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ABBOTT

Joseph S. Jenckes
Vice President

1730 M Street, N. W. Washington, D. C. 20036

Abbott Laboratories North Chicago, Illinois 60064

> 659-8524 659-1579

em Baker 628

April 23, 1981

Lyn Nofziger
Assistant to the President
for Political Affairs
The White House
Washington, D.C. 20500

Dear Lyn:

Within the next few days the White House will have to make a decision on how the U.S. Government will vote on the proposed World Health Organization Code entitled "The International Code of Marketing of Breastmilk Substitutes." The provisions of the Code severely restrict the sales and marketing of manufactured infant formula. The 34th Session of the World Health Assembly will meet in Geneva in May at which the United States will have an official delegation and cast a vote on this Code.

The Carter Administration favored a "Yes" vote on the Code. The Departments of State and Health and Human Services are now re-examining that position, and we understand they are trying to determine whether to "Abstain" or vote "No" on the Code.

Abbott Laboratories, along with Bristol-Myers and American Home Products are the major U.S. manufacturers of infant formula, and sell and market worldwide. The U.S. infant formula industry, along with the Grocery Manufacturers of America and the Emergency Committee for American Trade, have strongly urged State and HHS to recommend a "No" vote.

The fundamental premise of this proposed international Code is that marketing activities of infant formula manufacturers have caused a decline in breastfeeding. This is totally inaccurate and there is absolutely no data to justify that claim.

In addition to the faulty premise of the Code, the provisions of the proposed Code could never be implemented in the United States. The provisions that prohibit all advertising violate the 1st Amendment of the United States Constitution. Other provisions including the prohibition

of sales incentives or bonuses to employees; prohibition on distribution of product samples to the medical profession, and the restriction on proprietary product names are all contrary to the basic principles of competition central to the economic system of the United States and other western democracies.

Perhaps the most pernicious provision in the Code is the one which places total control of all information to be disseminated on infant formula in the hands of the government of any nation which adopts the Code.

The U.S. Government should not abstain from voting on this Code, but should strongly oppose the Code and vote "No." Abstention is a form of acquiescence. The U.S. Government should never support directly or indirectly any code developed by an international body which attempts to regulate an entire industry worldwide in a manner repugnant to our Constitution.

We would appreciate 10 minutes of your time to provide you with background materials and discuss the implications of this Code.

My warm regards.

Sincerely,

Joseph S. Jenckes

(hand delivered)

## THE WHITE HOUSE WASHINGTON

December 3, 1985

[IT102 293930PD]

TO:

JACK SVAHN

FROM:

BILL ROPER

CJ 👌

FYI.

Letter to Board of Directors,
from Gerald J. mossinghoff,
Dharmaceutical manufacturers
Association awing biles
initial reactions to WHO
Moirobi Conference

Gerald J. Mossinghoff
PRESIDENT



December 1, 1985

2939307D IT 102 F0006 HE006 C0088

GENTLEMEN OF THE BOARD OF DIRECTORS:

The following are my initial reactions to the WHO Nairobi Conference, which ended this past Friday.

### On the plus side:

- The international health activists got a lot less out of the conference than they had hoped for or anticipated.
- They wanted an endorsement by the conference to take to the 1986 World Health Assembly ("WHA") of an International Marketing Code along the lines of the Infant Formula Code. They did not get that.
- They wanted an endorsement by the conference of a so-called "Medical Needs" test -- under which even safe and effective drugs would be kept off the market if they did not satisfy a bureaucratic judgment that they would be better than or cheaper than existing drugs. They did not get that.
- They wanted WHO to assume the role of an international regulatory body. Dr. Mahler, the Director General of WHO, made clear time and again throughout the conference that WHO should not become a supranational regulatory body and that all of the decisions in these matters are national decisions to be made by national governmental authorities. He did go further than we would have hoped in seeing a leadership role for WHO in advising governments in these matters.
- The activists had hoped to come away from Nairobi with recommendations for concrete actions to take to the 1986 WHA. The only actions that the Director General will take to the 1986 WHA are proposals to set up and fund several so-called "committees of experts" to be convened after the 1986 WHA. WHO's budget is fixed through FY 1987 and we can expect the U. S. Government and other Western nations to oppose additional funding for these committees.

