

Trial by Gleevec

Being a human 'lab rat' isn't easy but it sure beats the alternative

By Terry Jennings

The day I had to tell my children that their father was going to die was the worst day of my life.

Lou had been diagnosed with gastrointestinal stromal tumor (GIST). He had one large tumor on the left lobe of his liver, surgeons told him, and 40 metastases on the right side, making the tumor inoperable. The most optimistic prognosis was two years. More than likely, doctors said, it would be two to six months. They closed him up and offered little hope.

I told my 13-year-old son that Daddy would probably not be with us for his sister's graduation in a year and a half – and definitely he wouldn't be here for his graduation.

I was wrong. Two years after that awful day, my husband is still with us. He attended our daughter's graduation. He is working full time

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Battling GIST with Gleevec (STI571)



LIFE RAFT GROUP

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Life Raft office up and running in New Jersey

From a motley collection of GIST cancer patients united solely via the Internet, the Life Raft Group now has a physical presence in Totowa, New Jersey, U.S.A.

The Life Raft's office opened Monday morning, Sept. 23, the day after Executive Director Norman Scherzer returned from a London symposium on Glivec treatment of gastrointestinal stromal tumor. Joining Scherzer in getting the office running were three others who are new to most Life Rafters.

Tricia McAleer is the group's part-time administrative assistant. The 21-year-old native of Bogota,

New Jersey, is a communications major at William Paterson University in Wayne, New Jersey, 20 miles west of New York City. The youngest of five siblings, she says family ranks No. 1 in her life, especially her nieces and nephews.

Jim Roy is the group's part-time IT (information technology) director. He's been the key to getting the computer network up and running, says Scherzer, handling everything from programming to the Internet to networking the office. Roy is a corporate IT manager and has 20 years' experience in data processing and IT consulting, Web design and maintenance. He's also

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Medicare coverage of Gleevec unlikely

National cancer advocacy groups have leveled harsh criticism at Senate negotiators from both parties for failing to include any significant improvements in benefits in pending Medicare legislation.

Signaling that progress will not be

possible before the Nov. 5 elections, Congress passed a stop-gap funding measure Oct. 16 and left town for a final bit of campaigning.

Especially grating to cancer advocates was that legislators are prepared to offer billions of dollars to hospitals, doctors, HMOs and other health care providers. Some patient

advocacy groups are crying foul this year, saying lawmakers should have done more to help beneficiaries instead of providers.

"Once the cancer community understands that the Senate leadership is prepared to offer more than \$40 billion in so-called provider give-

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and coaching two baseball teams. We call him the miracle man.

But he's more than that. Lou is alive because he dared enter a clinical trial for Gleevec. While there is still uncertainty about the long-term outlook, Lou and most patients on Gleevec have hope.

And yet as willingly as Lou and his fellow Gleevec patients handle side effects they view as minor — especially considering the alternative — being a human guinea pig poses a host of new challenges. There are the physical reactions to be recognized, managed and accepted. There are logistical matters associated with participation in this clinical trial — the need to travel every three months to obtain the pills and receive checkups. And then, of course, there is the emotional impact.

Persistence and chance

Two years ago, we'd never heard of Gleevec — or STI571, as the then-experimental cancer drug was known. Even if we had, we wouldn't have thought it could help Lou. The drug, developed by the Switzerland-based pharmaceutical firm Novartis, was proving spectacularly effective against a different cancer — chronic myelogenous leukemia. Patients' blood counts returned to normal shortly after using the drug. The results were fast, dramatic and — for many patients — long-lasting.

Dr. George Demetri, director of the Center for Sarcoma and Bone Oncology at Dana-Farber Cancer Institute in Boston, had begun lobbying Novartis to use the drug to treat GIST. But at that time, our local oncologists — one in Fairfax



The Jennings family, from left, Lou, Terry, Mary Katharine and Ben, taken in June 2001 right before Mary Katharine's high school graduation ceremony. One thing Lou really enjoys is coaching 15-year-old Ben in baseball. Last summer Ben hit the game-winning home run to clinch the district title for his all-star team, earning them a berth in the state tournament.

and one in Reston — were unaware of these developments.

Fortunately for my husband, he happened to have the disease at the right time and did not accept his death sentence gracefully. We fought. We got on the Internet and armed ourselves with information. Our local oncologists had advised us against reaching out for experimental treatments — better for my husband to spend the little time he had left with the family, not pursuing elusive, ineffective cures. We ignored that advice and visited Dana-Farber, M.D. Anderson Cancer Center in Houston and Memorial Sloan-Kettering Cancer Center in New York in search of experimental therapies.

