First Quarterly report, covering the period up to June 30 2005

The Science Panel began its work in March 2005. In March discussions started on the administrative and contractual arrangements, as well as the scope of the Science Panel's work. The first teleconference between the settling parties and the Settling parties took place on March 23. April was dedicated primarily to familiarizing ourselves with the literature and other documents related to the court case, which was largely supplied by both settling parties via CDs and hard copy. A large amount of the material supplied was unpublished. The published literature regarding health effects among humans was concentrated in a few epidemiologic studies of workers, most of which were either cohort mortality studies or cross sectional studies of hormones and cholesterol. It was perceived early on that the science panel should communicate with the Brookmar team concerning our assistance to their work and vice versa. A telephone conference involving the settling parties and Brookmar and visit of the Science Panel to Parkersburg, were scheduled and took place.

In May again we ontinued to explore the literature. In addition the Science Panel traveled to W. Va to meet with Dupont representatives at the Washington Works Plant and with Brookmar (conducting the health study) on May 20. This meeting proved very useful to the panel to understand the production process, appreciate the scale of emissions of C8 from the plant, and the nature of the community health study being conducted by Brookmar. A major conclusion of this trip was the need to work with Brookmar and build any future epidemiologic study upon their baseline data (blood samples for measuring C8 as well as clinical chemistries, and questionnaire with health and demographic data). Given that the Brookmar project envisions studying the entire population at risk in the area, it is logical that more extensive studies by the Science Panel should build on the Brookmar effort. A separate communication report has been provided by the Science Panel on the May 20 trip was delivered previously to the Garden City Group.

Subsequent to the May 20 trip separate efforts were made to discuss C8 issues with other scientists. Dr. Fletcher had some discussions with 1)David Ozonoff, a member of the EPA SAB Panel on PFOA, 2) David Warner Chemistry Professor in University of Massachusetts at Lowell who works on fluorinated surfactants and biodegradable substitutes, and 3) Michael Warhurst who works on chemicals policy at Lowell had earlier worked on chemicals policy in Europe on classes of chemicals including reviewing data on pfos and pfoa, Dr. Savitz had discussions with Dr. Emmett of the Univ of Pennsylvania who is conducting a cross-sectional medical study of approximately 400 residents living near the Washington Works Plant. This study is nearly complete and is similar to the Brookmar effort in that blood is being collected for measuring exposure and clinical chemistry, and a questionnaire is being administered.

Discussions of the draft contract took place with the GCG and settling parties and a modified text was agreed and signed by science panel members. Further

correspondence took place on the clause related to publication and a response to the revised proposed text was submitted by the science panel. At the time of writing we await the settling parties' response.

In June members of the Science Panel worked with Brookmar to revise the existing questionnaire which will be used for their study. Science Panel members argued that Brookmar should use validated questions from national surveys (NIEHS and NHANES surveys conducted by CDC), and spend considerable time preparing and submitting detailed proposed revisions to the questionnaire to gather information that was judged to be more useful, more valid and more comparable to existing survey data then in the draft we had seen. This involved contacting NIEHS and NHANES personnel, obtaining the questions used by these surveys, selecting out the relevant questions, and forwarding them to Brookmar. The Panel has had only limited success, however, in convincing Brookmar to use these questions. Nonetheless, we believe the current version of the questionnaire is improved over the original version.
Part of the problem was that Brookmar was under considerable time pressure finalize the questionnaire, and by the time the science panel had established channels of communication and cooperation with Brookmar it was not long before the deadline they had set themselves for completing their tasks..

The Panel also worked with Brookmar in June to develop a comprehensive list of the clinical chemistry tests which are going to be done with the blood samples, and in prioritizing which tests are most important when an insufficient amount of blood will be drawn to do all the clinical chemistry tests. The Science Panel believes that measurement of C8 is most important, followed by storage of a small amount of blood for future use, followed by measurements of lipids and hormones. .

An important issue regarding the Brookmar study is the plan to store some small amount of blood (eg, 5 ml) for possible future use. No use of this blood would be made without explicit future consent from study participants, however. It is quite possible that in the future the Science Panel may need to evaluate some things in the blood which were not evaluated in the baseline clinical chemistry, including genetic material. Indeed it would be anomalous for a study of this side not to set aside some blood.

During our meeting with Brookmar and on regularly since, by correspondence and teleconferences, the science panel has been in extensive discussion with Brookmar and to the settling parties regarding the ability of the Science Panel to re-contact the participants in the Brookmar study, and the nature and timing of informed participant consent to do so. The Science Panel strongly advocates a request for consent made during the initial visit authorizing possible future contact by the Science Panel and/or access of the panel to the personal data collected. Alternative suggestions for a later second consent form permitting Science Panel contact, which would be mailed to Brookmar participants, and

mailed back to Brookmar, were felt by the Science Panel to be inadequate and likely to yield a very low positive response rate compared to a face-to-face consent at the time of the blood collection. This is an important issue because the Science Panel will recommend future followup of the Brookmar study participants as key to future epidemiologic studies to determine the health effects of C8.

