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CONTENTS

EDITORIAL 85

NEW WMA SECRETARY-GENERAL 85

PRESIDENTIAL ADDRESS BY DR. YANK D. COBLE, JR, MD TO THE WORLD MEDICAL ASSEMBLY, TOKYO 86

WMA HAS A NEW PRESIDENT 86

MEDICAL ETHICS AND HUMAN RIGHTS MEDICAL ETHICS AND BEREAVEMENT 89

THE WORLD MEDICAL ASSOCIATION
STATEMENT CONCERNING THE RELATIONSHIP
BETWEEN PHYSICIANS AND COMMERCIAL ENTERPRISES 91

THE WORLD MEDICAL ASSOCIATION
REGULATIONS IN TIMES OF ARMED CONFLICT 92

THE WORLD MEDICAL ASSOCIATION
STATEMENT ON HEALTH EMERGENCIES
COMMUNICATION AND COORDINATION 93

NOTE OF CLARIFICATION ON PARAGRAPH 30
OF THE WMA DECLARATION OF HELSINKI 95

MEDICAL SCIENCE, PROFESSIONAL PRACTICE AND EDUCATION

ACCOUNT BY DR. JAMES APPLEYARD OF
HIS PRESIDENTIAL YEAR OF OFFICE 2003–2004 95

THE FUTURE OF MEDICAL TECHNOLOGY –
IMPLICATIONS FOR MEDICAL EDUCATION AND PRACTICE 97

BLAME YOUR GENES FOR A RESTLESS
NIGHT'S SLEEP – NEW RESEARCH REVEALED 99

WHO

NEW TOOLS AND INCREASED FUNDS
WILL BEAT MALARIA, SAY GLOBAL LEADERS 100

SKILLED ATTENDANTS VITAL TO
SAVING LIVES OF MOTHERS AND NEWBORNS 101

A GLOBALLY EFFECTIVE HIV VACCINE
REQUIRES GREATER PARTICIPATION OF
WOMEN AND ADOLESCENTS IN CLINICAL TRIALS 101

LANDMARK REPORT COULD INFLUENCE THE
FUTURE OF MEDICINES IN EUROPE AND THE WORLD 102

WHO AWARDS MILLION DOLLAR CONTRACT
FOR GLOBAL TREATMENT PREPAREDNESS ACTIVITIES 105

WMA SECRETARY GENERAL

FROM THE SECRETARY GENERAL'S DESK 106

WMA

THE CEREMONIAL SESSION OF THE WORLD MEDICAL
ASSOCIATION GENERAL ASSEMBLY, TOKYO 2004 107

MEETING OF THE WMA GENERAL
ASSEMBLY, TOKYO, 9TH OCTOBER 2004 108

REGIONAL AND NMA NEWS

PATIENTS' ACCESS TO CARE AT RISK WITH
AMERICA'S BROKEN MEDICAL LIABILITY SYSTEM 110

TOBACCO CONTROL CAPACITY BUILDING 112

WMA GENERAL ASSEMBLY, TOKYO 2004



THE PRESIDENT ADDRESSES THE EMPEROR AND EMPRESS
AT THE JMA RECEPTION



THE NEW PRESIDENT ADDRESSES THE WMA CEREMONIAL SESSION



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Editorial



Editorial

Those arriving in Tokyo for the Council, the Scientific meeting and the General Assembly of the World Medical Association, might be forgiven if they felt a sense of forboding when they were greeted with persistent and rather gloomy rain and mist. Indeed, this may well have been enhanced by the not insignificant earthquake one night and the typhoon two days later. However, the excellent scientific meeting, impeccable efficiency of the organisation and the warm hospitality of the Japanese Medical Association, more than compensated for the vagaries of the weather.

The meeting was further greatly honoured by the presence of the Emperor and Empress of Japan at the Opening Reception, and the Chief Secretary of the Cabinet (the Prime Minister being out of the country), the Minister of Health and the Governor of Tokyo at the Ceremonial session (*see report p. 107*).

The scientific session was also a success, addressing the advantages and the problems of advanced medical technology and also the subject of Continuing Medical Education and Physicians' Autonomy (*various papers appear in this issue*).

The General Assembly is reported on page 108. Among the decisions of the Assembly appears a note of clarification on article 30 of the Declaration of Helsinki. While this will undoubtedly not be the last we shall hear on this subject, interested parties will no doubt take their time to quietly consider and debate what appears to be the controversial issue of the rights of participants in clinical trials, before returning to the subject at some point in the future.

Meanwhile, the world moves on and the unavoidable delay in publishing this issue (due to illness), has meant that we have all experienced the terrible consequences of the "natural disaster" in South-East Asia. The global response in terms of aid, both financial and other resources, to this terrible event has been unprecedented. In all of this the medical profession, both through its national medical associations and other organisations geared to dealing with major disasters, reacted quickly and responsibly both in terms of provision of human resources and other forms of assistance. At the same time the profession and the population in general must not neglect the continuing needs of populations threatened by major scourges such as famine and other forms of deprivation, AIDS/HIV and Malaria. The needs of the world are huge – part of which depends on medical care. This is not only the responsibility of governments and administrations, but also a professional responsibility for the medical profession throughout the world.

Alan Rowe

New WMA Secretary-General

Dr. Otmar Kloiber has been appointed to be the next Secretary-General of the World Medical Association following Dr. Delon Human.

Dr. Kloiber is currently Deputy Secretary General of the Bundesärztekammer (German Medical Association) where for many years he was the Foreign Relations Advisor, and has extensive knowledge both of WMA, and the affairs of many national medical associations (particularly the problems in Central and Eastern Europe) and of international organisations and NGO's. Dr. Kloiber has also been a member of the German Parliamentary Commission on Law and Ethics in Modern Medicine. He had previously worked at the Max-Plank Institute in Cologne and was a Postdoctoral Fellow in the University of Minnesota USA from 1985-86. Dr. Kloiber will take up his post on the 1st February 2005.





Editorial

Presidential address by Dr. Yank D. Coble, Jr., MD to the world medical assembly, Tokyo

Following his investiture as President of the World Medical Association, Dr. Coble opened his address expressing his gratitude to those who elected him, to the retiring President and his fellow officers, to the Secretary-General, Dr. Delon Human, to the American Medical Association and its delegation at WMA, also to his WMA predecessors from the USA.

Dr. Coble continued

"All of you have given me opportunities to work hard for a worthy cause. To seek and to strive for the best health care for the people of the world, through the pursuit of the highest standards of medical care, medical education, medical ethics and medical science.

These things form the intellectual foundation and the creative spark of the art of medicine. They are ingrained in the Charter of the World Medical Association. They are our mission and our charge – "*Caring, Ethics and Science*" – the three fundamental, enduring traditions. Fulfilling this mission- living out these ideals- is what gives us the power to be strong, effective advocates for patients and for our profession the world over. Through changes in governments, changes in policies, changes in economic and in medical science and methods, we will flourish.

At this moment of history, the *wealth* of nations is not the most pressing issue; it is rather, the *health* of nations.

Indeed, one of the most pressing issues facing nations, be they first world or third-post-industrial or developing – is access to care, how to deliver medical and health care of high quality (including public health and preventive medicine) to the greatest number of their citizens, with the maximum possible efficiency. This at a time when the quality of medical care and the good health of our patients, face unprecedented challenges both locally and globally, natural and man-made.

These challenges include AIDS, SARS, resistant tuberculosis, Malaria, the threat of bio-terrorism, bureaucratic meddling, changing health policies, an unprecedented number of ageing citizens, unprecedented migration of physicians, and the need – in many lands if not most – for health care system reform. All of these things make

global co-operation essential if we as physicians are to protect the public health. Our increasingly open borders and our increasingly mobile populations are creating a rich environment for infectious agents, posing a serious threat to human health and international security. New infectious diseases such as SARS can emerge and travel swiftly around the globe, mutating and infecting less resilient hosts. These microbes respect no international borders or the landscape's physical barriers.

WMA has a new President

Yank D. Coble, Jr., MD, MACP, MACE, became President of the World Medical Association in Tokyo, Japan, in October of 2004. Dr. Coble served as Chair of the WMA's 2003-2004 Committee on Finance and Planning, has been a Delegate to the WMA since 2002, and is Past President of the American Medical Association.



A graduate of Duke Medical School, Dr. Coble also received a degree in clinical medicine of the tropics from the London School of Hygiene and Tropical Medicine. He is a clinical professor of medicine at the University of Florida School of Medicine and was formerly Professor of Medicine and Family Medicine and Chair of the Department of Community Health and Family Medicine. Dr. Coble is listed in "The Best Doctors in America" and in 2002 was selected by Modern Healthcare as one of the "100 Most Powerful People in Healthcare."

Under the auspices of the Office of International Research at the National Institutes of Health (NIH), he cared for patients and conducted medical research in Egypt, Nigeria and England from 1964 through 1969. During this time, he made site visits to more than 50 countries. Most recently, he served on the U.S. delegation to the WHO's 2003 and 2004 World Health Assembly.

Among his many leadership roles, Dr. Coble has been a member of the Advisory Committee to the Director of the NIH. He co-chaired both the 35th anniversary celebration of the NIH's Office of International Medicine and the 50th anniversary celebration of the Human Genome Project.

A distinguished leader in medicine, Dr. Coble is a Past President of the American Society of Internal Medicine, American Association of Clinical Endocrinologists, and American College of Endocrinology. He currently holds appointments on the boards of Research. America, National Osteoporosis Foundation, Institute of Medicine Roundtable on Environmental Health Sciences, Research and Medicine, Campaign for Public Health, and Hospice of Northeast Florida. He has also served on the Board of Directors of the National Quality Forum, the Joint Commission on the Accreditation of Healthcare Organizations and the National Guideline Clearinghouse of the Agency for Healthcare Research and Quality.

Dr. Coble and his wife Shereth reside in Neptune Beach, Florida and have five children and ten grandchildren.



Our weapons against these microbes are becoming less effective as they develop resistance to the drugs, which once kept them at bay.

For medicine to survive these threats, it must continue to push the boundaries of science and technology. By so doing we make longer, better lives available to all humankind. From these challenges, from adversity of all kinds we can learn as we overcome. Learn because we overcome.

Recently, I was in a country where physicians offered a candid admission – that their government delayed the medical community from releasing what they knew about SARS when they knew it.

Because of this, valuable time was lost addressing the epidemic and identifying the disease. This country's scientists knew the structure of SARS, knew what it was and how dangerous it was for two months before it could be reported. Ultimately this silence cost lives and cost the country \$80 million.

But because of physician inspired public pressure there has been a change. Physicians and other scientists in the country can now freely report their findings. This provided clear evidence of the value of disclosure, of co-operation and the transparency of science, not only for the health of a country, but for its economy and its wealth.

From adversity has come knowledge and progress in the fight against contagion.

In an African nation, a physician was discharged from his duties as a hospital superintendent in early 2002 for "insubordination", because he allowed a public health organisation to use space in his facility to administer HIV prophylaxis to rape victims. At the time when he was fired, that nation's Health Ministry prohibited the use of HIV drugs as a method of prevention and treatment after HIV exposure. Because of the international pressure brought to bear, in part because of this physician's case, this government changed its policy on HIV treatment.

Through the adversity suffered by these brave physicians, medicine was advanced.

These are the types of obstacles we face as a community, and which we must overcome together.

The traditions of medicine are what enable physicians to work together under difficult conditions.

Consider the Addis Ababa Fistula Hospital in Ethiopia, where in one of the world's most impoverished regions physicians treat women suffering from obstetric fistula, a debilitating childbirth injury still common in the developing world. Or Dr. Paul Farmer, who for 20 years has worked to develop a community-based health network in Haiti. He helped implement one of the first AIDS treatment programmes in the developing world and an innovative treatment for patients with multi-drug-resistant tuberculosis.

I have seen adversity and a common goal unite physicians with my own eyes. In Nigeria before the Biafran War, I helped work on a nutrition survey of the entire country – a co-operative effort with physicians from America and Nigeria (Ibo, Yoruba, Hausa and Faluni) all working together.

At the London School of Tropical Medicine at the time of the Six-day War in 1967, I watched Christian, Jewish, Muslim and Hindu physicians work side by side for the betterment of all nations, all faiths and all peoples.

Through adversity we find co-operation and innovation. We learn from each other and take inspiration from each other, because we are all in this together. We must delight in our diversity, but always remember the danger of discord. There is power only in unity. With enthusiasm, hard work and hope, we can take the challenges we face in medicine and turn them into opportunities for better health. But only if we remain responsible for our traditions of ethics, caring and science. Only if we work with our patients and others to topple the barriers to quality medical care. Only if we are active, united members of our profession.

Without science and its application, ethics and caring alone are merely good intentions, only well intentioned kindness.

It is our commitment to science and the lifelong process of learning that science, that directs, expands and makes unique what we do, as physicians. We must not permit others to diminish our scientific standards.

Ethics is what compels us to put the interests of the patient first, or in some instances, that of the public.

This is the heart of my message today – that everything we do, we do for our patients – The sick, the infirm, the elderly – those most vulnerable among us throughout the world, those who most need physicians, our traditions, our advocacy and our autonomy.

Sir William Osler said, "*Caring is the most important thing – so do it first. For it is the caring physician who most inspires hope and trust*".

In that spirit, I would like the members of the World Medical Association to be known as "The Caring Physicians of the World".

Toward that end, we are asking that each of our national medical associations too nominate one to three of their physician members who best reflect the principles of caring, ethics and science. We will select some 50 or 80 of these physicians and feature them in a publication to be distributed at our annual meeting in Santiago, Chile in October 2005. We are grateful for the support of the Pfizer Medical Humanities Initiative in this publication effort. The publication will be disseminated around the world to national medical associations, governments, foundations and other interested groups. This activity will also include a dedicated website, a series of regional meetings and bridges to other opportunities.

We seek the most caring physicians in the world, and we want the world to know who they are. We also want the world to know who we are at the World Medical Association- what we do, what we stand for, and the values we embrace in the service of our patients and the public health.

Caring – Ethics – Science

Our *Caring* is evident in our everyday work and the millions of hours of charity care we provide in the four corners of the globe.



Editorial

Our *Ethics* guide not only our practice of medicine, but also the practice of international physician organisations

Our *medical science* is evident in our growing success at treating and curing diseases once thought to be fatal, in the miracles of organ transplants, vaccines, chemotherapy, medical genetics and advanced technology.

Caring, Ethics and Science, are the watchwords of our profession. But everywhere I go around the world, physicians are being subjected to ever greater pressures. Subjected to forces that make it more and more difficult to live out the *credo* of our calling. The elimination of patient choice and the erosion of appropriate physician autonomy, put the sacred patient – physician relationship in jeopardy.

