PLENARY SESSION

OPENING SESSION

Mr. Patrick Kirwan
U.S. Delegate, APEC SME Working Group
Director, Trade Promotion Coordinating Committee Secretariat
U.S. Department of Commerce
PLENARY SESSION

CONSENSUS FRAMEWORKS: PLATFORMS FOR A CULTURE OF ETHICS AND INTEGRITY

Ms. Diane Biagianti
Chief Responsibility Officer
Edwards Lifesciences
Chile Consensus Framework:
Multistakeholder Process for Ethical business practices

Gastón Fernández Schiaffino
Head of Regulatory Affairs Division
Undersecretariat of International Economic Affairs
Ministry of Foreign Affairs
The Asia-Pacific Economic Cooperation (APEC) Forum

- Support sustainable economic growth and prosperity in the Asia-Pacific region.
- Engine of global economic growth in the 21st century
- Trade liberalization and Regional integration
- Support for the Multilateral Trade System and the WTO
- Promote policies in favor of open trade and investments
- Proactive relationship with the business community: ABAC

- 39% of the global population (2.9 billion people)
- 50% of global trade annually USD 16 Trillion
- 60% of Global GDP USD $45 Trillion
- Top 3 GDP (USA, Japan and China)
- Top 5 population (China, Indonesia and USA)
1. Trade Policy

2. The Chile Consensus Framework Process

3. Roadmap-Challenges
Some numbers...

- **28** FTA
- **64** Economies
- **86%** Global GDP
- **63%** Global Population
- **57%** Goods and Services/ GGP

**Record Non Copper Export** USD Million

- 1960: 149
- 1980: 2,518
- 2000: 11,999
- 2018: 38,975

**Exporter 2018**
- Fresh Cherries
- Grapes
- Blueberries
- Salmon

- **8,080** Companies
- **3,378 SMEs**
- **1,2** Jobs
- **95%**
  - CHINA (35%)
  - US (14%)
  - JAPAN (10%)
CURRENT AGREEMENTS

APAC

P4
Brunei Darussalam
New Zealand
Singapore

CENTROAMÉRICA
Costa Rica
El Salvador
Guatemala
Honduras
Nicaragua

ALIANZA DEL PACÍFICO
Colombia
Ecuador
Panama
Venezuela

MERCOSUR
Argentina
Brazil
Paraguay
Uruguay

EFTA
Iceland
Liechtenstein
Norway
Switzerland

EUROPEAN UNION
Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Netherlands
Poland
Portugal
Romania
Slovak Republic
Slovenia
Spain
Sweden
United Kingdom

TURKEY

APEC CHILE 2019
SOURCE: STUDIES Department, DIRECON-ProChile.
Since Chile joined APEC in 1994, exports to the region have increased by 790%.

**SMEs EXPORTS TO APEC**

- 57% PORCENTAJE
- US $ 895 IN VALUE
- 2300 IN NUMBER
1. Trade Policy

2. The Chile Consensus Framework Process

3. Roadmap-Challenges
APEC CHILE 2019 | PRIORITY

1. DIGITAL SOCIETY
2. INTEGRATION 4.0
3. SUSTAINABLE GROWTH
4. WOMEN, SMEs, AND INCLUSIVE GROWTH

• Visualizing / enhancing the role SMEs
• Promote the development, growth and competitiveness of SMEs.
CHILE CONCESUS FRAMEWORK PROCESS

• Engagement
• Heterogeneous: Recognition of different realities
• Cooperation
• Teamwork begins by building trust
• Commitment
• Alling toward a common vision
• Binding v/s Non-binding
• Public-Multi stakeholder Approach
• Understanding the trade costs of regulatory divergence (challenges and opportunities)
1. Trade Policy
2. The Chile Consensus Framework Process
3. Roadmap-Challenges
## Roadmap - Challenges

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<th>Oct</th>
<th>Nov</th>
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<td><strong>Governance and objectives</strong></td>
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<td><strong>Structure and methodology</strong></td>
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<td><strong>Objectives 2019 / 2020</strong></td>
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<td>Share common standards in line with APEC Principles</td>
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<td>Check ethical codes and identify Gaps</td>
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<td><strong>Implementation Strategy</strong></td>
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<td>Share experience and best practices</td>
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<td><strong>Outreach engagement new members</strong></td>
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<td><strong>Evaluation and monitoring 2019 / 2020</strong></td>
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<td><strong>New Strategy 2020-21</strong></td>
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Roadmap-Challenges

- National / International Coordination
- Leadership
- Momentum
- Multi stakeholder approach
- Commitment

*it takes .......to tango*
Gastón Fernández Schiaffino
Head of Regulatory Affairs Division
Undersecretariat of International Economic Affairs
Ministry of Foreign Affairs of Chile.
PLENARY SESSION

2019 APEC BUSINESS ETHICS FOR SMES LIGHTHOUSE AWARD

Adrian Cosenza, Chair
Australian Ethical Healthcare Alliance
OFFICIAL PLENARY PHOTOGRAPH

9:45 – 10:00
PLENARY SESSION

IMPLEMENTING CONSENSUS FRAMEWORKS:
UPDATES FROM THE REGION
10:00 – 10:30
The Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector

Australian Ethical Health Alliance

Adrian Cosenza  
AEHA Chair  
Australian Orthopaedic Association CEO

Alison Verhoeven  
AEHA Steering Committee  
Australian Healthcare and Hospitals Association CEO
What is the Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector (ACF)?