Because of the Brookmar's timetable of aiming to start fieldwork in mid July and thus the urgency of responding to requests from Brookmar on the above matters, the Science Panel has prioritized advising Brookmar and resolving the outstanding issues on data access and consent, over the detailed preparation of our research protocols. We will be able to return to focusing on developing our protocols and formulating a timetable, once the arrangements with Brookmar have been settled.

Quarterly report, Oct 1, 2005. Science Panel

July

We continued to work on the consent form issue. Brookmar rejected our proposal to include the language we need as additional consent questions to the Brookmar consent form, asking for Science Panel access to personal identifiers for the purpose of linkage and re-contact.. We responded on July 15 with a memo to the settling parties re-iterating our desire for an addition to the Brookmar consent form.

Drs. Steenland and Fletcher participated in a phone call July 14 with David Boothe and Andrew Hartten of Dupont, as well as counsel for both settling parties (silent participants), regarding the fate of C8 emissions from the Washington Works plant, including deposition in the water system over time.

The Science Panel drafted some preliminary outlines of the work they plan, as well as some timetables for this work.

August

In early August Dr. Steenland and Dr. Ryan of Emory (consulting on project) continued the discussion about emissions of C8 from the Washington Works plant and its deposition in the water system, in a phone call with David Boothe, Andrew Hartten, and Dr. Pausterbach, who has authored an article on the question as a consultant to Dupont. Dr. Barry Ryan of Emory also participated in this phone call.

A long phone call was held between the Science Panel, the Settling Parties and Brookmar trying to resolve the consent form issue, but no resolution occurred. Brookmar continues to refuse to change its consent form to give the Science Panel access to personal identifiers, and the Settling Parties cannot agree on this issue.

September

Dr. Steenland began work to hire a data manager to receive the Brookmar data without identifiers at Emory. A person was identified, and paperwork was begun, including an IRB submission. A proposed contract between Emory and GCG was written and sent to the Settling Parties.

The Science Panel wrote a letter to Judge Hill through Garden City, asking for a ruling on the issue of the consent form.

October 2005

The reply to the Science Panel letter to Judge Hill indicated that that the Science Panel lacked standing before the court, that the Settling Parties would need to file the request on behalf of the Science Panel. The Settling Parties asked the Science Panel if we wanted them to do so, and we replied yes. Instead the Settling Parties then reached agreement on this issue, and requested Brookmar to agree to our consent form proposal. Brookmar agreed to do so.

The Science Panel drafted a preliminary plan of research to be presented to Brookmar and the Settling Parties.

Emory IRB approval was granted to receive the de-identified C8 Health Project data and a contract was agreed upon to pay the data manager.

The Science Panel went to W Va on Oct 27-29 and met with Brookmar. At that time details on the new consent form and a handout to accompany it were agreed upon. The question of money to implement the new consent form was discussed, as was the introduction of the consent form in the middle of the C8 Health Project and the need to re-contact past participants to seek their consent. The Science Panel also presented their plan for research.

The Science Panel met on Oct 28 with Dupont scientists Robin Leonard and Bobby Rickart. We discussed the progress of the Washington Works mortality update.

The Panel met on Oct 29 with the Settling Parties in Charleston and presented its plan for research. The fact that a two-phase approach (association studies followed by probably link studies if necessary) was impractical was discussed and accepted by the Settling Parties. The Science Panel later sent a memo setting out the arguments for a one-phase approach to the Settling Parties. The implementation of the new consent form by Brookmar was discussed, as well as how to pay for it.

November

The Science Panel worked out in detail the new consenting process and signed an agreement with Brookmar to consent current C8 Health Project participants as of Dec 5 and also to attempt via mail and phone to consent past C8 Health Project participants starting in January. The agreement included a budget for Brookmar, to be paid out in increments via Garden City Group. Brookmar agreed to ask for participants' SSNs as at the same time they ask for consent for the Science Panel to have personal identifiable data for the purposes of record linkage with registries and possible re-contact with C8 Health Project participants.

A Frequently-Asked-Questions sheet was agreed upon by Brookmar and the Science Panel and went up on the Brookmar Website. It covers the relationship between the Science Panel and Brookmar.

Discussion between Dr. Steenland and the Emory IRB regarding the consent resulted in a ruling by the IRB that the Brookmar study was court-mandated and HIPAA-exempt, and not under the jurisdiction of the Emory IRB. It is likely that some variant of that ruling will apply to future studies conducted by the Science Panel. Dr. Fletcher also consulted with the IRB regarding the consent process and obtained approval for his IRB for this process.

Discussions were begun with the W Va and Ohio cancer registries, exposure assessment groups, and vital statistics groups regarding a proposed meeting between the Science Panel and these groups in January 2006.

