 is done right. I would love to see, in the future, some fund 6 7 that -- I don't think it would take a lot -- so that we could 8 continue the work that was begun to get this data resource so that everybody who has a scientific question could do what we do 9 with the NHANS, the National Health Assessment Data. Go to the 10 11 right place, you know, get the data. If it's going to be at a level where there's any question about identification or if it's 12 13 to be fully identified, simply, you know, work in the public 14 data set. Both of those conditions for different types of data sets would be a good thing for this population and a good thing 15 for science. 16 MR. DEITZLER: I don't have any further 17 18 questions. Thank you, Your Honor. I have no 19 MR. JANSSEN: 20 questions. 21 THE COURT: You may be excused, Doctor. 22 you. 23 MR. DEITZLER: And the last witness will be very

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brief. Bob Astorg.

[WHEREUPON, after being administered the oath, Robert G. 1 Astorg testified as follows, to-wit:] 2 3 DIRECT EXAMINATION BY MR. DEITZLER: 4 I think everybody in the room knows who you are but 5 0. the record might not, so would you state your name, please? 6 7 Α. I'm Robert G. Astorg. 8 Q. And what was your function with the C-8 Health Project? 9 I was the designated Settlement Fund Administrator. 10 Α. And what is your profession? 11 Q. I'm a Certified Public Account. 12 Α. 13 0. And do you have a report of what was done with the 14 money? 15 Α. Yes sir, I do. You've previously submitted interim reports, as I 16 Q. understand it? 17 18 Α. That's right; and each of those interim reports were, 19 on a limited basis, audited by the accounting firm of Harman and Thompson. 20 21 All right. And all the audits came clear? Q. Yes. 22 Α. 23 All right. And as to your final report, the only Q. 24 thing that's additional is what you did with the last amount of

remaining funds?

- A. Yes, there are two reports after they finished their audit and although there have been more money transactions in and out, the net effect of the between the audited number and the number that I completed with was five thousand dollars.
- Q. How much money was left over from the project after the Brookmar team did all their work in trying to get every person they possibly could from the population to get health history, blood draws, and then get them -- the data examined by West Virginia University?
- A. Eight thousand thirty-one dollars and fifty-eight cents.
- Q. And if that was divided among eighty thousand people, what would that be, about ten cents apiece?
  - A. I honestly can't do it without a calculator.
- Q. You're killing me Bob. So what -- according to the court order, what was done with the -- with the --
- A. It was -- it was -- a check was written to the Good Samaritan Clinic in Parkersburg, West Virginia.
- Q. Now I think my point I was trying to make earlier was that if we mailed a check to all the participants, the postage would be more than the amount that they would get, would you agree with that?
  - A. I would agree with that.

Q. All right. Do you have a copy of your final written report?

# A. Yes I do.

MR. DEITZLER: I'd ask that we mark that as an exhibit and file it with the court if that's okay.

Exhibit is marked as Plaintiff's Exhibit No. 1, Your Honor.

THE COURT: Okay. Thank you.

MR. DEITZLER: And I don't have any further questions for Mr. Astorg.

MR. JANSSEN: Nothing, Your Honor.

THE COURT: You may be excused; thank you.

MR. DEITZLER: Judge, that's all we have with regard to the Brookmar Health Project. And I already reported the DuPont number on the water filtering, which as I said, just is absolutely excellent on their part. I think when we went into the project we thought it would only cost around ten million dollars and they stepped up to the plate with the additional twelve million to get the job done. So it's just —they're a real community partner on that and they deserve to be commended. On the — we receive, as the parties, we receive what's called disbursement requests on what the science panel spends. We don't have an accumulation of those so I can't present that. Garden City Group would have that if the Court feels that it's appropriate to have that put into the record.

THE COURT: What -- what does that entail?

MR. DEITZLER: That will tell all -- all the money that was given to the science panel, who they contracted with, what they spent it for. In other words, tell the public where the money's going that's related to the project, which we get calls all the time about what's going on. And I -- you know, I don't know if we can report that or not.

And then the other thing was the end points on the studies that we had initially reported to the public that -- for instance, the heart disease study will be done in 2008; the community follow-up was -- the longest one 2011. There was an immune function that was supposed to be done -- you know, everybody's asking us these questions and I'm not in a position to present any answers to that to these people here.

MR. JANSSEN: Your Honor, again Larry Janssen for DuPont, the science panel I think is prepared to address those issues. I just want to make the Court aware that in addition to the expenses of the science panel, which are -- which are large. I don't have the exact amount on the top of my head nor is that -- is their work done. And they are just the tip of a very big iceberg here because they have a lot of not only staff but other technical folks working with them. But in addition to that, DuPont, pursuant to agreement and Plaintiffs' counsel and otherwise, have continued on and performed and

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    completed studies -- many studies -- of the Washington Works
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    Employee population and, in fact, I believe there are ongoing
    studies. So there is a massive amount of combined effort at
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    enormous expense being done.
                                  Well is that being made available?
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                   THE COURT:
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                   MR. JANSSEN:
                                  Everything is being made
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    available. I don't know if it's real-time but virtually so, to
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    the Plaintiffs as it is -- and to the -- to science panel?
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                   THE COURT:
                                  What about the public?
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                   MR. JANSSEN:
                                  Well I think that -- I don't know
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    if this is being posted, I know that it -- some of it is already
    being written up and published in scientific journals and that
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    is available. But I don't think that beyond that, at least from
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    my knowledge, that those studies are being sent out in any way
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    to the public. But they -- they are going to Plaintiffs'
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    counsel.
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                   THE COURT:
                                  I'm talking about the expenses
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    with Garden City.
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                   MR. DEITZLER: The Garden City Group, what
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    happens is when the -- to pay for the project, DuPont pays all
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    the bills but they pay into Garden City Group based upon
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    disbursement requests submitted by the panelist. And then each
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    individual disbursement request comes to both parties and then
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    if either party has an objection they can raise it. I don't
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think there have been any. And in -- so the -- but the

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repository right now is Garden City Group. They -- and they --
I assume that they keep tabulated totals of everything, which I
don't have --
                         You don't have any?
               THE COURT:
              MR. DEITZLER: I have the disbursement requests
but I don't have -- we don't get a tabulated total report from
Garden City; and then there's none on file in the Court. And
the -- the -- so if the Court would like to know what money is
being spent and to whom it's being spent, the parties not only
have that, other than Garden City Group which can -- could
submit a report and provide the Court will all that information.
And then that would make it accessible to the public.
               THE COURT:
                              I think it should be made
available to the public. Is there a problem with that?
                              I don't -- I don't see a problem
               MR. JANSSEN:
with that, Your Honor. It's just a -- just a matter of making
the request and getting their up-to-date -- of course it's not
final -- but up-to-date amount spent.
               THE COURT:
                              And I know we were scheduled for
three. I plan on rescheduling the other hearings so that we can
continue. What I will do is take a short break, and then the
science panel, I would like to put them under oath so that they
can give testimony and either side can ask any questions.
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I also felt that DuPont stepped up and did many things and Plaintiffs' counsel have worked together well. I guess my frustration is with the science panel. And I'll just let you know now that, you know, it seems like what was said by at least Dr. Duckerman that he's been able to find -- I quess he was unsure as to the technical use of the word probable link but I guess it raises the question as to I would like know, you're getting paid well to do this and I just don't see anything being done. And you're here today and gone tomorrow and, you know, people live here and they want answers. Some I'm frustrated. I get a report that, you know, you're going to let me know something in July. That's not good. July next year. I would -- and I will propose this now, I'm just so frustrated that perhaps select other names for a different science panel. So we'll take a break; you all can discuss that.