We were looking for a miracle — anything that could give us hope.

Surgeons at Sloan-Kettering urged a more aggressive response to Lou's disease. Removing the

large tumor on his liver, they said, could prolong his life because the liver regenerates itself, creating healthy organ tissue to carry on life functions. So less than two months after his first operation, Lou underwent surgery again. Ronald DeMatteo removed a 4 1/2-pound tumor along with the left side of Lou's liver. Not only did this give Lou a better prognosis, but DeMatteo found only four small metastases on the right side of the liver rather than the 40 our local surgeon had told us he had.

This was the first hopeful sign. But doctors at Sloan-Kettering didn't delude us. Once GIST has metastasized to the liver, they said, the cancer seeds the organ with malignant cells invisible to the surgeon's eyes.

So now we were searching for a systemic therapy — something that

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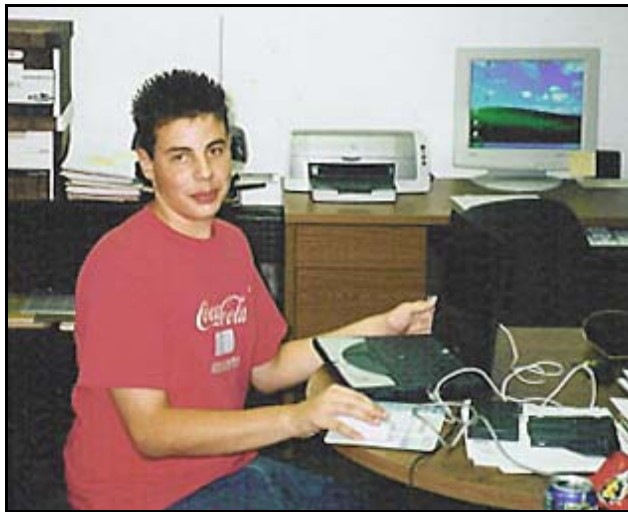
president of the New Jersey PC Users Group. Roy puts in 10 or more hours a week evenings and Saturdays. “Thank God we have him,” says Scherzer.

Help in getting the office up and running also came from a 13-year-old who got his volunteer position strictly through nepotism. Matthew Mattioli is Scherzer’s oldest grandchild – but he’s got references, having volunteered this summer at Passaic General Hospital in New Jersey. He has “a knack for putting things together,” says his proud grandpa. Like a lot of youngsters who’ve grown up with computers, hooking up the printer cable to the correct port on the computer tower is, well, child’s play. An eighth grader, Matthew is interested in computers, the Internet, music and drawing.

Outside of the Totowa office, the ranks of the Life Raft’s volunteers have grown by three. Roberta Gibson has agreed to act as accountant for the group and Tom Overley has accepted the post of general counsel. Bertrand de la Comble will serve as the Life Raft Group representative in France.

Gibson is a certified public accountant and a partner in the firm of John M. Arledge & Associates Inc. in Edmond, Oklahoma, U.S. A. She has more than 17 years experience in taxation, bankruptcy, law firm management consulting and business development. Her tax background includes health care professionals, and her firm works with non-profits both as auditor and as an authorized agent. Gibson will conduct the Life Raft Group’s an-

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That Tricia McAleer, above, the Life Raft Group’s administrative assistant. At left is Matthew Mattioli, 13, grandson of Executive Director Norman Scherzer. Below is James Roy, the information technology director who’s been helping to get everything on computer and the computers talking to each other.



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could go after those malignant cells and destroy them.

Soon after this surgery, as a result of our contacts with Sloan-Kettering and Dana-Farber, we found out about Gleevec, a signal transduction inhibitor that blocks the tyrosine kinase enzymes, the major drivers in the growth of cancer cells. Its side effects, unlike those of conventional chemotherapy, are tolerated well by most patients.

Novartis, at Demetri's urging, agreed to allocate resources to conduct a clinical trial for GIST patients. The Gleevec/GIST trials began in July 2000. Lou started that October, after the trial was expanded from 36 to 147 patients, based on encouraging early results.

Today, his small tumors are visible only as minuscule scar tissue in computerized tomography (CT) scans. About 90 of the other patients have had their tumors shrink by more than 50 percent, according to Demetri.

