Celebrating 10 Years!
1992 2002
ISCT
TELEGRAFT
International Society for Cellular Therapy
formerly ISHAGE
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Contents

ISHAGE: The Early Years

Scientific advances often occur in several laboratories nearly simultaneously. Similarly, the recognition of the need for organization of the newly formalized field of stem cell transplantation occurred among its practitioners nearly simultaneously. In 1987 and 1989, Adrian Gee, Sam Gross, and Diana Worthington-White brought together a nucleus of clinicians and scientists at the first two International Symposia on Bone Marrow Purging. So it was not surprising that the attendees at the Third International Symposium in San Diego in 1991 would recognize the need to address their common concerns about standards of practice and the probability of governmental regulation. Following a quick conversation on the final day of the conference, Adrian and I started corresponding and networking with like-minded colleagues. Adrian started the Herculean effort of putting together a new journal, eventually to be assisted by the incomparable Jean Winter, and I took to the fax and phone. Diana Worthington-White set up the membership base. Information gathering was a priority, so Bob Preti computerized the data from the first survey of laboratory practices. This North American core, together with Ellen Areman, Michelle Cottler-Fox, and Steve Noga assembled in Washington DC in the winter of 1991/92 to set up an educational non-profit corporation. The international growth of the fledgling society was reflected in the vote for incorporation in September of 1992 that was cast in unanimity by 42 individuals from the US, Canada, France, Germany, and Australia. When Bob Preti published the results of the laboratory survey less than a year later, 209 individuals from 26 countries and over 167 labs participated.

The immediate enthusiasm of the transplant community for ISHAGE was encouraging. In reviewing the early documents, I am struck by the number of very busy people who volunteered to help. Certainly everyone already had enough to do with their day job and no one really needed to spend hours in organizational meetings. But they attended organizing meetings at ASH, Keystone, ISEH, Denver, Ottawa, San Diego, and notably at the Opryland Hotel, surrounded by purloined poinsettias. Also impressive is the number of times in the early 1990's that delegations from ISHAGE met with an ever changing cast of US governmental representatives in private meetings and at CBER sponsored workshops, as the FDA struggled to devise a regulatory approach that made scientific sense. Time and again they listened with sympathy and courtesy as we explained our concerns.

ISHAGE cooperated with other organizations, and its members often sat on two or three committees simultaneously. Scott Rowley set up an advisory committee for hematopoietic progenitor cells standards for AABB. Phyllis Warkinten looked at the same issues for the NMDP Standards Committee. Dick Champlin started the American Society of Blood and Marrow Transplantation shortly after ISHAGE's incorporation, and joined with us in establishing the North American accreditation body, FAHCT. Ed Snyder of the AABB brought all interested

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organizations together in North American Task Force on Bone Marrow/Stem Cell Standards in 1995. Beck Haley of the American Red Cross shuttled between committees.

While the challenges were sobering and goals serious, the actual work was carried forward as a grassroots effort. There was a definite air of the Mickey Rooney/Judy Garland spirit of "Let's put on a show". We naively thought that enthusiasm with some small support from our local institutions could accomplish the entire task. The original table of organization was very simple: a Board of Directors led by a chairperson, to represent the breadth of the field, a treasurer to handle money, a secretary to handle membership, and a president to handle what wasn't anyone else's job. The only two committees were Legal and By-laws, and every member wanted to be on one or the other.

But the mandate for ISHAGE expanded and the members volunteered for each new task. Members organized meetings, arranged workshops, explored lab studies, set up chairs, printed fliers, distributed literature, and manned the ISHAGE information table at ASH between their own presentations. Late night debates highlighted the meetings-within-a-meeting (Can the IND system allow for sufficient freedom in research? How should we evaluate a graft? How to get orders submitted before products are processed? What about deemed status?). Rancorous committees were formed and reformed. The great CD34debate was launched. Papers were submitted to the official journal even before it was indexed. The Telegraft was named thanks to Mary Brouillette. Treasurer Bob Preti elicited belly laughs about a bank account that could hardly support a pun. Allen Eaves introduced the concept of the business plan, a management company, and teleconferencing. Scott Rowley, standards guru, oversaw the tumultuous publisher change. Andy Pecora searched long and hard for support for the annual meeting and his committee's purpose. Gunnar Kvalhiem and the inexhaustible Moya Berli rallied the Europeans. The workshops at the Vancouver meeting spilled out into the halls, and certain speakers (i.e., Jean Henslee-Downey) had such enthusiasm as to be hauled off the podium.

No list of members responsible for the early survival of ISHAGE/ISCT could include everyone who helped. A partial list of people not mentioned above would include EJ Shpall, Janice Davis, Carolyn Keever-Taylor, Rob Sutherland, Ineke Slaper-Cortenbach, Antonio Giulivi, Rainer Haas, Linda Kelley, Charles Carter, Lisa Hami, Neena Kapoor, Denis English, Susan Fautsch, Patrick Stiff, Terry Thomas, John Wagner, David Wuest, Yasuo Morishima, Herb Cullis, EJ Read, Charles Carter, Hans Johnsen, Philippe Henon, Ruth Ross, Beth McLeod, Malcolm Brenner, Ron Berenson, Jane Lebkowski, Peter Landsdorp, Ping Law, Anthony Ho, John Kemshead, Larry Lamb, Giuilana Pierson, Carlos Lee, Tom Moss, and JoLee Sproul. The problems posed by geography and politics were tackled head on by European members, notably Josy Reiffers, Salvatore Siena, Klaus Pantel, and Eckert Wunder. Bik To, Reg Lam-Po-Tang, David Ford, Annabella Chang, and Gail Lazzaro of Australia wrestled with similar problems of transplantation, compounded by those of distance.

I apologize to the other 200 founding members and to members who joined later whose names I have not listed above. Everyone's work, suggestions, papers, and criticisms contributed. While I sometimes worry that we sound too self-congratulatory, in the last ten years the members together have created an organization worthy of congratulations.

Nancy H. Collins

Cytotherapy

Official Journal of ISCT (formerly ISHAGE)

International Society for Cellular Therapy
formerly ISHAGE

Best Paper Award (Volume 4 - 2002)

The Cytotherapy Best Paper Award is for the best overall original paper published in a given volume of Cytotherapy, the official journal of the International Society for Cellular Therapy (formerly ISHAGE).

The 2002 Cytotherapy Best Paper Award of $2500 is supported by an educational grant from Miltenyi Biotec and will be awarded at the 9th Annual ISCT Meeting in Phoenix, Arizona, May 29-June 1, 2003.

Any paper published in Cytotherapy, volume 4, will be considered for the 2002 Award. The Award will be given to the author or co-authors of the paper. The ISCT Publications Committee will constitute the jury for the Award.

Judging criterion will include consideration of the paper's quality, the significance of the contribution to the field, originality, and the applicability of the science presented to improvements in processing or engineering cells for potential therapeutic purposes.

Cytotherapy Co-Editors:
Nancy Collins, MD & John Barrett, MD, FRCP

2002 Cytotherapy Best Paper Award Sponsored By:
Miltenyi Biotec

Profile of ISCT (formerly ISHAGE)

The first ISHAGE officers were as follows:

President	Dr. Nancy H. Collins
VP Eastern North America	Dr. Steven Noga
VP Western North American	Dr. Scott Rowley
VP Europe	Dr. Josy Reiffers
Treasurer	Dr. Adrian Gee
Secretary	Dr. Diana Worthington-White
Journal of Hematotherapy Co-Editors	Dr. Adrian Gee Dr. Nancy Collins
Nominating Committee	Ms. Ellen Areman Dr. Michele Cottler-Fox Ms. Janice Davis

Standing Committee Chairpeople	
Autologous Transplantation	Dr. Subhash Gulati
Allogeneic Transplantation	Dr. Steven Noga
Cellular and Molecular Techniques	Dr. Terry Thomas
Alternative Cell Sources	Dr. Dennis English
Cell Processing/Cryopreservation	Ms. Ellen Areman
Education	Dr. Ineke Slapper-Cortenbach
Legal/Regulatory	Dr. Scott Rowley
Directory	Dr. Allen Eaves Dr. Robert Preti
By-laws	Dr. Nancy Collins

Dr. Adrian Gee organised ISHAGE's first training course, "Multidimensional Flow Cytometric Analysis of Bone Marrow and Peripheral Blood Stem Cells," held March 9-10, 1993 under the tutelage of Dr. Leon W.M.M. Terstappen.

From these humble beginnings, the Society grew. Following is a summary of society-related and affiliated events from 1992-2002.

Year	Society Timeline	ISHAGE Meetings	Related Meetings	Progress of Field
1991	Society formulated at the 3rd International Symposia on Bone Marrow Purging and Processing (1991)		3rd International Symposium on Bone Marrow Purging and Processing. San Diego	
1992	Society officially incorporated Journal of Hemotherapy & Graft Engineering created as official journal of the Society & commences publication			
1993	N. Collins first ISHAGE President Bone Marrow Processing Survey conducted worldwide to identify labs & current practitioners. Data summarised by Robert Preti in Journal of Hematotherapy & Graft Engineering	1st International ISHAGE Meeting on Bone Marrow Processing and Purging. Orlando (Sept) [A. Gee]	Recent Advances in Hematopoietic Stem Cell Transplantation - Clinical Progress, New Technologies and Gene Therapy	
1994	First Issue of the Telegraft distributed. Giuliana Pierson the inaugural Editor Society membership: over 500		European Stem Cell Club Meeting and Symposium on Bone Marrow Transplantation in Stem-cell Disorders. Barcelona (Oct) [J. Garcia]	
1994-5	Society representatives had several meetings with the FDA. The National Task Force for Development of Standards for Hematopoietic Cell Transplantation formed between ISHAGE, ASBMT, AABB, NMDP, CMTG, and others		1st MRD Meeting. Munich (June) [K. Pantel & T. Msos]	

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Year	Society Timeline	ISHAGE Meetings	Related Meetings	Progress of Field
1995	FAHCT created. E. Shpall appointed President; P. Warkentin appointed Accreditation Committee Chair A. Eaves becomes 2nd ISHAGE President	2nd International ISHAGE Meeting. Vancouver (June) [A. Eaves] *Key Speaker: E. Donnell Thomas*	ISHAGE Europe Meeting. Germany (Aug)	
1996	Restructuring of society structure and bylaws First Tech Talk column in Telegraft [E. Areman] Fast growing regions by percentage basis were S. America, Canada, and Korea Society membership: over 900 First edition of FAHCT standards published		Recent Advances in Stem Cell Transplantation Meeting. San Diego (April) Cell Culture and Separation for Cells and Gene Therapy. Chicago (June) 1st FAHCT Inspector Training Workshop. Nebraska (Sept)	FDA approves first stemcell selection device (CellPro)
1997	S. Noga becomes 2nd Telegraft editor and solicits member input by asking for ideas by email which he proudly announces he is now able to receive on his new Pentium 200 FAHCT/ISHAGE/ASBMT file formal response to FDA's Proposed Approach to Regulations of Cellular and Tissue based Products First ISHAGE website created ESBMT & ISHAGE-Europe issue first draft of European standards on HPC Collecting, Processing, and Transplantation S. Rowley becomes 3rd ISHAGE President	3rd International ISHAGE Meeting. Bordeaux (June) [J. Reiffers] *First ISHAGE Annual Meeting held in Europe*	International Conference on Cord Blood Banking. Dusseldorf (January) [P. Wernet] International Symposium on Cord Blood Transplantation. Indianapolis (Mar) [H. Broxmeyer] Applications of Flow Cyto in BMSCT. Atlanta (April) [L. Lamb] 2nd course on Cell Culture and separation for Cellular Therapies (June) 4th European workshop on Stem Cell Methology. Vienna (Sept) [E. Wu der, P. Hocker, M. Dettke, G. Kvalheim]	FDA announces intent to regulate Cord Blood & Peripheral Blood Progenitor Cells Prototype CD34 selection device (Baxter) placed in Smithsonian Museum (initial team that worked on the device included: B. Lake, PhD; D. Chenoweth, MD, PhD; A. Gee, PhD; A. Hardwick, PhD; P. Law, PhD; A. Smith, PhD)
1998	FAHCT accreditation inspections begin FAHCT milestone: over 25 inspections and 5 accreditations	4th International ISHAGE Meeting. Baltimore *First Technical Breakfast sessions [E. Areman]* *First Corporate Symposia [Cobe BCT & Aastrom]* *"Tumor Detection in Stem Cell Harvest of Breast Cancer Patient" Symposium sponsored by the ISHAGE Tumor Evalution Committee*	*Ex Vivo* Expansion Satellite Symposium hosted by ISHAGE HPC Expansion Committee at IBMTR Meeting. Florida Autologous Blood Progenitor Cells Meeting. Italy [M. Marangolo, G. Rosti, & G. Kvalheim]	FDA calls for data regarding safety and efficiency an Cor Blood cells & Peripheral Blood Stem Cells for unrelated stem cell transplantation

