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HUMPHREY URGES COOPERATION IN DRUG INDUSTRY

Senate Majority Whip Hubert H. Humphrey (D-Minn.), called tonight on scientists in government, the nation's medical schools and universities, and the pharmaceutical industry to make 1964 the beginning of "an era of dynamic cooperation" to speed continued progress in the development and safe use of effective new drugs.

Accepting the American Druggist's "Man of the Year" Award at a dinner at the Statler Hilton Hotel here, Senator Humphrey pledged that he'll continue his own work to"encourage the development of beneficial drugs and help reduce their hazards."

Humphrey is chairman of a Senate Government Operations Subcommittee on Reorganization and International Organizations, which has been examining problems of drug development and evaluation, particularly the need for strengthening scientific communication among federal regulatory and research agencies, medical scientists and physicians in the universities, the industry's research and development staffs, and physicians in day-to-day medical practice.

"The superb life-saving drugs of recent years speak for themselves," Humphrey said in praising the "remarkable" accomplishments of U.S. pharmaceutical companies. But he added that this great industry "is not without its blemishes and those who are really the friends of the drug industry ought to want to see it do a better job."

He also praised the work of the U.S. Food and Drug Administration and pointed out that gains are being made at FDA - its medical staff is being greatly expanded, its drug reaction reporting system now covers several hundred hospitals, and the sxientific community generally has become

(MORE)

much more interested in FDA's scientific-regulatory problems.

"No other American industry is more weighted with the public health and welfare than our great pharmaceutical industry, and the allied professions which make its fruits available to every American and to people all over the world," Humphrey declared.

"In some fields, a near-miss is almost as good as a direct hit. But in the drug and medical fields, a near-miss can be fatal.

"So, no federal regulatory agency has higher responsibility in the health and welfare field than does FDA, with its great power over the development, manufacture, and distribution of drugs."

"Flaws do exist, both in industry and at FDA," Senator Humphrey said. "Flaws must be corrected. They can and will be corrected, if there is no cover-up."

Humphrey recalled President Johnson's recent plea for national unity in a broad new effort to assure peace, prosperity and general progress, and urged his audience of leaders from government, the academic world and business to make their own start in the drug field.

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ADDRESS BY SENATOR HUBERT H. HUMPHREY OF MINNESOTA

Accepting the American Druggist "Man of the Year"

Award in the Drug Field for 1963

Presented April 8, 1964 at Dinner

Sponsored by The National Association of Retail Druggists

at the Hotel Statler-Hilton, Washington, D. C.

MR. CHAIRMAN, DISTINGUISHED GUESTS.

It is a great honor to be the drug field's "Man of the Year" for 1963.

I truly appreciate the privilege of becoming a member of so select a group of leaders in pharmacy.

Some extremely able men have been chosen for this award in the past, and I can only hope that I merit the distinction half as much as they did.

As one who grew up in the drug field, it is a particular pleasure to greet so many old friends tonight. And I am grateful and proud to see in this audience men whom all of us recognize as leaders in the pharmaceutical industry, in pharmaceutical education, in media of drug communication, in medicine, and in other branches of the healing arts.

From my earliest years, the pharmaceutical sciences have meant a great deal to me. After all, our family's food, clothing and shelter depended on the success of my father's small drug store.

Now, the Humphrey Pharmacy is in its 61st year as a family-owned enterprise. If you're ever in Huron, we'd like to have you drop by Humphrey's drug store - we can use the business.

There were days and years in the 1930's when business wasn't what it should have been. It was some of our fine wholesale drug houses who helped to make it possible for our pharmacy to keep its door open when things were tough, with their generous credit allowances and other important services.

"Service" is a habit a man can't and shouldn't forget.

Today, in the U.S. Senate, "My door is open" to try to be of service to the pharmaceutical and allied sciences.

To serve in the Senate of the United States today and to have some responsibility for the leadership of that body is a high privilege, a great responsibility, and at times a heavy burden.

The burden feels lighter, however, whenever health progress is involved.

And what great progress there has been!

Every time I get a chance to visit at home, and drop by our drug store, I'm amazed to see again the great numbers of highly effective medications that pharmaceutical advances have brought to every one of us since I was a boy in my father's drug store.