December

Consenting for the Science Panel for current C8 Health Project participants began Dec 5 and apparently has a 90% positive response rate, although to date no quantitative data have been provided. It was further agreed that Brookmar would enter the SSN electronically from the consent form, in addition to providing a flag electronically indicating whether or not the participant had consented.

The Science Panel developed detailed plans for a press conference to announce its work to be held in Parkersburg, W Va, on Jan 25. It hired Salter and Ass. to handle the details of the press conference. It was agreed that the mailing to ask for past Participants to consent to Science Panel access to their personal identifiable data would begin right after the press conference. Detailed plans were also adopted for meetings with Ohio and W Va health authorities on Jan 24 and Jan 26.

A large batch of Brookmar data without personal identifiers was received by the Science Panel. Initial inspection of the data included developing the distribution of C8 exposure by age, location, sex, etc. Detailed plans were adopted for working with the data and developing common SAS data sets.

Jan/Feb/March (1st quarter) 2006, Science Panel

Consultants:

Dr Barry Ryan, Emory Univ, works on exposure assessment project, has signed confidentiality, independent consultant (hourly) but will move to university contract
Dr Scott Bartell, Emory Univ, works on exposure assessment and C8 half-life project, has signed confidentiality agreement, independent consultant (hourly), but will move to university contract
Dr Frances McCarty, Emory Univ, works on data processing, does not yet have access to confidential data, independent consultant (hourly) but will move to university contract
Dr. Beate Ritz, UCLA, will review Science Panel protocols, independent consultant hired for specific task with fixed fee
Dr. Dan Wartenberg, Rutgers Univ, will review Science Panel protocols, independent consultant hired for specific task with fixed fee
Dr. Matt Longnecker, NIEHS, will review Science Panel protocols, independent consultant hired for specific task with fixed fee.
Dr Frances McCarty, Emory Univ, works on data processing, does not yet have access to confidential data, independent consultant (hourly) but will move to university contract
Dr Giovanni Leonardi, UK Health Protection Agency, has been working on project protocol development. Reimbursed through contract with HPA.
Ms Kiran Nanchahal and Ms Neela Shah, London School of Hygiene and Tropical Medicine, have been working on background research and administrative support for project protocol development. Reimbursed through contract with LSHTM.

Proposal Development

Throughout the first quarter of 2006, the Science Panel was focused on gathering the needed information to develop detailed study proposals. This involved meetings with a series of collaborators at Brookmar, DuPont, Ohio and West Virginia Health Departments, and state Environmental Protection Agencies. We needed to determine what data would be available pertaining to both C8 exposure and health outcomes of interest in order to design studies that would be feasible and provide the information needed to address our charge. In addition to the specific meetings noted below, there were ongoing discussions among Science Panel members by telephone and e-mail, and discussions within each of our institutions among collaborators with whom we will do the research that is being planned.

January

The Science Panel visited Ohio Dept Health in Columbus, Ohio, and the Ohio DEP in Logan, Ohio1, to discuss collaboration in planned ecologic studies as well as to discuss exposure estimation.

The Science Panel gave a press conference in Parkersburg, W Va to announce its future research program and also met with Brookmar.

The Science Panel met with the W Va Bureau Public Health and the W Va EPA to discuss collaboration in planned ecologic studies as well as to discuss exposure estimation.

Science Panel set up public website or Science Panel activities and email account to deal with queries directed to us concerning consenting arrangements. Responded to about 10 queries shortly after the press conference.

Feb

Dr. Steenland had a phone call with Dupont to discuss a possible cohort incidence study of workers at Dupont's W Va plant, and a followup meeting was planned at Haskell labs for March.

March

Two members of he Science Panel met with Dupont at Haskell labs to discuss their cohort mortality study and job exposure matrix, and to discuss a possible cohort incidence study of workers at the Dupont W Va plant to be conducted by the Science Panel.

Dr. Steenland, Dr. Bartell, and Dr. Ryan had a phone conference call with Dennis Paustenbach regarding exposure assessment. A follow up meeting was planned to May in Pittsburgh between the Science Panel and Drs Bartell and Ryan with Dr. Paustenbach and staff.

April through Sept (2nd and 3rd quarters) 2006, Science Panel

Proposal Development

Throughout the first quarter and second quarters of 2006, the Science Panel was focused on writing detailed study proposals, having them reviewed, revising them, and finally sharing them with the Settlemnt Parties in July. In August and September the Science Panel has been focused on getting these protocols through our respective universities and getting IRB approvals.

April

The Science Panel had a phone conference with Brookmar regarding the ongoing consent process. Protocol development continues

May

The Science Panel traveled to Pittsburgh to meet with Chemrisk regarding their work in exposure estimation for C8 in the water supplies around the Wash Works plant. DFurther development of protocols.

June

Submission of draft protocols to 3 person peer review panel. Responses from peer review panel received, incorporated, and final protocols prepared.