• A consensus of shared values and ethical principles that form the basis of collaboration and interaction among organisations in the Australian healthcare sector
• A voluntary, sector-lead initiative
• Inclusive and embracing – all parties welcome to participate, listen and join ACF activities
What does it aim to achieve?

• Promote collaboration and interaction
• Encourage better dialogue, trust and respect
• Promote public confidence and trust
When was it launched?

• Australian delegation officially presented the *Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector* at the APEC Business Ethics for SME Forum, in Tokyo on **20 July 2018**
Who is involved?

• 71 member organisations:
  • Biopharmaceutical industry
  • Educators
  • Government authorities
  • Healthcare professionals
  • Hospitals/healthcare centres
  • Medical device industry
  • Patient communities
  • Third parties/distributors.
• Support and endorsement from every state and territory and the Federal Minister of Health
The signatories
The signatories
The signatories
Rapid Growth in Participation

- **December 2017**: 17 Participants
- **February 2018**: 30 Participants
- **April 2018**: 40 Participants
- **May 2018**: 50 Participants
- **June 2018**: 60 Participants
- **September 2019**: 71 Participants
Who does the Framework represent?

71 signatories represent approximately:

- 200,000 health professionals, employees and trainees
- 3.2 million consumers/patients
The Framework

• Signatories agreed to a simple yet effective set of ethical principles:
  • Substantive Principles
  • Procedural Principles
Primary role of the Framework

Designed to:

• Assist development and modification of policies and processes.
• Implement the principles articulated in the ACF
• Complement and strengthen the importance of collaboration

Not designed to:

• Focus on individuals
• Develop prescriptive policies
• Develop resources for specific organisations
• Mandate/monitor/regulate anything other than the reporting of activities related to the ACF
Primary role of the Framework

• Important for signatories to be prepared to be self reflective and self accountable

• Not aimed at being judgmental of individual organisations, but rather an exercise to ask members to measure themselves against the ACF

• Aim is to find common good and common purpose rather than establishing a process by which to reprimand, discipline etc
ACF workshops

- Since the initiative's launch, organisations have met on three occasions:
  - January (Sydney)
  - April (Melbourne)
  - July (Canberra)

- Participants ranging between 25 to 40 organisations
What is the Australian Ethical Health Alliance (AEHA)?

• The body to guide the implementation of the ACF

• Consists of those member organisations who are signatories to the ACF
Members of the Committee include:

- Adrian Cosenza, Australian Orthopaedic Association (Chair)
- Alison Verhoeven, Australian Healthcare and Hospitals Association
- Deborah Monk, Medicines Australia
- Jane Fitzpatrick, Australasian College of Sport and Exercise Physicians
- Leanne Wells, Consumers Health Forum of Australia
- Tracey Duffy, Department of Health
- Ian Burgess, Medical Technology Association of Australia
- Ian Kerridge, Royal Australasian College of Physicians

- Wendy Lipworth, Praxis Australia
- Peter Subramaniam Australian and New Zealand Society for Vascular Surgery
- Mary Warner, Department of Health
- Carolyn Stapleton, Australian College of Nursing
- Chris Ho, Skin Cancer College of Australasia
- Rachel Yates, Universities Australia.
ACF aims are supported by the AEHA Implementation Plan

• The Plan outlines the steps to enact the work of AEHA including:
  o Development of a structure for AEHA governance
  o Development of guidelines and self-evaluation form for member organisations to assist them in aligning their policies and processes with the ACF
  o Development of communication and engagement strategies.
Aim:

- To determine a governance structure for the Australian Ethical Health Alliance
- To develop Terms of Reference for the Australian Ethical Health Alliance Steering Committee
- To formalise the appointments of the Steering Committee.

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Deliverables and Measures</th>
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</thead>
<tbody>
<tr>
<td>1. Develop governance document for the Australian Ethical Health Alliance</td>
<td>30 June 2019 – Complete</td>
</tr>
<tr>
<td>2. Develop a Terms of Reference for Australian Ethical Health Alliance</td>
<td>30 June 2019 – Complete</td>
</tr>
<tr>
<td>steering committee</td>
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<tr>
<td>3. Determine whether the Australian Ethical Health Alliance should be</td>
<td>30 June 2019 – Complete</td>
</tr>
<tr>
<td>established as a legal entity</td>
<td></td>
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</tbody>
</table>
Implementation Guide and Self-Evaluation Form

Aim:

- To develop a guide that assists organisations with aligning their structure, policies and processes with the ACF principles by developing an implementation guide
- To develop a template that can be used by member organisations to self-evaluate on their activities related the ACF that is fair, practical, generative and non-punitive, and applicable to all signatories are applicable to all signatories.