Side Effects

For the most part, Gleevec's side effects have proven to be nag-

ging more than painful — diarrhea, nausea, fatigue, puffiness around the eyes, swelling in the extremities, muscle cramps, rashes, itching, cuts, thinning of the skin and broken capillaries in the eyes. Lou has the fragile skin of an old man, gets leg cramps bad enough to keep him awake nights, and his bloodshot eyes sometimes give him the appearance of a guy who's been boozing it up, but he doesn't complain. He's tried timing his pills and altering his diet to reduce intestinal upset, and he's found other strategies to improve his comfort in general.

Other Gleevec side effects such as low blood counts and neuropathy — a stinging and itching below the skin — can be severe enough to prevent some patients from continuing in the therapy. But most patients are able to carry on a normal life.

To help researchers track the occurrence and frequency of such side effects, each patient on the trial fills out a diary. On a clinical basis, this works very well, but from a human perspective it can be disquieting. The first time you experience a side effect, you are unsure whether it is a side effect or a

new medical condition requiring care.

For instance, a stuffy nose may be a run-of-the-mill virus or a result of fluid accumulation in the tissues. Cuts on the skin could be products of clumsiness or of Gleevec's causing the skin to thin. Fatigue after taking an antibiotic could be due to the condition being treated or an adverse drug interaction. One of the patients is noticing loss of vision. It is unclear whether this is a totally unrelated issue or the first manifestation of a very significant side effect.

The emotional impact is trickier. With cancer there are never guarantees; but when you are on a clinical trial, the possible outcomes are even more uncertain. The question about long-term effects is always present. And along with uncertainty comes fear.

It is thought that to prevent GIST from recurring, patients will have to take the drug for the rest of their lives. Those taking Gleevec hope and pray that there are no cumulative effects. The "optimum" dose has yet to be determined, so those taking 400 milligrams wonder if they are taking enough to en-

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nual audit and handle the group's tax return.

Attorney Overley is a partner in the Holland, Ohio law firm of Wagoner & Steinberg Ltd. He specializes in employment, housing, insurance subrogation and bankruptcy law. He's practiced in most local and state courts including the Ohio Supreme Court and federal

appellate courts.

De la Comble is the group's second country representative and joins his fellow Life Rafter across the channel, David Cook for the United Kingdom. The Paris resident will be the group's liaison to French patients and key physicians, and is already working to reach GIST patients who haven't yet

heard of the group.

The Life Raft Group now has members in 17 countries, and four countries — the United States, Canada, Mexico and Switzerland — are represented on the board of directors.

"What's amazing is we have yet to start an outreach program," says Scherzer.

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sure long-term success, while those taking 600 and 800 milligrams wonder if they are putting up with more side effects than necessary. They also wonder if some day, as is suspected to be happening with chemotherapy, someone will find that the therapy causes a substantial reduction in mental functioning. Experts don't know the answer because the drug hasn't been around long enough.

Patients wonder if they will always have to battle fatigue, muscle cramps, diarrhea and hemorrhaging eyes. It's a daunting prospect. While they can now make plans for the future, they still wonder whether the cancer will find a way to circumvent the blocking effects of the drug. While they are reassured by the strides continuing to be made in the field and the optimism of the medical team, they don't know how long they can count on the miracle to continue.

Getting By

Two things help GIST patients cope. The first is the high caliber of the medical professionals involved in the trial. In our experience, Dana-Farber's staff, led by Demetri, is not only knowledgeable and responsive but caring. Questions are always answered quickly and honestly. Patients and their families can communicate directly with the physicians via telephone or e-mail. Doctors are quick to offer effective advice on coping with the physical side effects. There is no time when you feel alone.

The other helper is an online support group, the Life Raft, started by trial participants and their fami-

lies. For them, the Life Raft is a forum to share their concerns and compare notes on side effects and possible remedies. Support group members praise understanding doctors and bash negligent, uncaring ones — most often local oncologists who misdiagnosed them or

unmanageable side effects, or when a member who has had good results has a "reawakening" in a tumor, you are devastated along with them. You pray that those who have relapsed will be helped by some new miracle; you pray even more ardently that the miracle will continue for the rest of you.

Lou and his fellow "lab rats," as Gleevec trial participant Marina Symcox calls the group, are experimenting not only with a drug, but with the reality of life after they'd resigned themselves to death. Norman Scherzer, the leader of the online support group, calls it "learning to live with hope again." Lou dares to hope that he will now see our youngest son's graduation, both college graduations and then weddings and grandchildren.

