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## INTERNATIONAL SOCIETY FOR CELL & GENE THERAPY

Established in 1992, ISCT is the global society fostering cell and gene therapy translation to the clinic. The society is comprised of over 2,400 cell therapy experts across five geographic regions and from over 60 countries. ISCT members are part of a global community of peers, thought leaders and organizations invested in cell therapy translation.

ISCT leads the field in the translational aspects of developing cell and gene-based therapeutics, advancing scientific research into innovative treatments for patients. ISCT has built a unique collaborative environment that advances three key areas of clinical translation: Academia, Regulatory and Commercialization. This has been achieved through long-term strategic relationships with global regulatory agencies, academic institutions, and industry partners internationally.

## **MORE INFO: WWW.ISCTGLOBAL.ORG**

### ISCT has co-founded two accreditation bodies:

Foundation for the Accreditation of Cellular Therapy (FACT), in partnership with the American Society for Transplantation and Cellular Therapy



Joint Accreditation Committee – ISCT & EBMT (JACIE), in partnership with the European Society for Blood and Marrow Transplantation



## **MISSION:**

To improve lives through safe and effective cell and gene therapies.

## **VISION:**

To drive clinical translation of cell and gene therapies worldwide.

## **VALUES:**

- Promote innovation in translational research
- Strive for excellence in everything we do
- Respect and support diversity and inclusivity
- Uphold the highest ethical standards
- Serve our members and advocate for our society



ISCT Membership continues to maintain a consistent upwards trajectory across the globe

**Cytotherapy**, the official journal of ISCT, is a leading publication in the Cell and Gene Therapy sector, with a growing impact factor at 4.218







## **Global Champions at the Cutting Edge**















ISCT is led by a range of global champions, delivering expertise across the translational spectrum to lead their peers in a common mission to advance the field. These leaders blaze trails, contributing towards each of the society's pillars of value. ISCT leaders are highly influential within their areas of expertise, and have been elected or nominated by virtue of significant achievements that have helped advance the field.





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PRESIDENT-ELECT

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CHIEF SCIENTIFIC OFFICER

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# Bruce Levine, PhD President, 2020-2022

Scientific Innovator and Co-Inventor of Kymriah, the first FDA approved gene therapy (CAR T-Cell based therapy)

GMP translational expert with proven success in academic spinout

Leader in global consensusbuilding and scientific collaboration

Dr. Bruce Levine, Barbara and Edward Netter Professor in Cancer Gene Therapy, is the Founding Director of the Clinical Cell and Vaccine Production Facility (CVPF) in the Department of Pathology and Laboratory Medicine and the Abramson Cancer Center, Perelman School of Medicine, University of Pennsylvania.

Dr. Levine has overseen the production, testing and release of 3,100 cellular products administered to over 1,300 patients in clinical trials since 1996. He is co-inventor of the first FDA approved gene therapy (Kymriah), chimeric antigen receptor T cells for leukemia and lymphoma, licensed to Novartis. Dr. Levine is also co-inventor on 27 issued US patents and co-author of >180 manuscripts and book chapters with a Google Scholar citation h-index of 89. He is a Co-Founder of Tmunity Therapeutics, a spinout of the University of Pennsylvania.

Dr. Levine is President of the International Society for Cell & Gene Therapy and serves on the Board of Directors of the Alliance for Regenerative Medicine. He has been interviewed by the NY Times, Wall Street Journal, Washington Post, NPR, Time Magazine, National Geographic, Forbes, Bloomberg, BBC, and other international media outlets.



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John Rasko, AO, MBBS, PhD, FRCPA, FRACP, FAHMS Immediate Past President, 2020-2022

Clinical pioneer in the use of adult stem cells and genetic therapy

Internationally recognized expert scientific communicator

Experienced leader of professional scientific organizations

John Rasko is a clinical haematologist, pathologist and scientist with an international reputation in gene and stem cell therapy, experimental haematology and molecular biology. In over 160 publications he has contributed to the understanding of stem cells and blood cell development, gene transfer technologies, cancer causation and treatment, human genetic diseases and non-coding RNAs.

Professor Rasko is an Australian pioneer in the application of adult stem cells and genetic therapy. Since 1999 he has directed the Department of Cell and Molecular Therapies at Royal Prince Alfred Hospital and the Gene and Stem Cell Therapy Program at the Centenary Institute, University of Sydney.

Professor Rasko's contributions to scientific organizations include co-founding (2000) and past-President (2003-5) of the Australasian Gene & Cell Therapy Society; Vice President (2008-12) and President (2018-20), International Society for Cell & Gene Therapy. He is a founding Fellow of the Australian Academy of Health and Medical Sciences. He is the recipient of national (RCPA, RACP, ASBMB) and international awards in recognition of his commitment to excellence in medical research, including appointment as an Officer of the Order of Australia.