The names of great drug companies of that era - respected old names like Eli Lilly, Parke Davis, Merck, Smith-Kline, Wyeth, Abbott, Squibb, McKesson and Robbins, to mention but a few, were as familiar to me as a child as they are today. I think of them today as friends, as I did then.

I am proud to work with an industry that has made such enormous contributions to the public health.

Our fundamental commitment is not to any self-interest, but to service of the larger interest, the public interest.

It is in that context that I have worked for and will continue to support enactment of the Quality Stabilization Bill. This is good legislation - good for the consumer, good for free enterprise.

So, too, the public interest has been uppermost in mind in connection with other drug legislation. That is the reason for my efforts to include pharmacy in the program of federal aid to professional schools in the health field and to provide for federal lease insurance for small business firms wanting to get into big shopping centers.

Advancement of the public interest is also the goal of the men and women who work in the federal agencies that regulate drug development, manufacture and distribution.

I have always sought to be a friend of these agencies. I've known George Larrick and many of his colleagues at the FDA ever since I came to Washington 16 years ago.

Commissioner Larrick worked with me a dozen years ago in the most helpful way in developing that major piece of drug control legislation that bears my name - The Humphrey-Durham Act. I have the warmest regard for him. He has been and is a dedicated and honorable public servant.

But the Humphrey-Durham Act, other amendments to the food and drug laws, including the Kefauver-Harris Drug Amendments

of 1962, important as they are, have not solved all the problems that confront the druq industry, the federal requlators and the Congress.

We are still exploring some of the unsolved problems.

The Subcommittee on Reorganization and International Organizations has given considerable attention to these problems.

This subcommittee's drug study has, at times, been somewhat painful - on both sides of the hearing table.

But, let it be remembered that the Subcommittee has always had a much broader interest than mere drug research and requlation.

This broader interest is, I believe, shared by virtually every member of this distinguished audience. It is to strengthen cooperation by all segments of our economy in advancing the Healing Arts. Also we seek to expand International Medical Research.

Our subcommittee could not possibly fulfill that broader program without the vital help of the American Pharmaceutical Industry. Your products and services are one of this country's greatest international assets.

If any American has any doubts about that, let him ask the Russians - or the Cubans.

Their drug industry is so primitive and inefficient, compared to ours.

I have been in a drug store in Moscow and can assure you, Mr. Khrushchev is not about to "overtake us."

At home or abroad, no other American industry is more weighted with the "Public Health and Welfare" than our great pharmaceutical industry, and the allied professions which make its fruits available to every American and to people all over the world.

In some fields, a near-miss is almost as good as a direct hit. But in the drug and medical fields a near-miss can be fatal.

So, no federal regulatory agency has higher responsibility in the health and welfare field than does FDA, with its great power over the development, manufacture, and distribution of drugs.

The superb life-saving drugs of recent years speak for themselves. Many can claim a share of some part in their development in this country and overseas, in academic and industry laboratories and in clinics. But no one can ignore the indispensable role which American Free Enterprise has played - in many instances, in discovery itself; in many more instances, in crucially aiding development; and in all instances, in manufacturing these great boons to mankind.

No other country can match the American drug industry's achievements.

But you and I know that the real test of excellence is not: "Are we First among the nations in drug science?" The fact is, the U.S. is tops in the "Drug League."

The real test is: "Are we in the United States as excellent in drug sciences - in drug purity, drug safety and efficacy - as we should be and can be?" The answer is: "Not yet."

Fortunately, outstanding members of this very audience are striving to make excellence in drug standards still more uniform.

That is my goal, too. They - you - have a job to do, therefore. So do I.

Together, we can help realize certain improvements.

As a legislator, it is my task to be frank and to help identify flaws which do exist, here and there.

Be assured that I also recognize my obligation to point out (as I do on every possible occasion) that the occasional flaws must be viewed in proper perspective.

American drugs do accomplish genuine miracles in saving lives, in reducing pain, preventing disability and shortening sickness.

Our joint goal is, therefore, to maximize the wonderful benefits of drugs.

On the other side of the coin, we know that there will always be some hazards if there is to be drug progress. So, our job is to reduce the hazards to whatever extent is possible.

The work of Congress has been twofold: To gather facts as to problems and needs -

- And then to point the way to constructive solutions.