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Deliverables and Measures</th>
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<tbody>
<tr>
<td>1.</td>
<td>Form a drafting group that will write the Implementation Guide and Self-Evaluation Form</td>
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<td></td>
<td>31 May 2019 – Complete</td>
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<tr>
<td>2.</td>
<td>Develop and circulate a draft outline of the Implementation Guide and Self-Evaluation Form</td>
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<td>30 June 2019 – Complete</td>
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<tr>
<td>3.</td>
<td>Identify and confirm member organisations that will be involved in a pilot of the Implementation Guide and Self-Evaluation Form</td>
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<td>30 August 2019 – Complete</td>
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<tr>
<td>4.</td>
<td>Assess the outcome of the pilot and determine if the Implementation Guide and Self-Evaluation Form can be applied to all signatories</td>
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<td></td>
<td>28 February 2020</td>
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<tr>
<td>5.</td>
<td>Finalise the Implementation Guide and Self-Evaluation Form and promote on the group’s website</td>
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<td></td>
<td>30 September 2019 – Complete</td>
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</tbody>
</table>
Communication and Engagement

Aim:

• To grow the Australian Ethical Health Alliance
• To raise awareness of the Australian Ethical Health Alliance and the ACF
• More specifically, to develop a website and a media and communications plan, and develop a process for holding annual workshops and other events.

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<thead>
<tr>
<th>Milestone</th>
<th>Deliverables and Measures</th>
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<tbody>
<tr>
<td>1.</td>
<td>Develop a media/communications working group</td>
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<td>2.</td>
<td>Determine the governance process for overseeing website design and content</td>
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<td>3.</td>
<td>Prepare material on Australian Ethical Health Alliance and ACF that can be disseminated by member organisations for publicity purposes</td>
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<td>4.</td>
<td>Prepare material on Australian Ethical Health Alliance and ACF that can be used by member groups at conferences</td>
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<td>5.</td>
<td>Identify relevant conferences/events at which member organisations can present and/or organise satellite workshops/symposia</td>
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<tr>
<td>6.</td>
<td>Conduct a needs analysis assessment on an annual workshop/seminar</td>
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<td>7.</td>
<td>Develop an AEHA media and communications plan, including a social media plan (to commence from April 2020) and a request for member organisation to advocate for the ACF principles</td>
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Communication and Engagement

- Publication of the journey and insights already well progressed

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<tr>
<th></th>
<th>Description</th>
<th>Date</th>
<th>Notes</th>
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<tr>
<td>8</td>
<td>Develop a protocol for how media statements and communications should be developed and released</td>
<td>Sep 2019 – Steering Committee agenda 1 Nov 2019</td>
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<td>9</td>
<td>Prepare an academic article for publication</td>
<td>Sep 2019 – Complete</td>
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<td>10</td>
<td>Develop a website</td>
<td>Sep 2019 – Complete</td>
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<tr>
<td>11</td>
<td>Launch website</td>
<td>September 2019 – Complete</td>
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<td>12</td>
<td>Nominate a person as the central point of contact for all media queries and allocate spokespersons</td>
<td>April 2020 – Steering Committee agenda 1 Nov 2019</td>
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Guide for Member Organisations

• Improving ethical practice and culture requires clear directions on how to implement principles

• *Guide for Member Organisations* provides practical advice and examples as to how organisations might align their practices and policies

• Activities not prescriptive

• All are asked to submit an *Annual Self-Evaluation Form* to be shared amongst member organisations

• Document pilot is planned
Where to from here?

The goal over the next 12 months:
• Encourage the implementation of the ACF principles
• Promote strategies on implementing ethics
• Significantly progress the AEHA Implementation Plan
• Engage member organisations
• Raise awareness of the Alliance
• Grow the member organisations of AEHA.
Lessons...Recommendations for APEC regions progressing a framework

- Allow organisations at any stage of their progress on ethics to join
- Ensure development and implementation is voluntary, consultative and collaborative
- Ensure principles are developed with an awareness of a potential broad-spectrum member group
Lessons...Recommendations for APEC regions progressing a framework

- Clear value proposition – relevance to existing ethics framework
- Senior political support early in process
- Use of language – commonly understood- non academic/non technical
- Flexibility in ‘ownership’ for each participant
- Use an ethical activities pilot to validate the relevance of implementation activities
Challenges...what we do not know...

- Will the Australian Ethical Health Alliance genuinely drive meaningful changes in ethical practices?
- How will we measure success?
- Is positive collaboration sustainable?
- Will an informal structure of governance and communication serve the community well once move beyond the enthusiasm in creating the movement?
The Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector

Australian Ethical Health Alliance

Adrian Cosenza  
AEHA Chair  
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Alison Verhoeven  
AEHA Steering Committee  
Australian Healthcare and Hospitals Association CEO
PLENARY SESSION

IMPLEMENTING CONSENSUS FRAMEWORKS:
UPDATES FROM THE REGION
10:00 – 10:30
IMPLICATIONS OF HEALTHCARE TECHNOLOGICAL DISRUPTION ON ETHICAL BUSINESS CONDUCT IN THE APEC REGION BY 2030

