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MYELOMA TODAY

A PUBLICATION OF THE INTERNATIONAL MYELOMA FOUNDATION

"Until There is a Cure... There is the IMF."

HIGHLIGHTS

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MESSAGE FROM IMF PRESIDENT

Dear Reader,

It's that emotional time of year again, when we reflect back on the past year or bygone times, sometimes with tears for what we've lost, and sometimes with smiles for what we've achieved and for the sweet memories of people who have touched our lives. It's also a time to look forward with hope and anticipation that the New Year will bring joy, peace and good health – it's a clean slate and anything can happen!

Susie Novis

This past year has been the IMF's most successful year ever, and we didn't do it alone. The IMF is made up of people of all races, from all walks of life and from diverse cultures. We are a kaleidoscope of humanity with a common bond – multiple myeloma – and a belief that one person can make a difference and two people can make a miracle.

The IMF is about education, support, research, and advocacy, and we're very grateful to the thousands of people who each year selflessly help the IMF help others. To these invaluable individuals we extend a very heartfelt thank you:

To the extraordinary doctors and nurses who have donated their time and expertise as faculty at the IMF Patient & Family Seminars;

To the outstanding support groups and their leaders who, like the IMF, believe that no one should have to face this alone. Working selflessly, they truly make a difference in the lives of patients, families, and caregivers – I can't imagine what any of us would do without them;

To the writers, editors, and proofreaders of the IMF's many publications including Myeloma Today and Myeloma Minute. These publications empower patients, giving them vital information on research advances and the latest in the treatment and management of myeloma;

To all the people who participate in advocacy, writing letters, calling their legislators, going to Washington DC to make their collective voices heard – you do make a difference;

To researchers around the world who are working on breakthrough projects both in the lab and in the clinic, bringing us new therapies, ever closer to a cure. To all the doctors, researchers, statisticians, data managers, and lab technicians who have agreed to collaborate with the IMF and work together on Bank On A Cure – we will unlock the DNA door to a cure;

To all the remarkable people who help the IMF fund these projects, many of whom hold fundraising events in every size, shape, and theme imaginable. From walk-a-thons, to golf tournaments, to letter writing campaigns, to hair cutting and styling, to a Fiesta for a Cure, they have worked so hard and have produced amazing results – we literally couldn't do it without you!

And finally to the IMF staff. I'm privileged to work with such a dedicated and talented team of people who send out over 1,000 information packages a month, who answer over 400 hotline calls and 200 emails a month, who organize seminars and events, who produce all of our written materials, and keep the web site humming with the most updated information available. They are dedicated, passionate, deeply caring people who never forget what it's all about and who we all work for – you.

Thank you all and here's to a Happy and Healthy New Year.

INTERNATIONAL MYELOMA FOUNDATION

Dedicated to improving the quality of life of myeloma patients while working toward prevention and a cure.

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ADVOCACY UPDATE: Congress Adjourns With Support for Myeloma Community

Greg Brozeit with Former President George Bush and Barbara Bush

By Greg Brozeit

Funding to help support the IMF Bank On A Cure® (BOAC) program and implement the Geraldine Ferraro Blood Cancer Education Program at the Centers for Disease Control and Prevention (CDC) highlighted the end of the congressional session for the myeloma and cancer communities.

Thanks to the persistent work of Sen. Kay Bailey Hutchison (R-TX), the conferees to the Labor, Health and Human Services, and Education appropriations bill approved $500,000 to help support the IMF's Bank On A Cure program. Bank On A Cure will create a comprehensive DNA bank to help researchers identify genetic markers to assist in diagnosis, facilitate prognosis, and determine drug efficacy not just for myeloma patients, but for all who are affected by cancer.

A recipient of the IMF Ribbon of Hope Award in 2002, Sen. Hutchison stated, "I have seen firsthand the devastation of multiple myeloma. We need every tool available to advance the diagnosis and treatment of this and other cancers. This DNA bank is just one of many examples of the ingenuity being employed in the fight against cancer, and I'm proud to stand side-by-side with the International Myeloma Foundation in this effort."

Sen. Hutchison also championed funding of $5 million for the CDC Ferraro education program. The funds will be used to establish nationwide education programs for patients and doctors for myeloma, leukemia, and lymphoma. Details of the program will be made public in the coming year.

The funding will not be finalized until the Senate returns to vote on the bill in January 2004. The House approved the bill containing these provisions on December 8, 2003.

Susie Novis and Sen. Kay Bailey Hutchison

MIXED MESSAGES ON RESEARCH AND CANCER CARE

In addition to Hutchison-supported issues, congressional conferees to the fiscal year 2004 Labor, Health and Human Services and Education appropriations bill agreed to a $1 billion increase for the National Institutes of Health (NIH). The 3.7% increase—which will bring the total NIH funding to slightly less than $28.3 billion—is significantly less than the 8-10% requested by the medical research advocacy community.

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ASH 2003: An Avalanche of New Information

What does it all mean, and where do we go from here?

Brian G.M. Durie, M.D.
Cedars-Sinai Comprehensive Cancer Center
Los Angeles, CA

By Brian G.M. Durie, M.D.

The huge number of presentations at the American Society of Hematology Meetings (ASH), December 4th – 9th 2003 in San Diego, capped a truly momentous year for myeloma research and new drug development. Earlier this year, bortezomib (VELCADE™) was approved by the FDA for the treatment of multiple myeloma patients who have received at least two prior therapies and have demonstrated disease progression. Finally, a new drug approved specifically for myeloma! But this was just the most obvious evidence of the increased focus on myeloma, a disease deserving fundamental research as a basis for the search for better therapies.

At ASH, several sessions focused on myeloma and related diseases, including the so-called **"Super Friday"** sessions on December 5th, Educational Sessions, IMF working group meetings, plus the formal oral and poster scientific presentations. Details of many of these sessions can be accessed electronically via the IMF website at *www.myeloma.org*. The "Super Friday" session dealt with challenging cases, including (topic/discussant in parentheses): **Initial Therapy** (Dr. Vincent Rajkumar); **Renal Failure** (Dr. James Berenson); **Role of Transplantation** (Dr. Jean-Luc Harousseau); **Refractory Myeloma** (Dr. Paul Richarson); **Novel Therapies** (Dr. Donna Weber); and **Neuropathy** (Dr. Robert Kyle). The "Myeloma Educational Session" covered **Advances in Biology and Therapy of Multiple Myeloma**. The IMF Myeloma Working Group addressed a number of topics, including the new **International Staging System** (ISS), as well as new criteria for **Response Evaluation and Endpoint Definitions**.

Although every abstract adds a new piece of information, it is helpful to summarize the major advances, which fell into several categories:

- **Role of high-dose chemotherapy with transplantation**.
- **Novel therapies**, including particularly bortezomib (VELCADE ™), thalidomide and analogs, arsenic trioxide, Doxil® (liposomal doxorubicin), Samarium and Holmium, and Atiprimod.
- **Prognostic factors and staging**, including molecular and cytogenetic studies.
- **Laboratory-based studies of biology**, e.g. stem cell analyses and signal transduction pathways, apoptosis, immunology and many other aspects of cell biology.
- **Clinical studies and diagnostic testing**, including the role of FREELITE™, MRI, FDG/PET scanning, and SNP analyses.

Transplant (Abstracts #135 - #138)

There was tremendous interest in the long-awaited results of the SWOG/ECOG/CALGB Intergroup randomized trial S9321 of high-dose therapy (HDT) versus frontline standard therapy using VBMCP (vincristine, BCNU, melphalan, cytoxan, and prednisone) (Abstract 135: presented by Dr. Bart Barlogie). And the answer was: **In this particular study, there was no improvement in overall survival for frontline HDT with transplant! There was a slight improvement in progression-free survival with high-dose therapy (25 vs. 21 months: p=.05). Explanations offered and discussed for the lack of improvement in overall survival were:**

- **52% (89 patients in total) in the standard treatment arm of the study received transplant at the time of relapse.** Thus the study in reality compared early transplant with late transplant, for about half the patients.
- **All the standard (VBMCP) treatment patients received high-dose cytoxan up front** for stem cell mobilization and harvesting. This "anti-myeloma intensification" may account for the better outcome with VBMCP in this S9321 study versus prior protocols (median overall survival of 52 months versus 37 months in prior protocols **without** high-dose cytoxan for mobilization).
- **The overall prognostic factors in this study were better than average**. Since transplant appears to be helpful, particularly for higher-risk patients (e.g. MRC study), but less so for "normal" or good-risk patients, this may account in part for the lack of transplant benefit.

