

Placebo use in Pfizer trial raises fears

□ Talks continue with pharmaceutical giant on modifying trial protocol

Use of a placebo in the new clinical trial of the experimental cancer drug SU11248 has sparked an effort by the Life Raft Group to revamp the trial to a more humane standard.

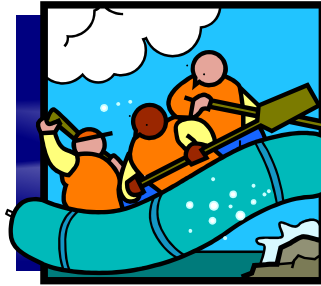
The heart of the issue: Why dying cancer patients who failed Gleevec therapy should be given a sugar pill.

The pharmaceutical giant Pfizer, maker of SU11248, produces such familiar products as Listerine mouthwash, arthritis pain reliever Celebrex, and the erectile pill Viagra. But it has relatively little experience with cancer treatments; indeed, the company's Web site (www.pfizer.com/main.html) lists treatments for 33 medical conditions – but not cancer.

Following a 90-minute telephone

See PFIZER, Page 2

Battling gastrointestinal stromal tumor



LIFE RAFT GROUP

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Partners against pediatric GIST



Conceptual agreement toward establishing a center of for pediatric GIST was reached Nov. 24. Seen above at Memorial Sloan-Kettering Cancer Center in New York are Drs. Pamela Merola and Leonard H. Wexler, with the Life Raft's Norman Scherzer and Tricia McAleer. **See story/Page 3**

Running for dad, and GIST patients worldwide

Lisa Roth, left, and sister Lorie Roth Cudzil are seen near the finish line of the Philadelphia Marathon, which they ran Nov. 23 in honor of their dad, Life Rafter Bill Roth. The sisters, with Lorie's husband, Jerry, not only ran thousands of steps but collected thousands of dollars for the Life Raft Group.



RUNNING FOR OUR DAD" read the banner headline on the one-page flier, and run they did – for 26 miles and 385 yards. Lorie Roth Cudzil, 28, and Lisa Roth, 25, ran the Philadelphia Marathon on Sunday, Nov. 23, in honor of their dad, Bill Roth, a Life Raft Group member diagnosed last January. "Our Dad is presently fighting this monster and winning," read their flier. "We can only hope and pray that his tumor continues to shrink."

See SISTERS, Page 4

PFIZER: Concerns raised over placebo in SU11248 trial

From Page 1

discussion Oct. 30 with Pfizer, Life Raft General Counsel Tom Overley and Executive Director Norman Scherzer went to Pfizer corporate headquarters in New York City on Nov. 11 and met with Krystyna Gurstella, director of professional and public relations, worldwide oncology; Dr. Chris Blakeley, forward development team leader for SU11248, and Susan Yarin, corporate media relations.

The goal was to formally introduce the Life Raft Group and to continue discussion of the phase III SU11248 trial. Talks continued Nov. 25 at the Life Raft Group office in Wayne, New Jersey.

Although many details about the clinical trial were discussed, the key issues remain the inclusion of a placebo for a third of the trial participants, and the lack of a plan for expanded access to the drug.

The current protocol calls for GIST patients with disease progression on Gleevec to be taken off of Gleevec for three weeks before entering the SU11248 trial. Upon entry, they would be randomly assigned to either a placebo or treatment group. They would be reassessed every six weeks.

Those in the placebo group who developed new tumors, or whose overall tumor mass grew at least 20 percent (this in addition to whatever progression they had while on Gleevec and while off Gleevec waiting to enter the trial) would be considered for cross-over into the treatment group.

At the most recent meeting, Pfizer agreed that those in the placebo group whose overall physical condition had deteriorated below minimum trial admission standards would nonetheless be given access to the drug.

In addition, Pfizer agreed to work with the Life Raft Group to find historical data and, if necessary, accumulate current data that would provide sufficient documentation about the re-



Pfizer and Life Raft Group members at the meeting at Pfizer headquarters. From left is Dr. Chris Blakeley, forward development team leader for SU11248, Krystyna Gurstella, director of Professional and Public Relations, Worldwide Oncology; Tom Overley, Life Raft Group general counsel; Norman Scherzer, Life Raft Group executive director, Susan Yarin, corporate media relations.



At left, Tom Overley and Norman Scherzer arrive Nov. 11 at Pfizer's corporate headquarters in New York City.

ality of progression of GIST patients without treatment. If successful, the objective would be to ask the FDA to modify the trial by eliminating the placebo requirement.