So it falls to us, we who represent international medicine to help restore pride, passion, enthusiasm and optimism among our colleagues wherever they practice, wherever they are challenged. The irony is that we are small, but our power to do good and to wield influence, is great.

We will reach out

- and encourage national medical associations to form where none exist today;
- to assist in the development of quality care and to enhance safety;
- and focus attention on developing world issues, HIV/AIDS, hunger and infectious diseases; violence, terrorism and torture; obesity, diabetes and cardiovascular disease; with Regional meetings of our WMA;
- in the houses of parliaments, the legislatures, the board rooms, in partnership with our brother and sister organisations.

And we will reach out with a strong, authoritative voice, as a fierce guardian of ethics and human rights on the international stage – because we remain the global voice of medicine.

It is a voice I have constantly heard in the years since I embarked on my course of study in international research – a journey that took me to Egypt, Nigeria and London. Since then, I have visited health care, edu-

cation and research facilities in more than 60 countries. These travels have given me unconditional respect for our global profession of medicine, and a deep sense of awe at the remarkable trust and hope which our calling commands and inspires.

I've witnessed the world of physicians like you more extensively that I could have imagined. I've seen your skill and caring and compassion in settings from the most advanced hospital to the most remote clinic, and seen how you manage the expectations created by innovations in medicine.

In these forty years I have seen much suffering – but I have also seen much relief of suffering. I have seen how good health leads to more literacy, more equality of opportunity in political and economic matters and in environmental improvements. When health improves, all other aspects of life improve. While health experts and economists may differ on how to go about it, the goal is the same, and the rewards are tremendous.

Politicians and governments like to think of medical care and research as a cost- an expense. But we know that medical care and research is an *investment*, a value – one with tremendous return.

In some countries there is a need for basics such as clean water, edible food and reliable electricity. But in these places they still know and respect their doctor. Our patients value medical research and innovation. They value medical care and they do not want their care undermined or withheld.

We must make sure that our patients understand how the problems we face as physicians undermine our ability to deliver that care. We need to communicate the value of our work and its importance to our patients, to the media and to our governments.

We need to continue to communicate the value of our work to each other. Few things are as central to the development of science and medicine as the exchange of information. By sharing information, either in journals or textbooks, or in international conferences such as these, we reaffirm what we understand about the art and science of medicine and broaden our knowledge base. These are gifts we bring back to our

patients and our communities – gifts we can use to make medical practice in our respective nations better, stronger than ever before.

Experiences such as this gathering are also gifts to us as physicians. They present opportunities for friendship, for greater understanding, not only of science and health policy, but also of culture and history. They challenge us to see our profession and ourselves from a new perspective, and change us for the better.

No one better understands the obstacles to quality health care than physicians and their patients. That is why, as WMA President I will take my cue from the people in the frontlines and make your agenda – your individual country's health care agenda, and your patients' agenda – my agenda – our agenda.

To fulfil this mission we have to be determined and stay that way – we can't give up or give in. This is a time of excitement and anticipation – for me a time of wonder and expectation. I look forward to working together as we shepherd the spirit of international medicine into this 21st century. I can only hope that my time as President will strengthen the bonds that unite us all. Bonds such as our shared commitment to the best science – to caring and compassion – and to excellence in every aspect of medicine – bonds such as our commitment to professional integrity, and to the ethic that requires us to put our patients first.

As physicians we can do much on our own, but we can do even more together. The WMA and its members are, and will continue to be an ethical beacon and a force of endless possibilities.

So let us continue to build bridges among our national associations and among the individual physicians in this room, and continue to share our dreams of better health for all. As I look ahead to the next year, it occurs to me that there is no greater gift than this *"To see medicine's traditions lived to the fullest, and to work to protect those traditions from harm"*.

How can we not be enthusiastic and optimistic about our profession with such enduring traditions- about our opportunity



to be useful and of value every day- and about the marvels of modern medicine?

There is an old Japanese proverb “*The go-between wears out a thousand sandals*”. We must be willing to wear out a thousand sandals – or more – in our advocacy for our patients and our profession.

Together, the family of medicine will bring its agenda to the global stage. We will encourage and lead patients and other partners to stand beside us. We will tear down the barriers that stand between our patients and us, and between us and quality medical care. We will be “The Caring Physicians of the World”.

Medical Ethics and Human Rights

Medical ethics and bereavement

Although there have been a great many publications and conference presentations on ethical issues related to death and dying, the ethical literature on the physician’s responsibilities to bereaved persons is relatively scant. In their interactions with the bereaved, physicians can either provide benefit or inflict harm, and so such interactions require ethical analysis and guidance. The bereaved are not the physician’s patients, so the well-established principles of the physician-patient relationship are not necessarily applicable.

In this article I propose a set of ethical principles for the interactions of physicians with the bereaved, namely, respect, compassion and truthfulness. The application of the principles will be illustrated by case vignettes. Particular attention will be given to the resolution of possible conflicts between principles, for example, compassion vs. truthfulness.

Ethical Responsibilities

The WMA *Declaration of Geneva* requires of the physician that “The health of my patient will be my first consideration”, and the *International Code of Medical Ethics* states, “A physician shall owe his patients complete loyalty and all the resources of his science”. However, the care of patients often involves interactions with family members, particularly when the patients are unable to make decisions about their own medical care. A considerable degree of consensus has developed on the ethical and

legal principles for dealing with family members in such situations, although the application of these principles is often problematic.² However, there has been very little consideration to date of the responsibilities of physicians to family members after the patient’s death.

Some might argue that physicians have no such responsibilities. Just as the physician-patient relationship ends with the death of the patient, so also do any professional relationships with the bereaved family members. If they are in need of consolation or some other type of care, they should seek it from bereavement counsellors, clergy or other specialists in the field.

A strong case can be made for an opposing view, namely, that physicians should address the needs of the bereaved. Sometimes physicians are the only ones who can fulfil these needs and their refusal to do so can result in harm to the bereaved. Examples of such situations are presented below.

Ethical Principles

Some of the ethical principles that govern the physician-patient relationship are equally appropriate to the relationship of physicians with the bereaved. Others, such as informed consent and confidentiality, are not as appropriate. The shared principles are these:

- *Compassion* – have understanding and empathy for those who are suffering.

- *Respect for persons* – acknowledge and promote their dignity and their autonomy.
- *Truthfulness* – do not lie, and be discreet when disclosing unwelcome or unwanted information.

Sometimes the application of these principles can be challenging, not least because they can conflict with one another. Moreover, the needs and wishes of the bereaved may conflict with those of the patient prior to death. It is, of course, preferable to anticipate and prevent conflicts before they arise. But if this has not been done, then a conflict-resolution process is required.

Case 1 – Compassion vs. truthfulness

Mr. A, a 30 year old single male, is admitted to an emergency ward with severe injuries resulting from an automobile accident and dies soon afterwards. Medical tests administered upon admission revealed the presence of heroin, which may well have contributed to the accident. When Mr. A’s parents arrive at the hospital, they ask the attending physician what caused the death. The physician wonders whether she should mention only the accident or should reveal the possible contributing factor as well. She fears that the family might be devastated by this knowledge.

This case demonstrates a conflict between the physician’s compassionate desire not to harm the family members and her duty to tell the truth. It is also about the limits of confidentiality. Traditional medical ethics was clear on this point, as is stated in the WMA *International Code of Medical Ethics*: “A physician shall preserve absolute confidentiality on all he knows about his patient even after the patient has died.” However, current medical ethics recognizes some exceptions to this principle. The British Medical Association advises that the obligation of confidentiality after the patient’s death “needs to be balanced with other considerations, such as the interests of justice and of people close to the



Medical Ethics and Human Rights

deceased person”.³ And the American Medical Association allows that, “When a family or other decision maker has given consent to an autopsy, physicians may disclose the results of the autopsy to the individual(s) that granted consent to the procedure”.⁴

In the case of Mr. A, it would be advisable for the physician to enter into discussion with the family to determine whether her fear of harming them is justified. Perhaps they already knew that their son was addicted to heroin, and therefore they would not be disturbed to know that this might have been a factor in his death. But if, after discussion, her fear is confirmed, she could be justified in withholding some information both to respect patient confidentiality and to avoid harming the family. Lying, however, is never permissible.⁵

Case 2 – Compassion and respect in the face of blame

Mrs. B is an elderly patient in a critical care unit for management of multiple organ failure. The medical team are agreed that there is no possibility of arresting her decline and that henceforth her care should be palliative only. The patient is non-communicative so the team turns to her family to seek agreement with this plan. The family members, perhaps hoping for a miracle, are adamant that the team continue their efforts to prolong the patient’s life. The team agrees reluctantly to do so. After five days of aggressive and apparently uncomfortable treatment, Mrs. B dies. The family members are angry and accuse the team of not doing enough to save their mother. Some of the team, among themselves, blame the family for Mrs. B’s unnecessary suffering and want to confront them openly about this. Others feel that compassion for the family requires that they accept these unjustified criticisms as part of the bereavement process.

In retrospect, the medical team may have wished that they had not acceded to the family’s wishes to continue aggressive

treatment for Mrs. B.⁶ However, they now have to make the best of a bad situation. It seems clear to them that the family’s grief at the death of the patient is compounded by their anger that the treatment was not successful and perhaps also by remorse for contributing to Mrs. B.’s prolonged suffering and dying. Team members may share this remorse, which is made worse by the family’s unjust accusation.

In such a situation, the medical team may well consider that they have no further responsibility to the family. However, as in the first case, the family members have needs that only the medical team can meet, and despite the obstacles, the team should try to provide compassionate help to the family in coping with their grief. This may involve inviting the family members to discuss the case while reassuring them that everybody had the best interests of Mrs. B. in mind, even though the decision to continue treatment was, in retrospect, probably not appropriate. Prior to encountering the family, the team members should meet by themselves and try to come to terms with their own remorse and anger.

Case 3 – Patient’s Directive vs. Survivors’ Needs

Mr. C. a 64-year-old man, has just died of a cardiac arrest. In his last will, made when he was 55, he stipulated that he did not want any funeral or memorial service. His surviving wife, four children and eight grandchildren were very close to him and are devastated by his death. Upon learning of his directive regarding no funeral or memorial service, they are torn between their need to bring closure to their grief at losing him and their desire to respect his wishes. To help resolve this conflict, they turn to his personal physician for advice.

Although the physician is not the decision maker in this case, he has been asked for advice because of his professional relationship with the patient while alive. The physician is faced with a conflict between his loyalty to his former patient and his compassion for the bereaved survivors. Here

again, the survivors’ grief at losing their loved one is compounded by another factor, in this case, his directive to have no funeral or memorial service. Even if the physician favours the survivors, he has to decide whether they have the right to counteract the express wishes of the deceased for their own benefit.

On this latter point, the physician must consider two opposing views. The first is that individuals have the right to dispose of their possessions after death, as expressed in their last will and testament, and nobody can change their decisions. Arguably this can apply to how their corpse should be treated, even though it is not considered property. The second view is that overriding previously expressed wishes regarding funeral arrangements cannot harm the deceased person and therefore is permissible if it will benefit others. At present there is no ethical consensus as to which of these views should prevail, and hence physicians have to decide for themselves which to favour in specific situations.

Conclusion

Each of these cases illustrates a conflict between important ethical principles. Although it is preferable that all principles be upheld, sometimes one must take priority over another. When such conflict arises, discussion among all those involved is important for reaching a decision that, if not unanimous, at least reflects a compromise that is tolerable to all. As medical authorities, physicians have a special responsibility to initiate such discussions and to contribute to their successful outcome.

John R. Williams

Readers’ comments on these cases are welcome and a selection will be published in the next issue of the Journal. Please send them to the Hon. Editor in Chief, Haughley Grange, Stowmarket, Suffolk IP14 3QT, United Kingdom, email: efmara@rowe110.fsnet.co.uk

¹ An earlier version of this article was presented at the 21st International Conference on Death and Bereavement, Eilat, Israel, 23-25



March 2004. The views expressed here are those of the author, not of the World Medical Association.

² WMA (2005) Medical Ethics Manual 47-50, available at www.wma.net

³ BMA (2004) Medical Ethics Today: The BMA's handbook of ethics and law (2nd ed.), London, BMJ Books, 439

⁴ AMA (2002) Confidentiality of Medical Information Postmortem, available at www.ama-assn.org/ama/pub/category/print/8354.html

⁵ Jackson, J (2001) Truth, Trust and Medicine, London and New York, Routledge

⁶ WMA (2005) Medical Ethics Manual 46 and 92, available at www.wma.net

The World Medical Association statement concerning the relationship between physicians and commercial enterprises

Approved by the WMA General Assembly, Tokyo 2004

A. Preamble

1. In the treatment of their patients, physicians use drugs, instruments, diagnostic tools, equipment and materials developed and produced by commercial enterprises. Industry possesses resources to finance expensive research and development programmes, for which the knowledge and experience of physicians are essential. Moreover, industry support enables the furtherance of medical research, scientific conferences and continuing medical education that can be of benefit to patients and the entire health care system. The combination of financial resources and product knowledge contributed by industry and the medical knowledge possessed by physicians enables the development of new diagnostic procedures, drugs, therapies, and treatments and can lead to great advances in medicine.
2. However, conflicts of interest between commercial enterprises and physicians occur that can affect the care of patients and the reputation of the medical profession. The duty of the physician is to objectively evaluate what is best for the patient, while commercial enterprises are expected to bring profit to owners by selling their own products and competing for customers. Commercial considerations can affect the physician's objectivity, especially if the physician is in any way dependent on the enterprise.

3. Rather than forbidding any relationships between physicians and industry, it is preferable to establish guidelines for such relationships. These guidelines must incorporate the key principles of disclosure, avoidance of obvious conflicts of interest and the physician's clinical autonomy to act in the best interest of patients.
4. These guidelines should serve as the basis for the review of existing guidelines and the development of any future guidelines.

B. Medical Conferences

5. Physicians may attend medical conferences sponsored in whole or in part by a commercial entity if these conform to the following principles:
 - 5.1 The main purpose of the conference is the exchange of professional or scientific information.
 - 5.2 Hospitality during the conference is secondary to the professional exchange of information and does not exceed what is locally customary and generally acceptable.
 - 5.3 Physicians do not receive payment directly from a commercial entity to cover travelling expenses, room and board at the conference or compensation for their time unless provided for by law and/or the policy of their National Medical Association.
 - 5.4 The name of a commercial entity providing financial support is pub-

licly disclosed in order to allow the medical community and the public to assess the information presented in light of the source of funding. In addition, conference organizers and lecturers disclose to conference participants any financial affiliations they may have with manufacturers of products mentioned at the event or with manufacturers of competing products.