So what conclusions can be drawn from this Intergroup study? Unfortunately, not as many as had been hoped. There is support for the notion that "upfront" and "delayed" transplant have an equivalent impact upon overall survival, as already shown in a French randomized study by Fermand et al. But there is also support for the conclusion that upfront "intensification" with high-dose cytoxan and/or stem cell transplantation can improve overall outcome. It remains unclear from this study which patient groups benefit from "intensification." The authors conclude that

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News & Notes

Patient & Family Meetings

If you missed out on the Fort Lauderdale Patient & Family Retreat, January 23-25, be sure to sign-up for our next seminar in Minneapolis, MN. Scheduled for March 12 and 13, the retreat will provide the latest news, updates and individual consultation from the world's experts in multiple myeloma. Dr. Brian Van Ness (Professor in the Department of Genetics, Cell Biology, and Development at the University of Minnesota), one of the foremost myeloma authorities and a lead investigator for Bank On A Cure™, is scheduled to speak. This is an excellent opportunity to meet Dr. Van Ness and gain the latest insights into current myeloma research. For complete details on this event and upcoming seminars in San Jose (CA), Teaneck (NJ), Vienna (Austria), and Ankara (Turkey), please visit *www.myeloma.org* and click on "Meetings and Events".

HealthTalk

To see and hear the latest news from leading authorities in the field of myeloma, visit our online web-cast section to access information about treatment and therapies. Topics include:

Relapsing and Refractory Multiple Myeloma: What's New in Research?

In this informative program, top multiple myeloma experts discuss new clinical trials for relapsing/refractory multiple myeloma, and one women shares her experience participating in a clinical trial.

Clinical Trial Update for Multiple Myeloma

Promising clinical trials are proving very beneficial in the treatment and possible remission of multiple myeloma. In this program, top experts discuss ongoing clinical trials and how they could affect treatment options.

To review all available web-casts, go to: *www.myeloma.org/myeloma/webcasts.jsp*

Around the World

With 101 myeloma support groups worldwide, the IMF makes available many of our publications in multiple languages. Currently we publish online or in hardcopy various materials in 13 languages. With the generous support of our Corporate Sponsors, the IMF has plans to expand the number of languages and publications we make available to the patient and family, medical and research communities. For more information about publications, please call us at 800-452-CURE (2873), or visit our website: *www.myeloma.org*.

In news from Europe, the International Myeloma Foundation (IMF) UK, held its first fundraising dinner on Monday, November 17, 2003. Over 300 guests attended the dinner at the Langham Hilton London where Alastair Campbell was the guest of honor and after-dinner speaker. The £156,500 ($ 270,000) raised at this event will go specifically toward Bank On A Cure™ (BOAC), the first comprehensive DNA bank for myeloma patients. The goals of BOAC are to allow doctors to target treatment for individual patients based on their genetic make up, to avoid side effects for those patients considered to be at high risk, and finally to understand the causes of myeloma. For more information about our U.K. offices and upcoming events, visit *www.myeloma.org.uk*.

Thank You!

During the Fall of 2003, many of you received our update letter and responded with generous donations to ensure we continue meeting the needs of patients and families dealing with myeloma. The IMF is very grateful for your ongoing support and we are honored to have this opportunity to publicly thank you. Be sure to keep an eye out for new information and updates in our Spring update letter.

2004 Brian D. Novis Research Grant Awards

By Robert A. Kyle, M.D.

Six of the world's most promising clinical investigators have been chosen to receive the 2004 Brian D. Novis Research Grants from the IMF in order to further research into better treatments, management, prevention, and a cure for multiple myeloma. The awards presentation took place on December 6, 2003, during the American Society of Hematology (ASH) 45th Annual Meeting. This is the 10th year that the IMF has made grants possible through donations from private individuals. The awards were bestowed by Dr. Brian Durie, IMF Chairman of the Board and scientific advisor to the IMF, and Susie Novis, President of the IMF.

Senior Grant Award

Manuel Penichet, M.D., Ph.D., Associate Researcher at UCLA, hypothesizes that antibody-avidin fusion proteins specific for the transferrin receptor (antiTfR IgG3-AV) can be used alone or in combination with other agents as a novel and effective antiproliferative drug in myeloma. He will first determine the effect of antiTfR IgG3-AV on cell proliferation and apoptosis in myeloma cells. He will then examine the synergistic effect of the combination of antibody-avidin fusion proteins specific for the transferrin receptor with other cytotoxic or sensitizing agents. He then plans to examine the in vivo anti-tumor activity of anti-TfR IgG3-Av alone or combined with another cancer drug in SCID mice bearing human myeloma cells. This represents a new approach to targeted therapy of myeloma.

Dr. Manuel Penichet

Junior Grant Awards

Dr. Marco Ladetto, Assistant Professor in Hematology at the University of Torino, has demonstrated that COX-2 expression is common in myeloma. His preliminary data indicates that nearly 35% of myeloma patients show increased expression of COX-2. He plans to determine the presence of COX-2 expression on a large number of myeloma patients at diagnosis, remission, relapse, and at progression. He will quantify COX-2 mRNA expression and demonstrate COX-2 in the bone marrow by immunochemistry as well as COX-2 expression analysis on assorted cell populations. He will evaluate the prognostic value of COX-2 expression in the outcome of therapy of myeloma.

Dr. Marco Ladetto

Dr. Chao-Lan Yu, Assistant Professor at Vanderbilt University, proposes to continue his studies on the suppression of cytokine signaling through SOCS-1 and SOCS-3 proteins. He has demonstrated that both SOCS-1 and SOCS-3 are present in undetectable levels in two myeloma cell lines. He hypothesizes that the SOCS-3 gene may be hypermethylated in myeloma cells. He has constructed recombinant retroviruses expressing SOCS-1 and SOCS-3 proteins. He plans to continue his investigation into the mechanisms of defective SOCS gene expression and the tumor-suppressing effects of SOCS protein. He will examine the role of hypermethylation of the SOCS genes which are involved in down-regulating cytokine stimulation. He will determine whether SOCS-3 is hypermethylated in myeloma and whether the enforced expression of SOCS proteins has an effect on apoptosis and cell growth.

Dr. Hideaki Ishikawa

Dr. Mathias Oelke, Research Associate at Johns Hopkins University, proposes developing artificial antigen presenting cells for adoptive immunotherapy for myeloma. The major problem is the presence of functional defects associated with autologous dendritic cells in patients with myeloma, as well as the lack of a reproducible and economically viable method for generating antigen-specific T-cells using autologous dendritic cells. His preliminary data indicates that HLA-Ig based artificial Antigen Presenting Complexes (aAPC) can produce antigen specific T-cells. If successful, the use of HLA-Ig based aAPC's would be a new approach to produce large numbers of specific T-cells for adoptive transfer in myeloma.

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IMF Calendar

January 23-25, 2004
IMF Patient & Family Retreat
Ft. Lauderdale, FL

March 12-13, 2004
IMF Patient & Family Seminar
Minneapolis, MN

April 4, 2004
"Running Paris" Marathon
Celebrating Jerry's Journey
Golden, CO

April 16-17, 2004
IMF Patient & Family Seminar
Vienna, AUSTRIA

April 22-24, 2004
Torino Clinical Meeting
Torino, ITALY

April 29 - May 2, 2004
ONS Annual Meeting
Anaheim, CA

May 8, 2004
Robert A. Kyle Lifetime Achievement Award
Honoring Bart Barlogie, M.D., Ph.D.
Little Rock, AR

June 5-8, 2004
ASCO Annual Meeting
New Orleans, LA

June 25-27, 2004
Annual IMF Support Group Leaders Retreat
Durham, NC

July 2004
IMF Patient & Family Seminar
Ankara, TURKEY

July 26, 2004
Kathy McCormick Memorial Golf Tournament
Hampstead, MD

September 18, 2004
IMF Patient & Family Seminar
Barcelona, SPAIN

September 24, 2004
IMF Patient & Family Seminar
Kyoto, JAPAN

September 25, 2004
IMF Patient & Family Seminar
Paris, FRANCE

October 1, 2004
IMF Patient & Family Seminar
Torino, ITALY

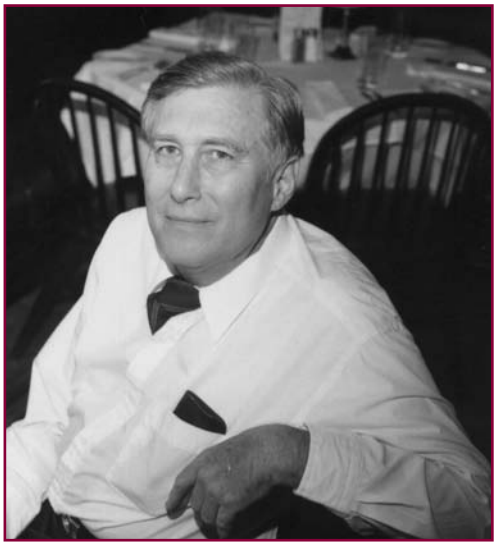
October 8-9, 2004
IMF Patient & Family Seminar
Teaneck, NJ

November 6, 2004
Ribbon of Hope Gala
Los Angeles, CA

December 3-6, 2004
ASH Annual Meeting
San Diego, CA

For more information, please visit the IMF online at www.myeloma.org or call us at (800) 452-CURE.