The Life Raft Group remains very concerned about the use of a placebo for GIST patients who have no other treatment options. Further talks are planned.

Life Raft, Sloan-Kettering to battle pediatric GIST

Creation of a center of excellence for pediatric GIST moved a step closer to reality when representatives of the Life Raft Group and Memorial Sloan-Kettering Cancer Center in New York City met Nov. 24.

Pediatric oncologist Dr. Leonard H. Wexler and Life Raft Group Executive Director Norman Scherzer agreed to work together to create a center for the treatment and management of pediatric

GIST. Also present was special fellow Dr. Pamela Merola and LRG administrative assistant Tricia McAleer.

“We have a small but growing number of pediatric GIST patients in the Life Raft Group — eight families so far and others on the way,” says Scherzer. “There is no center of medical excellence for the care of these young patients. Therefore we are going to create one.”

Plans are to create an international

registry of pediatric GIST patients, a pediatric tumor bank, a referral source at Memorial Sloan-Kettering for pediatric GIST patients and for pediatric GIST information.

The Life Raft will expand its pediatric GIST data base, create a Web site discussion group for pediatric GIST families and launch an outreach program through its Web site, newsletter and other networks to reach pediatric GIST families and their physicians.

Poss, Byrne, Book named to board of directors

□ New Web site design by Tami Margolis wows Life Raft board members

John Poss of Dallas, Texas, longtime Life Raft Group member and chief financial officer, was named to the Board of Directors at the quarterly board meeting Nov. 22-23.

He'll succeed Ulrich Schnorf, who remains the Swiss country representative.

The board will soon welcome two more new directors. Mia Byrne of Plymouth, Mich., and Bob Book of Carmel, Ind. were chosen to fill the board seats that will be vacated when the terms of Gary Golnik and Michael Matthews end Jan. 1.

“We reviewed a number of remarkable candidates to fill these very important seats, and are proud to announce the appointment of Mia Byrne, John Poss and Bob Book,” said board President Stan Bunn.

Meeting at the Life Raft Group office in Wayne, New Jersey, most of the meeting focused on the forthcoming phase III clinical trial for the Pfizer drug SU11248. A clinical trials advisory group was formed.

The board also reviewed the budgets for the current and coming fiscal year.



Pictured at the entrance to in the Life Raft Group office in Wayne, N.J., are, from left, John Poss, Norm Scherzer, Anita Scherzer, Bob Book, Stan Bunn, Dr. Arnold Kwart, Bernie Kaplan, Dean Gordanier and Allan Tobes.

Next year's budget was tentatively approved pending the results of the Life Raft Group's current fund-raising campaign.

“I would also like to extend a personal thank you to Gary and Mike for their unrelenting commitment and dedication to help our friends and families afflicted with GIST,” added Bunn. “Their contributions to this group and the board will not be forgotten.”

Board members were given a pre-

view of the new Web site designed by Tami Margolis and were thrilled with the results.

In addition to board President Bunn, Secretary-Treasurer Bernie Kaplan, director and CFO Poss, incoming director Book and Life Raft staffers, attending the meeting was Anita Scherzer, Dean Gordanier, Dr. Arnold Kwart, Bill and Fran Roth, Allan Tobes, and (via teleconference) Jerry Call and Tom Overley.

SISTERS

From Page 1

Besides hoping and praying and running a marathon, the sisters decided to do some fund-raising on behalf of the Life Raft Group as well.

“Our family is part of an amazing international support group called the Life Raft Group,” their flier explained. “In addition to supporting GIST sufferers by maintaining a listserv for them to share their troubles and triumphs, the LRG is constantly in contact with doctors, drug companies and other support groups ... Through careful research of medical literature, the Life Raft Group helps GIST patients understand their disease and helps them find the right doctors and cancer centers to treat it.”

“The Life Raft Group needs our help!” said the flier. “We would like to ask you to help us raise some much-needed money for the Life Raft Group. 100% of your contributions will go to help GIST sufferers around the world.”

“Thank you so much for your support,” it concluded. “Our father means the world to us!”