• The activists had hoped to use the Nairobi meeting for a major propaganda effort against the drug industry. Health Action International is skilled at writing flamboyant press releases, as you know. Press coverage, even in Nairobi, was not extensive and, for the most part, has been balanced.

### On the negative side:

- The Nairobi Conference opened up the UN deliberative system to selfstyled international consumer activists who do not represent the real health-care consumer groups such as the American Cancer Society, the American Heart Association, the Arthritis Foundation, etc., who look to the pharmaceutical industry for new cures and therapy.
- The proposal of the Director General to ask the 1986 WHA to set up a series of "committees of experts" will provide the international activists with a continuing series of "mini-Nairobis" to get press attention and to chip away at the firm resolve of WHO not to become an international regulatory body. For example, two areas that these committees will address are (1) "guidelines for ethical norms on pharmaceutical advertising and marketing" and (2) guidelines for national drug legislation.
- WHO contributed \$30,000 to the making of an outrageous Dutch film called "The Pill Jungle." It was to be shown to conference participants and the press at the conference. The film had not gone through the normal WHO screening procedures. During the conference, Dr. Joshua Cohen, speaking on behalf of Dr. Mahler, publicly disassociated WHO from the film, characterizing it as "unsuitable", and refused to let it be shown to the conference participants. It does bear the WHO logo and was shown to the press. We do not yet know if Dr. Mahler will take firm and effective steps to have the WHO logo removed from the film, which will be further distributed by the Dutch film company.

My reactions are based in part on a rapid-fire one-hour verbal summary by Dr. Mahler at the end of the conference of his impressions and plans for future actions. Apparently there will be a WHO press release on the conference later. A formal report on the conference will be prepared and released after a meeting of the WHO Executive Board in January. Final actions on the proposal to establish "committees of experts" will occur at the May 1986 WHA.

We should all be deeply grateful for the strong support we received from the U.S. Government at all levels in keeping Nairobi from getting out of control, particularly the very effective work of Frank Young before and during the conference.

I will report in greater detail on the conference and on the follow-on actions we propose at Wednesday's Board of Directors meeting. Attached is the IFPMA statement which we released late Friday night.

Sincerely,

Gerald J. Mossinghoff

Attachment

INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS

IEPMA

## News

FIM

FÉDÉRACION INTERNATIONALE DE L'INDUSTRIE DU MÉDICAMENTA. FEDERACION INTERNACIONALE DE LA INDUSTRIA DEL MEDICAMENTO

PRESS RELEASE

### IFPMA PRELIMINARY VIEW ON RATIONAL USE OF DRUGS CONFERENCE

The experts from the pharmaceutical industry believe that this has been a constructive conference and we welcome the low key discussion of the many issues involved in the use of drugs. We support Dr. Mahler's firm conclusions that the WHO cannot perform as a supra-national regulatory body. In his summing up, Dr. Mahler gave his impressions of the views expressed at the conference and outlined what he believed were the major responsibilities of all the key parties involved. The pharmaceutical industry agrees that most of the major decisions involving the use of drugs are decisions that must be taken by national governments.

Beyond this point, it is not possible to comment in detail on Dr. Mahler's extensive summary since many of the points are subject to widely ranging interpretation. In preparing its formal report on the conference and taking follow-on actions, however, it is important, in our view, that WHO continue to emphasize its international advisory role and leave legislative and regulatory actions to national governments.

