

MESOTHELIOMA APPLIED RESEARCH FOUNDATION

BREATH OF HOPE

Winter 2007

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BELIEVE

From the Executive Director



I am excited to move into 2008 as part of a community that is making history and working to save lives. Three months ago, at the 2007 International Symposium on Malignant Mesothelioma, the meso community gathered at the U.S. Capitol for the first time in history to call for a cure.

On October 4, over 120 patients, family members and loved ones, medical and research experts devoted to mesothelioma, and others who care passionately about ending the suffering caused by this disease, met with their respective Senators and Congressional representatives. We spent the day educating them about the tragic toll of mesothelioma. We urged them to finally ban asbestos, before more is introduced into our environment, creating even more danger. And most importantly, for the sake of all those now sick, or who will inevitably get sick because of exposure to all the asbestos already in our environment, we asked them to begin federal investment in the research necessary to develop effective treatments. By the end of that very day, 100 U.S. Senators had unanimously passed Senator Patty Murray's Ban Asbestos in America Act!

It still thrills me when I think about the power we have when we unite and use our personal stories and personal commitment to call for needed change. I am deeply grateful to each person who made the effort to be in Washington. I am also very grateful to the many who could not attend, but who have supported this effort both before and since with their letters and phone calls to their representatives.

That evening we assembled in a solemn vigil. Under a beautiful sunset, we gathered right in front of the Capitol Building, with the National Mall and Reflecting Pool behind us stretching all the way to the Lincoln Memorial. It was momentous in a way that I cannot describe, but I hope the pictures in this issue can convey some of it.

In the gathering dusk, we lit candles to remember our loved ones, and all those we have lost to this vicious disease. As I remembered so many dear names and faces, anger mixed with my sadness. How many lives could have been saved if the legislation had become law in 2001, when Senator Murray first introduced it? How many more wonderful people would be lost before it was finally approved in the House and signed by the President into law? How long till this callous disregard for human life would end?

There are no acceptable answers to these questions, and that is painful. But it also drives us forward. Senator Murray's bill reflects the reality of political compromise, and is not perfect. But it is a huge first step, both in limiting further asbestos exposures and in finally providing a federal investment in mesothelioma research. Once passed, it will begin to save lives, and with you, our advocates, we will work to bring that day as soon as possible.

We also will continue to support as much of the most promising meso research around the world as we can. The Symposium demonstrated the promise of this research and the progress being made. We learned about the advances in understanding the tumor cell, and the progress being made in biomarkers and treatment. For many, a highlight was the review of the many interesting projects going forward with Meso Foundation funding, and meeting and interacting with the researchers themselves. It was also inspiring to meet long term meso survivors, including Phil Lake, who was diagnosed with pleural meso eight years ago and throughout those years has benefited as new treatments became available "just in time." For those of you don't know Phil's inspiring story, we profile him in this issue.

To keep this life-saving progress moving forward as quickly as possible, the Foundation has just awarded another \$1 million in grants to support ten exciting new research projects. Much of this funding was made possible by the generous response to our year-end research appeal, and we are very grateful. You will be hearing more about this research as it progresses in future issues, and especially at next year's Symposium.

The 2008 Symposium will be in D.C. again, so that we can follow up on our advocacy efforts and make sure the legislation passes in this Congressional session. In order for us to have maximum political impact during what will be an election year, we have moved it up to June, the 26th through 28th. So mark your calendars; it will be an exciting time and I hope you can join us there.

Chris

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Phil Lake, Patient Profile

Phil Lake started his life fighting cancer. He had a kidney removed as part of his treatment for Wilms Tumor, a life-threatening malignancy that occurs in infants and young children. Phil recovered and had a normal childhood. But being diagnosed with pleural mesothelioma years later at age 39 left this cancer ‘veteran’ completely stunned: what started with a clinic visit for suspected pneumonia has ended up being the battle of his life.

For years Phil Lake worked in power plants as a millwright, often traveling for his employer far from his home in West Virginia. In March of 2000, he was working in Delaware when he began to experience vague respiratory symptoms including a cough and trouble catching his breath. Phil figured he had the flu or a cold that had been made worse by winter weather and the stress of being away from home. After spending a “small fortune” in over-the-counter remedies without success, he decided to go to a local walk-in clinic for some antibiotics to treat his problem. As part of their usual protocol, the clinic obtained a chest x-ray. “That’s when things got scary,” Phil remembers. “Doctors and nurses were running around, hooking me up to oxygen and calling for an ambulance. Everyone looked so serious.”