- 5.5 Presentation of material by a physician is scientifically accurate, gives a balanced review of possible treatment options, and is not influenced by the sponsoring organization.
- 5.6 A conference can be recognised for purposes of continuing medical education/continuing professional development (CME/CPD) only if it conforms to the following principles:
 - 5.6.1 The commercial entities acting as sponsors, such as pharmaceutical companies, have no influence on the content, presentation, choice of lecturers, or publication of results.
 - 5.6.2 Funding for the conference is accepted only as a contribution to the general costs of the meeting.

C. Gifts

6. Physicians may not receive gifts from a commercial entity unless this is permitted by law and/or by the policy of their National Medical Association and it conforms to the following conditions:
 - 6.1 The gift is only of nominal value.
 - 6.2 The gift is not in cash.



Medical Ethics and Human Rights

6.3 The gift, even one of nominal value, is not connected to any stipulation that the physician prescribes a certain medication, uses certain instruments or materials or refers patients to a certain facility.

D. Research

7. A physician may carry out research funded by a commercial entity, whether individually or in an institutional setting, if it conforms to the following principles:

7.1 The physician is subject only to the law, the ethical principles and guidelines of the Declaration of Helsinki, and clinical judgment in performing research and does not allow himself or herself to be subject to external pressure regarding the results of his or her research or their publication.

7.2 If possible, a physician or institution wishing to undertake research

approaches more than one company to request funding for the research.

7.3 Identifiable information about research patients or voluntary participants is not passed to the sponsoring company without the consent of the individuals concerned.

7.4 A physician's compensation for research is based on his or her time and effort and such compensation is in no way connected to the results of the research.

7.5 The results of research are made public with the name of the sponsoring entity disclosed, along with a statement disclosing who requested the research. This applies whether the sponsorship is direct or indirect, full or partial.

7.6 Commercial entities do not suppress the publication of research results. If results of research are not made public, especially if they are negative,

the research may be repeated unnecessarily and thereby expose future participants to potential harm.

E. Affiliations with Commercial Entities

8. A physician may not enter into an affiliation with a commercial entity such as consulting or membership on an advisory board unless the affiliation conforms to the following principles:

8.1 The affiliation does not compromise the physician's integrity.

8.2 The affiliation does not conflict with the physician's obligations to his or her patients.

8.3 Affiliations and/or other relationships with commercial entities are fully disclosed in all relevant situations such as lectures, articles and reports.

9.10.2004

The World Medical Association Regulations in times of armed conflict

**Adopted by the 10th World Medical Assembly, Havana, Cuba, October 1956,
Edited by the 11th World Medical Assembly, Istanbul, Turkey, October 1957, and
Amended by the 35th World Medical Assembly, Venice, Italy, October 1983 and
The WMA General Assembly, Tokyo 2004**

1. Medical ethics in times of armed conflict is identical to medical ethics in times of peace, as established in the International Code of Medical Ethics of the World Medical Association. The primary obligation of physicians is to their patients; in performing their professional duty, their conscience should be their guide.

2. The primary task of the medical profession is to preserve health and save life. Hence it is deemed unethical for physicians to:

a. Give advice or perform prophylactic, diagnostic or therapeutic procedures that are not justifiable for the patient's health care.

b. Weaken the physical or mental strength of a human being without therapeutic justification.

c. Employ scientific knowledge to imperil health or destroy life.

3. During times of armed conflict, standard ethical norms apply, not only in regard to treatment but also to all other interventions, such as research. Research involving experimentation on human subjects is strictly forbidden on all persons deprived of their liberty, especially civilian and military prisoners and the population of occupied countries.

4. The medical duty to treat people with humanity and respect applies to all patients. The physician must always

give the required care impartially and without discrimination on the basis of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, or social standing or any other similar criterion.

5. Governments, armed forces and others in positions of power should comply with the Geneva Conventions to ensure that physicians and other health care professionals can provide care to everyone in need in situations of armed conflict. This obligation includes a requirement to protect health care personnel.

6. As in peacetime, medical confidentiality must be preserved by the physician. Also as in peacetime, however, there may be circumstances in which a patient poses a significant risk to other people and physicians will need to weigh their obligation to the patient against their obligation to other individuals threatened.



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| <p>7. Privileges and facilities afforded to physicians and other health care professionals in times of armed conflict must never be used for other than health care purposes.</p> <p>8. Physicians have a clear duty to care for the sick and injured. Provision of such care should not be impeded or regarded as any kind of offence. Physicians must never be prosecuted or punished for complying with any of their ethical obligations.</p> <p>9. Physicians have a duty to press governments and other authorities for the provision of the infrastructure that is a prerequisite to health, including potable water, adequate food and shelter.</p> | <p>10. Where conflict appears to be imminent and inevitable, physicians should, as far as they are able, ensure that authorities are planning for the repair of the public health infrastructure in the immediate post-conflict period.</p> <p>11. In emergencies, physicians are required to render immediate attention to the best of their ability. Whether civilian or combatant, the sick and wounded must receive promptly the care they need. No distinction shall be made between patients except those based upon clinical need.</p> <p>12. Physicians must be granted access to patients, medical facilities and equipment and the protection needed to carry out their professional activities</p> | <p>freely. Necessary assistance, including unimpeded passage and complete professional independence, must be granted.</p> <p>13. In fulfilling their duties, physicians and other health care professionals shall usually be identified by internationally recognized symbols such as the Red Cross and Red Crescent.</p> <p>14. Hospitals and health care facilities situated in war regions must be respected by combatants and media personnel. Health care given to the sick and wounded, civilians or combatants, cannot be used for morbid publicity or propaganda. The privacy of the sick, wounded and dead must always be respected.</p> |
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The World Medical Association Statement on health emergencies communication and coordination

Initiated February 2004

Approved by the WMA General Assembly, Tokyo 2004

A. INTRODUCTION

1. In late 2002, an outbreak of a new severe acute respiratory syndrome (SARS) began in southern China. The disease, which was caused by the SARS coronavirus, spread internationally in late February 2003. The most severely affected countries were China, Canada, Singapore and Vietnam, all of which experienced outbreaks before the issue of global alerts by the World Health Organization (WHO). According to WHO data, altogether 8422 cases occurred in 29 countries; in the four afore-mentioned countries, 908 cases were fatal.
2. SARS was an especially difficult new disease to diagnose and treat - it passed readily from person to person, required no vector, had no particular geograph-

ic affinity, mimicked the symptoms of many other diseases, took its heaviest toll on hospital staff, and spread internationally with alarming ease. The spread of SARS along the routes of international air travel emphasizes the fact that pathogens know no boundaries and reinforces the critical need for global public health strategies.

3. The main outbreaks of SARS occurred in areas with well-developed health systems. If SARS had become established in areas with weak health infrastructure, it is unlikely that containment would have been achieved so quickly. But even in well-developed health care systems, certain very significant flaws were demonstrated during this epidemic:

- Lack of effective real-time, two-way communication channels to front-line physicians;
- Lack of adequate resources, stock-piles of medication and supplies to deal with this type of catastrophe;

- Lack of surge capacity within acute care and public health systems.

4. A gap between public health authorities (national and international) and clinical medicine was demonstrated during this episode. At its September 2003 General Assembly, the WMA adopted a Resolution on SARS that: „strongly encouraged the World Health Organization to enhance its emergency response protocol to provide for the early, ongoing and meaningful engagement and involvement of the medical community globally...”

B. BASIC PRINCIPLES

5. The international community must be constantly alert to the threat of emerging disease outbreaks and ready to respond with a global strategy. The Global Outbreak Alert and Response Network (GOARN) of WHO has a significant role to play in global health security by:
 - combating the international spread of outbreaks;
 - ensuring that appropriate technical assistance reaches affected states rapidly; and



Medical Ethics and Human Rights

- contributing to long-term epidemic preparedness and capacity-building. The WMA has been actively involved in GOARN, where appropriate. The role of GOARN must, however, be acknowledged and actively promoted within the medical profession.
- 6. Sovereign states have a responsibility to address the health needs within their borders. Today, however, many urgent health security risks are not confined by national boundaries. Early detection, through effective national surveillance systems, of unusual disease events that threaten public health, and international cooperation between WHO, its member states, and non-governmental partners like the WMA, are required to effectively respond to public health emergencies of international concern. A strengthening of the International Health Regulations to broaden their scope to include new and future health emergencies and enable WHO to actively assist States in responding to international health security threats will provide additional tools for global epidemic control.
- 7. Effective communication between WHO and the WMA, the WMA and its member National Medical Associations (NMAs), and NMAs and physicians can strengthen the information exchange between WHO and its Member States during public health emergencies.
- 8. Physicians are often the first point of contact with the emergence of new diseases; therefore they are in a position to aid in all elements of diagnosis, treatment and reporting of affected patients and prevention of disease. Physicians with key expertise must be incorporated into the health emergency decision-making process so that the impact of national and international directives on clinical settings and patient care is understood.
- 9. WHO and its Member States must work with the WMA and NMAs to proactively address the safety of patients and of

health professionals involved in caring for the sick during outbreaks of new diseases. Delays in identifying and distributing supplies of protective equipment to health professionals and their patients exacerbate anxiety and risk of spread of infectious disease. National and international systems that stockpile relevant and adequate supplies and rapidly move them to affected areas should be created or enhanced. All the principles employed in the safeguarding of patient safety should be respected and followed in emergencies such as SARS.

C. RECOMMENDATIONS

- 10. That the WMA and member NMAs should work closely with WHO, national governments, and other professional groups to jointly promote the elements of this Statement.
- 11. That the WMA urge physicians to a) be alert to the occurrence of unexplained illnesses and deaths in the community, b) be knowledgeable of disease surveillance and control capabilities for responding to unusual clusters of diseases, symptoms and presentations, and assiduous in the timely reporting of suspicious cases of illness to appropriate authorities; c) utilize appropriate procedures to prevent exposure of infectious pathogens to themselves and others; d) understand the principles of risk communication so that they can communicate clearly and non-threateningly with patients, their families, and the media about issues such as exposure risks and potential preventive measures (e.g., vaccinations); and e) understand the roles of the public health, emergency medical services, emergency management, and incident management systems in response to a health crisis and the individual health professional's role in these systems.
- 12. That the WMA encourage physicians, NMAs, and other medical societies to participate with local, national, and international health authorities in developing and implementing disaster preparedness and response protocols for natural infectious disease outbreaks. These protocols should be used as the basis for physician and public education.
- 13. That the WMA call on NMAs to promote and support WHO's GOARN as a control coordinating entity in combating global health security threats.
- 14. That the WMA call for the establishment of a strategic partnership agreement with WHO, so that in case of epidemics, health communication can be stepped up considerably and two-way flow of information ensured.
- 15. That WHO should coordinate the development of an inventory based on existing stockpiles of supplies, so that such supplies can be rapidly deployed and accessed by physicians involved in the care of victims.
- 16. That WHO should strengthen the International Health Regulations to broaden their scope to include reporting of new and future health emergencies, and to enable WHO to actively assist States in responding to international health security threats.
- 17. That international agreements should be proactively explored to facilitate the movement of health professionals who are involved in the management of epidemics.
- 18. That research in the field of emergency preparedness should be enhanced by national governments and NMAs where appropriate, to better understand current flaws in the system and how to improve preparedness in the future.
- 19. That education and training of physicians should be modified to take into account the realities and specific needs required in the event of emergencies, and to ensure that due diligence is paid to patient and health care worker safety when managing patients with acute infectious diseases.
- 20. That physicians everywhere in the world, including those in Taiwan, have unlimited access to WHO programs and information concerning health emergencies.



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.”

Medical Science, Professional Practice and Education

Account by Dr. James Appleyard of his Presidential year of office 2003–2004

It has been a great honour and privilege to have represented the World Medical Association over the last twelve months as your President. My enduring memory has been the warm, friendly and respectful welcome from physicians worldwide. This was a the reaffirmation of our Declaration of Geneva that „my colleagues will be my brothers and my sisters“. We all share a common professionalism underpinned by our core values.

My main theme has been **the Right of a Child to Health Care** advocating our **Declaration of Ottawa**, highlighting the gap between the rich and poor both between and within the nations of the World, seeking to raise awareness and encouraging professional links particularly in education and research. I was able to spread the message from Africa (at the Ugandan Medical Association and in South Africa), to America (in Miami at the Academy of Pharmaceutical Physicians, New York, at the Hispanic Development Foundation, Portland Oregon to the medical students during their Global Health Week) and in Malta, where the theme was taken up in a four minute television feature augmented by their own archives.

Emphasizing that Violence is a leading public health problem particularly impacting on the lives and wellbeing of children, it was possible to stress the message of the

Helsinki WMA statement on Violence at meetings in the UK, Dominica, and notably at the annual meeting of the International Federation of Medical Student Associations (IFMSA) in Ohrid, Macedonia where the major theme was “Violence and Health”.

Finally I addressed the Symposium on “The application of Children’s Rights” at the 24th International Congress of Pediatrics in Mexico. At the Congress, Ms. Carol Bellamy from UNICEF emphasized that six out of the eight Millennium Goals were Child focused and that these were the goals of each government of the nations of the World. (UNICEF is publishing a Report on “Progress for Children” this autumn), Joy Phumaphi from WHO stressed the “unfinished agenda” of the “Alive at Five” initiative also pointing out that 11 million children are dying each year from preventable and treatable conditions. Thus children are bearing 1/3 rd of the world’s burden of disease, 9/10ths of which was affecting the poorer countries who had the least resources to cope with it. She said that the conference knew who was at risk, where they were, what must be done and how to do it. There are several concomitant initiatives such as the “Child Survival Partnership” with UNICEF, WHO and the World Bank that WMA, as the Association of the Worlds’ Physicians needs to join and there are also two effective pilot projects “Child Watch Africa” and the Save the

Children’s “Saving New Born Lives”, which are physician driven.

I have contacted all our national medical association members about the need to develop the WMA Declaration of Ottawa further, and am currently collating the replies.

There were two other areas for which, as President, I sought your support. Firstly, action to stop the increasing health problems of sub-Saharan Africa and to try and include more African National Medical Associations in our work; and secondly, the importance of medical education in this mission. My first engagement was to attend the “Strategies for Survival” Conference of the South African Medical Association under the inspired leadership of Dr. Kgosi Letlape. In the very challenging times ahead, all the members of the profession in South Africa are united both in the ethical values that underpin medical practice and in their quest for improved health services for the underserved. At the Annual Meeting of the Ugandan Medical Association, there was an opportunity to meet the Presidents of the Kenyan and Tanzanian Medical Associations in conjunction with the World Health Organization who were discussing the setting up of an East African Medical and Dental Association.