November 29th

Cherchen 5/8 1130 Received 50 THE WHITE HOUSE I 1102 1838 HAY -8 PH 12: 24 WASHINGTON May 7, 1986 MEMORANDUM FOR THE PRESIDENT ROBERT H. TUTTLE FROM: United States Representation at the Thirty-ninth SUBJECT: World Health Assembly of the World Health Organization, Geneva Switzerland, May 5-16, 1986 Attached for your approval is a memorandum from Acting Secretary of State John C. Whitehead, recommending the United States delegation to the Thirty-ninth World Health Assembly of the World Health Organization, to convene in Geneva, Switzerland, May 5-16, 1986. The Office of Presidential Personnel concurred with this proposal April 29, 1986, and recommended the State Department proceed. C. Everett Kao Frank E. Z Cenneth Bart Thomas E. Malone No amouncement Original memoto STATE, 26A67 via merenger ow 5/9/86 pproved By the President May 8,

# DEPARTMENT OF STATE WASHINGTON

May 6, 1986

## LIMITED OFFICIAL USE

MEMORANDUM FOR: THE PRESIDENT

FROM: John C. Whitehead, Acting

SUBJECT: United States Representation at the

Thirty-ninth World Health Assembly

of the World Health Organization, Geneva,

Switzerland, May 5-16, 1986

The United States Government, a Member of the World Health Organization, has been notified of the convening of the Thirty-ninth World Health Assembly in Geneva, Switzerland, from May 5-16, 1986. I recommend, and the Secretary of Health and Human Services concurs, that you designate the Chief Delegate, Deputy Chief Delegate, and Alternate Delegates to this meeting as indicated on the attached list.

Public Law 643, 80th Congress, requires presidential designation of the Chief Delegate, Deputy Chief Delegate, and Alternate Delegates to sessions of the World Health Assembly. Senate confirmation is not required.

The individuals named on this list have been certified as to security in accordance with Public Law 643, 80th Congress, as amended by Public Law 298, 82nd Congress.

If you approve the proposed designations, the Department will formalize appropriate arrangements.

### Attachments:

1. List of proposed United States Delegation.

2. Biographic sketches.

APPROVED:

DATE:

May 8, 1986

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# DEPARTMENT OF STATE WASHINGTON

May 6, 1986

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APPROVED:

DATE:

May 8, 1986

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To AW & DH ow 5/7/86 9:15 am TO DC - 5/7/86 (3:40pm)

### UNDER SECRETARY OF STATE FOR MANAGEMENT WASHINGTON

May 6, 1986

## MITER OFFICIAL USE

MEMORANDUM FOR THE HONORABLE ROBERT HOLMES TUTTLE THE WHITE HOUSE

Subject: United States Representation at the Thirty-ninth

World Health Assembly of the World Health

Organization, Geneva, Switzerland, May 5-16, 1986

Transmitted herewith is a Memorandum for the President recommending the designation of the United States Representation at the Thirty-ninth World Health Assembly convening in Geneva, Switzerland, May 5-16, 1986.

Approval for these designations was received on April 29, 1986.

Jackie Wolcott

Vadire Wolcott

Special Assistant

Attachments: As stated.

# UNDER SECRETARY OF STATE FOR MANAGEMENT WASHINGTON

May 6, 1986

## LIMITED OFFICIAL USE

MEMORANDUM FOR THE HONORABLE ROBERT HOLMES TUTTLE THE WHITE HOUSE

Subject: United States Representation at the Thirty-ninth

World Health Assembly of the World Health

Organization, Geneva, Switzerland, May 5-16, 1986

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Approval for these designations was received on April 29, 1986.

Jackie Wolcott Special Assistant

Vadire Wolcott

Attachments:
As stated.

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9/22/03 COD

### OTIS R. BOWEN, M.D.

Position for which considered: United States Delegate to the Thirty-ninth

World Health Assembly

Present Position: Secretary of Health and Human Services

Office Address: Department of Health and Human Services

Washington, D.C. 20201

Born: February 26, 1918, Richland Center, Indiana

Legal Residence: Indiana

Marital Status: Married

Home Address: c/o Department of Health and Human Services

Washington, D.C. 20201

Education: B.A. 1939, Indiana University

M.D. 1942, Indiana University School of Medicine

Experience:

1952-56 Coroner, Marshall County Indiana

1957-58 &

1961-72 Member, House of Representatives, Indiana

(1965-66 Minority Leader, 1967-72 Speaker)