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Year	Society Timeline	ISHAGE Meetings	Related Meetings	Progress of Field
1999	Society membership: over 1100 M. Brenner becomes 4th ISHAGE President ISHAGE launches Cytotherapy as its official scientific journal [Co-Editors: A. Gee & N. Collins] FAHCT milestone: over 50 inspections and 10 accreditations ISHAGE Europe and EBMT agree to form JACIE - the joint Accreditation Committee of ISHAGE Europe and EBMT - as the European equivalent of FAHCT Inaugural Corporate Members: Amgen, Custom Biogen Systems, Imunex, MVE-Chart, Nexell, Schering Canada, StemCell Tecnologies, Systemix	5th International ISHAGE Meeting. Oslo [G. Kvalheim] *First scientifically-focused annual meeting* 1st GMP Workshop. Arizona [J. Davis]	2nd Meeting on Applications of Flow Cytometry in BMSCT. San Diego [L. Lamb] 1st AABB-ISHAGE Audio-conference Series. [L. Hami & I. Webb]	FDA Proposed Rule on suitability of cell and tissue donors
2000	ISHAGE creates first nonhematopoietic committee for Nonhematopoietic and Mesenchymal Stem Cells [E. Horwitz] R. Negrin becomes 5th ISHAGE President I. Webb becomes Telegraft Editor Phase I ISHAGE North American Breast Cancer Detection Study and European study on detecting tumor cells in centrally prepared and distributed immunocytochemical preparations ISHAGE response to DMSO shortage in North America NETCORD-FAHCT publish Cord Blood standards and plan inspections for 2001	6th International Meeting, San Diego (June) [M. Brenner] *First Annual Meeting planned with significant input of scientific committees* 2nd GMP Workshop. San Francisco [J. Davis-Sproul]	2nd AABB-ISHAGE Audio-conference series. [I. Webb, T. Lane, & L. Hami] 8th Annual International Meeting on Recent Advances in SCT. Germany [E. Ball, P. Law, & A. Ho]	Gene therapy "crises" invokes regulatory response and reaction in North America NIH Guidelines on Human Pluripotent Stem Cell Research

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Year	Society Timeline	ISHAGE Meetings	Related Meetings	Progress of Field
2001	FAHCT milestone: over 47 accreditations ISHAGE launches name change discussion S. Burger becomes Telegraft Editor	7th International Meeting, Quebec City (June) [R. Negrin] *combined with 3rd Meeting on Applications of Flow Cytometry in BMSCT [L. Lamb] and Miltenyi Corporate Symposia on "New Options for Innovative Cellular Therapy"* 3rd GMP Workshop. Orlando [J. Davis-Sproul]	3rd International Symposium on MRD. Hamburg [K. Pantel] Mesenchymal and Non Hempatopoietic Stem Cell Conference. New Orleans [E. Horwitz] Somatic Cell Therapy Symposium. Florida [S. Noga] 3rd AABB-ISHAGE Audio-conference Series [I. Webb] 9th International Symposium on Recent Advances in SCT. San Diego [E. Ball & P. Law]	NHLBI and NCI announce RFA for BMT clinical trials network FDA Final Rule on Establishment Registration and Listing: Human Cellular Tissues & Cellular & Tissue-Based Products FDA Proposed Rule on GTPs for Manufacturers of Human Cellular Tissues-Based Products
2002	J. Barrett becomes Cytotheraphy co-editor with N. Collins JACIE has second inspector training course ISHAGE obtains certification from State of California to grant CEUs for laboratory technologists certified in that state that attend ISHAGE programming where the credits are offered. Similar certification obtained from ASCP for non-Californian registered laboratory technologists FAHCT milestone: over 139 facilities inspected and 87 accreditations. Institutions accredited in 1997 applying for accreditation renewal Second Edition of FAHCT standards draft released ISHAGE formally adopts name change to: International Society for Cellular Therapy (ISCT) S. Noga becomes 6th President N. Collins retires as society's journal co-editor after 10 years G. Sharp and G. Kvalhern become Cytotherapy Co-editors with J. Barrett	8th International Meeting. Barcelona [J. Garcia] 2nd Somatic Cell Therapy Symposium. Florida [S. Noga & J. Davis-Sproul]	10th Annual International Advances in SCT. Heidelberg [A. Ho, E. Ball, & A. Wobus] 2nd Nonhematopoietic and Mesenchymal Stem Cell Conference. New Orleans [E. Horwitz]	Federal funding for embryonic stem cell research limited to existing stem cell lines

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ISCT Executive Committee (as of April 2002)

President	June 2000 - June 2002	Robert Negrin, MD
President-Elect	June 2001 - June 2002	Stephen Noga,MD, PhD
Treasurer	June 2001 - June 2003	Iain Webb, MD
Secretary	June 2000 - June 2003	Rob Ploemacher, PhD
Australasia, Regional VP	June 2000 - June 2002	David Ma, MD
Europe, Regional VP	June 2000 - June 2002	Salvatore Siena, MD
Japan, Regional VP	June 2000 - June 2002	Yasuo Ikeda, MD
Chair of the Advisory Board	June 2000 - June 2002	Malcolm Brenner, MB, PhD
Co-Editor of the Journal (Ex-Officio)	June 2001 - June 2002	Nancy Collins, PhD
Co-Editor of the Journal (Ex-Officio)	June 2001 - June 2006	John Barret, MD
Editor of the Newsletter (Ex-Officio)	June 2001 - June 2003	Scott Burger, MD

ISCT Europe Regional Executive Committee

Europe Regional VP	June 2000 - June 2002	Salvatore Siena, MD
Europe Regional VP-Elect	June 2001 - June 2002	Wolfram Brugger, MD
Europe Regional Secretary	June 1999 - June 2002	Joan Garcia, MD, PhD
Europe Regional Treasurer	June 1998 - June 2001	Klaus Pantel, MD, PhD

ISCT Advisory Board

Chairperson (Past-President)	June 2001 - June 2002	Scott Rowley, MD, FACP
Member (Past-Past-President)	June 2000 - June 2003	Malcolm Brenner, MB, PhD
Member (Past Secretary)	June 2000 - June 2003	Diana Worthington-White
Member (Europe Past-Regional VP)	June 2000 - June 2002	Gunnar Kvalheim, MD, PhD
Member (Japan Past-Regional VP)	June 2000 - June 2002	Shigetako Asano, MD
Member (Australia Past-Regional VP)	June 2000 - June 2002	Bik To, MD
Elected Member - MD/PhD	June 2000 - June 2002	Scott Burger, MD
Elected Member - MD/PhD	June 2001 - June 2003	Donna Przepiorka, MD, PhD
Elected Member - Technologist	June 2000 - June 2002	Carlos Lee, BSc
Elected Member - Technologist	June 2001 - June 2003	Jocelyn Cruz, MT

All Executive Committee Members are also ex officio members of the Advisory Board.

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ISCT Committee Membership - Scientific Committees

Committee	Chair(s): 2001-2003	Committee Membership: 2001-2003
1. Cord Blood	Joanne Kurtzberg, MD	1. Lee Ann Baxter-Lowe, PhD 2. Dennis Confer, MD 3. John Fraser, PhD 4. Adrian Gee Mbio, PhD 5. Rebecca Haley, MD, MT (ASCP) 6. Pablo Rubinstein, MD 7. Edward Snyder, MD 8. Tsuneo Takahashi, DSc 9. Donna Wall, DN 10. Peter Wernet, MD 11. Heidi Patterson 12. Tom Lane, MD 13. Elizabeth J. Shpall, MD
2. *Ex Vivo* Expansion	Elizabeth J. Shpall, MD	1. Shelly Heimfeld, PhD 2. Joanne Kurtzberg, MD 3. Ian McNiece, PhD 4. Robert Preti, PhD 5. Josy Reiffers, MD 6. Patrick Stiff, MD 7. Peter Wernet, MD 8. Paul Simmons, PhD 9. Arnon Nagler, MD 10. Eliane Gluckman, MD 11. John McMannis, PhD 12. Catherine Verfaillie, MD
3. Gene Therapy	Helen Heslop, MD	1. Scott Burger, MD 2. Marco Bregni, MD 3. Michael Brown, MD 4. Dagmar Dilloo, MD 5. Isabelle Riviere, 6. Keith Stewart, MB, CHB, FRCPC 7. Elio Vanin, MD, PhD 8. Iain Webb, MD
4. Graft Evaluation	Rob Ploemacher, PhD	1. Hans Johnsen, MD, DMSC 2. Steve Noga, MD, PhD 3. Rob Sutherland, MSc 4. Erik Braakman, PhD 5. Michael Keeney, ART, FIMLS 6. Emer Clarke, PhD 7. John Jackson, PhD 8. Miles Prince, MD 9. Kevin Sheehan, PhD
5. Immunotherapy and Dendritic Cells	Jeff Molldren, MD	[not yet determined at the time of printing]

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ISCT Committee Membership - Scientific Committees (continued)

Committee	Chair(s): 2001-2003	Committee Membership: 2001-2003
6. Nonhematopoietic & Mesenchymal Stem Cells	Edwin Horwitz, MD, PhD	1. Darwin Prockop, MD, PhD 2. Paul Simmons, PhD 3. Margaret Goodell, PhD 4. Diane Krause, MD, PhD 5. Armand Keating, MD, FRCPC 6. Peter Wernet, MD 7. Ineke Slaper-Cortenbach, PhD
7. Transplantation	Rupert Handgretinger, MD, PhD	1. Richard Champlin, MD 2. Mary Horowitz MD, MS 3. Patrick Stiff, MD 4. P. Jean Henslee-Downey, MD 5. Anthony Ho, MD, PhD 6. Helen Heslop, MD 7. Yoichi Takaue, MD
8. Tumor Evaluation / MRD	Klaus Pantel, MD, PhD	1. Amy Ross, PhD 2. Erik Ruud, PhD 3. Panteli Theocharous, MSc 4. Wilbur Franklin, MD 5. Thomas Moss, MD 6. Karen Fields, MD 7. Michael Kneba, MD, PhD 8. William Kruger, MD 9. Adrian Gee, M Bio, PhD 10. Gunnar Kvalheim, MD, PhD 11. Ken Bauer, PhD

ISCT Mission Statement

The International Society for Cellular Therapy (ISCT) serves as a global forum and voice for clinicians, scientists, and laboratory personnel engaged in basic research and development, translational studies, and the clinical application of all cellular research, processing, and therapies.