Dr. Julien Durand, JD, MBA

Executive Director Ethics & Compliance, Amgen

Chair of eBIC Future Health Technologies WG, IFPMA
APEC will be the World’s innovation powerhouse by 2030

- Top 10 largest Digital Tech companies
- 70% of Unicorns & promising SMEs
- 70% of global AI expertise
- 60% of global Biotech/Medtech expertise
Exponential Techs combining in unprecedented ways by 2030

Source: Frank Diana, Tata Consultancy Services
Biopharma & Medical Device most impacted by these Techs

1. DIGITAL HEALTH & EXTENDED REALITIES
   - Internet of Things & wearables
   - Mobile health apps
   - Blockchain
   - Telemedicine
   - Augmented & virtual reality
   - Digital biomarkers

2. MACHINE INTELLIGENCE (AI)
   - Natural Language Processing
   - Machine Learning
   - Virtual nurses & robo-doctors
   - Robotic Process Automation
   - Big health data
   - Virtual reps & employees

3. HEALTH ROBOTICS & MEDICAL DEVICES
   - Delivery & diagnostic devices
   - Robotic surgery
   - Brain-Computer Interfaces
   - Exoskeleton & bionic prosthetics
   - Nanotechnologies
   - Drones for health

4. GENOMICS & ADDITIVE TECHNOLOGIES
   - Gene sequencing
   - Gene editing
   - Gene therapies & stem cells
   - Bioprinting
   - Prosthetics
   - Proteomics
What if AI in health care is the next asbestos?

Jun 19, 2019

Artificial intelligence is often hailed as a great catalyst of medical innovation, a way to find cures to diseases that have confounded doctors and make health care more efficient, personalized, and accessible. But what if it turns out to be poison?

“I think of machine learning kind of as asbestos,” said BKC’s Jonathan Zittrain. “It turns out that it’s all over the place, even though at no point did you explicitly install it, and it has possibly some latent bad effects that you might regret later, after it’s already too hard to get it all out.”
Algorithms are changing the practice of medicine

For the First Time, a Robot Passed a Medical Licensing Exam

We should treat algorithms like prescription drugs

How Do You Regulate a Self-Improving Algorithm?

Can You Sue An Algorithm For Malpractice?

Al system 'should be recognised as inventor'

In the future, HCPs will become reluctant to perform diagnostics or surgery without machine assistance

Man told he’s going to die by doctor on video-link robot

Australian Researchers Have Just Released The World's First AI-Developed Vaccine

Time to Take 'Hippocratic Oath' for Engineering

Medical Devices Hit By Ransomware For The First Time In US Hospitals
Bioethics

Scientists call for global moratorium on gene editing of embryos

DNA testing firms are cashing in on our genes. Should we get a cut?

Japan approves first human-animal embryo experiments

Genetic engineering and biological weapons

Don’t change your DNA at home, says America’s first CRISPR law

Technoethics

New technologies for the brain require ethical approaches to innovation

South African doctors perform world’s first 3D middle ear transplant

An euthanasia expert just unveiled his ‘suicide machine’ at an Amsterdam funeral fair

Inside the Crypto World’s Biggest Scandal

Saudi Arabia’s robot citizen is eroding human rights
The last 10 years were about **Business Ethics**
The next 10 years will be about **Technoethics & Bioethics**

- Bioethics & Technoethics
- Algorithmic bias
- Algorithmic safety
- Beneficence of technologies
- Explainability of results
- Transparency & traceability
- Ethicality of decisions
- Auditability
- Diversity, discrimination & fairness

- Data integrity & privacy
- Data portability & interoperability
- Cybersecurity
- Future of work
- Accountability & liability
- Ownership & IP
- Robo-rights
- Dual-use & autonomous weapons
- What else?
Law vs. Technology

- Technological growth +
- Time +

- WHITE
- GREY
- BLACK

- Ethics-by-design
- Co-regulation
- Adaptive risk regulation
Unique opportunity to start working together NOW!

- Ethical technologies will:
  - strengthen APEC trade
  - foster sustainable economic development
  - avoid tech scandals and increase reputation
  - help achieve UHC coverage through health technologies

- Next steps:
  - Expand codes of ethics to include technologies
  - Collaborate to strengthen technological standards & interoperability
  - best practice sharing across border
Thank You!
ETHICAL BUSINESS CONDUCT AND RETURN ON INVESTMENT – WHAT TONE AT THE TOP MEANS FOR SMALL AND MEDIUM ENTERPRISES

Mr. Ken Reali

President and CEO, Clinical Innovations
FOSTERING ETHICAL COLLABORATION BETWEEN HEALTHCARE PROFESSIONALS AND THE MEDICAL DEVICE AND BIOPHARMACEUTICAL INDUSTRIES

Dr. Jeff Blackmer

Vice President for International Health
Canadian Medical Association
Fostering Ethical Collaboration between Healthcare Professionals and the Medical Device and Biopharmaceutical Industries

Dr. Jeff Blackmer
MD MHSc FRCPC CCPE
Vice President, International Health
Canadian Medical Association
Public perception
Professional perception (BMJ cover)
• Yes, we have a problem

• Yes, it still exists
Fundamental ethical principles

- The HCP’s first obligation is always the independent and unbiased promotion of the health and well being of their patients

- Other interests (e.g. research and publications, academic promotion, financial gain) are legitimate but must be secondary to patient care
When secondary interests have the potential to influence decisions with respect to patient care, there exists a *conflict of interest*
Just as physicians have a fiduciary duty to their patients, publicly held companies have a fiduciary duty to their shareholders to maximize profit and return on investment (this is *not* unethical)

These duties may not necessarily be mutually exclusive – but they are definitely not always mutually inclusive
Bottom line

- In most businesses, companies are able to target consumers directly.