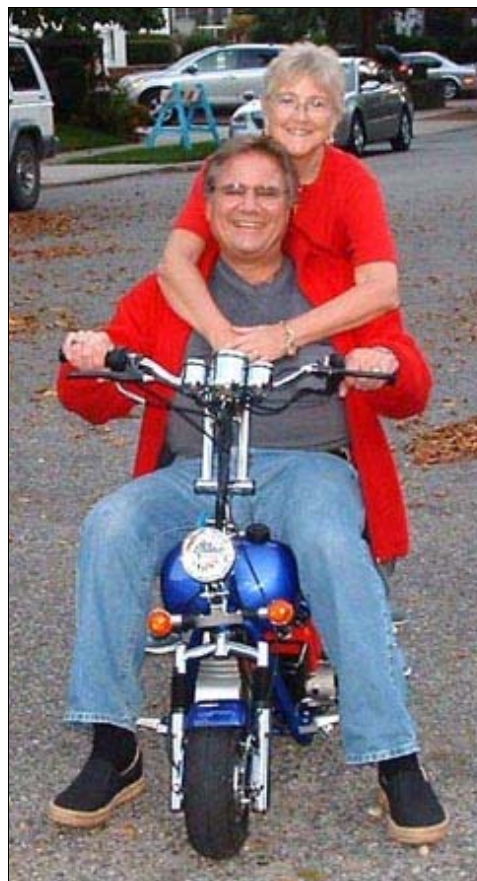
With the help of Lorie’s husband, Jerry, they started handing out the flier to family, friends and co-workers. Because it was only a week before the marathon, their ambitions were modest.

“To be honest, I was hoping to raise \$1,000 at school,” says Lorie, who lives in Queens and teaches out on Long Island. The sisters pinned much of their hope on Jerry, a bond trader at Goldman Sachs. “I thought Jerry might be able to raise \$10,000,” says Lorie.

Bill and his wife, Fran, live in New York. After attending the Life Raft board of directors’ meeting on Saturday, Nov. 22, they headed to Philadel-



Above, Jerry and Lorie Cudzil, who with Lorrie’s sister Lisa raised more than \$37,000 in honor of Bill Roth. At right, Bill Roth aboard his son-in-law’s mini-bike, with the woman he calls “my loving wife,” Frances.



phia to see their daughters run in Sunday’s marathon.

Saturday night, Bill’s daughters let him know what they’d been up to.

“The night before the race, we gave him a folder,” says Lorie. Inside was information on the marathon, a map of the route the sister would run – and the flier they’d been handing out. “When he saw the flier, he first looked puzzled, then he was speechless,” Lorie says. “That night and the next day, every time he wasn’t busy, he kept thanking us.”

Bill didn’t know how much money the trio had raised. “My daughter (Lorie) mentioned it was over \$2,000.” For that matter, Lorie and Lisa didn’t know either. Jerry had been busy collecting contributions, but hadn’t told his wife or sister-in-law. “Jerry kept it a secret from me until Thanksgiving,” relates Lorie.

The day of the marathon dawned clear and cool, perfect running weather. With Lorie living in New York City and Lisa living in Boston,

“we didn’t get to train together, just five long runs,” says Lorie.

Nonetheless, the sisters paced each other for the first 20 miles. That was when a couple of Lisa’s friends joined in the run to offer her morale support, and Lorie slowly inched ahead.

Bill and Fran got to see their daughters run. “Some of their friends had prepared a poster, and held it up along the streets as they ran by,” Bill recalls.

Lorie, runner no. 1857, covered the 26-mile, 385-yard route in 3 hours, 33 minutes and 36 seconds. Lisa, runner no. 1673, finished in 3 hours, 39 minutes and 6 seconds. It was the second marathon they’d entered together. A few years ago, it was Lisa who’d edged her older sister by about 8 minutes when they ran the Disney World Marathon in Florida.

But it wasn’t over yet.

A few days later, when the family gathered for Thanksgiving, Jerry let the sisters in on his secret: he’d collected more than \$30,000 by himself.

See **RUNNING**, Page 6

Lowering dose not advised

□ Doctor sees no cause to reduce Gleevec if it's working, well tolerated

Despite preliminary analysis of one North American study showing no difference in the effectiveness of 400 mg. vs. 800 mg. of Gleevec for GIST, patients on the higher dose should remain on 800 mg. as long as it works and side effects are manageable.

"It does not make sense to decrease the dose if it is working and well tolerated," Dr. Robert Benjamin, chairman of Sarcoma Medical Oncology at the M.D. Anderson Cancer Center in Houston, Texas, told the Life Raft Group recently.