IMFer Profile: The Art of Survival



Don Woodward

By William J. Lauttamus

His name is Don Woodward and he is a living multiple myeloma legend. In 1991, Don was visiting his in-laws on the West coast when severe back pain forced him to return home, where he was ultimately diagnosed with multiple myeloma.

Don grew up in the Washington, D.C. area and attended Washington-Lee High School in Arlington, Virginia. Then on to Stanford University and graduate school in international affairs at the George Washington University. He served four years on the Peace Corps staff before becoming a foreign service officer, which included assignments in Pakistan and Afghanistan.

Now a grumpy old man of 68, Don resides in a lovely tree surrounded home in McLean, Virginia, with his gorgeous wife Annette. How she has put up with his antics over the past forty years remains a mystery that only the Heavens understand. Always mentally alert, Don has the ability to totally decimate those within hearing range who are struggling linguistically, and the irritating part is that he is generally correct.

Don and Annette really represent John Wayne's "True Grit". After surviving the early days of modern multiple myeloma therapy (1991-1995), Don fell on black ice on his home driveway and severely fractured his left leg. The Woodward chapters since this incident in 1995 include a 15" steel plate, staph infection, and periodic severe pain. Yet they survive. How?

Don's most important helpful hint, which he stresses again and again, is to get access to a myeloma "guru" – a recognized and established expert in multiple myeloma – wherever he or she may be.

My wife, Monica, was diagnosed with multiple myeloma in December 2002. The following few months proved very difficult. After the initial shock, we looked to the standard medical community to provide suitable guidance. Wrong. If we hadn't found Don through the IMF, and weren't able to benefit from his knowledge and experience, I shudder to think what would have happened. Yet probably the majority of newly-diagnosed myeloma patients rely totally on their local doctor's advice and never fully consider all of the myeloma treatment options available to today's patients. My wife is now treated by a hematologist/oncologist who is very well versed in the treatment of multiple myeloma.

Don's second helpful hint is to maintain a positive attitude. If you have a spouse, family member, or friend who takes an interest in your welfare, it makes coping easier than going it alone. Our family has found that this can be reinforced through a support group. The IMF maintains a listing of myeloma support groups – in the U.S. and wordwide – which can be requested by phone or email.

Now retired, Don mainains a very active life. He travels, reads adventure novels avidly, frequently visits with family and friends, and participates in IMF activities as a member of the Board of Directors. Annette still maintains a full-time position in the hotel marketing field. As a multiple myeloma spouse, she

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Ask the Expert: What's New With the Use of VELCADE™ in MM?

Sagar Lonial, M.D.
Assistant Professor, Hematology Oncology
Director of Translational Research, B-cell Malignancy Program
Winship Cancer Institute
Emory University School of Medicine
Atlanta, Georgia

By Dr. Sagar Lonial

The past 12-18 months have seen the introduction of multiple new therapeutic options for patients with newly diagnosed or relapsed multiple myeloma. The annual American Society of Hematology (ASH) 2003 meeting was filled with reports of new agents and updates on recently novel combinations of existing agents for the treatment of multiple myeloma. This report contains a brief summary of some of the exciting data presented during the meeting utilizing the newly approved agent bortezomib (VELCADE™).

Dr. Orlowski and colleagues from the University of North Carolina reported on a phase I trial combining bortezomib with the liposomal agent Doxil®. The trial was open for any relapsed hematologic malignancy and 24 patients with myeloma enrolled in the trial. Among the 22 evaluable multiple myeloma patients, 5 patients achieved a complete remission (CR), 2 patients achieved a near CR, 8 patients achieved a partial remission (PR, > 50% reduction in serum protein), and 6 patients achieved either a minor response or stable disease. The toxicities from this trial were modest, and among a subset of patients who were considered non-responsive to Doxil® or other agents of similar class, significant responses were seen. A phase II/III trial evaluating this combination with fixed doses of both the Doxil® (40mg/m^2 on day 4) and bortezomib (1.3mg/m^2 on days 1,4,8, and 11) trial is planned.

Dr. Yang and colleagues from Cedars-Sinai reported on their trial combining oral melphalan with bortezomib at very low doses. This trial is based upon in vitro data from Dr. Bersenson's and Dr. Anderson's groups showing that there was significant synergy when these agents were given together, and that very low doses of both agents could be used. Dr. Yang started with doses of bortezomib of 0.7mg/m^2 (half the usual dose) given on days 1,4,8, and 11, with doses of melphalan as low as 1/10 the usual starting dose, and increasing up to higher doses of melphalan. In this dose escalation trial, 12 patients achieved a response with 10 PRs, and 4 patients who achieved minor response or stable disease. The only major toxicity was the expected suppression of blood counts seen with melphalan. Further study of this combination is also planned, and really highlights the benefit of well-designed clinical trials modeled after well-designed laboratory work.

Dr. Zangari and colleagues from Arkansas also presented data on the combination of bortezomib/thalidomide/dexamethasone. Nearly all of the patients in this trial had received prior transplant, 81% had received prior thalidomide, and 75% of the patients in the trial had abnormal cytogenetics. Because of concerns regarding neuropathy among recipients of both bortezomib and thalidomide, the thalidomide was started at a dose of 50mg/day and increased to a maximum dose of 200mg/day. Despite starting with a low dose of thalidomide in combination with the bortezomib, 22% of patients achieved a CR or near CR, and 50% of patients achieved a PR. Along with the impressive response data, the frequency of severe neuropathy (grades 3 or 4) was only 10%; about 50% of the patients did develop some neuropathy (grade 1 or 2). Overall the regimen was quite well tolerated, and is currently being studied in a larger group of patients, but should be done with careful attention to the issue of neuropathy.

In response to the overwhelmingly positive data with either single agent or combinations of agents with bortezomib, Dr. Jagannath and his colleagues from the Salick network reported on the first 16 patients enrolled to receive bortezomib as first-line therapy for symptomatic myeloma. In this trial patients received standard bortezomib at a dose of 1.3mg/m^2 on the day 1, 4, 8, 11 schedule every 21 days. Patients did not receive dexamethasone unless the response after 2 cycles was less than a PR, or the response after 4 cycles was less than a CR. Among the first 12 evaluable patients, 75% achieved either a PR or near CR, and stem cell collection and subsequent transplant have been uneventful thus far. While the authors are cautious about making predictions based upon this small cohort of patients, this preliminary analysis is promising not only from the standpoint of responses to initial therapy, but also because of the stem cell collection and transplant data that are planned as part of this trial. To date there is no reason to suspect that the collection of stem cells for a subsequent transplant is an issue for patients receiving bortezomib, but other studies will also address this issue.

Three abstracts were presented to further describe toxicities of bortezomib or its use in patients with renal insufficiency. The first was an abstract presented by Dr. Richardson from the Dana-Farber Cancer Center on behalf of the Summit and Crest studies looking at the problem of peripheral neuropathy. Among the patients entered into those two trials, 81% had neuropathy at the time of study entry, and 35% developed

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Did You Know?

Earn American Express® Points

The American Express® card makes giving easier. You can now donate online through a secure website at *www.guidestar.org/partners/amex/index.jsp* and earn Membership Rewards® points when you charge your contribution to an eligible, enrolled American Express Card. You will receive an email confirmation minutes after making your contribution. Best of all, donating online helps us reduce administrative costs. And that means we're able to put your generous support directly into research for a cure, patient and family initiatives, and educational conferences, workshops, and seminars. The IMF is proud to be listed on the American Express Donation site.

Matching Gifts

Some employers will match employee's gifts to the IMF. To obtain a matching gift form, please contact your employer's personnel or employee relations office. Send the form, accompanied by your donation, to the IMF and we will do the rest.

Real Estate

Real property, either in entirety or in part, can be deeded to the IMF. It is possible to arrange a sizable tax deduction by deeding a home to the IMF while continuing to occupy the property for life.

Gifts with Lifelong Income

Donors can transfer money, securities, or real estate in trust to the IMF and receive income for themselves or others for life. Donors may receive immediate tax benefots. And, ultimately, the IMF will receive the trust property.

The Gift of Giving

By R. Michael Shaw, CPA, JD

Now is the time to think about 2004 tax planning for charitable contributions. We at the IMF hope that you will help us continue our important work on behalf of the multiple myeloma community. Your support enables us to provide the many services we offer, including valuable programs designed to assist patients and caregivers. Here are a few tips to help make sure your contributions pay off on your tax return:

- To be deductible, contributions must be made to qualified exempt organizations, such as the IMF.