- However, consumers can’t buy most medications or devices unless they are prescribed or recommended by a HCP.

- So, industry targets HCP’s to try and convince them to prescribe their drug or use their product.
The good

- Important work by organizations like APEC has helped highlight ethical challenges and foster important conversations

- Codes of Conduct assist in setting standards and may be useful in ethical decision making
The bad

- There is not always consistency between Codes and organizational or professional culture/actual behavior

- Interests and incentives for the various parties involved are not always aligned and sometimes are diametrically opposed
“The bottom line is that if you don’t pay off the doctors, you will not succeed in pharmaceutical sales. Period.”

Jordan Katz, former US rep for Schering-Plough
“There is a big bucket of money sitting in every physician’s office. Every time you go in, you reach your hand in the bucket and grab a handful.”

Mike Zubillaga, Astra Zeneca marketing director in an internal memo, subsequently fired
“Anytime we had a paid relationship with a physician they increased their use of our drug. I hate to say it out loud, but it all comes down to ways to manipulate the doctors.”

Kathleen Slattery, former sales rep for Bristol Myers Squibb
Codes vs. Culture

- Are any of these quotes in any way consistent with current professional Codes, policies or internal standards?

- If not – how do we make sure the work being done here leads to a different outcome? How do we align Codes with Culture?
Challenges

- Find a way to consistently reconcile the (often competing) duties and fundamental professional obligations held by HCP’s and for-profit companies

- Facilitate genuine collaboration to achieve common goals
Opportunities

- In addition to development of Codes, address fundamental organizational culture

- Find a way to align goals and incentives between HCP’s and companies/their representatives

- For companies: Do well and do good
Shareholder Value Is No Longer Everything, Top C.E.O.s Say

Chief executives from the Business Roundtable, including the leaders of Apple and JPMorgan Chase, argued that companies must also invest in employees and deliver value to customers.

By David Gelles and David Yaffe-Bellany
Aug. 19, 2019

Nearly 300 chief executives, including the leaders of Apple, Pepsi and Walmart, tried on Monday to redefine the role of business in society — and how companies are perceived by an increasingly skeptical public.
Breaking with decades of long-held corporate orthodoxy, the Business Roundtable issued a statement on “the purpose of a corporation,” arguing that companies should no longer advance only the interests of shareholders.
 Businesses are pledging to fight climate change, reduce income inequality and improve public health.

It is an explicit rebuke of the notion that the role of the corporation is to maximize profits at all costs — the philosophy that has held sway on Wall Street and in the boardroom for 50 years.
This could create a unique (and bold) opportunity

- Realign internal culture and expectations away from profit maximization/shareholder returns and towards optimization of individual and public health

- Realign incentive programs away from profit and increased use of medications/devices and towards overall health outcomes for a condition or procedure
Ultimate Challenge

- Better align the interests and fiduciary obligations of HCP’s and industry

- Suggested end goal: That HCP’s and drug and device manufacturers develop policies and procedures that will incentivize and promote the use of the *right* drug or device at the right time for that particular patient in order to optimize patient outcomes *without* profit considerations.
Current state
Desired future state
LUNCH
PEDRO DE VALDIVA ROOM
(DOWNSTAIRS)
12:00 – 13:00
INDUSTRY ASSESSMENT: PROGRESS, CHALLENGES, AND RECOMMENDATIONS FOR THE REGION & SESSION ON STRATEGIES TO MEASURE THE POSITIVE IMPACT OF ETHICAL PRACTICES

Ms. Nancy Travis, Vice President, International Compliance and Governances, The Advanced Medical Technology Association (AdvaMed)
2019 Survey Results: Code Adoption

Enterprise Membership of Associations Who Have Adopted a Code or Code Commitment

<table>
<thead>
<tr>
<th>Year</th>
<th>SME Members</th>
<th>Associations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>9932</td>
<td>1920</td>
</tr>
<tr>
<td>2018</td>
<td>10074</td>
<td>2692</td>
</tr>
<tr>
<td>2017</td>
<td>10116</td>
<td>2525</td>
</tr>
<tr>
<td>2016</td>
<td>9413</td>
<td>2231</td>
</tr>
<tr>
<td>2015</td>
<td>9413</td>
<td>2231</td>
</tr>
<tr>
<td>2014</td>
<td>7622</td>
<td>1114</td>
</tr>
<tr>
<td>2013</td>
<td>7602</td>
<td>1075</td>
</tr>
<tr>
<td>2012</td>
<td>5766</td>
<td>796</td>
</tr>
</tbody>
</table>