[WHEREUPON, a brief recess was taken at this time after which the proceedings continued as follows, to-wit]:

THE COURT: All right. We're back on the record.

MR. DEITZLER: I think you -- if I understood your last comments before we broke you were going to ask the presentation from the science panel. Since neither party represents the science panel I guess they can just take the stand on their own.

THE COURT: Okay. And then both parties' attorneys can question as they desire. And I don't care who goes first. Whoever wants to come forward?

[WHEREUPON, after being administered the oath, Dr. Kyle Steenland testified as follows, to-wit:]

#### DIRECT EXAMINATION

## BY MR. JANSSEN:

Q. Well Your Honor, with the Court's permission I'll go first.

Dr. Steenland, you were in the courtroom and heard Judge
Beane's comments just before the brief recess that we had. We
can either start with your response to that, if you have one, or
I know that you -- because you met with all counsel here at a
luncheon before we started today -- I know that you had prepared
in advance a short statement or presentation and perhaps you'd
rather start with that; you're choice.

# A. I would. Am I free to do so, Judge?

THE COURT: [Nods head affirmative].

A. I understand that folks would like an answer to this question as soon as possible and that time has gone by. And I would like to say that we have been as diligent as we can in answering this question correctly, because you can answer quickly and wrong or you can answer after adequate times gone by and answer it the best that you can and hopefully be right. And

that's been our job from the beginning and that's what we've been doing.

There are several reasons that need to be spoken to about the strengths and weaknesses of the Safe Health Project data that is the basis for much of the work we've been doing.

First off, it's an extraordinary job -- Paul Brooks has described it -- to collect that much data so quickly and accurately. And it has formed a basis for almost everything we're doing. That said, there's, from an epidemiologic stand point -- from a scientific stand point -- trying to figure out whether you can determine probable links of disease in relation to higher or lower PFOA levels, there's some weaknesses in that data. And there's -- the two main ones are -- what we like to do is know whether people with higher PFOA or C-8 have more disease. And so you need to know who's got disease but you also have to know when they got it. And you have to know about what their PFOA levels, or C-8 levels in their blood, were likely to have been before they got the disease, not afterwards.

So we know from the C-8 Health Project what people's levels of PFOA in the blood were in 2005 and 2006. And we know people have reported history of disease at the time of the Safe Health Project. For example, they may say, I've had heart disease. However, it does not tell us when they had heart disease nor does it tell us what their likely PFOA level was before they had

that heart disease. So if you say someone had heart disease in 1992 we need to know what we think the PFOA level in the serum was before that, not after that. And so that depends on their residential history -- that's where they lived -- how far they lived from the plant; whether they were drinking public water or private water. We spent quite a bit of time reconstructing those residential histories and determining what direction the wind blew from the plant with the particles of C-8 on them; how long it took to get to the ground and how long it took to get from the ground into the groundwater and into the public water system so we can estimate what people have been drinking at what point in time.

That is a major, major thing to do. I -- to go into all the details of it would take a long time, but it is not an easy thing to do. We have completed that effort. We've published a couple and more things are in the pipeline. I think that would stand as a model of how you figured out what happened in the past from what you know in 2005. We had to figure out what the emissions from the plant was in the air; what went to the river; how much the river communicated with the groundwater supply overtime, starting in 1950 when DuPont began manufacturing C-8. And we had to determine how far the particles went before they were deposed on the ground; how long it took to get from the ground to the groundwater. We also had to determine whether or

not people were on private or public water, which is not an easy thing to do because water companies only have some suggestions about that; they can't tell you with accuracy. We had to reconstruct where pipelines were laid. This has been a major thing to do. And it's fundamental, determining whether or not people -- what their levels of C-8 or PFOA were in their body before they got sick, which is key.

The second thing you need to know is not only what water they drank but how long it takes to get out of their body, right? Because if you want to know what somebody had in their body in 1990 before they got the heart disease you need to know over time how much they drank and how fast it got excreted. Well how do you figure that out? In the literature there was some data about that based on about twenty-five people at 3M's plants in Minnesota; it was not adequate. It tells us that in three and a half years about half of the PFOA in your blood disappears.

We thought that this was insufficient data to make a real good conclusion so we -- we planned a study of two hundred people which -- and to the credit of the community, all of those two hundred people have consistently shown up and given us their blood over a four-year period after those water filters that DuPont installed went in. So after the C-8 went out of the -- out of the water we could see how fast it went out of the blood;

that was also critical. So you need to know what people drink and you need to know how fast it gets out of the body. These things cannot be answered quickly and they can't be answered with the C-8 Health Project data.

So, that said, the C-8 Health Project data was key to us because it gave us a list of people; it gave us a lot of self-reported data on demographics; it gave us a lot of stuff on cholesterol and blood measured by LabCorp. And it gave us a place to start, really. Because in our view, we had to follow people further. We couldn't just rest on the laurels of the C-8 Health Project to answer these questions for the reasons I've explained. We need to find out what people have had in their blood in the past and find out when they got this disease. And then we compare disease rates between those with high levels in their blood and those with low levels in their blood over time, not in 2005 but before they got disease.

So from a scientific stand point that is the only way you can answer this question about probable link. That said, we said once we get the data from Brookmar it's going to take us three years to conduct these studies we're conducting. I'm going to describe those studies because there's eleven of them. There's a reason why there's eleven of them.

I've described two, the half blood and the exposure study.

We got the data from Brookmar finalized after the re-analysis of

the errors in the blood that Paul Brooks described, in April 2008. It is now May of 2011. We have finished our research program and collected our data. We are now putting it all together and analyzing it. And I believe we've done pretty much what we said we were going to do. Furthermore, I think we've done it in a pretty fast timeframe for the way these things work in the world.

