



NTIAGO DE CHILE | 9-10 SEPTEMBER



JOINT SECTOR OPENING CEREMONY PRE-READ / BIOGRAPHIES

8:00-9:00: BADGE COLLECTION, HEADSETS, AND TEA/COFFEE SERVICE

9:00-9:20: OPENING KEYNOTE REMARKS

Biography of the Honorable Gilbert Kaplan:



Gilbert B. Kaplan was confirmed by the U.S. Senate and assumed his position as Under Secretary of Commerce for International Trade in the United States Department of Commerce in March 2018. In this role, he leads a workforce of 2,100 personnel within the International Trade Administration ("ITA"). He oversees three major units at ITA: Global Markets and the Domestic and Foreign Commercial Service, Industry and Analysis, and Enforcement and Compliance. The Global Markets team provides support to tens of

thousands of American exporters, with over 200 offices in the U.S and worldwide. Industry and Analysis is a powerhouse of expertise with an ability to leverage data analytics and implement strategies to strengthen global competitiveness of U.S. Industries. The Enforcement and Compliance staff are charged with enforcing U.S. trade laws, particularly antidumping and countervailing duty law, holding trading partners accountable for their international commitments to ensure a level playing field at home and abroad. Prior to assuming his current position, Mr. Kaplan was a partner at King & Spalding and part of the International Trade Practice Group. He is a graduate of Harvard Law School and Harvard College.

Biography of the Honorable Rodrigo Yáñez Benítez:



Rodrigo Yañez is the vice minister of trade at the General Directorate of International Economic Relations in Chile. During President Piñera's previous administration, from 2010-2014, Rodrigo served as senior advisor on international and regulatory affairs to the Presidency, where among his duties, he developed foreign policy proposals and oversaw the implementation of domestic policy initiatives for different ministries. He previously worked as director of financial advisory services at Deloitte

where he led the Business Intelligence and Anticorruption, Compliance & Regulatory Advisory service lines. He was ranked by Chambers & Partners Latin America 2018 as a Leading Practitioner in the field of Compliance. Yañez was also a member of the Panel on Public Works Concessions (2014–2018), board member of Chile's Public Enterprise System (2013–14), and Intl Cooperation Agency Board (2012–14). Rodrigo holds a JD from Pontificia Universidad Católica de Chile and a MSc in regulation from the London School of Economics and Political Science (LSE).

9:20-9:30: PROGRAM OVERVIEW AND DELEGATE BRIEFING

Biography of Ms. Tricia Van Orden:



Tricia Van Orden serves as the Overseer of the *Business Ethics for APEC SMEs Initiative* and Deputy Director of the Trade Promotion Coordinating Committee (TPCC) Secretariat at the International Trade Administration (ITA) within the U.S. Department of Commerce. In this role, she coordinates trade promotion strategies across 20 federal agencies and among states and localities to better assist and to improve the competitiveness of U.S. exporters. With a focus on small business export promotion,





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Ms. Van Orden also serves as the U.S. delegate to the Asia-Pacific Economic Cooperation (APEC) Forum Small and Medium Enterprises Working Group. Previously, Ms. Van Orden worked at the Inter-American Development Bank, where she led training programs to increase the capacity of small businesses to access capital. She started her career as an aide in the U.S. Senate working on foreign affairs and international trade policies.

DISTRIBUTORS PORTAL SESSION PRE-READ / BIOGRAPHIES

9:30-9:45: TRANSITIONS TO SAN CRISTOBAL C AND TAKE SEATS

9:45-10:00: OPENING SESSION

<u>Description</u>: Following remarks by the Overseer, participants will provide their name and organizations. Delegates will then come to the front of the room for a group photograph.

Biography of Ms. Tricia Van Orden:



Tricia Van Orden serves as the Overseer of the *Business Ethics for APEC SMEs Initiative* and Deputy Director of the Trade Promotion Coordinating Committee (TPCC) Secretariat at the International Trade Administration (ITA) within the U.S. Department of Commerce. In this role, she coordinates trade promotion strategies across 20 federal agencies and among states and localities to better assist and to improve the competitiveness of U.S. exporters. With a focus on small business export promotion,

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10:00-10:15: A DECADE IN REVIEW - MEDICAL DEVICE SECTOR AND ETHICAL BUSINESS CONDUCT

<u>Description:</u> Ms. Nancy Travis will provide participants with a concise review of the capacity-building and training activities that APEC has undertaken since 2012 to strengthen ethical business practices in the medical device sector. This review will take stock of the achievements that have been made in code of ethics adoption and harmonization around the world and the opportunities that remain.