- Only contributions actually made during the tax year are deductible. Credit card charges and payments by check are deducted in the year they are given to the charity, even though you may not pay the credit card bill or have your bank account debited until the next year.

- If your contributions entitle you to merchandise, goods, or services, including admission to, for example, a charity ball, banquet, theatrical performance, or sporting event, you can deduct only the amount that exceeds the fair market value of the benefit received. For an item purchased at a charity auction, only the price paid in excess of the value of the item purchased is deductible.

- Donations of stock or other property are usually valued at the fair market value of the property. For stocks and bonds with an active market, the fair market value is the average price between highest and lowest selling price on the valuation date. This can be very beneficial if the stock or bond is worth considerably more than what you paid for it.

- Those who donate their cars may also claim only the fair market value of the car. The fair market value takes into account many factors, including the vehicle's condition. The fair market value may differ substantially from the car's Blue Book value. For vehicle donations, you must document the both the car donation and its fair market value.

- You might also want to consider a contribution through some type of trust that would enable you to keep current income from the property but donate the balance to the IMF after your passing. In most cases, you would get a current deduction for the present value of the property being donated.

- For a contribution of $250 or more, you can claim a deduction only if you obtain a written acknowledgment from the qualified organization. A person donating property valued at more than $5,000 must obtain a qualified written appraisal with the exception of publicly traded securities.

For more information, please visit the IMF website at *www.myeloma.org* for a link to Smith Barney's booklet *Giving Back: Techniques for Charitable Giving*. If you have questions about the deductibility of charitable contributions, you can download *Publication 526: Charitable Contributions*, and *Publication 561: Determining the Value of Donated Property*, from the Internal Revenue Service's website at *www.irs.gov*. We also recommend that you discuss all substantial charitable contributions with your tax advisor as everyone's situation is different.

Note: R. Michael Shaw is a member of the IMF Board of Directors. For more information about making a donation to the IMF, please contact Suzanne Battaglia at 800-452-CURE (2873) or *SBattaglia@myeloma.org*.

Dallas Patient & Family Seminar: An Open Letter To The IMF

Peter and Lucy Tischler

By Peter Tischler

Medical care has two aspects: medicine and care. Because of technology, the medicine has taken great strides forward in recent decades; but care seems to keep falling further and further behind. Insurance companies rule and we're often lucky to get fifteen minutes of a doctor's time — sometimes we're shunted off to a Physician's Assistant or nurse.

Bob and Benetta Tindall with Susie Novis

As myeloma is not, for the most part, a young person's disease, most of us remember and long for the days when doctors would make house calls and knew you by name without having to consult a chart. However, maybe those days are not gone entirely, because on November 7-8, the IMF made a house call to Texas. Susie Novis, Dr. Brian Durie, Mike Katz, IMF faculty and staff came to Baylor University Medical Center in downtown Dallas to give us their treatment, their care. They taught us, they listened to us, they ate meals with us, they helped us, and they cared for and about us. And then, **they** thanked **US**, not the other way around!

Patricia and Bob Larzelere

By their tradition, the IMF always has Dr. Durie attend the Friday afternoon meeting of the local support group. Our North Texas Myeloma Support Group was eagerly looking forward to having him all to ourselves for a couple of hours. At the eleventh hour, however, Susie and Brian had to make an important stop in Boston and would arrive in Dallas too late for our meeting.

Dr. Vesole

Dr. Stone

Susie came up with a wonderful solution. She found an excellent substitute doctor for our group meeting and also arranged for Brian to be available at the Saturday afternoon breakout session. Most of our support group attended that session to get their questions answered. In addition, our members were able to network with Brian and the IMF Faculty throughout the weekend.

Maria and Lee Hansen with Susie Novis

Susie threw us a party (she's really good at that!) on Friday night at the Fairmont Hotel, with a cocktail reception and dinner. She honored some of the attendees, including many from our group, for our support of the IMF.

William and Marcia Sawyer with Lynn Schroff

IMF staffers Spencer Howard, Lisa Paik, and Debbie Birns smoothed out bumps as they appeared throughout the weekend. If there were a phrase to characterize their work, it would be "they cared for us." Greg Brozeit arrived on Saturday and, with his characteristic passion, implored us to write and call our congress-people about funding concerns. Greg also stopped by our support group table and complimented the group.

Yelak Biru, Teresa and Phillip Westine, and Loul Haugs

And so, we in north Texas had a house call where we were given everything we needed to feel better. We were honored, praised, exhorted, educated, touched, hugged, laughed with, cried with, and loved. We received **CARE**. And we are very, very grateful.

Thank you, Susie; thank you, Brian; thank you, Mike; thank you to all

Dorothy and Hollis Tinsler with Susie Novis

Running for a Cure

By Sue Trerise

I decided to register for Ironman Florida in November, 2002, because I wanted to do something to honour Werner Mark, a friend of the family from our days in the small town of Orangeville in Ontario, Canada. Our children grew up together, attended each other's birthday parties, learned to ski, and went to school together. We spent a lot of time socializing with the Marks, playing bridge, having dinner parties, and having fun outdoors.

Werner died from multiple myeloma in June, 2002, while still in his early fifties, just as his three children were blossoming into young adults. Werner's wife Nora explained to me how much he suffered during his last months, with his fragile bones breaking from simple movements that those of us who are healthy take for granted. This seemed so ironic to me, as I had always admired Werner's athleticism.

I remember him running in the dark through the streets of Orangeville in winter after putting in a long day at work as an engineer for Husky. He was very dedicated to health and fitness. I felt very blessed to be healthy enough to take on the challenge of an Ironman which entails a 2.4 mile swim, 112 mile bike ride, and a 26.2 mile run done consecutively. So I entered the race and began training with a group of friends from Milton, Ontario, where I now live.

We were fortunate to have a wonderful and experienced coach who planned all of our workouts for us and motivated us to finish our long bike rides and three-hour runs in all types of weather. In winter, we would train on bike trainers in our basements, swim with a local Masters swim team, and run outdoors. When the spring came, we started to bike outdoors, extending the rides to four and five hours at a stretch. In May, we began swimming in Lake Kelso with our wetsuits on to keep us warm. All of us entered shorter triathlons to practice tranisitions and test our fuel (food and sports drinks) for Ironman Florida. We had a lot of fun as we got fitter, even though the training took up to 15-18 hours a week. I have been doing triathlons for 10 years but I was still daunted by the thought of doing an Ironman. Fortunately, I was training with athletes who had Ironman experience. Their advice and assistance was invaluable to me as I got closer to race day.

In September and October 2003, I started my mental preparation for the race and kicked off my fundraising efforts for multiple myeloma. I was very excited by the response that I received through Active Giving.com, the fundraising website associated with Ironman Florida. I sent emails to friends and they forwarded them on to their friends and that really helped get the word out. I heard from many people that I hadn't been in touch with for years because of the fundraising for Werner, and that was extremely gratifying. I know that Nora and her children, Christina, Andrew, and Darren were also quite touched by the generosity of so many friends and associates from years past.

On November 1, my husband and I travelled to Panama City Beach where Ironman Florida was held. We stayed with nine other participants from my training group in Milton and had a wonderful group of cheering spouses and partners to inspire us while we were on the course. We continued a light regimen of training and familiarized ourselves with swimming in the ocean (a new experience for many), windy bike courses, and routes for the bike and run.

Race Day dawned on November 8 with perfect conditions – sunny, with flat water, not much wind, and a temperature of about 80 degrees. We plunged into the Gulf of Mexico at 7:00 am and our Ironman journey had begun! I had a fantastic time! I kept thinking to myself, "How lucky I am to be able to do this!" I seriously felt like I had been training my whole life to do this type of event. And everything went like clockwork. I had no real problems to speak of, nothing went wrong with my equipment, my fuel did the job, my body didn't hurt too much. I had one low period when I came to the second loop of the run where I thought, "Oh no. I have to go out and run another 13 miles in the dark!" But the group from Milton was cheering me on and, after I had a couple of handfuls of M&Ms and changed my socks, I was ready to finish what I had started. And whenever I started feeling sorry for myself, I remembered what Werner had suffered with in fighting his cancer and got on with the job...

Finally, I reached the last mile of the marathon run and was overcome with emotion. I had this picture of Werner running in the dark, back in Orangeville, looping through my brain all the way to the finish line. The roar of the crowd as I came closer was unbelievable! I ran with everything I had left in me and crossed the finish line in 13 hours, 26 minutes, and 36 seconds – about an hour and a half earlier than I had expected. I was thrilled, amazed, and totally exhilarated! What an experience!

