
Global Perspective of Human Subjects Protection

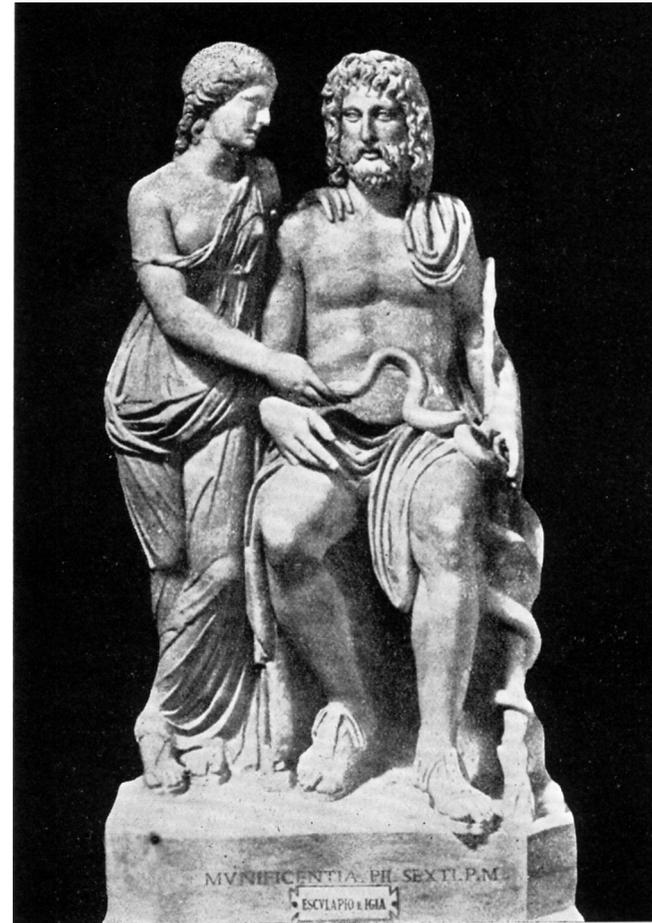
Dr James Appleyard

Past President W.M.A.

August 19th 2006

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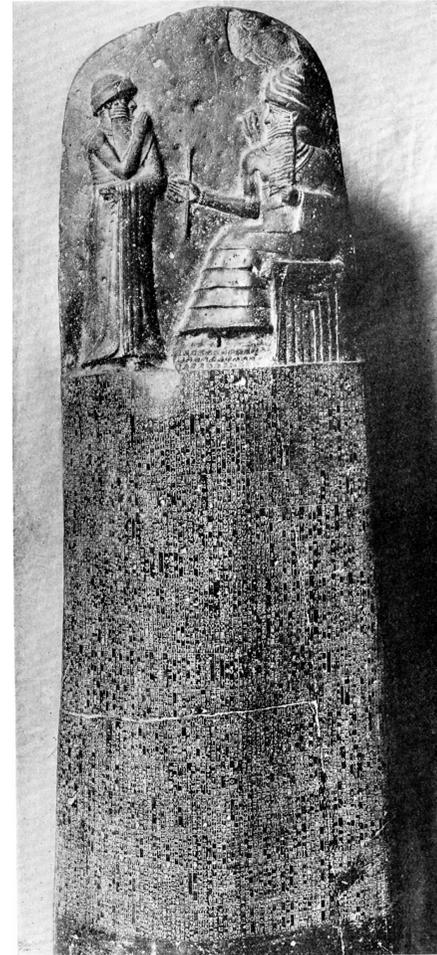
- Sketch out some historical landmarks
- Review the evolution of the WMA's Declaration of Helsinki
- Some controversy surrounding it
- Look to the future