For trial participants as well as their spouses and loved ones, a new appreciation for life develops when given a second chance. You remind yourself that you need to value every minute. You try not to make too much of day-to-day problems. You place a priority on family and relationships.

But try as you may, sometimes life just gets in the way. You fight with the kids over their homework. You're drawn in different directions trying to keep up with work, the family and the household. Although I feel terribly guilty when this happens, I tell myself that it's all right. It's all right because that's life. And that's what we now have before us ... the hope and reality of life.

Editor's note: Terry's article was published in the July 2 issue of The Washington Post.

Quote:

"For trial participants and their loved one, a new appreciation for life develops when given a second chance. You remind yourself that you need to value every minute ... You place a priority on family and relationships."

— Terry Jennings, wife of GIST survivor Lou Jennings

discouraged them from taking part in the drug trials. Discussions range from the wishful (Medicare approval of oral anti-cancer drugs like Gleevec) to the mundane (the best flavor of "gook" to take for CT scans). Patients lean on each other in the anxious days before check-ups, and cheer or commiserate over the results.

As members of the support group, we learn quickly about other patients' progress. We are encouraged by news of others' successes. On the other hand, when a member dies or has to drop out because of

Medicare: Billions to providers, zip to cancer patients

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backs and nothing for people with cancer, they will be very angry,” said Ellen Stovall, president of the National Coalition for Cancer Survivorship (NCCS).

Among the provisions left in the lurch was the Access to Cancer Therapies Act, S. 913, which would make oral anti-cancer drugs eligible for Medicare coverage. The bill had broad bipartisan support, with more than half of all Senators signed on as co-sponsors and more than three-fourths of all House Members co-sponsoring the House counterpart, H.R. 1624.

“I thought it was a done deal,” said Norman Scherzer, executive director of the Life Raft Group. “How naive to trust that when more than 50 percent of Senate and more than 50 percent of the House sign on, that it will actually see the light of day.”

Noted Stovall: “We were particularly hopeful that the leadership of the [Senate] Finance Committee, mostly coming from rural states, would appreciate the distinct advantages of oral cancer medications to their constituents, who might not have ready access to a local oncologist. Failure to address this clear need is a great disappointment.”

Among the drugs that would have been immediately covered for cancer patients under the legislation were the new targeted therapies like Gleevec, which has very impressive results in previously untreatable cancers with only minor side effects, as well as widely-prescribed drugs like tamoxifen and others which have been demonstrated to prevent recurrence of breast cancer.

Gleevec, said Scherzer, “will save the life of approximately 70 percent of those who take it, for whom there is no other treatment. Medicare, the law, has a technical defect, an oversight, in that it doesn’t cover oral cancer medication.

When it was written, nobody had ever heard of an oral cancer drug.

“If people take a far less effective, far more expensive traditional che-

thes is possible, albeit unlikely. The one item that may get funding is the so-called “provider give-backs.”

In 1997, Congress cut billions of dollars from Medicare to balance the federal budget. Lawmakers restored some of the money after health providers complained the reductions were too deep.

This year, the House passed a package giving Medicare health providers about \$30 billion. Many lawmakers have said that much like previous years, the provider give-back package may be the only agreement Congress is able to reach concerning Medicare.

“No one has given up on the issue of prescription drugs,” said Michael Siegel, spokesman for the Senate Finance Committee. “In the meantime, we do feel very good about this giveback package. It’s going to help beneficiaries by improving not only the access but the quality of care, such as at nursing homes, at home health care programs and hospitals.”

Cancer patients hoping for Medicare coverage of oral drugs like Gleevec will probably think otherwise.

“The Senate negotiators could have made a significant down payment on an eventual comprehensive benefit by including S. 913, but chose not to do so,” said Stovall. “Cancer patients will feel betrayed by that unfortunate decision.”

Editor’s note: Sources for this story include the National Coalition for Cancer Survivorship, US Oncology’s LegisLink, and the Associated Press.

Quote:

“Once the cancer community understands that the Senate leadership is prepared to offer more than \$40 billion in so-called provider give-backs and nothing for people with cancer, they will be very angry.”

— Ellen Stovall, president of the National Coalition for Cancer Survivorship
information gleaned from the

motherapy — more costly because it must be administered by health care professionals, often in a hospital setting — Medicare will pay for it,” Scherzer said.