Concerning medical education, my aim was to raise awareness of international issues in a sustainable way by encouraging all medical students to do a month’s elective in a developing country and to suggest “exchanges” during residency training programmes, with the support and encouragement of joint research initiatives. I visited the International Department of Cornell Medical School where 40% of the students already have international assignments, met the Dean of New York College of Medicine and joined an inspired core of dedicated medical students who had arranged a Global Health Week at Oregon Health and Sciences University in Portland, Oregon. The energy and enthusiasm apparent at the International Federation of Medical Students Associations (IFMSA) in Ohrid, Macedonia, where I participated in the impressive opening ceremony held in the



Medical Science, Professional Practice and Education

Roman Amphitheatre, bodes well for the future. Members of the IFMSA are given free associate membership of the WMA after they graduate and have to move on from their own association. I hope as many of these young and dedicated physicians will attend our meetings and continue to help shape the future.

Our continuing work with other international professional associations is essential if we are to get our important messages across to the wider world community. I attended the excellent International Federation of Dentist's (FDI) first Regional Conference on Oral Health of the African Region, where the importance of including the major oral health problems within the collaborative general health programs was stressed in the presence of the Ministers of Health, WHO, representatives from Academia and dental practitioners. This was an inclusive conference dealing with the particular problems of the Region and one which we should be emulated in other Regions. The *European Forum for Good Clinical Practice* held a Conference on Clinical Research involving Academia, Industry, Medical Organizations, NGOs., seeking to influence current European legislation. The *European Platform for Patient Organizations* also expressed a concern to rescue reliable, ethical research initiatives on children.

The *World Health Professions Alliance Conference* held in Geneva after our Council Meeting in Divonne was a major innovation for the WMA. It is essential that we use such forums to join with other health professional colleagues to help tackle the global problems such as AIDS in a coordinated way. We must rise above the unnecessary turf battles that have belittled us all. The combined energy should be used to advocate our own shared policies so that together we can have much greater impact.

We are also a Founder Member of *Oxford Vision 2020* dedicated to the prevention of the forecast pandemic growth of largely preventable chronic diseases in the low and middle income countries and the poorer segments of society in the developed world. The forum includes academia, industry, professional and other non governmental

organization, patient groups and young people. It focuses on three risk factors tobacco, diet and lack of exercise, and four chronic diseases, diabetes, cardiovascular disease, chronic lung disease and some cancers, which lead to 50% of deaths globally. Our profession should set an example and follow the lead of our American colleagues with regard to diet, smoking, and exercise and reduce our own BMI's!

During a meeting of the Maltese Medical Association, I had the opportunity to encourage policy development to implement the Framework convention on Tobacco Control in a meeting with the Minister of Health. Some progress has been made with regard to the hazards of passive smoking on the island. Increasingly other countries are following the example of the Republic of Ireland. I wrote to the Prime Minister in the UK but he has so far failed to respond to the lead of his own Chief Medical Officer.

As the global representative body of some 7 million physicians we have a duty to support our "brothers and sisters" in times of great difficulty. In conjunction with our Human Rights Unit I tried through contacts to help free Dr. Biscet who is still languishing in a Cuban Jail as a result of his endeavors to promote human rights.

Some 10,000 doctors were **on strike** when I visited the Dominican Republic. Their concerns were the deteriorating situation in Government Hospitals, and the catastrophic effects of the fall in the value on the peso on basic maintenance of hospitals and on their own salaries. With the President of the Colegio Medico Dominicano I visited the Hospital General Materno Infantil and met the faculty, residents and the administration. The acute services budget was running at 15% of the hospitals needs. Hospital blackouts could last up to 13 hours, and sometimes the only available light during emergency operations had been from the LCD display of a mobile phone.

The **collapse** of the health system in Zimbabwe, whose government has ratified with the other African Countries the WHO's "Right to Health", is a humanitarian disaster with an additional 20,000 children dying each year in the year 2002 than

would have died ten years previously. Cuban doctors have been imported to try and reverse the effects of the loss of physicians from the country but they are unable to provide a proper primary care service because of language difficulties, and have settled in the cities. I met a dynamic group of non governmental organizations including the Amani Trust, Amnesty International, Zimbabwe Association and ZADHR to be informed about the current culture of repressive violence and torture in Zimbabwe which is being reinforced by the "War Veterans" and Youth Militia.

At the BMA Annual Representative Body in Llandudno, I met Dr Raj Doolabh, who then was Treasurer of the Zimbabwe Medical Association, one of our member associations. He did not expect significant change in Zimbabwe until Mr. Mugabe retired. Members of the opposition were being denied treatment for HIV/Aids. By-elections caused by their deaths allowed their replacement by ZANU members. Raj Doolabh suggested that the main help physicians from outside Zimbabwe could give their colleagues in Zimbabwe was through Continuing Medical Education, which is now mandatory in the Country. It was hoped that it would be possible to arrange a meeting with the ZIMA executive during a conference on AIDS which Dr. Letlape was organising in September but unfortunately this has not been possible.

Physicians in Iraq have started to develop links with the WMA following the attendance of Dr. Brennan on their behalf at the Council Meeting in May. At a recent Iraqi Medical Specialty Forum in Washington I met some Iraqi physicians from Baghdad and several others who had emigrated to the US. The security situation for physicians was very serious. Dr. Khalili, a Neurosurgeon, who had been kidnapped himself, said the main problems were security, a regular supply of electricity and water and the maintenance of medical supplies and provisions for Government Hospitals. On the other hand the budget for Health had been increased from \$16 million in Saddam Hussein's time to \$905 million. 600 extra medical facilities for essential care had been developed with 110 primary health care centers. Certain areas of the



country such as Kurdistan were peaceful and safe. It was suggested that a conference including all interested national medical associations in the region might be held to look how the health problems in the Region and in particular how those in Iraq could be addressed. This is a contribution that the WMA might make with the WHO subject to funding which I gather could be raised.

My last visit before handing over the badge of office to the President-elect, Dr. Yank Coble, was to talk about "Professionalism" at the annual meeting of the Icelandic Medical Association, a subject already taken up by the Editor of the WMJ. Here it was emphasized that we need to guard our professional autonomy by ensuring the

highest standards of education, care and ethics.

This last visit had a timely topic for reflection and illustrates the importance of the WMA continuing to support the work of physicians worldwide.

"Wherever the Art of Medicine is loved, there is also the love of humanity"

Hippocrates 400 BC

*James Appleyard MA (Oxon), MD (Kent),
FRCP (Lon), FRCPCH (UK)
President of the World Medical Association
2003–2004*

short supply in Holland. When cereal grains again became plentiful after the war, the incidence of coeliac sprue rapidly returned to previous levels. It was subsequently demonstrated that the gluten moiety of wheat was the offending agent. This simple observation has improved the quality of life of many thousands of people, including some of my relations.

There are also other factors of determinants of health that have had a tremendous impact on global health, these include patient education, improved diet and recognition of environmental factors. Inventions not directly related to medicine have also played an important role. For example, the invention of refrigeration may have saved more human lives than any other. Having said this, most people would still probably agree that, on balance, medical technology has had a positive impact on patient health and well-being. Life expectancy in most countries around the world has increased significantly and other markers of health, such as neonatal and maternal mortality, have also improved.

In general, medical technology has enhanced diagnostic accuracy and efficiency.

This has allowed physicians to see, diagnose and treat more patients in a shorter period of time, an important development in those many places with insufficient medical human resources. Patients live longer and have higher quality of life because of developments such as insulin pumps, prosthetic heart valves and artificial joints. However, in many parts of the world including my own country, great advances in medical technology have not generally translated into the large leaps in productivity as witnessed in other industries.

It would now appear that what we once referred to as the "future" of medical technology is nearly upon us.

Advances previously thought to be in the realm of science fiction are fast approaching reality. Among the numerous examples of medical technology, the most widely discussed is the genetic/genomic revolution.

Following the unravelling of the human genome, we have been witness to widespread and diverse predictions regarding

The future of medical technology – Implications for medical education and practice

Address to the World Medical Association (Tokyo, Japan)

**Henry Haddad, MD, FRCPC
Past President
Canadian Medical Association**

Thank you very much for asking me to speak to you today. It is indeed a great honour, and I would like to express my gratitude to our Japanese hosts for having invited me to address this distinguished gathering.

As many of you know, medical technology has revolutionized both medical education and the clinical practice of medicine in most parts of the world. Some people may still view advances in the field as a relatively recent development, and medical technology as a modern phenomenon.

However, medical technology as we understand it has been developing over many years, from the discovery of medical applications of radioactivity by Roentgen to the isolation of insulin by our own Canadian researchers Banting and Best. More recent developments have included implantable medical devices such as pacemakers and artificial valves, and the refinement of

organ transplantation techniques and antirejection drug regimens.

Although medical technology is not new, its development has certainly accelerated significantly, and keeping up with these changes has become a difficult challenge for many medical practitioners.

Before expanding on the concept of medical technology, it may be useful to take a step back and consider human achievements which are in today's terms decidedly "low-tech". Some of our most prominent medical practitioners, such as Pasteur, Burkett, Osler and Freud worked without the benefit of high technology.

It was in 1950 that Dicke suggested, in a landmark study, that certain dietary cereal grains were harmful to children with a coeliac sprue – a malabsorption disorder that is potentially fatal. He acutely observed that the incidence of coeliac sprue in children in Holland during World War II was markedly reduced and that previously diagnosed coeliac patients improved during the war years. During this period, grain production such as wheat and rye flour, were in



Medical Science, Professional Practice and Education

future applications of this new knowledge. The genomic revolution has raised many questions:

- Is the development of designer drugs based on a person's genetic makeup far off?
- Is gene therapy for currently untreatable conditions on the horizon or will the potential roadblocks prove insurmountable?

And what of stem cell transplantation?

- Is it truly the answer we have been seeking to help cure diabetes, Parkinson's Disease and spinal cord injury?

Along with these questions, which tend to provoke much excitement and optimism amongst medical practitioners and their patients, are other, potentially more troubling ones, which also deserve some attention and discussion.

Who will have access to these new technologies?

Access to care remains a major concern in many parts of the globe.

Access to care based on need rather than ability to pay, is still a pipe dream for most. It is certainly possible that as medical technology advances further, inequities in access to care will become more rather than less apparent and profound.

Wealthier nations who are able to fund the development of technologies will move further ahead, while those without the resources to compete will fall further behind.

This also has to do with the broader issues of resource allocation and priority setting. Hi-tech interventions tend to be relatively more expensive, both in terms of initial capital outlay and recurrent expenditures.

We need to ask ourselves how far we should go in allocating scarce resources to meeting increasing patient demands for these more costly interventions, when the end result may be decreased availability of simpler, but often equally effective, treatments. For example, many countries, including Canada, devote inadequate resources to caring for the terminally ill. It

is difficult to compare results seen from the use of medical technology to the benefits of compassionate care at the end of life. But decisions about where to allocate our precious resources must be made, and we must grapple with the issue of what kind of rationing in health care is morally acceptable.

Will predictive genetic testing disadvantage those with a genetic susceptibility to diseases for which there is no cure? For example, the development of a test could determine with certainty that a person would develop incapacitating and untreatable cancer or a neurological disorder at a young age would be likely to affect their insurability and employability if insurers and employers were able to gain access to this information. Currently the insurance industry is lobbying for exactly this type of access.

This threatens to have a detrimental impact on the doctor-patient relationship.

Presently in Canada it is known that in approximately 11% of medical encounters, the patient withholds relevant medical information because of concerns about who will have access to this data (including employers, banks and insurance companies). In the United States this percentage appears to be about 15% of patients. This problem is likely to become worse over time, with the advent of predictive genetic testing and the use of electronic health records, which could be accessed by other parties. If more medical information is withheld, and many experts estimate that the figure will rise to 20% of patients, the doctor-patient relationship will be further compromised, and there can be little doubt that patient care will suffer.

And what about the psychological impact of this type of information on these patients?

Just because we have the ability to uncover certain medical information, does that mean we should, especially when treatment or cures do not exist?

Does the benefit of planning for the future outweigh the potential burden of knowing when this future will end? Experts in this important field are currently considering these questions and others.

Will those who bear the burden of medical research ultimately reap the rewards of discovery? There are many examples of studies done in populations which ultimately do not derive the primary benefits from their results. There is no reason to believe that technological research might be any different, and as physicians we must do whatever we can to guard against this, and to ensure that the burdens and benefits of medical research are equitably distributed, – a major concern of the WMA:

Where is the line drawn between innovative medical practice and medical research? If a surgeon is perfecting a new procedure such as implantation of a new mechanical pump, does this qualify as standard medical practice or as research? The distinction can be a critical one. If it is research, it would require review by a duly constituted research ethics board and would be subject to a different standard of informed consent. Oversight and monitoring of the procedure would also be more stringent in many parts of the world if it were considered to be research rather than standard treatment.

Does the advance of medical technology further skew the balance between art and science in the practice of bedside medicine towards science, and what impact will this have on the education and development of future physicians?

Over many centuries, medical practitioners relied on the art of medicine to help relieve suffering. This was true for both diagnosis and treatment. As a very famous Canadian physician, Sir William Osler, once said: "Always listen to the patient, they will tell you the diagnosis." **The point is that testing should never be used as a substitute for a good history.** The emphasis is today – and I see this every day at my University Hospital – on scan and blood test. Keep repeating to your students that there is nothing more satisfying or more informative than sitting down with the patient and really considering what they are saying. Sir William Osler was right – "Technology is there to complete the art of medicine – it is not a substitute"!

However, in modern times, the thorough bedside medical examination has often given way to the full-body or MRI scan. The



long and emotional discussion about the impact of a person's physical illness on their psychological well-being has been replaced by the prescription for the newest anti-depressant, often one the patient has seen advertised on TV. These changes have altered the physician-patient relationship, and usually not for the better.

Medical students today train in an environment with a bias towards specialization of care, often driven by rapid advances in technology.

Physicians cannot be expected to keep up with every new development when the body of medical knowledge is, by some estimates, doubling every year. These factors have led to increasing subspecialization and the gradual erosion of the role of the primary care practitioner, which is so crucial to the maintenance of overall patient health and well being.

Students are also often attracted to the more glamorous and higher paying specialties, which not coincidentally, are often those which make the most use of technology.

Unless we are able to swing the pendulum back towards the art of medicine, and demonstrate to a greater number of students the merits and rewards of primary practice, we will see a further decline of the doctor-patient relationship and a further dehumanization of the practice of medicine. This is not in the best interest of either the physicians or their patients.