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Jacques Galipeau, MD, FRCP(C)
President-Elect, 2020-2022

Internationally recognized expert and educator in clinical applications

Clinical leader in cell therapy standards and applications for Mesenchymal Stromal Cells

Developer of fusion engineered cytokines known as fusokines

Jacques Galipeau, M.D., FRCP(C), is the Don and Marilyn Anderson Professor of Oncology within the Department of Medicine and UW Carbone Comprehensive Cancer Center at the University of Wisconsin in Madison, and is Associate Dean for Therapeutics Development at the University of Wisconsin School of Medicine & Public Health.

Dr. Galipeau has an NIH-funded research program in the study and use of mesenchymal stromal cells as an immunotherapy of illnesses including cancer and immune disease. He is an internationally recognized expert in translational development of cell therapies and the sponsor of a series of FDA-sanctioned clinical trials examining the use of autologous marrow-derived mesenchymal stromal cells for immune disorders, including Crohn's disease and graft vs host disease. He has also developed the field of fusion engineered cytokines known as fusokines, as a novel pharmaceutical means of treating immune disorders and cancer.

Dr. Galipeau is the director of the University of Wisconsin Advanced Cell Therapy Program whose mission is to develop personalized cell therapies for immune and malignant disorders and to promote and deploy first-in-human clinical trials of UW cell therapy innovations to improve outcomes for children and adults.



LEADERSHIP

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# Queenie Jang, MBA, BSc (Pharmacy) Chief Executive Officer

Proven senior executive in the biomedical / pharmaceutical industry

Expert in building productive and effective organizational consensus and partnerships

Highly experienced in strategies for business development and organizational growth

Ms. Jang is a senior executive with over 25 years of business leadership and management experience in the biomedical / pharmaceutical industry in both private and public companies. As CEO and Chair; Executive Management Committee of ISCT, International Society for Cell & Gene Therapy, Ms. Jang leads a global organization of innovators and KOLs in academia, regulatory and industry which serves to catalyze harmonized clinical translation of cell and gene therapies to the clinic worldwide.

Through her extensive business leadership and management experience in the biomedical/pharmaceutical industry in both private and public companies, Ms. Jang has led the emergence of ISCT as the leading global cell therapy society focused in regulatory, commercial and academic thought leadership.

Prior to her CEO role with ISCT, Ms. Jang was Officer and VP of Corporate and Business Development at Conjuchem Biotechnologies Inc. through the Conjuchem IPO, and executed multiple licensing agreements leveraging the company's proprietary peptide technology platform. In the pharmaceutical industry, her leadership roles included; VP Strategy and Marketing with Sanofi in North America, senior Marketing and Business Development management roles with DuPont and GSK.



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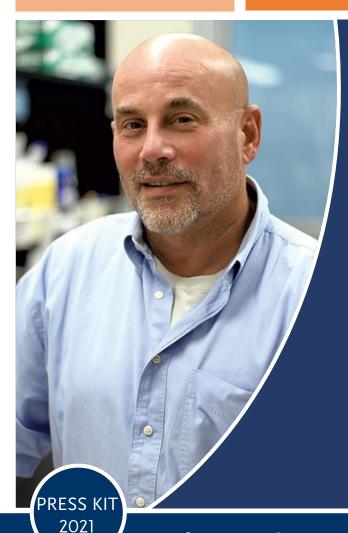
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# **Daniel J. Weiss**, MD, PhD Chief Scientific Officer

Internationally recognized leader in ex vivo lung regeneration & cell-based therapies for lung diseases

Clinical practitioner with history of benchmark publications

Founder of the UVM Stem Cells and Cell Therapies in Lung Biology Conference

Daniel J. Weiss, MD, PhD, is Professor of Medicine and Professor of Cell and Molecular Biology at the University of Vermont. Dr, Weiss is recognized internationally as a leader in the area of 'ex vivo' lung regeneration and in cell-based therapies for lung diseases, with a longstanding interest in lung repair and regeneration after injury, notably gene and cell therapy approaches for lung diseases.

Recent published work in cell therapy approaches for lung diseases has included several benchmark publications that have included the first ever trial of cell therapy for emphysema. Dr. Weiss also instituted a biennial meeting held at the University of Vermont, Stem Cells and Cell Therapies in Lung Biology and Diseases, that is widely viewed by the NIH, FDA, and non-profit Respiratory Disease Foundations as the major meeting in the field.