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So that said, let me describe what we thought had to be done to figure this out. I mentioned the half life study, the study of how fast it gets out of your blood. And I mentioned the reconstruction of exposure over time. So what else did we need to do? Well first of all, we felt we needed to go back and interview these people again and determine what disease they reported, similar to before, but also when they got that disease and any new disease they might have gotten since their measurements in 2005 or what their PFOA was in their blood. so we did that; we interviewed thirty thousand community members who are adults and we interviewed about five thousand workers at DuPont plant. We've done it twice. We have also, in addition, matched the records of those thirty thousand community residents with both the West Virginia and Ohio Cancer Registry, with the National Death Index to find out who died and what they died of; and with the United States Renal Data System to see if they had kidney disease.

We take all these sources of information plus the selfreport. We add to that the medical record validation that we
also are conducting -- which has been mentioned, is a difficult
thing to do -- and which we expect to get the last data delivery
we're going to get which is in September, will be the medical
record validation. So we've interviewed thirty-five thousand
people and we've matched their records to a variety of disease
sources. We've put that together; we've estimated what their
past levels of PFOA were in their blood and we're going to try
and figure out and we're going to report to the Court which
chronic diseases show, if any, a higher rate of disease in
people with more PFOA if their blood over time before they get
sick.

I challenge -- I don't know if I'd say challenge -- other epidemiologist in this world -- but I don't think you can do this a whole lot faster and get a descent answer than we've done it. We are scheduled to report on time, I believe, what we know.

Now let me address the cholesterol question which we've heard some testimony about. We reported -- we got the data in April 2008, final data, from Brookmar. And in the end of 2008 Tony was a --

MR. FLETCHER: October 8th was the status report.

24 BY MR. JANSSEN:

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Α. On October 8th, which was what, five months later, a report to the Court that there was an association between cholesterol and PFOA, which we then published in 2009 or 2010. So we brought this to light, as well as Alan Ducatman at WVU. And the problem is that because you see in the blood of people in 2005 that high cholesterol is related, correlated, associated with higher PFOA you don't know which came first. You don't know if the PFOA precede the elevation of cholesterol. That's a fundamental thing you need to know, that exposure precedes disease. You can't tell that from that data. Therefore one of the studies we designed was what we call the Callback Study. We brought eight hundred people back in, two or three years later -- well probably three or four years later -- after their blood was measured in 2005; and Dr. Fletcher has headed this effort. And we measured their cholesterol again after those filters had been put in. So when the filters were put in the PFOA dropped. So the question is: Did the cholesterol drop? Because if these things are related in some way -- you've got to think about it, if -- if PFOA is higher in 2005 and cholesterol is higher in those people, is that because they -- they run together for some reason we don't understand biologically about how blood and cholesterol works, or is it because the PFOA causes cholesterol to go up? Well you can answer that by -- by bringing these eight hundred people back in and seeing where their cholesterol

has dropped. We know their PFOA has dropped; we measured it again. Those filters have taken it out of the water system. So now the question is: Does the cholesterol drop at the same time? That gives you a whole lot better way to answer the question whether there's a probable link between cholesterol and PFOA.

THE COURT: What happens if they're on

cholesterol medicine?

WITNESS: We take that into account. We know whether they're on Statins and we take -- either take them out or we analyze them separately.

So that's been our approach to that. So that half life study -- excuse me, that Call Back study of eight hundred people not only considers cholesterol but every kind of cross-sectional thing that was measured in 2005 like immune markers, liver enzymes, kidney function. So all that stuff, if it's been elevated by PFOA -- uric acid -- when that PFOA goes down, those things will go down. That's the definitive way to find out about that and that's what we've done. That data's just been delivered to Tony. We'll be analyzing it and we'll be -- we'll be using it and making a decision about whether these bio -- what we call biomarkers -- cholesterol, uric acid, things you can measure in the blood, are related to PFOA.

I won't get into the question of whether hypercholesterolemia is a disease. We -- we'll get into that

but not at this moment. We will say whether we think cholesterol is related to PFOA. And more importantly we'll say whether heart disease is related to PFOA because cholesterol -- you can have high cholesterol and it increases your risk of heart disease but you might not get heart disease. So the question -- the bottom line is, from a health standpoint, did you get heart disease from that high cholesterol and did the PFOA give you heart disease? And we'll answer that question. We'll answer it based on the interviews of thirty thousand people in the community and the five thousand people in the workers.

THE COURT: When?

MITNESS: We'll answer it in July of 2012.

And if we have an answer before that we'll answer before that.

And for some outcomes, which do not depend on the cohort -- long cohort follow-up studies with the interviews, we will make an answer before on probable link. And I'm specifically referring to the reproductive studies. Those studies are independent of several things I've mentioned; they don't depend on these reinterviews that we've done for thirty thousand community residents and five thousand workers. And we should be able to answer the probable link question on reproduction this year, that's before Christmas. I think I'm under oath and I won't swear to a specific date, but that's our goal. And I believe

that's possible.

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Now I want to mention a few of the other studies that are being done. I said we designed eleven studies and I've mentioned a number of them but not all of them. And they're -the reason that you can't do some studies -- one study that's going to answer all these questions about these different diseases. So, for example, we are doing the study of neurodevelopment where we look at cognitive testing and IQ testing in children -- David, correct me if I'm wrong, he's leading that -- five to twelve in that age range. And we've taken -- we've got -- taken these vans out to folks houses and measured, with great cooperation from the community, four hundred kids, if I'm not mistaken. And that will give us a very good answer on whether there's any neurodevelopment relationship between PFOA and -- and these -- these -- these tests we're conducting.

So there's also several other studies that we're doing.

We're doing a geographical study of cancer to see whether areas with higher PFOA historically have had higher rates of cancer on a global basis; that is to say within say a census block group or a zip code. Have those ones with higher PFOA had higher cancer rates? We've had some difficulty getting date from the West Virginia Cancer Registry because they've changed staff.

And what I mean by a difficulty I mean a year, not months here.

That difficulty, I believe, has been overcome. It's not been easy to overcome.

I think I could go on to describe these studies but they are on our website; you can read about them. And every time we find something along the way we report it to the Court in what's called a Status Report. We put that Status Report on the website; it's public the moment we deliver it to the Court. We try and provide information to the public as soon as we can, consistently. And you can read about all these studies on our website. You can read all the Status Reports.

So where we going from here? As I mentioned, we have almost all the data we need now. I think the last will come in September with the medical record validation. We are getting medical record validation of approximately twenty thousand people, which means you have to go to the Cleveland Clinic and the Huntington VA Hospital and the Ohio State University Hospitals and ask them to provide medical records. And they might be a little busy. And if you have three hundred requests that they might not honor them the next day. So that's been a laborious process. It's key -- it's key because we need to know as much details as we can about the disease in terms of the date of diagnosis, again critical, and to validate those self-reports.