I am very grateful to my friends, family members, and colleagues who made a donation to my fundraising efforts and helped me reach for my dream. I know that all the donors would join me in hoping and praying that the funds raised will someday soon help to find a cure for multiple myeloma and other related cancers.

2003 Member Fundraisers in Review

Susie Novis and Dr. Brian Durie with Francoise and Jerry Pransky

By Suzanne Battaglia

This has been a banner fundraising year for the IMF, thanks in large part to our members' untiring dedication and ingenuity in developing and executing compelling fundraising events. The IMF has been able to meet its 2003 goals well in advance of our projected target and new and long-time members are already contacting us to get on the 2004 IMF calendar of events! Here are some of the highlights of the 2003 IMF events:

Our more sports-minded members held various tournaments, walks, runs, swims, and other athletic events. The **Malone Family's 1st Annual IMF Multiple Myeloma Golf Outing** featured a hole in one and a donated Harley Davidson, the **Corporate Challenge Charity Golf Tournament** was a smash hit, and the **2nd Annual Ralph Ferrizzi Memorial Golf Tournament**, the **Gary C. Heuer Golf Tournament**, and the **J.C. Invitational Golf Tournament** exceeded all expectations! Other creative events included Lisa Doyle's **Mile High March for Myeloma**, held in honor of her dad, Ed Davenport, the Haaz Family **"I Walked for Bob" Walk and Breakfast**, held in honor of Bob Haaz, the New York Bike Tour's **Biking for Bernstein**, held in honor of Elliot Bernstein, and **March Madness**, a basketball game organized by Julie Iodice, a student and staunch IMF supporter for years. **A Race for Richie** was organized by young Jared Bornstein for his Bar Mitzvah and in honor of his Dad – what a wonderful gesture! The annual **WAMP Swim-A-Thon** was a huge success once more this year and we thank Liz Stafford and her family for continuing this wonderful event.

In the music and entertainment genre, **Robert Cait at the Laugh Factory** was a hilarious night of comedy at the famous stand-up comedy club in Hollywood. IMF member Domenic Guastaferro performed several wonderful classical concerts, including **Mozart to Musicals** and **Handel**. The **2nd Annual Musicians Against Myeloma** concert, organized by IMFer Naomi Margolin in

WAMP Swim-A-Thon

honor of Lee Grayson, brought together dozens of musicians for an afternoon of music and laughter.

Jerry Pransky orchestrated the first **Fiesta for a Cure** benefit at the Mountain Gate Country Club in Los Angeles. The event, replete with high-end raffle and auction items, was an outstanding success, and will be duplicated in other cities throughout the country.

Other IMFers spearheaded fundraisers based on their own innovative ideas, such as **Hair Cares**, Kerri Marioni's day of beauty in which a local salon donated all their proceeds from the day to the IMF. Also in the fashion and beauty mode was **Fashion For A Cure**, once again organized by the remarkable Ashley Barit in honor of her mom, Jerra. Gabriela Seidler and Rebecca Soffer grew their hair for a year in honor of Gabriela's mother, then held a hair-cutting event. The hair went to **Locks of Love**, an organization that makes wigs for kids with cancer, while money raised from the party, raffles, and

Ashley Barit with Fashions 4 A Cure model

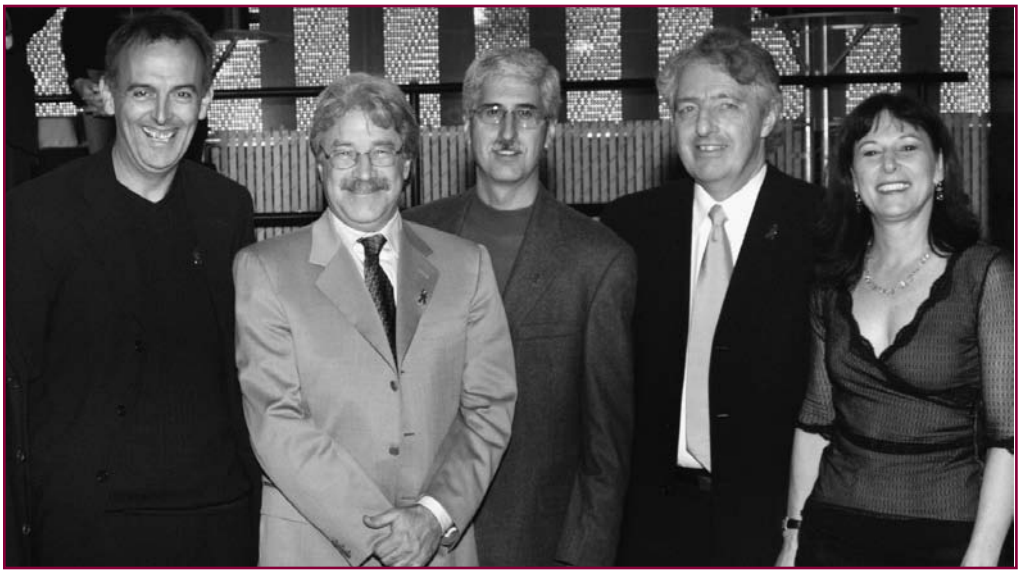
donations went to the IMF. What a wonderful way to help so many people!

The Fusco Family **5th Annual Yard Sale for MM** was its usual success, as was the **Arizona Chiliheads Cookoff**. And to end the year, Kit and Cindy Crawford, who participated in their community's **Christmas At the Faire** event, donated the proceeds from the preview and raffle to the IMF in honor of the event's founder, myeloma survivor Carol King.

These events demonstrate the committment, resourcefulness, and ingenuity of our membership. We thank you and look forward to your participation in 2004!

Mile High March for Myeloma

Note: If you have a fundraising idea, Suzanne Battaglia is waiting for your call at 800-452-CURE (2873) or email at *SBattaglia@myeloma.org*. She will provide IMF materials and advice on how to make your event successful and fun. Whether it's a bake sale or sports event, or something that's never been done until you do it, the IMF is here to support and help you make it a suc-



Guest of Honor Dr. Richard Klausner with Bank On A Cure co-chairs Dr. Gareth Morgan and Dr. Brian Van Ness, and Dr. Brian Durie, and Susie Novis

By the Unknown Patient

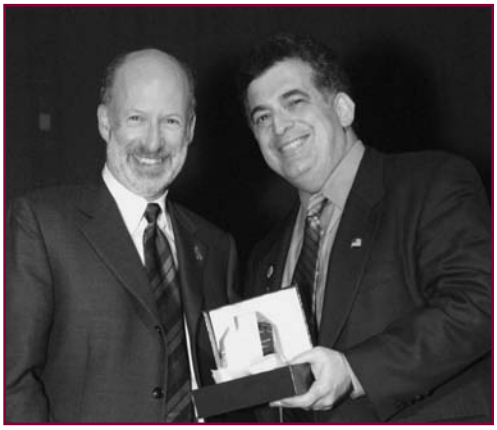
The Unknown Patient was really excited to get on the plane for Seattle. He had been to Seattle on business many times before, at one point doing a weekly cross-country commute to work with a local "dot com" during the Internet gold rush. This trip, though, wasn't about work. It was about honoring some very special people, seeing old friends, raising money for the IMF, and playing tourist. What could be better?

Arriving at his hotel on Friday, your Unknown traveler was just in time for an IMF board Meeting discussing some pretty exciting projects, most notably Bank On a Cure (see *http://boac.org*) and the International Prognostic Index (*see http://ipi.myeloma.org*). After the board meeting, he joined IMFers Mike Katz and Naomi Margolin, along with staffers Suzanne Battaglia, Spencer Howard, and Kelly Cox to check out arrangements for the gala. The gala site was the Experience Music Project (EMP) museum, located near Seattle's famous "Space Needle." It's a cool building, inside and out. And it looked even cooler that day because

Dinner co-chair Karen Chandler

IMFer Mike Katz was previewing a multimedia presentation about the IMF on the JumboTron outside the museum and on HDTVs inside the museum.

After this business was done, the Unknown Patient talked Mike and Naomi into playing tourist, making their way to one of Seattle's weirdest attractions, the Underground Tour, a hysterical tongue-in-cheek recounting of the history of the city, focusing on its chronic problems with water. For some Unknown reason, Seattle's founding fathers built the city on a tidal flat. Not surprisingly, those homes were destroyed by flooding and the city was plagued by persistent problems with unsavory sewage backups and outrageous political corruption leading to fiscal ruin and construction fiascos. Ultimately, these issues were resolved by covering up the old city and rebuilding on higher ground. Below the streets of Seattle, there is an abandoned city, complete with sidewalks and storefronts.



