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Diabetes to enter the space age?

PIMS could radically improve the lot of 1.5 million diabetics, but fiscal chiseling may keep it from happening.

In yet another of the biomedical spinoffs from the space program, scientists from the Johns Hopkins University Applied Physics Laboratory under sponsorship of the NASA/Goddard Space Flight Center have developed a device that could revolutionize the treatment of America's approximately 1.5 million insulin-dependent diabetics, and save billions of dollars, possibly as much as half of the annual medical and indirect costs of diabetes, such as lost productivity, which the American Diabetics Association estimated at $20.37 billion in 1987.

The device, known as the Programmable Implantable Medication System (PIMS), has been spectacularly successful in 16 patients in which it has been evaluated on a trial basis over the last two and one-half years.

PIMS is but one of innumerable modern medical technologies spawned by the space program. In fact, without NASA technologies, the majority of the equipment in intensive care units as well as operating rooms would not exist, or be much more primitive.

The impact of space technology is most evident in command systems, telemetry, power systems, miniaturization, and long-term reliability. This is because of the similarity of circumstances which confront a spacecraft in outer space and an implanted device in the inner space of a human body. In both cases there is a need to monitor and intervene, by remote control, in regions which are not directly accessible without some difficulty.

According to Robert E. Fischell, who developed the PIMS, "The device has characteristics very similar to an orbiting spacecraft. PIMS includes a command system; a telemetry system; a miniature, long-life power system; and very large-scale integrated circuit chips. It has also been designed and fabricated using space reliability and quality assurance techniques."

In the course of his testimony before the House Committee on Science, Space, and Technology on April 13, Fischell listed its advantages:

"1. A precise medication rate is available. The desired physiological effect can be obtained while reducing overdosage. This could decrease buildup of tolerance and side effects.

"2. Perfect compliance can be achieved, without requiring patient compliance.

"3. Medication can be delivered with any desired periodicity.

"4. Accidental or deliberate overdosage is prevented.

"5. Decreased use of medication is possible;

"6. More appropriate medications can be used.

"7. Medications that would normally require the patient to be hospitalized could safely be given on an outpatient basis."

In sum, the PIMS allows the correct dose of the appropriate medication to be delivered to the appropriate organ at the right time, thus maximizing therapeutic effects and minimizing side effects.

Does it really work? At the same session the subcommittee heard the testimony of Professor F. Jackson Piatrow of American University, an insulin-dependent diabetic who was the first person to receive the pump in November 1986. As Dr. Piatrow stated, "It has worked perfectly ever since and has contributed to a marked change for the better in my control of diabetes and in my psychological adjustment to the disease."

When will this breakthrough in medical technology become available to the 1.5 million insulin dependent diabetics in the U.S.? Perhaps never.

To begin with, the three-year trial period of the initial program is drawing to a close, and as Dr. Piatrow stated: "We would feel unfairly used if the worst case scenario—compulsory removal of the pump—were to come to pass.

"We are assured that no one contemplates extraction of the pump just because an arbitrary time limit has been reached. At the same time, there is no question that the PIMS program is over.

"No more federal money is going into the program to sustain it, even though the program is effective and well received."

Not only is the pilot program coming to an end, but FDA approval for commercial sale will require the testing of an additional 100 units by the medical device company licensed to produce the device. The problem is that even if FDA approval is granted, which appears almost certain from the results to date, there is no reimbursement from Medicare or any insurance company for these devices. Thus only wealthy individuals will be able to afford the approximately $8,000 initial cost of the pump, whereas if the same technology were used to create a heart pacemaker or a new dialysis machine, all the expenses would be covered by insurance or Medicare.

While the savings to society from one spinoff medical advance could nearly equal NASA's entire annual budget, fiscal quckery may yet triumph.