

Health Project Leaders 'Plowing New Ground'

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Story by Juliet A. Terry

PARKERSBURG -- When Art Maher and Dr. Paul Brooks were approached about leading the C8 Health Project, Maher said they were intrigued by the challenge.

Both were retired but had the requisite pedigree to direct a never-before-done scientific study into the effects of perfluorooctanoic acid (C8) contamination in drinking water.

A class of plaintiffs sued DuPont in 2000 for C8 contamination, and the parties reached a settlement four years later. Rather than litigate their claims, DuPont agreed to spend \$70 million on a health project to collect data from thousands of people in six defined water districts and improve water filtration in this districts. A scientific panel then will study that data to determine whether C8 exposure had adverse health effects.

If the panel determines C8 is hazardous, DuPont will spend an additional \$235 million on a medical monitoring program for class members. If the panel determines C8 exposure does not have ill health effects, DuPont's involvement in the litigation is concluded.

Harry Deitzler, the Charleston attorney who represents the plaintiffs in the class-action lawsuit against DuPont, said both sides worked toward this "scientific solution" to litigation.

"The concept of a science panel was jointly conceived during mediation to resolve the issue for both parties as an alternative to submitting it to a jury," Deitzler said. "The advantage to the residents is the end result is not left to infinite appeals and also the fact that the water is filtered almost immediately."

Right Men for the Job

Finding someone to direct that health project, however, was key because it was projected to involve tens of thousands of current and former residents of communities in Ohio and West Virginia near the Washington Works plant.

Maher was the former CEO of St. Joseph's Hospital, and Brooks was a physician and former administrator at Camden-Clark Memorial Hospital who also had created his own health care business.

"We got a call (in October 2004) from one of the attorneys on the plaintiffs' side who asked if we were available and interested in a project he felt would be a real interest to us and also would present an intellectual and business challenge to us," Maher said. "... They felt the two of us could do the job."

Brooks and Maher formed Brookmar, and Wood County Circuit Court assigned them as project leaders responsible for collecting data from thousands of people on a \$70 million budget.

"We were going to help determine whether there is an association between consumption of C8 in water and disease," Maher said. "We started thinking, 'How can we do this? The estimated population for the class was 80,000.'"

Convincing even 10,000 to 20,000 people to provide detailed personal health information and blood samples would be no easy task, he said, but the men behind Brookmar believed they were right for the job.

Getting Started

Maher said they believed it would take a significant incentive to convince people to participate in the health project.

"We settled on \$400 -- \$150 for the questionnaire and \$250 for the blood test. And really, since the blood test involved 51 different blood chemistries, it's equal to about \$600 in medical testing, so they got \$1,000," Maher said. "... We also decided people wouldn't come to Parkersburg to be tested. We would go to the people as opposed to them coming to us."

Brookmar decided to use mobile, modular units in the water districts covered by the settlement -- Belpre, Little Hocking, Tappers Plains/Chester and Pomeroy water districts in Ohio and the Lubeck and Mason County public service districts in West Virginia. As Brooks and Maher formulated their plan, they brought in CPR Solutions Group to computerize the entire data collection process. CPR is a Charleston-based firm that handles everything from accounting solutions to electronic medical records and medical practice management systems. Troy Young, CPR's executive vice president and chief technology officer, already had worked with Brooks on an earlier project, so Maher said it was a natural fit to include CPR in the C8 Health Project.

"This had never been done before that we were aware of," Young said. "We designed, implemented and supplied the technical infrastructure to this project."

Fine-tuning the Protocol

Before any testing could begin, Brookmar and CPR each had to blaze its own trail, so to speak, to create a protocol that was scientific and efficient.

On Brookmar's end, it recruited retired nurse Patsy Flensburg and medical records expert Susan Arnold to help direct the project, which would be open to anyone who lived, worked or went to school in one of the six water districts for any consecutive 12-month period leading up to Dec. 3, 2004.

"We were literally plowing new ground," Maher said. "We had to develop our own questionnaire, then we had to develop criteria for eligibility -- what you have to have with you to prove your eligibility."

Brookmar proceeded methodically, Maher said, and held various town meetings and focus groups in the water districts so residents could voice their concerns. That input, he said, proved critical when constructing the parameters of the questionnaire and the testing process.

They wanted to be able to have participants show up at a testing site, submit their 72-page questionnaire, have a blood test and get their check for \$400 all in one visit, Maher said.

For CPR, that meant combining medical and accounting software programs that never before had worked as one.

"We designed the workflow and how to collect the data accurately," Young said. "Some of the software was commercially available and others we had to customize for the project. We have practice management/electronic medical records software and accounting software, but we had to develop software to link the two together. ... The system was that you left with the check -- that's why everything had to integrate so closely."

The entire system was designed to encourage participation, Young said. He suggested Brookmar offer the detailed questionnaire on the Internet. Maher said he didn't believe people would submit the document online, but he was wrong. "I hoped to get maybe 10,000, but out of the more than 70,000 questionnaires we received, 92 percent were filled out on the Internet," Maher said.

Flood Gates Open

As Brookmar prepared to open its first testing site in Lubeck, they had no idea how many people to expect, Maher said.