July

Two members of the Science Panel met in NY with the Settlement parties and shared with them 10 protocols and corresponding budgets. Analyses were conducted by 2 Science Panel members on trends in C8 measurement over time in the Brookmar data.

August

The Science Panel met via phone and also had a conference call with Brookmar on further consenting and other issues. IRB packages developed. First budget/protocol packages submitted to respective universities.

September

Summary abstracts were prepared for eventual posting on the Web. Contact was made with several possible companies to handle public relations. IRB packages submitted. Budget/protocol packages submitted to respective universities. More budget/protocol packages submitted to respective universities.

Quarterly report, Oct-Dec 2006

Oct: the Science Panel worked on preparation of a November press conference to announce its research agenda and further recruitment of study subject via an appeal for more consents from C8 Health Project participants. Work continued on getting contracts between universities and the Garden City Group, as well as with university IRBs. LSHTM IRB approval granted for geographic cancer study and reanalyses of C8 Health project data.

Nov: On Nov 13 Tony Fletcher and Kyle Steenland traveled to W V and Ohio and met with the Dept of Health Services in Charleston, with the Mason County Commissioners, and with WVU Parkersburg faculty. On Nov. 14 Drs Fletchers and Steenland held a press conference to announce Science Panel studies, met with the Settling Parties to try to resolve any problems in conducting the Worker Cohort study, and met with the Washington County Commissioners. On Nov 15 Tony Fletcher went to Columbus and met with OH Department of Health to discuss the Geographic Cancer study, to Morgantown, Pittsburgh and Baltimore to discuss design issues and select lab for immunological work (Johns Hopkins was chosen). Work continued on getting contracts between universities and the Garden City Group, as well as with university IRBs.

Dec: The Science Panel had a phone call with the Dupont Epidemiology Advisory Board regarding the Worker Cohort study. Work continued on getting contracts between universities and the Garden City Group, as well as with university IRBs; work continued on protocol development and preliminary analyses of C8 data at LSHTM.

Quarterly report Jan-March 2007

January: The Science Panel had a conference call with Brookmar to discuss various issues, including when the final data set from the C8 Health Project might be ready. Work continued on getting contracts between Emory University and the Garden City Group, as well work with the Emory IRBs. Contracts between Mt. Sinai and Garden City Group finalized, and Mt Sinai IRB approvals obtained.

Feb: The Science Panel had a conference call with the Dupont Epidemiology Advisory Board regarding the protocol for the Worker Cohort study. Subsequently revisions to the protocol were made by Kyle Steenland. Work continued on getting contracts between Emory university and the Garden City Group, as well as with university IRBs. Contract between Mt Sinai and sub-contractor Battelle put in place. Feb 12-13 Tony Fletcher traveled to Boston University and the University of New Jersey to discuss design issues in the geographic cancer study. On Feb 14-16 he attended Society of Toxicology, Current Concepts meeting on PFOA, Arlington Va. On Feb 16 he travelled to Chapel Hill NC to meet with Battelle and review progress in geocoding work.

March: Emory IRB approvals obtained for five Emory studies. Work continued on getting contracts between Emory university and the Garden City Group; work continued on protocol development and preliminary analyses of C8 data at LSHTM. Science Panel members had a conference call to discuss data requirements for the C8 exposure assessment. David Savitz had a conference call with the Ohio and West Virginia health departments to initiate procedures for accessing and using birth and death certificates.

C8 Science Panel Quarterly report, April-June 2007

April:
Contracts were signed between Emory and GCG for all five Emory studies. At the end of April Science Panel members Steenland and Fletcher visited Charleston and Parkersburg WV: to meet several journalists for interviews to inform the public about the start of the C8 Half Life study and take any questions on Science Panel studies in general; to meet personnel at the WV Health Dept to update them on Science Panel studies; and to discuss public communications with Salter and Associates. Panel Member Savitz continued to work with the Ohio and West Virginia health departments to identify the scope of the available birth and death data.

May:
Panel members Fletcher and Steenland visited EPA in Research Triangle Park NC, they gave a presentation of an overview of science panel studies and to learn about EPA and NIEHS C8 research. They met with sub-contractor Battelle to review progress in the C8 half-life study and address geocoding. Panel member Fletcher visited Morgantown WV met with Professor Ducatman at WVU to discuss C8 data issues of common interest to the Science Panel and the C8 Health Project. Panel member Fletcher visited visited Columbus to visit the Ohio Health Dept to update them on Science Panel studies and Boston MA, to discuss C8 project design issues with researchers at Boston University School of Public Health. Panel Member Savitz applied for access to birth and death certificate data in Ohio and West Virginia: the Ohio IRB met and reviewed the application. The half life study began screening and enrolling participants in May. 200 participants are now enrolled and have completed two rounds, with a questionnaire and blood sample in each round.