As Chief Scientific Officer of ISCT, Dr. Weiss oversees the strategic positioning and movements of the scientific committees and working groups of the Society, in addition to representing the interests of the scientific committees on the Board of Directors.







**LEADERSHIP** PRESS SAMPLES CONTACT **OVERVIEW** 

CHIEF REGULATORY OFFICER



## Karen M. Nichols, Esq. **Chief Regulatory Officer**

Patent attorney with laboratory background and significant experience in corporate leadership

**Expert in Quality & Operations and Compliance** in lab manufacturing

Proven leadership in coordinating regulatory advocacy in CGT sector

Karen Nichols is VP, Regulatory CMC and Quality, at Vertex Cell and Gene Therapies. Prior to this, she was VP, Regulatory and Quality, at Magenta Therapeutics.

Prior to this, Ms. Nichols spent over 30 combined years at Magenta Therapeutics, PerkinElmer, Genzyme Corporation, Immunogen, Inc. and Wyeth Pharmaceuticals, in various leadership positions in Regulatory Affairs, Quality Operations and Corporate Compliance.

As Chief Regulatory Officer of ISCT and Chair of the North America Legal and Regulatory Affairs Committee, Ms. Nichols oversees the annual FDA Cell Therapy Liaison Meeting, the ISCT Global Regulatory Perspectives initiative, and regulatory advocacy on behalf of the Society.

She completed her undergraduate studies at the State University of New York in Biology, followed by a JD from Suffolk University. She is registered with the Massachusetts bar and the US Patent and Trademark Office as a patent attorney.







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# Anthony Ting, PhD Chief Commercialization Officer

Business leader with significant scientific experience in clinical context Successful translational leadership with MultiStem®, an investigational stem cell product

Proven scientific expertise in the development of regenerative medicine therapies

Dr. Ting is Chief Scientific Officer of Bone Therapeutics. With over thirty years of experience in cell and stem cell biology, he has developed a wealth of leadership experience and hands-on expertise in translational clinical studies with adult stem cell therapies.

Prior to this, Dr. Ting had a tenure of over nineteen years at Athersys, where he began as a Senior Scientist and rose through the ranks, culminating in his prior role as Vice President of Regenerative Medicine and Head of Cardiopulmonary Programs. Within this role, Dr. Ting was responsible for all stages of the development of MultiStem® from the bench to the bedside. During his time with Athersys, Dr. Ting managed all programs in the cardiovascular and pulmonary areas at the Company, as well as the evaluation of potential new uses for the cell therapy product. Dr. Ting serves on several regenerative medicine society committees including the International Society for Cell & Gene Therapy and the Alliance for Regenerative Medicine.

Prior to his work with Athersys, Dr. Ting was a Principal Investigator and Head of the Screening for Novel Inhibitors group at the Institute of Molecular and Cell Biology (IMCB) at the National University of Singapore.







PRESIDENTIAL TASK FORCE ON THE USE OF UNPROVEN AND/OR UNETHICAL CELL AND **GENE THERAPIES** 



Laertis Ikonomou, PhD Chair



Daniel J. Weiss, MD, PhD Vice Chair, Science



Aaron Levine, PhD Vice Chair, Ethics



Karen M. Nichols, Esq Vice Chair, Regulatory



Miguel Forte, MD, PhD Vice Chair, Industry



Rachele Ciccocioppo, MD Member, Ex-Officio ISCT Deputy CSO



Bruce Levine. PhD Member, Ex-Officio **ISCT President** 



Jacques Galipeau, MD, PhD Member. Ex-Officio **ISCT President-Elect** 



INTERNATIONAL SOCIETY FOR CELL &GENE THERAPY PRESIDENTIAL TASK FORCE Use of Unproven and/or Unethical Cell & Gene Therapy

The ISCT Presidential Task Force on the Use of Unproven and/or Unethical Cell & Gene Therapies is comprised of prominent experts in the cell and gene therapy field, spanning academia, industry and regulation.

The Task Force strives to characterize unproven and unethical cell and gene interventions, and to promote safe and effective practices worldwide.

**COVID-19 Research Spotlight and Patient Resource** Library

Reference Guide -**Talking About Unproven Cell-Based** Interventions

List of Cell/Tissue/ Gene products with marketing authorization

#### PRESIDENTIAL TASK FORCE COMMITTEE MEMBERS **Natividad Cuende** Megan Munsie Sarah Chan **Leigh Turner** Massimo Dominici Alok Srivasta John Rasko **Alexey Berseney** Patricia Zettler





PRESIDENTIAL TASK FORCE ON THE USE OF UNPROVEN AND/OR UNETHICAL CELL AND GENE THERAPIES

REGULATORY ADVOCACY

ISCT ANNUAL AND REGIONAL MEETINGS

## Regulatory Consultation and Support (Click each title to learn more)

With the goal of building consensus within the cell and gene therapy sector, ISCT has developed several programs that help to build bilateral communications between regulatory bodies and industry/community stakeholders, and continues to provide consultation and support to regulatory bodies seeking advocacy from the field around the globe.