To further its mission, ISCT:

- provides communication, discussion, education, and training regarding recent developments in both the basic science and laboratory practices in cytotherapy;
- facilitates the performance of collaborative scientific studies;
- promotes the validation of standardized technologies;
- represents the membership to other professional organizations and regulatory bodies; and
- participates in standards-setting activity and accreditation of voluntary accreditation groups.

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ISCT Committee Membership - Standing Committees

Committee	Chair(s): 2001-2003	Committee Membership: 2001-2003
1. Legal and Regulatory Affairs	Donna Przepiroka, MD, PhD	1. Janice Davis-Sproul MAS MT(ASCP) 2. James Martinec, MT(ASCP) 3. Scott Rowley MD FACP 4. Elizabeth Shpall MD 5. Phyllis Warkentin MD 6. Lothar Kanz, MD 7. Gesine Kogler, PhD 8. Sarah Dickerson, MT(ASCP) 9. William Janssen, PhD 10. Linda Kelley, PhD
2. Educational Affairs	Terry Thomas, PhD	1. Janice Davis-Sproul, MAS, MT(ASCP) 2. John Kemshead 3. Ineke Slaper-Cortenbach, PhD 4. L. Bik To, MD, MRCP (UK), FRCPA, FRACP 5. Millie Fleetwood, PhD 6. Ryuju Tanosaki, MD, PhD 7. Gerhard Fritsch, PhD
3. Membership Services	Moya Berli (Chair) Michelle Sugrue, MS, MT, SBB (North America, Co-Chair)	1. Gail Lazarro, 2. Panteli Theocharous, MSC, PhD 3. Kathy Loper, MHS, MT(ASCP) 4. Adriana Seber, MD
4. Publications	John Barret, MD, FRCP	1. J. Graham Sharp, PhD 2. Gunnar Kvalheim, MD, PhD 3. Janice Davis-Sproul, MAS, MT(ASCP) 4. Helen Heslop, MD 5. Carolyn Keever-Taylor, PhD 6. Klaus Pantel, MD, PhD 7. Heather Sutherland, MD, PhD, FRCP 8. Adrian Gee, PhD 9. Nancy Collins, PhD
5. Technologists	Carlos Lee, BSc (Co-Chair) Donna Rill, MT(ASCP) (Co-Chair)	1. Janis Davis-Sproul, MAS, MT(ASCP) 2. Karen Edward, MT(ASCP) 3. Douglas Padley, MT(ASCP) 4. Renee Smilee, MT(ASCP) 5. David Ford, MappSc, FAIMLS 6. Chris Chun, MT(ASCP), HP(ASCP) 7. Joy Cruz, MT(ASCP), SBB 8. Giovanna Cameron, RT(CSLT)

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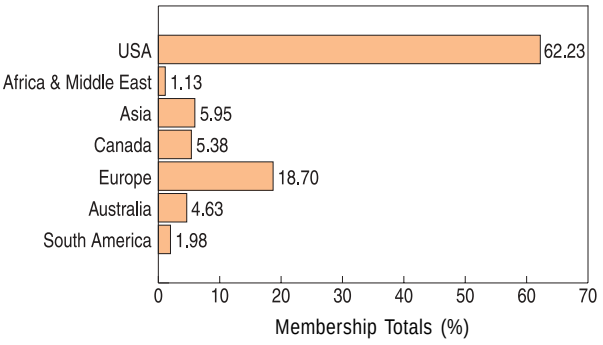
ISCT Membership Information (As of April 2002)

ISCT had a total of 1,026 Members in 2001. Approximately 16% of 2001 members were new members. As of April 2002, ISCT has 1,060 members and is on course to finish the year with more members than its has ever had in its 10-year history.

Membership Statistics

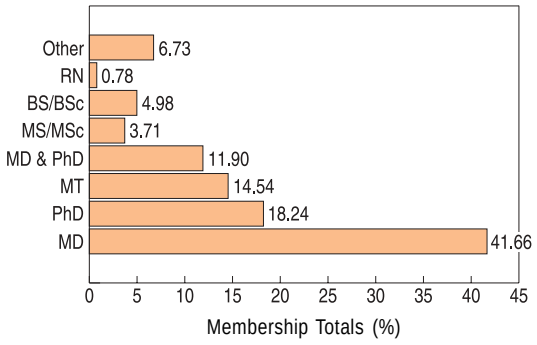
A geographic breakdown of ISCT membership in 2002 looks as follows:

Membership by Region in 2002



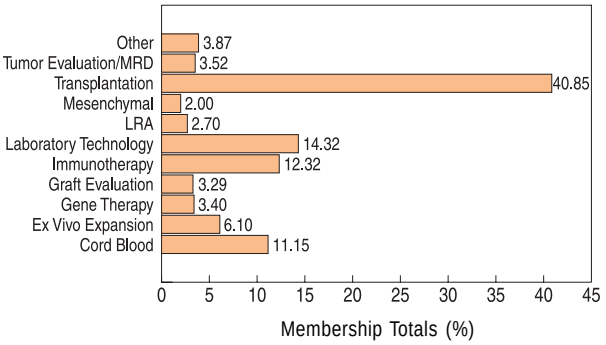
A breakdown of ISCT membership in 2002 by degree looks as follows:

Membership by Credentials/Degrees in 2002



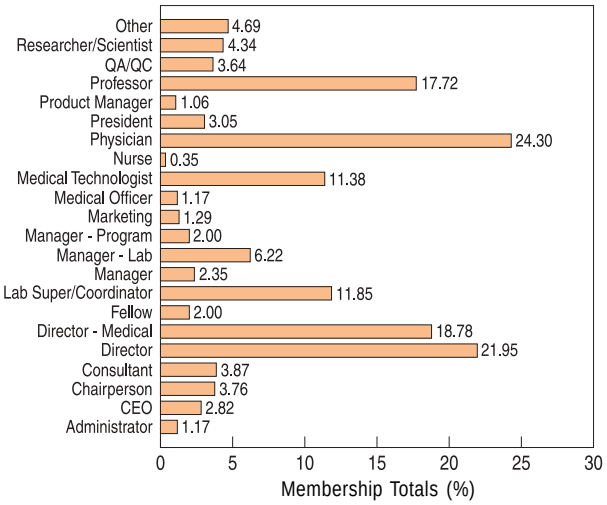
Based on a survey conducted in conjunction with the 2002 member application and renewal form, the following is an approximate guide to the various Areas of Practice represented by the ISCT membership (note that the survey allowed for more than one selection resulting in more than 100% when totalling the categories).

Areas of Practice



Based on a survey conducted in conjunction with the 2002 member application and renewal form, the following is an approximate guide to the various Job Categories represented by the ISCT membership (note that the survey allowed for more than one selection resulting in more than 100% when totalling the categories).

Job Category



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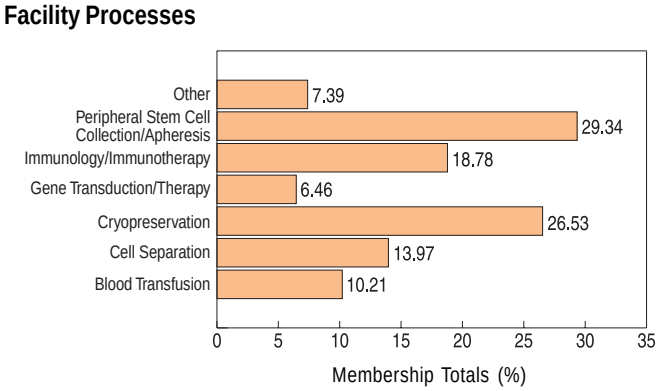
Membership Statistics (continued)

Based on a survey conducted in conjunction with the 2002 member application and renewal form, the following is an approximate guide to the various Facility Processes which represent the primary activity of the ISCT membership (note that the survey allowed for more than one selection resulting in more than 100% when totalling the categories).



ISCT Publications

Cytotherapy

The official scientific journal of ISCT is Cytotherapy. ISCT is developing Cytotherapy as the home for translational research in cellular therapy, first reports of exciting applications of laboratory research in the clinic, and papers on practical application of cellular therapies.

Founding Editors:

- Adrian Gee, PhD (1992-2001)
- Nancy Collins, PhD (1992-2002)

Current Co-Editors:

- John Barrett, MD, FRCP (2001-2006) (senior)
- J. Graham Sharp, PhD (2002-2007) (incoming)
- Gunnar Kvalheim, MD, PhD (2002-7) (incoming)

Cytotherapy has been selected:

- by the National Library of Medicine to be indexed in the *Index Medicus* and *MEDLINE/PubMed* on its *MEDLARS* system,
- for indexing and abstracting in Chemical Abstracts,
- for coverage by the Institute for Scientific Information, and
- is indexed in:
  - Science Citation Index Expanded (also known as SciSearch),
  - ISI Alerting Services,
  - Current Contents/Life Sciences, and
  - Current Contents/Clinical Medicine.

A subscription to Cytotherapy is included in an Active Membership in ISCT and is delivered both in print and electronically. An electronic-only subscription is available through an E-Membership in ISCT.

Readership is comprised of approximately 1100 subscribers worldwide.

Cytotherapy is published by Martin Dunitz of the Taylor & Francis Healthsciences Publishing Group. Currently it is published six times per year.

For advertising rates, specs, and contacts see the Cytotherapy page on the ISCT website (www.celltherapy.org) or on the Martin Dunitz website (www.dunitz.co.uk).

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Telegraft

The Telegraft is ISCT's newsletter published quarterly by the society's head office. The subscriber base is the entire society membership. The extent to which the distribution exceeds the subscriber base varies with each issue as the newsletter is used extensively in society promotions at meetings, trade shows, mailouts, member drives, etc.

The current Editor is Scott Burger, MD of Merix Biosciences. Past Editors include Steve Noga, MD, PhD (Sinai Hospital), Iain Webb, MD (Millenium Pharmaceuticals), and Giuliana Pierson, PhD (Children's Hospital of Philadelphia). For advertising rates and specs see the Telegraft page on the ISCT website.

Foundation for the Accreditation of Cellular Therapies - FACT

FACT is a nonprofit corporation developed by the International Society of Hematotherapy and Graft Engineering (ISHAGE) and the American Society of Blood and Marrow Transplantation (ASBMT) for the purposes of self-assessment and accreditation in the field of hematopoietic cell therapy.

FACT has established standards for the provision of quality medical and laboratory practice in hematopoietic cell transplantation; conducts inspections, and accredits programs that will encourage health institutions and facilities performing hematopoietic cell transplantation to voluntarily meet these standards; and recognizes compliance with standards by issuance of Certificates of Accreditation. For more information on FACT see their website at www.FAHCT.org or the new website coming to www.FAHCTwebsite.org.

Background

In 1992 The International Society for Hematotherapy and Graft Engineering (ISHAGE) was formed as a professional society representing scientists and physicians working in the area of hematopoietic stem cell graft manipulation. ISHAGE developed the first draft of the Standards for Hematopoietic Cell Collection and Processing.