Industry Associations with a Code or Code Commitment

<table>
<thead>
<tr>
<th>Year</th>
<th>Associations with a Code or Code Commitment</th>
<th>Associations without a Code or Code Commitment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>13</td>
<td>16</td>
</tr>
<tr>
<td>2013</td>
<td>17</td>
<td>13</td>
</tr>
<tr>
<td>2014</td>
<td>18</td>
<td>12</td>
</tr>
<tr>
<td>2015</td>
<td>25</td>
<td>6</td>
</tr>
<tr>
<td>2016</td>
<td>27</td>
<td>6</td>
</tr>
<tr>
<td>2017</td>
<td>29</td>
<td>4</td>
</tr>
<tr>
<td>2018</td>
<td>29</td>
<td>5</td>
</tr>
<tr>
<td>2019</td>
<td>31</td>
<td>3</td>
</tr>
</tbody>
</table>

http://m克里斯tones.apec.org
http://l克里斯tones.apec.org
### 2019 Survey Results: Code Implementation

#### CODE GOVERNANCE

<table>
<thead>
<tr>
<th>Code Governance Indicator</th>
<th>Percent “Yes” in 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide one-on-one assistance to members on the code</td>
<td>91%</td>
</tr>
<tr>
<td>Distributed the code to all members within the last two years</td>
<td>77%</td>
</tr>
<tr>
<td>Procedures in place to review the code and ensure it is up-to-date</td>
<td>64%</td>
</tr>
<tr>
<td>Offering ethics training for third party intermediaries</td>
<td>41%</td>
</tr>
<tr>
<td>Sufficient resources to support code activities</td>
<td>41%</td>
</tr>
<tr>
<td>Offering ethics training to individual sales representatives</td>
<td>36%</td>
</tr>
<tr>
<td>Code compliant or violation procedure</td>
<td>32%</td>
</tr>
</tbody>
</table>
2019 Survey Results: Code Implementation

CODE ALIGNMENT

REPORTED EMBRACE OF THE FIVE FUNDAMENTAL PRINCIPLES OF THE APEC KUALA LUMPUR PRINCIPLES BY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT:

<table>
<thead>
<tr>
<th>Year</th>
<th>Did Not Indicate/Unknown/Or Association Not Yet Formed</th>
<th>Some</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>5</td>
<td>4</td>
<td>22</td>
</tr>
<tr>
<td>2018</td>
<td>7</td>
<td>3</td>
<td>21</td>
</tr>
<tr>
<td>2017</td>
<td>10</td>
<td>2</td>
<td>19</td>
</tr>
<tr>
<td>2016</td>
<td>13</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>2015</td>
<td>16</td>
<td></td>
<td>15</td>
</tr>
</tbody>
</table>
2019 Survey Results: Code Implementation

MEMBER COMPANY ADHERENCE

SELF-ASSESSMENT ON CODE PERFORMANCE BY 31 ASSOCIATIONS WITH A CODE / COMMITMENT

- Not Well: 3 (10%)
- Excellent: 9 (29%)
- Unknown: 9 (27%)
- Well: 6 (19%)
- Acceptable: 4 (13%)

MEMBER IMPLEMENTATION RATE BY 31 ASSOCIATIONS WITH A CODE / COMMITMENT

- 76-100%: 9 (29%)
- 51-75%: 2 (6.5%)
- 26-50%: 4 (13%)
- 0-25%: 4 (13%)
- Unknown: 12 (38.5%)
2019 Survey Results: Code Implementation

EXTERNAL ENGAGEMENT

Interest to Heighten External Stakeholder Engagement:

- 76% yes

Associations reporting that they have distributed the code to non-members:

- 38%

Associations building awareness for code of ethics with non-members through formalized collaborations such as consensus frameworks:

- 48%
Thoughts on Strategies to Measure the Positive Impact of Ethical Practices

1. AdvaMed has particular interest in assessing the positive impact of ethical practices on business success, particularly for SMEs, and innovation.

2. We would also support measuring the positive impact of ethical business practices on other areas, including the economy and public health.

3. APEC has led consortiums on research before and could do so again.

4. The approach should be scaled over time, perhaps with a narrow scope in the first phase and expanded scope after initial results are demonstrated.
INDUSTRY ASSESSMENT: PROGRESS, CHALLENGES, AND RECOMMENDATIONS FOR THE REGION AND STRATEGIES TO MEASURE THE POSITIVE IMPACT OF ETHICAL PRACTICES

Mr. Thomas Cueni

Director General, International Federation of Pharmaceutical Manufacturers and Associations

Industry Co-Chair, APEC Biopharmaceutical Working Group on Ethics
2019 Survey Results: Code Adoption
### Code Governance

