Implantable Artificial Organ Systems:

A Dilemma in the Interaction of Biologic, Engineering,

Governmental and Philosophic Considerations

The "Artificial Metabolic Pancreas" will be presented as a scientific problem in physiologic control. The relationship of the biologic requirement to the engineering problem will be treated. When this process is successful, a "device" is created. What happens when an attempt is made to exploit such a development for the benefit of the patient? The existence of a need for patient protection and research regulation by government is an important question today. What is the role of academia or basic research and what is the role of industry or developmental research? We shall present the view of the agency charged with this regulatory role as well as considerations of its effect upon the overall scientific process involved.

5:30 Introduction

Sidney K. Wolfson, Jr., MD, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania

5:40 Complexities of the Blood Sugar Level in Diabetics, the Role of Insulin, and the Difficulties These Cause with the Programming of Insulin Delivery Systems

Samuel P. Bessman, University of Southern California School of Medicine, Los Angeles, California

6:25 FDA View of Device Investigation

D. Link, Food & Drug Administration, Silver Spring, Maryland

7:00 Impact of the Medical Device Act in Implantable Innovations

Norman Latker, Attorney, Washington, D.C.

7:35 Discussion with audience participation

Norman Latker, Attorney, Washington, D.C.

7:35 Discussion with audience participation

This form will be submitted *directly* to the printer.

PLEASE TYPE

All Information Requested *MUST* be Included

Session #_____
(We will fill in)

Implantable and Indwelling Biosensors
(SESSION TITLE)

Time: 1:00 p.m.

Date: May 21, 1979
(We will fill in)

Sponsored by:_____
(If Applicable)

Chair: Sidney K. Wolfson, Jr., M.D. Univ. of Pittsburgh, School of Medicine, Pittsburgh, PA
(Name, Degree(s), Affiliation, City, State)

(PLEASE INCLUDE ALL CO-CHAIRPERSONS.)

Jiri Janata, Ph.D., Department of Bioengineering, University of Utah, Salt Lake City, Utah

Chair: Sidney K. Wolfson, Jr., M.D. Univ. of Pittsburgh, School of Medicine, Pittsburgh, PA
(Name, Degree(s), Affiliation, City, State)

(PLEASE INCLUDE ALL CO-CHAIRPERSONS.)

Jiri Janata, Ph.D., Department of Bioengineering, University of Utah, Salt Lake City, Utah

1:00 Introduction

S. K. Wolfson, Jr., MD, University of Pittsburgh School of Medicine, Pittsburgh, PA

1:05 Towards the Development of an Implantable Semiconductor pH Sensor

P. W. Cheung, PhD, Ji-Min Lee, MS, W. H. Ko, PhD, Departments of Bioengineering and Engine Design Center, Case-Western Reserve University, Cleveland, Ohio

1:25 Continually Recorded Changes in Intracellular pH: Effects of Hypoxia and Cardiac Glycosides

P. Hollander, PhD, Department of Pharmacology, Ohio State University, Columbus, Ohio

1:45 Ion Sensitive Field Effect Transistors with Heterogeneous Membranes

B. Shiramizu, J. Janata, PhD, S. D. Moss, MS, Department of Bioengineering, University of Utah, Salt Lake City, Utah

2:05 In Vivo Continuous Monitoring of K^+ and pH in Animals Using ISFET's

B. A. McKinley, MS, J. Saffle, MD, W. S. Jordan, MD, J. Janata, PhD, S. D. Moss, MS, D. R. Westenskow, PhD, Departments of Anesthesiology, Surgery and Bioengineering, University of Utah, Salt Lake City, Utah

2:25 Break

2:45 A Miniature Optical Transducer for the In Vivo Measurement of Tissue Hemoglobin Oxygen Saturation

P. W. Cheung, PhD, Department of Bioengineering, Case-Western Reserve University, Cleveland, Ohio

2:45 A Miniature Optical Transducer for the In Vivo Measurement of Tissue Hemoglobin Oxygen Saturation

P. W. Cheung, PhD, Department of Bioengineering, Case-Western Reserve University, Cleveland, Ohio

3:05 Prospect for an Artificial Pancreas and Glucose Measuring System

S. Aisenberg, PhD, M. Stein, BS, Applied Science Laboratories, Gulf & Western Research and Development Group, Waltham, MA

3:25 Development of an Implantable Glucose Sensor Incorporating Catalytic Metal Electrodes

J. Giner, PhD, J. S. Soeldner, MD, H. Lerner, PhD, L. Marincic, PhD, C. K. Colton, PhD, J. R. Guyton, MD, Joslin Research Laboratories, Giner, Inc., Department of Chemical Engineering, Department of Pathology, Harvard Medical School

Health
Industry
Manufacturers
Association

1030 Fifteenth St., N.W.
Washington, D.C. 20005
(202) 452-8240

KIRKPATRICK & LOCKHART
RECEIVED
FEB 2 1979
WASHINGTON, D. C.