The American Society for Blood and Marrow Transplantation (ASBMT) was formed in 1993 as a professional organization representing physicians and investigators involved in the clinical conduct of hematopoietic progenitor cell transplantation. The society has more than 800 members predominantly in the United States and Canada. ASBMT developed the first draft of the Clinical Standards for Hematopoietic Cell Transplantation.

In December 1994 ISHAGE and ASBMT merged their Standards into a single document covering all aspects of hematopoietic cell therapy (collection, processing, and transplantation). The two societies established FAHCT in order to develop a voluntary Inspection and Accreditation Program based on the joint Standards.

FAHCT Name Change

In 2002, following the lead of its parent organization, the International Society of Hematotherapy and Graft Engineering (ISHAGE), the FAHCT Board of Directors approved a name change for the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) to The Foundation for the Accreditation of Cellular Therapy (FACT).

This change is a reflection of the rapidly evolving field of cellular therapy and the expansion of treatment options available since FAHCT's inception in 1994.

Utilization of FAHCT Standards, and the FAHCT inspection and accreditation process have expanded dramatically over the past six years, beyond hematopoietic cell therapeutics to several new areas including, but not limited to, mesenchymal stem cells, immunotherapies, dendritic cells, and islet cell therapies. FACT remains committed to providing a comprehensive and equitable, voluntary, inspection and accreditation process for facilities involved in therapeutic cell harvest, processing and transplantation.

FACT Accreditation

The FACT Inspection and Accreditation Program was developed by Dr. Phyllis Warkentin, Chairman, FACT Inspection and Accreditation Committee, the FACT Directors and Officers, as well as the ISHAGE and ASBMT Regulatory and Standards Committees. The first inspections began in September of 1997.

The Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) has initiated its voluntary comprehensive standard-setting, inspection, and accreditation program that encompasses all phases of hematopoietic collection, processing and transplant. FACT invites you to participate in the process by applying for accreditation using the online Accreditation Application Forms from the FACT website.

From the Editor's Desk

Scott Burger, MD and Meredith Burger

As ISCT celebrates its tenth birthday, I have enlisted the help of an expert in this area to provide valuable perspective.

"My father asked me to help write this column because ISCT is turning ten and in a few weeks I'll turn ten too. He asked me to write about what I feel about turning ten years old, and how I think I'm different now compared with ten years ago, and what I think I will be like ten years from now.

What I feel is this tingling sensation. Every other birthday felt just like... well, a birthday. I think it was around my 6th birthday that I started wanting something ***more*** *in my birthdays. I think my 10th birthday will be exactly what I need. It's a big step in growing up. I think life will be different because... I don't know why, but ten seems* ***a lot*** *closer to 13 than 9. It's also your first double-digit age, so that feels pretty good.*

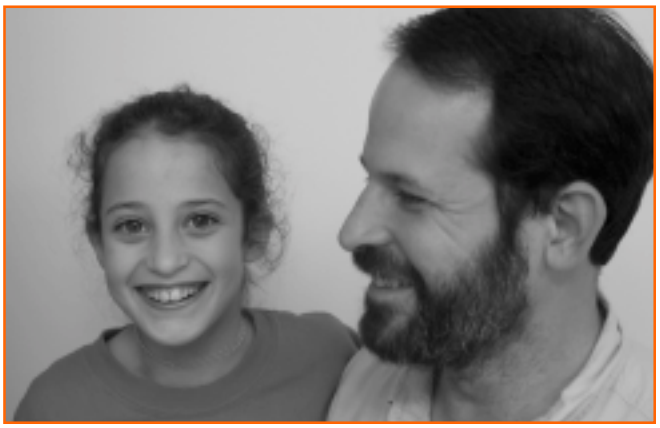
I can't remember anything about what I was like ten years ago, of course. I had just been born! My parents told me about other things that happened ten years ago, like Hurricane Andrew, and the reunification of Berlin. Mall of America is celebrating its tenth birthday too.

In the next ten years I expect I will grow up much more than I did in the past ten years. Perhaps three times as much. I don't think I'll fight with my brother as much. I think my school work will be better too. In the next ten years I'll go through middle school and high school, and by the end of ten more years I'll be in college. I'll be independent. I'll be able to drive my own car. I'll be a lot more responsible. A lot more."

10 Years Already!

Well, not everything about Meredith's point of view fits exactly with our society celebrating its tenth year, but some aspects are telling indeed. That tingling sensation of turning ten may not quite be widely felt, but certainly ISCT and cellular therapy both look quite different now compared with 1992. Did anyone imagine, ten years ago, the range of cellular therapies being studied today, or the widespread public interest in stem cell therapies? Surely the next ten years will see changes much greater yet. Our field will grow up still more than in the past ten years, with stronger scientific foundations, yet-to-be imagined new applications, and powerful evidence from clinical trials.

As for independence, fighting with one's brother - I do see some parallels there. I'm sure ISCT's relations with related societies will continue to improve in the years to come, even through our teenage years, and that our society will grow and prosper. Happy birthday, ISCT, and best wishes for many more. Happy birthday, Meredith. I never imagined ten years could pass so quickly.



ISCT Telegraft is published by the International Society for Cellular Therapy.

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10 Year Members

International Society for Cellular Therapy
formerly ISHAGE

ISCT would like to recognize the members who form our first group of "10 Year Members". Each of the following individuals was a founding member of the society in 1993, and has remained a member in every year since. Many thanks to all of you for your support throughout the years:

Douglas Adkins, MD
Tauseef Ahmed, MD
Michael Alcorn, PhD
Carlos Bachier, MD
Edward Ball, MD
Francesco Bertolini, MD, PhD
Sharon Bleau, MA
Brian Bolwell, MD
Joel A. Brochstein, MD
Annabella Chang, PhD
Curt Civin, MD
Nancy Collins, PhD
Herbert Cullis,
Janice Davis-Sproul, MAS, MT(ASCP)SBB
Antonio De Laurenzi, MD
Barrett Dick, MD
William Dodge, PhD
Douglas Dooley, PhD
Robert Dracker, MD, MHA
Carol Duma, Bs
John Edwards, MD
Denis English, PhD
Michele Fox, MD
Cesar Freytes, MD, FACP
Gerhard Fritsch, PhD
Adrian Gee, MIBiol, PhD
Sebastian George, MD
Antonio Giulivi, MD, FRCPC
Jeffrey Goldman, MD
Jerome Gottschall, MD
Michael Haeusler,
Rupert Handgretinger, MD, PhD
R. Alan Hardwick, PhD
Shelly Heimfeld, PhD
P. Jean Henslee-Downey, MD
Jeane Hester, MD
Anthony Ho, MD, PhD
Peter Hokland, MD
Anne Husebekk, MD, PhD
Tadahiko Igarashi, MD
John Jackson, PhD
Peter Jacobs, MD, PhD
Anna Janowska, MD, PhD
William Janssen, PhD
Christopher Juttner, MB, FRACP
Neena Kapoor, MD
Chatchada Karanes, MD
Armand Keating, MD, FRCP(C)
Carolyn Keever-Taylor, PhD
Morris Kletzel, MD
Sulabha Kulkarni, PhD
Joanne Kurtzberg, MD
Gunnar Kvalheim, MD, PhD
Lawrence Lamb, PhD
P.R.L. Lam-Po-Tang, MD
Hillard Lazarus, MD
Carlos Lee, BS
Ann LeFever, PhD
Michael Lill, MD
Michael Loken, PhD
Roland Lonser, MD
Beth MacLeod, MT(ASCP)
Deborah Magee, MT(ASCP)SBB
Kenneth Mangan, MD
Pedro Marin-Fernandez, MD
Bruce McLeod, MD
Anna Merino, MD
Jeffrey Miller, MD
WooSung Min, MD, PhD
Thomas Moss, MD
Mark Mullaney, BS
Regina Mullaney,
Stephen Noga, PhD, MD
Marie Olszewski, MT(ASCP), SH(ASCP)
Young Paik, MD
Mary Paoli, MT(ASCP)SBB
Ravi Patel, MD
Asim Pati, MD
Andrew Pecora, MD, FACP
Irene Philip, MD
Giuliana Pierson, PhD
Luis Pineiro, MD
Frank W.M.B. Preijers, PhD
Robert Preti, PhD
Oswald Prinoth, MD
Donna Przepiorka, MD, PhD
Barbara Reeb, MT(ASCP)
Robert Rifkin, MD
Amy Ross, PhD
Jorge Rossi, PhD
Marc Rovito, MD
Scott Rowley, MD, FACP
Indira Sahdev, MD
Kathleen Sazama, MD, JD
Maryellen Scavone, MT(ASCPSBB)
Shanta Sharma, PhD
Kirtikant Sheth, MD, FACP
Mark Shields, MT
Tsiporah Shore, MD, FRCPC, FACP
Elizabeth Shpall, MD
Fritz Sieber, PhD
Daniel Tabak, MD
Imad Tabbara, MD
Yoichi Takaue, MD
Mary Territo, MD
Terry Thomas, PhD
Arabella Tilden, PhD
Christy Tyer, MT(ASCP), SC
Donna Wall, MD
Meng Yu Wang, MD
Phyllis Warkentin, MD
B. Barry Weinberger, DO, MPH
Stephanie Williams, MD
Jane Winter, MD
Diana Worthington-White, MEd
David Wuest, MD
David Yawn, MD
Lolie Yu, MD
Axel Zander, MD, PhD, FACP

10 Year Member Musings

International Society for Cellular Therapy
formerly ISHAGE

Its amazing to think back to the earliest, pre-ISHAGE cell therapy meetings, the Bone Marrow Purging and Processing meetings. The initial meeting had been planned for 50 people, and had double that number of registrants. This, and similar situations at subsequent meetings, should have been our best indication that the society would grow and become much more successful.

I am excited to be the incoming ISCT president. Times are changing, and changing for the better, in both scientific and regulatory aspects of our field. It is good to know that ISCT will continue to be at the forefront of these changes. I also look forward to collaborating with other societies, such as AABB, ASHI and ASBMT, in reaching our common goals.

Steve Noga, MD, PhD
Sinai Hospital of Baltimore
Baltimore, MD, USA

This Society has faced important challenges since its creation, as we, the members, also have, in our respective countries, setting up techniques of graft engineering and different protocols to give better health assistance to our patients. After ten years of witnessing the Society's constant worldwide development and renewal of goals, its encouraging, reassuring and stimulating to be part of it.

Jorge Rossi, PhD
Hospital De Pediatra Juan P. Garraghan
Buenos Aires, Argentina

When ISHAGE was created there was an urgent need for a society were scientist and clinicians could meet and discuss translation research of hematopoietic stem cells. Today other societies also cover these topics. Therefore, to become a success, ISCT need to create an organization that focuses on translation research of the new and exciting areas of cellular therapy.

Gunnar Kvalheim, MD, PhD
The Norwegian Radium Hospital
Oslo, Norway

My introduction to ISCT came as a postdoctoral fellow in the laboratory of Adrian Gee, so I got to see ISHAGE born from the skybox, the center court, the front-row seat, and the sideline! It was a very exciting time as I watched the people whose papers I had read shuttle in and out of the South Carolina Cancer Center as the society's initial work was beginning. Although I have now been in this work long enough (and have seen enough disasters and disappointments) to be jaded, I am not. I remain upbeat and excited, and I thoroughly enjoy working with my colleagues in ISCT. Hopefully when we write these musings ten years from now, we will remember how we used to do allogeneic transplant and combination chemotherapy for cancer and rejoice in the improved quality of life that improved diagnostics and targeted therapies promise.