**2019 Survey Results: Code Implementation**

<table>
<thead>
<tr>
<th>Code Governance Indicator</th>
<th>Percent “Yes” in 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distributed the code to members for input before adoption</td>
<td>97%</td>
</tr>
<tr>
<td>Distributed the code to all members within the last two years</td>
<td>95%</td>
</tr>
<tr>
<td>Designated staff or a member to oversee code activities</td>
<td>89%</td>
</tr>
<tr>
<td>Procedures in place to review the code and ensure it is up-to-date</td>
<td>87%</td>
</tr>
<tr>
<td>Sufficient resources to support code activities</td>
<td>87%</td>
</tr>
<tr>
<td>Code compliant or violation procedure</td>
<td>87%</td>
</tr>
<tr>
<td>Provide one-on-one assistance to members on the code</td>
<td>70%</td>
</tr>
<tr>
<td>Offer one or more code trainings to members per year</td>
<td>65%</td>
</tr>
</tbody>
</table>

[833x18] [http://mcprinciples.apec.org](http://mcprinciples.apec.org)  
[833x6] [http://klprinciples.apec.org](http://klprinciples.apec.org)
2019 Survey Results: Code Implementation

CODE ALIGNMENT

TOP 5 PROVISIONS OF THE APEC MEXICO CITY PRINCIPLES ALIGNED WITH INDUSTRY ASSOCIATION CODES OF ETHICS (PERCENTAGE OF SURVEY RESPONDENTS)

- Promotional Information and Activities: 100%
- Interactions with Healthcare Professionals: 97%
- Educational Items and Gifts: 92%
- Compliance Procedures and Responsibilities: 89%
- Samples: 89%

LOWEST 5 PROVISIONS OF THE APEC MEXICO CITY PRINCIPLES ALIGNED WITH INDUSTRY ASSOCIATION CODES OF ETHICS (PERCENTAGE OF SURVEY RESPONDENTS)

- Clinical Trials: 79%
- Support for Continuing Medical Education: 81%
- Safety of Medicines: 81%
- Adherence to Principles: 82%
- Public Sector Relationships and Procurement: 83%

http://mcprinciples.apec.org
http://klprinciples.apec.org
2019 Survey Results: Code Implementation

MEMBER COMPANY ADHERENCE

**REPORTED MEMBER IMPLEMENTATION RATE BY THE 56 ASSOCIATIONS WITH A CODE / COMMITMENT**

- **16** (UNKNOWN)
- **1** (26-50%)
- **8** (51-75%)
- **31** (76-100%)

**SME MEMBERSHIP OF REPORTED MEMBER IMPLEMENTATION RATE BY THE 56 ASSOCIATIONS WITH A CODE / COMMITMENT**

- **917** (76-100%)
- **2978** (51-75%)
- **340** (26-50%)
- **1485** (UNKNOWN)
2019 Survey Results: Code Implementation

EXTERNAL ENGAGEMENT

COORDINATION WITH NON-MEMBER STAKEHOLDERS ON ETHICAL PRACTICES AND/OR YOUR CODE OF ETHICS

IF THERE IS COORDINATION, ACTIVITIES INCLUDE:

- Your Government
- Healthcare Professionals
- Patient Groups
- Third Party Intermediaries (distributors)
- Regular communication
- Training and capacity building initiatives
- Involvement in the development and implementation of Consensus Framework process

Non-member Companies
Biopharmaceutical Industry Associations: Greatest Opportunities

- Reducing Costs
- Communication
- Low Complaints
- High-Standard Alignment
- Member Adherence
- Training
- Culture of Integrity
- Leadership Commitment
- Member Engagement
- Collective Action across Industry
- Stakeholder Engagement
Biopharmaceutical Industry Associations: Greatest Challenges
Thoughts on Strategies to Measure the Positive Impact of Ethical Practices

1. Focus on positive impact of ethical business practices on our economies, businesses, health systems, and/or innovation.

2. We may want to pick one or two specific areas and start there.

3. Quality research is paramount and this may take time.

4. Strategy should include diversity in approach, with contributions from both side of the Pacific and both developed and developing economies.
GOVERNMENT STRATEGIES TO ENCOURAGE ETHICAL BUSINESS CONDUCT

• Convening Power
• Procurement
• Regulatory Practices
• Enforcement Recognitions and Incentives
• Government Supported Business Ethics Training
• Trade Agreements
GOVERNMENT STRATEGIES TO ENCOURAGE ETHICAL BUSINESS CONDUCT

Ms. Claudia Ortega Forner
Public Prosecutor’s Office, Chile

Mr. Ricardo Miranda Zúñiga
Legal Advisor, ChileCompra

Ms. Sabrina Chan
Senior Executive Director, Hong Kong Association of the Pharmaceutical Industry

Ms. Faye Sumner
Chief Executive Officer, Medical Technology Association of New Zealand (MTANZ)
GOVERNMENT STRATEGIES TO ENCOURAGE ETHICAL BUSINESS CONDUCT

• Convening Power
• Procurement
• Regulatory Practices
• Enforcement Recognitions and Incentives
• Government Supported Business Ethics Training
• Trade Agreements
This certifies that

EDWARDS LIFESCIENCES NZ LTD

is a member of the Medical Technology Association of New Zealand

31 March 2020

For the year ending

609028

Membership Number

Faye Sumner CNZM, Chief Executive
AFTERNOON TEA / COFFEE BREAK
(OUTSIDE SAN CRISTOBAL ROOM)
14:45 – 15:00
PLENARY SESSION