February 16, 1979

Mr. Norman Latker
1233 Munsey Building
1329 E Street, N.W.
Washington, D.C. 20004

Dear Norman:

Enclosed is a copy of the tentative final regulation for Investigational Device Exemption, May 12, 1978.

It was a pleasure to meet with you and to discuss the benefits of the Patent Procedures Act on HIMA's members.

Yours truly,

Les

L. Leslie Hamilton, Ph.D., P.E.
Director, Medical Engineering
and Electronics

LLH/vli

Enclosure

An association representing the medical device and diagnostic product industry

From Duke Gets Position

Dr. Henry G. Grabowski, a Duke University economist who specializes in studies of government regulation of the pharmaceutical industry, has been appointed an adjunct scholar of the American Enterprise Institute (AEI).

The institute, located in Washington, D.C., is a non-partisan, non-profit organization which studies public policy issues but takes no positions.

Grabowski is on leave from the department of economics at Duke as a visiting scholar at the Health Care Financing Administration of the Department of Health and Human Services.

Grabowski's research for AEI will concentrate on public policies affecting health and regulation. He will conduct research at Duke as part of the institute's academic outreach program.

Three of Grabowski's studies on the economics of regulation have been published by AEI.

University of Pittsburgh

SCHOOL OF MEDICINE
Department of Neurological Surgery

March 19, 1979

CROWDY & NEIMAN
RECEIVED
MAR 21 1979
WASHINGTON, D.C.

Mr. Norman Latker
1233 Munsuy Building
1329 E Street
Washington, D.C. 20004

Dear Mr. Latker:

According to the AAMI office, all invited speakers will receive complementary registration for the upcoming meeting in May. This is in agreement with what I have already said to you. You will find a packet at the registration desk when you arrive in Las Vegas.

I have made an inquiry regarding hotel reservations and have been told that you should receive a hotel reservation form from AAMI within a few weeks after the abstracts were received. This may already be in your hands, but if not, my advice is not to wait for it beyond April 1. For this reason, I am enclosing a xerox copy of the form which I have and which I am sure can be used in lieu of the original.

If you have any problems, don't hesitate to contact me. I am looking forward to our meeting in May.

Sincerely,

Sidney K. Wolfson, Jr., M.D.
Professor of Neurosurgery and Surgery
Chairman of The AAMI Sessions on
Biosensors and Implantable Artificial
Organ Systems

SKW:llj

Enclosure

Enclosure

MONTEFIORE HOSPITAL, 3459 FIFTH AVE., PITTSBURGH, PA. 15213 • (412) 683-1100 EXT. 487

Hotel Reservation Information

The official convention hotel for the AAMI 1979 Annual Meeting is Caesars Palace.* A hotel reservation form listing convention room rates is printed below.

A block of rooms has also been reserved at the Flamingo Hilton. A reservation form for the Flamingo Hilton is printed below.

Hotel reservation forms should be returned to the address printed on the individual forms. When making phone reservations be sure to specify you are attending the Association for the Advancement of Medical Instrumentation meeting.

***Note: Room reservations for both Caesars Palace and the Flamingo Hilton are only guaranteed if reservations are made 21 days prior to the meeting. AAMI cannot guarantee that space will be available after the 21-day cut-off date.**

See back cover for information on an optional instant hotel/air travel reservation system.

Return to: Caesars Palace, Reservation Dept., 3570 Las Vegas Blvd., Las Vegas NV 89109

ASSOCIATION FOR ADVANCEMENT OF MEDICAL INSTRUMENTATION
MAY 20-24, 1979

Reservations must be received by CAESARS PALACE no later than **May 6, 1979**. Rates quoted on a daily basis–European Plan

Please make the following reservations:

GUEST ROOM

☐ SINGLE or DOUBLE OCCUPANCY $39.00

SUITES

☐ PETITE—Combined bedroom and parlor $60.00

☐ DELUXE—Parlor and bedroom $115.00
Additional bedroom available

☐ ROYAL—Parlor and bedroom $145.00
Additional bedroom available

WILL ARRIVE May _____ 1979 TIME _____

WILL DEPART May _____ 1979 TIME _____
(PLEASE PRINT)

FIRM NAME _____

NAME _____

ADDRESS _____

CITY _____

STATE _____ ZIP _____

This reservation will be acknowledged. Reservation will not be held after 6:00 p.m. unless hotel is notified of your exact arrival hour.

FIRM NAME _____

NAME _____

ADDRESS _____

CITY _____

STATE _____ ZIP _____

This reservation will be acknowledged. Reservation will not be held after 6:00 p.m. unless hotel is notified of your exact arrival hour.