Lawrence S. Lamb, Jr., PhD
University of South Carolina, South Carolina Cancer Center
Columbia, SC

It has been a pleasure to be associated with this wonderful organization. I will always remain proud of our original graft engineering committee, which conceived of and than carried out the work leading to the first international standard model of CD 34^+ cell enumeration now called the ISHAGE method.

Andrew L. Pecora, MD
The Cancer Center at Hackensack University Medical Center
Progenitor Cell Therapy, LLC
Hackensack, NJ

As a Medical Technologist who joined the clinical research ranks 13 years ago, I would like to say how proud I am of the advancement of cellular therapies offered our patients today. With continued cellular and stem cell research as well as gene therapies, I feel medicine has a promising future to develop cures for our cancer patients and others. Being a member of ISHAGE/ISCT has allowed me to meet many caring people in this field. Presenting posters at our meetings helped me grow professionally and personally. I hope institutions can find the funds to allow their technical personnel to take part in these national meetings, allowing them to present and grow like I did. Attending national meetings allows one to network with peers by sharing ideas, technical procedures and offering problem solving experiences. All of this is so important in a field that is constantly changing.

Christy Tyer, BSMT(ASCP)SC
Duke University Medical Center
Durham, NC

As one of the first European members of the Society, I take pleasure in congratulating it with a very successful first decade. ISHAGE/ISCT has been a source of continuing support for me in my function as Physician-in-Chief for a stem cell cryopreservation and research. With your scientific meetings, courses, journal, the Telegraft and - not least - an extremely active home page, help has never been far away. Moreover, the regulatory issues and the accreditation procedures instituted in Northern America and the active participation of the various scientific boards of the Society has served as models for us in Europe. All the best for the next many decades!

Peter Hokland, MD
Århus University Hospital
Århus, Denmark

I would like to congratulate the Society on its 10^{th} year anniversary and anticipate that we will continue to be a driving force in the exciting developments in cellular therapies in the coming years.

Mary Territo, MD
UCLA School of Medicine
Los Angeles, CA

Looking Back: ISCT Pictures (1992-2002)

Looking Back: ISCT Pictures (1992-2002)

Cytotherapy on PubMed-MedLine

It is with great pleasure that we announce that Cytotherapy is now live on MEDLINE and PubMed. Currently, content from the latest three issues are posted and you will see additional content being added in the coming days and weeks including retroactive posting of all volumes 1-3 and each new issue as it is released.

Although this is long-overdue, it is nonetheless a very exciting development in the growth of Cytotherapy as a journal and for ISCT as a Society. This will have immediate impact on the journal's profile and impact factor. In combination with our publisher, Martin Dunitz, we will now launch an aggressive promotions campaign for what we believe is a very high quality scientific journal at the heart of the society and the field.

We are particularly grateful to each of you for remaining committed to Cytotherapy during its early growth period and intermittent development struggles. We thank you for continuing to contribute your work to the journal and for supporting it in all the ways you have. We are particularly indebted to Dr. Adrian Gee as a founder of the society and journal, to Dr. Nancy Collins for her tireless efforts in bringing us to this point by her dedication over the last decade, to Jean Winter for bringing the journal to print each and every issue, and, most recently, to our new publishing team at Martin Dunitz (Maire Collins, Cate Lund, & Iain Mellor) for performing the many small miracles that have had to be performed to bring the journal closer to the stage it should be at this point in its maturity. We are also very grateful for the recent contributions of Dr. John Barrett who has brought to the journal fresh ideas, perspective, and a burst of energy that have definitely pushed things forward of late. We look forward to the contributions of incoming Co-Editors Dr. Gunnar Kvalheim and Dr. Graham Sharp to add to Dr. Barrett's efforts as we continue to develop a quality scientific journal.

We trust you will continue to support Cytotherapy, consider it when choosing a publication for your work, and spread the word regarding the journal. Thank you again for each of your contributions.

2002 ISCT Corporate Members

ISCT is committed to forging strong relationships with corporate colleagues. We have developed an annual Society Membership program which allows corporate members to stay in touch with society members, issues, and marketing opportunities.

ISCT wishes to express its appreciation to the following corporate members in 2002 for their support and participation in the Society and for the support of those who have done so over the past decade.

Corporate Partners

Amgen
www.neopogen.com

NEUPOGEN® is a 175 amino acid protein manufactured by recombinant DNA technology NEUPOGEN® has been shown to be safe and effective in accelerating the recovery of neutrophil counts following a variety of chemotherapy regimens.

Baxter Oncology
www.baxteroncology.com

The Baxter Oncology portfolio consists of cytotoxic therapies that treat a variety of cancer types as well as cell selection storage, washing, and expansion products that are primarily targeted to stem cell transplant centers.

Corporate Patrons

Celmed Biosciences
Celmed BioSciences is a new subsidiary created by Theratechnologies in June 2001 in order to maximize the significant potential offered by its cell therapy activities. With facilities in Canada and the US, Celmed is dedicated to the treatment of neurological, hematological and immunological disorders using adult stem cell technologies. By integrating personalized medicine and basic molecular biology tools revealing each individual genomics and proteomics profile, Celmed dedicates its efforts to develop new biological selective therapies.

Sigma-Aldrich
Sigma-Aldrich is a leader in life sciences offering media, cytokines, growth factors, and antibodies for the culture and study of stem cells. Many of our products are manufactures under cGMP and are suitable for use in clinical studies.

THERAKOS, A Johnson & Johnson Company
THERAKOS, a Johnson and Johnson company, is a worldwide leader in extracorporeal disease management through the establishment of extracorporeal photoimmune therapy as a standard medical practice. Our UVAR ® XTS TM System and UVADEX ® Methoxsalen Sterile Solution are approved for the palliative treatment of skin manifestations in Cutaneous T-Cell Lymphoma.

Merix Bioscience
Immunotherapy company poised to assume leadership in the emerging market of personalized vaccines for the treatment of localized and metastic cancers.

Corporate Supporters

Custom Biogenic Systems
Cryogenic Equipment.

Incara Pharmaceuticals
Adult-derived progenitor-enriched liver cells for treatment of chronic liver disease and in-born errors of metabolism.

Kirin Brewery Pharmaceutical Division
Pharmaceuticals.

Oncosis
Oncosis is developing a lineup of new clinical and research instruments, reagents, and disposable products based on its PhotosisT technology platform for highly-accurate, high-throughput, laser-based processing of living cells.

XCYTE Therapies
XCYTE Therapies is developing and commercializing novel cell-based therapeutic products that harness the power of the immune system to treat cancer and infectious disease.

Continued on page 23

Continued from page 12

For additional information on the benefits of Corporate Membership, or on how your company might become a Corporate Member, contact the Lee Buckler at: ISCT HEAD OFFICE, Suite 401, 777 West Broadway, Vancouver, B.C Canada, V5Z 4J7. Phone: 1.604.874.4366; Fax: 1.604.874.4378, Email: headoffice@celltherapy.org

Basic Corporate Members

BD Biosciences Immunocytometry Systems
Immunocytometry Systems is a business Division of BD Bioscience. We develop advanced flow cytometry tools that support many applications immunology, hematology, and cell biology - from routine sample analysis to high-speed, high-performance multi-color cell sorting.

Biosafe SA
Biosafe SA specializes in blood processing equipment for cell therapy and transfusion medicine. Its novel technology SEPAX allows fully automated processing of stem cells from umbilical cord blood, peripheral blood, or bone marrow.

Chimeric Therapies
We develop and process for infusion, human hematolymphoid cellular products engineered to specification for therapeutic use in human diseases.

Cordlife Pte
Stem cell banking, R&D, and therapeutic support.

Edwards Lifesciences Research Medical Inc.
CRYOSERV™ Cryopreservative Solution.

Gambro BCT
Healthcare professionals in the field of therapeutic apheresis worldwide rely on the COBE® Spectra™ Apheresis System to achieve better patient outcomes. Through continuous innovations in cell collections and graft engineering, we support a broad range of cellular and plasma therapies for the treatment of cancer, congenital, and immune disorders. Together we can achieve the best donor and patient outcomes and improve the quality of life for people around the world.

Genentech Biooncology/IDEC Pharmaceuticals
Genentech, Inc. is a leading biotechnology company using human genetic information to develop, manufacture and market pharmaceuticals that address significant unmet medical needs. Herceptin® (Trastuzumab) for first line therapy in combination with paclitaxel and as a single agent in second and third line therapy for patients with metastatic breast cancer who have tumors that overexpress the HER2 (human epidermal growth factor receptor2) protein; Rituxan® (Rituximab) for the treatment of patients with relapsed or refractory low-grade or follicular, CD20 positive, B-cell non-Hodgkin's lymphoma; TNKaseT (Tenecteplase), a single-dose clot-busting agent for the treatment of acute myocardial infarction (heart attack);Activase® (Alteplase, recombinant), a tissue-plasminogen activator to dissolve blood clots, for treating patients with acute myocardial infarction, patients with acute massive pulmonary embolism (blood clots in the lungs), and for treating patients with acute ischemic stroke (brain attack) within the first three hours of symptom onset; and CathfloT Activase® (Alteplase), a tissue plasminogen activator, for the restoration of function to central venous access devices.

Kirin Brewery Cell Therapy Group
Developing Cell Therapies.

Miltenyi Biotec
Magnetic cell sorting; advanced flow cytometry, separations for molecular biology.

MVE-Chart Industries
World class manufacturers of Cryonic equipment including LN2 freezers, small-to-large storage units, vacuum pipeline, etc.

SEBRA
SEBRA is a world leader in producing precision instruments for sealing fluid filled plastic tubing, monitoring blood flow and collection volumes, equipping mobile blood collection sites and providing technology used by catheter manufacturers and biotechnology companies throughout the world. It has earned this strong position by providing customers with innovative, dependable products and the highest level of technical and customer service.

StemCell Technologies
StemCell Technologies provides a wide range of products for experimental cell biologists, hematologists, immunologists and oncologists. These include growth and asssay media for primitive and differenntiated cells, cell separation systems. tumor enrichment products, embryonic stem cell reagents, antibodies, cytokines, etc.

StemSoft Software
StemSoft Software develops data management and outcome analysis software exclusively for oncologists, hematologists and stem cell processing professionals. Since 1993, clinicians, laboratory technologists, data managers and research coordinators at more than 250 institutions in 32 countries have discovered the benefits of StemSoft solutions for patient management, stem cell processing and storage management, BMT registry reporting, and outcome analysis.

Titan Pharmaceuticals
Titan Pharmaceuticals, Inc. is a diversified biopharmaceutical company focused on the development and commercialization of novel treatments for central nervous system (CNS) disorders, cancer and other serious and life-threatening diseases. In the CNS arena, Titan is developing iloperidone for the treatment of schizophrenia and related psychotic disorders, and Spheramine® for the treatment of Parkinson's disease. Spheramine®, which is currently in Phase I/II clinical testing, is Titan's first application of its patented cell-coated microcarrier (CCMT) technology. A cell-based therapy, Spheramine is designed to restore declining neurologic function in patients with Parkinson's disease. Titan is also developing a novel drug delivery system designed to provide long-term release of CNS therapeutics and several innovative cancer therapeutic products, three of which are novel monoclonal antibodies that stimulate the patient's immune system to attack cancer cells.