Related Materials:

- APEC Kuala Lumpur Principles: PDF Here
- APEC Nanjing Declaration : <u>PDF Here</u>
- APEC Ministerial and Leaders Recognition : View Here
- 2019 APEC Report on Code of Ethics Implementation in the Medical Device Sector: PDF Here





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Biography of Ms. Nancy Travis:



As Vice President for International Compliance and Governance at the Advanced Medical Technology Association (AdvaMed), Ms. Travis leads the association's efforts to promote codes of ethics for the medical technology industry worldwide. She was instrumental in launching the *Business Ethics for APEC SMEs Initiative* and the Inter-American Coalition for Business Ethics in the Medical Technology Sector. In addition to her policy focus, she addresses key issues related to association governance at AdvaMed, including management

of the Board. Nancy has 20 years of international affairs and leadership experience, with a particular focus on advocacy related to market opening and trade issues. She advised key government officials on trade agreements as well as World Trade Organization accession negotiations. Throughout her career, she has received a number of exceptional performance and superior honor awards.

10:15-10:30: A HISTORY OF STRENGTHENING ETHICAL THIRD PARTY INTERMEDIARY RELATIONSHIPS IN THE MEDICAL DEVICE SECTOR

<u>Description:</u> Building upon the previous presentation, Ms. Faye Sumner will offer participants a brief history of the medical device sector's work to strengthen ethical third party intermediary relationships, with the most recent and significant milestone including the launch of APEC guidance in 2017 and the Tokyo Action Agenda in 2018. Faye will offer insights into how the efforts undertaken to-date have led the Business Ethics for APEC SMEs Initiative to pursue a distributors' ethics portal to support capacity-building.

Related Materials:

- APEC Guidance for Ethical Third Party Intermediary Relationships in the Med. Device Sector: <u>PDF Here</u>
- Tokyo Action Agenda: Recommendations to Promote Ethical Third Party Intermediary Relationships in the Medical Device Sector through 2021: <u>PDF Here</u>

Biography of Ms. Faye Sumner:



Faye Sumner is the Chief Executive Officer for the Medical Technology Association of New Zealand (MTANZ). As CEO, she has been at the forefront of negotiations with the Government in the development of proposed New Zealand medical device regulations and the move to centralized procurement of medical devices for New Zealand. Faye introduced the Code of Practice for New Zealand's medical technology industry in 2005 and has since served as an international leader in strengthen ethical business practices.

Faye was a member of the Asia Pacific Economic Cooperation (APEC) Code of Business Ethics for Medical Devices Expert Working Group that developed the 2011 KL Principles. In the 2018 Queen's Birthday Honours, Faye was appointed Companion of the New Zealand Order of Merit (CNZM) for her services to the medical technology sector. Faye is a Registered Nurse with a business qualification from the University of Auckland Business School. Faye is a Trustee of the University of Auckland, School of Medicine Foundation and a member of the University's MedTech Centre of Research Excellence Governing Board. Faye is a Board member on two Government Crown Entities; NZ Artificial Limb Board and NZ Standards Approval Board. Faye is also a deputy Chair of the NZ Heart Foundation and Chair of the Heart Health Trust.





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10:30-10:45: WORK PLAN PRESENTATION OF THE MEDICAL DEVICE DISTRIBUTORS' ETHICS PORTAL

<u>Description:</u> With Nancy and Faye having provided a comprehensive overview of the Initiative's history to strengthen capacity for medical device companies and associations, as well as to identify and adopt best practices in ethical third party intermediary relationships for the sector, Michelle Wagner will present a work plan – aligned with the Tokyo Action Agenda – to translate the previously release APEC Toolkit of resources into a distributors' ethics portal. Delegates are encouraged to preview the work plan below.

Related Materials:

Draft Work Plan for the Medical Device Distributors' Ethics Portal: PDF to be Included in Next Version

Biography of Ms. Michelle Wagner (Facilitator):



Michelle has been working in the healthcare industry with Johnson & Johnson for 14 years. Michelle commenced her career with Johnson & Johnson Medical in Australia as the Director of Compliance. Michelle was the first full time Compliance Officer in Asia Pacific for Johnson & Johnson. Michelle has held various positions in Johnson & Johnson of increasing experience. In 2013, Michelle assumed the position of Regional Sector Lead for Compliance for Medical Devices in Asia Pacific and sat on the Regional Leadership

Team for Medical Devices Asia Pacific. In 2015, Michelle took on the additional responsibility of the Johnson & Johnson Vision franchise. In 2018, Michelle was appointed Global Lead, Third Party Intermediary and Supply Chain Ethics & Compliance. In this position Michelle leads a global team providing leadership, strategic and tactical direction and oversight of Third Party Intermediary risk management as well as managing a robust compliance program for Supply Chain. Prior to joining Johnson & Johnson, Michelle gained valuable compliance experience at the Australian Securities Exchange in Sydney and the Securities Investment Board in London and as a chartered accountant for KPMG and Ernst & Young in Sydney. Michelle hold a Bachelor of Economics (majoring in Accountancy and Business Law) from the University of Sydney and Michelle is a qualified Chartered Accountant. Michelle sits on the Code Authority Committee for the Medical Technology Association of Australia (MTAA) and represents MTAA to the *Business Ethics for APEC SMEs Initiative*.