Dr. Fred Appelbaum accepts the Quality of Life Award on behalf of the Fred Hutchinson Cancer Research Center from IMF's Mike Katz

Much of Saturday was spent with more IMF board discussions and final preparations for the gala. It passed in a flash and the Unknown Patient soon found himself in a large tent outside the museum, getting an early peek at the silent auction items. Besides hotel and spa packages, jewelry, artwork, and gift certificates, there were some wonderful handicrafts donated by local patients and caregivers. The Unknown Patient also spied IMFers Robin and Michael Touhy gawking at a very cool

Michael Tuohy sets the mood

Tom and Mary Blakney accept the Ribbon of Hope Award on behalf of the MM FIGHTERS!

The Schwartz Family accepts the Courage Award on behalf of John Schwartz

electric guitar (Robin later bid on and won the guitar, surprising her lucky and talented hubby). Bidding was brisk at the auction, but the Unknown Patient managed to pick up an autographed "Everybody Loves Raymond" script and some handicrafts. He was happy to lose a number of items because some persons even more stubborn than your Unknown bidder refused to say "Uncle" and drove the price way into the stratosphere.

Dr. Robert A. Kyle and Dr. Richard Klausner

More money for a good cause – the IMF! At the auction, even when the Unknown Patient loses, we all win!

The crowd then moved into the museum for the dinner. Emcee Michael Brown asked the boisterous guests to simmer down and then introduced IMF President Susie Novis and Chairman Brian Durie. Susie and Brian welcomed everyone and then introduced Michael Touhy, a myeloma surivior, who sang his original composition, "I'm Not Leavin'," accompanying himself on his guitar. Michael's song strikes a chord with the

The JumboTron welcomes IMF supporters to the Experience Music Project

Unknown Patient, who, like Michael, isn't planning on leaving anytime soon.

Next up was Mike Katz, who presented the IMF Courage Award to the family of John Schwartz, who lost his valiant struggle with myeloma last year. John set an example for all of us, working tirelessly and giving generously to help fellow myeloma patients. Mike then talked about how important education is in our personal battles with myeloma. "Knowledge is power," said Mike. "And, in the war against myeloma, support groups are our weapons of mass instruction." After ducking for cover while the crowd reacted to that horrible pun, Mike presented the IMF Ribbon of Hope Award to Seattle's support group, the Northwest Multiple Myeloma Fighters. Mary and Tom Blakney and other gregarious group members accepted the award.

Dinner co-chair Teresa Perez celebrates an auction victory

Excitement followed as audaciously aggressive auctioneer April Brown whipped the crowd into a philanthropic shopping frenzy as they bid for a prodigious parade of wonderful items. April's humor and enthusiasm was infectious.

April Brown whips the crowd into a philanthropic shopping frenzy

She even led an impromptu auction appeal to make donations to help jump start Bank On A Cure. Bravo April and bravo to all of our generous bidders!

Next, the IMF Quality of Life award was presented to the world-renowned Fred Hutchison Cancer Research Center, which has played a key role in many important discoveries about myeloma and other cancers. In 2002, the IMF held its first Interactive Seminar at the Hutch, hosted by Dr. Bill Bensinger and IMFers John Schwartz and Rich Dennison. Dr. Fred Applebaum accepted on behalf of the Hutch.

Please see next page

Who Is The Unknown Patient?

Recently, a number of IMFers have contacted the Foundation wondering just who this Unknown Patient is and why he chooses to hide his identity. Well, the good news is that it's a long story. The Unknown Patient was diagnosed thirteen years ago—so don't believe everything you read about survival times.

Although very active in the myeloma community and in cancer advocacy, he chooses to keep a low profile about his disease outside those circles. Why is that? Does he have some Unknown psychological disorder? Is he in denial? The answer is none of the above. He has always been a stubborn person. When he was diagnosed, he read the statistics about myeloma and spent some time cursing the Unknown chain of events that put him in this predicament, grieving his fate. He realized he had hit bottom when he found himself sitting at his piano, playing "O Terra Addio" ("O Earth, Farewell") from Verdi's Aïda. It was at that point that he decided to focus on living now and leave the dying part for later. He also decided that he did not want to tell his mother about his illness, which meant that he did not want her tripping over his name in print talking about myeloma.

He began writing for Myeloma Today ten years ago, authoring the first edition of the IMF Patient Handbook. He asked Susie Novis not to use his name. Together they came up with the pen name "Unknown Patient," drawing their inspiration from "The Unknown Comic," a performer who did a standup routine with a paper bag over his head.

In the ensuing years, the Unknown Patient has "bar mitzvah'd" three sons, celebrated his 25th wedding anniversary, attended all three sons' high school graduations, two sons' college graduations, joined the IMF's Executive Board, served a term on the Board of Directors of a billion dollar corporation, made senior partner at his day job, served two years as President of his Synagogue, chaired patient advocate committees at the National Cancer Institute and the Eastern Cooperative Oncology Group, served as a patient consultant for the Food and Drug Administration, started two in-person support groups as well as an internet listserv for myeloma and amyloid patients, and on and on. His mother never found out about his disease, passing away peacefully earlier this year at the age of eighty-seven. So, your Unknown scribe hopes you will forgive him his eccentricity as long as his luck holds out and progress in research keeps out ahead of the beast we call myeloma.

Many of you know or have guessed his generally Unknown identity. If any of you are really desperate to know who he is or would like to contact him, feel free to send him an email at unknownpatient@myeloma.org or send him a letter at the IMF.

Gala - continued

More money for a good cause!

Next, Mike Katz presented guest of honor Dr. Richard Klausner with his award. Mike found it appropriate that we were in a venue more suited to rock stars than scientists, because, "Dr. Klausner is truly a rock star in cancer research." Rick revamped the clinical trials system, instituted bold new programs in genetics, molecular biology, and targeted therapies. A brilliant scientist and a passionate and articulate advocate for cancer research, Dr. Klausner was the first NCI Director to speak at an IMF Patient & Family Seminar, giving of his scarce personal time to bring a message of hope to hundreds of patients and caregivers. He currently heads the Gates Foundation's Global Health Program, whose goal is to improve the quality and equity of health care worldwide.

The rest of the evening was filled with good food and good friends, as well as a tour of the museum which contains many treasures from the world of music. The Unknown Patient barely made it into bed before his 4am wakeup call, signaling the end of a great weekend as he cautiously careened through the concourse to board his 6am flight back to the East Coast.

Mary and Kelly Cox with Jean T. Brewer and Dr. Brian Durie

Note: To take part in next year's IMF Gala, please contact Stephen Robertson at 800-452-CURE (2873) or via *srobertson@myeloma.org* for more information.

Research Grants - continued

Dr. Francesco Piazza, Research Assistant at the University of Padova, will study the roles of CK2 and GSK-3 serine-threonine kinases in the regulation of proliferative and survival pathways in myeloma. CK2 phosphorylates IkB in the C-terminal PEST domain, altering its stability. This PEST domain is also a substrate for calpain-mediated degradation of IkB phosphorylation by CK2. CK2 may facilitate its calpain-dependent degradation in B-lymphocytes. He plans to assess the importance of CK2 directed IkB phosphorylation in myeloma. NF-κB drives transcription of c-myc which is crucial for proliferation in myeloma. He also plans to test whether the NF-κB and CK2 may collaborate in the c-myc pathway and influence myeloma cell proliferation and apoptosis. These findings suggest that CK2 counteracts apoptosis. GSK3β can also modulate NF-κB function. GSK3β has been shown to be essential for the onset of an NF-κB derived antiapoptotic transcriptional program downstream of T1Fk. He aims to study how GSK3β affects NF-κB downstream.

Dr. Hideaki Ishikawa of Yamaguchi University will undertake the investigation of the molecules controlling myeloma cell growth and application for therapy. This research grant is made possible through IMF Japan in memory of Aki Horinouchi. Mr. Horinouchi was the founder of IMF Japan.

The IMF appreciates the evaluation and preparation of critiques of the research grant proposals by Professor Håkan Mellstedt and other IMF Scientific Advisors serving on his committee of reviewers.

although the overall results with treatment in S9321 were better than in prior standard-dose protocols, the low CR (complete response) rate of 17% may explain the lack of added benefit with the upfront high-dose therapy.

The next Abstract, #136, also presented by Dr. Barlogie, emphasized the importance of achieving complete remission as an essential step toward achieving benefit from transplant, including extended survival. For the Total Therapy I and II patients treated in Little Rock, the achievement of complete remission is what translates into longer overall survival.

This presentation was followed by another that also failed to show improved overall survival with stem cell transplant versus standard-dose chemotherapy (in this case, standard therapy with alternating VBMCP and VBAD [vincristine, BCNU, Adriamycin, and dexamethasone]). The long-term results from the Spanish study group (Abstract # 137: Dr. Joan Bladé) were presented and included details of a higher CR rate in the transplanted group (30% versus 11%: p=0.0002). However, there was no improvement in disease-free or overall survival with the high-dose therapy. In this case, the results were influenced by the fact that randomization to receive high-dose therapy did not occur until after the initial induction chemotherapy was administered and response was observed. Randomization was therefore not on what is called an "intent to treat basis." This excluded poorer-risk patients, which impacts the outcome of the study.