From the President's Desk

Robert Negrin, MD

ISHAGE, now ISCT: The Present

ISHAGE at ten years? No, it can't be! Creating a new society must be similar to raising a child. The first years are filled with purpose and grand ideals. We marvel at every moment. One can look at the creation of such an organization with awe. Those clairvoyant few who came up with the idea of creating a society based upon organizing laboratory workers, scientists and clinicians around the concepts of bettering cellular therapeutic products, what a grand idea! Although our Society was initially focused on the use of hematopoietic stem cell grafts, who could have believed that our field would be discussing various treatment options such as cellular therapy for strokes, heart disease, diabetes, neurological disorders and spinal cord injury, to name a few. The many people critical to this task have been highlighted in Nancy Collins' comments to whom we all owe a debt of gratitude.

As we look back over the last 10 years, it hasn't always been pretty. Hopefully we have passed through our difficult teenage years where we struggled through many controversies including how we count the cells, how we report our results to the scientific community and how we run our journal, to name a few. We have gone through growing pains and a few legal ones that any young organization must endure.

Now as we mature, what is clear is that we have survived and by all criteria we are stronger than ever. Our membership is up, our meetings have been well attended and successful both scientifically and financially. We even have a few dollars in the bank. Our journal, Cytotherapy, under the able leadership of Nancy Collins and now John Barrett, continues to gain momentum and has become a strong voice in the community. We have initiated, nurtured and sustained important dialogue, education and policy. Our relationship with our sister organizations, ASBMT and FACT, secures our identity and our future. With our new name, we look forward with the calm confidence of young adulthood for bigger and brighter things ahead of us. Many people have been crucial to this task, I can not name them all. For me, the helpful advice of many has been critical. However, among the many individuals central to our success, I would like to specifically acknowledge Malachite Management and Lee Buckler who have been indispensable, laying the groundwork, providing the follow-up, chasing after the money, providing the appropriate spin and even a bit of legal advice from time to time.

I look forward to thinking back of where we have come from 10 years from now as we move towards newer horizons. It has been a fun ride but I can firmly say the best is yet to come.

ISCT E-Membership

The International Society of Cellular Therapy (formerly ISHAGE) is pleased to announce the creation of its newest Membership option: The ISCT E-Membership.

The ISCT E-Membership includes all the benefits of Active ISCT Membership except all subscriptions and correspondence are delivered on-line and/or by e-mail. Access to Cytotherapy will be provided on-line by the publisher and the Telegraft will be available on-line at the ISCT Website (www.celltherapy.org). Meeting announcements and registration information, general society updates, and other regular mailings will be provided by e-mail.

ISCT E-Membership has been created to ensure timely delivery of our journal, Cytotherapy, and newsletter, the Telegraft, to those international members for whom regular mail delivery times are slow. Additionally, the cost of an E-Membership is significantly reduced ($75/yr) and still delivers all the same member-benefits. We hope this assists those colleagues in countries where the currency valuation makes the cost of ISCT membership in US Dollars too high to be practical.

We encourage our international colleagues to join ISCT through our new E-Membership. We hope to work more closely with all of you in the future as the field of cellular research and therapies grows around the world.

An Open Letter to the Human Research Community

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

April 17, 2002

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Telephone: 301-496-7005
Fax: 301-402-0527

To Those We Serve:

It is hard to believe that only a year and a half ago, we were only laying out a blueprint for remodeling our national system for protection of human subjects in research. One can easily lose track of time, particularly in Washington, where some things never stay the same, and others never seem to change. Recently, preparations for an upcoming Senate hearing on human subjects protections afforded an opportunity for me to reflect on all that has happened over these past 18 months, all of which have been challenging.

No one will deny that human research is in the midst of a dramatic period of change, a period that brings with it anxiety and frustration as well as hope. Anyone who has lived through the remodeling of a kitchen knows how disruptive the process of change can be, but the results are well worth the wait and the inconvenience.

A key element of the remodeling process in human research protections is the move from a system focused on regulatory compliance to a system focused on prevention of harm. Many times over the past year and a half we have heard the sound bites and catch phrases - “shared goals and shared responsibilities,” “flexibility with accountability,” “do it right because it’s the right thing to do.” For all of us in OHRP, these are more than words... they are our mantra and our mission.

We are now at a critical juncture in the transition to our new system. OHRP has worked long and hard with many of you to develop a new quality improvement program, one that offers support and consultation, one that seeks collaboration, not confrontation. The program was announced at the December meeting of Public Responsibility in Medicine and Research, and a more formal announcement was posted on our website a few weeks ago. Now, we are ready to go, and it is your turn to take the initiative.

While we await final approval of our directed self-assessment tool, we will begin scheduling quality improvement (QI) consultations for the next 6 months as we build out this program to its full capacity of 60 consultations per month. All of the consultations involve a self-evaluation of a program by its staff, with follow-up from the staff of our Division of Assurances and Quality Improvement. Some follow-up may be through calls or correspondence. Others may involve videoconferences or on-site consultation visits. All of them will be collegial and constructive. Our highest priority will be those institutions that receive the greatest federal support for research. I am hoping that institutions will choose to volunteer to participate in this program now.

Why now? What is so important about today? Why not wait until next year? Why should we be first? The answer is simple and clear. This program, upon which the successful transformation of our oversight system depends, cannot proceed unless those institutions engaged in human research take the initiative to volunteer to participate.

Is there an alternative? Yes, of course there is. There are many who remain skeptical that a system focused on prevention and quality improvement can be effective. These are often the same critics who believe that only through stronger oversight and enforcement activities can meaningful change result. OHRP wants to prove them wrong.

Clearly, there is a necessary and appropriate role for oversight and enforcement, even penalties in egregious cases, but I believe that the vast preponderance of scientists, IRB members, and institutions are well intentioned. I have seen first hand in my visits to institutions across the country the remarkable efforts that are being made to strengthen programs, educate individuals, and ensure the well-being of research participants. Participation in OHRP’s new Quality Improvement Program is a critical first step in building confidence and trust in the human subjects protection process, to show that we can “do it right, together.”

In “Field of Dreams” they said, “If you build it, they will come.” Now is the time for action. I urge you to take it. You can learn more about the program from our website at http://ohrp.osophs.dhhs.gov, or volunteer by sending an e-mail to QI@osophs.dhhs.gov. Please contact us today to set a time for your consultation.

Sincerely,
Greg Koski, PhD, MD
Director, Office for Human Research Protections

Tech Talk... Sterility Testing

In this edition of Tech Talk, we discuss some issues that have recently come up in our field. They include Sterility Testing criteria and the new cell processing guidelines chapter from the USP. We begin by encouraging... no, BEGGING everyone to complete the online survey on the ISHAGE website. This will be used for data for conversations with the FDA. Replies are critical as we need to assess current practice in regard to sterility testing on products in our field.

Monitoring sterility of processes and products are in an integral part of any quality plan. Recent conversations with the FDA and ISHAGE regulatory affairs have indicated that current perspectives are changing. It is in our best interest to propose acceptable practices, which ensure product safety but are also financially feasible, accessible and adequate for our procedures. We have reviewed some of the practices as well as documents on sterility testing. The results of the above mentioned survey will be most helpful. A summary of our findings is included below. The descriptions are our own interpretations and not exhaustive in nature. Our suspicion is that most labs have two levels of microbial sampling depending on processing. The first applies to minimally manipulated, PBSCs for example, and entails submission of a sample to the micro lab via direct inoculation onto media or inoculation into some automated method, such as the Bactec system. Samples are usually collected upon receipt and at defined intervals or completion of processing. These generally run less than $30 or so and are performed alongside patient diagnostic samples. The second scenario applies to gene therapy or other extensively manipulated products (i.e. *ex vivo* expansion, cell activation) which are cultured long term and entails sending a sample to a reference lab for USP or CFR sterility. These generally cost $250-1000 depending on product inoculation parameters, validation testing, and lab fees. These two scenarios represent extremes of the spectrum and certainly, many products and practices fall in between.

The Code of Federal Regulations carries the weight of the law and 21 CFR 610.12 details sterility procedures and is available on the FDA's website. Specifically, it prescribes media and culture conditions. It does not specify a "clean room" but conversations with FDA officials indicates that the expectation is that the facility performing the microbial testing should be at least as clean as the facility manufacturing the product. The FDA plans to meet this summer to discuss revisions to these guidelines.

The United States Pharmacopeia is a guideline for the Pharmaceutical Industry. This 2400+ page book details all aspects of GMP production and monitoring. Effective this year (January 2002, 25th edition), it will be updated annually. Hard copies or on line subscriptions are available at www.usp.org. Sterility testing is outlined in chapter <71> and is performed in a clean room or stand alone isolator. It is much more detailed than the CFR assay and does not allow for retest to confirm positive cultures. The biggest surprise comes here with the price tag, at estimates in excess of $1000 per sample (see Table 1)

All assays have their pros and cons and we leave it for you to draw your own conclusions. Both CFR and USP are a long way from the automated blood culture bottle or routine media inoculation.

But there is hope... This year the USP has added a new chapter (1046), *Cell and Gene Therapy Products*, outlining Cell Therapy and Gene therapy current manufacturing and administration practices, and the challenges that we face

trying to develop appropriate quality control testing for identity, dose, potency, purity and safety for cell and gene therapy products. The USP recognizes that as we try to conform to regulations developed for licensed pharmaceutical products we are limited by fundamental differences. Sample testing size and the need for the "rapid-release" of products often precludes us from applying pharmaceutical based regulations. As stated in USP, "Even well-defined tests such as those described under *Sterility Tests* (71) may not be directly applicable to certain cell and gene therapy products. For some cell and gene therapy products, large quantities of clinical material may not be available during early clinical development. Some required tests (e.g., sterility) may have to be modified. Consultation with the regulatory authorities is advised." The USP further states that "automated sterility testing methods that rely on colorimetric detection or continuous monitoring may be acceptable if they are validated." The USP encourages the development of new validated analytical test methodologies, such as PCR or DNA- or RNA-hybridization dot blot analysis, for mycoplasma, bacteria and adventitious agents as an alternative to 14 and 28 day cell culture bioassays (24 USP-NF <1046>, 1st supplement).

It reasons that there is no one perfect test and the hope is that a Quality Plan including surveillance of products, processes and other tests such as endotoxin or purity will contribute to the overall assurance of product sterility. As we work to define product quality test measures that ensure product safety and adequate surveillance, we are influenced by what is reasonable, economical and accessible for our procedures. So it is imperative that those who mandate the laws in which we operate hear our opinions.