10:45-11:15: MORNING TEA/COFFEE BREAK





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11:15-12:15: DISTRIBUTORS PERSPECTIVES AND CHALLENGES

<u>Description:</u> The leaders of medical device distributor associations and companies will provide feedback on the work plan presented by Michelle Wager. Michelle will facilitate the discussion with panelists as well as open the discussion to participants to provide their inputs. The association leaders providing feedback on the draft work plan, as well as other Forum participants, should consider the following questions:

- Are SME distributors and third party intermediaries the right or only target audience for this resource?
- What approaches should be considered in order for industry associations to routinely utilize this resource for the benefit of their member companies?
- Are the five phases of the resources appropriately segmented? Would you make any adjustments or expand upon the kinds of materials that are already indicated?

Biography of Ms. Ma Ensheng:



Ensheng has 17 years of experience working as a trade official in the Government of the People's Republic of China, with a focus on trade remedy and WTO affairs. He has served as a Deputy Division Director in the Trade Remedies and Investigation Bureau of the Ministry of Commerce since 2014. Previously, he has been posted to the Bureau of Fair Trade for Imports and Exports at the Ministry of Commerce, to the Economic & Commercial Counsellor's Office of the Chinese Embassy to Canada as Third Secretary, later becoming Deputy Division Director

of Division III of Imports Investigation of the Bureau of Fair Trade (2011-2014). He joined the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCCMHPIE) in 2018 and served as Deputy Director of Department of Legal Affairs and Strategic Planning. CCCMHPIE is one of the largest medical device and biopharmaceutical industry associations in the APEC region with over 1,650 member enterprises, nearly 1,500 of which are SMEs. Ensheng graduated in 2001 from Shenyang University of Technology with a Bachelor's Degree in Law, and in 2016 from Lee Kuan Yew School of Public Policy, National University of Singapore with a Master's Degree in Public Management, which includes spending a semester as a Lee Kuan Yew Fellow at the Harvard Kennedy School of Government.

Biography for Mr. Omar Neyra:



Mr. Neyra is the President of the Health Guild (COMSALUD) of the Lima Chamber of Commerce in Peru, one of the largest business organizations in the economy. He was elected to this position in 2018 and will serve through 2020. Concurrently, he is the Chief Executive Officer of Euro Dental Medical Import as well as the President of the Peruvian Academy of Stomatology through 2020. Neyra represents COMSALUD on the Inter-American Coalition for Business Ethics in the Medical Device Sector. He holds a Doctorate in Public Health and

researcher in biomaterials. He is a frequent speaker at National and international conferences on a variety of health matters.

Biography of Mr. Eduardo Del Solar:

Biographical details to be included in the next version.





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Biography of Mr. Bruno Boldrin:



Bruno Boldrin Bezerra is the executive director of Abraidi - Brazilian Association of Importers and Distributors of Health Products and 1st vice-president of ABIIS - Brazilian Alliance of the Innovative Industry of Healthcare Products. He is an outspoken advocate on strengthening ethical business practices in the sector and has championed numerous Initiatives across Brazil. He serves on the Executive Committee of the Inter-American Coalition for Business Ethics in the Medical Technology Sector. Bruno has a degree in international

relations and MBA in public management, politics and government. He has ten years of experience in advocacy and government affairs.

12:15-13:00: NON-INDUSTRY CONSIDERATIONS

<u>Description:</u> Coordinated efforts to strengthen ethical third party intermediary relationships in the medical device sector are not solely confined to medical device companies and their third parties, such as distributors. this final session before lunch, Bronwen Taylor, Adrian Cosenza, and Jo Watson will share reflections as well as facilitate a discussion with Forum participants on the role of non-industry stakeholders in this effort. The Toky Action Agenda includes governments and healthcare professionals with goals to achieve implementation of Al Guidance for Ethical Third Party Intermediary Relationships. Questions that Forum participants may want to consider in advance of this discussion include:

- How do ethical third party intermediary relationships in the medical device sector concern healthcare professionals? What role can healthcare professionals take in supporting these efforts?
- How do patients benefit from ethical third party intermediary relationships? How do ethical third party intermediary relationships support patient-centered healthcare?