It was Benjamin who reported on the North American Intergroup study of Gleevec in GIST (S0033) at the annual meeting of the American

Society of Clinical Oncology held May 31-June 3 in Chicago. At that gathering of 25,000 cancer professionals, Benjamin said early trial results from 746 patients from 57 institutions showed no difference in response time to progression between 400 mg. and 800 mg. doses.

Noting that the counterpart European study with more patients (946) did show longer time to progression on the 800 mg. dose, and that crossover data in the North American study suggested that crossover appeared beneficial in some cases, Benjamin suggested patients already on the higher dose should stay there.

Whether it will prove better is the main question researchers hope to answer, he said. "The data are still not in on whether higher doses will ultimately prove better,"

Benjamin's comments came about after the Life Raft Group's Norman Scherzer brought some patient con-

Quote:

"It does not make any sense to decrease the dose if it is working and well tolerated."



— Dr. Robert Benjamin

cerns to his attention in an exchange of e-mails in late October. Patients who were on the higher dosage were concerned that the North American study would be used as a basis for lowering their dosage, or that their insurance companies would no longer pay for the higher dosage.

Benjamin, when contacted, responded promptly by asking "what do you need me to do to help." This article is the result.

In Memoriam

There have been 30 deaths in the Life Raft Group to date:

Debbie Nance, 38, Oct. 2, 2000, wife to Eddie, mother of Chris.

Jim Ackerman, 49, Jan. 16, 2001, husband to Betsy, father of Jill and Tom.

Jim Perham, 63, May 2001, husband to Karen, father of Craig, Kathy, Jennifer.

Amy Barney, 25, June 10, 2001, wife to Reed, mother of Joshua.

Jeff Prichard, 52, July 11, 2001, husband to Joyce, father of Gregory and Scott.

Ron Martinez, 60, July 25, 2001, husband to Jo Ann, father of Ron, Wendy, Natalie.

Ehud Nehemya, Aug. 7, 2001, father to Einat Zelinger, father-in-law of Ophir Zelinger, Hadar Nir.

Bruce Gunn, 43, Nov. 8, 2001, husband to Roisin, father of Seamus, Liam, Brendan and Aislinn.

Robert Carr, Dec. 30, 2001, father of Robert, Steven, Scott and Melissa.

Jonathan Montague, 23, Jan. 19, 2002, son of Ray and Sheila Montague, brother to Jamie, Adam, Meghan.

Robert Lecca, 49, Jan. 28, 2002, husband to Diane.

Jacob Winfield Waller III, 67, March 31, 2002, husband to Jerry, father to Rita, Richard.

Mary Golnik, 50, April 18, 2002, wife to Gary, mother to Timothy.

Ana Maria Baldor-Bunn, 30, April 19, 2002, wife to Stan, mother to William.

Stewart "George" Wolf, 51, April 19, 2002, husband to Maggy, father to Thomas.

Michael Cornwell, April 19, 2002, husband to Cathy.

Jerry Pat Rylant, 61, May 5, 2002, husband to Pamela, father of four, grandfather to 10.

Jill B. Meyer, 53, June 9, 2002, mother of Aliza.

Todd Hendrickson, 44, June 29, 2002, husband to Janet, father to Max, Tyler and T.J.

Chet Duszak, 79, Oct. 5, 2002, husband to Kay,

father to Lori.

Nora Shaulis, 42, Nov. 4, 2002, wife to David, mother to Griffin.

Howard Delapenha, 41, Dec. 14, 2002, husband to Sandra, father to Joshua and Hannah.

Kathy Colwell, 45, Jan. 5, 2003, wife to Tom, mother of Katherine, Mary and Tom.

Cynthia G. Whitson, 64, Jan. 19, 2003, wife to Jerry, mother to Steve, Jill, Randy and Donna.

Abdul Hai, 76, Feb. 26, 2003.

William Lawson, 56, July 3, 2003, husband to Gwen, father of Cory, Jennifer and Rhonda.

Laura Blanchette, 47, Aug. 4, 2003; wife of Mitch, mother of Sarah and Curtis.

Maryann Klein, 56, Sept. 4, 2003; wife of Gary, mother of Michelle, grandmother to Brandon.

Pat Ford, 48, Sept. 6, 2003; wife to Brad, mother to David and Laura.

Frank Weigand, 66, Oct. 24, 2003; husband to Ruth, father to Susan and Dave.