Diane Kadidlo and Kathy Loper

Table 1

Parameter/Criteria	Hospital Microbiology Lab	21 CFR 610.12	USP 24 <71>
Facility	• Routine micro lab • Open; countertops • Non sterile goves • Can perform gram stains (if needed) • Some anecdotal reports of false positives • May result in contamination during inoculation	• No specific requirements • Exempts certain specific blood products and non injectables	• Clean room or isolators • Addresses different products (devices, topical, etc)
Media	• Various medias or broth • May include both bacterial and fungal component • Some facilities incorporate medias from CFR into program for cellular therapies	• Fluid thioglycollate for bulk and final • Soybean caesin for final product	• Thio and SB caesin • Special procedure for media with penicillin or cephalosporins (ensures against inhibition of culture) and specifies validation of qty. of B-lactamase to add
Incubation Time	• 7-14 days depending on SOP • Fungal cultures often 28 days • Automated methods may be subcultured for positive ID and sensitivity	• Fluid thio 30-35C for 14 days • SB caesin 20-25C for 14 days	• 14 days • Fluid thio 32.5 ± 2.5 • SB Caesin 22.5 ± 2.5
Assay	• Automated bottle system • Direct inoculation • Can retest if sample permits	• Specifies media examination days • Specifies subculture requirements • Allows for retest to confirm positives	• No allowance for retest
Sample Requirements	• Stated on collection bottles by manufacturer • Varies with facility SOP	• Specifies culture volumes • Different requirements for products containing mercury	• Requires bulk and final testing
Negative Controls	• Varies with facility • Often relies on QC performed by commercial media manufacturer	• Requires media incubation, 7 days, no inoculum	• Incubate for 14 days • Requires validation to ensure media is not fungistatic or bacteriostatic (inhibition)
Growth Promotion	• Varies with facility • Often uses positive controls for QC • Organisms for positive controls vary	• Must be tested for growth promotion using 2 organisms • Requires aerobic and anaerobic for thio • Requires Candida for SB caesin	• Specifies number and type of organisms to grow • Must grow within 5 days
Innoculum	• In cell processing facility or in micro lab	• Intended for Biologics • Stringent sample requirements including 'bulk' and 'final' container testing • Specifies volumes and quantity from lot • References USP for water insoluble products	• Specifies volumes • Specifies no. of articles (ratios) to be tested • Three inoculation methods • Recommends membrane filtration method whenever possible
Cost	• Varies with facility • Often <$30	• Varies with facility • Most testing labs modify USP to include both CFR and USP • Similar to USP	• Varies with facility • $150-700 for culture, depending on inoculum • $150-1200 for validation, inhibition study

Upcoming Meetings

2nd Annual Mesenchymal & Nonhematopoietic Stem Cells Meeing
New Orleans, Louisiana, USA. September 26-28, 2002. For more information contact the ISCT Head Office: Tel: 604.874.4366; Fax: 604.874.4378

Cell Culture & Separations for Cell & Gene Therapies
15th Annual ASME Bioprocess Technology Seminars. Paradise Point Resort, San Diego, California, USA. October 28-November 1, 2002. Registration fee discount for ISCT/ISCT members. For more information contact Brandy Smith: Tel: 212.591.7413; Email: smithb@asme.org; Website: www.asme.org/education/techsem/bio.htm

2003 ISCT Annual Meeting
Phoenix, Arizona, USA. May 29-June 1. For more information contact the ISCT Head Office: Tel: 604.874.4366; Fax: 604.874.4378; Email: ISCT2003@celltherapy.org

USP General Chapter <1046> Cell and Gene Therapy

Overview for ISCT Telegraft

USP was founded in 1820 and is a non-government organization that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other technologies. At USP's 1995 Quinquennial Convention, USP's members encouraged the organization to develop an informational General Chapter to describe and encompass methodologies and current best practices for cell and gene therapies, standards for reagents and materials used, and information regarding the appropriate use of these technologies. Work on this General Chapter began in 1997 under the auspices of the USP Advisory Panel on Gene and Cell Therapy. The panel consisted of clinicians, scientist and regulators working in these fields who volunteered their time and expertise. The chapter summarizes the information that this panel would have liked to have known if they were starting out in the field.

This General Chapter was first published for public review and comment in the *USP Pharmacopeial Forum*, volume 26, number 1 (January-February 2000). A sizable number of encouraging comments were received requesting additional clarifications on the points made in the first proposal; a revised proposal to address these comments was published in the *Pharmacopeial Forum*, volume 27, number 1. After a favorable second public review, the revised proposal was approved by the Executive Council of the USP Council fo Experts and became an official USP General Information Chapter with the USP25-NF20, First Supplement (official date, April 1, 2002). During this time, the Advisory Panel on Gene and Cell Therapy has evolved into and was superceded by the current USP Expert Committee on Gene Therapy, Cell Therapy and Tissue Engineering.

Although most General Information Chapters are written with approved products in mind, this chapter has included a development perspective. The chapter is divided into several subsections, including manufacturing of both cell and gene therapy products, on-site preparation and administration, analytical methods for, stability, storage, shipping and labeling of these products. It covers products currently regulated by the FDA as well as those which are not, like bone marrow transplants. The chapter emphasizes the systems that should be in place to manufacture and administer these products safety. For instance, the manufacturing section only outlines possible manufacturing scenarios but it details systems that should be in place for sourcing of raw materials, characterization of cell and viral banks, in process controls, specifications and considerations when validating these types of products. The many factors that should be considered when designing a gene vector are listed.

The physician's perspective is important. The panel viewed any formulation or preparation of a cell product at the clinic as an extension of manufacturing at the company and discusses the types of controls and systems that need to be in place. Patient monitoring after treatment is included as most of these therapies are novel and patient reaction can be very idiosyncratic. Finally, the panel recognized that these products may have to be administered in life threatening situations even if the product fails to meet all of its pre-established release criteria. The chapter describes systems that should be in place for such products in these cases.

The examples given in <1046> are relevant to cell and gene products. This is especially true for the extensive analytical methods section. For instance, the potency assay for a cell product might evolve from number of viable cells for early clinical lots to the expression of some critical proteins for later clinical lots to the functioning of the cells (or key set of proteins) for commercial lots. The panel tried to demonstrate that the principles of the ICH guidelines, especially those for biotechnology derived products, could apply to cell and gene products even if the guidelines specifically state that they did not apply. The chapter and panel worked to define the jargon used in this field. There is a glossary at the end of the chapter which will help to standardize the terminology used by these fields. The panel avoided some jargon; they did not discuss "minimally manipulated" cell products as they felt that the practices described in this chapter should be used for any cell product. The goal of this chapter and its specific examples is to go beyond any particular regulatory guidance to make all regulatory guidances relevant to the field of cell and gene therapy.

Copies of the General Information Chapter <1046> Cell and Gene Therapy Products may be obtained by subscribing to the *USP-NF*. Subscription information is available on USPs' website, www.usp.org. Individual copies of this General Chapter are also available for $150 and may be obtained by contacting USP at custsvc@usp.org. Questions or comments concerning the content of this General Chapter may be directed towards stdsmonographs@usp.org.

Sally S. Seaver and Ian F. DeVeau

Are You Ready For GTP?

There are only nine months left before the registration and listing rule is effective for "Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products" (21 CFR 207.20(f)) who fall within the categories of hematopoietic stem cell establishments described by the final registration rule. The final rules on donor suitability and good tissue practice have not yet been published, but the FDA has posted guidance documents pertaining to these areas.

The nuances of the regulations can be very important to our daily practices. For example, "testing" refers to the actual performance of the assay. Thus, it has been clarified for us by the FDA that establishments which perform the serologic testing of blood samples from donors under the rule will need to register even if those establishments are not directly involved in the care of the donors. Consequently, if a hospital or clinic with a collection center currently sends out infectious disease screening studies to contract labs, either those labs will have to register or the collection center will need to find a registered lab to do the assays.

Members are encouraged to use the ISCT Discussion Page to exchange information regarding compliance with the regulations.

ISCT members can familiarize themselves with the rules and the guidance documents via the LRA web page at: http://www.ishage.org/committees/LRAcommittee.htm. The information available includes:

Guidance

- Validation of Procedures for Cell Processing
- General Principles of Software Validation
- Electronic Submissions of INDs
- Human ES and Stem Cell derived articles
- Good Manufacturing Practice
- Nucleic Acid Testing of Donors
- Biological Product Deviation Reporting
- Donor Screening

Workshop Reports

- Clinical Application of Flow Cytomerty to Human cells
- CDC Guidelines for Preventing Opportunistic Injections

Other

- Regulatory Aspects of Gene Therapy
- FAQs on FDA Registration Rule

ISCT will continue to post at this site links to guidance and other valuable public information as it becomes available.

Donna Prezpiorka

ISCT 2002 Technologist Travel Award

ISCT would like to congratulate the Recipients of the ISCT Technologist Travel Award for 2002. Each recipient will receive $500 USD to subsidize the cost of travel to the ISCT Annual Meeting in Barcelona.

Cecilia Götherström, BSc
Karolinska Institute
Stockholm, Sweden

Julie Gruber-Allickson, MS, MT(ASCP)
Diabetes Research Institute
Miami, FL, USA

Helen Huls, BS
Baylor College of Medicine
Houston, TX, USA

Diane Leigh, MS
Cleveland Clinic Foundation
Cleveland, OH, USA

Marc Lenjou, MT
Antwerp University Hospital
Antwerp, Belgium

Marie Olszewski, MT(ASCP), SH(ASCP)
Children's Memorial Hospital
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Flávio Henrique Paraguassú-Braga
Center for BMT/National Cancer Institute-Brazil
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Michael Schumm, VMD
Kinderklinik der Universitaet
Tuebingen, Germany

Charlotte Tammik
Karolinska Institute
Huddinge, Sweden

Zilton Vasconcelos, BSc
Brazilian National Cancer Institute
Rio de Janeiro, Brazil

Second Edition FACT Standards

The Second Edition of the FACT Standards is now available for purchase. Copies may be ordered online at www.factwebsite.org. Look for the "Top Ten Changes in the FACT Standards, Second Edition, 2002" in the box to the right.

Continuing Education for Apheresis Inspectors

A FACT Inspector continuing education course for apheresis inspectors will be offered at the annual American Society for Apheresis Meeting in Orlando, Florida on June 1, 2002. Inspectors of Collection Facilities or Laboratories are not required to hold a doctoral degree. Nurses or technologists with the appropriate supervisory experience affiliated with FACT-accredited or applicant facilities are welcome. To register for the workshop, please contact the FACT Office at 402-561-7555.

Accredited Facilities

Four additional BMT centers have gained FACT accreditation since the last issue of the *Telegraft*. FACT has now accredited 103 centers. There are 98 other centers in various stages of application, inspection or accreditation pending.

The latest facilities to gain voluntary accreditation, along with their Program Directors are listed in the categories below:

Autologous peripheral blood progenitor cell transplantation, including collection and laboratory processing:

- Lahey Clinic Autologous Transplant Program, Burlington, MA. Program Director: Arthur Rabinowitz, MD
- Scripps Blood and Marrow Transplantation Program, La Jolla, CA. Program Director: James Mason, MD

Allogeneic & autologous marrow and peripheral blood progenitor cell transplantation, including collection and laboratory processing:

- Baylor University Medical Center, Dallas, TX. Program Director: Edward Agura, MD
- Children's National Medical Center, Washington, DC. Program Director: Naynesh Kamani, MD

For a complete list of accredited facilities, please visit the FACT website.

Linda Miller

FACT Accreditation Office: (402) 561-7555
www.fahct.org

Facilities Registered	201
Facilities Inspected	143
Accredited	103
Inspected/Pending Accreditation	40
Inspections in Process	15
Facilities Completing Checklists	43
Inspectors Trained	306

Just the FACTs

Top Ten Changes in the FACT Standards
Second Edition, 2002

The following is a brief synopsis of the major changes in the new FACT Standards, Second Edition, 2002. A more detailed, technical explanation will be provided in the guidance sections of the Accreditation Manual, Second Edition, 2002, to be published this Fall.

