I will talk about the activities of the World Medical Association (WMA) to develop its proposed declaration on ethical considerations regarding health databases and bio-banks.

The WMA agreed to support the Icelandic Medical Association in its fight against an Icelandic Government bill to establish a central health database for the entire population of Iceland in around 1998. The WMA General Assembly agreed to a request that the WMA Secretary General should assist the Icelandic Medical Association in seeking to clarify with the Icelandic Government the incalculable ethical consequences of the data collection Bill.

The WMA General Assembly in Ottawa in 1998 expressed its position to support Icelandic doctors’ strong will to fight against the Bill. The second slide cites the words of Dr. Torben Pedersen, then President of the Danish Medical Association who is supportive of the Icelandic Medical Association’s efforts (Slides 1 and 2).

Its Council Session in Santiago in 1999 also confirms its commitment to patient confidentiality which is one of the most important cores about this problem (Slide 4).

The WMA and WHO held a joint seminar in Geneva in May 2000 entitled “Ethical implications of centralized health databases.” A joint seminar facilitates both the exchange of information and the future development of policy by the respective organizations (Slide 5).

The WMA Council Session in Divonne-les-Bains, France in May 2000 decided on the need for guidelines after holding a joint seminar in Geneva with the World Health Organization, where physicians’ representatives from across the world expressed their concern about the threat to privacy of patients’ records. Dr. Anders Milton, the then Chair of WMA pointed that it is essential that to allay public concern about the growing development of these databases, internationally acceptable guidelines are drawn up to govern their use. And any guidelines must address the issues of privacy, consent, individual access and accountability (Slides 6 and 7).

The WMA General Assembly in Washington 2002 adopted a statement on ethical considerations regarding health databases. The first revision was discussed in the Council Session in Plague in 2012 with the Icelandic Medical Association as a rapporteur. This action was succeeded in Bangkok in the same year where a working group was established to develop a proposed revision of this document (Slides 8 and 9).

In 2013, the WMA General Assembly in Fortaleza, Dr. Snædal noted that there were several options for defining the scope of the WMA work in this area. The WG Chair made a motion requesting that the WG be instructed to continue its work on the broad concept of health databases. The motion was approved (Slide 10).

This year three doctors from the US, Korea and Iceland were invited by the Japan Medical Association to its conference on medical infor-
mation technology on February 9 and delivered a presentation, “Big Data/Analytics and the US Healthcare System: Big Opportunity, Big Responsibility” by Dr. Robert Wah from the AMA, “ICT and Healthcare in Korea, Present and Perspectives” by Dr. Dong Chun Shin from Korea and “Centralized Health Databases Lessons from Iceland” by Dr. Jon Snædal from Iceland (Slide 11).

The WMA also held a WG meeting in Reykjavik in March 2014 to more closely discuss this topic (Slide 12).

These efforts will be succeeded to the WMA Council Session which will be held in Tokyo in April of this year. We will expect further development of the discussion there toward the adoption of this document in its general assembly in Durban in the coming October (Slide 13).
Joint seminar of WMA and WHO May 2000

"Ethical Implications of Centralized Health Databases"

May 3, 2000

WHO Headquarters, Geneva, Switzerland

- This event has now been planned in conjunction with the World Health Organization.
- Other international organizations should be consulted to obtain their views on the ethical implications of Central Health Databases.
- A joint seminar should facilitate both the exchange of information and the future development of policy by the respective organizations.

WMA Council Session (Divonne Leis Van) May, 2000

WMA to Draw Up Health Database Guidelines

New international ethical guidelines for the development of centralized health databases are to be drawn up by the World Medical Association.

The association decided on the need for guidelines after holding a joint seminar in Geneva with the World Health Organization, where physicians' representatives from across the world expressed their concern about the threat to privacy of patients' records.

WMA Council Session (Washington), October 2002

Adoption of the WMA Statement on Ethical Considerations regarding Health Databases

- The privacy of a patient's personal health information is secured by the physician's duty of confidentiality.
- Confidentiality is at the heart of medical practice and is essential for maintaining trust and integrity in the patient-physician relationship.
- The primary purpose of collecting personal health information is the provision of care to the patient.
- Care must be taken to ensure that secondary uses of information do not inhibit patients from confiding information for their own health care needs, exploit their vulnerability or inappropriately borrow on the trust that patients invest in their physicians.
- Patients' consent is needed if the inclusion of their information on a database involves disclosure to a third party.
- National medical associations should co-operate with the relevant health authorities, ethical authorities and personal data authorities at national and other appropriate administrative levels, to formulate health information policies based on the principles in this document.

WMA General Assembly, Bangkok, 2012

Dr. J. Snaedal presented the proposed Revision of the WMA Declaration on Ethical Considerations regarding Health Databases and Comments, and proposed that a working group be established to further discuss the document.

The Council set up a working group to look at the proposed Revision of the WMA Declaration on Ethical Considerations regarding Health Databases and Comments.

The constituent members of the WG: Iceland, Denmark, US, Israel, Australia and Germany.
JMA Conference on Medical Information Technology
Feb. 9th, 2014
JMA Auditorium
International Session

- "Centralized Health Databases Lessons from Iceland"
  Jon Snæ Ballard, Chair of Medical Ethics Committee of the Icelandic Medical Association
  Former President of the World Medical Association

- "ICT and Healthcare in Korea, Present and Perspectives"
  Dong Chun Shin, Professor, Department of Preventive Medicine, Yonsei University
  College of Medicine, Administrative Director, Yonsei University Severance Hospital
  Chair, Executive Committee of International Relations, Korean Medical Association

- "Big Data/Analytics and the US Healthcare System: Big Opportunity, Big Responsibility"
  Robert Wah, President-elect of the American Medical Association

Slide 11

WMA Work Group meeting on Health Databases and Biobanks
Reykjavik 7. March 2014

Agenda – final draft

09:00 - 09:15 Opening of the morning session
  Jon Snæ Ballard, Icelandic Medical Association (IMA)

09:15 - 09:45 "IT technology in the Medical Services"
  Robert Wah, American Medical Association (AMA)

09:45 - 10:15 "Big data, research and policy"
  Maia Koch-Hansen, Danish Medical Association (DMA)

10:15 – 10:45 "Use of Health Data in a University Hospital"
  Maria Henningsdottir, IcMA

11:00 - 11:30 "Consent in health care and data protection law - Possible Impacts of the EU’s (Draft) Data Protection Regulation on consent in research"
  Annabel Seaborn, WMiA

11:30 - 12:00 "Biobanks, practical use in a divergent society"
  Aamir Zeel, South African Medical Association (SAMiA)

12:00 – 12:30 "Ethical aspects of Biobanks"
  Wellington Armstrong, IcMA

Afternoon, Closed session of the WGO.

Slide 12

WMA Council Session (Tokyo), April 2014
24–26 April 2014
Hotel Nikko Tokyo

- Thursday, 24 April
  Opening Plenary Session of the Council
  Medical Ethics Committee
  Finance and Planning Committee

- Friday, 25 April
  Finance and Planning Committee
  Socio-Medical Affairs Committee

- Saturday, 26 April
  Council Plenary Session
  Conclusion of Council Session

Slide 13