Return to: Flamingo Hilton, Attn: Sales Dept., P.O. Box 15557, Las Vegas NV 89114

ASSOCIATION FOR ADVANCEMENT OF MEDICAL INSTRUMENTATION
MAY 20-24, 1979

Please Check Accommodations Desired
(Rates subject to 6% room tax)

☐ SINGLE OCCUPANCY $36.00

☐ DOUBLE OCCUPANCY $36.00

☐ TRIPLE OCCUPANCY $43.00

One night's deposit must be received by **May 1, 1979** or reservation is subject to cancellation without notice.

Please make reservations for _____ persons

Name(s) _____
Last First

Address _____

City _____ State _____ Zip _____

Arrival Date _____ Time _____

Probable Departure Date _____

Please return prior to April 20, 1979. 48 Hour cancellation notice, prior to arrival, is required by the Flamingo Hilton for deposits to be refunded.

City _____ State _____ Zip _____

Arrival Date _____ Time _____

Probable Departure Date _____

Please return prior to April 20, 1979. 48 Hour cancellation notice, prior to arrival, is required by the Flamingo Hilton for deposits to be refunded.

File w/ Technology Transfer

Technology transfer

Dr. Nolan B. Sommer, senior vice president of American Cyanamid, spoke late last month at Georgetown University in Washington, D.C., on some of the problems facing multinational companies today. Here, verbatim, is part of what he had to say.

A major issue of broad importance to the international community concerns the transfer of technology across national boundaries. It has become a controversial subject largely because of its effect on a variety of special interests. For example, the Third World and the industrialized countries take differing views within the context of the North-South dialogue; U.S. multinational companies—who develop and apply a tremendous amount of technology—and the host governments debate about the conditions under which innovation is to be rewarded, safeguarded, and exported; and U.S. labor and certain academic critics question the benefits to the U.S. economy of the flow of technology to other lands.

Quite a few charges and misunderstandings have been generated over the years, essentially over the question of who is helped or harmed by technology transfers.

It is well to remember that technology transfer is not a new phenomenon. We have been engaged in sending and receiving foreign investment and the scientific advances tied to it for generations. And through those years the world has benefited—including the United States. The process is inexorable and will continue as long as both the sender and receiver profit or benefit.

The developing countries recognize that the technology developed by western industries can speed their economic and social development. Consequently, they have pushed for rules that would accelerate that flow, rules designed to "liberate" technology from the multinational companies who develop and implement it, making it available worldwide. Unfortunately, such an approach can be destructive to the aspiration of the less developed countries for greater industrial and social development and dangerous to the continued growth of all nations.

First and foremost, technology transfer is a voluntary process; it cannot be compelled, although it can be retarded or halted. Second, to the extent that the less developed countries try to devise shortcuts to the acquisition of high technology, there is the danger that traditional protections afforded to research and development, namely, patents and trademarks, will be weakened. And finally, technology transfer involves much more than the mere passing of research results and sophisticated equipment from a multinational company to a host country. Rather, it encompasses the overall package of management skills, investment and innovative techniques, as well as access to developed markets that are necessary to fully exploit technology. The host country must be ready to accept it.

Based on these considerations, therefore, I would make the following observations; the first to domestic critics, the second to the developing nations.

To those in the United States who argue that the transfer of U.S. technology abroad is inimical to the domestic economy, I would point out that receipts by U.S. companies from royalties and fees are at a level of about $4 billion a year—more than nine times the amount paid out in royalties and fees by U.S. firms. A U.S. Chamber of Commerce estimate of the total value of production associated with these receipts is close to $85 billion. This translates into jobs and economic growth. In fact, all of the available evidence we have shows that the export of technology generates more employment in the U.S. than is lost as a result of production abroad that uses U.S. technology.

To those in the less developed countries who want to appropriate the technology of the multinational companies I would argue that technology transfer must be a voluntary act, one which is mutually profitable to both the transferor and the transferee. If forthcoming guides for technology transfer no longer safeguard such "intellectual property" nor make it profitable to export it, corporations will neither develop nor transfer the fruits of their research. What happens then to economic development and the quality of life in the Third World? □

C&EN editorials represent only the views of the author and aim at initiating intelligent discussion.

To those in the less developed countries who want to appropriate the technology of the multinational companies I would argue that technology transfer must be a voluntary act, one which is mutually profitable to both the transferor and the transferee. If forthcoming guides for technology transfer no longer safeguard such "intellectual property" nor make it profitable to export it, corporations will neither develop nor transfer the fruits of their research. What happens then to economic development and the quality of life in the Third World? □

C&EN editorials represent only the views of the author and aim at initiating intelligent discussion.

Oct. 3, 1977 C&EN 5

The Alliance has promulgated a Policy on Intellectual Property that has been accepted by all participants. All data from Alliance Laboratories will be placed in the public domain by dissemination on the Internet. Funding for the Alliance will be sought from a consortium of major pharmaceutical companies, in addition to this response to RFA GM-99-007.