THE FUTURE OF THE NANJING DECLARATION

Ms. Tricia Van Orden, Overseer, Business Ethics for APEC SMEs Initiative
## Business Ethics for APEC SMEs Initiative: Medical Device & Biopharmaceutical Sectors

### Strategic Assessment of 2020 Commitments

**Updated August 2019**

### INPUTS

<table>
<thead>
<tr>
<th>Who Provides What</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Industry (SMEs)</strong> Commitment to engage directly with the initiative and local industry associations to strengthen their own capacity</td>
</tr>
<tr>
<td><strong>Industry (Large Enterprises)</strong> Commitment to engage directly with the initiative and local industry associations to strengthen their own capacity and to lend resources (expertise, financial, or otherwise)</td>
</tr>
<tr>
<td><strong>Industry (Associations)</strong> Commitment to engage directly with the initiative and their members to strengthen the capacity of enterprises within their economy and to lend resources (expertise, financial, or otherwise)</td>
</tr>
<tr>
<td><strong>Industry (Third Parties - Distributors, Marketers, etc.</strong> Commitment to engage directly with the initiative and local industry associations to strengthen their own capacity</td>
</tr>
<tr>
<td><strong>Governments</strong> Commitment to serve as partners and foster regulatory environments that encourage ethical conduct and lend resources where appropriate (expertise, financial, or otherwise)</td>
</tr>
<tr>
<td><strong>Healthcare Professionals / Healthcare Providers</strong> Commitment to engage directly with the initiative at all levels to build capacity, align practices, and lend resources (expertise, financial, or otherwise)</td>
</tr>
<tr>
<td><strong>Patients</strong> Commitment to provide all stakeholders with routine inputs and to advocate for APEC Principles</td>
</tr>
</tbody>
</table>

### ACTIVITIES

<table>
<thead>
<tr>
<th>What We Do Together</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Setting Best Practices</strong> Identify, align, and endorse the highest standard ethical business practices across all member economies.</td>
</tr>
<tr>
<td><strong>Capacity Building</strong> Facilitate adoption and implementation of the highest standard ethical business practices by all industry and non-industry actors relevant to both sectors, supporting opportunities between and within member economies.</td>
</tr>
<tr>
<td><strong>Monitoring and Evaluation</strong> Setting indicators to quantify progress in the adoption and implementation of high standard ethical business practices across all member economies, while actively monitoring this process to determine changes over time and evaluating results.</td>
</tr>
</tbody>
</table>

### OUTPUTS

<table>
<thead>
<tr>
<th>The Products of Our Work</th>
</tr>
</thead>
<tbody>
<tr>
<td>APEC RoA: Latin America Principles &amp; APEC Mexico City Principles</td>
</tr>
<tr>
<td>APEC Trade and Investment Ethics Experts’ Sessions (All Sections)</td>
</tr>
</tbody>
</table>

### OUTCOMES

<table>
<thead>
<tr>
<th>The Changes from these Products (Quantifiable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgement to Chiefs</td>
</tr>
<tr>
<td>Reconciliation and support to strengthen ethical business practices by APEC Economic Leaders and Ministers</td>
</tr>
<tr>
<td>Expanding the total number of trade associations signing the code of ethics or code of conduct from 62 (2012) to 86 (2019), more than doubling the number across APEC</td>
</tr>
<tr>
<td>Initiating in 10 APEC economies for the first time - and extending best practices to nearly 20,000 enterprises</td>
</tr>
<tr>
<td>Improved code implementation by using indicators across a range of industries, including improved governance, alignment with best practices, member adherence, and external engagement (see 2019 APEC Reports for further details on indicators)</td>
</tr>
<tr>
<td>Adoption of “Consensus Framework” agreements for multi-stakeholder ethical collaboration in nine APEC economies (Australia, Canada, Chile, China, Japan, Korea, New Zealand, Russia, and United States) to guide businesses as they work with others under development, benefitting not only the region’s health organizations but also the economies of the participating member economies</td>
</tr>
<tr>
<td>From 2012 to 2018, in-person “train-the-trainer” capacity-building sessions for over 1,500 senior leaders from every stakeholder and every APEC economy</td>
</tr>
</tbody>
</table>

### IMPACT

<table>
<thead>
<tr>
<th>The Benefits from these Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Economic</strong> Strengthen growth and cross-border trade, competitiveness; reduce public waste and regulatory/enforcement burden</td>
</tr>
<tr>
<td><strong>Business</strong> Strengthen domestic and cross-border market access for SMEs, facilitate fair competition in the marketplace, promote productivity, reduce reputational and legal costs.</td>
</tr>
<tr>
<td><strong>Social</strong> Strengthen health system outcomes for patients, improve confidence/trust in healthcare system, access to life saving and enhancing products, and expand local innovation capabilities.</td>
</tr>
<tr>
<td><strong>Innovation</strong> Strengthen trust between stakeholders that is necessary to expedite the discovery or improvement of new products and processes, while strengthening confidence in investment.</td>
</tr>
</tbody>
</table>
CLOSING SUMMATION AND LOOKING AHEAD

Ms. Tricia Van Orden, Overseer, Business Ethics for APEC SMEs Initiative