As we have focused more attention on acute care and life-saving technologies, have we neglected areas such as public health and health promotion? Certainly much of the attention and publicity tends to be focused on those medical interventions that save individual lives – the coronary bypass, the new cancer treatment, the kidney transplant. And while this attention (and, not coincidentally, much of the funding) has been focused on acute care and the impact of new advances, the public health and promotion infrastructure has been slowly deteriorating.

We need look no further than SARS for an example. Billions of dollars world-wide are currently being poured into the development of medical databases so that, for

example, emergency physicians can access patient information and test results at the touch of a button. This we would all agree is a positive development-improving health care and eventually hopefully reducing cost. In the meantime, public health care workers in Toronto were faced with a completely outdated and inadequate computer system to try and track new cases of SARS and their contacts during the height of the epidemic. In many offices, sticky notes were used instead of computer databases to keep track of new developments. While we may have learned a lesson from this example, whether or not we can apply it in a meaningful and ongoing way remains to be seen.

Finally, will the emphasis currently placed on technological research and its translational application detract both attention and funding from equally important basic science research?

Twin Studies

Blame your genes for a restless night's sleep – new research revealed

New research carried out by doctors in the Twin Research Unit at St. Thomas' Hospital, London, U.K. indicates that genetic factors make a "substantial contribution" to common sleep disorders.

Professor Tim Spector, Director of the Unit, has revealed the results of a new study of almost 2,000 pairs of female twins during a press briefing at the Science Media Centre.

1,937 pairs of identical and non-identical twins from the Twin Research Unit database were asked questions on sleep disorders such as obstructive sleep apnoea (OSA) and restless legs syndrome (RLS).

Dr. Adrian Williams, a co-author of the research study and Consultant in the Sleep Disorders Centre at St. Thomas' Hospital, says: "Sleep disorders are surprisingly common and it is increasingly recognised that they can have a devastating impact on sufferers' everyday lives."

Just as medical students are more likely to be attracted to the more glamorous specialties, so too will scientists in training often follow their mentors as they pursue the dollars and glory promised by the next technological miracle. Let me conclude by saying that, overall, we have been well served by advances in medical technology, and our patients in general are living longer and healthier lives because of these developments.

However, we must not push ahead blindly or unquestioningly.

I have tried to raise several questions, which I think require further thought and discussion. Until we can answer these questions, and others, the future of medical technology is likely to remain uncertain at best and troubling at worst.

"For example, OSA affects approximately 24% of men and 9% of women aged 30 to 60. It even contributes to road traffic accidents when sufferers fall asleep at the wheel."

Twins were asked, in connection with OSA, if they ever snored and, if so, how often their snoring disturbed others or caused them to wake up – they were also asked if they experienced daytime sleepiness.

In relation to RLS, twins were asked if they ever experienced an urge to move their legs during the night to relieve tingling or numbness and also if they ever found their legs jerked involuntarily during the night.

Key findings of the research study include:

- Genes contribute significantly to sleep disorders – approximately 50% of the variance in liability to these symptoms is due to genetic factors.



World Health Organization

- Heritability was estimated to be 42% (disruptive snoring), 45% (daytime sleepiness), 54% (restless legs) and 60% (legs jerking).
- An important strength of the research study is that these heritability estimates have been corrected to take into account other influences on the symptoms of snoring and daytime sleepiness such as sufferers being overweight or heavy smokers.

Professor Spector says: "These results suggest a substantial genetic contribution to the symptoms of both obstructive sleep apnoea and restless legs syndrome and that could be good news for people who suffer from

these conditions if the genes responsible can be identified.

"One reason the genes for disruptive sleep may have persisted is that poor sleep patterns make people gain weight and retain fat. These genes may have helped our ancestors through periods of famine and the Ice Age."

The Twin Research Unit was originally set up at St. Thomas' Hospital (London U.K.) in 1992 to look at the role that genes play in the development of rheumatic diseases in older women and has now expanded to look at most common diseases, behaviours and traits.

nearly half a million of these new nets each year and hopes to ramp up production to pass the one-million mark in 2005.

The latest generation of highly effective malaria treatments known as artemisinin-based combination therapy (ACT) offer a cure that so far has met only minimal resistance from the malaria parasite. Derived from the *Artemisia annua* (sweet wormwood) plant traditionally used to treat malaria in China, these medicines have become the drug of choice for more than 40 countries (20 of them in Africa), and demand for them has increased rapidly.

The factory visit took place in the context of the 9th board meeting of the Global Fund, which was held in Arusha from 17–19 November. "The Global Fund has committed nearly US\$ 1 billion over the coming two years and expects to scale up malaria funding substantially," said Global Fund Executive Director Feachem. "These funds will be used by countries to purchase both preventive and curative tools – including long-lasting nets, artemisinin-based combination therapy, and insecticide spraying where suitable – for maximum impact against malaria." The Global Fund is also working with Roll Back Malaria partners to provide the financial incentives that will bring a new malaria vaccine to the market.

"This is a new era for malaria control," declared the Roll Back Malaria Partnership's Executive Secretary Coll-Seck. "Demand for this latest generation of effective malaria-control tools is increasing rapidly, and so is funding. If we can replicate the success of A to Z to ensure an adequate supply of long-lasting insecticidal nets, and work with pharmaceutical companies to ensure ACT supplies, we will demonstrate the true power of public-private partnerships by dramatically reducing malaria deaths."

Background

To provide a coordinated global approach to fighting malaria, the Roll Back Malaria Partnership was launched in 1998 by the World Health Organization, the United Nations Children's Fund (UNICEF), the

World Health Organization

New tools and increased funds will beat malaria, say global leaders

Arusha, Tanzania – New technologies for malaria prevention and treatment, combined with an increase in available funding, are fuelling optimism in the fight against malaria. Global leaders gathered in Arusha for the launch of the Olyset® Net at A to Z Textile Mills – the first factory in Africa to produce this long-lasting insecticidal mosquito net – agreed that conditions were right for a massive scale-up in the battle against the disease, which claims more than a million lives each year and hampers development, especially in Africa.

The President of the United Republic of Tanzania, Benjamin W. Mkapa, delivered a message of hope to a group of dignitaries including US Secretary of Health and Human Services Tommy Thompson, Roll Back Malaria Partnership Executive Secretary Awa Marie Coll-Seck, and Global Fund to Fight AIDS, Tuberculosis and Malaria Executive Director Richard Feachem, as well as representatives of the

Roll Back Malaria partners who had made the A to Z technology transfer possible.

"Long-lasting insecticidal nets are Africa's best hope for preventing malaria, and we are very proud that Tanzania is the home of Africa's first manufacturer of these nets," said President Mkapa. "We hope that this shining example of technology transfer and strengthening of local industry will serve as a model for similar efforts, making the nets more affordable and available to the millions of Africans who need them."

The technology for long-lasting insecticidal nets, which embed insecticide within the net's very fibres and therefore retain their efficacy for up to five years without retreatment, was transferred to Tanzania last year in a groundbreaking collaboration between private and public sector players including the Acumen Fund, Sumitomo Chemical, the World Health Organization, UNICEF, ExxonMobil, and Population Services International. A to Z Textiles now produces



United Nations development Programme (UNDP) and the World Bank. The Partnership's goal is to halve the global burden of malaria by 2010.

The Partnership now includes malaria-endemic countries, their bilateral and multi-lateral development partners, the private sec-

tor, non-governmental and community-based organizations, foundations, and research and academic institutions and has succeeded in raising global awareness of malaria, generating increased resources and achieving consensus on the tools and priority interventions required to control the disease.

MDG target of increasing the proportion of births attended by a skilled attendant to 90% by 2015.

The shortfall is most acute in the developing world. In developed countries and countries in transition, the average rate is above 90%. The lowest levels are in Eastern Africa (33.6%), South-Central Asia (37.5%) and Western Africa (39.6%), with much higher levels in South America (84.8%). Globally, only 61% of all childbirths are attended by a skilled birth attendant.

"Life-threatening complications occur in 15% of all births," says Joy Phumaphi, Assistant Director-General of Family and Community Health at WHO. "For a mother and her newborn, a skilled birth attendant can make the difference between life and death. Not only can they recognize and prevent medical crises on the spot, but they can refer women for life-saving care when complications arise."

The joint statement defines a skilled attendant, sets out what skills they should have, and the training and support they need. In their statement, WHO, ICM and FIGO jointly urge the international community, professional associations and donors to make skilled care for all pregnant women and their newborns a priority – focusing on increasing the number of skilled birth attendants, strengthening their capacity and increasing the resources available to them.

Midwives/Gynaecologists

Skilled attendants vital to saving lives of mothers and newborns

Geneva – The number of skilled attendants in developing countries needs to be increased by at least 333,000 if the international community is to meet the Millennium Development Goal (MDG) of reducing maternal deaths by two thirds by 2015, according to a joint statement* issued by the World Health Organization, the International Federation of Gynaecologists (FIGO) and the International Confederation of Midwives (ICM).

A skilled attendant is a health professional with the competencies for care during normal birth and the capacity to recognize, manage and refer complications in the woman and newborn. Skilled attendants play a pivotal role in reducing maternal and newborn mortality and morbidity, says the joint statement of WHO, ICM and FIGO. The statement calls for better monitoring and reporting on progress in achieving the

Aids

A globally effective HIV vaccine requires greater participation of women and adolescents in clinical trials

Geneva – Greater participation of women and adolescents is needed in HIV vaccine clinical trials, according to a group of international experts, who attended a consultation on HIV vaccine trials in Lausanne, Switzerland.

The meeting, organized by the World Health Organization and the Joint United Nations Programme on HIV/AIDS (UNAIDS), brought together for the first time 40 experts from around the world to address the issues of gender and age in par-

ticular, as well as race in HIV vaccine-related research and clinical trials.

"We have identified measures aimed at rectifying the injustice stemming from the frequent exclusion or low participation of women and adolescents in HIV vaccine clinical trials. Clinical trial enrolment needs to be more inclusive, so the benefits of research are more fairly distributed," said Dr. Ruth Macklin, co-Chair of the meeting and a bioethics professor at the Albert Einstein College of Medicine in New York City.

Studies show that women, when exposed to HIV, are at least twice as likely to become



World Health Organization

infected with HIV as their male counterparts. In parts of sub-Saharan Africa, girls and young women are up to six times more likely to be infected than their male peers. Girls and young women aged 15-24 make up 62% of the young people in developing countries living with HIV or AIDS. "Women and girls are particularly vulnerable to HIV infection for biological, social and economic reasons," said Dr. Catherine Hankins, Chief Scientific Advisor at UNAIDS, who spoke at the opening of the meeting.

Youth and young adults are also at high risk for HIV: about half of new HIV infections in the developing world occur among 15 to 24 year olds.

"In spite of the epidemiological reality, women and adolescents, especially girls, have often had minimal involvement in clinical trials of HIV vaccines, as compared to men. This is in spite of the fact that they would be major beneficiaries of a future HIV vaccine," said Dr. Saladin Osmanov, Acting Coordinator, WHO-UNAIDS HIV Vaccine Initiative, WHO. The Initiative promotes the development of an HIV vaccine, including through the facilitation of clinical trials.

Reasons for the lack of participation of women and young people in HIV vaccine trials to date are numerous and include: lack of empowerment, independent decision-making and education in some settings; social isolation; discrimination; pregnancy and the potential effects of a candidate vaccine on a foetus; stigma associated with high-risk behaviour; trial enrolment criteria; and issues concerning confidentiality and informed consent. For instance, the participation of a minor in a clinical trial would require the parents' or guardian's consent, and youth must fully understand what receiving a candidate HIV vaccine does or does not mean for their health.

Experts agreed that these obstacles could and should be overcome because HIV vaccines need to be tested in a heterogeneous population, particularly in those most in need of vaccine. Vaccines for several infectious diseases have shown varying levels of efficacy in different gender, age and racial or ethnic sub-groups. The 1998-2003 trial

of VaxGen's AIDSVAX, the only candidate vaccine so far to reach Phase III efficacy testing in large numbers of people, found that although the vaccine was not effective overall, non-whites and women possibly had some degree of protection. This finding merits further investigation.

More than 30 promising, new candidate HIV vaccines are currently being tested in human clinical trials, the majority of which began in the past four years. The number of AIDS vaccine candidates in small-scale human trials has doubled since 2000. The trials are taking place in 19 countries. A safe, effective and affordable vaccine against HIV would be a powerful arm against the AIDS epidemic which continues to infect five million adults and children and kill three million people every year.

The international HIV vaccine research mission is to develop HIV vaccines that are licensed, acceptable, available and accessible by all populations regardless of their gender, age, socio-economic status, race, ethnicity or country, and that are effective across the board. Special attention must be paid to ensure that vulnerable groups, particularly women and girls, benefit from an HIV vaccine.

Recommendations – covering ethics, policy, advocacy, community participation,

clinical trial design and research gaps – issued at the consultation will form the basis of a policy document that will help guide those designing and conducting HIV vaccine clinical trials. An important suggestion for future work was to study HIV clinical trial sites with enrolments that include appropriate numbers of people from different sub-groups, and to try to better understand the barriers that have prevented wider participation.

The challenges to the creation of an HIV vaccine are mainly economic, primarily due to the lack of incentive by the private sector to engage in product development. However, new momentum has been generated in the field of HIV vaccine research. In June 2004, the G8 countries endorsed a Global HIV Vaccine Enterprise to accelerate efforts to develop an HIV vaccine through an expanded capacity to test and manufacture vaccines, the establishment of vaccine development centres around the world and the development of an integrated global clinical trials system allowing laboratories to easily share data.

Represented at the consultation, co-sponsored by WHO and UNAIDS, were governmental public health research institutions in developing and industrialized countries, medical schools, industry, foundations and non-governmental organizations.

Priority Medicines

Landmark report could influence the future of medicines in Europe and the world

Gaps in pharmaceutical research and innovation can be closed, says WHO report

Geneva – The World Health Organization has released a groundbreaking report which recommends ways in which pharmaceutical research and innovation can best address health needs and emerging threats in Europe and the world.

Priority Medicines for Europe and the World, commissioned by the Dutch Government as current president of the European Union

(EU), identifies a priority list of medicines for Europe and the rest of the world, taking into account Europe's ageing population, the increasing burden of non-communicable illness in developing countries and diseases which persist in spite of the availability of effective treatments. The report looks at the gaps in research and innovation for these medicines and provides specific poli-



cy recommendations on creating incentives and closing those gaps.

At present, pharmaceutical research and development are based on a market-driven incentive system relying primarily on patents and protected pricing as a prime financing mechanism. As a result, a number of health needs are left unaddressed.

The report identifies gaps for diseases for which treatments do not exist, are inadequate or are not reaching patients. Threats to public health such as antibacterial resistance or pandemic influenza, for which present treatments or preventive measures are unlikely to be effective in the future, also require immediate action.