So where does all this leave us right now? Clearly, the decisive role for transplant as a part of frontline therapy is coming into question. Implications from Dr. Barlogie's presentations and prior French (IFM) and UK (MRC) data indicate that transplant is particularly helpful for some poorer-risk patients (e.g. high pretreatment serum β2 microglobulin, such as > 8 or > 10 mg/dl) and/or patients failing to have complete remission prior to the procedure. But it is also true that good-risk patients achieving CR can do unusually well with autotransplant. It seems reasonable to attempt to achieve complete remission, whether that be with a single and/or a tandem (double) autologous transplant procedure. **However, this shifts the focus of attention to achieving complete remission** as an endpoint in the effort to achieve longer survival. As discussed below, several exciting new drug combinations can produce complete remissions (e.g. thalidomide plus melphalan/prednisone; several VELCADE™ combinations). The relative efficacy of autotransplant will now have to be assessed either **combined with**, or **compared to**, these novel therapy combinations. The new question is therefore: **Does complete remission achieved by single or double autotransplant, thalidomide/dexamethasone combinations, or VELCADE™ combinations translate into an equivalent remission and/or survival benefit?**

Developing new partnerships at the IMF booth at ASH 2003
(l-r) Susie Novis, Dr. Brian Durie, Dr. Robert Kyle, and guests

In Abstract #138 (IFM 9903 and 9904: Dr. Philippe Moreau) the disappointing interim results (based upon 24 months of follow-up) combining single autotransplantation with mini allogeneic transplant were presented. The "single auto/mini allo" combination was **not** superior to double autologous transplant and carried a substantial added risk of complications. It seems the IFM will prefer the double auto approach for future studies. It is worth noting that double transplant, which produces complete remission in patients who were not in complete remission with a single autotransplant, confers added benefit.

Three posters dealt with autotransplantation (Abstracts #1630, #1651, #3656). Dr. Bhawna Sirohi (#1630) presented the results from the Royal Marsden in the UK, evaluating long-term survivors, including 13 patients in first complete remission for over 10 years. Predictors for long survival were: complete remission with pre-transplant induction, which is pertinent to the above discussions; younger age (< 55 years); and a trend for lower serum ß2 microglobulin (median 2.6 mg/dl) and normal serum Albumin (i.e. ISS Stage I patients).

The Boston results with high-dose melphalan for amyloidosis (Abstract # 1651) were presented. Durable remissions and improvement in quality of life were reported for 312/700 (56%) of amyloid patients treated between 1994 and 2002.

A novel approach to transplant was reported from the Mayo Clinic (Abstract # 3656: Dr. Angela Dispenzieri) utilizing high-dose 153-Samarium EDTMP [Quadramet™], a bone-targeting radiopharmaceutical combined with high-dose melphalan. Note that this is different than Holmium. The addition of the high-dose Samarium in a study of 46 patients showed promising results. The radiopharmaceutical was safe and well tolerated, and very good responses were

Please see next page

observed (29% complete remission; 18% very good partial remission; 49% partial remission). Further studies are planned.

Novel Therapies

It is hard to encompass all the nuances of the numerous novel therapy presentations. The bortezomib (VELCADE™) presentations are summarized as part of a separate ASH 2003 review. The local group in Los Angeles was particularly pleased with the excellent early results using VELCADE™ as a frontline therapy (Abstract # 1650).

The primary oral session on novel therapies covered Abstracts #507-#510. The longer- term follow-up results were presented from IFM study 95-01 involving 489 patients treated with melphalan/prednisone-based or dexamethasone-based regimens. Interestingly, the best outcome, including quality of life, was simply with melphalan/prednisone, which remained the "gold standard" for the IFM group in this setting of newly diagnosed patients 65-75 years of age. However, the greatest attention focused on Abstract #509, presented by Dr. Antonio Palumbo for the Torino-based myeloma group. In this study, 56 patients with newly diagnosed myeloma were treated with **melphalan/prednisone combined with thalidomide 100 mg per day**. This protocol was generally well tolerated and produced results substantially better than usually observed with melphalan/ prednisone alone. At the time of presentation, the overall response rate was an amazing 94%, including 47% having very good partial remission or better.

At this point the numbers in this Italian study are small and the follow-up very short. Since time to first progression is a critical endpoint in assessing therapeutic benefit, some further time is required to truly assess these exciting results. The myeloma community will be "staying tuned" to hear the assessment in 2004. Likewise for an innovative study from the Greek Myeloma Study Group (Abstract #510: Dr. Meletios Dimopoulos) evaluating pulsed thalidomide therapy combined with cytoxan and dexamethasone. This study of 43 patients showed significant anti-myeloma activity in previously treated myeloma and was associated with less frequent occurrence of peripheral neuropathy and deep venous thrombosis complications than with continuous thalidomide therapy protocols. Again this regimen deserves further evaluation.

On a separate topic (Abstract #508: Dr. Morie Gertz), the results with rituximab as treatment for Waldenstrom's Macroglobulinemia were presented. This was an ECOG phase II pilot study. Rituximab demonstrated significant activity, producing 52.2% objective plus minor responses in both previously untreated and relapsing Waldenstrom's.

Other abstracts dealing with novel therapies which were of particular interest included Abstracts #252, #825-#832, #1639, #1650, #1653, #1654, #2544, #3456, and #3492. Just to highlight a few aspects, there were follow-up data related to the several thalidomide analogs: Revimid (#825), Actimid (#829 and #3456), and ENMD-0995 [Entremed] (#1654). These new analogs are moving through clinical trial development with promising results. The pivotal trials with the "lead compound," Revimid, are ongoing and will undoubtedly produce results for submission to the FDA.

As discussed elsewhere, there were numerous presentations related to bortezomib (VELCADE™). Perhaps most interesting were the continued very promising results with the three-drug combination of VELCADE™, thalidomide, plus dexamethasone, which is very active in patients with refractory myeloma (Abstract #830). A small point was the observation that bone alkaline phosphatase (from osteoblasts) increased in the serum with successful VELCADE™ therapy (Abstract #2544), indicating possible reactivation of osteoblasts. There were several presentations involving arsenic trioxide (e.g. Abstract #827) and Doxil® (e.g. Abstracts #831 and #1653).

The numerous presentations of drugs at the preclinical stage were, as always, hard to evaluate, but the number was impressive and very encouraging. It is important to note that results in the laboratory with myeloma cell cultures do not necessarily translate into patient results, but may do so.

One interesting follow-up was a prospective, sequential, randomized trial (Abstract #832: Dr. Ruben Niesvizky) from Weill Medical College evaluating the role of Biaxin™ combined with low-dose thalidomide and dexamethasone. This study is showing clear evidence in a randomized study that Biaxin™ can augment the response with dexamethasone alone and/or with thalidomide.

Prognostic Factors and Staging

Abstracts #662, #664, #1634, #1638, #3491 and #3492 dealt with prognostic factors and staging. The new International Staging System (ISS) for myeloma was presented (Abstract #664: Dr. Philip Greipp for the IMF Myeloma Working Group).

This staging system is the result of detailed statistical analysis of over 11,000 myeloma patients from around the world treated with standard or high-dose therapy. The system is very simple to use and worked well for all patient subgroups. It is proposed for widespread use, particularly in the clinical trial setting. The Greek Myeloma Study Group (Abstract #3492) presented data indicating that the new staging system works well for their dataset. The MD Anderson group (Abstract #3491) also presented supportive data analysis, although for some reason in their analyses, the use of serum Albumin for their patients identified only a small subset of patients, versus 31% in the original I.S.S. data set. They also emphasized the added discrimination of levels of serum ß2 microglobulin greater than 5.5 mg/dl (i.e. >8, >10, or higher). This trend is also seen in the I.S.S. dataset, but identifies relatively small high-risk groups. Overall, it is very exciting to have available a new, simple, widely

applicable staging system. The full implementation of this system will take time and is discussed elsewhere.

In Abstract #662, Dr. John Shaughnessy and colleagues provided insights into the future of myeloma prognostic factor classification and staging. Using the sophisticated myeloma cell gene expression profiling techniques developed at the Arkansas center, a model for prognostic classification using three genes was presented. The patterns of gene expression were highly predictive. Since this technology is not currently broadly applicable, this is not proposed as a practical staging system. The information is rather used in reverse fashion to indicate the biologic importance of these genes in myeloma pathogenesis and behavior.

