

**WORLD MEDICAL ASSOCIATION**  
**DECLARATION OF**  
**HELSINKI**  
**2<sup>nd</sup> REGIONAL MEETING**

**AGENDA**

Sao Paulo Medical Association (APM) Hall, Sao Paulo, Brazil  
(Av. Brigadeiro Luiz Antônio, 278, Bela Vista)

24-25 February 2023

**FRIDAY, 24 FEBRUARY**

**09:00 – 9:10**

**Welcome**

- **Dr. Cesar E. Fernandes**, President, Brazilian Medical Association
- **Dr. Carlos V. Serrano Jr.**, International Relations Director, Brazilian Medical Association

**09:10 – 9:35**

**An Introduction to the DoH**

- **Dr. Jack Resneck Jr.**, President, American Medical Association
- **Dr. Otmar Kloiber**, Secretary General, World Medical Association (WMA)

**09:35 – 10:45**

**An Overview of the Ethical Principles of the Use of Placebo**

- *Moderator:* **Dr. Roseli Nomura**, Adjunct Coordinator of the National Research Ethics Commission - Brazil (CONEP), Adjunct Professor - Escola Paulista de Medicina - UNIFESP, Associate Professor - Faculty of Medicine - University of São Paulo, Advisor to the Scientific Director of the Brazilian Federation of Gynecology and Obstetrics - FEBRASGO.
- Participants:
  - **Dr. Jose Humberto Fregnani**, Superintendent of Teaching and Research at the A.C. Camargo Cancer Center; Former Member, National Research Ethics Commission - Brazil (CONEP); Lecturer in the Graduate Program at Hospital de Câncer of Barretos & A.C. Camargo Cancer Center
  - **Dr. Carla Saenz**, Regional Ethics Advisor, Pan American Health Organization

**10:45 – 11:00**

**Break (15 min)**

**11:00 – 12:00**

**Discussion: The DoH & its Principles on the Use of Placebo**

- **Moderator: Dr. José Luiz G. do Amaral**, President, Medical Association of Sao Paulo; Former President, World Medical Association Brazilian Medical Association.
- Participants:
  - **Dr. Kloiber**
  - **Dr. Resneck**
  - **Dr. Sergio Surugi de Siqueira**, Professor & Research Ethics Committee Member, Pontifical Catholic University of Parana; External Member, Research Ethics Committee of the Pan American Health Organization

**12:00 – 13:30**

**Lunch (1h 30min)**

**13:30 – 15:00**

**Discussion: Use of Placebo: Trial-design & Methodological Best Practices**

- **Moderator: Dr. Joao Massud Filho**, Senior Consultant on Drug Development, Professor of Post-graduation Course on Pharmaceutical Medicine, Honorary Fellow- Faculty of Pharmaceutical Medicine, UK, Visiting Researcher and Professor At Aeronautics Technology Institute (ITA), Regulatory and Clinical Consultant – Beigene Brazil.
- Participants:
  - **Dr. Zaida Arteta**, President, Confederación Médica Latinoamericana y del Caribe
  - **Dr. Paulo A. Lotufo**, Professor of Medicine/Center for Clinical & Epidemiologic Research Director, University of Sao Paulo
  - **Dr. Alfredo J. Mansur**, Professor in Cardiology, University of Sao Paulo, Director of Clinical Staff, Instituto do Coracao (Heart Institute), Sao Paulo University Medical School; Coordinator of the Ethics Committee, Hospital das Clinicas, Sao Paulo University Medical School, Member & ad hoc & CONEP
  - **Dr. Jose C. Nicolau**, Professor, University of Sao Paulo Medical School; Director, Acute Coronary Diseases Unit, Heart Institute Member, Steering/executive committees of & 70 multicenter clinical trials

**15:00 – 15:15**

**Break (15 min)**

**15:15 – 16:45**

### **Discussion: Ethical Considerations for the Use of Placebo**

- *Moderator:* **Dr. Miguel R. Jorge**, Member, Review Committee of the WMA International Code of the Medical Ethics (2022); Former President, WMA.
- Participants:
  - **Dr. Dirceu Greco**, Professor Emeritus, Infectious Diseases and Bioethics, School of Medicine, Federal University of Minas Gerais
  - **Dr. Mariela Mautone**, Professor & Coordinator of the Bioethics Unit of the Faculty of Medicine, University of the Republic (Udelar), Uruguay
  - **Dr. Saenz**
  - **Dr. Dominique Sprumont**, Founding Member, Institute of Health Law of the University of Neuchâtel; Executive Committee Member, Council for International Organizations of Medical Sciences (CIOMS)

**16:45 – 17:00**

### **Summary & Closing Remarks**

- **Dr. Resneck**
- **Dr. Serrano**

**19:30**

### **NETWORKING DINNER**

(Offered by AMB – Local TBD)

## **SATURDAY, 25 FEBRUARY**

**09:00 – 09:05**

### **Opening Remarks**

- **Dr. Resneck**

**09:05 – 10:45**

### **A Conversation on Regional Regulatory Perspectives on the Use of Placebo**

- *Moderator:* **Dr. Resneck**
- Keynote Speakers & Discussion Participants:
  - **Dr. Lais Souza Bonilha**, Coordinator, CONEP
  - **Dr. Hilary Marston**, Chief Medical Officer, United States Food and Drug Administration

**10:45 – 11:00**

### **Break (15 min)**

**11:00 – 11:40**

**Q&A: Aligning the DoH with the CIOMS Guidelines on the Use of Placebo and Beyond**

- Dr. Sprumont

**11:40 – 11:45**

**Summary & Closing Remarks**

- Dr. Resneck

**11:45 – 13:45**

**Closed Workgroup Meeting (over lunch)**

Only WMA DoH Workgroup members

**11:45 – 13:45**

**Lunch**

To all participants not on the Closed Workgroup Meeting

**13:45 – 14:00**

**Break (15 min)**

**14:00 – 16:30**

**City Tour** (Leaving from APM Hall and return to Hotel Porto Bay and Canopy by Hilton)



**AMA 175 YEARS**