“I’m disappointed, somewhat disillusioned, and really pissed,” said Scherzer. “It’s American politics at its worst.”

With Congress slated to return for a “lame duck” session Nov. 22, action on some if not all of these is-

Life Rafterers get together in Arizona

Trio of GIST survivors get acquainted over two days in Phoenix area

An impromptu meeting of Life Raft members took place Oct. 18-19 in the Phoenix, Arizona, U.S.A.

Kathy Flom reports that she and husband Herb had a “last minute thought that it would be fun if any of the Rafterers would be available to meet for coffee while we were in the Phoenix area.”

“Phoenix is about a 3- to 4-hour drive from our home in Lake Havasu City,” Kathy writes. “Eleanor and Steve Lewis accepted our offer and agreed to meet us at the Arizona State Fair.

“Eleanor’s story really touched our hearts as she talked about her surgery and the doctor indicating that they had completely removed the tumor and appeared to have clear margins. Unfortunately, it metastasized a few months later and the doctors gave her little hope of survival.

Even though Herb never had surgery, Kathy says those words “little hope” and “get your affairs in order” rang all too close to home.

“These were the awful words we heard back in January of 2001.”

It turned out Herb and Eleanor started on Gleevec trial one month apart back in February/March of 2001. And there they sat at the state fair, 21 months later, “swapping life stories about kids and grandkids, the nuisance and sometimes humorous side effects of Gleevec, and genuinely enjoying life and taking things one day at a time,” Kathy writes.

“Eleanor gives much credit to



Kathy Flom provided this photo of the get-together at an outlet mall in Tempe, Ariz.

Steve for being such an awesome husband and caregiver and encouraging her to keep fighting when she was initially too sick to care.

“All four of us enjoyed our chat so much that Eleanor and Steve decided to join us the next day at the AZ Outlet Mall in Tempe, Ariz., where we met Billie Baldwin and her friend Joe.

“Billie is a petite retired schoolteacher with a warm smile and lots of energy,” says Kathy. “Billie recently had a tumor removed with clear margins but Billie is doing her homework by gathering all the information that she can in case the dragon returns. She is educating herself and her doctors on GIST and current treatments.”

Billie was joined by her close friend, Joe, who shared his expertise of Web page construction and how to access some neat freebie

sites on the Internet.

“All of us were extremely thankful for Life Raft Group and the host of information and support available to us in one confidential spot. We discussed how knowledgeable and quickly Norman responded to some of our urgent requests for information and support.”

Billie brought an email from Dick Kinzig stating that he and Linda Martinez will be planning an Arizona Life Rafter meeting in February 2003 which we all look forward to attending.

“We also discussed if Richard could get us group rates on pink thongs so it would be easier to identify each other at group meetings in public places,” Kathy writes. “Richard?”

“It was a great weekend filled with beautiful weather, beautiful people and beautiful stories!”

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Who are we and what do we do?

The Life Raft Group is an international, Internet-based, non-profit organization providing support through education and research to patients with a rare cancer called GIST (gastrointestinal stromal tumor), most of whom are being successfully treated with an oral cancer drug Gleevec (Glivec outside the U. S.A.) This molecularly targeted therapy inhibits the growth of cancer cells in a majority of patients. It represents a new category of drugs known as signal transduction inhibitors and has been described by the scientific community as the medical model for the treatment of cancer.

GIST is a rare soft tissue cancer, notoriously resistant to traditional chemotherapy and radiation. Before Gleevec, the only treatment for slowing this cancer was surgery.

The Life Raft Group started in July 2000 as GIST patients and caregivers in the Gleevec (STI571) clinical trials, and later extended membership to all GIST patients. We became a nonprofit group (501-c-3) in the U.S.A. as of June 10, 2002.

Privacy

Privacy is of paramount concern, and we try to err on the side of privacy. We do not send information that might be considered private to anyone outside the group, including medical professionals. However, this newsletter serves as an outreach and is widely distributed. Hence, all newsletter items are edited to maintain the anonymity of members unless they have granted publication of more information.

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Our primary means of communication is through a confidential, secure listserv operated by the Association of Cancer Online Resources, ACOR (www.acor.org).

Disclaimer

We are patients and caregivers, not

doctors. Any information shared should be used with caution, and is not a substitute for careful discussion with your doctor.

As for this newsletter: read at your own risk! Every effort to achieve accuracy is made, but we are human and errors occur. Please advise the newsletter editor of any errors.