Swiss representative has busy fall

□ Alliance forged with German GIST patients via Das Lebenshaus

By Ulrich Schnorf

I have been a member of the LRG since Feb. 4, 2002, and country representative for Switzerland since January 2003. I am a founding member and Swiss representative of Das Lebenshaus, the German GIST/CML patient group. The latter is not working solely through the Internet because many European patients over 50 are not used to the Internet.

This is a short report on my activities in the fourth quarter of 2003:

Oct. 4: The first Medical Cancer Congress is held in Basel, Switzerland, at the annual meeting of the German, Austrian and Swiss Societies for Oncology and Hematology, Oct. 4-8. An entire day was reserved for information and discussion with patients. The speaker (director) of Das Lebenshaus, Markus Wartenberg, and I represented both Das Lebenshaus and the Life Raft Group. We had a stand and handed out information and made contacts with comparable patient organizations.

Nov. 14-15: First patient meeting of Das Lebenshaus is held in Heidelberg, Germany. Forty-two GIST patients and caregivers from Germany and

Switzerland were briefed by the most experienced German GIST oncologist, Dr. Peter Reichardt of Charite, Berlin. He spoke about GIST, Gleevec, the mechanisms of Gleevec resistance and possible actions. Reichardt has already started clinical research with PKC412 and RAD 001 from Novartis. He will start with SU11248 from Pfizer beginning of January 2004. He was very open and positive towards us.

We also had much exchange of experience between the patients. The meeting was perfectly organized by Wartenberg, with Reichardt directing the medical discussions.

Das Lebenshaus will work on producing patient brochures and a small manual for the foundation, and establishing local patient groups over the next two to three months.

Wartenberg and I visited Prof. Leyvraz (CHUV, Lausanne, Switzerland), who performed the clinical research of Gleevec for GIST in Switzerland and leads the GIST center of excellence there. We also met the new director of oncology at the University Hospital of Zurich, Prof. Knuth. We handed out information about Das Lebenshaus and the Life Raft Group. They promised to



SCHNORF

inform their patients. They were very cooperative and positive about our ideas.

Nov. 23: Swiss Television Programme 1 broadcast an hour-long Cancer Gala. The last five minutes was on GIST and Gleevec, and used a film made previously of my GIST history and how I fought GIST with the help of my wife and a friend who went into the Internet late in 2000. The film showed me doing sports, hiking and working on the Internet. They showed the home page of the Life Raft Group, the page for registration as a member of the LRG, and the home page of Das Lebenshaus. I was able to speak live and invited GIST patients and their caregivers to contact me for building up a Swiss GIST patient group.

The main topics of this TV broadcast the thymus cancer of a very famous and popular Swiss TV editor, breast cancer and prostate cancer, and fundraising for the cancer league.

I made a lot of contacts by phone, fax and e-mail, and have already contacted five future members of the Swiss group to whom I sent information on LRG and Lebenshaus, including Web site addresses and a letter of my intent to form a group the first next year. It will have Internet links to the LRG, but because of language and geographic circumstances, we will remain a subgroup of Das Lebenshaus.

RUNNING: 'We just want the best for our dad'

From Page 4

Together, Lorie, Lisa and Jerry got to tell Bill that more than \$37,000 was being donated to the Life Raft Group in his name.

"I was completely shocked," Bill says. "Norman (Scherzer) called a few days later, and he was shocked." But his daughters and son-in-law "all believe in the Life Raft Group and what it's doing."

Bill is understandable proud of his daughters and his son-in-law of 18 months.

"My son-in-law is a very giving person, a very dedicated person. He really cares."

Jerry, Lorie and Lisa are also basking in the glow that comes with helping others, and discovering that so many are willing to help.

"People came up to me and were so concerned about my dad," says Lorie. "And they were so generous ... the people at school that know me, the people that know Jerry at his work, everyone was so nice, so giving."

"We just want the best for our dad," Lorie adds.

And Bill ... well, he's still thanking his children.

New York Life Rafterers meet at Gilda's Club



The second meeting of the New York City Area Life Raft Group took place Monday, Nov. 24, at Gilda's Club in Manhattan. Present, from left, is Norman Scherzer, Jerry Cudzil, Rita Raj, Tricia McAleer, Dan Cunningham and Bernie Kaplan. The group shared stories and support, and planned future meetings. The size of New York City may necessitate two groups — one meeting midweek in the city alternating with weekends in a suburb.