So all that said, we hope to take all this data together

and integrate it and then determine whether people with more PFOA in their blood over time have more serious chronic diseases and report on probable links by July, 2012 at the latest. And we say report on probable links, we intend to provide data on whether or not there's a probable link for all serious chronic disease outcomes that have been discussed in the literature that is possibly linked to PFOA.

THE COURT: Well let me ask you something about that, why is it all on that day? Why can't it be as you determine it?

WITNESS: That's a fair question. I -- I -- don't have an exact plan on July 11th, 2012. It could be that we get some done in May and some done in June and some done in July and we will do that if we can.

But as far as the number of such reports, there will be one on each of these chronic diseases that have been associated in the literature, potentially, with PFOA. And I refer to all the major chronic diseases that involve heart disease, stroke, diabetes and cancer -- and cancers not one disease its many -- liver disease and kidney disease. So a lot of major disease classes there.

In addition, we will -- so we'll summarize the evidence for and against and we'll give a judgment that this probably linked or not, in our view. And we will also do that for any findings

along the way which are unexpected, which are not previously discussed in the literature or suspected, but which pop out and say yeah, there's something going on here. So I can't tell you exactly how many status -- probable link reports there will be but they'll be a bunch. And along the way, as we've been doing for the last three years, anytime we find something important that doesn't -- isn't sufficient to tell us the final answer but it's an important piece of evidence and it's sitting in our hands, we report it to the Court and that's called a Status Report. And we will continue doing that until we deliver a probable link. And we will deliver that probable link as soon as we know, as soon as we confidently can say this is what's going on.

That's all I got to say.

### BY MR. JANSSEN:

Q. Now Dr. Steenland, let me ask you just a few questions. Of course you and the other two science panel members were selected jointly by the attorneys for the class and by the attorneys for DuPont, basically me and Larry Winter. And since that time, over the last six years, during you -- during the time that you and your companions have designed these studies have there been any influence or attempt to influence what studies, you do or the design of the studies by any of the attorneys involved here?

- A. No, and I want to congratulate both sides of the settlement for strictly maintaining neutrality. And we are strictly neutral. We don't have an agenda here. We are hired not to have an agenda. We still don't have an agenda. We're not going to have an agenda. We're going to report what we find.
- Q. Over the last six years since you've begun this project, have -- from time to time have you and your other science panel members had face-to-face meetings with the attorneys involved here, both sides?
- A. We have; we tried to continually report where we're going, how we're doing it. There've been no surprises here.
- Q. Yeah. And at that meeting -- and by the way, the meetings are always with the attorneys for both sides together, none of us -- none of the attorneys meet with you separately or privately, do they?
- 17 A. No.

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- 18 Q. Has that ever happened?
- 19 A. No.
  - Q. During the time that we had these meetings, and often times they're telephone conference calls --
- 22 A. Uh-huh. [Indicating yes].
- Q. -- among us, do the attorneys ask questions much like the Judge has asked here? You know, what's going on; how long

this is taking; why is this taking so long?

A. Yes.

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- Q. Why is it costing so much?
- A. Yes.
- Q. And you explain to us until we understand, just basically like you're doing here?
  - A. Yes.
- Q. Okay. So in a sense, none of the angst or questions that the Judge has asked or expressed are anything new to you because you've been hearing it from us, correct?
  - A. Yes.
- Q. Okay. But you keep telling us that taking this
  project on as you have, if you're going to do it by God you're
  qoing to get it right?
  - A. Yes.
- 16 Q. Okay. That's it. Thank you.

## 17 CROSS EXAMINATION

### BY MR. DEITZLER:

Q. Dr. Steenland, on the medical record validation, we, meaning the attorneys and your group, have had some discussion of some difficulties that you all had in getting medical records and I'd like to take this opportunity to have you put on the record for the Court the importance of securing those medical records and the fact that they will be kept de-identified.

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Because what will happen if -- if the facilities, the Cleveland Clinic or Ohio University or whoever you need the records from, if they decline to produce the records based upon a consent from the participant or a consent from the participant's executor if the participant is dead, then what we would have to do is come to the Court and present evidence as to why that information is needed, why it is essential and how it will be protected in return for which we would ask the Judge to enter an order ordering the production of those records. And then we, the attorneys, would have to take that order to the state where the facility is located, probably in the county where the facility located, and ask a judge there to give validity or enter an order in that county ordering the facility to produce the records. And I know from talking to the Cleveland Clinic attorneys that they would -- they would comply with such an order but to do that we really have to have some good factual foundation upon which the Judge can make findings that the records are one, necessary; that the production is lawful and that the identities of the persons will be protected the same as with all the other data. In other -- the -- not only is it important for this Court and this hearing for the purposes of the type of data that you're gathering, it's important to the public health of the world. And so if you could address that. And I know that was a really long question but you're a lot

smarter than I on those topics, so if you could lay that foundation for the Judge in the event that we need that order, then we might be able to come in and file for it later.

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A. Harry, I'm sure you're a lot smarter than I am on these questions, but particularly the jurisdiction of this Court, which I originally imagined Judge Beane could just tell the Cleveland Clinic what to do, which turns out to be not -- not actually the case.

But no, we need the medical records. They're kept confidential because we guarantee to our ethics review boards at Emory University and at Brown University and at the London School of Hygiene and Tropical Medicine that we would keep them confidential and that's how it works. It's -- and we need them because, as I mentioned, we need -- we need to be able to validate what people say and look at those dates of diagnosis. And that's -- that's fairly key to what we're doing. I think we've been able to work around having to go outside of West Virginia, say, and enter into judicial proceedings to try and get these medical records in other jurisdictions. Primarily because, as you know in the case of The Cleveland Clinic, they -- they said well go back to the participants and get a new consent form, a different kind that looks better to us; and we've done that. And that's true of several other medical facilities as well.

And I think that that's laborious because you have to go to five hundred people and get them to sign something again. It takes months. And you don't get them all. But we've gotten most of them and I fully expect that the medical facilities that want the special forms will comply when we deliver those forms to them. So I'm thinking, I'm hoping, that this is not going to go forward as a problem in the future. I think it's been resolved.