"This report identifies health gaps and potential solutions. It is particularly timely for a continent where an ageing population faces increasing health problems, and for a world where old and new threats no longer respect national borders," said Dr. LEE Jong-wook, Director-General of WHO from the Ministerial Summit on Health Research, taking place in Mexico.

In addition, the report addresses obstacles where effective medicines could be better delivered to the patient. It emphasizes fixed dose combination medicines (medicines which include more than one active ingredient in one pill) as worthy of further research and development. Finally, it looks at particular groups such as children, women and the elderly, who have frequently been neglected in the scientific or medicine development process.

The 17 priority conditions identified by the report are:

Future public health threats: infections due to antibacterial resistance; pandemic influenza;

Diseases for which better formulations are required: cardiovascular disease (secondary prevention); diabetes; postpartum haemorrhage, paediatric HIV/AIDS, depression in the elderly and adolescents;

Diseases for which biomarkers are absent: Alzheimer disease; osteoarthritis;

Neglected diseases or areas: tuberculosis; malaria and other tropical infectious dis-

eases such as trypanosomiasis, leishmaniasis and Buruli ulcer, HIV vaccine;

Diseases for which prevention is particularly effective: chronic obstructive pulmonary disease including smoking cessation; alcohol use disorders; alcoholic liver diseases and alcohol dependency.

The report suggests that Europe can and should play a global leadership role in public health, as reflected by its history of social services provision and social safety nets for all citizens. In many developing countries, the poor are increasingly affected by the chronic diseases that are widespread in Europe, including cardiovascular disease, diabetes, tobacco-related diseases and mental illnesses such as depression. Moreover, the ten countries that joined the EU in 2004 have additional public health challenges.

For all number of diseases that affect people in all members of the EU, no effective and safe medicinal treatment is yet available (e.g. Alzheimer diseases and several cancers). For some diseases, potentially large markets exist for medicines (e.g. breast cancer) and associated pharmaceutical research is likely to be intensive for certain therapeutic classes. For other categories of medicines, the number of patients is low (e.g. cystic fibrosis) or the market-driven pharmaceutical industry has failed to pursue research and development (e.g. new medicines for tuberculosis).

Innovative solutions

The report suggests that efforts to shorten the medicine development process without compromising patient safety would greatly assist in promoting pharmaceutical innovation. For instance, the EU could create and support a broad research agenda through which the European Agency for Evaluating Medicines (EMA), national regulatory authorities, scientists, industry and the public would critically review the regulatory requirements within the medicine development process for their relevance, costing, and predictive value.

Health authorities are responsible for medicines reimbursement decisions that aim to

ensure safe and effective treatment for all patients, while reconciling this with budgetary constraints. Health and reimbursement authorities and manufacturers should agree on general principles for the evaluation of future medicines. For example, the EU Commission and national authorities should support a research agenda on the various methods of rewarding clinical performance and linking prices to national income levels. The report authors believe that these measures will help encourage industry to invest in the discovery of innovative medicines that address priority health care needs.

The report maintains that where the market is strong and the problem is poor understanding of the basic biology of the disease, investment in basic research and in facilitating innovation by the pharmaceutical industry will be needed. Where the biology is well understood but the market is weak, public support for breaching the gap between basic and clinical research – possibly through public-private partnerships and other not-for-profit development initiatives – will be the preferred solution. Where the biology is not well understood and there is also a weak market, then biological research can be supported while market incentives are created for the pharmaceutical industry, through reducing barriers to innovation and through improving reimbursement rewards.

The report points out that major pharmaceutical gaps have been closed in the past. For example, until 1975 the main treatment for severe peptic ulcer – a common ailment – was surgery. Following a long period of focused research in biological mechanisms underlying ulcer disease, effective medical treatments were discovered. These breakthrough discoveries, combined with the discovery that most ulceration was caused by a bacteria treatable with antibiotics, made surgery unnecessary.

The recommendations contained in the report could have a significant impact on research innovation and policy, with support from European leaders. The report was discussed further at a High Level Meeting in the Hague on November 18th 2004.



World Health Organization

Common Genetic Test

First standard adopted by WHO

Geneva – The first international standard for a human genetic test has been approved by the World Health Organization. Use of the standard will help to improve the accuracy and quality of laboratory results worldwide from a frequently used genetic test. This test identifies a genetic predisposition to thrombosis – a potentially life-threatening blood condition – and could therefore enable people to take preventive measures.

“Establishment of the first international standard for a genetic test is an important milestone. Genetic testing procedures are playing a vital and growing part in clinical medicine. This new standard will help to ensure that the tests are giving accurate results worldwide,” said Dr. Davie Wood, Coordinator of Quality Assurance and Safety of Biologicals at WHO.

The newly established standard, formally called an international Reference Panel, relates to the testing of patients for a particular genetic mutation known as Factor V Leiden. Discovered in 1994, this mutation is one of the most common genetic risk factors for venous thrombosis (blood clot), and is involved in 20–40% of all cases. Factor V Leiden induces a defect in the natural anti-coagulation system.

The test for Factor V Leiden is one of the most frequent genetic tests carried out in clinical laboratories. It determines the presence or absence of the mutation, which has been shown to result in a seven-fold to 80-fold higher risk of thrombosis depending on whether the individual carries one or two copies of the gene respectively.

The new standard was agreed at the 55th session of one of WHO's longest-standing committees, the WHO Expert Committee on Biological Standardization (WHO ECBS) which met from 15 to 18 November in Geneva. It is composed of ten global experts from academia, industry and national regulatory authorities, as well as 25 advisors.

One of WHO's key functions, specified in its Constitution, is to develop, establish and promote international standards with respect to biological and other products. WHO is the world authority on biological standards, and has established more than 300 standards covering vaccines; blood products; therapeutic biological products, such as insulin; and diagnostic tests, such as those that detect HIV in a blood product.

Researchers are currently investigating whether or not there is a link between air travel and deep vein thrombosis. This is one example of a condition which may be more likely as a result of the Factor V Leiden mutation. Having information about their genetic make-up could allow travellers at risk to take additional precautions.

The standard for Factor V Leiden was developed by WHO partner and the leading international laboratory for biological standards, the National Institute for Biological Standards and Control (NIBSC) in the United Kingdom, in collaboration with colleagues from the clinical National Quality Assessment schemes for Blood Coagulation and the Royal Hallamshire Hospital in Sheffield, UK.

“This is an important step in genetic medicine. I am delighted that the NIBSC has taken the international lead in developing the first WHO standard for a genetic test. This will provide information on susceptibility to venous thrombosis, and ultimately will deliver clinical benefits for people at increased risk of developing thrombosis,” said Professor Gordon Duff, Chairman of the NIBSC Board. NIBSC is currently developing several other new reference standards to support testing for a range of other clinically important genetic characteristics.

DNA-based genetic testing offers enormous promise for improved disease management by giving doctors better information about patients on which to base diagnosis and decisions about treatment or counselling. It also offers the potential for better targeting of therapies and drugs to those patients most likely to benefit. Hundreds of different genetic tests are currently available.

A recent study estimated that in the European Union alone more than 700,000 genetic tests were performed in 2002; and found that at

least 700 laboratories and 900 clinical centres in Europe were carrying out genetic tests.¹ Though the exact number is unknown, it is likely that millions of genetic tests are being carried out worldwide each year.

Setting standards is particularly critical as genetic testing has expanded to more and more laboratories throughout the world. Genetic testing must be done consistently in all laboratories around the world and to high standards in order to give confidence in the results.

A standard for a biological product is essentially a yardstick (either on paper or in an ampoule, in which there is a specially prepared reference material) which enables laboratories around the world to compare results. The work of the WHO Expert Committee on Biological Standardization contributes to global public health in a fundamental way since the written guidance and reference preparations established on its recommendations define international technical specifications for the quality and safety of biological medicines and in vitro diagnostic procedures.

Once a WHO collaborating laboratory physically creates a standard, it is typically evaluated by 15 other top laboratories. The WHO ECBS reviews all the laboratory data and decides to approve or not the proposed standard for international use. The rigorous assessment of the standard for the Factor V Leiden genetic test was carried out by an international panel of investigators in conjunction with the International Society on Thrombosis and Hemostasis (ISTH).

The announcement of the first international standard for the genetic diagnosis of the Factor V Leiden mutation is a significant step forward in the assurance of high quality genetic testing. In the future, the WHO ECBS will likely approve standards for other genetic tests, the increasing use of which will enable prevention and early treatment of genetic disorders, improving quality of life.

¹ Ibarreta, D., Elles, R., Cassisman, J.-J., Rodriguez-Cerezo, E., and Dequeker, E. Towards quality assurance and harmonization of genetic testing services in the European Union. *Nature Biotechnology*, 22, 1230–1235 (October 2004).



Aids

Who awards million dollar contract for global treatment preparedness activities

Geneva – The World Health Organization is awarding a US\$ 1 million contract to a global consortium of people living with HIV/AIDS and treatment activists to help prepare people living with HIV/AIDS (PLWHA) for antiretroviral (ART).

Following a competitive process, the Collaborative Fund for HIV Treatment Preparedness consortium – a programme created in 2003 to channel funds for community-based education, managed by the US-based organization Tides Foundation – was awarded the contract through WHO's 'Preparing for Treatment' programme.

The WHO initiative supports community-based treatment preparedness activities as part of the drive to increase access to treatment and prevention in line the "3 by 5" target to get three million people living with AIDS on antiretroviral treatment by the end of 2005.

"People living with HIV/AIDS need to know about antiretroviral medicines. Those who currently have access to treatment need this knowledge to be informed about their treatment and to ensure they know how and when to take their medicines. Those without access need this knowledge in order to become active in advocating for scale up in their countries," said Dr. LEE Jong-wook, WHO Director-General.

In implementing the million dollar grant, Tides Foundation-Collaborative Fund is supporting more than 30 networks of PLWHA around the world in treatment preparedness activities, including treatment literacy projects and civil society advocacy initiatives.

The Collaborative Fund distributes funding to regional networks of people living with HIV/AIDS who then establish grants initiatives and tendering processes at the community level. In each of these regions, workshops are already under way to help devel-

op the treatment preparedness agenda. Supporting the 'Preparing for Treatment Programme', UNAIDS has contributed over US\$ 100,000 over the past year to these regional meetings and will be providing a 'best practices' document based on experiences of programmes in late 2005.

"UNAIDS is pleased to support WHO in this innovative movement to expand treatment access. Providing people living with HIV with the necessary tools to access treatment is vital to improving their quality of life and engaging them in expanding access to treatment and care," said Dr. Peter Piot, UNAIDS Executive Director.

"This proposal ensures the participation of people living with HIV/AIDS in all aspects of the programme and at all levels of decision-making and activity," said Dr. Jim Yong Kim, Director of the HIV Department at WHO.

Treatment preparedness activities aim to give people on or in need of antiretroviral treatment easy-to-understand information about issues such as how HIV works in the body, HIV testing, opportunistic infections, the different treatment types available and how they work, how to take treatment correctly and the support services that are available.

This information can be conveyed in many ways, including through workshops, publications and other activities designed to educate communities about obstacles to accessing treatment and enable them to contribute to local treatment policy development and advocacy efforts. All treatment preparedness activities aim to ensure the meaningful involvement of people living with AIDS and their communities in decisions regarding their care, including the distribution of resources.

"This is perhaps one of the greatest UN-led examples of implementation of the GIPA (Greater Involvement of People with AIDS) principle [established in 1994]. The con-

tract award shows a commitment to a community-driven model, relying on the expertise of people living with AIDS and community-based groups to developing projects they need to do. It also acknowledges that treatment preparedness is as important a component of the "3 by 5" success as is receiving the drugs", said David Barr, Senior Philanthropic Advisor for Tides Foundation.

In addition to WHO, the Collaborative Fund is supported by a growing number of donors from around the world including Rockefeller Foundation, Ford Foundation, Open Society Institute, the Stephen Lewis Foundation, and AIDS Fonds Netherlands. To date, US\$ 3.4 million has been raised to support activities through the end of 2005 and fundraising for continued activities is on-going.

The concept of treatment preparedness was defined at the international treatment preparedness summit, held in Cape Town, South Africa in March 2003 and was based originally on examples of activists preparing for their own treatment. The summit led to the creation of the Collaborative Fund to generate funding for such activities.

WHO's 'Preparing for Treatment Programme' was initiated in July 2004 when WHO called for applicants with global reach and local capacity in the world's most affected countries to submit tenders to design and operate programmes. With over 140 enquiries, some 30 tenders were reviewed by a WHO panel before the award of the contract to Tides Foundation-Collaborative Fund.

"Making this happen has been a dream for WHO and underlines the recognition that the future of health belongs as much in the hands of those affected as those who care for them. Treatment preparedness is key to "3 by 5" and a first instalment towards reaching universal access for all who need it," said Dr. Kim.

The million dollar contract is the first of what WHO hopes will be an ongoing process within the Preparing for Treatment Programme with the aim of supporting additional community-based treatment preparedness activities as funding becomes available.

The **Tides Foundation** has a long history of administering community-based grant pro-



WMA Secretary General

grammes in countries worldwide including Brazil, Afghanistan, Sierra Leone, Peru, Russia, Ukraine and Croatia, as well as across the United States. The Foundation manages over 300 donor advised funds and over the past decade has administered more than \$235 million in grants to not-for-profit organizations. To help countries achieve this goal, WHO provides normative guidance and direct technical support in country.

The **World Health Organization** aims to help people attain the highest possible level

of health by providing leadership on normative issues and technical assistance to its 192 Member States. In 2003, WHO joined UNAIDS in declaring the lack of HIV/AIDS treatment to be a global public health emergency and jointly launched the “3 by 5” target to get 3 million people on treatment by 2005. To help countries achieve this goal, WHO provides normative guidance and direct technical support in country.

ther investigate and debate some of the more pressing water and ocean issues such as sanitation, ocean preservation, the biomedical potential of the oceans and access to water. Several high-level leaders attended the event, including the Executive Director of the World Health Organization tasked with Environmental Health, Dr. Kerstin Leitner. It is tragic and prophetic that this event preceded the tsunami disaster. In the aftermath of the tragedy, all the water- and ocean-related issues discussed during the meeting came into play in the most dramatic fashion. Please read the full report on the symposium, including slides and speeches, at www.worldoceanforum.org.

From the Secretary General's Desk

During February 2005 I will leave the office of WMA Secretary General. After eight years of service to the WMA and the medical profession, I can only say that it was a tremendous privilege and an outstanding experience. May I use this opportunity to thank you all from the bottom of my heart for your support and care during my tenure. At the same time I would like to express my sincere congratulations to my successor, Dr. Otmar Kloiber from Germany. Otmar has a wealth of experience and the WMA is fortunate to have such a champion of medical ethics and sound health care policy join our team.