Brockstein speaks of Chicago area group

By Dick Kinzig

The Chicago Chapter of the Life Raft Group held its quarterly meeting Sunday, Nov. 23 at the Wellness Place in Inverness, with 17 members attending. New members, Pam and Mark Lewkovich, were introduced to the group. This was Howard Reich's first meeting but he is no stranger to the group since his contributions started at the ASCO convention. Members came from as far away as Indianapolis, Decatur, IL. and Milwaukee, Wisc.

The guest speaker was Dr. Bruce Earl Brockstein from the Medical Oncology Department of Medicine of Evanston Northwestern Healthcare Hospital. Dr. Brockstein is assistant professor of medicine at Northwestern University. After hearing the bio of

each GIST survivor, Brockstein gave his comments about several of the issues raised, as well as his observations on the several hospitals in the area and their cancer centers for GIST treatment.

There were many questions asked as well. Brockstein provided a description of the services offered at Evanston Hospital for GIST patients. He himself has several GIST patients under his care, including three from our group.

Jim Hughes, Howard Reich and Dick Kinzig provided information from their interview at Northwestern Memorial Hospital in search of the Chicago area's Center of Excellence. They met with Drs. Leo Gordon, Steven Rosen, Mary Mulcahy and An-



BROCKSTEIN

drew Evens to inform them of the Life Raft Group and to outline what the group is about. Life Rafterers requested that they create a write-up on the benefits and care that Northwestern can offer for GIST patients and that will be shared once it is forthcoming. A similar write-up was obtained from the U. of Chicago and appeared in the October LRG newsletter.

Carol Berres joined us and gave a report on the Sugem trial at Dana Farber Cancer Institute, having returned from Boston a few days previous to the meeting. She had good reports on her health.

After a brief report on fundraising and membership, we adjourned to partake in refreshments and members had a good chance to visit with each other and exchange ideas.

The next meeting is scheduled for Sunday, March 21 at Wellness Place.

THE LIFE RAFT GROUP

E-mail: liferaft@liferaftgroup.org
 Internet: www.liferaftgroup.org

● 40 Galesi Drive
 ● Wayne, NJ 07470

● Telephone: 973-837-9092
 ● Fax: 973-837-9095

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). The Association of Cancer Online Resources provides the group with several listservs that permit members to communicate via secure e-mail. Many members 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. Several new drugs are now in clinical trials.

How to join

GIST patients and their caregivers may apply for membership free of charge at the Life Raft Group's Web site, www.liferaftgroup.org or by contacting our office directly.

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 articles are edited to maintain the anonymity of members unless they have granted publication of more information.

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John Poss
 and **Gerald Knapp**

nscherzer@liferaftgroup.org
tmcaleer@liferaftgroup.org
jcpoos@swbell.net
jroy@liferaftgroup.org
guitarman335@msn.com
[dnrgibson@yahoo.com](mailto:dnrngibson@yahoo.com)
mebmcb@wowway.com
richardpalmer@hawaii.rr.com
Jerry.Call@attbi.com
tami@comcast.net
jcpoos@swbell.net
gsknapp@winfirst.com

Life Raft country representatives

Australia
 France
 Iran
 Mexico
 Netherlands
 Poland
 Switzerland
 United Kingdom

Greg Ladbrooke
Bertrand de la Comble
Negar Amirfarhad
Rodrigo Salas
Ton de Keijser
Bartosz Szczesny
Ulrich Schnorf
David Cook

lad57b@bigpond.com
bdelacomble@oreka.com
negaraf@sympatico.ca
rsalas@maprex.com.mx
akeijser1@chello.nl
bsz1974@yahoo.com
ulrich.schnorf@dplanet.ch
D.Cook@sheffield.ac.uk

Life Raft area groups

Chicago, U.S.A.
 Detroit, U.S.A.
 Los Angeles, U.S.A.
 New York, U.S.A.

Richard Kinzig
Allan Tobes
Floyd Pothoven
Dan Cunningham
 and **Bernie Kaplan**

rjkinz@aol.com
atobes@comcast.net
floyd@lasersealer.com
CunninghamDA@coned.com
BBKap@aol.com

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SBunn@BSTGlobal.com
BBKap@aol.com
liferaft@attbi.com
mike@caster-rack.com
rsalas@webtelmex.net.mx
nswplas@mb.sympatico.ca
jcpoos@swbell.net

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Donations, payable to The Life Raft Group, should be mailed to:

The Life Raft Group
 40 Galesi Dr.
 Wayne, NJ 07470

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