June:
Panel members held conference call with WVU to discuss C8 analysis and QA issues. Panel members negotiated and agreed with Brookmar on process for access to raw QA data on C8. Panel members held conference call with settling parties to discuss obligations on disclosure to the press. Panel members responded to a press query seeking detailed financial information about science panel studies, following advice from the settling parties this was limited to a brief overview. Panel Member Savitz completed IRB review and approval at both the Ohio and West Virginia health departments and is proceeding to work out the mechanisms for accessing the needed health records. For the occupational study, completed contract between Emory and UMass Lowell, UMass Lowell IRB approval received. Susan Woskie and Kyle Steenland had two conference calls with Dupont staff regarding previous job exposure matrix, the Flair database and other exposure assessment issues.

Science Panel: Quarterly report July 1- Oct 1, 2007

July

July 2. Science Panel member Kyle Steenland and colleague Susan Woskie travel to W Va to visit Dupont plant pursuant to worker study

July 30. Science Panel phone call

July 31. Science Panel phone call with Alan Ducatman to discuss quality control issues and possible collaboration on C8 Health Project data

August

August 10. Science Panel member David Savitz received the first installment of birth records data from the Ohio Department of Health.

August 31 Science Panel speaks with settling parties regarding progress of studies. Dr. Savitz proposes a new study of neurobehavioral development in children. He will send a protocol to the settling parties. Dr. Fletcher will finalize his protocols and send them with a budget to the settling parties.

August 31. Science Panel member Kyle Steenland and colleague Susan Woskie speak to Robin Leonard and colleagues at Haskell Labs/Dupont in preparation for their visit on Sept 5.

September

On Sept 5 Science Panel member Kyle Steenland and colleague Susan Woskie went to Haskell Labs to confer with Robin Leonard and associates regarding the job-exposure matrix used in the worker cohort study. We had a productive meeting and asked for some followup material.

On Sept 10 Science Panel members Kyle Steenland and Tony Fletcher went to W Virginia and met with Rotary Club members in Parkersburg and interested citizens in Pomeroy in an effort to let the public know what we are doing.

On Sept 11-12 the Science Panel met together in Atlanta Georgia with all colleagues involved in Science Panel studies, in what should become an annual event. Attendees for all or part of the 2 day session included Susan Woskie (U Mass Lowell, worker cohort study), Barry Ryan (Emory, exposure study), Scott Bartell (U Cal Irvine, half life study), Hyeong-Moo Shin (U Cal Irvine, graduate student, half life and exposure study), Antonia Calafat (CDC, measures C8), Veronica Vieira (Boston University, geocoding for exposure study), Mike Luster (Univ W Va/NIOSH, immunology aspects of Dr. Fletcher's call back study), Giovanni Leonardi (London Sch Hygiene Tropical Med), Dr. Fletcher's call back study) , Christopher Lyu (Battelle, on multiple studies) , Jessica

MacNeill (Emory, multiple studies), Cheryl Stein (Mount Sinai, reproductive studies. All studies were discussed as well as a number of data issues with the C8 Health Project data.

Sept 11. The Science Panel spoke with Alan Ducatman regarding collaboration on analyses of C8 Health Project data. A tentative agreement was reached on such collaboration.

September 26. Science Panel member David Savitz spoke with David Bellinger (Children's Hospital Boston) to further develop the proposal for a neurobehavioral study in children.

Science Panel: Quarterly report Oct 1,2007- Dec 31, 2007

October

Contract with Battelle for geocoding on birth records study was implemented between Mt. Sinai and GCC.

Partial data received from both Ohio and West Virginia health departments for birth records study (Mt Sinai).

Received Emory IRB approval to contact study C8 Health Project participants and their water companies to check the validity of self-reported water district.

Questionnaire for community cohort study finalized.

Tony Fletcher in US to meet with colleagues at BU School of Public Health and WV Cancer registry to discuss Geographic cancer study & meet with Ron Salter in Parkersburg to discuss public relations needs

Subcontracting agreement reached in principle with BUSPH and Science Panel; Work starts at BUSPH on geographic study pending signing of contract

November

Tony Fletcher in US to meet with meet with Lubeck and Little Hocking water districts and OH EPA to discuss historical evolution of water supply & meet with OH cancer registry to discuss Geographic cancer study & meet with colleagues in WVU to discuss C8 study and data quality issues

Tony Fletcher in US to meet with colleagues at BU School of Public Health and WV Cancer registry to discuss Geographic cancer study; and participate in meetings at Rutgers on exposure assessment strategy and statistical methods for geographic study.

Proposal for study of C8 and Neurobehavioral Development was drafted, discussed, and is nearly final.

Letters go out to C8 Health Project participants requesting permission to review their records with water district.

Two-day meeting in NJ of two Science Panel members (Fletcher/Steenland) and six collaborators on exposure assessment and geographical studies.

Work initiated on data cleaning of residence file from C8 Health Project file of March 2007.