Fact-finding means issue-finding and clarifying. It

never means tarnishing of anyone's good name. It would be unthinkable for anyone to blacken the good name of a great industry, of great professions or of dedicated civil servants.

But, just as blackening names would be unfair to individual interests, so, conversely, whitewashing flaws - would be harmful to the public interest.

Both extremes must be avoided.

Fortunately, there is much progress to report. I commend industry, medicine and F.D.A. for this progress.

In the non-governmental area, the Commission on Drug Safety has completed its significant study.

Here in Washington, F.D.A. has been enabled to "tool up" to meet its expanded responsibilities. F.D.A. now has 41 full-time doctors of medicine in its new drug branch. As recently as 1960, it had only six working full-time.

F.D.A.'s drug reaction reporting program today covers several hundred hospitals. Until last Fall, it has never involved more than 30.

Much better liaison has been developed among the U.S. Public Health Service, the National Institutes of Health and F.D.A.

Perhaps equally important, the interest of the scientific community generally in F.D.A. and its scientific-regulatory problems has been substantially increased.

In this connection, there must of course be a proper balance within F.D.A. between science and regulation, including inspection. F.D.A. remains a regulatory arm.

This year, for the first time, in many years, the F.D.A. budget, unfortunately, does not provide for an increase in the number of inspectors. This despite the fact that F.D.A.'s inspection workload continues to increase as a result of new laws, expansion of industry and population growth.

F.D.A. continues to need the facilities and manpower with which to perform its vital inspection and other regulatory duties. So, too, the work of education and voluntary compliance must proceed apace.

Pharmaceutical interests are necessarily varied. But in the diversity, federal and private, there is still a deep underlying unity.

And it is on the goals which unite us (goals which are far more important than our occasional differences) - that I should like to conclude these thoughts.

A few weeks ago, in a major address, here in our nation's capitol, President Lyndon B. Johnson issued a ringing call for national unity. He appealed to business, labor, the farmer, everyone in America, in short, to work together for peace, prosperity and general progress.

Here in this great gathering tonight are men and women who are leaders in communities across the land. You are more than distinguished businessmen representing large and small enterprises, wholesale drug companies, independent retail pharmacies; you are more than educators, medical practitioners, communicators, govern-

ment officials, honored members of the Senate and House. You are leaders to whom the public looks for examples and for guidance.

You, I - all of us - can help carry out President Johnson's summons to unity in the nation, if we make our own start in this inspiring drug field. We can work together, first among ourselves, where we have common responsibilities and interests, and then by turning our vision outward, as individual background makes possible - to other unsolved problems, elsewhere.

Thus, we can make at least a first step toward the great goals projected for us by our President. To the extent we are successful in this endeavor, we will all be entitled to the accolade, "Man of the Year."

In our own area of health, we need a national dialoque, - a friendly, frank, understanding discussion about drug and other medical problems, about trends, emerging needs, obstacles, stepping stones.

We need - not carping criticism, not rancor, not invective, not suspicion - but ever more reason and good will.

The pharmaceutical industry faces its greatest era of opportunity for service.

This country's population "profile" is changing. We have more people, more elderly people, more young people than ever before.

We can help them - we can help ourselves - make all our previous health progress look "insignificant."

To do so, we need to tap the fullest genius of the pharmaceutical sciences.

We need more drug research, better research, better conversion of findings from the best research into the best education and the best practice.

If we do this, we can free men from disease and disability to a greater extent than we have even hoped.

America and the world look to you in this audience for some of tomorrow's brightest achievements.

In another field, leadership will send a man to the moon.

But here on Earth, it is in your field, in the pharmaceutical sciences, that man can - for more significantly - be launched into his healthiest era of history.

More than for any other goal but peace, the world is waiting, hoping, praying for your goals - our goals. I refer to still more effective answers to cancer, heart disease, mental illness, arthritis and other scourges.

Already, the "answers" which you have provided - the superb medications which medicine prescribes, which pharmacy dispenses - have thrilled our hearts.

We are confident the best is yet to come.

It is my privilege, my honor, my duty to try to assist you.

You - leaders of the professions and of industry - are in in the vanguard.

We who are public officials pledge to help you realize the next "Decade of Drug Progress."

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