10. Removed Cord Blood Collection Standards-Available in NETCORD-FAHCT Standards. The Clinical FACT Standards include transplantation of cord blood.
9. Each Clinical, Collection, and Processing section now contains expanded and relevant standards regarding Quality Management, personnel, policies and procedures, Adverse Reactions, Validation, and safety requirements. "Section A" now covers only terminology, abbreviations, and definitions.
8. Created parallel subsections where possible, i.e. section B4.000 is Clinical Quality Management, section C4.000 is Collection Quality Management, and section D4.000 is Processing Quality Management.
7. Included a comparison chart between the first edition FAHCT Standards and the second edition FACT Standards (Appendix II).
6. Expanded the Clinical Facility Standards regarding minimal number of new patients transplanted annually and pediatric expertise requirements for Programs that treat pediatric patients.
5. Moved Donor selection and evaluation to the Clinical Facility Standards. Collection Facility Standards cover donor evaluation and management.
4. Data Management now collected on IBMTR/ABMTR Transplant Essential Data (TED) Forms.
3. No longer refer to progenitor cells as "components". Revised the names of progenitor cell products to be consistent with ISBT 128 nomenclature.
2. Infectious disease testing requirements now list communicable diseases for which to test, not the specific testing methodologies; mirrors FDA terminology.
1. Created a new, handy-dandy Label Chart to clarify the label elements required at collection, processing, and transportation.

Sarah Litel-Smith

Mesenchymal and Nonhematopoietic Stem Cells: Focus on Adult Stem Cells

The biology and therapeutic potential of nonhematopoietic stem cells is currently one of the most exciting areas in biomedical research. Laboratories from around the world have directed their efforts toward understanding the developmental and transplantation biology of stem cells derived from post-natal animals and the pace of new clinical initiatives is increasing. This rapidly growing interest amplifies the importance of our Society, which seeks to bring together investigators, scientists and laboratory professionals throughout the realm of cellular therapy.

Once again, ISCT is assisting investigators and scientists by providing a forum for the exchange of ideas and dissemination of knowledge, by hosting, in conjunction with St. Jude Children's Research Hospital and Tulane University Health Sciences Center, the Second Annual Meeting on Nonhematopoietic and Mesenchymal Stem Cells: Focus on Adult Stem Cells," in New Orleans September 26-28, 2002. This meeting follows the successful gathering in March 2001 where attendees distilled the state of the art knowledge and advanced ideas for the future of our field. The upcoming meeting promises to be even more exciting as we have organized speakers from the most basic biology to preclinical applications and the current clinical trials. We will discuss controversies such as cellular engraftment versus cellular therapy and hear about the most recent and innovative clinical trials of adult stem cells. ISCT is providing an outstanding opportunity for established investigators and scientists to share their most current data and for young investigators and scientists to interact with leaders in our field. I encourage all interested "cell therapists" to join us for this exciting and surely productive meeting.

Edwin M. Horwitz

2nd Annual Meeting on Mesenchymal and Nonhematopoietic Stem Cells
Focus on Adult Stem Cells

Date: September 26-28, 2002

Location: New Orleans, Louisiana, USA

Abstract Deadline: July 15, 2002

Topics: Biology of Adult Stem Cells, Stem Cell Therapy of Skeletal and Cardiac Muscle, Mesenchymal Cell Therapy to Support Hematopoietic Stem Cell Engraftment and Regulatory Issues Surrounding Clinical Trials of Adult Stem Cells

Program Chairs:
Edwin Horwitz
Darwin Prockop
Armand Keating
Brian Butcher
Malcolm Brenner

Keynote Speaker:
Ronald D.G. McKay

Confirmed Speakers:

Tim Brazelton	Diane Krause
Giuliana Ferrari	Andra Miller
Alan Fine	Lars Olson
Francesco Frassoni	Donald Phinney
Stanton Gerson	Mark Pittinger
Margaret Goodell	Darwin Prockop
Marc Hedrick	David Shine
Karen Hirschi	Paul Simmons
Edwin Horwitz	Evan Snyder
Jeffery Kocsis	Catherine Verfaillie

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Further information, registration, hotel and abstract forms may be downloaded from the ISCT website at www.celltherapy.org.

Sponsored by the International Society for Cellular Therapy, ISCT (formerly ISHAGE), St. Jude Children's Research Hospital and Center for Gene Therapy of the Tulane University Health Sciences Center

Cytotherapy - Upcoming Issues

Volume 4, Number 2

Editorial: *The International Society for Cellular Therapy Honoring Both a New Mandate and Old Responsibilities (Break out the Iced Tea!)* NH COLLINS

Ex vivo expansion of human cord blood primitive hematopoietic progenitors and transplantable stem cells using human primary bone marrow stromal cells and human AB serum. M YAMAGUCHI, F HIRAYAMA, H MURAHASHI, H AZUMA, N SATO, H MIYAZAKI, K FUKAZAWA, K SAWADA, T KIOKE, M KUWABARA, H IKEDA, K IKEBUCHI.

Selection of autologous CD4$^+$ T-cells for adoptive T-cell substitution in patients with CD23$^+$ B cell chronic lymphocytic leukemia. M DETTKE, R BERGER, S JURKO, G MITTERBAUER, JD SCHWARZMEIER, P HOCKER.

The storage and re-infusion of autologous blood and bone marrow as back-up following failed primary haematopoietic stem cell transplantation-a survey of European practice. B POTTINGER, M WALKER, M CAMPBELL, TL HOLYOAKE, IM FRANKLIN, G COOK.

Isolex 300i CD34-selected cells to support multiple cycles of high-dose therapy. HM PRINCE, J BASHFORD, D WALL, D RISCHIN, N PARKER, GC TONER, JF SEYMOUR, D BLAKEY, D HAYLOCK, P SIMMONS, P FRANCIS, M WOLF, EH JANUSZEWICZ, G RICHARDSON, J SCARLETT, P BRIGGS.

CliniMACS CD34-selected cells to support multiple cycles of high-dose therapy. HM PRINCE, D WALL, D RISCHIN, GC TONER, JF SEYMOUR, D BLAKEY, D HAYLOCK, P SIMMONS, M WOLF, EH JANUSZEWICZ, D WESTERMAN, G RICHARDSON, J SCARLETT, P BRIGGS.

Viability of cryopreserved bone marrow (BM) progenitor cells stored for more than a decade. AD DONNENBERG, EK KOCH, DL GRIFFIN, HM STANCZAK, JE KISS, TM CARLOS, DM BUCHBARKER, AM YEAGER.

Immune escape mechanisms of childhood acute lymphoblastic leukemia and a potential countering role for dendritic-like leukemia cells. P HAN, C STORY, T MCDONALD, K MROZIK, L SNELL.

Brief Report: Use of selected CD34$^+$ cells in the treatment of relapsed/progressive Hodgkin's lymphoma: a single center experience. J LAKOTA, V BALLOVA, L DRGONA, P DURKOVIC, A VRANOSKY.

Abstracts from the Therapeutic Products Innovation vs Quality Meeting. October 5-6, 2001. Adelaide, South Australia. Meeting Report by PG DYSON, S NIUTTA.

Meeting Program & Abstracts

Abstracts from the Bone Marrow Transplant Scientist's Association of Australasia. October 25, 2001. Rydges South Bank, Brisbane, Queensland, Australia. Scientific Summary by A TRICKETT.

Meeting Program & Abstracts

Volume 4, Number 3

Editorial: *Allogeneic stem cell transplantation - dinosaur or bird?* J BARRETT.

IN FOCUS: Stem cell transplantation for lymphoma. Guest Editor: R CHAMPLIN. *Stem cell transplantation for lymphoma.* R CHAMPLIN.

Autologous hematopoietic transplantation for low grade lymphomas. JG GRIBBEN.

Long-term follow-up of patients with chronic lymphocytic leukemia treated with allogeneic hematopoietic transplantation. IF KHOURI, MJ KEATING, RM SALIBA, RE CHAMPLIN.

Autologous and allogeneic transplantation for aggressive non-Hodgkin's lymphomas. SM SMITH, D GRINBLATT, K VAN BESIEN.

Hematopoietic stem cell transplantation for Hodgkin's disease: current status. P ANDERLINI.

Intensive chemotherapy with hematopoietic stem cell support for children with recurrent or refractory non-Hodgkin lymphoma. JT SANDLUND, L BOWMAN, HE HESLOP, R KRANCE, H MAHMOUD, C-H PUI, G HALE, E BENAIM.

The choice of allogeneic or autologous hematopoietic transplantation for non-Hodgkin lymphomas. C HOSING, RE CHAMPLIN.

Storage of blood for in vitro generation of dendritic cells. R SYME, D CALLAGHAN, P DUGGAN, S BITNER, M KELLY, J WOLFF, D STEWART, S GLUCK.

Enhanced expansion and maturation of megakaryocytic progenitors by fibronectin. P HAN, XH GUO, CJ STORY.

Three-dimensional culture of murine hematopoietic cells with spatial development of stromal cells in nonwoven fabrics. T SASAKI M TAKAGI, T SOMA, T YOSHIDA.

In vitro interactions between gd T cells, dendritic cells and CD4$^+$ T cells; implications for immunotherapy of leukemia. Z YE, S HALEY, AP GEE, J HENSLEE-DOWNEY, LS LAMB.

Abstracts from the 5th Tokyo International Symposium on Cord Blood Transplantation. June 23, 2001. Institute of Medical Sciences, The University of Tokyo, Tokyo, Japan

Meeting Summary & Abstracts

Dear Colleagues,

We are very pleased to host this year's ISCT annual meeting in Barcelona. This is one of the oldest Mediterranean cities with a rich cultural background and plenty of art, architecture and historical sites. All this coexists with modern urbanism and a thriving commercial sector. Here, you will also enjoy a mild climate, a beautiful seaside and some of the finest European cuisine.

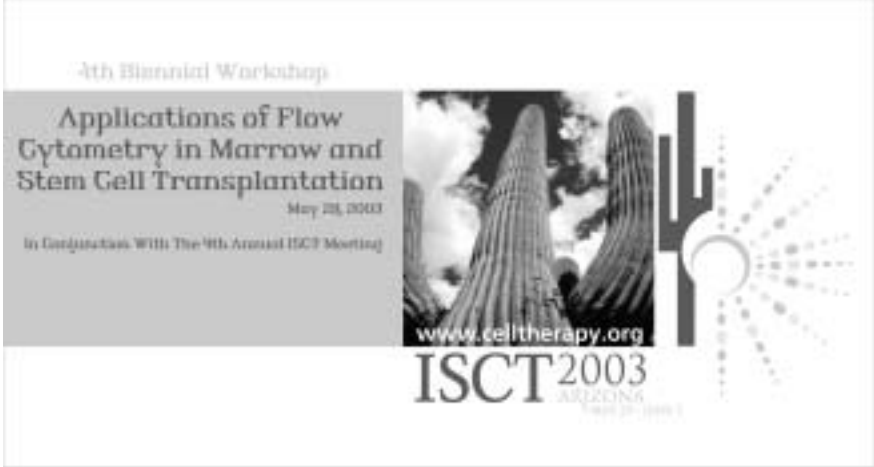
We have organized the meeting paying special attention to the current "hot" scientific topics such as stem cell biology and regenerative medicine, immunotherapy, new approaches for hemopoietic transplants, and the new targets for molecular therapies. Workshops, technical sessions, subcommittee meetings, educational activities and a corporate symposium will complete the scientific offerings.

We invite and welcome you to o these three days of science and pleasure.

Welcome to Barcelona.

Joan García, MD, PhD
President of the ISCT 2002 Organizing Committee

Telegraft Editorial Board



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