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Hammuradi Code

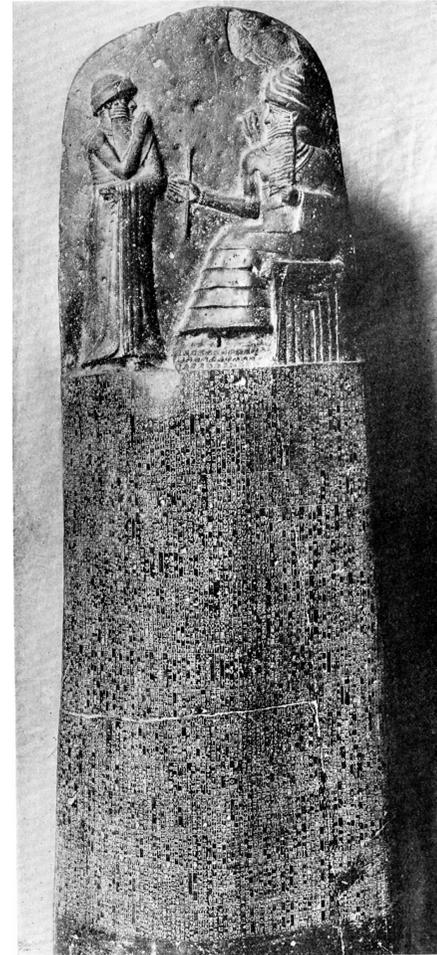
2000 BC



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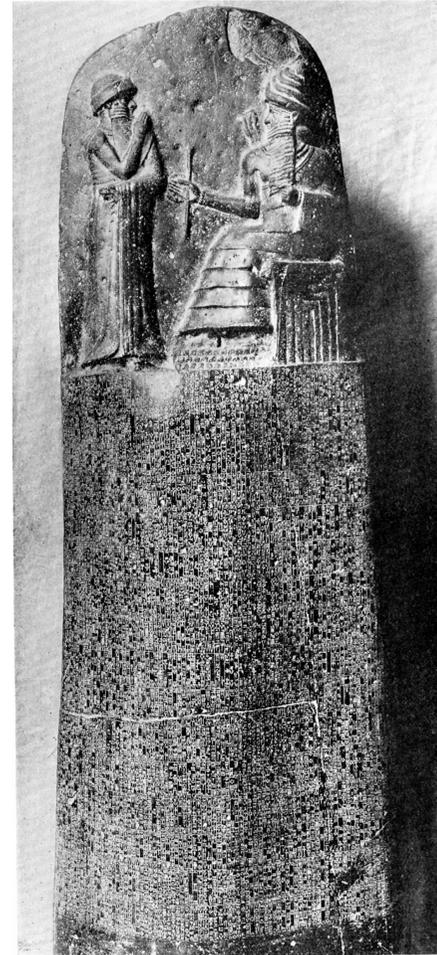
Included

- Regulation of the Profession,
- Scales of fees
- Penalties for Malpractice



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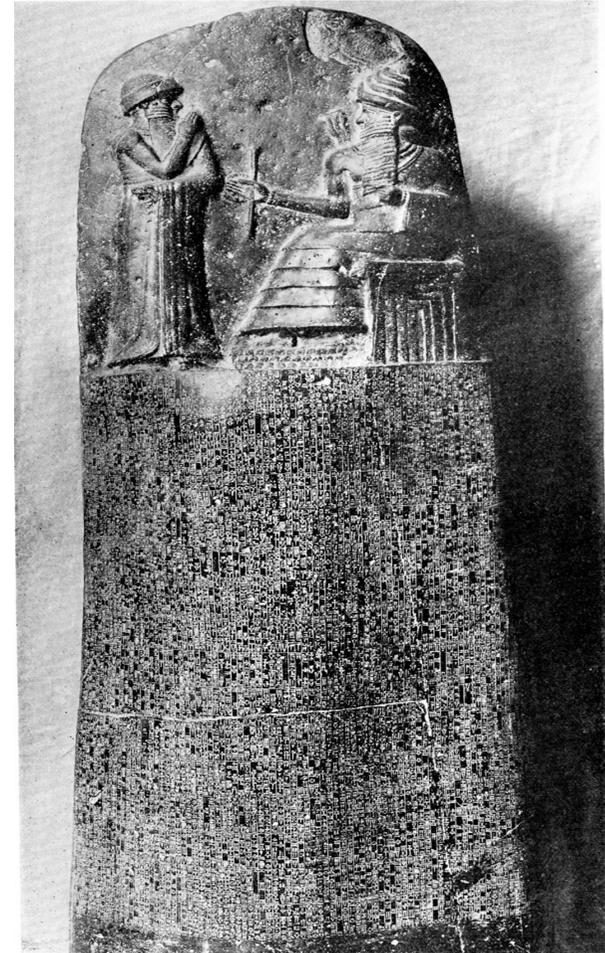
“If a doctor has treated a severe wound of a slave of a poor man with a bronze lancet and caused his death, he shall render slave for slave”



