

pursuing a career in the armaments industry, which could have been very lucrative, he would dedicate his life to building technologies that would improve the human condition.

Among his many achievements are the following: a vast improvement over pacemaker technology, which then made that available to so many millions of people whose lives have been changed because of it and extended because of it.

He also was involved in inventing, and it was his invention, a diabetic pump, a small mechanism that attaches to the body and allows patients to escape some of the worst ravages of diabetes.

He perfected the fully implantable cochlear implant, an electronic device that provides patients, some of whom have never been able to hear, with the ability to hear sound almost as well as those of us who hear naturally.

His latest invention and innovation would allow diabetics to receive their insulin through an inhaler rather than a syringe, a huge breakthrough that could be so meaningful to so many people who are suffering.

His achievements ought to serve as an example of the power of innovation in our country. Just as incredible as his inventions themselves, Dr. Mann accomplished all of this with private funds. And instead of relying on government grants or contracts, Dr. Mann made the risky investments of his own and those of his investors; and then, with his labor and genius, when it paid off, he reaped the benefits, which he then plowed back into more research to help even more people eliminate even more suffering.

Instead of receiving assistance from his government, Dr. Mann has, instead, run into bureaucratic obstacles time and again. As legislators, we have a responsibility to ensure that the Federal Government's actions, at the very least, do not thwart the heroic innovators such as Dr. Al Mann.

For this reason, I submit for the CONGRESSIONAL RECORD a letter Al Mann recently penned. I encourage all of my colleagues to read what he has to say and to take seriously the disturbing observations with our current system, as well as his recommendations on how we can ensure that the incredible potential of human innovation can be and will be brought to play in improving the lives of the American people and people everywhere.

LETTER FROM AL MANN: The Senate has just passed a bill to speed the availability of generic drugs. Hopefully that bill will die in the House. I say that the problem is not the pricing of drugs but the cost. What are needed are means for effectively lowering the expense and time to get a new drug approved. That would lower the costs and hopefully the pricing of drugs, and that would certainly be a worthwhile objective.

I am shocked and disappointed at the lack of understanding of this issue by the Congress. I certainly agree that we must seek ways to lower health care expense. I say that to do so we must focus on ways to LOWER

the COST of providing health care NOT just targeting the PRICE.

There are multiple reasons for the price of drugs, but I assert that the earlier generic drug law has actually led to an INCREASE in the PRICING of drugs. It takes as long as 15 years—or even longer—and \$1–\$1.5 billion to gain regulatory approval of a new drug. With only 20 years of exclusivity before a generic drug is approved it should be obvious that the price of a new drug must be very high just to recover the development cost let alone a profit. Even the price of the generic version of a drug is typically only moderately discounted from the innovative drug rather than priced based on the manufacturing cost.

If you question the impact of the current generic drug law just ask yourself how many \$5 and \$10 drugs there were before that law. It only costs pennies to make a pill. However, only by charging high prices can the high costs of pharma development be recovered with any profit during the brief period of patent protection remaining after regulatory approval.

Passing legislation to further ease and speed the availability of generic drugs will not likely lower pricing; if anything it would likely just reduce innovation of new drugs. That slowing is already beginning; most of the major pharma companies have already begun downsizing R&D. Surely that is not in our interest when there are new advanced technologies that could significantly improve and extend life.

We need to evaluate how we can speed and lower the cost of bringing a new drug to market rather than counting on the generics. There are various approaches that should be explored. One approach might be to delay approval of a generic to allow more time of exclusivity rather than to ease the generic regulatory process. There was such a delay built into the earlier bills, but that was certainly not adequate. Unfortunately it will not be easy to reverse the pricing practices of drugs—the companies and Wall Street have all gotten used to the high prices.

Of course the price of drugs is but a tiny part of the cost of health care. We ought to be reexamining many aspects of our health care system. We do need to reduce the price of health care—including the cost and the price of drugs. However, the challenge is not so simple as just approving generic drugs more quickly.

In fact the problem is not just the pricing; today many potentially valuable improvements and even new breakthrough drugs do not ever reach the market because of the regulatory hurdles. This problem and the costs will certainly become far greater as we move to more personalized medicine.

The consequence of easing the creation of generics may even worsen from what we see today; future breakthrough therapies may simply not become available in the U.S.! I just heard from a very credible person of a meeting of 12 advanced pharma companies discussing how to deal with the current regulatory challenges. I am told that 11 of those 12 companies are intending to launch their new products outside the U.S. and just to ignore the U.S. patients. Heretofore wealthy foreign patients came to the U.S. for superior medical treatment. Perhaps that practice may be reversing.

We want to protect our people from unsafe drugs. The challenge is how to do so in a more cost effective and more timely manner. I have suggested that we should redirect the regulatory standards to concentrate on safety, to lower the initial bar for efficacy to minimal requirements during a reasonable safety trial and then to issue a "provisional" approval. That provisional approval would be subject to a thorough review of clinical bene-

fits compared to risk AND cost in something like a more rigorous REMS program.

Our nation is in a crossroad on many fronts. In health care the barriers are preventing our ability to topple diseases such as cancer and Alzheimer's that so many of us will face. Not only are we harming and even precipitating death of many of our people but we are losing economic growth and the engine for good paying jobs. Our government is the most significant obstacle to medical progress today. We have new tools from new science that could make such a difference if only there were not the barriers to innovation that we see today.

I am 86 years old and surely my objective is not self serving. For the past four decades I have been committed to trying to find solutions to unmet and poorly met health care needs. Yet I am so disgusted by the overly restrictive process to medical innovation that has been created by our government that I have begun to sell off most of my several ventures. It is no longer worth the effort and the agony.

I am sending this communication to all the Representatives whose e-mail addresses I have. I would appreciate your forwarding this to your other colleagues.

ALFRED E. MANN.

## RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess until noon today.

Accordingly (at 10 o'clock and 37 minutes a.m.), the House stood in recess.

□ 1200

## AFTER RECESS

The recess having expired, the House was called to order by the Speaker at noon.

## PRAYER

The Chaplain, the Reverend Patrick J. Conroy, offered the following prayer:

God of grace and goodness, thank You for giving us another day.

Your divine wisdom and power are abundantly sufficient for our many needs. Endow the Members of this assembly with a loyalty that never wavers and a courage that never falters as they seek to fulfill the high and holy mission which You have entrusted to them.

May it be their purpose and all of ours to see to the hopes of so many Americans that we authenticate the grandeur and glory of the ideals and principles of our democracy with the work we do.

Grant that the men and women of the people's House find the courage and wisdom to work together to forge solutions to the many needs of our Nation and ease the anxieties of so many.

May all that is done this day be for Your greater honor and glory.

Amen.

## THE JOURNAL

The SPEAKER. The Chair has examined the Journal of the last day's proceedings and announces to the House his approval thereof.