Related Materials:

 Tokyo Action Agenda: Recommendations to Promote Ethical Third Party Intermediary Relationships in the Medical Device Sector through 2021: <u>PDF Here</u>

Biography for Bronwen Taylor:



Bronwen Taylor became vice president, compliance and risk management at Stryker Corporation in August 2013. As vice president, compliance and risk management, Bronwen is responsible for the coordination of compliance programs and liability-avoidance efforts worldwide. Bronwen joined Stryker in March 2000 as chief financial officer for operations in the South Pacific. She subsequently served as vice president and chief financial officer and as director of operations for South Pacific. She relocated to Michigan in January 2006 to become

Stryker's first chief compliance officer. In 2007, Bronwen became vice president of internal audit and compliance, and in 2010 she moved to Newbury, United Kingdom, to become vice president, chief financial officer for European commercial operations. Prior to joining Stryker, Bronwen held senior finance positions with financial services and global mining companies in Australia. She started her career as an accountant





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with Coopers & Lybrand (now PricewaterhouseCoopers) and held various positions in the firm's Australian and United Kingdom locations. She holds a bachelor's degree in business administration from the Queensland University of Technology and an MBA from Monash University. She is also a fellow of the Chartered Accountants Australia New Zealand.

Biography for Adrian Cosenza:



Adrian is the Chair of the Australian Ethical Health Alliance, Australia's consensus framework group with over 70 signatories representing over 200,000 healthcare professionals and over 3.2m patients/consumers and presently the largest consensus group of its type globally. Adrian is also the Chief Executive Officer of the Australian Orthopaedic Association (AOA), having joined AOA in July 2010. Over the past nine years, Adrian has led the modernisation of AOA into a vibrant and respected leader in the field of

orthopaedics. Today, the AOA is in its sixth year of a major global benchmarked transformation of its orthopaedic surgical and education program as well as addressing leading aspirations in research, ethics and professionalism. Adrian is an experienced CEO and seasoned director, having served in an executive capacity in three industries including medical education, technology and banking and finance and in a director capacity on over 15 boards in four country jurisdictions. He is also the current Chief Executive Officer of AOA Research Foundation and is also the first national CEO CookOff Brand Ambassador for OzHarvest. He Is currently Chair of the Australian and New Zealand Sarcoma Association. Adrian is the Australasian Ambassador for the International Medical Education Leaders Forum and serves on the Global Planning committee. Adrian has three degrees - Bachelor Commerce & Masters of Commerce from the University of New South Wales and MBA from IMD Lausanne Switzerland Adrian is a Fellow of three professional bodies Australian Institute of Company Directors, Financial Services institute and CPA Australia.

Biography of Ms. Jo Watson:

Jo Watson is Deputy Chair of the Consumers Health Forum of Australia, the economy's leading patient Organization and an active member of the Australian Ethical Health Alliance (AEHA), or Australian Consensus Framework, launched in 2018. Jo is also a member of the Business Ethics for APEC SMEs Initiative's patient Organization network. Further biographical details to be included in the next version.

13:00-14:00: NETWORKING LUNCH (SAN CRISTOBAL A)





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GROUP A: INTER-AMERICAN COALITION PRE-READ / BIOGRAPHIES

14:00-14:05 DELEGATES ARRIVE AND TAKE SEATS

14:05-14:25: WELCOME REMARKS AND CODE OF ETHICS LAUNCH BY ASOCIACION DE DISPOSITIVOS MEDICOS DE CHILE (ADIMECH)

Biography of the Honorable Gilbert Kaplan:



Gilbert B. Kaplan was confirmed by the U.S. Senate and assumed his position as Under Secretary of Commerce for International Trade in the United States Department of Commerce in March 2018. In this role, he leads a workforce of 2,100 personnel within the International Trade Administration ("ITA"). He oversees three major units at ITA: Global Markets and the Domestic and Foreign Commercial Service, Industry and Analysis, and Enforcement and Compliance. The Global Markets team provides support to tens of

thousands of American exporters, with over 200 offices in the U.S and worldwide. Industry and Analysis is a powerhouse of expertise with an ability to leverage data analytics and implement strategies to strengthen global competitiveness of U.S. Industries. The Enforcement and Compliance staff are charged with enforcing U.S. trade laws, particularly antidumping and countervailing duty law, holding trading partners accountable for their international commitments to ensure a level playing field at home and abroad. Prior to assuming his current position, Mr. Kaplan was a partner at King & Spalding and part of the International Trade Practice Group. He is a graduate of Harvard Law School and Harvard College.