The clinic doctor, unable to see Phil’s left lung on the x-ray, immediately had Phil admitted to the local medical center. Phil recalls his initial difficulty in grasping the full scope of his situation. “I kept insisting that I just needed some antibiotics so I could go home and get well again. And the doctor kept saying ‘You don’t understand – we can only see one of your lungs. You need to go to the hospital – you could drop dead from something like this.’” By the time things began to sink in, Phil was being admitted to Christiana Hospital for drainage of a massive pleural effusion, and a complete work-up. It wasn’t long until he had a preliminary diagnosis: malignant pleural mesothelioma.

Phil’s occupational history was positive for asbestos exposure. He repaired and maintained the heavy equipment used in manufacturing and power production, machinery that was often insulated with asbestos. “The stuff was all around us – we used to knock it off pipes with a hammer and toss it aside,” he says. “No one told us otherwise. It wasn’t until the 90’s that we learned what it was, and that it could be harmful. That’s when we started taking precautions about handling and breathing it.” Unfortunately, Phil was to find out that

the precautions were too little too late to spare him from developing mesothelioma.

Phil’s wife and parents drove up from West Virginia to transport Phil home for further medical evaluation. The doctors at Christiana had offered little hope, stating that they had found “inoperable cancer” of the left lung. They advised Sarah Lake to take her husband home and “get his affairs in order.” When Phil returned to West Virginia, he was determined to



fight on. He met with oncologist James Frame and pulmonologist Robert Crisalli at Charleston Area Medical Center, who confirmed the mesothelioma diagnosis utilizing Video Assisted Thoracoscopy. Dr. Crisalli, recognizing the need for expert intervention, researched the latest findings and referred Phil to Dr. Harvey Pass at Detroit Medical Center.

Within two weeks of his clinic visit in Delaware, Phil was in the operating room in Detroit, undergoing Extrapleural Pneumonectomy (EPP) with Dr. Pass. During the surgery, Dr. Pass removed Phil’s left lung, a portion of his diaphragm and pericardium, and the left pleural membranes. Phil did well following his EPP, spending about a week in

the hospital recovering. Dr. Pass, impressed with the care Phil had received at home, transferred him back to Charleston Medical Center for follow-up care. Phil had to be admitted briefly for drainage of fluid that had accumulated after his EPP, then received outpatient chemotherapy consisting of Cisplatin and Gemzar. For the next three years, Phil was symptom free. In 2003, his mesothelioma recurred.

By this time, Alimta had just won FDA approval to be used on a compassionate-use basis only. Realizing that this new chemotherapy offered his patient the best option for continued survival, Dr. Frame applied for FDA permission to use it for Phil. Phil had Alimta in combination with Cisplatin, and again, saw his mesothelioma halted. But Phil and his family had no time to rest and enjoy their victory. Within the year, Phil’s old enemy, renal cancer, had recurred in his remaining kidney, and he was off to Cleveland Clinic to do battle with yet another form of cancer.

For the next two years, Phil was busy fighting the renal cancer that had spread from his left kidney to his right hip. He was treated with radiation and chemotherapy, and then required surgical replacement of both hips due to complications from the renal cancer and its treatment. He had barely recovered

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Understanding Clinical Trials

by Mary Hesdorffer, NP, Medical Liaison

For many newly diagnosed patients the words “clinical trial” conjure up negative images of being used as a “guinea pig” and not having any control or say in the treatment they receive. But actually, participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical knowledge. Researchers in mesothelioma are truly trying to make a difference, and they have designed trials with the expectation that there will be some benefit. So it is important that patients, family members and all of us in the meso community understand the basics about clinical trials.

Before joining a clinical trial, a participant must qualify for the study. The factors that allow someone to participate in a clinical trial are called “inclusion criteria” and those that disallow someone from participating are called “exclusion criteria”. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

There are many clinical trials available and it is difficult to determine which trial might be right for a particular patient. Performance status, pre-existing medical conditions and the number of prior treatment regimens are considered.

- Phase I studies attempt to find the maximum tolerated dose and the toxicity profile of the drug, and secondarily, at what dose responses are seen. They usually include a variety of tumor types. Therefore, I caution patients to only participate in a Phase I designed by a mesothelioma specialist, as the other Phase I studies may not have a rationale applicable to meso.
- Phase II builds on information from the Phase I.... This is usually for one particular type of tumor or for tumors that share a characteristic targeted by the proposed drug.
- Phase III is when a new regimen is tested against a standard treatment, and is seeking FDA approval.
- Stage IV is a post-approval data collection tool that will look at other parameters as well as gathering more data on the drug’s side effects, since it will be given in larger numbers than those accumulated during the study’s prior phases.

The time to enter into a clinical trial is when a patient is in relatively good shape and does not have many symptoms that cannot be controlled. A patient with serious symptoms may be offered an approved regimen with a demonstrated response rate, in order to get the patient under good control first.