Abstract #1634 was an analysis of UK (Medical Research Council [MRC]) data from 2,745 patients with respect to the prognostic significance of different types of myeloma. The major conclusion was that Bence-Jones or light chain only myeloma patients fared less well with long-term follow-up versus the IgG and IgA types. Likewise for IgD myeloma, summarized in Abstract #1638. Patients with IgD myeloma and Bence-Jones myeloma have very similar disease patterns.

International Staging System (I.S.S.) for Multiple Myeloma

STAGE 1	**$ß_2M < 3.5$** **ALB > 3.5**
STAGE 2	**$ß_2M < 3.5$** **ALB < 3.5** **or** **$ß_2M$ 3.5 – 5.5**
STAGE 3	**$ß_2M > 5.5$**
Footnote:	**$ß_2M$ = serum $ß_2$ microglobulin in mg/dl** **ALB = serum albumin in g/dl**

Laboratory-based Studies of Biology

There were numerous presentations on this topic, but some of special interest were #1609, #1612 - #1614, #2511, #3461 and #3467.

There was a particular focus on the impact of myeloma upon bone cell functions. Several abstracts addressed the impact upon osteoblast functions, which are inhibited as disease transitions from MGUS (Abstract #1614) to more active myeloma (Abstract #1609, #1612, #1613 and #3461). In Abstract #1614 from the Hammersmith Hospital in London, the interesting point is made that osteoclast activity is increased in MGUS patients, but is compensated for by increased osteoblast activity and renewed bone formation. Conversely, in active myeloma, osteoblast function is inhibited by various mechanisms, including directly (Abstract #1609), via RANKL, IL-6, and IL-11 (Abstract #1612), and via IL-3 (Abstract #1613). Abstract #3461 emphasizes the role of bone morphologic protein-2 (BMP-2) and Wnt antagonists upon osteoblast inhibition. The osteoblast is a new target for planned therapeutic interventions.

Abstract #2511 from ECOG evaluates the impact of polymorphisms of cytokine genes upon overall patient outcome in phase III trial E9486. Of particular interest, patients with high-producer TNF-alpha phenotype have the poorest survival. This analysis is part of a pilot project for the ongoing IMF genetic project called Bank On A Cure™, discussed in detail elsewhere.

The final abstract in this section (#3467) is the basis for a separate article, entitled "In Search of the Myeloma Stem Cell." (Also in "Myeloma Minute" and "Myeloma Today.")

Clinical Studies and Diagnostic Testing

Again, there were numerous presentations, but several of note were Abstracts #1630, #1656, #2545, #2546, #2547, #3481, #3489, and #3493.

Two studies dealt with Zometa® as treatment for myeloma bone disease (Abstracts #1630 and #2545). In Abtract #1630, by Dr. Iuliano and colleagues from Cantazaro, Italy, the radiopharmaceutical Samarium-153 EDTMP was combined with Zometa® as treatment of elderly myeloma patients with progressive, painful bone disease. The combination proved to be remarkably effective with reduction in myeloma M-component in some cases. This very interesting observation in eight symptomatic refractory patients will undoubtedly form the basis for further studies. In the other abstract, #2545 from the Cleveland Clinic (Dr. Tahir Latif), it was reassuring to see that with careful monitoring, there was no increased frequency of renal toxicity with Zometa® versus Aredia® (pamidronate). However, caution was clearly indicated with elevated baseline serum creatinine levels. Other renal risk factors also need to be proactively assessed.

Three abstracts dealt with the role of imaging. Abstract #2546 highlighted the importance of MRI of the spine in identifying asymptomatic patients at high risk for disease progression. Abstract #3493 from France confirmed the utility of whole body FDG/PET imaging, especially to rule out (or in) any additional myeloma lesions in patients presenting with apparently localized disease (e.g. solitary plasmacytoma). Since FDG/PET detects both bone and extramedullary disease, Abstract #1656, which identified frequent extramedullary disease as a pattern of progression following thalidomide-based therapies, was of particular relevance. Monitoring with FDG/PET is therefore particularly important in this setting.

Abstracts #2547 and #3481 dealt with the important role of the serum FREELITE™ test for disease mon-

Please see next page

ASH 2003 - continued

itoring. Changes in FREELITE™ are very helpful for evaluating efficacy of high-dose therapy (Abstract #2547: Arthur Bradwell, Birmingham, UK) and the potential transition from MGUS to active myeloma (Abstract #3481: Dr. Rajkumar, Mayo Clinic). In the latter study, the presence of monoclonal serum free light chains by FREELITE™ predicted risk of progression from MGUS to active myeloma. A final interesting study related to MGUS was Abstract #3489, indicating a higher than expected incidence of secondary cancers among patients with MGUS.

From this rapid review of ASH 2003, the avalanche of data is clear. This overview of the meeting's highlights reveals the amazing progress being made in myeloma research and the great hopes we all share for new and better therapies in the near future.

Ask the Expert - continued

neuropathy during the trials. Patients who developed more severe neuropathy on study were the ones who entered with a greater degree of neuropathy at the onset of therapy. The dose of bortezomib was reduced or held in the study for 19% of the patients, and 5% required discontinuation of the drug because of neuropathy. Among the patients with neuropathy that developed on study, 74% of the neuropathy resolved back to baseline over a median of 99 days.

Dr. Lonial and colleagues from the Winship Cancer Institute and the Summit and Crest investigators, presented an analysis of the thrombocytopenia seen in the phase II trials of bortezomib in multiple myeloma. They also evaluated the impact of bortezomib on a platelet growth factor normally found in the blood known as thrombopoietin. Across all patients for which there was data, there was an average of a 60% reduction in the platelet counts during the course of therapy which rapidly recovered back to baseline during the 10 day rest period of each cycle. Additionally, the baseline platelet count at the initiation of each cycle of therapy increased over the course of 8 cycles of therapy. The response of blood thrombopoietin levels associated with the reduction in platelet counts seen in patients on bortezomib was as expected, and was not thought to be related to the etiology of the thrombocytopenia. This observation in concert with the proposed mechanism of action, support the use of bortezomib with appropriate platelet support even in the context of thrombocytopenia during therapy.

Finally, Dr. Jagannath evaluated the use of bortezomib among patients with renal insufficiency on the Summit and Crest trials. His review demonstrated that the response rates and toxicities were similar when compared against patients with normal renal function, and that therapy could be continued without dose adjustment or reduction based solely upon the renal function. The frequency of missed doses or dose reduction was similar to the larger population with normal renal function.

There were other studies presented utilizing in vitro models of myeloma growth and development that addressed the combination of bortezomib with other novel agents. From this perspective, it appears that bortezomib works well with other chemotherapies as well as with other targeted molecular agents that are in development or currently available. It is now incumbent upon physicians caring for patients with myeloma, as well as myeloma patients themselves, to enter trials designed to evaluate these novel combinations, and to help all of us improve the level of care and cure for patients with multiple myeloma.

Advocacy - continued

Funding for the National Cancer Institute (NCI) was set at $4.77 billion, an increase of $170 million or 3.5% over last year's funding level. Currently, NCI funds approximately 28% of its approved grants. That percentage will likely translate into a decrease in overall research activity.

Medicare reform may also hold some unforeseen surprises for myeloma and cancer patients. The legislation President Bush signed into law on December 8, 2003 will limit Medicare reimbursement for drugs prescribed by oncologists by as much as $1 billion per year beginning on January 1, 2004.

The leadership of the American Society of Clinical Oncology (ASCO), commenting on the proposed change that will take as much as $16 billon out of the oncology drug reimbursement system over the next ten years, wrote, "The effect of these very substantial changes in payment will be significant for cancer care in communities across the country. Among other things, we are anxious that these changes will have significant unintended consequences for cancer clinical trials upon which we all depend for progress against disease for future generations."

Another big issue for the cancer community—coverage for oral cancer drugs—will be included in the prescription drug benefit beginning in January 1, 2006. Until then, some patients will be allowed to participate in a small, limited access pilot program through December 31, 2005. It is currently unclear how and if off-label drugs such as thalidomide will be covered after January 1, 2006.

Don Woodward - continued

tries to spend part of her day focusing on normal things that help her relax and cope with multiple myeloma.

Note: Don Woodward has served on the IMF Board of Directors since 1993. He has graciously made available his telephone number (703-356-4231) to the readers of this newsletter. He has provided hope to countless newly diagnosed multiple myeloma patients.

International Myeloma Foundation Honor Roll

The IMF thanks all individuals, organizations and corporations who have contributed to IMF programs and projects. With their generosity and encouragement, we look forward to continuing our commitment to the myeloma community. This Honor Roll reflects monetary gifts of $250 and above made between November 1, 2002 and November 30, 2003. We also thank everyone who has donated time, knowledge, expertise, and products to the IMF.

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