Q. Well in the event that it isn't and in the event that you need those records, my recommended procedure would be that you provide a sealed list of the participants from whom you need records --

# A. Uh-huh. [Indicating yes].

Q. -- which would go to the Court for entry of the order. But along with that, if you could explain in just a little more detail, in the event that this would come up, so that you don't have to come back and testify live at that time, just exactly what the -- what the actual necessity is other than -- than speaking in the abstract, well we need them because it's important. If you could just put a little bit more in the record and --

# A. Sure.

Q. Because if you need that, that's the procedure that counsel will follow to try to get you what you need.

# A. Appreciate it.

Q. So if you'd tell us a little more about why they're needed.

- A. Oh. Well if a guy says they had diabetes in 1992 you would like to know, if we went to the medical record, if there's one, they had adult onset diabetes or juvenile diabetes and if they had it in 1992 or they had it in 1989 or whether they just doctor told them they had high sugar in 1992 and didn't diagnose that as diabetes exactly. So you know, you're going to get false positives there where people report diseases that they don't actually have. They may report the wrong disease. And they are quite likely to report the wrong date when they got it. And as I mentioned, it's very critical to us to know the date that these diseases occurred. So I don't know if that answers your question?
- Q. That's a pretty good answer. And I appreciate that you could give a kind of Reader's Digest version; and I think that would be sufficient.

Among the diseases that you mentioned, and one of the questions that we get from a lot of people, is -- and I know it's on your list but I just wanted to tell the Judge and the people about the reduced immune function, for example, which is not listed on the list of diseases but would affect a lot of diseases. Can you assure everybody that that's being looked at?

A. It is. Well we -- in our interviews we will ask,

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"Have you had an immune system disorder diagnosed?" And so again, I think Paul said a lot of these things are validated well. Well immune system diseases are that's not because it's a bit vaguer. It's a -- you can say, you know, I had brain cancer; you're pretty darn sure. But if you said I had immune disorder, you know, irritable bowels syndrome or Crohn's 7 disease, you may not be totally on top of that. So that one's 8 one in particular where -- where we need to -- to get that medical validation. But yes, we will evaluate immune diseases and we will evaluate immune system measurements in the blood, because 12 they're two different things. It's similar to the cholesterol and the heart disease dilemma. One's something you measure in the blood and the others a clinic disease. We will do both. 14 15 Ο. I don't have any further questions. Thank you for your time. 16 Nor do I, Your Honor. Thank you. 17 MR. JANSSEN: 18 THE COURT: Okay. Thank you. 19 WITNESS: You're welcome. Now my other 20 panel members may want to chime in. 21 THE COURT: Okav. 22 DR. SAVITZ: I don't have anything to add unless there's other questions specifically. 23 24 MR. JANSSEN: You might want to identify

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    yourself for the Court and the folks in the room.
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                   DR. SAVITZ:
                                   I'm David Savitz from Brown
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    University.
                   MR. JANSSEN:
                                   Yes, now wait a second. That's --
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    that's -- you're not going to get away that easy.
         You're an epidemiologist?
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                                   That is true.
                   DR. SAVITZ:
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                   MR. JANSSEN:
                                   Yeah. And --
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                   DR. SAVITZ:
                                   Want me to --
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                   MR. JANSSEN: Why don't you --
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         [WHEREUPON, after being administered the oath, Dr. David
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    Savitz testified as follows, to-wit:]
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                            DIRECT EXAMINATION
    BY MR. JANSSEN:
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15
         Α.
              Shall I start again?
16
         Q.
              Yeah, state your name for the record.
17
              Okay. I'm David Savitz.
         Α.
18
         Q.
              And I'm going to lead you in these questions. You're
19
    an epidemiologist?
20
         Α.
              Yes I am.
21
         Q.
              You are now employed at the Brown University?
22
              That's correct.
         Α.
23
         Ο.
              In what capacity?
24
         Α.
              I am Professor of Epidemiology and also jointly with
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0. Are you a medical doctor? No I'm not. Α. At the time that Mr. Winter and I first communicated Q. with you, you were at a similar position at Duke University? University of North Carolina. Α. Q. Ah. That's an important distinction; let the record Α. reflect, please. THE COURT: One has a football team, the other doesn't. BY MR. JANSSEN:

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- Q. All right and then you took a similar position at -
  14 in New York City?
- 15 A. Right, at Mount Sinai School of Medicine.

the Department of Obstetrics and Gynecology.

- Q. That's right. And you've been a member of the science panel from the -- from the beginning?
- 18 A. That's correct.
- Q. And as I appreciate it, the, or a -- one of the main focuses of your inquiry has been to look at reproductive and birth issues?
- A. That's right, reproductive and child development issues.
- Q. That's right. And you may be able to come to your

findings, your probable link findings, one way or another before July of 2012?

- A. That's right, we're anticipating that sometime -- as I said, I wish I could be more precise with it -- but sometime this fall that we should be able to pull together all the relevant information and that would be a sufficient volume and quality of information to make a determination.
- Q. And the -- the -- the point that Dr. Steenland was making about the necessity of determining whether the disease came before the exposure has lesser application when you're looking at what you're looking at; is that correct?
- A. Well that's not entirely true in the sense that we were also dependent on the estimates of exposure, not just the estimate of course, the -- you know, the measurement in 2005 or 2006, but we're looking at pregnancies that may extend back into the 1970s or 1980s. And so we needed these historical estimates to have an idea of what the exposure levels were at the time a given woman was pregnant; that's both for the participants in the C-8 Health Project but also then the community residents more generally.
- Q. Okay. And I appreciated that, I just wanted to clarify that. So the fact that you're able to come up with your findings this fall, perhaps as much as a half a year or more before the others, isn't a matter of simply you were the most

diligent of the team?

- A. No, that -- that I cannot possibly claim. I mean the distinction is that for the adult -- just broadly speaking -- chronic diseases, everything from immune function, cardiovascular disease, cancer and so on are all dependent on the follow-up -- the following forward from the -- the folks involved in the C-8 Health Project, that follow-up that Kyle Steenland is leading and those are all, in a sense, dependent on the same data resource. For the reproductive health measures and the child development measures we are not dependent on that component.
- MR. JANSSEN: That's all I have, Your Honor.
- 13 | Thank you.

## CROSS EXAMINATION

# 15 BY MR. DEITZLER:

- Q. Thank you for taking your time to come down today, and I want to thank you on behalf of the many people of the community that are dependent on your results. And I hope that you understand the frustration level with them and the fact that the case, from their perspective, has gone on and on and on and they feel like they should have had a jury verdict six years ago. So I hope you all understand the concern about that.
- A. And I -- and I am sympathetic. It's the -- it is -- you know, each step of this obviously had its timeline

associated and it's certainly not uncommon in doing epidemiology to -- it's very hard to appreciate from the outside just what is involved and these aspects of it that truly are not under our direct control, that we can wake up in the morning and -- I do wake up in the morning and say what can I do today to move this along? And it is -- in doing the things I can do. And there are issues of just the time to -- to organize the data; the time to get medical record information and so on that truly is not, you -- you know, subject to just the willful decision of the investigators. There's a process, because we're doing research in the real world, it's -- it's some of the real-world processes that we simply can -- have to allow for.