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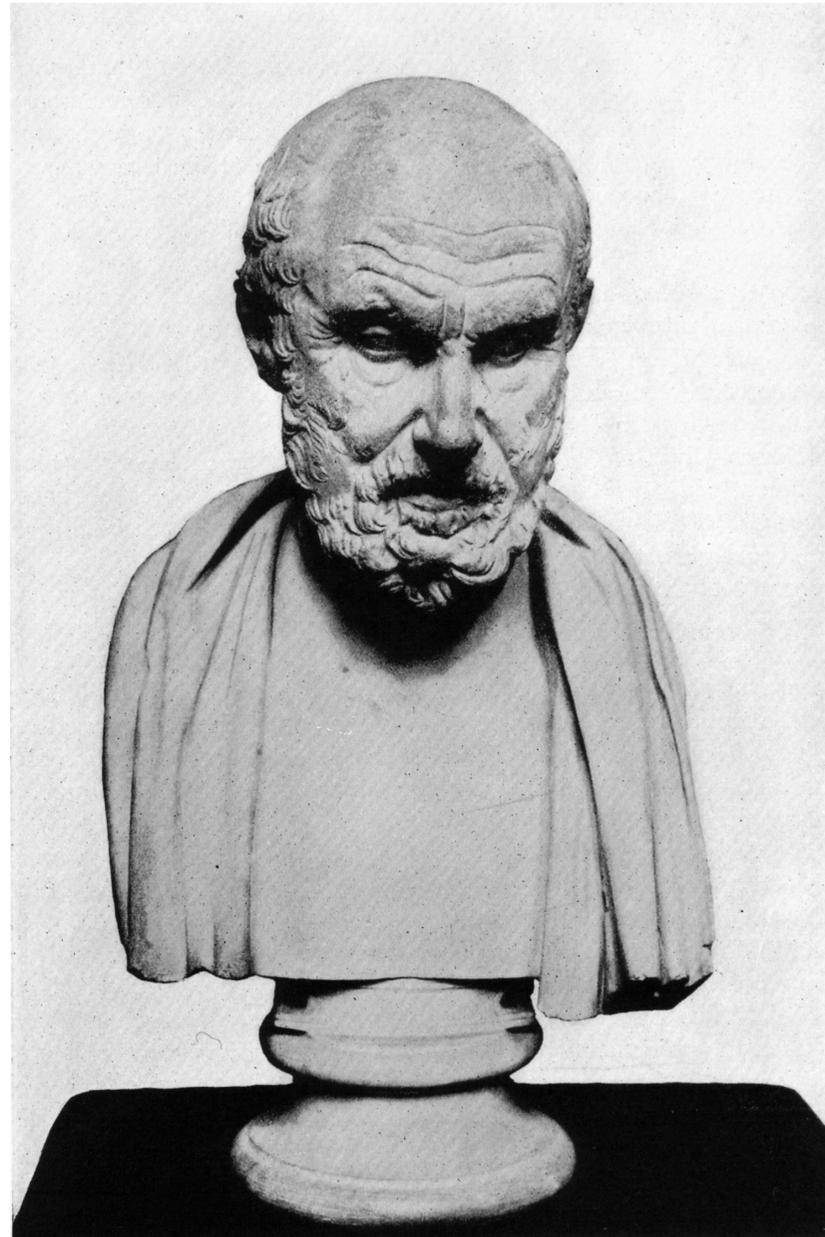
Lex Talionis