The last four months have been a particularly impressive period in the existence of the WMA, and I would like to mention three reasons why:

WMA General Assembly in Tokyo, Japan

Medical leaders from around fifty countries of the world gathered, during October 2004, in the Imperial Hotel, Tokyo for our annual Assembly. Most fittingly, it was the Emperor and Empress of Japan themselves who wished to welcome the leaders to this historic occasion. Having started the meeting in such an auspicious way, the rest of the meeting followed suit with high quality

discussions and content. The Japan Medical Association excelled in developing a world-class scientific session on the relationship between advanced medical technology and medicine. Dr. Yank Coble was inaugurated as the new WMA President and had the opportunity to officially launch the “Caring Physicians of the World” project (www.caringphysicians.info). This is the most ambitious Presidential project to date, with the development of a book on examples of physicians from around the world who vividly display the traditional values of medicine – science, ethics and care. In addition, he will be visiting most of the WMA Member Associations during regional meetings planned for 2005.

World Ocean Forum in New York, USA

The WMA identified the important link between water and health as one of the priority areas for the organization some 3 years ago. It was decided to develop a more comprehensive policy on this subject, which was completed when the WMA General Assembly in Tokyo adopted the WMA Statement on Water and Health (www.wma.net – see “Policy”). In addition, a two-day symposium was planned with the World Ocean Observatory to fur-

Launch of the WMA Ethics Manual

It is incredible to think that despite the fact that medical ethics is more than 2000 years old, there is no one universally used training manual for the teaching of medical ethics. The WMA had adopted a Statement on the Inclusion of Medical Ethics and Human Rights in the Curriculum of Medical Schools Worldwide (www.wma.net – see “Policy”) during 1999, and it was therefore quite fitting that the WMA develop a simple and concise ethics training manual for use by medical students and physicians. The WMA Director of Ethics, Dr. John Williams, did a splendid job in putting this manual together along with a committed team of advisors. At a launch event in January 2005, the first edition of the manual was released to the press and some partner organizations. The launch was a huge success, as we are confident the distribution and use of the manual will be. The manual can be downloaded from the WMA website at www.wma.net.

Looking at the huge strides the WMA has made over the last quarter, it bodes well for the future growth and expansion of the WMA and the profession. It gives me great joy to see this happen as I leave the WMA stage. Thank you and au revoir.



The Ceremonial session of the World Medical Association General Assembly was held in The Imperial Hotel, Tokyo 9th October 2004

The meeting was opened by the President, Dr. James Appleyard, who welcomed the Mr. Assodo Chief Secretary of the Cabinet (representing the Prime Minister who was abroad), the Minister of Health and the Governor of Tokyo.

The Secretary General, Dr. Delon Human introduced the delegations of the National Association Members of the WMA, and the official observers from other international organisations.

Dr. Uematsu, President of the Japanese Medical Association expressed his pleasure at being able to welcome the members of the WMA to Tokyo once again after 29 years. He was delighted to see 500 people present during the Assembly and considered that there had been very valuable exchanges of information at the Scientific Sessions during which various aspects of Advanced Medical Technology had been discussed, including Medical Ethics, IT and Healthcare. There was much valuable information which would contribute to the advance of World Peace. The JAMA looked forward to successful conclusions at the end of the Assembly. Referring to the earthquake the previous day and to the tornado to be expected later, he expressed the view that, no doubt, these were part of the global weather changes.

The President then thanked Dr. Uematsu and the Japanese Medical Association for their excellent organisation and hospital during the Assembly. He then introduced Mr. Assodo who extended the good wishes of the Prime Minister who had planned to be present but had had to travel to Vietnam. He informed the assembly that the approaching Typhoon was unusually large and warned delegates not to leave the hotel. However, he then cheered them with news of expected good weather the next day. Japan had been challenged by new infections such as SARS and AIDS.

Expectations of the population were rising. On the other hand, after referring to the increasing role of the Japanese Medical Association, he drew attention to the rise in life expectancy between 1997 and 2003 from 76,68 to 85. Infant mortality had fallen from 1 to 3 per 10.000. All of these were due to the efforts of the nation and of the doctors. Health Care reform was a universal challenge, notably with the increase in the elderly population and the diminishing birth rate, also the economic and environmental environments. Safety is a key to health care. The discussions of the Assembly on Medical Healthcare Technology and Medical Ethics was particularly timely. The Japanese were trying to introduce safety of health technology into health care. He hoped that the outcome of the meeting would enlarge the understanding of these issues. He felt that the World Medical Association is an organisation which contributes to the world's good future.

Mr. Ossuchio the Minister of Health, congratulated the Assembly. WMA had a fifty year history of engagement in major problems affecting health care globally. The WMA works with the World Health Organisation and other international organisations to enhance the health of the peoples of the world.

In Japan, Healthcare Services and advanced technology have improved the health of the people. The major challenges were Safety, Quality, and higher efficiency in Health Care, he looked forward to benefiting from the conclusions of the discussions on Health Care Technology. Finally he also expressed his thanks to the Japanese Medical Association for their work in organising this meeting.

The governor of Tokyo Mr. Ishihara pointed out that medicine in Japan was referred to as Western Medicine. However there was also a school of Oriental Medicine which, contrary to belief, was a schematic system of care.



Recently there had been an evaluation of this type of medicine by members of the Japanese Medical Association and now Acupuncture had been included in the Japanese Healthcare system. He personally values the work of experts in acupuncture which, he noted, was appreciated also in the USA. He quoted various examples of naturopathy applied successfully to various conditions ranging from obstetric complications to diseases of the liver and of the kidney. He specifically referred to CHI and to Chiropractic and stressed that they were not Sharmatic. It was important that there should be co-operation between both systems of medicine. He urged physicians to be generous in their approach to oriental medicine and closed by referring to the fact that the Japanese enjoyed the greatest longevity in the world.

Dr. Blachar, Chairman of Council, expressed the appreciation of the Assembly to the three high representatives of government and authority in Japan for kindly attending and addressing the Assembly. He then paid tribute to Dr. James Appleyard, the retiring 54th President who had served the Association with great distinction. Dr. Appleyard had many accomplishments. Personally Dr. Blachar had enjoyed the association with a fellow paediatrician who also had three children. Dr. Appleyard had brought to fruition the Declaration of Ottawa on the Rights of the Child and had consistently lobbied for children's rights to health and for child health services. In addition he had promoted Oral health and had supported the ICRC project on notification of torture and the treatment of torture victims. He had been chairman of the Ethics committee 1995-99, and oversaw the Declaration of Helsinki changes, speaking in New York,



World Medical Association

Japan, Malta, Uganda and many other places.

Dr. Appleyard had enhanced the image of WMA. He had been most a helpful person to work with and had greatly assisted the Chairman in promoting the changes within the organisation. Dr. Blachar looked forward to his playing a further role in the future.

Dr Appleyard in response expressed his enjoyment of the work in his past year as President. ----(see *text of speech page 95*) Dr. Blachar then presented Dr. Appleyard with the Past President's medal and conferred on him lifelong membership of the WMA.

The Secretary General then invited the incoming President Dr. Coble, to take the Presidential Oath, following which he was invested as President and delivered his Presidential address (see *page 86*).

Dr. Moon, retiring Vice Chair of Council then briefly addressed the Assembly expressing his pleasure at being invited to make some closing remarks. The WMA was founded in 1947 by a group of idealistic physicians, to build something better out of the ashes of World War II. WMA has done this by issuing declarations over the years

and helping to define Medical Ethics and standards in a changing world. It had worked to promote idealistic ideas and continue the ethical tradition of the medical profession. WMA now includes 84 National Medical Associations and millions of doctors. Huge strides have been made in health care and in human rights. For all. Tokyo is very memorable because Advanced Medical Technology and related issues promise together with IT to improve global health. He could think of no better way to address the agenda of global health care and Health for All. He expressed his appreciation of Dr. Uematsu and the leaders of JAMA for the hospitality enjoyed by all during the Assembly. Thanks to this he had been able to witness the Tokyo Assembly as a great occasion. He gave a special tribute to the work of Dr. Tsuboi for his leadership over many years to millions of doctors. Finally he paid a tribute to Dr. Delon Human for his work over the past seven years, for his tolerance and patience and devotion to the WMA. He thanked him and expressed the best wishes of everyone his future. The audience rose and endorsed this appreciation.

Dr. Coble thanked Dr. Moon for his address and closed the meeting.

referred to earlier remarks about the meaning of service, namely "helping doctors doing a good job and to save our patients". He thanked Dr. Delon Human for his work in restructuring the secretariat, and opening new networks and new avenues to explore. He was proud to be here also as a successor to Dr. Andre Wynen who had been designated Secretary General 29 years ago in Tokyo. For Dr. Kloiber the commitment of the representative members of the Assembly was most important and gives power to the WMA. National Medical Associations' commitment is what counts. If the members did not carry this out, WMA would be nothing. His primary job was to ask for this and to service their commitment. The first priority was the Dues, and the second was to participate and work in the WMA. Continuing the reconstruction was dependant on members' support and participation leading to a strong, visible organisation for the future.

The Assembly then adopted the following:

- A note of clarification on paragraph 30 of the Helsinki Declaration (see 95)
- A Statement on Physicians and Commercial Enterprises (see 91)
- A statement on Water and Health
- Amendment to the Regulations in times of Armed Conflict (see 92)
- A statement on the World Federation of Medical Education
- A statement on Health Emergencies Communication and Co-ordination (see 93)

An Addition to Section M of the WMA Schedule of Functions and Operation Policies also was adopted.

Applications from the Vietnamese Medical Association and the Estonian Medical Association were unanimously approved with acclamation.

The Assembly also approved the themes of the 2005 Santiago General Assembly scientific meeting "Health Care system reform" and "Access to Medicine".

Meeting of the WMA General Assembly, Tokyo, 9th October 2004

Dr. Begenholm reported that the Credential's Committee had verified that there were 35 Members present who were in good standing. This amounted to a total of 87 votes, and that 65 would be necessary to adopt any proposal relating to Medical Ethics.

After the Annual Report of Council and the Standing Orders had been adopted, Dr. Letlape (South Africa) was unanimously elected President-elect.

Dr. Letlape expressing his appreciation of the responsibility of this office and thanking the Assembly, said this was the time of the new President and his remarks would be brief. He referred first to the very few

Junior doctors present and speculated that if the age of the President was linked to life expectancy, for South Africa the age would be 39. He intended to carry forward the work of Drs. Millymakki, Appleyard and Coble, not only in advocating "patients first" but also "patients' rights". This would fit the theme of "Access to Medical Care" in Chile 2005 and would be most appropriate. There was inequality in South Africa, where, with finite resources, privatisation was a key issue.

Dr. Otmar Kloiber, Secretary General-elect, then addressed the Assembly, thanking Council and those who supported him for the trust they had placed in him. He



Approval was also given for the meeting in 2008 to take place in Seoul, in the anniversary year of the Seoul Medical Association.

Following the Treasurer's report, the Financial Statement for the year 2003 and the budget were adopted.

The report of the Associates meeting, which included their resolution concerning Enforced Sterilisation, was approved.

The Assembly then proceeded to an open session

The first speaker from the **Frauenarzte-Verlag** (Germany), referring to the lack of representation of women both in the Assembly and on the platform, pleaded for the enlistment of more women doctors who care about the medical profession and patients. It should be possible for the organisations of women doctors and the WMA to work together.

Dr. Arumugam (Malaya) was concerned that the topic of "Oriental medicine" had been raised during the formal ceremonial session of the Assembly and asked whether WMA had any policy on this. Ministers did not know whether or not medically-qualified doctors should be involved in this. He referred to "over the counter" sales and traditional medicine treatments now comprising 50% more than Western medical activity in the East. **Dr. Blachar** responding asked whether this was controllable. He felt that WMA should have a policy and hoped that an NMA would produce a background paper for discussion. **Dr. Human**, the Secretary General, hoped that the Malay Medical Association would send a consultation paper. He commented that WMA had a position on this. There were no controls on this type of medicine. He would send a paper to the MMA. Then **Dr. Haikerwal** (Australia) informed the meeting that legislation governing this issue in Victoria, Australia was the first in the world.

Dr. Adu-Gyanfi (Ghana) spoke about the importance of student exchanges and also, in relation to human resources, mentioned that while in 1969 there were 5500 doctors for a population of 7 million, now there were only 6500 for a population of 20 million.

Dr. Millymakki (Past President) drew attention to the absence of delegates from Turkey, although they sent their greetings. Recently there had been three strikes by Turkish doctors, respectively of one, one, and two days duration, during which doctors saw all emergencies and any sick children. The strike related to the need for more financing of health care. She also reported that 85 doctors were in court, including members of the doctors' Chamber. Doctors, who were classified as civil servants, had the right to be members of a Union, but not the right to strike. NMAs should be in touch with the Turkish Medical Association to assist their colleagues. **Dr. Human** reported that he had spoken to the Vice-President of the Turkish Medical Association to give support to their leaders. He had written to the Ministers of Health, of Justice and of Foreign Affairs concerning the unfair trial of 85 doctors, including their leaders. There was a conference of the Turkish doctors during this week. The WMA would try to send a WMA leader to be present at the trial.

Dr. Montgomery (Germany) referring to the comments from Ghana, said that doctors' workload in much of the world was rising to such an extent that some could work no more. There was a problem concerning the Worktime Directive in the EU, and in the USA doctors were working 90 hours a week. WMA could define a safeguard mechanism when the workload was too great. **The Secretary General** said this suggestion was useful and asked the BAK to produce paper on physician "burn-out" etc.

In response to a question from **Dr. Masson** concerning the doctor and other health workers condemned to death in Libya, **Dr. Human** reported that the WMA and ICN had met the Libyan delegation during the World Health Assembly. They received a poor reception from the delegates who despite offering to send them a reply, had not responded so far despite three reminders. As an NGO, WMA would continue to seek discussions with the government.

Dr. Chan Yee Shing (Hong Kong) observed that Chinese Medicine is not alternative medicine, it is mainstream. There is a need to deal with question of its recognition and registration. There is a

problem concerning the difficulties with standardisation. There were major medico-legal problems. For example in the case of coronary heart disease treated under both western and eastern medicine, when there is a lawsuit how can the court rules on the problem. In the scientific discussion of the previous day the medical profession seemed to be moving in the direction of Medical Technology. Physicians were working as members of a team. If the two professions were to be treated equally this was very difficult as there was no scientific basis for Traditional Medicine. He wondered whether WMA could help.