Biography of Tulio Oliveira:



Tulio Oliveira is the Johnson & Johnson Medical Devices Vice President for the Southern Cluster (Argentina, Chile, Perú, Ecuador, Uruguay, Paraguay and Bolivia) since May 2019. He has been with Johnson & Johnson for the past 16 years in positions across Latin America and in the United States. In his prior role as Franchise Director for the Southern Cluster of the surgical division of Medical Devices, Ethicon, he led Sales and Marketing strategy. His leadership was focused in addressing an advanced talent development agenda and built diverse and high performing teams. It resulted in making the Southern

Cluster the fastest growing Cluster for Ethicon in 2017 and 2018. Prior to that role, Tulio successfully completed an International Development Program at Ethicon in Somerville, New Jersey in the Global Strategic Marketing team where he led upstream and downstream marketing initiatives and the global strategic planning process for the Franchise. Tulio joined Johnson & Johnson as a Sales Representative for Ethicon Products in 2003 in Brazil, and progressed to roles of increasing responsibility in Sales, Marketing and Business Development areas. Tulio holds a Bachelor Degree in Business Administration from Universidade Federal do Rio Grande do Norte, Brazil and a degree from Escola de Administração de Empresas de São Paulo from Fundação Getúlio Vargas. His non-profit activities include President of the Board for Operation Smile Brazil, he is a founder and the first President of the Medical Devices Industry Association in Chile (ADIMECH), and he is the sponsor for the Women's Leadership Inclusion Program in the Southern Cluster.

14:25-14:30: COALITION PHOTO WITH THE HONORABLE GILBERT KAPLAN





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14:30-15:30: CHILEAN MULTI-STAKEHOLDER PERSPECTIVES ON STRENGTHENING ETHICAL BUSINESS PRACTICES

<u>Description:</u> Following the launch of the ADIMECH code of ethics, a diverse panel of stakeholders from Chile will offer perspectives on fostering collective action to strengthen ethical collaboration and build trust across Chile's health system.

Biography of Hon. Javier Ignacio Macaya Danus:



The Honorable Javier Macaya Danus is a Member of the Chamber of Deputies, Chile's lower house of the bicameral Congress. He is serves on the Health Commission of the Chamber of Deputies and Chief of Deputies of the Independent Democratic Union (UDI). Macaya is also a senior Member and Former Acting President, Vice President, Secretary, and Treasurer of UDI. He is also the head of the Economic Commission and the Professional Commission within UDI. Macaya was most recently elected again for a third legislative period by the Sixth Region of the Liberator Bernardo O'Higgins (2018-2022).

He was elected Elected Deputy on behalf of his UDI party for the Sixth Region of the Liberator Bernardo O'Higgins (legislative period 2010-2014 / 2014-2018). He was also a Member of the Health and Finance Commissions of the Chamber of Deputies of Chile, Member of the Economic/Finance/Health Committees since 2010. Macaya was also President of the Health Committee from 2011-13 and led legislating the Law on Drugs, Food Labeling Law, Tobacco Law, among others.

Biography of Ms. Cecilia Rodriguez:



Cecilia Rodríguez is a Social Communicator with studies in Public Health. After working for several years for the public health system, she was diagnosed with a rheumatic chroni condition. From that moment, she started advocating for patients and patient involveme through different initiatives. Founder of the Patient's School, a strategy implemented at t public health system for self-management programs. She also is the founder of Fundació

Me Muevo, a patient lead organization for patients with rheumatic diseases. Today she is also the directo of the Patient's School at Universidad Mayor.

Biography of Dr. Eghon Guzmán:



Since 2017, Dr. Guzmán has served as the President of Association of Scientific Societies of Chile (ASOCIMED) and will hold this term until 2020. He is also the President and an Honorary Member of the Chilean Society of Obstetrics and Gynecology as well as the President, Honorary Member, and Teacher of the Chilean Society of Ultrasonography in Medicine and Biology. Dr. Guzmán is the Creator, Founder and President for 6 years of the American College of Obstetricians and Gynecologists of the Chilean Section of ACOG

as well as an Honorary Member of the Canadian Society of Obstetricians and Gynecologists, Bolivian Society of Obstetricians and Gynecologists, and Opposing member of the Peruvian Society of Obstetricians and Gynecologists. He was the Women Program Advisor of the Ministry of Health of Chile from 2014 to 2017. Today he is also a Coordinator of the Southern Cone in the professional development of the Latin American Federation of Obstetrics and Gynecology (FLASOG) as well as the founder of Multiple World Societies of Obstetrics and Gynecology. Dr. Guzmán is also the Editor in Chief and reviewer of multiple international and national magazines.