An eye for an eye
A tooth for a tooth

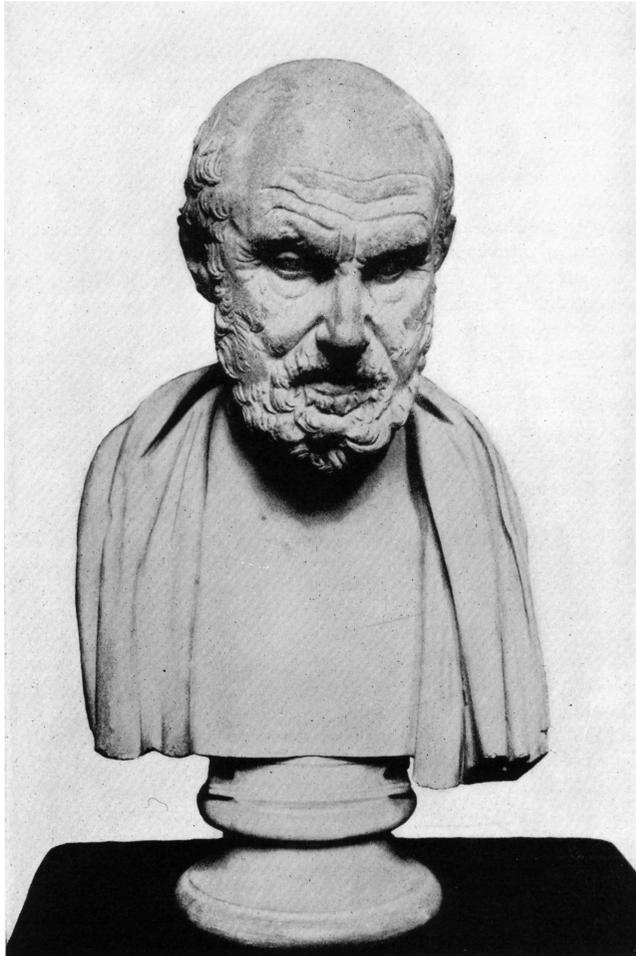








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There are in effect two things, to know and to believe one knows.

To know is science, to believe one knows is ignorance

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'Personal' Codes of Practice

- Thomas Percival in England
 - William Beaumont in U.S.A
 - Claude Bernard in France
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National Codes of Practice

1900 Directive on Human Experimentation
Prussian Minister of Religious,
Educational and Medical Affairs

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National Codes of Practice

Circular on innovative therapy and Scientific
experimentation 1931

Reich Minister of Interior

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National Codes of Practice

Advisory Resolution on the procedures for testing new medicinal substances and methods which may present a hazard for the health and life of patients

By the Bureau of the Medico-Scientific Council of the People's Commissariat for Health in the USSR 1936

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Nuremberg Code 1947

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1948 United Nations Universal Declaration of Human Rights

Included concepts of Human Dignity

Self determination

Freedom from Interference

Welfare Protection

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- International Covenant on Civil and Political Rights – U.N General Assembly

Adopted Dec 1966

Came into force May 1976

“No one shall be subjected without his free consent to medical or scientific experimentation”

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Other National Initiatives

American Medical Association 1946

Principles of Human Experimentation

UK Medical Research Council 1953

Memorandum on Clinical Research

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Other National Initiatives - USA

The Belmont Report 1979

Respect for Persons

Beneficence

Justice

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Potential benefits must outweigh hazards

The need for informed consent

A distinction between Scientific and Clinical Research



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In Biomedical Research introduced concepts of:-

- Potential benefits must outweigh hazards
 - The need for informed consent
 - The need for research protocols to be scrutinized by 'Ethics Committees
 - A distinction between Scientific and Clinical Research
-

Declaration of Helsinki

International Impact

1993 CIOMS Guidelines affirm

“That the Declaration of Helsinki is the fundamental document in the field of ethics in biomedical research and has had considerable influence of international, regional and national legislation and codes of conduct”

Declaration of Helsinki

International Impact

CIOMS Guidelines 1982 - Objective

“To indicate how the fundamental ethical principles –as set forth in the Declaration of Helsinki, particularly in developing countries, taking into account culture, socioeconomic circumstances, national laws and executive and administration arrangements”

Declaration of Helsinki

International Impact

The 1995 WHO Guidelines for 'Good Clinical Practice' for trials on pharmaceutical products include the affirmation that the current revision of Declaration of Helsinki is the

“accepted basis for clinical trial ethics and must be fully followed and respected by all parties involved in the conduct of such trials”

Declaration of Helsinki

International Impact

In **Japan**

Ordinance No 28 (1997) of the Ministry of Health and Welfare

“that clinical trials should be performed in accordance with ethical principles based on the Declaration of Helsinki and the standards laid down in the ordinance”

Declaration of Helsinki

International Impact

The **Chinese** Clinical Trial Administration Norms (1999)

“ ..all research involving human subjects must comply with the ethical principles of the Declaration of Helsinki and the 1993 CIOMS guidelines..”