The FDA had not recognized any drug as a “standard of care in mesothelioma” until the combination of Cisplatin and Alimta was approved in 2004. A phase III study compared what was thought to be the most active drug, Cisplatin, against Alimta plus Cisplatin. This blinded study demonstrated that Alimta increased survival time overall, and so Alimta was given expedited FDA review. Through this process Alimta became the first drug FDA approved for the treatment of mesothelioma.

Prior to the approval of this regimen the most commonly accepted regimen was Gemcitabine with either Cisplatin or Carboplatin. While neither of these combinations have been tested against Alimta-Cisplatin, many mesothelioma oncologists believe that they are a close second to the Alimta combination.

In the more common cancers, numerous clinical trials have been conducted and there are many approved regimens. But the mesothelioma cell biology mechanisms which might be the best targets for drug therapy are not yet well understood. Also, the relatively small number of patients makes it hard to accrue enough patients for clinical trials, and makes the market small for a new meso drug. As a result, relatively few mesothelioma clinical trials have been completed through Phase III. Meso specialists therefore often will recommend single drug or combination regimens that have not received approval for mesothelioma but that have demonstrated some activity in Phase II studies – even though it is difficult to speak about the results of these studies in clear statistical percentages, since the numbers of patients in mesothelioma Phase II studies are usually so small. We often use data from European trials as well, and when they have published benefits, we consider them for patients who do not meet clinical trial criteria or do not wish to participate in a trial.

The Foundation sponsors grants to researchers pursuing mesothelioma clinical trials, and also generates information regarding the various clinical trials at centers that treat mesothelioma. We communicate regularly with many of the leading researchers in the country, and can assist you in securing appointments as well as offer guidance regarding the clinical trials you might be eligible for. For personal help, you may call me directly at 877.End.Meso (877.363.6376) or email me at mhesdorffer@curemeso.org.

To learn more about clinical trials I suggest reading:

Trends in the Risks and Benefits to Patients With Cancer Participating in Phase 1 Clinical Trials

<http://jama.ama-assn.org/cgi/content/abstract/292/17/2130>

Phil Lake, continued

from this latest surgery, when in mid-2006, his mesothelioma recurred in the left side of his chest. The tumor appeared to be localized. Therefore, Phil and his medical team decided to treat it with Intensity Modulated Radiation Therapy (IMRT), a newly developed method of applying radiation very precisely. Fortunately, this was successful, and once again, the mesothelioma was halted.

Despite all he has endured, Phil Lake considers himself blessed for a number of reasons: he was diagnosed rapidly, and received expert care; he has lived eight years with a disease that usually carries a prognosis of less than two years; and thanks to the evolving improvements in meso treatment, he has won multiple battles and been able to spend quality time with his wife and daughter, watching his little girl blossom into young adulthood.

Phil's goals are twofold. First, he'd like to see his daughter off to college. Second, he wants to see the mining, production, and use of asbestos halted, everywhere. Phil understands why asbestos was once used so extensively. "It was the perfect product for the jobs we wanted it to do," he acknowledges. "But now that we know there is no safe threshold – that even a little exposure to asbestos can cause massive suffering - it makes no sense to continue using something that causes this much harm." Phil shakes his head in amazement when he recalls a recent event: he was helping his daughter's high school renovate a locker room for the girls' softball team, and was astonished to see that asbestos that had been removed from the school was sitting outside in an open dumpster with only a small warning sign attached to it. "That's foolhardy,"

he says, "People need to understand that anyone can get this disease. We are just beginning to reap the results of the fact that the stuff is everywhere. And I don't want another person to go through what we've been through as a family."

Phil speaks up against asbestos use whenever he can, and feels strongly that those who knowingly covered up the dangers of asbestos and placed workers and families at risk should correct the damage they have done. He and Sarah attended the Foundation's recent Symposium in Washington DC in order to participate in advocacy efforts to ban asbestos and obtain federal funding for mesothelioma research. He also reaches out to mesothelioma victims to provide hope and inspiration, as well as some hard-won advice. "Mesothelioma is an individual disease," he states. "Every case is unique, just as every individual is, and my personal experience is not an exact blueprint for others to follow step by step." What Phil believes is crucial to survival is to "educate yourself about the disease, and find physicians you can work with, not as a passive victim, but as a collaborator in your own healing."

Phil also says that "This disease is all about hope, and not regrets." While it might be human nature to rue past actions, they cannot be undone – it is the future that counts. Right now, Phil requires no treatment, but he is aware that there may come a time when one or both of his cancers become active again. He'll face that challenge when the time comes, but for now, he is content to have survived for one more day. And he'll live each day he is given to the fullest, spending time with his family, and building memories to last a lifetime.

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