Continued negotiation on Subcontracting for BUSPH

December

Tony Fletcher in US for meeting at Chapel Hill with Battelle to discuss geocoding progress for geographic studies, other teams join by teleconference

Science panel drafts clarifying statement on the issue of determining an 'association' versus 'probable link' and transmits it to settling parties

Battelle contract modification drafted to increase from one to two the interviews in the community and worker cohort studies, moving the first one up to 2008, followed by a short one in 2010-2011.

Contract between Mt Sinai and Garden City to support geographic analysis by BUSPH is implemented.

Memorandum of understanding developed between Science Panel and WVU (Alan Ducatman)

Teleconference between science panel and settling parties.

Quarterly report Jan-Mar 2008

January

Science Panel Phone call. Overview of current situation

Phone call with Dupont re: worker cohort data

Conference call with Battelle on address cleaning strategy.

Preparation of amendments to Emory-GCC contracts for worker and community cohort study

Contract put in place between Mt Sinai and Boston University for geocoding and work on the exposure study.

Science Panel received from W Va vital registry birth data from 1957 - 2004 and fetal death data from 1967 - 2004. We submitted 2,492 addresses to Battelle for geocoding.

Feb

Science Panel member Tony Fletcher traveled to Boston University School of Public Health (BUSPH) for discussions on managing the geographic cancer study, to NIOSH and WVU in Morgantown on the cross sectional and short term follow up studies, to Salt Lake City for discussion with other science panel researchers

For geographic cancer study, progress in BUSPH finalized terms of a subaward from Mt. Sinai School of Medicine.

BUSPH received university IRB approval to work with cancer data from Ohio Cancer Registry

Science Panel member Savitz finalized the proposal for the C8 Neurodevelopment Study and submitted it for approval to the Garden City Group. We received IRB approval for the project from Mount Sinai.

Science Panel member Tony Fletcher accepted invitations to give a presentation at the EPA PFAA Days II Workshop Agenda, NC June 3-4 2008, and in a symposium on the Immune system and Perfluoroalkyl Acids proposed to the SOT meeting, MD March 2009.

March

Progress on characterizing history of water supplies; Greg Howard and Alicia Fraser of BUSPH spent a week at the Ohio EPA regional office in Logan, OH, collecting data on the historical development of the four water districts in the study area.

Emory IRB approves Science Panel providing C8 results from C8 Health Project to those who have consented to Science Panel followup.

Dupont delivers data to Battelle enabling initial contact with workers via introductory letter.

Emory contracts with GCC and Battelle amended to allocate new funds to allow two interviews instead of one for the worker and community cohort study.

Emory sent the results of editing the C8 Health Project residential file to Brookmar for their information.

Ongoing correspondence with Brookmar on access to data. They have been cleaning the questionnaire data and doing QA on new C8 results. Assured by Brookmar that delivery of final data to panel was very soon now.

Science Panel developed, with Battelle, Science Panel Logo and design for paperwork and Website. Started review of scope and content of webpages. Redesign of website implemented.

BUSPH created an address conversion database that matches pre-E911 addresses to new E911 addresses using information from county E911 programs. Very successful in pilot: 173/179 successfully geocoded addresses in a subsample of Washington and Wood County residents. Abstract submitted for ISEE on this methodology exercise.

Science Panel finalized memo of understanding with Alan Ducatman of WVU, Dr. Ducatman determining if this needs to go through WVU administration

C8 Half Life study has successfully completed five rounds of blood draws on about 200 subjects since beginning in May 2007.

From Ohio, Science Panel received vital registry birth data from 1960 - 2004. We are in the process of standardizing and cleaning the data. Once complete, we will send addresses to Battelle for geocoding

Science Panel Quarterly report April-June 2008

April

Science Panel phone call, overview of general situation

Science Panel member Fletcher visits Morgantown and meets with Prof Luster and colleagues at NIOSH regarding immune studies, with Prof Ducatman and colleagues at WVU regarding joint work; visits Boston and meets with Dr Vieira and colleagues regarding geographic study progress.

Cleaning of residential history file from C8 Health Project in progress (throughout the period of the Quarterly Report)

Geocoding of residences from the C8 Health Project (throughout the period of the Quarterly Report)

Analyses in London of prevalence of cancer in cross sectional dataset (throughout the period of the Quarterly Report)

Exposure study: completed modeling of air concentrations and particle deposition on combination of fine grid (near Washington Works Plant) and coarse grid (further removed from plant.)

Exposure study: completed validation of Paustenbach, et al. results for air exposures.

May

Science Panel phone call with settling parties

Science Panel press releases regarding introductory letters for community and worker cohort studies, availability of C8 results from Science Panel

Community and worker cohort study: introductory letters sent out

Science Panel website updated to allow people who have consented to Science Panel followup to request their C8 results from C8 Health Project

Exposure study: completed particle size distribution sensitivity analyses indicating importance of this parameter in determining deposition-related exposures. Requested further data from DuPont on this parameter.