1973-81 Governor of Indiana

1975-77 Member, Commission of Federal Paperwork

1976-77 Member, President's Committee on Science and Technology

1977-79 Member, Advisory Commission on Intergovernmental Relations

1981-83 Member, Presidential Advisory Committee on Federalism

1982-84 Chairman, Advisory Council on Social Security

1985-present Secretary, Department of Health and Human Services

### C. EVERETT KOOP, M.D.

Position for which considered: United States Delegate to the Thirty-ninth

World Health Assembly

Present Position: Surgeon General and Deputy Assistant Secretary for Health

Office Address: Department of Health and Human Services

Washington, D.C. 20201

Born: October 14, 1916, Brooklyn, New York

Legal Residence: Pennsylvania

Marital Status: Married

Home Address: c/o Department of Health and Human Services

Washington, D.C. 20201

Education: A.B. 1937, Dartmouth College

M.D. 1941, Cornell Medical College

Sc.D. 1947, Graduate School of Medicine,

University of Pennsylvania

Experience:

1948-81 Surgeon-in-Chief, Children's Hospital of Philadelphia,

Philadelphia, Pennsylvania

1949-81 Professor of Pediatric Surgery, School of Medicine of the

University of Pennsylvania

1976-81 Professor of Pediatrics, School of Medicine of the University of

Pennsylvania

1981 Surgeon General of the United States Public Health Service and

Director of International Health, Department of Health and

Human Services, Washington, D.C.

1982-present Surgeon General and Deputy Assistant Secretary for Health

Department of Health and Human Services

### GERALD P. CARMEN

Position for which considered: United States Delegate to the Thirty-ninth

World Health Assembly

Present Position: Representative of the United States of America to the European

Office of the United Nations, with the rank of Ambassador

Office Address: Department of State

Washington, D.C. 20520

Born: July 8, 1930, Quincy, Massachusetts

Legal Residence: New Hampshire

Married Marital Status:

Home Address: c/o United States Mission to the European Office of the United

Nations, Geneva, Switzerland

Education: B.A. 1952, University of New Hampshire

Experience:

1944-59 Stock Clerk, advanced to Vice President, Carmen Automotive

Stores, Inc., Manchester, New Hampshire

1959-79 Owner, Car-Go Home and Auto Centers, Inc., Manchester Consulting and Real Estate, Mach I, Inc., Manchester 1979-82 1980

Transition Team Leader, Department of Housing and Urban

Development, Washington, D.C.

1981-84 Administrator, General Services Administration, Washington, D.C. 1984-present

Representative of the United States of America to the European Office of the United Nations, with the rank of Ambassador,

Geneva

### FRANK E. YOUNG, M.D., Ph.D.

Position for which considered: United States Delegate to the Thirty-ninth World Health Assembly

Present Position: Commissioner of Food and Drugs, U.S. Department of Health and

Human Services

Office Address: Department of Health and Human Services

Washington, D.C. 20201

Born: September 1, 1931, Mineola, New York

Legal Residence: New York

Marital Status: Married

Home Address: c/o Department of Health and Human Services

Washington, D.C. 20201

Education: M.D. 1956, University of the State of New York

Ph.D. 1962, Western Reserve University

Experience:

1970-79 Chairman, Department of Microbiology, University of Rochester,

Rochester, New York

1970-79 Director of the Clinical Microbiology Laboratories, Strong Memorial

Hospital, New York

1970-84 Pathologist, Strong Memorial Hospital

1976-79 Microbiologist in Chief, Strong Memorial Hospital

1979-84 Dean, School of Medicine and Denistry, University of Rochester

1979-81 Director of the Medical Center, University of Rochester

1981-84 Vice President for Health Affairs, University of Rochester

### KENNETH J. BART, M.D.

Position for which considered: United States Delegate to the Thirty-ninth

World Health Assembly

Present Position: Agency Director for Health

Office of Health, Room 709, SA-18 Office Address:

Agency for International Development

Washington, D.C. 20523

Born: June 11, 1939, New York, New York

Legal Residence: Maryland

Marital Status: Married

c/o Agency for International Development Home Address:

Washington, D.C. 20523

Education: B.A. 1959, Middlebury College

M.D. 1964, State University of New York, Syracuse

Internship & Residency in Pediatrics, Yale New Haven Hospital, New Haven, CT M.P.H. 1980, M.S. HP&M, 1981, Harvard