- Q. Are there any specifics that you can add to what Dr. Steenland already provided as to -- to the -- why it takes so long? And the other thing you might clarify, even though you didn't get the final data until 2008, you all had been running data and pretty much knew what direction things were going from the outset, didn't you?
- A. Well we had -- you're right, as Dr. Brooks said, we were getting partial data. But ultimately until we had the clean data -- and I don't mean to imply it was dirty before but it is -- there's a lot of reconciliation and correction to be done -- we really couldn't begin the analysis. We could plan the analysis; we could think it through; we could anticipate,

but until that final data set arrives and it is -- even by the standards of epidemiology -- this is a massive data set. This is quite unusual in its scale that the problems or challenges, if you will, are magnified. That the management of the data, understandably, took some time to get to that point. And there are many parts, if you will, of -- the clock didn't start running until that point, even knowing it was coming, there's a number of things in the time sequence that couldn't be done until that data arrived.

- Q. I guess what I was asking you to assure the public of was that even though you didn't have the 2005 data you knew what additional data you had to draw prospectively and you were already in the process of drawing that data so that the delay until 2008 didn't delay your drawing of the other data that you needed to follow-up?
- A. That's correct, the planning; the acquisition of some of the data sources; the development of the background information for exposure, there was a lot going on, but some things that could only go forward from that point, that's correct.
  - Q. Thank you.
- 22 THE COURT: Anything else?
- MR. DEITZLER: No further questions. I'm sorry.
- 24 BY THE COURT:

Q. I guess -- I'm just trying to understand what each of you do. I know you leave here and you go back to your university; do you work for the university doing other things or are you exclusively dealing with your obligations under this project?

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We all have a mix of responsibilities, other projects Α. that might be funded by the National Institutes of Health or other -- other entities. And in each case we are -- I mean there's some similarities, we are -- ultimately as principal investigators we are the ones responsible for making the work go forward, having it be done correctly. Having said that, and again the -- obviously the invoices will reflect it; there are many other people involved. There are academic collaborators who have some expertise that we don't have but is important to the project. There are -- there are field staff that go out and actually hands-on gather the data. People that, you know, handle the data files and so on. And so we are managing a serious of projects as well as teaching graduate students and so on. And so that there's a -- we try to estimate a certain proportion of our time that is needed to keep this project going as well as it can go. And again, I can see from the outside it might seem gee, if we just devoted all of our time it would go much, much faster. But in -- in the kinds of allocations we make, whether it's twenty percent of our time or thirty percent

-- and again the invoices would reflect that -- that's the amount that we judged would let us efficiently do the things we need to do to keep it going forward, hiring and supervising and sometimes just pushing along. And so we are managing multiple projects that way at any given time.

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- Q. And have you or the other two members looked to get any other grants or anything as it relates to C-8?
- We have not, so far, moved in that direction but we are hoping to. That, as was mentioned -- there's an immediate issue here, of course, of reaching these probable link determinations and we're not let anything distract us from that. But there are also important issues that Dr. Ducatman raised as well about the health of this population generally. We recognize that this probable link assessment and our understanding and interpretation of it is a fairly, if you will, modest level of certainty as science goes. It's not causality; it's not, you know, beyond a reasonable doubt; it's -- we understand the language, at least as we're interpreting it. There will still be many questions when we are done about the health effects of C-8 and other perfluorocarbon chemicals. It's not that we have any illusion that we're going to end that or that that avenue of research will end and we would individually and, you know, to the extent it works that way, collectively be interested in pursuing some of those important scientific

issues. And I would hope that this population and this community, if willing, could help in going beyond that even, beyond the -- the -- the immediate bounds of focusing on the probable link determinations, but to really try to address important public health issues more -- more universally, if you will.

- Q. And I guess it's just my concern and I think you've at least addressed some of it, that they're obstacles that you've faced that caused delay, but I just want to make it clear that the delay is not caused by lack of time on your part or that you're interested in other matters beyond other issues as it relates to C-8 other than looking to see whether there's a probable link or no probable link.
- A. That -- again, I can certainly understand that and that's why I say that I think they're many -- maybe it's sort of an usual job in that way -- where you look at it and if we're spending twenty percent and it's taking us this long well why not spend fifty percent and, you know, cut the time in half.
  - Q. And I understand that that's not the case --
  - A. Right.
  - Q. -- but I just want to be clear that --
- 22 A. Yes.

 $\mathbb{Q}$ . -- you all aren't looking at other issues as it relates to C-8. I mean I think your main focus is to determine

whether or not there is a probable link or there is not a probable link --

A. That's right.

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- Q. -- as it relates to these various diseases that you've outlined, and additionally the other areas.
  - Well, and to be specific, one of the judgments we have Α. to make, and I spoke with the settling parties about this -- we talked about it a little bit over lunch -- the judgment of when do we have enough to make a probable link determination, which is something that obviously there may be varying opinions on. But it's something that as the science panel we have asked ourselves the question. Okay, with the completion of this study, is it now time? Do we have a sufficient level of confidence to be able to draw a conclusion here? And it's something that we are collectively and individually trying to make sure that we don't let -- again, if you will, interesting scientific questions, important public health questions even, tempt us away or distract us from the question of do we have enough under the terms that have been laid out for us -- as we understand them -- do we have enough to make this determination. And we are, again, in good faith doing our best to make sure that we don't persist longer than is needed to make that assessment. It's a fair question and I completely understand; and it is something that we do think about.

Q. Okay.

THE COURT: Any other follow-up?

MR. DEITZLER: I'm beginning to feel like Colombo

here, for those that are old enough to remember Colombo.

#### RE-CROSS EXAMINATION

# BY MR. DEITZLER:

- Q. You brought up one question that a lot of the people that have called me have asked about. When you get done gathering the data on your follow-up, will that be placed in the public domain with the Court the same as the Brookmar data so that anybody else that wants to do follow-up studies will be able to, if properly qualified, do follow-up studies as well?
- A. It's something, again, I don't know if Kyle wants to speak to that but we certainly will fulfill that obligation subject to these issues from the institutional review boards and those who have provided the data. The -- managing the issue of the de-identification and confidentiality to meet the standards that -- I guess federal standards that are applicable to that. And so subject to the confidentiality concerns being managed properly, yes we, of course, will comply with that part of the agreement.

MR. JANSSEN: Are you finished?

MR. DEITZLER: Yes, sir.

RE-DIRECT EXAMIATION

# BY MR. JANSSEN:

of your work, do you not?

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- Q. You're going to -- you all collectively or
  individually -- intend to submit to scientific journals your
  analysis and findings and the supporting data at the conclusion
  - A. Well again, just to clarify, we will -- we will -- we have been and we will continue to generate scientific reports.