Declaration of Helsinki

International Impact

The **Indian** Council of Medical Research issued ethical guidelines for biomedical research on human subjects in 2000 refers specifically to the Declaration of Helsinki in one of the introductory rubrics

Declaration of Helsinki

Revisions

- 1st 1975 Tokyo
 - 2nd 1983 Venice
 - 3rd 1989 Hong Kong
 - 4th 1996 Somerset West. S. Africa
 - 5th 2000 Edinburgh
-

Declaration of Helsinki

1975 Revision

Basic Principles

- 1.2 Independent Committee review of Research Protocols**
 - 1.5 Interests of Human Subject must prevail over interests of Science and Society**
 - 1.8 Obligations regarding accuracy in publishing**
 - 1.9 Enhanced requirements for Informed Consent**
 - 1.12 Protocol must declare that the requirements of the Declaration of Helsinki adhered to**
-

Declaration of Helsinki

1975 Revision

Medical Research Combined with Professional Care

8.2 Best current therapy should be the comparator arm

8.3 Assurance of access to best proven methods

8.4 Refusal of Research participation not to affect doctor patient relationship

8.5 When Doctor considers it essential not to obtain informed consent

Declaration of Helsinki

2000 Revision

Changes made

8 Research on people from vulnerable groups

13 Ethics Committees have right to monitor research
conflicts of interest to be disclosed

16 Design of studies to be publicly available

21 Protection of Confidentiality of information about patient

Declaration of Helsinki

2000 Revision

Changes made

- 22 Provisions where consent cannot be obtained in writing
 - 25 'Consent' changed to 'Assent' with respect to research involving children
 - 26 Provisions where consent from the subject is not possible
 - 31 Requirement to fully inform patient what aspects of their care related to the research
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Declaration of Helsinki

2000 Revision

Changes made

Para 32

Use of proven techniques to save life or re-establish health should be made the object of research and the results recorded and published where appropriate

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Declaration of Helsinki

Para 29

The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists

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- **Note of clarification on paragraph 29 of the WMA Declaration of Helsinki**
 - The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:
 - - Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or
 - - Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.
 - All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.
-

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- **ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE**

Para 30

- At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study
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- **Note of clarification on paragraph 30 of the WMA Declaration of Helsinki**
 - The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.
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“there is no doubt that the Declaration of Helsinki – still less than 2000 words in length – is one of the most succinct documents encapsulating the principles guiding research ethics in existence”

Carlson, Boyd and Webb

Brit J Clin Pharmacol 2004 57.6 695

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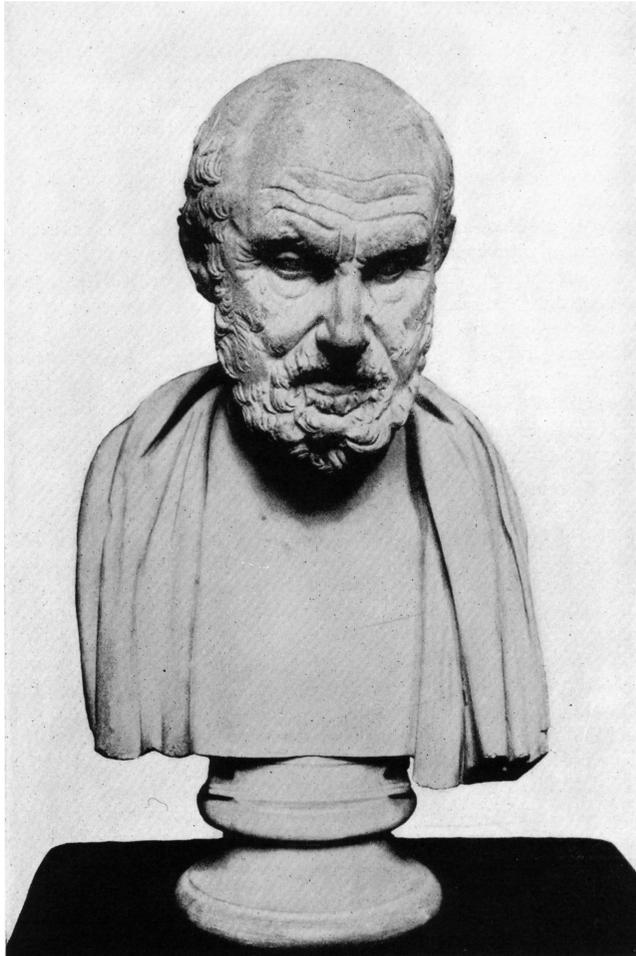
Declaration of Helsinki

“It can be read from beginning to end in less than 10 minutes”