That site opened its doors July 25, 2005, and the project was off and running. "We were just overwhelmed. We blew the servers and had to revamp it to handle the volume, Maher said. "It was like a flood. We opened the gates, and it was like a flood of people came in. ... The goal we were given was 20,000 to 40,000 people. Dr. Brooks and I set a goal of 60,000. We ended up with just about 70,000."

He said people underestimated the incentive of \$400 for each person who agreed to participate in the project.

"We had as many as 11 members of one family show up, and each one of them got \$400. The money was deemed to be tax free, so there were a lot of happy people at Christmas time," Maher said. "The money that DuPont put into this project ended up being spent right here in the community."

Maher added that community support also was key to the success of the health project, and the town meetings proved critical in keeping the public informed of the process.

"We had tremendous support of local media who reported on this without taking a stance on the litigation," he said. "Emotions run high. People worried DuPont would be run out of town because it's a big employer, and others who didn't care about DuPont worried someone's demise was caused by C8. Our job was to be independent, not on anyone's side."

DuPont's Washington Works' Plant Manager William H. Hopkins said the company encouraged its own employees to participate in the study.

"We have 1,800 full-service employees and another 500 contract workers. ... We had many who participated in the Brookmar study," Hopkins said. "Anyone who asked me, I encouraged them to do it. We (DuPont) asked for this health study to be as complete as possible. Our commitment is to produce safe products and protect the environment and our employees."

Saving Lives

Testing nearly 70,000 people for C8 and 51 other blood chemistries had a positive side effect. The health project ended up saving some lives.

"We had built medical alerts into our system if lab results showed an abnormality," Maher said. "The labs were run daily, and if there was a problem, they contacted us, and we called the person and informed them of the problem, telling them to see their physician or go to the ER."

"We know we did save some lives," he said. "We know we made people aware of critical problems, and they have called to thank us. It's not a huge number, but if you save one life, you've done something."

For most participants, they received their results about 10 days after their test and were advised to take them to their physician to incorporate the results in their medical records.

To keep the integrity of the data intact, Brookmar contracted with one lab in Pennsylvania to conduct the C8 testing, and used a second lab in Canada to provide quality assurance. Years down the line, if someone challenged the C8 test results, the project could show it had a second lab verifying everything.

The remaining portion of the blood test, which involved testing for 51 separate blood chemistries, was contracted to LabCorp based in Columbus, Ohio. As a national testing company with many locations, LabCorp offered a way for people who had moved as far away as California to participate in the project.

Leaving a Legacy

Within 11 months, Brookmar managed to collect questionnaires and blood samples from close to 70,000 people, and Maher said they still are amazed they were able to do it without many problems.

"We were literally flying by the seat of our pants and drawing on our own education and experiences. There was no formula to follow, no outline," Maher said. "People have said in academic circles that they still would have been talking about the questionnaire."

Brooks and Maher added one more step to the project to ensure its legitimacy -- they arranged to store the serum left by all participants. They used part of the \$70 million budget to pay for five years of storage at the West Virginia University tissue bank.

"If the results are challenged, this will protect Brookmar and its integrity," Maher said. "Also, when it's all finished, these data sets will be public domain, so scientists can use the material."

"We feel it's a legacy we're leaving, an added benefit. We've even set up criteria for scientists to use when they want to access the sera," he said. "... We're trying to leave a trail that can be picked up and followed."

Their legacy also includes evidence of being good money managers.

"We're real close. We're watching each dollar," Maher said. "We submitted a budget to the court ... and then Paul and I had to stick to it. It's just good management."

Deitzler had nothing short of praise for Brookmar's management of the health project.

"The health project would have been impossible without Paul Brooks and Art Maher," he said. "They had the medical knowledge, credibility within the community, personal creativity, individual drive and commitment to their community which made the project a success. Their success could not have been replicated by any other persons or entities of whom I am aware anywhere in the United States.

"The sheer magnitude of the task is still incomprehensible to most people," Deitzler said. "There was no blueprint for them to follow, and some of the things that were expected of them were beyond even predictability."

The Next Phase

Continuing to make its own way through the project, Brookmar is engaged in another activity that Maher said has not been part of public health assays before -- validating self-reported diseases.

"Susan Arnold is going back to validate self-reported illnesses. We got consent forms from participants to access their medical records just for that area," he said. "If someone says they once had cancer, for example, we're now going back and asking their doctors for the medical record that shows the diagnosis. ... We've done 10,000 of those, and we have 30,000 to go."

Brookmar and CPR will spend the rest of this year preparing the data for the science panel -- three epidemiologists who will take an estimated four to five years studying the data of 70,000 samples to determine whether C8 exposure in drinking water affects people's health.

In addition, the panel will have the opportunity to study the health characteristics of a massive pool of similarly situated subjects and see what kinds of information those 51 other blood chemistries tested in C8 project tell them anything about that part of the Ohio Valley.

As DuPont and other interested parties settle in for what could be a long wait for word on whatever the dangers of C8 exposure may be, DuPont, Brookmar, CPR and the lawyers involved in the settlement have blazed a trail that Maher said could offer a viable alternative to litigation in the future.