    There's not a plan, at least right now, specifically. The probable link determinations per se are a matter for Court. I don't -- again, there may be ways down the road that somehow that makes its way in but we're sort of separating out the peer-reviewed scientific reports from the probable link
  - Q. That was the -- that was the distinction that I was trying to make.
- 16 A. Okay.

determinations.

17 | Q. Okay.

Honor?

- 18 MR. JANSSEN: Now you're ready to move on, Your
- 20 THE COURT: Yes.
- MR. JANSSEN: If you would go back to the jury
- 22 box and there's something poetic about you being in a jury box.
- 23 | Dr. Fletcher would you take the stand?
- 24 [WHEREUPON, after being administered the oath, Dr. Tony

1 Fletcher testified as follows, to-wit:] DIRECT EXAMINATION 2 BY MR. JANSSEN: 3 You came all the way from London for this, did you 4 5 not? Yes I did. 6 Α. 7 State your full name -- we're going to let you talk. Q. Okay. My name is Dr. Tony Fletcher from the London 8 9 School of Hygiene and Tropical Medicine. I'm an epidemiologist 10 there. 11 Are you a medical doctor as well? I'm not a medical doctor, no. 12 Α. You've been a part of the science panel from the get-13 Q. 14 go, correct? 15 Α. Correct. All right. Now you've heard -- you've been sitting 16 0. 17 here and listening to Dr. Steenland and now Dr. Savitz so you know what they said, and is there anything in addition to what 18 19 they said that you think would be useful to bring to the Court's and these folk's attention? 20

I'd like to just amplify one aspect of it which is

that we're both a set of individuals and a team. We're a set of

individuals in that the eleven component studies that -- that

Dr. Steenland enumerated, have been subdivided for practical

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Page 90

reasons so the job gets done. We have sole responsibility, one for each of those activities. And -- although we keep an eye on each other. And then we also work as a team. The objective of making a decision about a probable link for one or more diseases is a team effort on the -- that involves us working together to synthesize and interpret that data.

So I thought maybe to give a specific example, one of the categories of disease on the list is thyroid disease. Now information is being collected on diagnosed thyroid disease. The medical validation will provide confirmation that the diagnostic category and the date given for the diagnosis is correct and that can be linked to the incidents of disease as reported and diagnosed and validated can be linked to potential patents with previous C-8 exposure.

There's also the large data set collected by -- by Brookmar that we're in the process of re-analyzing to see whether or not there are cross-sectional associations between elevation -- shifts in the thyroid hormones or the proportion of people with -- with subclinical thyroid disease that you can only really pick-up from looking at the clinical markers.

We're also re-testing a sample of the population to see whether or not there's a time trend; whether or not there's a longitudinal association. Now we're not doing -- we're not doing that for kind of the luxury of scientific inquiry. That

is part of the evidence that we need to accumulate to judge the plausibility and therefore the degree to which we would assign the probable link to an association. Particularly weak associations with disease, you rely more on the supplementary information about the plausibility of the mechanisms that we get from -- from looking at the clinical markers.

So -- so we're in -- different members of us are leading on different components of that information but we then bring it all together and -- and we had to wait -- in that example we have to wait until the data that takes the longest to collect, which is the -- the cohort data -- is ready.

- Q. And just in case folks are interested and they probably are, what particular studies or aspects of this have you taken on?
- A. I've been involved in three studies of those -- those eleven. One is a section of outcomes that we're looking at in relation -- in the large data set, the C-8 Health Project data set, focusing in particular on immune markers, thyroid disease, liver disease -- sorry, liver function, kidney function, immune function. And the geographical cancer study looking at geographical presence of cancer in relation to -- to -- to patents of C-8 in the community. And the third is this -- this repeated markers, calling in the eight hundred people to get -- to get repeated measures, focusing in particular on shifts in

## immune function.

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MR. JANSSEN: That's all the questions I have, Your Honor.

I would like to point out something for the Court, if I may, because it's often lost in the -- in the shuffle. When you were reviewing the agreement -- the Settlement Agreement as I know you did. You told us you did. You saw a provision in here about -- something about three years and the anticipated time it would take and that was one of the bases for the settlement. Ιſ -- if -- if -- this fact sometimes gets lost, this Settlement Agreement, when it was negotiated and executed by the parties, did not contemplate the -- the Brookmar data. It didn't --Brookmar was not part of any discussion. What the Settlement Agreement provided was that DuPont would pay, among other things, seventy million dollars to the class. You know, for class purposes as described here. The counsel for the Plaintiffs decided, and I'm not arguing one way or another about that, but decided that one of the main purposes of the Settlement Agreement would be to collect this broad data that Brookmar did so that what would happen is that this Settlement Agreement contemplated one thing in terms of studies and then all of a sudden we -- we are faced with -- and the scientists are faced with -- the world's largest collection of data so far as we know -- as you heard Mr. [sic] Brookmar say. And he

described the logistic issues with that, but they were similar issues for the -- for the science panel as epidemiologists.

THE COURT: And I guess my frustration was, and I heard what Dr. Brooks said on behalf of Brookmar --

MR. JANSSEN: Yeah.

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THE COURT: -- but I get the sense that -- I mean he was able to, through his company, accomplish a lot and do very well in a short amount of time. And I'd almost -- you know, I just hate to say this, but I would think if it was turned over to anybody else they might still be working on the questionnaire. And so I guess that's my frustration. I feel like, you know, I needed to hear what was happening and -- and, you know, have an understanding. I think we need to set these more often. And I would encourage, because what they've been able to share just in this short amount of time, that we have another hearing and -- and I don't plan to participate but if you could do something to allow the public to come forward and ask the questions because I think that's what gets lost. You know, I'm hearing that people are tired of hearing about C-8 now because they just feel like nothing is being done. And I understand that frustration. And in my looking at this, you know, I question it and that -- that was why I wanted to share that with all of counsel and the science panel. And I think that's what the community wants to know because obviously, you

know, the members here that are in this courtroom care and want answers. And they've been able to understand at least part of what's going on. But I would suggest that — that between you two and the science panel members that you set something else up here to allow the public to come forward and ask questions in a forum that can be administered in some way so that — that you all aren't fielding all these calls. And I appreciate knowing that some of this information has been available online.

But I also would like information from the Garden City as are the expenditures. That's another separate aspect that -- that I would like to be able to see and know what's going on as well.

MR. JANSSEN: Well Your Honor, thank you for calling this. I think it's been very, very useful and I think - I think it's absolutely critical for all the parties and for the Court not to -- to do -- do anything without really hearing what they have to say that would in anyway immune the -- or cause -- raise doubts about the integrity of the science panel members, or the process or their work that they're doing. Because the whole reason for doing this is to get the right answer for these people. You know, and -- and if these people somehow lose confidence in it, they think it's not being done right, then -- then that doesn't -- that just doesn't serve any of us. So I didn't want to preach but I feel strongly about

this issue. We've collectively put a lot of our professional lives into trying to do this right.