School of Public Health

Experience:

1967 Pediatrician, Albert Schweitzer Hospital Deschapelle, Haiti 1967-69

Epidemic Intelligence Service Officer (EIS), Centers for Disease

Control (CDE), U.S. Public Health Service, Medical

Medical Epidemiologist and Pediatrician, Division of Epidemiologist 1968-71

Pakistan-SEATO Cholera Research Laboratory, Dacca, East

Chief of Party, Integration of Health Services Project, Ministry of 1971-75

Health, Nepal, Kathmandu; Health Sector Officer, Agency for

International

1975-76 Medical Epidemiologist, Enteric Disease Branch, Bureau of

Epidemiology, CDC, Atlanta, Georgia

Medical Director, Kidney Donor Activity, Bureau of Epidemiology, 1976-79

CDC, Atlanta, Georgia

Chief, Surveillance, Investigations, Research Branch, Division of 1981-85

Immunization, CDC, Atlanta, Georgia

Agency Director for Health, Agency for International 1985-present

Development, Washington, D.C.

### THOMAS E. MALONE

Position for which considered: United States Delegate to the Thirty-ninth

World Health Assembly

Present Position: Deputy Director, National Institutes of Health

Office Address: National Institutes of Health, Room 132

James A. Shannon Building

9000 Rockville Pike, Bethesda, Maryland 20205

Born: June 3, 1926, Henderson, North Carolina

Legal Residence: Maryland

Marital Status: Married

Home Address: c/o National Institutes of Health, Room 132

James A. Shannon Building

9000 Rockville Pike, Bethesda, Maryland 20205

Education: B.S. 1948, North Carolina College

M.S. 1949, North Carolina College Ph.D. 1952, Harvard University

### Experience:

1950 <b>-52</b>	Teaching Fellow, Harvard University
1952-58	Instructor and Assistant Professor of Zoology, North Carolina College
1958-60	Resident Research Associate (NAS Postdoctoral Fellowship), Argonne National Laboratory, Chicago
1960-61	Assistant Professor of Biology, Loyola University, Chicago
1961-62	Visiting Lecturer, Sabin Branch, Chicago Teachers College
1961-62	Visiting Lecturer, Evening Division, Illinois Institute of Technology, Chicago
1962-63	Grants Associate, Division of Research Grants, National Institutes of Health, Bethesda
1963-64	Assistant Chief, Research Grants Section, Extramural Programs, National Institute of Dental Research
1964-66	Deputy Chief, Extramural Programs Branch, National Institute of Dental Research
1966-67	Chief, Periodontal Diseases and Soft Tissue Studies, Extramural Program, National Institute of Dental Research
1967-69	Chairman, Department of Biology, American University of Beirut, Beirut
1969-72	Associate Director of Extramural Programs, National Institute of Dental Research
1972-77	Associate Director for Extramural Research and Training, National Institutes of Health
1977-present	Deputy Director, National Institutes of Health

Acting Director, National Institutes of Health

7/1/81-4/30/82

Proposed United States Delegation to the Thirty-ninth World Health Assembly, Geneva, Switzerland, May 5 through 16, 1986

### Chief Delegate:

Otis R. Bowen, M.D.,
Secretary of Health and Human Services,
Department of Health and Human Services.

### Deputy Chief Delegate:

C. Everett Koop, M.D.,
Surgeon General,
United States Public Health Service,
Department of Health and Human Services.

### Delegate:

Gerald P. Carmen,
Representative of the United States of America to
the European Office of the United Nations,
Geneva, Switzerland.

### Alternate Delegates:

Frank E. Young, M.D.,
Commissioner of Food and Drugs,
Food and Drug Administration,
Public Health Service,
Department of Health and Human Services.

Neil A. Boyer,
Director for Health and Transportation Programs,
Bureau of International Organization Affairs,
Department of State.

Kenneth Bart, M.D.,
Director for Health,
Agency for International Development.

Thomas E. Malone, Ph.D.,
Deputy Director, National Institutes of Health,
Department of Health and Human Services.