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15:30-16:00: AFTERNOON TEA/COFFEE BREAK

16:00-16:15: COALITION MEETING READOUT FROM BUENOS AIRES (24 JULY 2019)

<u>Description:</u> Steven Bipes will provide an overview of the Coalition's discussion and outcomes from the most recent meeting in Buenos Aires, Argentina on 24 July as well as a status update on the Coalition Action Plan.

Related Materials:

- Bogota Principles: View Here (Multiple Languages)
- Coalition Action Plan: View Here (Multiple Languages)
- 2019 Report on Code of Ethics Implementation by Coalition Industry Association: PDF Here
- Outcomes Summary from July 2019 Coalition Meeting in Buenos Aires: <u>PDF Here</u>

Biography of Mr. Steven Bipes:



Steven Bipes is the Associate Vice President for Global Strategy and Analysis at the Advanced Medical Technology Association (AdvaMed). He is responsible for AdvaMed's work in Latin America and Africa as well as with Good Regulatory Practices, International Standards and Technical Barriers to Trade. Previously, Mr. Bipes was Executive Director of the American Chamber of Commerce in Rio de Janeiro and served on its board of directors (2013-2016). Prior to the AmCham, he served as Senior Advisor in Brazil to the Albright

Stonebridge Group (2012-2015). From 2009-2011, Mr. Bipes served as Executive Director of the U.S. Section of the Brazil-U.S. Business Council in Washington, DC. In these responsibilities, he was responsible for developing, promoting, and executing programs and policies related to advancing trade and investment. Before joining the Council, Mr. Bipes served as Senior Director of international policy for the American National Standards Institute (ANSI) with prior experience in the telecom, manufacturing, and software industries, working extensively with U.S. and foreign government agencies to eliminate regulatory barriers to international trade. Mr. Bipes earned his B.S. in electrical engineering from Purdue University and a certificate in executive nonprofit leadership from the Georgetown University Public Policy Institute.

16:15-17:00: BEST PRACTICES SESSIONS AND INTERACTIVE DISCUSSION ON "EXTERNAL STAKEHOLDER ENGAGEMENT ON THE CODE" BY MEDICAL DEVICE ASSOCIATIONS

<u>Description:</u> Industry's collective work to ensure strong code governance, code alignment with best practices, and higher rates of member company adherence are each vital steps that should continue to progress. However, these steps alone would be insufficient. Codes of ethics, both at the association and individual enterprise level, should also be well understood by external stakeholders across the health system. This includes relevant government agencies, healthcare professionals and providers, and patients, among others. In this session, Diane Biagianti will offer specific strategies for industry associations across the Americas on how they can strengthen engagement on their codes of ethics with external stakeholders. This session will also cover the "non-member dilemma" and strategies to engage non-member companies on your association's code.





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Biography of Ms. Diane Biagianti:



Diane Biagianti is Vice President and Chief Responsibility Officer at Edwards Lifesciences ("Edwards") based in Irvine, California where she has responsibility for the Company's global ethics and compliance program. Since Diane joined Edwards in May 2011, she has actively served to advance the Business Ethics for APEC SMEs Initiative through mentorship of numerous industry associations in the development of new codes of ethics. 2013, she received the PwC Award for Leadership in the Advancement of Ethics in the

Medical Device Industry. In 2017, 2018, and 2019 during Diane's leadership, Edwards was recognized among the World's Most Ethical Companies. Most recently, Diane received the prestigious 2018 Warren Christopher Values Award, an honors that recognizes those who live the core values of excellence, leadership and superior citizenship. Prior to joining Edwards, Ms. Biagianti served as Senior Vice President and General Counsel of Advanced Medical Optics ("AMO"). Prior to joining AMO, she was Vice President and Assistant General Counsel of Experian Information Solutions and an associate with the law firm of O'Melveny & Myers LLP.

17:00-17:30: PERSPECTIVES ON ETHICAL COLLABORATION FROM CGU AND ETHICA SAUDE IN BRAZIL

<u>Description:</u> Brazil is advancing several innovative models in multi-stakeholder collaboration to strengthen ethical business practices in the medical device sector. Experts from the economy's public and private sector will share their perspectives on today's efforts and what to expect in the future. They will also allocate some time for questions from participants.

Biography of Dr. Alexandre Krügner Constantino:



He is Federal Auditor of Finance and Control of the General Comptroller Office (CGU) of the Brazilian Federal Government since 2014 and has been acting as the Secretary of Transparency and Prevention of Corruption, in the area of Private Sector Integrity Promotion. Alexandre is a graduate in Law and Sociology as well as a specialist in State Law, Master and Ph.D. in Political and Social Theory by State University of Campinas. He also completed a research period in Berlin and at the Flensburg University, Germany.