MR. DEITZLER: I had a question for Dr. Fletcher.

#### CROSS EXAMINATION

# BY MR. DEITZLER:

- Q. On the determination of the plausibility of the mechanisms, your probable link determination does not require any peer review or publication first, does it?
- A. Not formally, but I would advocate that where we -where interim findings are coming out, that a part of the
  evidence on which we would base the probable link and can be
  made public as we do in a status reports as soon as -- as soon
  as we know that. When they can be submitted for peer review, I
  think it's a form of quality assurance that can instill extra
  confidence in the validity of those results.
- Q. I understand in the scientific community you have peer review of causation, but is there such a thing as peer review of probable link?
- A. No, I mean that -- the language of probable link I've never met before and I haven't seen in any other context than in these kinds of court cases.
- Q. So you will not be waiting for any peer review or publication before determining -- making your probable link determination?

- A. Correct, no I wasn't -- when I was talking about peer review I was referring to specific statistical findings, specific results --
  - Q. Okay.

- A. -- which would be part of the evidence on which we based the probable link. But as I think we're -- we're clear in order to meet the deadline that we've announced. But we will, as soon as we have sufficient information to be able to make a probable link, we will do so and you'll be the first to know.
- Q. Okay. Well thank you for making that clarification. So basically when you're talking peer review you're talking peer review of the statistical analysis and not peer review of the probable link?
- A. Yeah, the specific papers like those that have been already referred to, yes.
- Q. But the -- but the probable link findings will not be held up based on that and then --
- A. No.
- Q. We're getting these questions about, you know, why -why is it being held up and that's the only reason I was asking
  that.
  - A. No, it's not -- I'd like to emphasize that our work program is not and will not be held up by the peer review

process because that can take six months, nine months to -- to - to get a paper approved for publication as you can tell from
the time difference between the Status Report that you see and a
subsequent paper appearing. And I can imagine you could be
angry if you had to wait a year in between us knowing and you
knowing. And we will not be doing that, no.

- Q. Have you ever done an epidemiological study before where there was a large population and the entire population was sampled?
- A. This is unique and it's no secret that the four hundred dollar incentive is -- is ten times or more higher than the normal incentive payment offered to participants in any kind of community study. And that, I guess, was part of the very high take-up. But it's -- it's extraordinary. I mean it was ninety percent or more. And a common response rate in a community study is twenty or thirty. So no, this -- this provides a very high quality set of information because of that high participation rate.
- Q. So in your -- your career as an epidemiologist, generally speaking, you don't get to study the whole population like this, you only get a sample of the population which then is limited by the statistical validity of the samples?
- A. Well there's two issues with taking a sample. One is that the number is smaller so there's a bit more uncertainty

which is -- which is one form of limitation. But the other is 
- is -- is that it's -- there is a -- there is a -- a refusal

rate which means that the sample won't necessarily be

representative. And here you've actually solved both of those

problems by having the whole population so that the size and

therefore the statistical precision is very low but also the

bias is very low because you have such a high participation

rate.

- Q. So what Larry Janssen has pointed out that you've got a lot more data than we anticipated, that's a positive instead of a negative?
  - A. Without a doubt; yes I agree.
- Q. Thank you.

THE COURT: Nothing else?

MR. JANSSEN: Nothing further, Your Honor.

16 THE COURT: Okay. Thank you.

17 WITNESS: Thank you.

18 | THE COURT: Counsel have anything else?

MR. DEITZLER: No Your Honor, thank you for asking us to come and provide a status report. I think it's been very helpful to us as we field calls from not only our eight hundred to a thousand clients that are registered as clients but we get calls from all members of the class, which has been reported is estimated to be sixty to eight thousand

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people. We know there are sixty-nine thousand nine hundred some, or whatever the number was, actual people and they're calling and asking us what is going on. And -- and I just -- I appreciate the Court having all of us appear before the Court and report the status. I think it was important for them to know what -- what the Brookmar people did with regard to -- to their work with the money that was allocated. I think it's important that they know that DuPont went far above their initial estimate of what it would cost to do the water filtering. And -- and really DuPont has gone far above what the estimates were for the science panel. I think the initial estimate was that the science panel would cost about five million dollars I think their -- their financial report, within the corporation, which is over thirty million dollars, so --MR. JANSSEN: It's more than five million. But you'll -- you'll -- you'll see the exact amount when we get the data from Garden City. MR. DEITZLER: Did you want to give a timeline for that? I assume Garden City can put it out pretty quick? Should we just jointly file it? MR. JANSSEN: I think what we do, Mr. Deitzler, is we'll do it the way we customarily do it. One of us -- we will take the burden of doing that. We'll communicate with Garden City, copy to you, making the request. And we'll hear

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   what they have to say? And I assume that they'll say here it
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   is.
                   MR. DEITZLER: I always appreciate it when the
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   hourly attorneys take the lead.
5
                   THE COURT:
                              And if there's a problem with --
   with them furnishing it then we'll invite them here. But
6
   hopefully it will be forthcoming.
7
                   MR. JANSSEN: I don't anticipate a problem.
8
9
                   THE COURT: Okay.
10
                   MR. JANSSEN: It's -- there's -- there's no --
11
    there's no secret about it. It's just that I didn't think that
12
    it would be something that would be of interest to the Court.
13
    But I understand what you're asking and why.
14
                   THE COURT: Okay. Thank you. Thank all of
    counsel.
15
16
                   MR. JANSSEN: Okay.
                   THE COURT: All right. We're adjourned.
17
18
    Thank you all.
19
                                ---000---
20
21
22
23
24
```

1 STATE OF WEST VIRGINIA, 2 COUNTY OF WOOD, to-wit: I, Stacy Harlow, Official Court Reporter, Certified Court 3 Reporter, and Notary Public in and for the State of West 4 5 Virginia, hereby certify that the foregoing is a true and accurate transcript of the proceedings reported by me, and 6 herein translated into the English language. 7 8 I certify further that I am neither counsel to nor attorney 9 for any of the parties herein and have no pecuniary interest in 10 the outcome of the same. 11 I certify further that the transcript within meets the 12 requirements of the Code of the State of West Virginia 51-7-4, 13 and all rules pertaining thereto as promulgated by the Supreme Court of Appeals. 14 When spellings are in question, the words are spelled 15 16 phonetically and marked with an asterisk (\*). 17 IN WITNESS THEREOF, I hereunto set my hand and affix my 18 seal of Office at Parkersburg, West Virginia, on the 6th day of June, 2011. 19 20 21 STACY HARLOW Stacy Harlow 22 Official Court Reporter 

My Commission Expires: August 25, 2019.

Notary Public

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