Carlson, Boyd and Webb

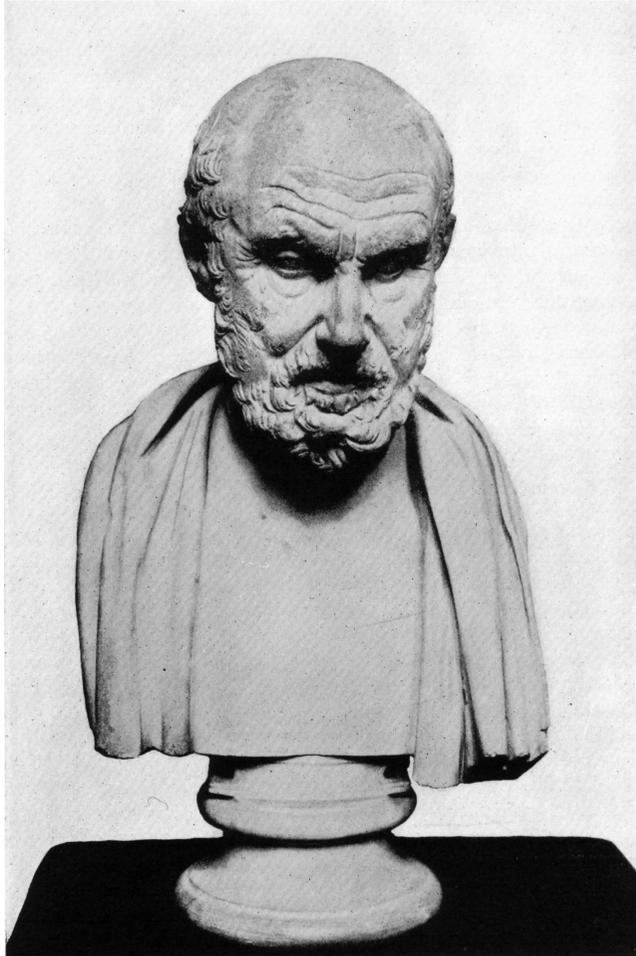
Brit J Clin Pharmacology 2004 57.6 695

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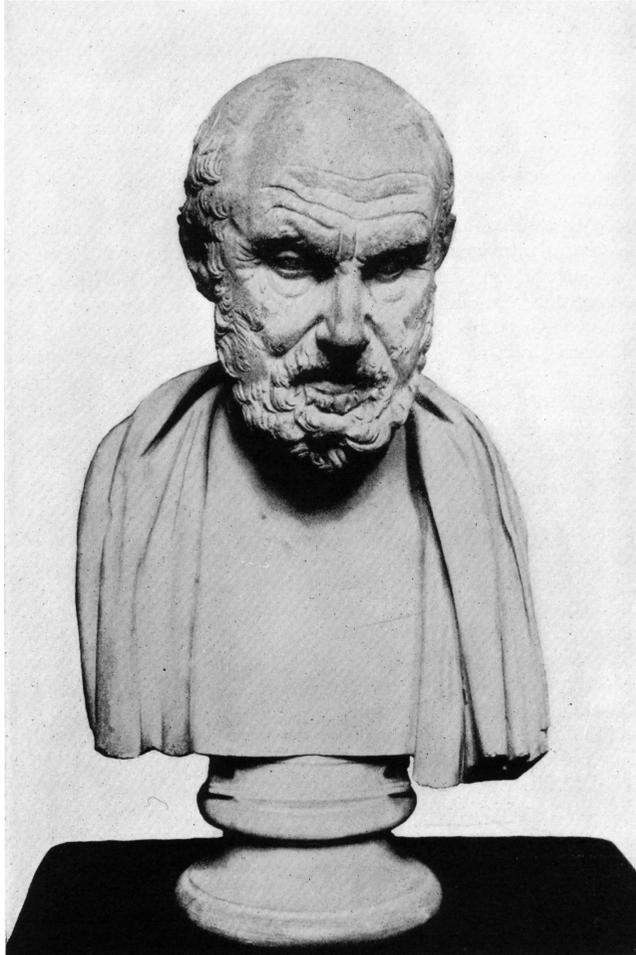
Life is short
The Art is long
The occasion fleeting
and
Judgment difficult

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*Thank you
for
your attention*

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Wherever the Art of
Medicine is loved,
there is also the
love of Humanity.

Hippocrates 400 BC

Medical Conscience

Wherever the Art of Medicine is loved,
there is also the love of Humanity.

Hippocrates 400 BC

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