Biography of Mr. Carlos Gouvêa:



Carlos Gouvêa is the leader of several association, including Executive Director at the Health Ethics Institute, as Executive President at CBDL – Câmara Brasileira de Diagnóstico Laboratorial (Brazilian Chamber for In Vitro Diagnostics), Vice President at ABIIS (Brazilian Alliance for Innovative Healthcare Industry) and as Director at ABIAD – Brazilian Association of the Special Purpose Food Industry. He is also a founding member of ALADDIV – The Latin American Alliance for the Development of In Vitro Diagnostics. Carlos graduated in Public Administration and Law and holds an MBA degree (OneMBA –

University of North Carolina, Erasmus Universiteit, University of China in Hong Kong, Tec de Monterrey and FGV – Fundação Getúlio Vargas). After a short experience at the Legal Area, focusing on Corporate Law at O'Melveny & Myers and Goulart Penteado, Iervolino & Lefosse (Linklaters), he worked in Marketing at Unilever and at Courtaulds, before joining Coopers & Lybrand.





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17:30-17:45: SUMMARY OF CONCLUSIONS AND PREVIEW OF PLENARY

<u>Description:</u> Andrew Blasi will overview a recorded list of recommendations and action items provided by the Coalition MEETING participants and inquire whether any adjustments are necessary. He will then provide a brief overview of what delegates should expect for the plenary session on Tuesday, 10 September, including arrival instructions and where to find your seats. Andrew will also remind delegates to proceed to the lobby at 18:15 for shuttle transfer to the Welcome Reception.

Biography of Mr. Andrew Blasi:



Andrew Blasi is a director at Crowell and Moring International, where he guides the development and management of large-scale international, multi-sectoral partnerships. He has offered support and expert guidance to the Business Ethics for APEC SMEs Initiative since it was launched in 2010. He has also supported every APEC economy that has pursued the adoption of a consensus framework agreement. Prior to his current role, Andrew served as the Pamela Harriman Foreign Service Fellow to Ambassador Robert

Tuttle at the U.S. Embassy in London. Andrew has also worked in the Congressional Liaison Office of the Australian Embassy in Washington, D.C. and the U.S. House of Representatives Foreign Affairs Subcommittee on Europe. Andrew serves on the Board of Trustees for Florida House on Capitol Hill, a nonprofit, nonpartisan organization that serves as the state's embassy in Washington, D.C. He is a graduat of the Mason School of Business at the College of William and Mary, where he also completed the Southeast Asia Business Immersion Program and advised a campaign profiling high-standard labor practices.

17:45-18:15: SCHEDULE BREAK

18:15-19:00: DEPART SHERATON LOBBY FOR RECEPTION AT U.S. AMBASSADOR'S RESIDENCE

19:00-21:00: WELCOME RECEPTION (TRANSPORTATION PROVIDED)





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GROUP B: ASIA STRATEGY SESSION PRE-READ / BIOGRAPHIES

14:00-14:15 DELEGATES ARRIVE AND TAKE SEATS

14:15-15:30: REFLECTIONS ON PROGRESS: MEDICAL DEVICE CODE HARMONIZATION IN ASIA

<u>Description:</u> Building upon her opening presentation during the morning session, Nancy Travis will facilitate an interactive, small group discussion among Forum participants will interest in strengthening code of ethics implementation across Asia in the medical device sector. Participants in this session may include delegates from the Asia-Pacific region (rather than the Americas) or who have strong interest in achieving code of ethics harmonization in Asia. Nancy will encourage interventions from the leaders of several Asia-Pacific based medical device industry associations, including <u>Michelle Wagner (Australia)</u>, <u>Katsumi Kojima (Japan)</u>, <u>Faye Sumner (New Zealand)</u>, and <u>Rhoel Laderas (Philippines)</u>, among others, to provide their assessment on the 2019 APEC Report on Code of Ethics Implementation in the Medical Device Sector (website link below) and what more can be done to realize the Nanjing Declaration's goals.

Related Materials:

- APEC Nanjing Declaration : <u>PDF Here</u>
- 2019 APEC Report on Code of Ethics Implementation in the Medical Device Sector: PDF Here

Biography of Ms. Nancy Travis:



As Vice President for International Compliance and Governance at the Advanced Medical Technology Association (AdvaMed), Ms. Travis leads the association's efforts to promote codes of ethics for the medical technology industry worldwide. She was instrumental in launching the *Business Ethics for APEC SMEs Initiative* and the Inter-American Coalition for Business Ethics in the Medical Technology Sector. In addition to her policy focus, she addresses key issues related to association governance at AdvaMed, including management

of the Board. Nancy has 20 years of international affairs and leadership experience, with a particular focus on advocacy related to market opening and trade issues. She advised key government officials on trade agreements as well as World Trade Organization accession negotiations. Throughout her career, she has received a number of exceptional performance and superior honor awards.