Dr. Appleyard (the President), referring to the problem raised by Ghana mentioned the importance of links with Medical Institutions in the West to help developing countries. He cited as an example a Surgeon from Germany who went for three months to work in a hospital in which there was no surgeon. Such a three months period could not only provide much needed assistance but also a valuable experience. Other alternatives were Fellowships linked with Medical Academic Institutions, or for individual doctors just to go and assist. He urged National Medical Associations to take this message back to their own countries and stressed the importance of such links being established as between equal partners.

Dr. Harma from the International Rehabilitation Council for Torture Victims, referred to the real problem for doctors who have been treating victims of torture in Turkey. The work of the WMA both in connection with the Tokyo declaration and more recently with the new initiative on training doctors in connection with the Istanbul Protocol was very valuable. He also referred to the recent Lancet article on





Regional & NMA News

possible involvement of physicians in Middle Eastern prisons and the Norwegian Medical Association/WMA programme of training for prison doctors and others in Human Rights. IRCT sought a WMA partnership.

Dr. Blachar (chairman of Council) spoke of the visits to Morocco, Uganda and Georgia in connection with the Istanbul/EU project of training in how to recognise victims of torture.

Dr. Grewin, (President of CPME), had written to the relevant EU Commissioner concerning the Turkish situation.

Dr. Letlape (South Africa) informed the Assembly that in South Africa legislation recognising traditional medicine is producing problems, as there is competition for limited resources, which were already in great difficulty. One part of traditional medicine is spiritual – there was a family tradition of training its members who were initiated into healing. If patients don't recover the blame lay with their ancestors!

A speaker from the Thai delegation reported that they had 30,000 doctors for a popu-

lation of 63 million people. Herbal medicine has been known for 200 years and does work in a limited context. Currently the Ministry of Health and the University were conducting a trial under the Professor of Medicine from Hong Kong. He pointed out that because of the very few physicians in rural areas the population has to use Traditional Medicine.

The Vietnamese delegation commented that the discussion was really about oriental medicine. There was a need for a careful look at the evidence. If the evidence is positive we should accept it.

Dr. Blachar, summing up, welcomed the discussion. There was clearly a need to look into the problems and he welcomed the Malayan lead.

After a presentation by the Chilean delegation in preparation for next year's Assembly, **Dr. Blachar** thanked the Japanese Medical Association for their great organisation and hospitality in the organisation of the Assembly, and extended his thanks to the Council, the Secretary General and to the staff of WMA.

ficient that only 22 cents in the dollar actually goes toward compensating those injured for economic losses, and 24 cents goes toward non-economic damages⁶. Consider, too, that in most jurisdictions, personal injury lawyers can receive as much as 50 percent of a jury award, and it becomes more clear why personal injury lawyers fight tooth-and-nail to defeat reasonable measures at limiting non-economic damages in state legislatures and the U.S. Congress. The U.S. medical liability tort system is the personal injury lawyers' cash cow.

The bitterness of the dispute can be traced directly to personal injury lawyers' desire to maintain the status quo of a civil justice system where multimillion-dollar jury awards benefit a very few, but have negative ripple effects that affect many. Blockbuster medical liability cases in 2003 in the United States have included verdicts and settlements of \$112 million, \$70 million, \$50 million, \$40.4 million and 10 that were \$20 million or more⁷.

The broken system becomes obvious when you consider that 70 percent of all cases filed against physicians are closed without any payment⁸. As a surgeon, I don't operate on demand. There must be valid indications. And surgeons get instant peer review. Every appendix I remove for the preoperative diagnosis of appendicitis is examined by a pathologist. If it was found that 70 percent of my operations were on normal appendices, I would not be allowed to operate. Shouldn't attorneys also be subject to peer review for the cases they file? Why is that personal injury attorneys are not held to a similar standard? Why is that these attorneys rarely – if ever – sanctioned for filing a suit without merit?

This lack of accountability is very expensive. Even though 70 percent of claims are dropped or dismissed, they still incur legal costs that average \$16,743. Expense costs for settled claims average \$39,891 and claims in which the defendant wins at trial, \$85,718.⁹ Now consider that on any given day, there are 125,000 suits active in the U.S. court system, and the costs grow exponentially.

Regional & NMA News

Patients' Access To Care At Risk With America's Broken Medical Liability System

By Donald J. Palmisano, MD, JD

Immediate Past President,
American Medical Association

The United States is not alone in confronting the deleterious effects of overzealous personal injury lawyers who seek million-dollar awards and settlements that result in scores of physicians restricting their services and patients losing access to care.

Reports from the United Kingdom state how negligence claims against physicians are rising¹ as are the expected payouts – £150m by 2010². In Australia, increased concern has led to "several of the country's

states and territories taking action to limit damages for non-economic loss and cap economic loss,"³ among other measures. And in New Zealand, health officials are alarmed by the large increases in payouts. In Wales, for example, claims have remained relatively steady, but payouts have seen from £63.3 million to £117.8 million from 1999-2000 to 2002-2003⁴.

In the United States, the costs are even more severe. Medical liability tort costs have increased from \$9.5 billion in 1991 to more than \$21 billion by 2001⁵. But rather than the money going to compensate injured parties, the U.S. tort system is so grossly inef-



Snapshot of a Crisis

There are 20 states which the AMA believes are in a full-blown medical liability crisis¹⁰. We define this crisis after careful analysis of several key factors, including:

- The magnitude of patients losing access to health care.
- What type of medical liability reform legislation currently exists in a state – and for how long the reforms have been in place.
- The actions of a state court system to uphold or overturn medical liability reforms.
- The affordability and availability of professional liability insurance.
- The actions of a state's legal community, particularly the trend of increasing frequency and severity of jury awards.

Medical liability reform has been the AMA's top legislative priority for several years. Our fight has been on two simultaneous fronts: namely the U.S. Congress and the state legislatures throughout the country. We also have supported state medical societies in their efforts to protect existing reforms before state supreme courts¹¹.

Unfortunately, the U.S. Congress and state legislatures have become the battlegrounds for deciding whether patients will have access to care. Because of a runaway legal systems, patients have suffered as physicians have been forced to relocate, retire early, or restrict their services – such as delivering babies or performing trauma surgery¹².

In my travels across the United States, I have personally spoken with scores of physicians who have given up part of their practice because of excessive lawsuits and skyrocketing liability insurance premiums. It is distressing to hear a young paediatric specialist tell the story of how he moved to the Mississippi Delta as part of “a calling” to treat rural patients, but he was forced to leave the state after being sued by patients who did not even realize they were suing him. One patient who hoped to earn a few thousand dollars said “I’m kind of upset. I

do not want him leaving because of all the suits. If we run off all the doctors, what are the people gonna do?”¹³

It is even more distressing to be speaking to a group of America's top surgeons about this crisis and learn from a young surgeon that he “understood the crisis all too well because he recently lost his son because there was no neurosurgeon available.” Mississippi surgeon John Lucas, III, MD, told me that his son was in a car accident and needed immediate neurosurgical intervention, but the area's neurosurgeons had already either quit doing head trauma cases or had moved away. His son had a correctible problem if immediate attention by a neurosurgeon could be given. Dr. Lucas did everything he could to expedite the transfer and find a neurosurgeon. Unfortunately his son John Lucas IV died despite the subsequent transfer.

A Solution Exists

Experience tells us that there are a few states that have had long-term medical liability reforms: California, Colorado, Indiana, Louisiana, New Mexico and Wisconsin. They all have in common a reasonable limit on damages. California, in particular, places a \$250,000 limit on non-economic damages, and there is no limit for economic damages. If a patient is harmed by negligence, the AMA strongly believes that the patient should be able to receive fair and quick compensation. The model the AMA has advocated for the United States Congress to pass into law is the California model which gives all medical expenses, lost wages and benefits, future wages and benefits, child care costs and more, but limits non-economic damages to \$250,000. Without a proven performer such as the California \$250,000 limit on non-economic damages, the system breaks down. The majority of individuals in the United States House of Representatives and the Senate as well as President Bush favor such a law but a minority of Senators filibuster it and currently there are not the necessary 60 votes to overcome the filibuster.

California's reasonable reforms also include limits on attorney contingency fees,

allocating responsibility for damages fairly, providing for periodic payment of damages over time, and more. California's law – formally known as the Medical Injury Compensation and Reform Act (MICRA) – was enacted in 1975. Between 1976 and 2002, medical liability insurance rates have increased in the United States by 750 percent. In California, they only have increased 245 percent. MICRA is the reason why an obstetrician pays about \$69,000 per year for professional liability insurance while the same physician would pay more than \$277,000 per year in Southern Florida, which does not have MICRA-style reforms. MICRA provides the predictability and stability for the liability insurance market that moderates physicians' insurance rates and protects patients' access to care.¹⁴

Recent State Actions Cause for Optimism

In the recent November elections, four states had constitutional ballot measures regarding different medical liability reforms. In each case, the AMA stood side-by-side with our state medical societies to present the facts. In each case, our opposition tried to suggest that there was no need for reform, that the status quo worked just fine to protect patients.

In Florida, where women have been forced to wait as long as six months for a mammogram because radiologists are scared to read them, the physicians won a great victory. Despite personal injury lawyers and their supporters spending an estimated \$24 million, voters enacted new limits on contingency fees. Now, patients will be assured to receive at least 70 percent of the first \$250,000 of a jury award; and 90 percent of any amount more than \$250,000.

In Nevada, where Jim Lawson died in circumstances similar to Dr. Lucas' son, and scores of women searched for months to find a doctor to deliver their babies, the medical community also had a great victory when voters amended the state constitution to eliminate all exceptions to the state's \$350,000 limit on non-economic damages. Previously, a crafty personal injury lawyer



Regional & NMA News

could use rhetorical arguments to circumvent the cap.

In Oregon – despite the fact that more than 40 percent of the state's neurosurgeons and nearly one quarter of its obstetricians have already stopped providing certain services or will soon do so – voters narrowly defeated (50.7 percent to 49.3 percent) a measure that would have restored a \$500,000 limit on non-economic damages. The AMA is deeply concerned Oregon's crisis will become worse.

And in Wyoming, where rural health care is the norm, the loss of even one physician can have negative consequences. But despite widespread examples of physicians restricting their practices and patients being forced to drive an hour or more to find care, voters narrowly defeated a measure designed to allow the legislature to enact a limit on non-economic damages. However, voters did approve a measure that could lead to legislation enacting medical review panels to weed out the frivolous cases currently choking the system.

Clearly, these results are mixed, but they show forward momentum, building on the outstanding win in Texas in 2003 where the legislature passed reforms and the citizens voted to change the state constitution to be certain the new law would allow caps on non-economic damages. Since enactment of the Texas law, the largest insurer of physicians in Texas lowered the medical liability premiums 17%. The AMA plans on carrying that momentum into 2005. We will continue to work with our champions in Washington, D.C., as well as in the halls of state legislatures across the country. We stand ready to support our international colleagues in their efforts as well, including the efforts to enact patient safety legislation akin to the successful Aviation Safety Reporting System of voluntary confidential reporting of errors or "near-misses" for review by experts, with feedback for a system change to enhance safety and then communicate the lesson learned to all in a "no shame, no blame" de-identified manner. Such a proposed law, entitled the Patient Safety and Quality Improvement Act, has passed both the House and Senate in the United States Congress but it is questionable whether it will get out of the conference committee during the few days left in the 2003-2004

Tobacco Control Capacity Building

At the British Medical Association's TCRC* meeting, held in Edinburgh during the 50th anniversary year of the 1954 paper by Doll, participants heard a keynote address by its author. Sir Richard Doll, after outlining the latest evidence of the health effects of tobacco stressed that the important messages were that in Europe half of all smokers are killed by their smoking, a quarter of whom are killed by middle age, stopping smoking extends lifespan, and that doctors must become involved. He suggested that the choices open to doctors were to make a commitment to reduce smoking rates, or to do nothing and see tobacco related illnesses increase! Presentations were also made by Sir Richard Peto and Dr. Carolyn Dressler, Head of Tobacco Control at WHO's IARC and many others.

Participants each outlined their individual priorities for action and in a joint resolution agreed to make every effort to persuade member states to ratify the WHO Framework Convention of Tobacco control and also welcomed the WHO Code of Practice for Health professionals' organisations

*The Tobacco Control Resource Centre (TCRC) the global first such institution – was founded in 1998 by the British Medical Association, WHO Europe, and supported by the European Commission Commission.

Congress. We also continue to support the National Patient Safety Foundation (NPSF) that we founded with others. To date we have contributed \$7.3 million to it and are very proud of its extensive patient safety bibliography and teaching modules.¹⁵

In my 40+ years as a physician, I have witnessed the miracles of organ transplants, vaccines, chemotherapy, and more. Today, we can treat birth defects with the baby still in the mother's womb. We can perform microsurgeries on the brain. We can re-attach severed limbs. Tomorrow holds great promise here in the United States and abroad, but we must safeguard our future. The rising threat of unchecked lawsuits and out-of-control costs threatens us all, which is why we must share the commitment to be relentless in the fight to enact reasonable reforms that protect patients' access to the courtrooms without sacrificing our patients' access to medical care.

1. "Hospital awards bill to cost E400m," The Sunday Tribune, Dec. 7, 2003.

2. *Ibid*

3. "Liability insurance: a global concern," Insurance Day, Sept. 9, 2003.

4. "Claims now cost NHS trust more," South Wales Evening Post, Sept. 2, 2003.

5. U.S. Tort Costs: 2002 Update. Trends and Findings on the Costs of the U.S. Tort System. Tillinghast-Towers Perrin. Appendix 5.

6. *Id* at 17.

7. *VerdictSearch*:

<http://www.verdictsearch.com/news/top100/> (note: page last accessed June 8, 2004)

8. Physician Insurers Association of America, PIAA Claim Trend Analysis: 2002 edition (2003), exhibit 1-2.

9. Physician Insurers Association of America (PIAA) testimony United States House of Representatives Committee on Energy and Commerce Subcommittee on Health, February 23, 2003

10. For an extensive look at America's medical liability crisis, please visit www.ama-assn.org/go/crisismap

11. The AMA filed amicus briefs in support of existing medical liability reforms in Wisconsin and West Virginia in 2004.

12. Several patient-specific examples of the loss of care can be found in the November/December 2004 issue of the *Saturday Evening Post*. See: Open Forum: "Why Your Doctor Might Quit," by Donald J. Palmisano, M.D.

13. *Clarion-Ledger*, July 29, 2002

14. To ensure an accurate and extensive discussion of MICRA and other types of reforms, including action in the U.S. Congress and state legislatures, the AMA has prepared a research compendium, *Medical Liability Reform – Now!*, which is regularly updated. See www.ama-assn.org/go/mlrnow for the most recent version.

15. Visit the NPSF at www.npsf.org

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