**ISCT provides consultation and support** to regulatory bodies seeking advocacy from the field around the globe, including:

- United States Food & Drug Administration (FDA)
- Health Canada
- Australian Therapeutic Goods Administration (TGA)
- European Medicines Agency (EMA)
- World Health Organization (WHO)
- International Organization for Standardization (ISO)

# FDA Cell Therapy Liaison Meeting (CTLM)

Since 2004, ISCT has been the host coordinating up to 17 global stakeholder organizations in the annual FDA Cell Therapy Liaison Meeting (CTLM). These closed meetings enable the cell and gene therapy community to inform the FDA of specific concerns, challenges and recent developments to advance the regulatory field.

# Health Canada Cell Therapy Stakeholder Group (CTSG)

The CTSG bilateral meeting, chaired by ISCT, was initiated for manufacturers in the field to interact directly with Canadian regulatory authorities. **Since 2014**, the Biologics and Radiopharmaceutical Drugs Directorate has met with national stakeholder organizations through CTSG meetings

# International Organization for Standardization (ISO)

ISCT is a **Category A Liaison** to the International Organization for Standardization and participates actively in ongoing CGT standards development.





PRESIDENTIAL TASK FORCE ON THE USE OF UNPROVEN AND/OR UNETHICAL CELL AND GENE THERAPIES

REGULATORY ADVOCACY

ISCT ANNUAL AND REGIONAL MEETINGS



TOP FIVE (BY LIVE ATTENDANCE & VIEWS)

LIVE SESSIONS



- ISCT CSO Global Showcase on COVID-19, Part I: "The Force Awakens"
- Mesenchymal Stromal Cells: Full Circle from Basic Research Insights to Clinical Trial Updates
- Advances and Emerging Technologies in Immune-Mediated Cancer Treatments
- Is Big Pharma Ready for Industrial Scale Cell and Gene Therapy?
- Presidential Plenary: Mastering Pluripotent Cells with Therapeutic Intent

ISCT Annual Meetings target core issues in Cell and Gene Therapy translation, drawing professionals from across industry, academia, and regulatory spheres with the purpose of building consensus that advances the field.











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## **2020 ISCT ANNUAL REPORT – READ HERE**

# **ISCT Key Press Releases**

## September 14, 2020

ISCT issues key findings and recommendations following 2020 Annual Meeting for cell and gene therapy

**Read More** 

### May 11, 2020

**Read More** 

ISCT demands proper clinical investigation for COVID-19 therapies

## March 25, 2020

**Read More** 

ISCT takes a stand against organizations marketing unproven COVID-19 cell and gene therapies

## October 21, 2019

**Read More** 

ISCT forms cell and gene therapy sector-wide coalition combating rise of unproven commercial cell banking services

## November 18, 2018

ISCT publishes annual report on cell and gene therapy market authorizations

Read More

patients

May 14, 2018

ISCT supports FDA

stem-cell injunctions

and proposes wider

action to protect

Read More

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## ISCT in the Media

Read more by clicking each logo



### 17 SEPT 2020

From the fringe of the fringe to the brink of a revolution in medicine; this is the cell and gene therapy story as told by the society that was there at the very beginning – the ISCT"



### 14 SEPT 2020

"When you've got a deadly disease, every minute you are taking a bogus therapy takes away time from a treatment that's proven..."



### 17 JUN 2020

"Book-ending plenary sessions on COVID-19 set the scene for a lot of the discussions this meeting around developing a robust supply chain, clinical trial protocol or manufacturing process..."

# BioProcess International

## 30 MAR 2020

"The ISCT has long been fighting against unproven cell and gene products and services from rogue actors looking to profit from ill-informed and sometimes desperate patients."



### 31 JAN 2020

"To explore how outsourcing can prove beneficial for cell and gene therapy (CGT) development, Pharmaceutical Technology spoke with Miguel Forte, chief commercialization officer, ISCT, CEO of Bone Therapeutics..."

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Since 2017, ISCT has worked with Image Box Communications to manage its media strategy, and to cultivate media-based relationships and outreach within the cell and gene therapy sector.



## For media and press queries about ISCT, please contact:

Neil Hunter

Life Sciences Director, Image Box Communications neil.hunter@imageboxpr.co.uk

## Queries may also be directed to ISCT Head Office

Ken Ip

Coordinator, Communications and Education ken@isctglobal.org