15:30-15:45: AFTERNOON TEA/COFFEE BREAK

15:45-16:15: INPUT SESSION ON STRENGTHENING ENGAGEMENT IN THE BUSINESS ETHICS FOR APEC SMES INITIATIVE BY ASIAN GOVERNMENTS AND HEALTHCARE PROFESSIONAL ORGANIZATIONS

<u>Description:</u> As U.S. Delegate to the APEC SME Working Group and Director of the Trade Promotion Coordinating Committee (TPCC) at the U.S. Department of Commerce, Patrick Kirwan works closely with Ms. Tricia Van Orden (Overseer) to ensure robust engagement by many stakeholders in the *Business Ethics for APEC SMEs Initiative*. This includes active engagement by governments and healthcare professional organizations. As this Initiative seeks ever more ambitious goals, this short input session will ask interested delegates to offer thoughts on the following questions:

• What more can be done to draw greater interest by governments and healthcare professionals to





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the annual APEC Business Ethics for SMEs Forum?

 Would your organization like to nominate specific government or healthcare professional bodies to invite to the next APEC Business Ethics for SMEs Forum?

Biography of Mr. Patrick Kirwan:



Kirwan is the Director of the Trade Promotion Coordinating Committee Secretariat at the U.S. Department of Commerce. In this capacity, he coordinates a network of 20 government agencies to improve federal trade promotion and finance programs to increase U.S. exports. He has focused specifically on developing commercial strategies for key markets and improving federal/state cooperation on export promotion. Kirwan also serves as U.S. delegate to the APEC SME Working Group. Prior to his current role,

Kirwan has served as Acting Deputy Assistant Secretary for Domestic Operations, where he oversaw the operations of the 105 export assistance offices of the Department of Commerce. He has also spent two years in the White House at the Domestic Policy Council working on a variety of trade-related issues. As part of the Office of the President, Kirwan participated in the development of a number of strategic trade initiatives in areas such as electronic commerce, international standards setting, trade finance, and Asia policy.

16:15-16:45: INPUT SESSION ON MEASURING THE POSITIVE IMPACT OF ETHICAL BUSINESS PRACTICES IN THE MEDICAL DEVICE SECTOR

<u>Description:</u> Patrick Kirwan also works closely with Ms. Tricia Van Orden (Overseer) to ensure the <u>Business Ethics for APEC SMEs Initiative</u> remains at the forefront of pursuing high-standard ethical business practices for the benefit of all actors in our economies. For the past several years, there has been a call for this Initiative to support research that would measure the positive impact of ethical business practices in the medical device sector. Possible areas of focus for this research could include macroeconomic benefits to APEC economies, microeconomic benefits to APEC SMEs, health system benefits to APEC patients and consumers, and innovation benefits to APEC growth and competitiveness. This short input session will ask interested delegates to offer thoughts on the following questions:

- Do you support heightened efforts by this Initiative to research the positive impact?
- If so, what are your preferred areas of focus and would you recommend a research partner institution within your economy?

16:45-17:00: SUMMARY OF CONCLUSIONS AND PREVIEW OF THE PLENARY SESSION

<u>Description:</u> Katie Nunner will overview a recorded list of recommendations and action items provided by the session participants and inquire whether any adjustments are necessary. The recorded list will then be submitted to the Overseer. She will then provide a brief overview of what delegates should expect for the plenary session on Tuesday, 10 September, including arrival instructions and where to find your seats. Katie will also remind delegates to be in the Sheraton lobby at 18:15 this evening for shuttle transfer to the Welcome Reception.





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Biography of Ms. Katherine Nunner:



Katherine Nunner is a consultant at C&M International where she supports international public-private partnerships and business strategy. She is the Co-Chair for Anti-Corruption and Corporate Social Responsibility at the Association of Women in International Trade (WIIT) and holds a certification in health care compliance from Seton Hall School of Law. Previously, Katherine advanced the World Bank's private sector practice engagements including partnerships in accessing financing for early stage entrepreneurs and social

impact bonds. She has also advised companies and implemented an investment fund in the Caribbean. Katherine has published case studies for the LSE in foreign direct investment in emerging markets. She holds a Bachelor of Science in economics management from Ohio Wesleyan University and an MSc in development management from The London School of Economics & Political Science (LSE).

17:00-18:15: SCHEDULE BREAK

18:15-19:00: DEPART SHERATON LOBBY FOR RECEPTION AT U.S. AMBASSADOR'S RESIDENCE

19:00-21:00: WELCOME RECEPTION (TRANSPORTATION PROVIDED)