Half-life study: blood samples collected for 194 of 200 original participants with 3 outstanding appointments; at one year study retention rate higher than expected

Science Panelist Fletcher visits Parkersburg meets with Paul Brooks, Lisa Collins & Ron Salter, journalist from local cable station; visits court science panel document collection. And, with Greg Howard from BUSPH (geographic study) visited Water districts Lubeck, Tuppers Plain and Mason to discuss historical development of pipe distribution network

Detailed GIS maps now completed by BUSPH (geographic study) for all six water distribution systems in the study area, and progress made towards completing pipe locations and installation dates. Preliminary work was completed on a study comparing geocoding methods in rural areas using E-911 addresses. An abstract was accepted to the 2008 ISEE conference for this work.

June

Science Panelists Fletcher and Steenland attend EPA PFOA conference in Research Triangle Park, North Carolina. Fletcher gave a presentation on the Science Panel activities. Collaborators Bartell and Vieira also attend.

Science Panel members Fletcher and Steenland meet with Battelle regarding geo-coding issues, along with collaborators Bartell and Vieira

Discussions begun via conference call between WVU, Science Panel, and CDC regarding lodging of C8 Health Project data set at CDC

Half life study: CDC lab completes analyses of 1000 blood samples for first 6 months of half-life study

Exposure study: Acquired groundwater modeling software and began preliminary work with the software.

Science Panel Quarterly report July-Sept 2008

July

Susan Woskie from U Mass Lowell, who collaborates on the worker cohort study, travels to Dupont in Delaware for work on the Worker Cohort study exposure assessment

Birth Records Study: Battelle continues geocoding addresses (ongoing throughout report period)

Neurodevelopment Study: planning meeting held in New York between Mount Sinai and Battelle

Science Panelist Fletcher visits US and has research meetings with Immunology team in Johns Hopkins on longitudinal study, meetings with BU team on geographic study in Boston and Science Panelist Savitz in New York

Geographic study: pipe mapping in water districts and review of docket files, ongoing.

August

Sci Panelist Steenland and collaborator Susan Woskie travel to Washington Works plant for work on the Worker Cohort study exposure assessment

Sci Panel phone call

Interviews begin for Community and Worker Cohort studies

Half-life study: 12-Month follow-up data collection was completed with successfully blood collection for 197 participants (100% of 12-Month follow-up target).

Dr. Vieira, collaborator with Sci Panel, makes presentation at Dioxin meeting in Birmingham UK on pharmacokinetic modeling of C8

Sept

Interviews continued for Community and Worker Cohort studies. As of the end of September, the project team completed 3000 interviews with the Community study participants and 500 interviews with the Worker study participants.

Lab analyses completed for first year of samples from half life study; interim data analysis begins

Russ Detwiler joins exposure study team at UC Irvine to oversee groundwater modeling efforts

Neurodevelopment Study: recruitment population identified; Battelle recruiting field

staff

Data cleaning for analysis of C8 Health Project data on birth outcomes continues and is nearly complete

Revision of Science panelist Fletcher's protocols for the Settling Parties, including communications with subcontractors.

Geographic study. Digitized pipe mapping of all 6 water districts completed and will be confirmed with each district in turn. Communications with Battelle on completing the geocoding of the C8 Health Project address file. Piloted geocoding methods for assigning exposure locations.

Summary by study

Some studies involve more than one set of results, each usually involving one health outcome. Here such multiple results from a given study are referred to as reports.

Study 1. Cross-sectional analyses of C8 Health Project data (Steenland). Study being done in collaboration with WVU. 3 reports completed on these data, focused on 1) factors associated with C8 levels in the community, 2) adult cholesterol levels in related to C8 levels, and 3) diabetes in relation to C8 levels. Summaries of these studies will be presented to the settling parties and the court in October. Future work led by Dr. Steenland will concern uric acid. All these reports should be completed by the end of 2009. These reports will not provide conclusive evidence regarding whether there is a probable link between C8 and disease because 1) one cannot determine whether C8 exposure preceded or followed the outcome of interest, and 2) in many cases the outcome is a biomarker and not a disease per se. Nonetheless they will provide useful evidence to add to the overall picture.

Study 2. Cross-sectional analyses of C8 Health Project data (Fletcher). These studies are being done in collaboration with WVU. Dr. Fletcher is preparing reports on immune markers and cancer prevalence. Investigators from WVU will take the lead on some other endpoints. All these reports should be completed by the end of 2009, and will provide useful evidence to add to the overall picture. Later reports by Dr Fletcher on non-cancer diseases such as kidney, liver and thyroid disease are planned to be completed by July to December 2010, after we have integrated historic exposure data and date of disease onset. Taken together with all the other data in the literature, these last studies on kidney, liver, and thyroid disease should form the basis for making a decision about probable link between them and C8 in 2011.

Studies 3 and 4. Community and worker cohort studies (Steenland). These studies are progressing on schedule, with completion expected in 2011. Participation rate in interviews has been high, on the order of 90%-95%. Subjects report a higher proportion of medical conditions which are to be medically verified than anticipated, which may

result in a need for supplemental funds for these two studies. These studies are anticipated to provide important evidence regarding whether there is a probable link between C8 and disease because they are follow up studies in which it is clear that C8 exposure preceded disease. Taken together with all the other evidence, they will provide the basis for a judgment about probable link for chronic diseases such as cancer, heart disease, diabetes.

Studies 5 and 6 (Savitz). Birth outcomes based on birth records and on C8 Health Project data on births. The former will consider birth outcomes based on vital records in W Va from 1982-2004 and in Ohio from 1992-2004. The latter will consider all reported births among women in the C8 Health Project within the period 2000-2005. Outcomes for both studies include preterm birth, fetal deaths, and low birth weight. In addition, the analysis of the C8 Health Project will also consider miscarriages and birth defects. Both these studies are on target to be completed in 2009. Analyses are well underway of the data from the C8 Health Project and data from vital records on births in Ohio and W. Virginia have recently been obtained, so analyses can now begin. Both these studies, taken together, should provide sufficient evidence of whether or not there is a probable link between reproductive outcomes and C8 exposure prior to birth in 2010. Again the parallel exposure study will provide key data allowing assessment of exposure to the mother during pregnancies. The timely completion of the birth outcomes study depends on the timely completion of the exposure study.

Study 7 (Fletcher). Geographic patterns of cancer. This study addresses the relationship between past C8 exposure and cancer incidence from 1993 to about 2006 based on geographic areas. This study will cover areas in W Va and Ohio both in an out of the 6 contaminated water districts. About 500,000 people live in these areas. Exposure assignment is not as precise as in the community cohort study, because the same exposure will be assigned to all individuals in a geographic area, rather than to each individual. The timely completion of this study again depends on the timely completion of the parallel exposure study. The study is currently on target to be completed in 2010. Results of this study will not by themselves be sufficient, but will form part of the evidence considered to determine whether there is a probable link between cancer and C8.

Study 8 (Fletcher). Follow-up Study of C8 and Immune, Liver, Kidney and Endocrine Function. The study will be important because of its longitudinal nature; it will consider change in biomarkers over time in relation to change in C8 exposure. Particular attention will be given to markers of liver, kidney, endocrine and immune function. Blood samples will be taken from 800 people in 2009 and compared with data on these same people in 2005-2006 during the C8 Health Project. Additional more specific immune screening tests will allow the assessment of the response of the immune system to C8 exposure, and infectious disease risk in relation to C8 will also be assessed. Results are expected in 2010. Results on biomarkers in this study are expected to provide important evidence for the assessment of the relation between liver disease, kidney disease, thyroid

disease, and auto-immune disease with C8. However, such results will not be in themselves sufficient for assessing a probable link between C8 and these diseases.

Study 9 (Steenland, Ryan). Exposure study. This study has been delayed about a year and results are expected in late 2009. This study is key to most other studies, because it will enable us to estimate C8 exposure in the past. This is done by considering a fate-transport model for C8 leaving the plant via air emissions and emissions into the Ohio river. Then we must estimate the time it takes to get into groundwater, the likely level in drinking water, and the pharmacokinetics of serum levels in relation to drinking water. Two unforeseen issues have arisen of importance, namely the flow of groundwater and the size of particles emitted from the plant. Both of these have important implications on the amount of C8 expected to be in public water systems. We have added two people to the study team who are specialists in groundwater. Of great important is the timely completion of a contact modification putting these people on the Univ of Irvine subcontract.

Study 10 (Steenland, Ryan, Bartell). The half-life study. This study is on track to be completed in 2011. This study takes advantage of the installation of filters for C8 in the public water systems of Lubeck and Little Hocking. We will look at the decline in C8 once these filters are in place. We also have a baseline level just before the filters were installed. We have already tested 200 participants four times during the first year of this study, with very high response rates, and analyses of the excretion rate of C8 during this first year is underway. This study is key to developing a pharmacokinetic model in the parallel exposure study, so that we can estimated serum levels at any point in time given intake via drinking water. Previous studies of half-life of C8 have been based on small number of people, eg, 20 workers at 3M.

Study 11. Neurobehavioral development in children (Savitz). This study is on track and should be completed in 2011. To date the list of children to be recruited has been assembled, contracts have been let, and data collection is anticipated to begin next year. Results of this study should provide evidence of whether there is a probable link between C8 and neurobehavioral development in children. The parallel exposure study should allow knowledge of estimated exposure during childhood for each child. Taken together with all the data in the literature, this study should provide the basis for determining whether or not there is a probable link in 2011.